IN OUR OWN HANDS:

A case study on mobilizing demand for HIV prevention for women

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A case study on mobilizing demand for HIV prevention for women

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The authors would like to thank the staff of the Sophia Smith Collection at Smith College for their invaluable assistance. As the oldest US collection of women's history manuscripts and archives, the Collection now houses the Global Campaign for Microbicides (GCM) files.

The authors would also like to acknowledge all the funders whose support made GCM's work possible. Most of all, we would like to thank the thousands of women and men who endorsed, supported, and partnered with GCM in doing this work and who are carrying it forward in other ways now.

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Acronyms and abbreviations

AFC	AIDS Foundation of Chicago
AIDS	Acquired Immune Deficiency Syndrome
The Alliance	Alliance for Microbicide Development
AMAG	African Microbicides Advocacy Group
ARV	antiretroviral
CAB	community advisory board
CAHR	Canadian Association for HIV Research
CAS	Canadian AIDS Society
CHANGE	Center for Health and Gender Equity
CIDRZ	Centre for Infectious Disease Research in Zambia
CoP	community of practice
EU	European Union
GAF	Gender AIDS Forum
GCM	Global Campaign for Microbicides
HDN	Health and Development Networks
HIV	human immunodeficiency virus
IAVI	International AIDS Vaccine Initiative
ICAD	Interagency Coalition on AIDS and Development
ICW	International Community of Women Living with HIV/AIDS
IFH	International Family Health
INN	Indian Network of NGOs working in HIV/AIDS
IPM	International Partnership for Microbicides
IRMA	International Rectal Microbicides Coalition
JAAIDS	Journalists Against AIDS
MAG-Net	Microbicides Advocacy Group Network
MCC	Medicines Control Council (South Africa)
MDA	Microbicide Development Act
MMCI	Microbicides Media and Communications Initiative
N-9	nonoxynol-9
NACC	National AIDS Control Council (Kenya)
NGO	nongovernmental organization
NHVMAG	Nigeria HIV Vaccine and Microbicides Advocacy Group
NIH	US National Institutes of Health
PATH	Program for Appropriate Technology in Health
PrEP	pre-exposure prophylaxis
SAMRI	South African Microbicide Research Initiative
STI	sexually transmitted infection
SWAA	Society for Women and AIDS in Africa
TB	tuberculosis
UN	United Nations
UNAIDS	Joint United Nations Programme on HIV/AIDS
USAID	US Agency for International Development
WHAF	Women's Health Advocacy Foundation (Thailand)
WHAM	Women's Health Advocates on Microbicides
WHO	World Health Organization

Executive summary

Between 1998 and 2012, the Global Campaign for Microbicides (GCM) served as a vibrant and unique platform for advocacy to accelerate access to new HIV prevention tools, especially for women. Initially based in the United States, GCM worked collaboratively with nearly 350 endorsers and partner nongovernmental organizations (NGOs), and at its height, had staff in Africa, Asia, Europe, and North America.

In addition to its instrumental goal of expediting microbicide development, GCM was dedicated to moving the existing model for biomedical product development from a traditional scientific/technical approach to one that engages collaboratively with affected communities, and particularly trial participants. It sought to bring a gendered and rights-based perspective to the process of funding and conducting clinical trials. With a relatively small staff and budget, GCM implemented broad-based advocacy strategies by collaborating with ally organizations working in women's health, HIV/AIDS, sexual and reproductive health and rights, gender, and human rights.

As a bottom-up, citizen-led coalition of individuals and nonprofit organizations, GCM was relatively unique among issue-specific health movements. First, rather than seeking to accelerate a research agenda identified by scientists, GCM identified the need for new prevention tools by and for women and put this demand on the scientific agenda. Second, unlike other health advocacy groups that draw their energy from those directly affected by a disease or their family members to advocate for better treatments for the disease, GCM had the more difficult task of mobilizing individuals with the goal of preventing *future* infections.

Unaffiliated with any product developer, government, or research institution, GCM focused on raising awareness of, and public demand for, woman-initiated HIV prevention tools. With advocates in Europe and North America, it mobilized political pressure that multiplied governmental funding for microbicide research and development many times over between 1999 and 2007. This public funding was essential because the pharmaceutical industry had not yet committed substantial financial resources to microbicide development. Simultaneously, GCM worked in developing countries to promote inclusion of community voices in the design and implementation of microbicide trials in their communities. This required not only advocating for community involvement but also providing the training, resources, and support that community members and local NGOs needed to collaborate knowledgeably with researchers.

GCM addressed this need across the educational and economic spectrum using a wide variety of strategies. It built, for example, an audible demand for microbicides among grassroots women by providing in-person trainings on microbicides in 15 languages* and creating a picture-based curriculum on vaginal health for use with non-literate audiences. It prepared those who were educated non-scientists to advocate knowledgeably for microbicides by creating an online textbook and teaching a "virtual classroom" course on the subject. Seventy percent of those using these online resources were African

* Bemba, Dutch, English, French, Hindi, isiXhosa, isiZulu, Kikuyu, Kinyarwanda, Kiswahili, Setswana, Nyanja, Russian, Spanish, and Urdu.

advocates and clinical trial staff interested in building their capacity to educate others and participate meaningfully in discussions in their own countries. GCM recognized that recruiting public support and raising awareness was a first step but that equipping people to carry the message forward themselves was the essential second step to building an enabling environment for microbicides. Thus, GCM adopted an "each one teach one" approach as originally articulated in the African-American civil rights movement. It sought to first equip people and then move them to take action, in whatever spaces they occupied, to help make HIV prevention tools for women a reality.

Following a thorough external review in 2007, and in light of the field's evolution and the changing funding environment, GCM decided to refocus its goals, staffing, and resources to work primarily on developing a supportive policy and civil society environment in Africa for new HIV prevention options. By scaling up its staffing capacity and programmatic focus in three African countries, GCM was able to engage more closely with key stakeholders in Africa and develop deeper connections with the communities most affected by HIV. There, GCM provided research literacy trainings to civil society members and advocates, engaged in "deep outreach" work to explore directly whether and how microbicides might fit into the lives of women in greatest need, and positioned staff in elected or appointed positions on national strategic planning committees to advocate for the inclusion of policy language supportive of GCM's goals in the national HIV/AIDS strategic plans of target countries.

By 2012, the microbicides advocacy landscape, as well as GCM's place in it, had changed dramatically. In July of that year—following consultations with the global health community, the GCM steering committee, and advocacy partners, and in considering the needs of the broader HIV prevention field—the decision was made to close GCM.

GCM was established to generate political pressure for increased investment in microbicide development and to ensure that the rights of trial participants, users, and communities were represented and respected throughout the development process, and carried out this mission over nearly 15 years. Although much remains to be done to ensure that women's health remains a priority on the HIV prevention research agenda, GCM put women's HIV prevention needs on the map, helped to create a new scientific field, and successfully built and carried out one of the few social health movements for prevention.

This document offers a history of GCM as a global organizing effort and locates it within the history of both the women's health movement and the AIDS movement. Too often, grassroots movements and organized campaigns become the victims of their own success; as their agenda is accepted and absorbed by the mainstream, the vital role of early advocacy is forgotten or obscured. We offer this history to help ensure that GCM's contributions become part of the historical record and to provide insights and lessons that can help inform future efforts to organize around important global issues.

PATH / Teresa Guillien

The Global Campaign for Microbicides (GCM) was founded as a broad-based, international advocacy platform to accelerate access to new HIV prevention options, especially for women. GCM worked to generate and amplify the demand for microbicides, especially in countries with donor governments. It created the political will that dramatically increased the global budget for microbicide research.

Introduction

"What if no reliable, male-controlled HIV prevention tool yet existed? Wouldn't the demand for one be deafening?"

~ HIV Prevention Activist 1998

In 1998, the Global Campaign for Microbicides (GCM) was founded as a broad-based, international advocacy platform to accelerate access to new HIV prevention options, especially for women. Relatively small in size, GCM at its largest had 17 staff members working out of a secretariat based at PATH in Washington, DC and satellite offices in Brussels, Delhi, Johannesburg, Nairobi, and Ottawa. More importantly, it had 348 nongovernmental organization (NGO) endorsers and partners with which it collaborated to carry out its mission. GCM defined endorsers as organizations that signed on to a statement supporting GCM's goals but did not necessarily collaborate directly with GCM. Partners, a subset of the endorsers list, were organizations with which GCM collaborated on significant projects on an ongoing or periodic basis.

GCM envisioned itself as an umbrella—an inclusive and cohesive structure under which the advocacy actions of its partners and endorsers were unified and amplified. GCM also contributed its own unique and authoritative advocacy voice to the ongoing policy and process debates that advanced the HIV prevention field and shaped its progress.

This document describes GCM's strategy for putting HIV prevention for women—and particularly microbicide research, development, and introduction—on national and international policy agendas and how its approach played out within various contexts. It also identifies lessons that may be drawn from GCM's experiences, with the hope that they may prove useful to others undertaking similar work in the future.

GCM's 14-year history is divided here into four chronological phases. Spanning 1987-1998, "Setting the stage for a movement" describes the events that led up to the formation of GCM in 1998. "The early years" reviews GCM's establishment and evolution between 1998 and 2002. The narrative then moves from a chronological perspective to focus on how GCM defined and sought to realize its three core goals. Since work toward these goals was shaped by specific objectives, many of them regionally defined, these three "Goal" sections are also subdivided by region, as shown in the table of contents. The report describes, for example, how Goal 1 was pursued in North America and Europe, among constituencies in the developed word. Goal 2 was pursued mostly in developing countries. Goal 3 work addressed field-wide challenges through the various initiatives described in that section.

At this point, the report returns to a chronological framework, describing the turning point that GCM reached in 2008-2009 and the deepening work in Africa done between 2009 and 2012. It then concludes with a summary of the factors leading to GCM's closure in 2012 and the lessons learned from this case study.

Setting the stage for a movement

In 1987, advocates from the field of women's health and contraceptive research began discussing the need for new female-initiated HIV prevention tools to supplement the male condom. In the United States, researchers recognized this need and began testing the efficacy of nonoxynol-9 (N-9), a contraceptive gel, against HIV. A 1989 study conducted among sex workers in Kenya foreshadowed the field's eventual conclusion regarding this product: it was, sufficiently irritating to vaginal tissue that frequent use could facilitate HIV risk.[1] Other studies in the 1990s, however, suggested that it might be effective in reducing risk,[2,3] and since the need for anything that would accomplish this was urgent, research on N-9 continued until 2000.

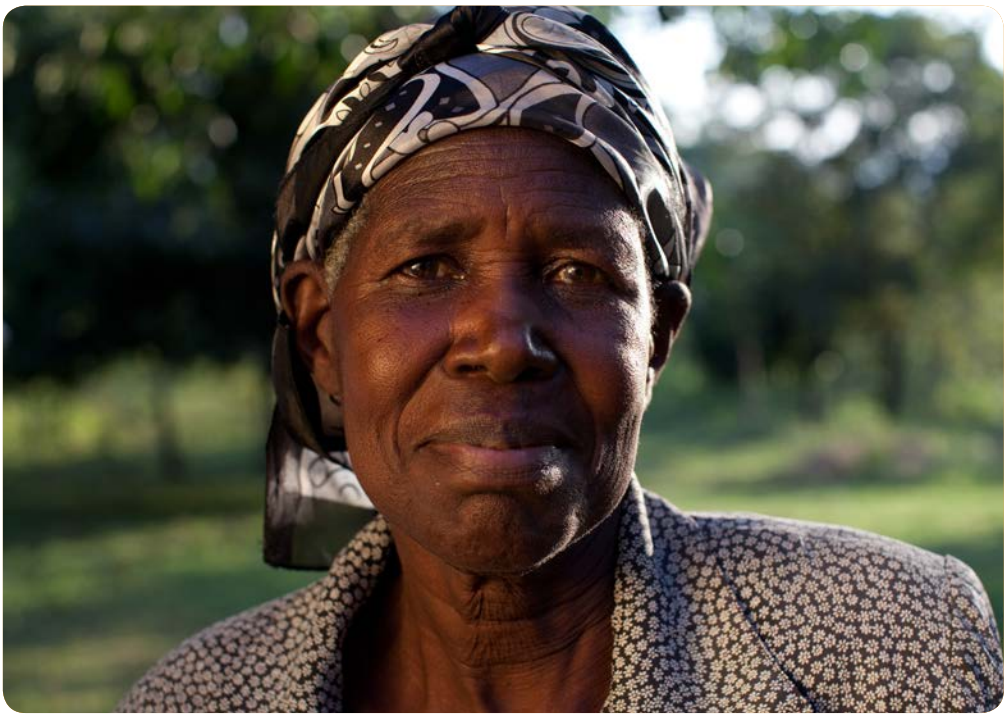
The first civil society demand for microbicides was articulated by activists from the fields of women's health, contraceptive research and development, and HIV/AIDS. Appalled by the escalating evidence of women's vulnerability to HIV infection, they felt compelled to demand prevention options that (unlike the male condom) women could use without a partner's active involvement. They also shared a core commitment to the rights of individuals and communities to make their own health care decisions and have a voice in shaping the health care policies affecting them directly. Microbicides advocacy took root, for both technical and philosophical reasons, at the intersection of the women's health movement and AIDS activism.

> "We need tools that will allow women to protect themselves. This is true whether the woman is a faithful married mother of small children or a sex worker trying to scrape out a living in a slum. No matter where she lives, who she is, or what she does, a woman should never need her partner's permission to save her own life."
>
> ~ Bill Gates, Jr.XIV International AIDS Conference, 2006

These activist demands were informed by the voices and experience of female grassroots advocates who in multiple forums began to articulate how condoms were not a viable option for many women, especially within the context of their long-term partnerships. These women began to envision the idea of a woman-controlled HIV prevention tool, articulating their vision during interviews conducted in 15 global settings by the International Center for Research on Women in the late 1980s.[4]

In 1990, South African epidemiologist and advocate Zena Stein published "HIV prevention: the need for methods women can use" in the *American Journal of Public Health*.[5] Stein's call was taken up by community-based advocates at the US National Conference on Women and HIV Infection, who insisted on inclusion in the formal conference recommendations a demand for HIV prevention "methods which are woman-controlled and may be used without detection by their sexual partners."[6] These public statements broke the silence in both the scientific and the public policy worlds that had surrounded women's urgent need for an HIV prevention tool they could initiate and use without their partner's

active cooperation. Putting the issue "on the table" in such public settings gave legitimacy to the growing advocacy demand alternatives to the male condom.



PATH/ Eric Becker

The first civil society demand for microbicides was articulated by activists from the fields of women's health, contraceptive research, and HIV/AIDS. Appalled by the escalating evidence of women's vulnerability to HIV infection, they felt compelled to demand prevention options that women could use without a partner's active involvement.

Meanwhile, Lori Heise, a gender and health expert funded by the Ford Foundation, was collecting evidence on the influence of intimate partner violence on HIV prevention and family planning programs. In 1990, at an HIV prevention conference session conducted by Heise, frontline AIDS educators voiced their frustration about the belief that male condoms were a viable option for married women. A Ugandan woman observed, "If they can send a man to the moon, why can't scientists find a way to protect women and still allow them to get pregnant?" Intrigued by the question, Heise contacted scientists at the US National Institutes of Health (NIH) and the World Health Organization (WHO) in search of an answer. They assured her that such a product was theoretically possible to develop but that, as Heise later reported, it might not be feasible to test and probably was not necessary because "women aren't that at risk" of HIV (personal communication, August 23, 2006).

The latter statement typified an underlying attitude regarding women's risk that persisted in the developed world (where the majority of people diagnosed with HIV were and are men) despite the epidemiological evidence to the contrary. The Joint United Nations Programme on HIV/AIDS (UNAIDS) estimated that women comprised about 44 percent of all adults living with HIV globally in 1990, with regional variations among women from more than 50 percent in sub-Saharan Africa to less than 20 percent in western and central Europe and North America. While systems for collecting data on HIV prevalence were still gearing up in many regions in 1990, an early, universal priority was placed on HIV testing in antenatal clinics, which produced the numbers on which these estimates largely rely.[7]

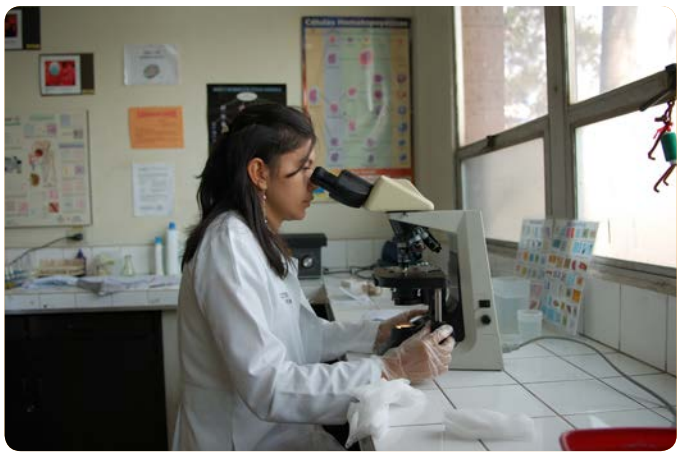
Heise contacted Dr. Christopher Elias, then a senior associate at the Population Council, who had written an article in 1991 suggesting vaginal gels, which he called "virucides," as one approach to addressing the epidemic of reproductive tract infections among women globally.[8] Strategizing together, they determined that jump-starting the development of such products would require the collaborative engagement of multiple sectors, including scientists engaged in contraceptive research (as they had the necessary expertise in developing vaginal products), advocates who understood the urgent need, and policymakers with the political clout and resources to support such research.

Later that year, Heise and Elias convened the first consultation on microbicides among women's health advocates and researchers affiliated with the Population Council, the NIH, the Contraceptive Research and Development Program (CONRAD), Family Health International, and the US Food and Drug Administration. This meeting set the stage for constructive engagement between two sectors that had been at odds for years. Feminist activists had long been critical of the population control movement and the contraceptive

research establishment for prioritizing reduction in human numbers over women's reproductive health and autonomy.[9] They criticized early research abuses and questioned the population movement's almost exclusive focus on limiting births through long-acting contraceptives, rather than on addressing the socioeconomic forces that encouraged large families and the structural issues that constrained women's reproductive decision-making, such as gender-based violence, economic discrimination, and lack of education.[10]

The overriding need to defend women against HIV required collaboration that bridged this divide. This was further advanced by another 1991 meeting sponsored by WHO and the International Women's Health Coalition that brought women's health advocates and scientists together to discuss contraceptive research priorities. The resulting meeting report called for greater attention to barrier methods of contraception that are user controlled and help protect against infection as well as pregnancy. WHO's involvement in convening this meeting and endorsing its conclusions gave further weight to a growing consensus that HIV prevention had to be added to the research agendas of institutions and funders that had, to date, focused largely or exclusively on contraception.

Frustrated by the slowness with which the issue was gaining traction, 40 women's health leaders issued a call for accelerated research into microbicides as part of a declaration of priorities feeding into the upcoming International Conference on Population and Development to be held in Cairo. The "Program of Action" that emerged from the Cairo conference was slated to serve as a steering document for the United Nations Population Fund for the coming decade. The leaders' efforts resulted in getting the need for microbicides mentioned as an important priority in the Program of Action in two places—a substantial advocacy win for the nascent movement.



PATH/Mike Wang

The microbicide advocacy movement grew rapidly between 1993 and 1997, spurring increased scientific research and donor support for women-controlled HIV prevention options.

Another strong indication of the emergence of a new policy priority is always the allocation of new or redirected government funding to support it. The first trickle of public funding for microbicide research emerged in 1992 from the UK Medical Research Council for work to develop an "intravaginal virucide"[11] and from the NIH to explore vaginal ecology as it relates to disease transmission,[12] its first step toward microbicide research.

Soon after, the scientific community began working in coalition to advance the issue. In 1994, the International Working Group on Microbicides was formed, with initial support from the WHO Global Programme on AIDS, to facilitate collaboration among research institutes working on microbicides.

Simultaneously, the first efforts to develop novel microbicides were underway. The Population Council started researching the sexual transmission of HIV and screening compounds for potential microbicidal activity in 1989. By 1993, its researchers had identified a candidate known as PC 515 (subsequently called Carraguard®), which was promising enough to move into clinical trials. That year, Women's Health Advocates on Microbicides (WHAM), convened by Heise and Elias, formed as a network of 11 internationally representative women's health networks that came together to bring a women's health advocacy voice to the process of shaping the Population Council's nascent microbicide research effort.

WHAM met semiannually for several years, helping to design the Population Council's multicountry study of women's formulation preferences, reviewing draft trial protocols, exploring ways to better monitor informed consent in clinical trials, and providing recommendations to the Population Council's leadership. Its work

culminated in 1997 with Practical and Ethical Dilemmas in the Clinical Testing of Microbicides, an international symposium in which participants from 15 countries outlined consensus points on how best to conduct large-scale clinical trials to evaluate the effectiveness of microbicides in reducing the risk of HIV infection.

The field's rapid maturation between 1993 and 1997 made it impractical for WHAM to continue to focus advocacy attention exclusively on the work conducted by the Population Council. New actors had entered the arena and the locus of microbicide activity was shifting from the laboratory to the field as candidate products began to enter clinical trials. So in 1997, WHAM formally disbanded in order to allow a more inclusive advocacy movement to evolve.

The early years

The joint work of WHAM and the Population Council, together with the research advances supported by US and UK funding, propelled the new field forward and attracted the attention of a small but increasing number of public and private research institutions. The International Working Group on Microbicides published its first recommendations in 1996,[13] while some female HIV/AIDS activists began building awareness of microbicides within their constituencies. Sessions on the need for microbicides and the status of their development were presented at the first US National Conference on Women and HIV/AIDS in 1997.[14]

Two new organizations were formed in 1998: the Alliance for Microbicide Development ("the Alliance") and the Global Campaign for Microbicides and Prevention Options for Women (GCM's original name). Founded by Polly Harrison and Kevin Whaley, the Alliance was a multidisciplinary, multisectoral consortium designed to advance the needs of scientists, small biotechnology companies, and nonprofit research groups. The Alliance also worked closely with key advocacy groups, importantly GCM, to increase funding and policy support for microbicide research and development.

The Alliance essentially shaped the microbicides field by monitoring developments and facilitating information

Patrick McKern

GCM was officially launched in 1998 and aimed to shift the existing model for product development from a traditional scientific/technical approach to one that engages collaboratively with affected communities, particularly trial participants and host communities.

exchange via its product database, pipeline review, weekly e-bulletins, quarterly journal, annual meetings, policy advocacy, and ad hoc convening around common concerns. In 2004, the Alliance developed and then managed the Microbicide Donors Committee and its "Quick" Clinical Trials Working Group: investigators implementing later-stage microbicide trials who met and communicated regularly to share information and strategize promptly and collectively about problems, challenges, trends, and successes.[15] While several people who defined themselves primarily as advocates (rather than as scientists, developers, or funders) were members of the Alliance, it was not an advocacy network, per se. The Alliance and GCM fulfilled closely complementary functions and worked together frequently but existed as separate entities to maintain their distinct foci while working with overlapping constituencies.

GCM was officially launched in July 1998 at the XII International AIDS Conference in Geneva. The brainchild of Heise and other key players, it set out to move the existing model for product development from a traditional scientific/technical approach to one that

engages collaboratively with affected communities, particularly trial participants and host communities. GCM brought an explicitly gendered and rights-based perspective to the development of microbicides and other HIV prevention tools. It set out to define, articulate, and facilitate processes for operationalizing this perspective in the funding and conduct of clinical trials.[16]

Its founders, emerging from the women's health movement and AIDS activism, believed that doctors and patients—researchers and consumers of medical research—could negotiate a common agenda. The first full edition of *Our Bodies, Ourselves*, published in 1971, was emblematic of the decade's transformative women's health movement, which encouraged women to move from being passive recipients of health care to active, well-informed consumers, and to take responsibility for establishing doctor-patient relationships that were, ultimately, controlled by the patient.[17]

The Denver Principles, a similarly defining document drafted in 1983 by the Advisory Committee of People with AIDS (a precursor to the US-based National Association of People With AIDS), built on this heritage. The document unequivocally listed the rights of people living with HIV/AIDS as including the right to "obtain full explanations of all medical procedures and risks, to choose or refuse their treatment modalities, to make informed decisions about their lives…."[18] and to "[b]e involved at every level of decision-making and specifically serve on the boards of directors of provider organizations…."[19] Armed with the Denver Principles, the AIDS activist movement not only demanded consumer autonomy in medical decision-making but also engagement with the research institutions involved in developing HIV/AIDS-related treatment, as demonstrated by the confrontations and gradual collaboration in the late 1980s and early 1990s between the AIDS Coalition to Unleash Power and its spinoff, the Treatment Action Group, and the NIH and US Centers for Disease Control and Prevention.[20] The demand by microbicides advocates (and, subsequently, HIV prevention advocates more broadly) for a voice in setting publicly funded prevention research agendas and full transparency in the progress of microbicide research was a direct extension of this evolving view of the rights of consumers to participate in shaping the research and care they needed.

As AIDS activists and women's health activists themselves, the founders of GCM brought this perspective, together with the knowledge that effective interaction with health care providers and researchers required that they first educate themselves sufficiently on the science to become informed negotiators. Thus, GCM was determined to build the capacity of NGOs and their networks to advocate for and participate in decision-making around research agendas and clinical trial implementation.

GCM set out to accomplish three goals*:

1. Generate political pressure for increased investment in microbicide research and greater access to the female condom and other cervical barrier methods.
2. Promote stronger civil society involvement to ensure that the rights and interests of trial participants, users, and communities are fully represented and respected at all stages of research, development, and product introduction.
3. Enable trials to proceed efficiently by addressing emerging challenges, such as research findings and political landscape shifts, that affect ethical decision-making, media interpretation issues, and political and community perceptions of the trials.

Given resource limitations, GCM decided to target its efforts to two categories of countries: those rich enough to serve as donors to the microbicide effort and those where large-scale microbicide trials were occurring or would likely occur. To feasibly determine a candidate microbicide's effectiveness, large-scale trials had to be conducted in countries where HIV incidence rates were high enough to reveal the degree of protection (if any) provided by the test product. These conditions existed primarily in sub-Saharan Africa, although microbicide trials have also been conducted in India and Southeast Asia.**

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* Some language in this report, including these goal statements, has been taken directly from the GCM website and GCM-produced reports, grant applications, etc. It is repurposed here without specific citation because it was originally generated by the authors, all of whom are former GCM staff.

** Since Latin American, eastern European, and central Asian countries do not fit into either the first or second priority categories above, these regions were not the focus of substantial GCM organizing. Several strong partner organizations in these regions did, however, endorse GCM and carry forward microbicides education and mobilization in their own ways, using adapted and localized GCM materials and making important contributions to GCM's knowledge base.

Under the guidance of its 12-member international steering committee, GCM staff worked to raise awareness about microbicides via the media, conference presentations, community workshops, and outreach to policymakers. By 2001, more than 70 NGOs worldwide had endorsed GCM. Its needs exceeded the capacity of its original home at CHANGE (the Center for Health and Gender Equity), then a small US-based women's health NGO. Heise stepped down from her co-directorship of CHANGE in January 2001, and GCM's steering committee hired her to assume full-time leadership of GCM. GCM was invited to relocate its secretariat to the Washington, DC offices of Program for Appropriate Technology in Health (PATH), a sister organization headquartered in Seattle, Washington, and led by Elias, its new president. PATH's institutional mission at the time—to find innovative solutions to public health problems, especially those affecting the health of women and children—was a good fit for GCM.

Between July 2000 and February 2002, the Rockefeller Foundation's Microbicide Initiative convened an international group of scientists, research organizations, advocacy groups, pharmaceutical representatives, United Nations (UN) organizations, and donors to examine the field and recommend strategies to accelerate microbicide development. The Initiative organized itself into four working groups and invited Heise, as GCM's director, to co-chair the group on advocacy, public education, and resource mobilization. *Microbicides: A Call to Action*, authored by Heise and others as the working group's final report, offered the following as part of its blueprint for advocacy action: "[P]riority should be given to building the capacity of NGOs and their networks to advocate for microbicides and to participate actively in decision-making around research agendas and clinical trial implementation."[21]

This statement, in a nutshell, summarized GCM's central purpose. The activities described below (under Goals 1 and 2 in particular) show how GCM mobilized NGOs to advocate effectively for investment in microbicide research and development and for their right, as civil society representatives, to be involved in shaping how the field conducted the process of making microbicides a reality. This work was accomplished by a relatively small staff and budget—a feat that was only possible because of GCM's highly collaborative style and wealth of endorsers and partners.

Only strong political will could ensure the continuous flow of adequate public funding needed to make microbicides a reality. Such will does not automatically follow from public health need. On neglected issues (such as those mostly affecting the poor and women), it must be deliberately cultivated and then translated into concrete, strategic action. GCM's work, as described below, sought to "make visible" and then mobilize the strong but untapped public demand for HIV prevention alternatives to the male condom.

Goal 1: Generating political pressure for increased investment

The pharmaceutical industry, usually the engine of new drug development, demonstrated little interest in microbicide research and development because of the relatively low profit potential (given that the largest markets would be in developing countries) and because of the uncertainty that accompanies developing an entirely new class of product. Pharmaceutical executives often make decisions informed by the estimated cost of developing a new product and the likely return on their investment. Because no product analogous to a microbicide existed, it was impossible to predict how regulators would respond to a microbicide or what the likely market would be. Industry's ongoing reluctance to invest in microbicide development is illustrated by the fact that, in 2011, less than 1 percent of the total global funding for microbicide research and development came from the private sector. The remaining 99+ percent was provided by government and foundation grants.[22]

The money to fund microbicide research and development was (and is) controlled primarily by developed-country governments, so GCM's work on its first goal started in the United States and expanded

David Jacobs

GCM sought to enlist the support of advocates likely to be supportive of microbicides due to their interest in women's health, family planning, human rights, and HIV/AIDS.

into Canada, western Europe, and Australia—countries with the resources and potential willingness to invest in microbicide research and development.

Rather than try to build a movement from scratch, GCM sought to enlist the support of various "natural allies," groups likely to be supportive of microbicides by virtue of their interest in women's health, family planning, human rights, and/or HIV/AIDS. National groups were targeted because of their ability to lend access to their grassroots constituencies, as well as to assist at a national or regional level with policy or legislative work. Among the first to sign on as GCM endorsers, for example, were the Reproductive Health Technologies Project, Fundación para Estudio e Investigación de la Mujer (Foundation for Studies and Research on Women), the National Women's Health Network, the International Center for Research on Women, the Society for Women and AIDS in Africa (SWAA), and the Alan Guttmacher Institute.

This recruitment took various forms, ranging from one-on-one meetings to large conference presentations. Pragmatically, GCM's outreach emphasized the direct benefits that an effective microbicide could offer each constituency addressed, as well as the ethical mandate to insist that wealthier countries invest in a tool that could substantially reduce HIV spread among women and men in poorer countries.

Those agreeing to endorse GCM were asked to promote its goals and objectives in whatever ways they could fit into their already full workloads. Since its endorsing organizations tended to be overstretched already, GCM offered a menu of relatively easy options for participation. Among these were including insertion of pre-prepared articles in their newsletters, circulating GCM's petition along with their other materials, putting information on their websites, and sponsoring educational events that GCM planned and conducted. GCM acquired 348 NGO endorsers worldwide, dozens of which became active partners in GCM's work by taking on more labor-intensive collaborative efforts with GCM. As an NGO coalition, GCM did not accept endorsements from any microbicide developers or research institutions, funders, commercial enterprises, or governmental entities.

To overcome the challenge inherent in creating demand for a product that did not yet exist, advocates needed a basic knowledge of the mechanics of HIV transmission,

the current status of microbicide research, and the steps taken to ensure that the research was conducted ethically. GCM developed a wealth of materials and tools specifically designed to meet the needs of emerging advocates, starting with:

- Standardized Microsoft PowerPoint presentations consisting of slides and a script that could be adapted as needed to suit local audiences.
- "Action kit" materials that could easily be localized and reproduced as presentation handouts.
- "How to" fact sheets and instructional materials to guide less experienced organizers through various GCM activities, such as organizing a community forum or interacting with the media.

"With condoms, safer sex is his decision. We want to make it yours."

~ slogan on Microbicide Development Act organizing materials, 2000

These basic materials were provided to new endorsers as rapidly as possible to encourage them not only to absorb the information, but also to share it with others. The standardized PowerPoint presentations, for example, made it easy for new advocates to present the information to others with confidence. The action kits provided them with handouts that could be translated and adapted as needed to suit their communities' needs. These products were very positively received by new advocates, who said that they would not have felt comfortable "wading into" the challenge of explaining microbicides to others without these supports. The "how to" fact sheets, together with regular phone meetings and email contact with GCM staff, helped many endorsers to move into becoming partners, by giving them the tools and motivation they needed to initiate their own local activities.

GCM also identified itself as open access, meaning that people were welcome to download, adapt, and distribute its materials widely. This not only promoted uptake and use of the materials, but also helped to ensure consistency of messaging across various constituencies. Interested partners were encouraged to adapt and add their logos to GCM pieces rather than writing their own materials on the subject. To maintain accuracy, GCM only asked that they not alter any of the core information in te pieces.

GCM faced the challenge of simultaneously remaining flexible enough to represent the civil society arm of a multiregional microbicides movement while also communicating a coherent identity that could establish its own credibility. Its "Petition for Greater Investment in Microbicides," first circulated at the XII International AIDS Conference in Geneva in 1998, became a crucial organizing tool for this purpose. The petition was a basic statement of support for microbicides that individuals were asked to sign.

It is indicative of GCM's practical approach that its founders primarily approached women who were waiting in line to use the conference center toilets to discuss GCM and solicit their signature on the petition. The directness of both the approach and the topic matched well, and women were highly receptive to these conversations, especially since they occurred during time that was seldom put to any other good use (given that this preceded the advent of cell phones).

"The money is now flowing for microbicides, thanks to you. Keep up the pressure!"

~ CDC staffer call to GCM 2002

Introducing the petition in all kinds of settings gave advocates an opening to "squeeze in" conversations about microbicides and women's HIV prevention needs at conferences, public events, health fairs, and meetings focused on broader issues. Collecting signatures became a concrete activity that interested organizations could take on immediately, even if their direct involvement in microbicide research was still years away. The number of signatures collected by countries individually and in the global aggregate, as well as the range of countries represented by the petition signers, became an advocacy talking point enthusiastically cited by endorsing organizations. Perhaps most importantly, collecting signatures on the petition was the first GCM activity

that united advocates from both the developed and the developing world in a tangible, common objective.

In 2004, GCM delivered the petition to governments gathered in Dublin for the first European Union (EU) Conference on New HIV Prevention Technologies. Civil society representatives from Belgium, India, the Netherlands, Nigeria, Spain, South Africa, and the United Kingdom unfurled the enormous display of more than 200,000 signatures from around the globe, some simply thumbprints, collected since 1998.

The following profiles the various objectives GCM pursued in specific countries and regions, and how it adapted its organizing style to accommodate local realities.

United States

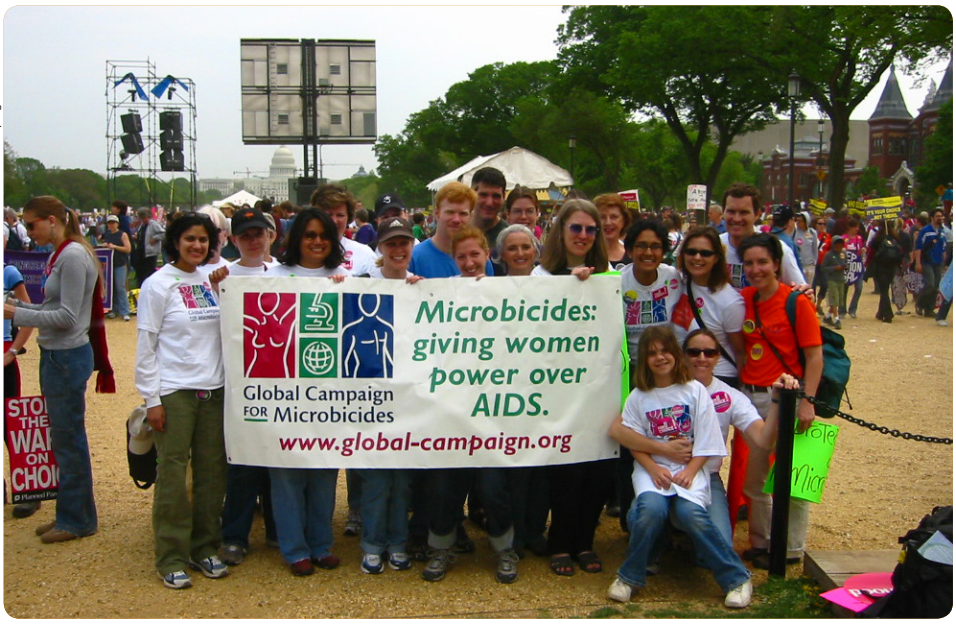
In 1999, GCM drafted a "Ten Point Plan to Accelerate Microbicide Development" that was adopted by the US President's Advisory Council on HIV/AIDS as a basis for its recommendations to President Bill Clinton in 2000. Starting in 2000, GCM's US-based efforts centered around the Microbicide Development Act (MDA),[23] a bill first drafted by GCM, the Alliance for Microbicide Development, and other partners working in collaboration with the bill's legislative sponsors, Congresswomen Connie Morella (R-MD) and Nancy Pelosi (D-CA). In March 2000, GCM organized a "lobby day," at which more than 50 scientists and advocates made 22 visits to key congressional offices to urge support for the bill , including the office of then Senator Barack Obama.

To support the bill, GCM launched a grassroots recruitment effort in ten key legislative districts, where it successfully persuaded endorser NGOs to become GCM partners (an escalated level of involvement) and host "Campaign sites."These sites were NGO coalitions assembled by the partner organizations and their colleagues that carried out local advocacy activities supported by guidance and small grants from GCM. The primary objective was to urge elected representatives to actively support the MDA and funding allocations in the federal budget for microbicide research and development.

The MDA was introduced in Congress six times between 1999 and 2008. Although it never passed, the tens of thousands of phone calls, emails, and letters to Congress generated by the local GCM sites and their networks had the intended effect, resulting in the implementation of the MDA's two primary provisions through other governmental mechanisms: a dedicated microbicide research and development unit that was created within the NIH in 2007, and a steady increase in federal funding for microbicides from 2000 to 2010. Other provisions of the bill were subsequently incorporated into other legislation, including the Global Sexual and Reproductive Health Acts of 2010[24] and 2011[25] and the Ending the HIV/AIDS Epidemic Act of 2012.[26]

With its partners, GCM utilized an "inside/outside" approach, whereby the advocacy efforts of external stakeholders were complemented by the less visible activity of advocates working within political structures

Global Campaign for Microbicides



GCM staff and partners participate in a rally in Washington, DC, as part of the campaign's US advocacy efforts.

to produce results. In addition to generating external expressions of grassroots support for the MDA, for example, GCM also worked with the Alliance for Microbicide Development, the International Partnership for Microbicides (IPM), the National Women's Health Network, and other allies to influence the "line item" budget decisions being made by congressional appropriations committee members. Inside advocates met with key congressional staffers, submitted questions for NIH budget hearings, proposed draft language on their issue for congressional appropriations reports, and engaged in other advocacy interventions that had substantial impact.

US federal investment in microbicide research and development tripled from $28 million in 1999[27] to $92 million in 2004.[28] The initial boost occurred after the first international conference on the topic, Microbicides 2000, was held in Washington, DC. Convened biannually in a city hosting substantial microbicide research, subsequent conferences were held in Antwerp, London, Cape Town, Pittsburgh, and Sydney. The inaugural conference, however, allowed the NIH to highlight its progress in the field and helped to generate a jump in federal funding to $61.3 million in 2001.[29]

US GCM sites remained active and continued to result in increased funding until GCM's US organizing was discontinued in 2009 in order to redirect available resources to GCM work in Africa. By that time, the US annual investment in microbicides had virtually doubled from its 2004 level, standing at $178 million and comprising 73 percent of the total global investment in microbicides.[30]

Canada

After meeting Canadian advocates at the Microbicides 2000 conference, GCM staff established a partnership with the Canadian AIDS Society (CAS) that led to the creation of a nationwide Microbicides Advocacy Group Network (MAG-Net). CAS put microbicides on the agenda at Canada's first National Conference on Women and HIV/AIDS in 2000 and made it a plenary presentation topic at a national skills-building symposium for HIV/AIDS agencies in 2001, thus facilitating MAG-Net recruitment.

With the Canadian Institutes of Health Research and the Interagency Coalition on AIDS and Development (ICAD), MAG-Net explored strategies for stimulating research on microbicides in Canada and generating government support. In 2003, two candidate microbicides were under development in Canada. The Canadian government provided modest funding to one (CA$300,000), an investment far less than its level of support for HIV vaccine research. In 2004, however, the Canadian government made its first major investment in microbicide research and development, a CA$15 million, three-year contribution to IPM.

Between 2002 and 2005, MAG-Net (with GCM support) hosted quarterly calls featuring experts in the field to inform its growing membership and fuel discussion of the Network's advocacy agenda. It developed and disseminated a range of original research updates and fact sheets, as well as adapting and translating GCM materials for distribution in Canada.

GCM's *Giving Women Power Over AIDS* photo exhibit (discussed further below) was translated into a bilingual format and adapted for Canadian audiences in 2007, traveling from British Columbia to Quebec as it was displayed by MAG-Net members across the country.

Canadian microbicides advocates and MAG-Net members organized four government-funded interdisciplinary Microbicides Symposia between 2003 and 2007. In 2006, Canada became the first country in the world to publish a multisectoral, government-sponsored "Microbicides Action Plan," which outlined recommendations on:

- Policy and regulatory issues.
- Cross-departmental and cross-sector mechanisms for collaboration.
- Steps to accelerate microbicide development and delivery.
- The domestic and global contributions that Canada needed to make to accomplish this goal.

Canada's annual funding for microbicide research and development rose from CA$0 in Fiscal Year 2000 to CA$2.7 million in Fiscal Year 2007.

In 2009, GCM, CAS, and ICAD co-hosted a satellite session on the Action Plan at the Canadian Association for HIV Research (CAHR) annual conference. The response was very positive, and at the conference's closing plenary, CAHR president Dr. Brian Conway suggested that microbicides should feature more prominently in the 2010 conference. Unfortunately, MAG-Net ceased operation in 2010, shortly after GCM was forced to discontinue its organizing activities in Europe and North America due to a shift in priorities of one of its major donors.

Europe

In 2002, the UK Department for International Development funded a £16 million (US$20 million) five-year grant to the newly created Microbicides Development Programme, a consortium of UK research institutions and five African nations devoted to developing an effective microbicide. Simultaneously, the Rockefeller Foundation established IPM, a US-based public-private partnership created to facilitate the development, licensing, and distribution of a microbicide to women in the developing world.

GCM's European arm, GC Europe, was launched shortly thereafter.* At the Microbicides 2002 conference in Antwerp, GCM, IPM, and International Family Health (IFH, a London-based NGO that agreed to house and help fund the GC Europe secretariat) convened a meeting that launched the mobilizing effort, starting with a preconference training to prepare communities new to the microbicides issue for the conference's scientific debates.

The challenge of launching a multicountry effort designed not only to influence individual European governments but also the European Union as a whole was daunting in its complexity. Starting in the United Kingdom, GCM seconded an American staffer to work at IFH for three months to map out assets (which included a few partners in London and the Netherlands) and develop a start-up strategy.

This resulted in:

- The hiring of a local GC Europe coordinator.
- Recruitment within the first year of several key European NGOs, starting with the UK National AIDS Trust and Ireland's Cairde.
- Formation of the UK/Ireland Campaign for Microbicides.

As in North America, one of the local coordinator's first tasks was to develop materials that could be sent to all existing and newly recruited endorsers to help them start mobilizing their own constituencies. This required translating and adapting existing GCM materials and

PATH /Mike Wang

GCM's initial work in Europe focused on developing materials that could be sent to endorsers to help them start mobilizing their own constituencies.

* On February 20, 2002, a day-long meeting to plot strategy for mobilizing resources and political will in Europe was hosted by IFH and GCM in London. A total of 25 people from key European NGO groups attended.

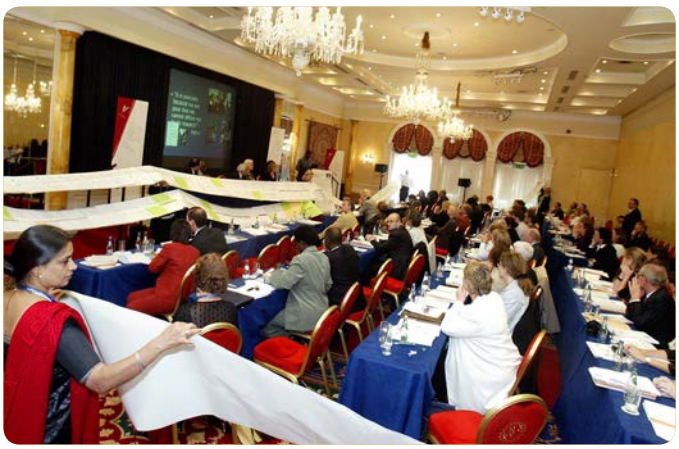
collaborating with partners to develop publications such as *Microbicides: The Case for Europe*, designed to engage policymakers and advocates.

By 2004, GC Europe had established GCM sites in Belgium, Denmark, Norway, Spain, and Sweden. While Ireland held the EU presidency in 2004, advocates got language urging increased funding for microbicide research incorporated into the *Dublin Declaration on Partnership to Fight HIV/AIDS in Europe and Central Asia*, a document shaping the European Union's response to HIV/AIDS. This achievement highlighted GCM's progress toward building advocacy and influence in Europe.

When IFH closed in 2004, GC Europe moved to Brussels (de facto capital city of the European Union) to share office space with IPM, the International AIDS Vaccine Initiative (IAVI), and the Stop AIDS Alliance (an initiative of the International HIV/AIDS Alliance and AIDS Fonds). This change of venue took GC Europe to the next level, enabling it to increase outreach and contact with new and potential NGO partners on the continent and to maintain direct contact with EU parliamentarians, European Commission staff, and other policymakers.

As co-located allies, the four organizations increased their capacity exponentially to track relevant EU policy developments and keep a close eye on funding commitments made by European donors. This co-location also facilitated GCM and IPM's use of a coordinated "inside/outside" approach to influencing European governments. While IPM worked to engage civil servants in key ministries, GCM mobilized NGO allies in the development, women's health, and HIV/AIDS fields, thus bringing pressure to bear on donor governments from two angles. While productive overall, this synergy unfortunately contributed to confusion among donors, which sometimes believed that they were supporting the microbicides field as a whole by making grants to IPM (one among several major players in the field).

Global Campaign for Microbicides



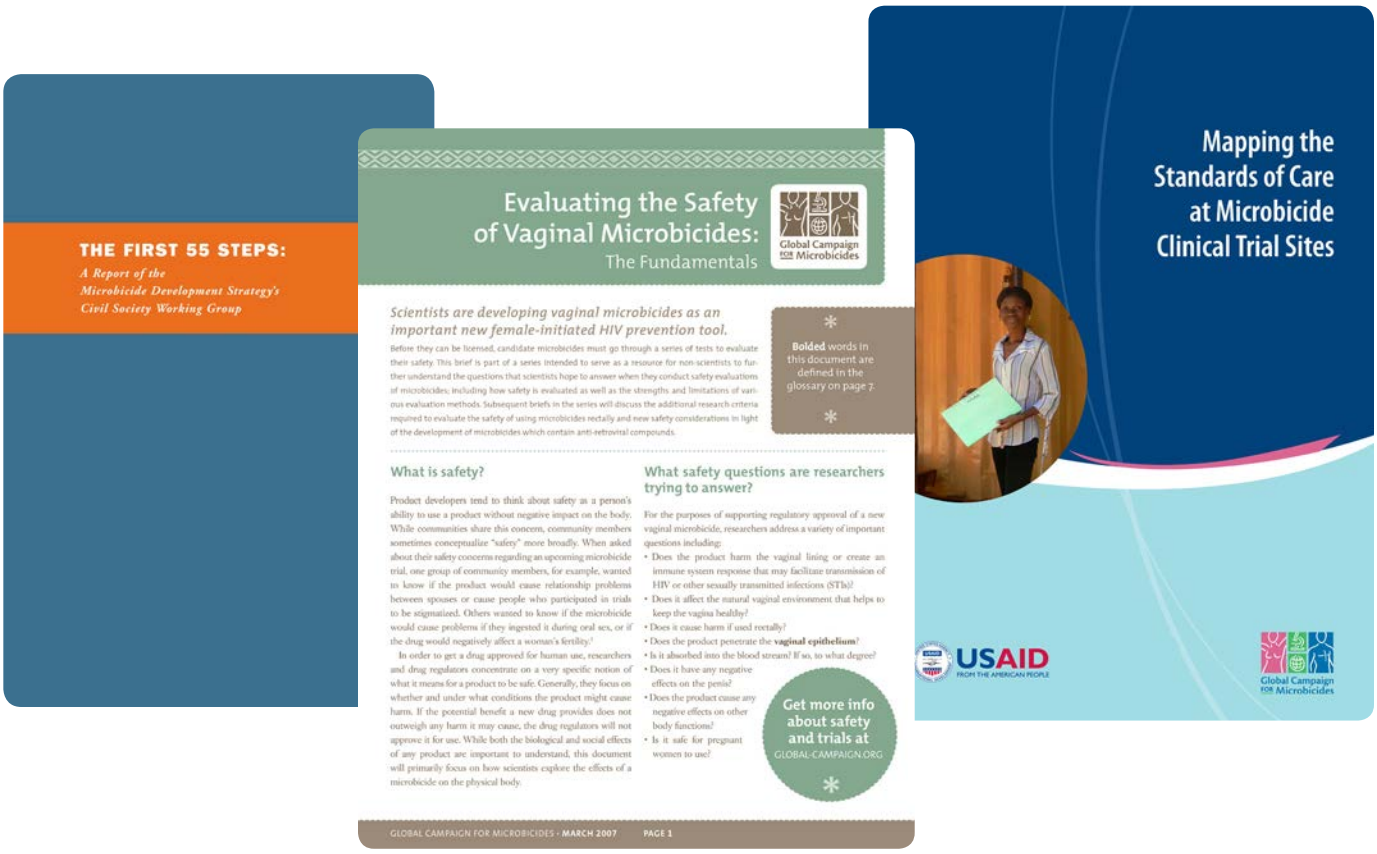
At a European Union meeting on New HIV Prevention Technologies in 2004, GCM partners unfurled completed copies of a microbicides petition that included more than 200,000 signatures collected globally from people demanding condom alternatives.

Between 2000 and 2007, European funding for microbicide research and development increased from US$0.7 million to US$59.6 million. By 2009, GC Europe had active sites in ten European countries and was circulating materials in Dutch, English, French, Russian, and Spanish. When GC Europe closed in April 2009 (due to resource constraints), 11 European governments and the European Commission were actively funding microbicide research. Of the top 15 public and philanthropic funders, ten were European. These figures stand as evidence of the achievement of Goal 1 objectives in Europe.

Community education tools

As noted above, educating new endorsers and potential partners about microbicides was one of GCM's first tasks in every region. In addition to the tools developed for this (PowerPoint presentations, action kits, etc.), GCM also recognized the need for materials to educate the general public and reach out to potential allies through print and electronic media. Its small budget, however, required GCM to focus on low- or no-cost ways of getting media attention and relying on the provocative nature of its subject to attract public attention. GCM characteristically started with some form of the question, "What if women had a way to protect themselves from HIV that did not involve men using condoms?"

In its first two years, GCM staff published dozens of print articles and were interviewed by National Public Radio, the BBC, and local public radio and television affiliates, and mentioned in print in *Newsweek, the Journal of the American Medical Association*,[31] *AIDS Patient Care*,[32] *Reproductive Health Matters*,[33] *HIV Plus*,[34] the *Sexual Health Exchange*,[35] and other periodicals. Following this introduction and throughout its history, GCM spokespeople (staff and steering committee members) were regularly contacted by press at all levels when reporters were covering HIV prevention, women, and



GCM created a wide range of tools and materials to reach and educate partners and the general public.

microbicides. GCM staff also regularly published original pieces in academic journals, the popular press, and the electronic literature.

In developing countries, where NGOs are commonly expected to pay for coverage in the mainstream press, GCM boosted its media presence by partnering with Health and Development Networks (HDN), an NGO that engaged and developed the skills of community-based journalists. GCM contracted with HDN to support a team of key correspondents writing specifically on microbicides. Primarily young writers in developing countries, HDN staff covered regional and international AIDS-related conferences occurring in their regions, while also producing conference newspapers and reports.

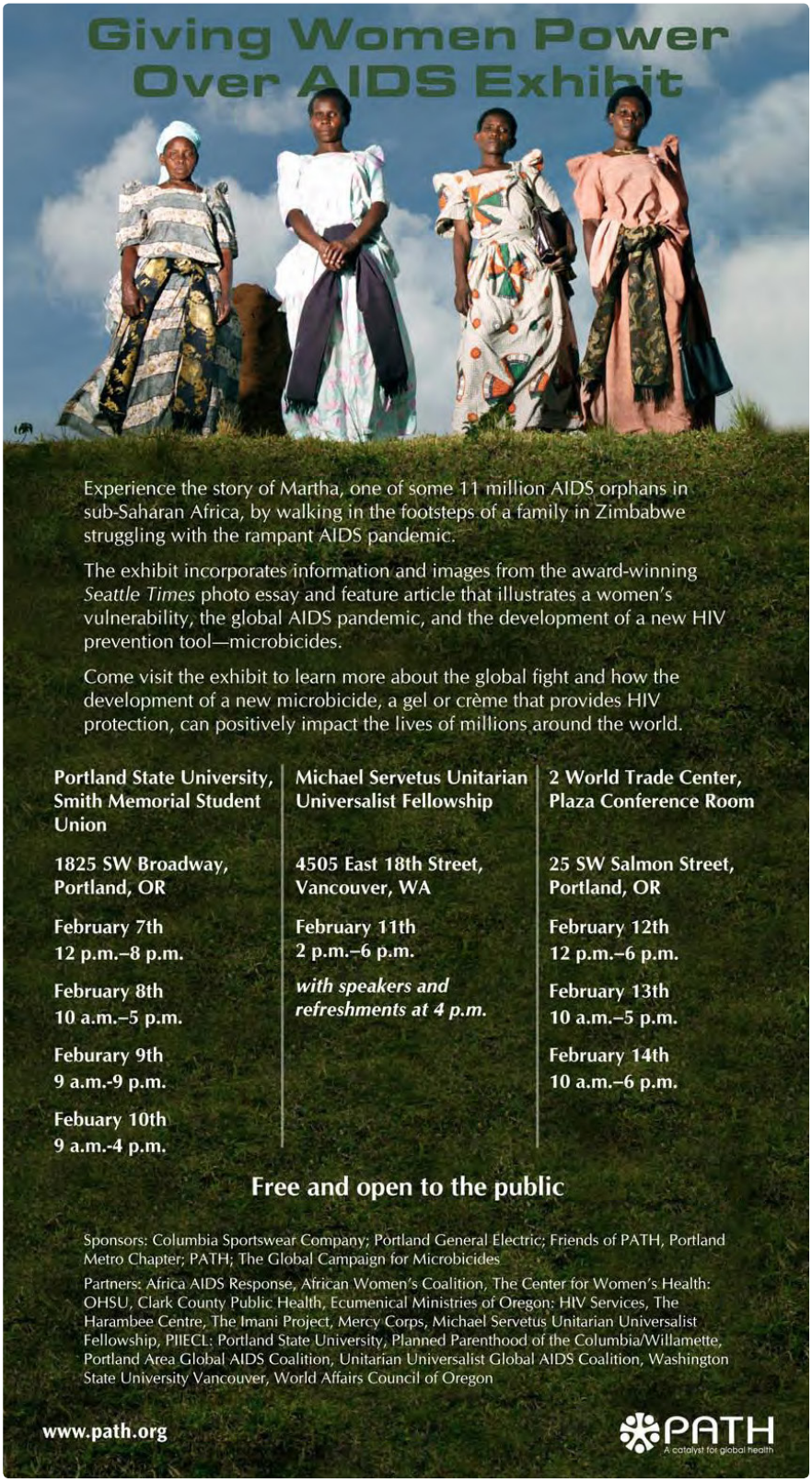
HDN also moderated several online discussion forums, organized by region and issue, to facilitate civil society information-sharing and implementation of a coordinated advocacy response. One of these, *Microbicides This Week*, was introduced at GCM's request as a feature of HDN's popular Gender-AIDS Forum (which had approximately 2,000 subscribers in more than 30 countries). It served as an international exchange on microbicide activities and information that invited discussion and debate. In 2003–2004 alone, HDN covered microbicides at 12 conferences and made 70 postings related to prevention methods for women, reaching a far broader audience than would have been possible otherwise.

GCM also created tools to reach and educate the general public. Among these were two traveling photo exhibits, one that toured in Europe and North America in 2005-2009 and another that toured in South Africa and internationally in 2011-2012. The first exhibit, ***Giving Women Power Over AIDS***, told the story of Ruth Njawara Chimuonenji, a Zimbabwean woman who contracted HIV from her husband and feared, as she was dying, that her young daughter would meet the same fate. This account by Paula Bock was first published as a photo essay in the *Seattle Times*, entitled "In Her Mother's

Shoes."With permission from Chimuonenji's family, the author, and the publisher, GCM re-interpreted it as a walk-through exhibit of ten collapsible, double-sided panels with a high-production finish that could easily travel, stand on its own, and be set up by anyone, anywhere. GCM added panels providing key information on the status of microbicide development and the political challenge of getting it funded, leaving the viewer with a clear message about the need for action on the issue.
The exhibit provided a searing look at the core of the need for female-initiated HIV prevention options.

Giving Women Power Over AIDS was displayed in more than 70 locations im multiple countires, including universities and community colleges, libraries, art galleries, state and national capitol buildings, city halls, churches, and major conference venues. It was on display in the European parliament in Brussels, the United Nations headquarters, and the Dutch Ministry of Foreign Affairs. Displayed in Finland's parliament for two weeks, the exhibit sparked debate on the role that Finland could play in HIV prevention research. After its showing in the European parliament, several members of the parliament confirmed that prior to the exhibit event, they had not understood women's vulnerability to HIV. The exhibit was also on display at the US capitol building when then Senator Barack Obama introduced the MDA on International Women's Day, March 8, 2007.

In 2011, GCM launched a second photo essay exhibit, ***The Hope Exhibition: A Day in the Life...***, at the 5th Southern African AIDS Conference. Displayed in 13 panels, it was a visual narrative depicting the lives of six former microbicide trial participants in Zimbabwe. The exhibit communicated human stories behind large-scale vaginal microbicide and pre-exposure prophylaxis



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(PrEP) studies, providing insight into the lives of the study volunteers and the challenges faced by trial staff. By connecting audiences to the realities behind the research effort, the exhibit served to mobilize advocates, donors, and policymakers in support of HIV prevention research while renewing the sense of purpose among stakeholders in the field. The exhibit was subsequently displayed at a range of venues, including the 2011 International AIDS Society conference in Rome, US Agency for International Development (USAID) World AIDS Day events, the Microbicides 2012 conference in Sydney, and the XIX International AIDS Conference in Washington, DC in 2012. GCM staff also developed a book containing the exhibit's photos and essays that reflects the thoughts of the women featured in the exhibit.

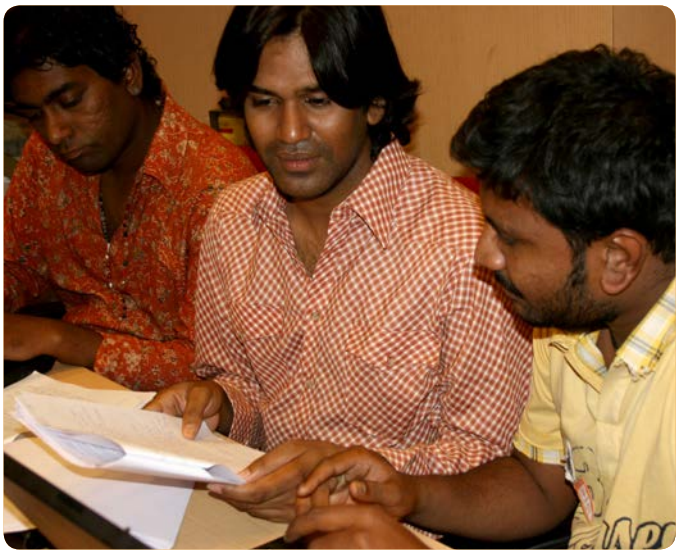
In 2004, GCM created a short film, ***In Women's Hands***, a tool for advocates around the world to use in their own communities. As with the exhibits, the film presented the often unheard voices of women and communities who could most benefit from new HIV prevention options. It also shared the excitement of a growing advocacy movement to meet this need. The film wove together the stories of women in Baltimore, USA, and KwaZulu Natal, South Africa (two areas hard hit by HIV), as well as those of microbicide trial participants and men living in hostels far from home in South Africa. It also featured advocates, policymakers, and researchers who continued to push for a microbicide despite limited resources and other challenges.

The film was translated into Spanish, and more than 800 copies had been distributed and viewed as of 2012. A discussion guide was sent with all copies to encourage advocates to organize a screening event followed by discussion. Such orchestrated showings occurred in more than 185 cities and 50 countries globally. In 2006, for example, a film screening in Delhi on World Health Day drew an audience that included reproductive and sexual health and rights workers, professionals from other health sectors, and researchers from the Indian Council of Medical Research. The film was so well received that it was translated into Hindi and Tamil for additional outreach in India.

While it is difficult to quantify the direct impact of films and exhibits, these tools effectively multiplied the voices of microbicides advocates across the globe, most of whom were volunteers. Using these tools, advocates could provide authoritative and moving accounts of the issue without a GCM staffer being present, and confidently present their roles in the work of GCM. For long-time GCM partners, the exhibits and film provided a new way to deliver an old message and re-invigorate engagement on the microbicides issue with their constituencies.

Mobilizing gay men

In 2000, UNAIDS announced that its COL-1492 trial had been stopped because the test product, nonoxynol-9 contraceptive gel, not only did not reduce HIV risk, but if used frequently, might actually increase risk by disrupting the vaginal lining. One of the many repercussions of these findings was Population Council research to assess N-9's effect on rectal tissues, which showed the drug to be even more damaging in the rectum than the vaginal cavity. Since the 1980s, some manufacturers had been adding N-9 to sexual lubricants and condoms to attract customers with the implied (but never explicitly stated) suggestion that using N-9-coated condoms and lubricants could make sex even safer.



PATH /Satvir Malhotra

GCM engaged gay men's health organizations across the globe in an effort to increase their interest in advocating for safe, effective rectal microbicides.

GCM strongly maintained the value of N-9 as an important contraceptive option for women at negligible risk of HIV. But given the Population Council data, GCM felt compelled to raise awareness of the potential risk of using N-9-containing products during anal intercourse—both to dispel the myth that such products were protective and to create distance between N-9 use associated with HIV risk and the much greater anticipated safety of future microbicides. GCM also saw promotion of this message as an opportunity to engage gay men's health organizations and possibly increase their interest in advocating for safe, effective rectal microbicides.

In 2002, GCM publicly issued a "Call to Remove N-9 from Condoms and Lubricants." Endorsed by a broad-based coalition of more than 85 leading scientists and health groups, the statement called on condom and lubricant manufacturers to voluntarily remove N-9 from their products. As the list of endorsers steadily grew, all US manufacturers of sexual lubricants removed N-9 from their products, as did several small condom manufacturers. In 2004, two major companies, Durex Ltd. and CondomDepot.com, stopped manufacturing and selling N-9 condoms. Responding to pressure from GCM advocates, the Public Health Agency of Canada produced a fact sheet highlighting the risk of using N-9 rectally, and the UK National Health Service issued guidance indicating that N-9 condoms were no longer recommended. The US Food and Drug Administration did not comment on N-9 and condoms.

GCM then asked the AIDS Foundation of Chicago (AFC, an organization successfully engaged in health advocacy among gay men) to head up an effort to promote advocacy for rectal microbicides. In 2005, the International Rectal Microbicides Coalition (IRMA) was co-founded by AFC, GCM, CAS, and the Community HIV/AIDS Mobilization Project. GCM staff served on IRMA's steering committee until 2009 and appreciated the group's steadfast emphasis on the need for rectal microbicides by all individuals having anal sex—women as well as men.

IRMA's growth was slow, as many people perceived rectal microbicides as a far future possibility and were more focused on current HIV prevention efforts. But by 2011, IRMA had published three groundbreaking reports, the first of which documented the lack of funding and support for rectal microbicide research and the consequent dearth of research underway to develop a rectal microbicide. Subsequent reports highlighted data on the frequency of anal sex (among both heterosexuals and homosexuals) and its underreported role in the AIDS epidemic. IRMA pushed for a more coordinated rectal microbicide research agenda and more open discussion of the topic in the media and at conferences. By 2012, IRMA's moderated listserv had reached 1,100 active subscribers around the world, promoting discussion not only of the research but also the politics of microbicides, homophobia, and the full range of HIV prevention technologies. The first clinical trial of a candidate rectal microbicide was funded in 2010 and completed in 2011, a milestone that would have been much longer in coming absent these advocacy efforts.

Goal 2: Promoting stronger civil society involvement in a scientific endeavor

GCM's second objective—promoting civil society involvement in the scientific process of microbicide research and development—focused on the roles that communities in the developing world could play in the creation of microbicides. These included:

- Helping to structure the research agenda.
- Ensuring that community views and perspectives are addressed in trial designs.
- Creating political pressure to ensure that resulting products, if effective, rapidly become accessible and affordable to local residents.

As noted above, the large-scale trials of a microbicide's effectiveness must be conducted where new infection rates are high enough to make it possible to gauge a test product's impact. These conditions exist primarily in sub-Saharan Africa, although trials have also been conducted in India and Southeast Asia. Since Latin American and eastern European countries neither fit into the trial host category nor the potential donor government category, they were not the focus of substantial GCM organizing. Despite this, several

strong partner organizations based in these regions carried forward microbicides education and organizing in their own ways, using GCM materials and other resources, and their input contributed substantially to GCM's knowledge base.

Stimulating high levels of community involvement in microbicide trials in developing countries was challenging for two reasons. First, there was little or no tradition of such involvement, and research networks often saw it as an unnecessary complication to their work.[36,37] Second, the long history of human rights abuses occurring within the context of medical research generated distrust in many communities about researchers' intentions and left the impression that all researchers treated participants like "guinea pigs."[38] This was exacerbated by the frequency with which successful products tested in developing countries remained unavailable or unaffordable to those in whose bodies they had been tested. They were marketed, instead, in affluent countries, where greater profits could be made. GCM had to approach its work on Goal 2 in ways that honestly addressed these pressing concerns and demonstrated, over time, GCM's durable commitment to working with communities to change that paradigm.

One way GCM expressed this commitment was by using an organizing approach it called "leading from behind." This required viewing collaborative projects as opportunities to invest time and energy in building the capacity of smaller partner organizations to lead the project implementation process. The approach also emphasized shared decision-making with partners and generously distributing public credit for successful outcomes, even when GCM had shouldered the majority of the project's workload and expense.

While labor intensive, this approach yielded valuable results. It built GCM's reputation for working in solidarity with its partners and expanded the capacity of smaller or less experienced partners to carry forward their own advocacy initiatives at the local and national levels. It also helped to produce well-informed advocates who understood the mechanics of science and were well-positioned to counter myths, misperceptions, and rumors about microbicide research when they arose, thus reducing the risk of the type of spiraling public misunderstanding that can undermine trials.

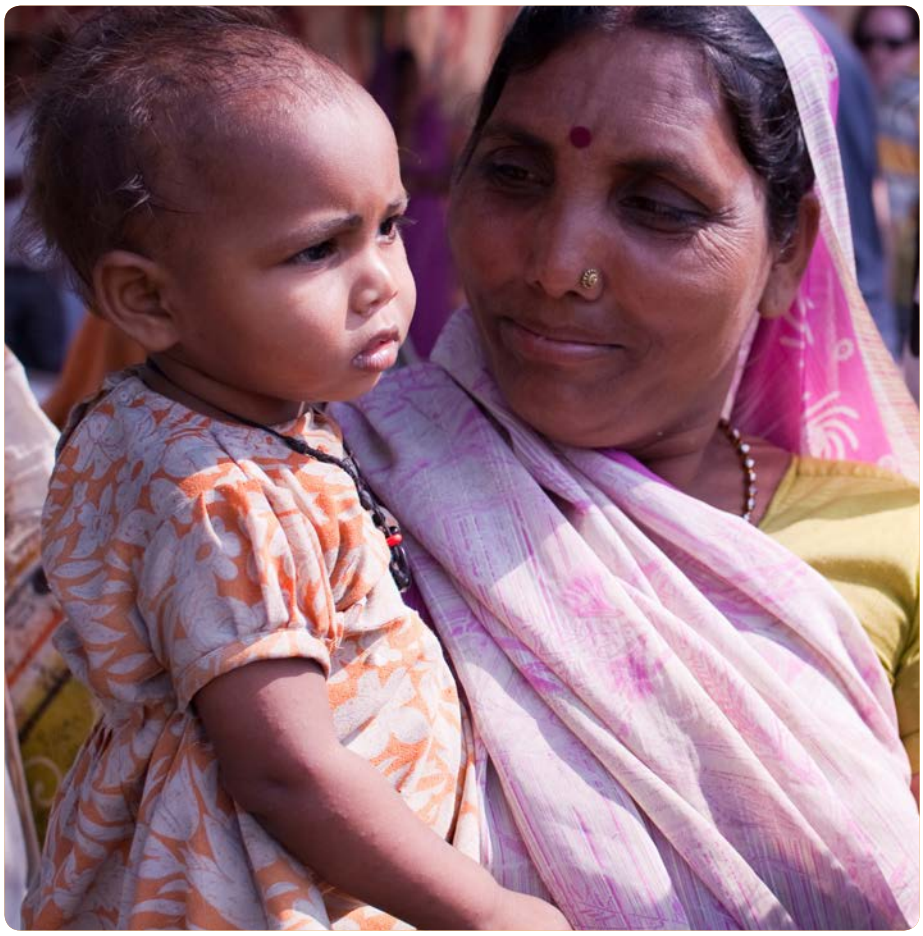
GCM set two complementary, equally critical objectives by which to measure its progress in mobilizing advocates in developing countries. It sought to:

1. Create channels to give voice and visibility to the strong but unarticulated demand for microbicides in communities hardest hit by HIV, thus producing compelling evidence for use by advocates in the global North to bolster their case for increased investment by donor governments.
2. Help foster the agency of key advocates in developing countries by delivering capacity-building resources (training, materials, and some funding) and publicly supporting their right to play active roles in shaping microbicide research, development, and, ultimately, access.

Not surprisingly, resource-poor communities decimated by AIDS were interested in microbicides as a future possibility but prioritized work to increase use of immediate prevention options, such as gaining access to female condoms, which are still not widely available in many countries. In these settings, GCM expanded its frame to join advocacy with donor agencies and health ministries for greater access to the female condom and other prevention methods—and talked about microbicides as part of a wider HIV prevention agenda. Many of its educational and outreach activities in those countries were framed as "increasing HIV prevention options for women" and were carried out in collaboration with female condom advocates and other HIV prevention advocates.

Another emerging theme was the early enthusiasm of organizations of HIV-positive women, led by the International Community of Women Living with HIV/AIDS (ICW), for microbicides as an option to help them to protect their partners (possibly without having to disclose their own HIV status) and pursue pregnancy without putting a partner at risk. Their position was controversial because it contradicted the conventional emphasis on HIV testing, disclosure, and continuous condom use. Researchers also worried that this advocacy angle over-promised the protective ability of microbicides. They noted that plans to test bidirectional effectiveness (protecting partners as well as users) were not yet on the horizon. Positive women responded by asserting their right to benefit from the results of science, and the ensuing debate resulted in recognition

by the scientific community that bidirectional protection had to be added to the research agenda—an example of the success that negotiation between researchers and advocates can have.



PATH /Lesley Reed

GCM undertook a range of activities in India, such as convening key microbicide stakeholders and creating a vaginal health training curriculum designed for use with low-literate women.

India

In 2001, the Indian Network of NGOs working in HIV/AIDS (INN) invited GCM to make a presentation at its Fifth National Convention in Ahmedabad. India's National AIDS Control Organization had been in place since 1987, and microbicide trials in India started in 1998 with a Phase 1 trial of an N-9 suppository. By 2001, clinical trials on Praneem and BufferGel®, two other candidate microbicides, were also underway, and India was reported to have the largest population of people living with HIV/AIDS in the world.

In 2002, GCM, INN, and PATH's India office jointly convened a Community Stakeholders Meeting on Prevention Options for Women. This brought together representatives from HIV/AIDS and women's rights organizations to meet with researchers and government officials. Several Indian NGOs became GCM partners during this time with the encouragement of the Gujarat AIDS Awareness Project, an early endorser, and the staff of PATH India.

In 2003, a National Policy Meeting convened by GCM and the Indian Council of Medical Research resulted in a recommendation that a National Working Group on Microbicides be formed. Launched in 2006, the working group included community leaders, journalists, advocates, and researchers who agreed to convene dialogues with national policymakers and explore the lessons learned from the introduction of past technologies in India. GCM proposed to support the working group by bringing forward grassroots concerns and insights on preferred product attributes, the involvement of communities in trials, research ethics, and preparing for product introduction.

To accomplish its agenda, GCM hired two staff members in the PATH India office. These staff began to reach out to Indian women's groups, which had historically been very critical of new reproductive health technologies and suspicious of medical research. GCM organizers built bridges with these groups, ensuring that feminist activists were involved in key debates early on and that their concerns were taken seriously.

GCM staff also conducted a policy mapping exercise to gather stakeholders' inputs into a microbicides advocacy strategy for India. This project examined the crucial gaps and obstacles in leadership, infrastructure, human capital, policies, funding, and other resources that were possibly hindering progress in microbicide development in India. It also yielded insights on how to create a supportive environment for accelerated and ethical research and eventual introduction of microbicides in the country.

Leading up to the Microbicides 2008 conference in Delhi, GCM staff established a moderated listserv focusing on microbicides and other HIV prevention technologies. Called "Female STI/HIV Prevention Options Today" (F-SPOT), this listserv enabled advocates, researchers, and community members to share information and engage in broader dialogues with stakeholders working in other areas of HIV prevention. This not only enabled GCM to share information with its partners and endorsers (and these participants to talk to each other), it also helped facilitate interest and broad participation in the global Microbicides 2008 conference, which was attended by more than 1,100 scientists and advocates.

Finally, GCM's India staff created a vaginal health training curriculum designed for use with low-literate community women. Combining visual materials with a thorough script and discussion guide for presenters, the eight-unit curriculum familiarized women with how their bodies function at each stage of life and set the stage for talking about how microbicides and other HIV prevention technologies work. Tested among key population focus groups, this tool considerably expanded the team's ability to work effectively in low-literate communities.

Southeast Asia

Between 2000 and 2001, the Population Council conducted an acceptability study of Carraguard®, a candidate microbicide, in Thailand. This proximity to microbicide research motivated the Thai Women's Health Advocacy Foundation (WHAF), a GCM partner, to integrate microbicides into its program of reproductive and sexual rights advocacy. WHAF conducted a series of workshops and other events for its constituency and met with female parliamentarians to discuss the issue.

Given the possibility that more microbicide trials would take place in this region, GCM set out jointly with IFH (also involved in the region) to help strengthen this nascent organizing by bringing Asian advocates to its 2003 International Advocates Meeting, as well as to the Microbicides 2004 conference held in London. At both meetings, participants expressed interest in creating a more formal microbicides network in Southeast Asia. GCM subsequently worked with the Asia Pacific Council of AIDS Service Organizations to conduct trainings in the region and commissioned an NGO mapping to identify supportive organizations and key microbicide-related issues of interest in Southeast Asia.

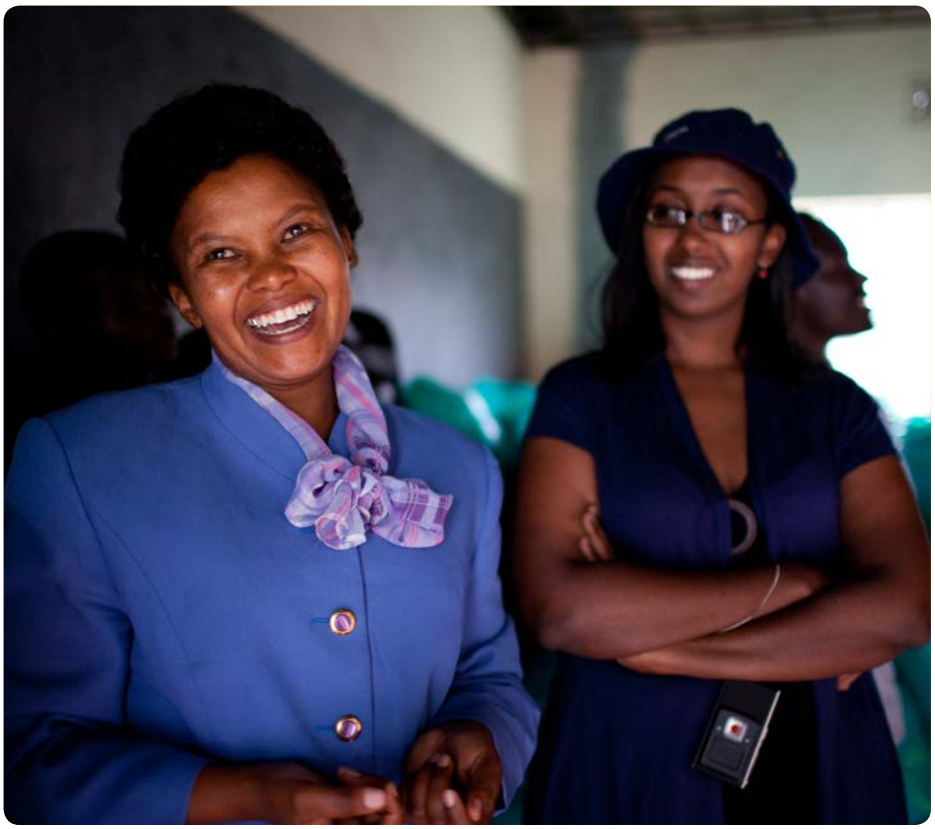
These efforts bore little fruit, however, because key partners were overloaded with other work. Then it became obvious that the region was unlikely to host future trials, due to declining HIV incidence, and interest waned further. GCM discontinued mobilizing efforts in the region since it no longer fit into either of the categories identified for target regions (potential donors or places where microbicide trials were occurring).

Heng Chivoan

GCM worked with partners in Southeast Asia to strengthen efforts aimed at creating a more formal microbicides network in the region.

Africa

Gugu Dlamini, a 36-year-old volunteer for South Africa's National Association of People Living with HIV/AIDS, was beaten to death in 1998 by a mob of her neighbors, who accused her of "shaming her community" by revealing on the radio that she was HIV positive.[39] At that time, 30 percent of all adults in KwaZulu Natal, the province in which the murder occurred, were estimated to be HIV positive, and fully half of all new HIV infections worldwide were occurring among African women,[40] a trend driven by gender-based power imbalances, as well as by women's greater physiological vulnerability to HIV.



PATH /Eric Becker

GCM worked closely with African microbicide trial sites, where trial sponsors were implementing mechanisms to foster transparency and build trust in research efforts.

Entering this highly charged political environment, GCM acknowledged first and foremost that developing a clinically effective microbicide was only one part of the challenge. Unless these products were developed with close attention to factors affecting their acceptability and affordability to women at highest risk of HIV, their impact would be negligible. Since much-needed information about women's preferences and needs resided with the women themselves, GCM argued that it was essential for women's voices to be a central part of product research and development processes.

The challenge of engaging with women and the NGOs supporting them in this already volatile climate was further exacerbated for GCM by the N-9 trial data released in 2000. Presented at the XIII International AIDS Conference in Durban, South Africa that same year, these data showed that use of contraceptive gel containing N-9 might have increased HIV risk among trial participants who used it frequently. Many people saw this news as signaling that microbicides were dangerous to pursue. Some were also angry that a trial had heightened some participants' risk of HIV and felt that the researchers should have foreseen and prevented this.

GCM worked to raise awareness of the protective measures put in place to reduce trial participants' risk and emphasized that N-9 had not been developed as an anti-HIV agent, but since it was being used by millions of women to prevent pregnancy, it was important to evaluate its safety within the context of HIV and to evaluate observational data that it may reduce transmission of gonorrhea, chlamydia, and possibly HIV. While N-9 proved ineffective and possibly harmful if used frequently, more than 50 novel microbicide candidates (not containing N-9) were in development, with seven promising enough to be in late-stage clinical trials. Nevertheless, N-9 remained a prominent concern raised frequently by African organizations, and GCM's sensitivity in responding to their skepticism was critical to its ability to make progress.

By 2000, GCM staff had identified and contacted interested potential partners in Ethiopia, Ghana, Kenya, Rwanda, Senegal, and Zambia. Community workshops on microbicides (frequently starting with discussion of the N-9

results) were underway in multiple locations. GCM was also presenting at regional and national conferences on HIV and reproductive health wherever possible and working closely with SWAA to provide education on clinical trials and research into new prevention options for women. These efforts were welcomed by people already keenly interested in engaging in activism to address women's vulnerability to HIV.

In July 2001, GCM sponsored its first International Advocates Meeting in a Washington, DC suburb. This meeting was scheduled to follow the UN General Assembly Special Session on AIDS, held in New York City, so that GCM could bring allies to both meetings and thereby expand its visibility at the United Nations. GCM's three-day meeting brought together 60 microbicides advocates from 28 countries, almost a third of them African, to unify partners from widely divergent settings around a central agenda. It also generated a wealth of new strategy ideas, provided essential cross-cultural learning, and reinforced participants' sense of the urgency of the task at hand.

At the same time, GCM was also working with African microbicide trial sites, where trial sponsors, for the first time, were implementing community advisory boards (CABs) and other community involvement mechanisms to foster transparency and build trust in the research enterprise. With USAID funding, GCM brought together "community engagement" staff from eight clinical trial sites in four Southern African countries in Johannesburg in 2003 for a three-day "Dialogue on Community Involvement in Microbicide Clinical Trials," co-hosted by the South African Microbicide Research Initiative (SAMRI). The conclusions that emerged from this meeting included:

- CABs, customarily the sole point of community contact with trials, were not always the optimal mechanism for involving communities.
- A number of other community involvement strategies were consequently evolving and being tested by trial staff.
- Since research institutions and communities work best together when genuine partnership between them exists, explicit discussion of the terms and benefits of these partnerships must become an ongoing part of the field's discourse.

These findings supported GCM's contention that a "seat at the table" had to be defined broadly and reserved specifically for community representatives. Without this, it was impossible to ensure that all those standing to gain or lose from the microbicide development process would be able to participate in making the important decisions shaping the process. These seats could only be occupied effectively, however, by individuals with access to the training, resources, and support they needed to "hold their own" in these discussions. By working with local partners to make such capacity-building available, GCM sought to advance the field from valuing *community input* to instead recognizing and appreciating the practical and ethical value of *authentic partnerships* with the communities hosting the trials and that would be the primary users of microbicides.

Within this period, GCM was also raising issues with clinical research staff that had not yet been addressed, such as:

- The need to provide contraceptives as part of the trials to minimize loss of participants due to pregnancy.
- The significance of maintaining consistency in counseling messages to maximize women's adherence to product use.
- The importance of establishing effective referral and support systems for women experiencing domestic violence.

With other NGOs and treatment activists, GCM opened discussions with South African government officials about their plans to expand provision of antiretroviral (ARV) drugs to people living with HIV/AIDS—a factor with serious ethical implications for clinical trials because of the obligation to ensure that participants who seroconvert during a trial have ongoing access to ARV treatment. In 2003, GCM was invited to present its work at the launch of SAMRI before an audience of researchers, provincial and national government officials, and representatives of communities hosting microbicide trials.

Nigeria

Interaction between GCM staff and Journalists Against AIDS (JAAIDS) in Africa began in 2001 and evolved into one of GCM's strongest partnerships. A pioneering activist and journalist, Omololu Falobi, founded JAAIDS in 2000 as a network of journalists committed to getting high-quality information to the public about HIV/AIDS and to providing training and support to journalists covering the epidemic. Two of its members attended GCM's International Advocates Meeting in 2001, relaying news of their work with the Nigerian government's HIV Ethics Committee and indicating that microbicide trials might be starting shortly in Nigeria.

During the drafting of Nigeria's National HIV Vaccine Plan in 2001-2002, JAAIDS members met frequently with other HIV prevention-focused advocates, and these connections were further strengthened during the Microbicides 2002 conference in Belgium. In 2003, they collectively formed the Nigeria HIV Vaccine and Microbicides Advocacy Group (NHVMAG), which flourished so rapidly that 25 Nigerian advocates attended the Microbicides 2004 conference in London.

NHVMAG, with GCM support, organized its first Nigerian National Advocates Meeting in 2004 and began regularly holding media roundtables and other events to educate members and others about microbicides. With GCM, NHVMAG delivered trainings on ethical reasoning in HIV prevention trials for members of the Nigerian institutional review boards. When controversy erupted after the 2005 closing of a tenofovir PrEP trial in Nigeria, GCM supported NHVMAG in holding a national consultation to collect input for Nigeria's contribution to the UNAIDS meetings on HIV prevention trial ethics.

NHVMAG (subsequently renamed the New HIV Vaccine and Microbicide Advocacy Society) has since produced numerous useful tools for Nigerian and other advocates, including a situation report, a training manual for community mobilization, and many other reports, fact sheets, and media resources. Its work has become a model for other national and regional advocacy networks seeking to influence the HIV prevention research agenda in their settings.

African Microbicides Advocacy Group

At GCM's 2003 International Advocates Meeting, a number of African endorsers came together to form their own coalition dedicated to implementing a microbicides advocacy agenda specifically for Africa. As the African Microbicides Advocacy Group (AMAG), they organized a consultation during the Microbicides 2004 conference to which they invited activists, researchers, scientists, policymakers, service providers, and program managers. There, they planned for "concerted and collective advocacy action to push the microbicides agenda in a way that recognizes our context and perspectives as advocates in Africa."[41]

At this meeting (funded by GCM and IFH), the new AMAG steering committee was introduced and participants were invited to identify their priorities and concerns. In addition, a listserv was established to facilitate ongoing discussion among AMAG members. In 2004-2006, GCM funded AMAG (through its South African NGO host, the Gender AIDS Forum [GAF]) to conduct a regional mapping of advocacy activities and capacities, produce materials introducing AMAG to the public, and continue its e-forum discussions. GCM also supported GAF in its efforts to address local concerns about the N-9 trial results. With GCM funding, GAF trained and equipped local microbicides facilitators, conducted outreach to policymakers, and networked with like-minded activists including ICW, the Asian Pacific Microbicides Group, and AMAG's membership across Africa.

During this time period, the AMAG steering committee made it clear that while it valued GCM's expertise and financial assistance, it felt uncomfortable with the idea of GCM hiring its own Africa-based staff and preferred that GCM continue to invest in supporting AMAG staff. In 2006, however, GCM leadership decided that it was necessary to hire indigenous GCM staff in Kenya and South Africa in order to accomplish its mission and to manage its growing network of African relationships.

GCM's collaborative work with AMAG continued despite disagreement on this issue. GCM, AMAG, and other partners, for example, issued joint press releases and co-convened conference calls when pivotal clinical trial

results were released to enable advocates to discuss the new information and get their questions answered. GCM and AMAG, along with other partners, also co-sponsored and organized the "Advocates' Corner" space and events at each of the biennial Microbicides conferences held between 2006 and 2012. Further, AMAG founded the Omololu Falobi Award for Excellence in HIV Prevention Research Community Advocacy, an honor presented at these conferences by a coordinating committee made up of AMAG, AVAC, GCM, IRMA, NHVMAG, and other partners in the field.

East and Southern Africa

In consultation with its steering committee, GCM decided to hire regional hub staff in both Kenya and South Africa. Both were countries that sponsored large-scale microbicide trials and were well-placed to support advocates in other countries where HIV prevention research was underway. At the time, this included Rwanda, Tanzania, and Uganda in East Africa; and Botswana, Malawi, Zambia, and Zimbabwe in Southern Africa.

Staff presence on the ground enabled advocates to make better use of the available opportunities to network with local partners, engage trial host communities and researchers, and press for greater attention to women's prevention needs among policymakers. In 2007, for example, GCM partnered with IAVI and key women's organizations in Uganda to bring this message to the Heads of Commonwealth member countries. As a result of affective advocacy, the Kampala Communiqué stated that "Heads of Government…acknowledged the need to invest in services and prevention tools, including vaccines and microbicides, to contribute towards the goal of universal access to HIV/AIDS prevention, treatment, care and support by 2010."[42] Just as the Dublin Declaration language in 2004 signaled a sea change among EU policymakers, the Kampala Communiqué also signaled an unprecedented statement of support by Commonwealth policymakers and a change in their level of awareness of the need for microbicides.

"The material was covered in a simplified way which was easy to understand and also easy to share with other colleagues and the community. . .. I liked the practical approach of the training where we are allowed to role play. It is a very good way of teaching one can't forget easily."

~ Training participant Mazabuka, Zambia June 2009

Localized GCM materials were translated into Kiswahili (the shared language in Kenya, Tanzania, and parts of Rwanda and Uganda) and Kinyarwanda to meet Rwandan demand. GCM conducted a major mapping exercise in 2008 that included visits with 27 national organizations, the Rwandan AIDS Commission, and a microbicide clinical trial site in Mwanza, Tanzania. This provided GCM with the information and contacts needed to build a strong, well-networked constituency in these four countries and equip them with advocacy tools and capacity-building training, thus fueling their desire to advocate for more and better woman-initiated HIV prevention options.[43] This was followed by a host of other activities, including:

- Training workshops at the national and provincial levels, as well as in communities hosting HIV prevention trials.
- Adoption of an online course on microbicides (see below) as part of the curriculum at Makarere University, one of the oldest and most prestigious universities in Africa.

As elsewhere, GCM catalyzed interaction between women's health organizations, HIV/AIDS agencies, and human rights activists. Hosting a session at the 2008 Association of Women in International Development Global Forum in Cape Town enabled GCM to engage women's organizations on HIV prevention for women as a gender rights issue, not just a health issue. GCM forged relationships and worked particularly closely with the Health Rights Advocacy Forum and the Kenya Medical Women's Association to promote understanding among health professionals of the intersection between HIV, gender, and human rights.

Engagement with governmental entities similarly flourished. In 2006, GCM became a member of the Kenyan National HIV Vaccine Research Sub-Committee of the Ministry of

Health and worked to move the group toward an expanded view of HIV prevention needs and potential options, including microbicides and PrEP.

Strengthening research literacy

In 2006, GCM undertook the challenge of creating **Microbicides Essentials**, an online course, in response to frequent requests from advocates for more in-depth information about the science behind microbicide development, safety, and acceptability research, as well as succinct advocacy messages. As a virtual textbook, the course was designed to build the capacity of clinical trial staff, advocates, and other stakeholders to speak knowledgeably and answer questions regarding the complexities of microbicide development and testing. In consultation with target audiences, GCM developed both online and CD-ROM versions of the course to ensure its accessibility to people with limited or prohibitively expensive Internet access.

Launched in 2008, the course was made available free of charge and certificates from GCM were sent to those who completed it successfully. In post-course questionnaires, course users expressed appreciation for the depth that it offered in various subjects, the scientific animations, and the easy-to-read graphics. GCM focused on three primary strategies for getting the course into use:

- Independent learners using it online or via CD-ROM.
- Conducting GCM-led virtual classrooms, a three-month distance learning course in which groups of 15 learners took the course and met regularly via conference call with an online tutor.
- A blended learning curriculum in which learners could take the course on their own and then come together with trainers and other learners for a three-day in-person course that reinforced and provided a chance to practice what they had learned.

Some organizations, particularly clinical trial networks, required their staff to take the course as a part of new job orientations or professional development. Within two years of its launch, 216 people had earned certificates from GCM for completing the course online. More than 600 people had used parts of the course, collectively completing 2,142 modules. One-third of those learners were clinical trial staff, another third advocates, and the remaining third were HIV educators, bench scientists, government officials, and other stakeholders. More than 70 percent of the course graduates in 2009 were from Africa.

While labor and resource intensive to create and maintain, the course made an important contribution to GCM's goals by building the capacity for informed civil society involvement in the field and establishing broader communication among advocates, clinical trial staff, and those involved in microbicides at other levels. Participants not only learned from it but also absorbed a common base of terms and context for use in future discussions, all of which facilitated ongoing, collaborative, and multisectoral involvement in microbicide research and introduction at the local level.

PATH / Mike Wang

GCM created online courses and other mechanisms to build the capacity of clinical trial staff, advocates, and other partners to speak knowledgeably and answer questions regarding the complexities of microbicide development

Goal 3: Enabling trials to proceed efficiently by addressing emerging challenges

This third goal encapsulated GCM's work to resolve key ethical, policy, and communication dilemmas that can (and have been shown to) impede trials or undermine community support.

Large-scale clinical trials are, by their nature, expensive and labor intensive to conduct. Trials financed by private pharmaceutical companies are conducted under industrial confidentiality protections and required to release relatively little information to the public. Greater transparency is required of publicly funded trials (those supported by governments and philanthropic institutions) and they are subject to constant media scrutiny. This has the useful effect of promoting accountability, but it also means that trials can be endangered if media coverage is inaccurate or sensationalized.

Trial sponsors are challenged to show why a particular trial is needed (since public funders do not have the profit motive that drives corporate research agendas) and to maintain public confidence and political faith in the value of the trial throughout its implementation. Mathematical modeling is one tool that GCM used to contribute to building public and policymakers' understanding of the potential benefits to be obtained from microbicide research.

Mathematical modeling

In 2002, GCM collaborated with the London School of Hygiene and Tropical Medicine to develop a mathematical model, which projected that if even a small proportion of women in lower-income countries used a 60 percent efficacious microbicide in half of their sexual encounters in which condoms were not used, 2.5 million HIV infections could potentially be averted over three years.[44] This estimate has since been refined with better data, and subsequent models have been developed. However, the speed with which such estimates are taken up by the media and used to discuss the relative merits of specific areas of research underscore the value that mathematical modeling has in terms of enabling people to think about such topics.

The London School team, with GCM, subsequently developed modeling tools enabling policymakers to generate country-level estimates of the possible impact of a microbicide given specific data on the scope and nature of their national HIV epidemic. Facilitating access to such evidence-based estimates enhanced policymaker support for the research necessary to develop microbicides.

Ethical challenges

Charges that research is conducted unethically can also stop trials and destroy public and political support for them, as shown by public reaction to the N-9 trial data discussed earlier. In 2002, GCM began addressing the increasingly complex questions raised in microbicide research by creating a Research Ethics Initiative through which it sought to:

- Build consensus among investigators, advocates, ethicists, and others in the microbicide community around ethical issues arising during microbicide trials.
- Build capacity among NGOs and other civil society representatives regarding biomedical ethical reasoning and how it is expressed in the conduct of trials.
- Help find the appropriate balance between the need to protect the rights and interests of trial participants and host communities and the urgency of the need to develop a safe and effective microbicide.

In 2003, GCM convened an international ethics consultation to update the consensus points reached at the 1997 WHAM meeting and address issues that had emerged since then as a result of actual experience with large-scale Phase 3 effectiveness trials. With 64 participants from 12 countries, participants analyzed the complexities of such issues as the ethical obligation to include, as a part of the "standard of care" package, ongoing access to ARV drugs in low-resource settings for trial participants who acquire HIV. They also addressed the ethical parameters of enrolling adolescent

girls in microbicide trials, the role of male partners, and whether placebo-controlled trial and confirmatory studies would still be ethically appropriate once a candidate microbicide demonstrated partial efficacy. The meeting report, *Rethinking the Ethical Roadmap for Clinical Testing of Microbicides*,[45] is still a benchmark in the field. Subsequent GCM research on ethical issues included standard of care mapping of six trial sites; consultations on standards of HIV prevention provided in trials; and a consultation organized in collaboration with the AIDS Vaccine Ethics Group in South Africa on ethical challenges associated with enrolling adolescents in clinical trials.

GCM also developed a participatory training course on ethical reasoning and HIV prevention trials, designed to prepare advocates to engage effectively in the debates on these issues in their own countries. The course familiarized participants with the logic of biomedical ethical reasoning and the existing international guidelines for clinical research. It also highlighted how ethical principles frequently contradict one another and engaged participants in the work of figuring out how different principles should be balanced and interpreted in such situations.

These exercises gave participants the opportunity to practice applying ethical principles and reasoning to real-life case examples. Between 2003 and 2009, the course was presented in Belgium, Nigeria, Rwanda, South Africa, Thailand, Ukraine, and the United States. Partner groups requested it for their own networks and also organized its presentation to national and local policymakers and members of institutional review boards in countries where trials were taking place.

Community involvement at trial sites

In 2004-2005, two major PrEP trials, launched in Cambodia[46] and Cameroon,[47] were disrupted and ultimately cancelled by their respective governments because of strong opposition by local advocates and the subsequent incendiary press coverage of the conflicts. Sensationalized trial-related media coverage also appeared periodically elsewhere, including in Nigeria, South Africa, and Zambia. These costly and disruptive developments provided sharp reminders of how insufficient proactive community engagement can threaten the viability of research trials.

Authentic community engagement not only helps ensure that trials proceed smoothly but can also improve the quality of trial data. Ensuring that trial protocols and procedures are acceptable to the trial's participants and incorporate locally understood languages and customs increases the likelihood that participants will adhere to those protocols and report their behaviors accurately to researchers. Community support is also essential for the successful introduction and future acceptance of study products should they prove effective.

Even though microbicide trial networks generally understand this, investments in full and robust community involvement and the local staff required to make it happen are among the first budget lines cut when research funding is reduced. In November 2007, GCM held a meeting of research staff working at the site level, most of them community outreach personnel, to discuss their needs. They observed that while information-sharing occurs within research networks, almost no mechanisms existed for sharing experiences, lessons learned, and better practices with colleagues across networks and those working in independent research centers. They strongly endorsed GCM's proposal to facilitate a "community of practice" (CoP) around community engagement in HIV prevention to fill this gap.

> "I can see the day when I hide my microbicide in my vegetable garden and when I go to pick up veggies, I can quickly put it in my vagina and go inside the house with no worries about being infected with HIV by my husband."
>
> ~ Tholakele, GCM discussion participant Soweto, South Africa, 2011

Launched in April 2008, the Community Involvement CoP brought together community staff working at trial sites, community program managers, and others working on related issues to talk about current challenges and engage

in collective problem-solving. At its height, this CoP had more than 65 members from 14 countries representing civil society organizations; HIV prevention trial sites; research networks; and vaccine, microbicide, and PrEP trial sponsors.

GCM facilitated communication among members through monthly CoP teleconferences, a web-based resource center, and in-person annual meetings. An SMS (short message service) alert system was used to remind members about upcoming calls and inform them of new resources. Direct member-to-member communication was also facilitated by a CoP member directory, which included members' photos, contact information, and areas of expertise.

The Microbicides Media and Communications Initiative

Even when sensationalized news coverage does not halt major HIV prevention trials, it can still impede governmental and public receptiveness to hosting future trials. In 2006, GCM began work with partners to establish the Microbicides Media and Communications Initiative (MMCI) to help the wider microbicides field anticipate and respond proactively to the communications challenges posed by the conduct of large-scale effectiveness trials in Africa and other resource-limited settings.

In collaboration with other advocates, communications experts, and trial sponsors, GCM charted a strategy for improving stakeholder outreach, media relations, training, and crisis management at trial sites. This strategy included regular conference calls among MMCI members (hosted by GCM) to discuss common misperceptions and to develop and review key messages about technical and other related issues, such as the cost, effectiveness, and timing of microbicides. It also included the development of rapid response teams to deal with media flare-ups or unexpected developments in the field. The action of these teams was crucial when trials closed unexpectedly or produced unanticipated results.

MMCI's messaging documents, prepared for crisis and non-crisis situations, were distributed to communications officers and advocates worldwide. In 2008, MMCI published a communications handbook, which provided templates and other communications tools to equip advocates, communicators, and all members of the HIV prevention research community with essential background information and skills to effectively communicate around microbicide development. Links to prevention research sponsors and communications and advocacy groups were included.

MMCI became a CoP in which communications officers and other media-associated research staff could confidentially exchange information and solicit input from peers. Staffed by GCM in South Africa, MMCI coordinated regular membership calls, confidential briefings, and in-person messaging workshops, as well as annual meetings for its members.

2008–2009: A key turning point for GCM

In 2007–2008, GCM undertook a major external review and strategic planning process to discuss issues, assess past performance, and chart a course for the future. This process was facilitated by external consultants and involved in-depth interviews with more than 40 stakeholders and two strategic planning meetings with its steering committee and staff. Emerging from this process, it was determined that GCM should:

- Retain its leadership in microbicides but ***expand its advocacy into PrEP and other HIV prevention tools***, especially as they relate to women.
- Prioritize strengthening the capacity of advocates in African countries hosting clinical trials, while sustaining its outreach to advocates in Europe and North America.
- Focus its capacity-building efforts on improving science and research literacy.
- Move its international secretariat to Africa within the next two years.

With these marching orders, during the period 2008–2009, GCM adopted a new organizational structure that would facilitate cross-regional work teams, and began shifting resources increasingly to Africa.

MEDIA DISTORTION AND SENSATIONALISM CAN STOP CLINICAL TRIALS

Events in the Mazabuka District of Zambia illustrated the effect that media mis-statements or sensationalistic coverage can have on the progress of clinical research. In December 2011, results of a UK-funded clinical trial showed that PRO 2000, a candidate microbicide, had no protective effect. Conducted in South Africa, Tanzania, Uganda, and Zambia, this trial had been the focus of great hope because previous research findings suggested that it might be effective in reducing women's HIV risk. In response to the disappointing news that it was not, an online publication called the Zambian Watchdog attacked the trial, and stated that "half of the volunteers for the clinical trial of the Microbicide Gel. . . in Mazabuka are feared to have contracted HIV due to alleged failed efficacy of the drug."

This inflammatory statement was picked up immediately by other online sources, as well as radio and television. A firestorm of debate followed, in which the Mazabukan member of parliament declared that any further clinical trials would be banned in the area.

Fortunately, the Microbicides Media and Communications Initiative (MMCI), staffed by GCM in South Africa, was in place to respond immediately and engage researchers, government officials, and others in countering this misinformation. MMCI highlighted the fact that the trial, approved by the Research Ethics Committee of the University of Zambia, was conducted in accordance with high ethical standards.

The Centre for Infectious Disease Research in Zambia (CIDRZ) organized a briefing for government officials on the benefits of HIV prevention research, and they invited GCM to present on the basics of how such research is done. GCM also immediately organized a public event in collaboration with CIDRZ for the media, local nongovernmental organizations, traditional healers, and other community members. With long-term women's health advocate Professor Nkandu Luo, GCM discussed with participants why research took place in Africa, and what the results meant. They also reviewed how the trials are conducted and why some seroconversions inevitably occur, despite the researchers' best efforts to protect participants. GCM followed this with a series of informal community events and discussions that built understanding of research.

Following this, the mood changed, and in February 2011, Zambia's health minister, Kapembwa Simbao, announced that clinical trials scheduled to occur in Zambia would proceed.

The ability of GCM to fully operationalize the work plan that emerged from this process was complicated, however, when a major donor made the institutional decision to greatly reduce funding for GCM and eliminate support for advocacy efforts in the global North. The timing of this announcement left little time to seek alternative resources and forced substantial cutbacks in GCM programming in Canada, Europe, and the United States. GCM did, however, secure funds to support its drastically revised work plan for the next three years.

Also during this time, GCM's founder and long-time leader, Lori Heise, decided to step down as director to make way for new leadership and new vision. After working to make microbicides a reality for almost two decades and securing the organization's next phase financially, Heise resigned in June 2009.

Deepening work in Africa

Under new leadership, GCM increasingly focused on cultivating "deep outreach" with the eventual users of microbicides. The rate of scientific progress suggested that access to the first effective microbicide might be only a few years away, making it important to start preparing advocates and communities for the regulatory and product introduction issues that would inevitably accompany this next phase.

GCM also revised its approach to government engagement by positioning its African staff in elected or appointed positions on national strategic planning committees and other governmental committees, where they could advocate directly for GCM's issues while continuing to work with local civil society stakeholders to build their capacity to move into these positions.

In addition to Kenya and South Africa, GCM chose to make Zambia its third African focus country. Controversies over past trials had left all HIV prevention research vulnerable there, so it made sense to concentrate capacity-building and advocacy in Zambia.

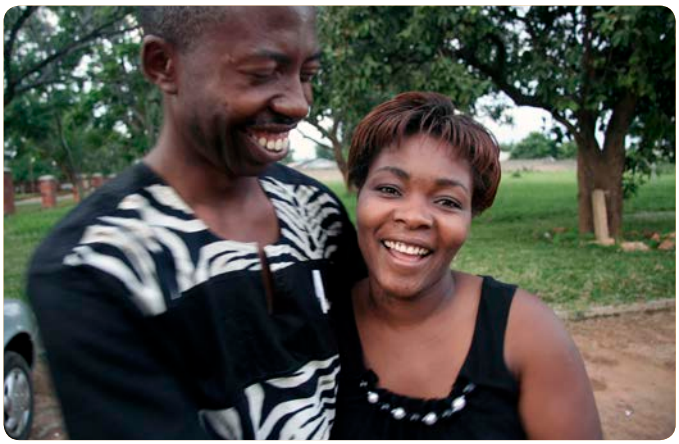
By 2010, GCM had completed its transition to a South African secretariat and almost all of its staff was based in Kenya, South Africa, and Zambia. It had also reconfigured its steering committee membership to include policy, advocacy, and research leaders in HIV prevention for women in sub-Saharan Africa. These two developments enabled GCM to engage more closely with key stakeholders in Africa and develop deeper connections with the communities most affected by HIV.

GCM's community education presentations also expanded to include a broader range of HIV prevention options. Presentations introduced participants to both microbicides and PrEP, and familiarized them with ongoing research to determine the effectiveness of both methods. Staff provided Prevention Research Literacy Trainings in the local languages in all three countries to civil society members and advocates, thus building participants' capacity to conduct their own community-level education and to present their experiences and findings at global forums.

"With a microbicide, a woman, my daughter, myself, will have a say in sexual matters and HIV prevention."

~ Female church leader Kericho, Kenya

GCM also allotted substantial time to engaging with communities at highest risk of HIV, for the purpose of public education and to gather the perspectives of potential end-users and relay them to inform product introduction. This deep outreach work sought to explore directly whether and how microbicides might fit into the lives of the people in greatest need of additional HIV prevention tools. To do this, female GCM staff engaged women in informal group conversations in settings where they could converse freely in the absence of men. This occurred in makeshift hair salons and market stalls, and at communal water taps, gathering points in urban slums and rural areas where indoor plumbing is rare.



David Jacobs

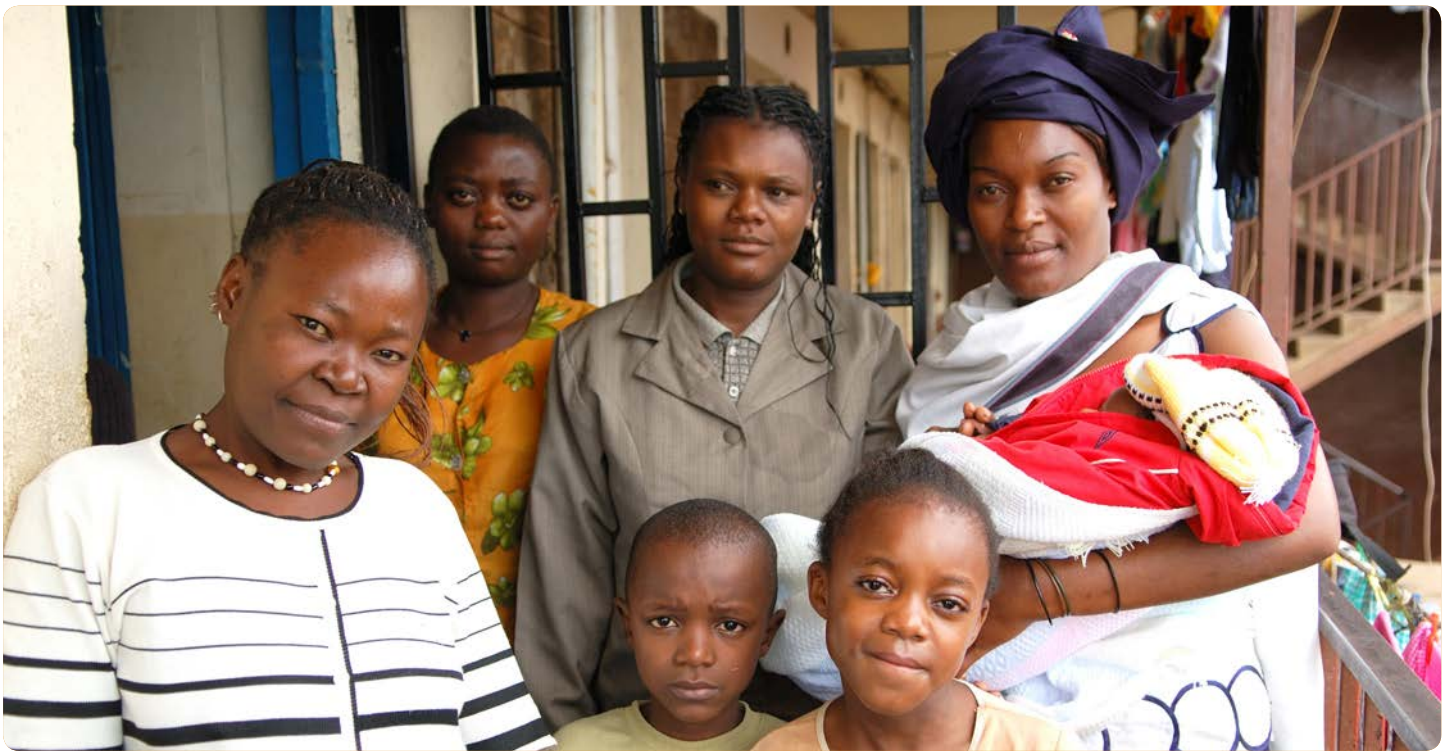
In GCM's later years, the campaign increasingly focused on cultivating deeper partnerships and outreach with the eventual users of microbicides.

The staff used storytelling techniques to encourage women in these settings to engage in autobiographical dialogues that illuminated how and with whom they made decisions about sex and other aspects of family life. After sharing information about microbicides, the staff sought women's perspectives on how a microbicide product might fit into their lives and possible challenges associated with use. They noted the levels of enthusiasm and/or concern that women expressed in connection with this prospect.

A male GCM staff member in Kenya similarly engaged men in spaces such as bus parks, where informal group conversations among men occur. After initiating conversation, he introduced the idea of microbicides and elicited men's thoughts around HIV risk, their relationships with women, and how they felt a microbicide product might or might not be useful in those relationships. The purpose of these discussions was both to understand men's concerns and expectations and to nurture men's potential roles in supporting women's interest in microbicide use.

A third constituency targeted for this deep outreach was women in professional organizations, such as nurses, midwives, and teachers. GCM reached out to such women to discuss the roles they could play as both educators and early adopters of this new technology. Given their credibility and influence in their communities, these professional women were positioned to be "microbicide champions," to provide GCM with points of contact to relay information about microbicide introduction (when

PATH/Mike Wang



In its later years, GCM focused on extensive outreach to several different constituencies—including communities at greatest risk of HIV and women in professional organizations—in three focus countries in Africa.

it occurred) into their communities. They could also be instrumental in promoting awareness, dispelling myths, and responsibly generating demand for this new technology.

Also during this period, GCM accelerated efforts to position its staff on key governmental bodies. In October 2009, GCM staff met with the Kenyan Director of Medical Services, the Chief Health Secretary at the National Council for Science and Technology, and senior management of the National AIDS Control Council (NACC) to discuss the importance of including research for woman-initiated HIV prevention options in the national HIV strategic plan and other health policies. As awareness increased at this level, GCM and other civil society advocates were invited to join key technical working groups, and GCM took a seat on the national Gender Technical sub-Committee and the Inter-agency Coordinating Committee for HIV and AIDS.

In partnership with NACC, the United Nations, and civil society advocacy organizations, GCM hosted the first Kenya Women's HIV Prevention Symposium in 2010,[48] and, at NACC's request, GCM staff chaired the task force that developed the *Accelerated Country Action for Women, Girls, Gender Equality and HIV*.[49] This plan not only committed the Kenyan government to providing support to woman-initiated HIV prevention options, but also listed the indicators to monitor fulfillment of this commitment. GCM was also invited to join the Kenya AIDS Research Coordination Mechanism, the committee responsible for setting guidelines for conduct of research and shaping the national HIV/AIDS research agenda.

This work continued to increase after the release of the CAPRISA 004 data in 2010, which showed that a 1% tenofovir gel provided moderate protection against sexually transmitted HIV. This proof of concept—hard evidence that a vaginally inserted microbicide could work—expedited the field's preparations for product introduction. A confirmatory trial was immediately initiated, with the expectation that if these results could be reproduced, the regulatory approval process and introduction of the first vaginal microbicide might get underway as soon as 2014-2015.

South Africa and Zambia

By 2011, GCM's South African office was implementing a two-pronged approach: community mobilization in the areas where clinical trials were occurring and advocacy targeted to national policymakers, including those within the National Department of Health and the Medicines Control Council (MCC, South Africa's regulatory agency for the evaluation of new drugs). GCM undertook work with the MCC to prepare for the Council's impending consideration of tenofovir gel as a microbicide, if the confirmatory trial data expected in 2014 validated the findings of the CAPRISA 004 trial.

GCM opened a Zambian location in 2009 to work out of PATH's Lusaka office. With a diverse team of locally hired staff in East and Southern Africa, GCM was well-positioned to integrate into local structures and policymaking venues, offering capacity-building trainings and locally adapted materials to NGOs and other opinion leaders.

GCM's Prevention Research Literacy Trainings were particularly popular and offered in several languages, including Kiswahili and Kikuyu in Kenya, isiZulu, isiXhosa, and Setswana in South Africa, and Nyanja and Bemba in Zambia, as well as English in all locations. These trainings were critical to GCM's credibility and its success in building public understanding of why HIV prevention trials were needed in countries where HIV incidence was high.

Misunderstanding around this point, if left unaddressed, could have closed clinical trials in Southern Africa, as it had elsewhere in the world. GCM's active promotion of accurate information on the ground was essential to maintaining governmental and civil society support for microbicide research because it countered recurring rumors that the conduct of these trials in African countries was another form of exploitation imposed by developed countries (see text box).

The campaign continued to work collaboratively with African partners to advance its agenda, but it faced increasing challenges in the funding environment and in determining the maximal balance of direct advocacy engagement and support of advocacy conducted by others. In an effort to increase engagement with local advocacy partners as well as to increasingly target local governments in ultimately preparing for a future microbicide, GCM continued to pursue its mission. In 2009, GCM organized the inaugural South African Women's HIV Prevention Summit and the second in August 2011. In partnership with IAVI, IPM, and several governmental entities, the events were convened under the auspices of the South African National AIDS Council's Women's Sector. GCM's Africa director advocated for the inclusion of language on women and girls and their HIV prevention needs in South Africa's National Strategic Plan on HIV, STIs and TB. GCM convened a similar Zambian summit in 2011 in collaboration with the Zambian government's Gender in Development Division and IAVI.

Also in 2009, the Alliance for Microbicide Development, founded in the same year as GCM, closed its doors. Changes in the advocacy landscape continued to shift and GCM continued to reassess its place in the community.

The final transition

GCM was initially established to generate political pressure for increased investment in microbicide development and to ensure that the rights of trial participants, users, and communities were represented and respected throughout the development process. Over the course of nearly 15 years, GCM helped to achieve these initial goals and was a champion for the ethical development of and access to HIV prevention options, especially for women. The dedicated staff and steering committee members advanced the field by mobilizing political will, enabling ethical clinical research, and strengthening advocates' and communities' involvement in research and clinical trials.

But by 2012, the HIV prevention field had changed significantly. In the time since GCM was established, the contributions of multiple partners and advancements in the field meant the context for this critical work was dramatically different. As the range of advocates working in HIV prevention expanded and new potential interventions

"If GCM doesn't have strong positioning, not just of science but in leadership roles, as findings from the new studies come forward, women will be left behind because they won't be sitting at the table and won't be part of the negotiating/decision-making process."

~ GCM Steering Committee Member, 2011

were explored, the support for what some viewed as a "narrow" focus on microbicides was increasingly considered less relevant. Other HIV prevention research advocates had created bolder public profiles, built different and broader alliances, and, thus, competed more successfully among the limited pool of donors. Several key donors for GCM's work shifted their funding priorities, and GCM's core funding suffered significantly as a result. With fewer donors and less overall funding, GCM was forced to reduce staff and activities and reconsider its role.

In considering the future of GCM, PATH (where GCM was housed) engaged in broad consultation with the global health community about the value added of GCM in this new political environment. While people were nearly unanimous in their assertions of the transformative role that GCM had played in creating a movement in support of HIV prevention tools for women, there was also growing recognition that other partners were well-suited to move the field to the next level. In many ways, GCM had accomplished what it initially set out to do, and it was time for others to lead a new era in HIV prevention advocacy.

In July 2012, PATH announced its decision to close GCM, a decision made "[a]fter serious considerations and deliberations about the needs of the HIV prevention field relative to GCM's current scope and funding situation."[50] Those who had worked with GCM over the 14 years of its existence (as staff, steering committee members, funders, volunteers, and partners) had the satisfaction of taking part in achieving three important accomplishments.

First, GCM took a lead role in changing that scenario by generating and amplifying the demand for microbicides, especially in countries with donor governments. It created the political will that, in turn, dramatically increased the global budget for microbicide research. In 1998, microbicide researcher Sharon Hillier (now principle investigator for the Microbicide Trials Network) said, "We can make good, safe microbicides publicly available if we choose to. We have everything we need to make it happen—except the will and the money."[51] GCM's work had helped to change the funding landscape for microbicide development.

Second, GCM played a central role in making it clear to research institutions that authentic community involvement in the conduct of clinical trials and the development of HIV prevention products is not only the right thing to do but also the smart thing to do. GCM's work demonstrated that investing in research literacy training and community engagement pays off in better and more accurate self-reported data, better adherence to trial protocols, and invaluable learning about what makes a product acceptable or unacceptable to those likely to use it.

Finally, GCM's existence started with the introduction of the word "microbicides" and lasted through proof of concept. Microbicides went from being an unpronounceable and unnecessary idea in many people's minds to a scientific reality poised to move from the laboratory to household use. Ensuring that the science moved forward and that the women with greatest need for microbicides had a defining voice in their creation was GCM's goal. Although much remains to be done to ensure that women's health remains a priority on the HIV prevention research agenda, the Global Campaign for Microbicides put women's HIV prevention needs on the map, helped to create a new scientific field, and successfully built and carried out one of the few social health movements for prevention.

Lessons learned

This section lists some of the most cogent lessons derived from GCM as a case study in bottom-up, citizen-led organizing around a global need. With minimal resources, GCM implemented broad-based advocacy strategies to advance a very specific issue. This is work that cannot be accomplished without intensive collaboration with allies. The lessons identified here may be useful to other NGOs seeking to mobilize action under similar circumstances.

Lesson 1: Organizing on a global scale and across cultures is difficult, especially when partners are participating for ideological reasons, rather than payment or material benefit. The organizer reaching out to identify partners and solicit their participation must maintain constant flexibility, pragmatism, and a willingness to accept (and celebrate) incremental movement toward the goal.

Creating a network of successful collaborations among geographically and culturally diverse groups of actors can be accomplished effectively if:

- Partners in each region are part of the discussion when local objectives are set and timelines created. Local people have a realistic view of what can be achieved locally, how long it is likely to take, and what resources will be needed.
- Organizers are willing to offer a broad menu of options for participation and fully support partners in undertaking whatever level of involvement they feel comfortable with at a given time. Since success breeds success, a small advocacy activity well accomplished may lead to greater levels of involvement in the future.
- Partners are asked for their candid input into what projects and approaches will and will not work in their region.
- Organizers accept that partners bring their own norms, expectations, work styles, and interests to the table and that these will vary widely from group to group and region to region.
- Efforts made by partners are rewarded with public acknowledgement. Broad-based, voluntary campaigns work when people feel they are part of a valued, credible, and effective network that is making progress together.

To grow, GCM had to approach each new country and potential partner with openness to learning about their unique conditions, needs, and expectations. Over time, GCM developed substantial expertise in negotiating and implementing collaborative activities that advanced its mission within the context of locally defined initiatives, priorities, and objectives.

Lesson 2: No country or constituency is monolithic in its views. It is sometimes necessary to gather a broad range of opinions, take action despite competing views, and work through tensions this may create, rather than seeking full concensus in order to avoid controversy.

GCM refrained for almost three years (late-2003 through mid-2006) from hiring African regional staff in deference to AMAG's preference that the work be done exclusively by African-led organizations. When GCM decided in 2006 to proceed with hiring African staff to work locally, the productivity and credibility of those staff added greatly to GCM's track record of success. It might have been wiser for GCM to move forward with this direct effort earlier, as it did on other continents. GCM solicited external input on this difficult issue from other partners in the region before making the decision to proceed with local hiring. It is possible that soliciting this broader input earlier might have resulted in an earlier decision to proceed.

Lesson 3: Sometimes expanding advocacy focus, shifting emphasis, or even rebranding is a good thing.

GCM questioned itself regularly as to whether it should focus primarily on one prevention technology (microbicides) or significantly broaden its scope. Raised at the outset with regard to female condoms, pre-2000, GCM was presented in some settings as the Global Campaign for Microbicides and Prevention Options for Women (a title eventually abandoned as unwieldy). At its 2006 steering committee meeting, GCM decided to expand its focus to include other emerging prevention technologies (such as PrEP) but to retain its unique focus on women's needs relative to these other technologies. GCM communicated this by developing materials on PrEP, circumcision, and other approaches and addressing these in its presentations and activities. But it did not undertake any highly visible announcement of this change, nor did it rebrand itself in any way. This may have limited GCM's appeal in the eyes of donors at a time when some competitors were emphasizing that their work spanned the whole HIV prevention field.

Lesson 4: Being able to work within an existing multinational organization's infrastructure in terms of office space, human resources, etc., can provide important benefits. On the other hand, it also has associated costs.

Being a project of PATH, an international organization with a presence in more than 70 countries, spared GCM most of the logistical, legal, and management work that similar organizations encounter when locating staff in multiple countries. PATH's decision to open a Johannesburg office in 2005 was instrumental in GCM's ability to bring on South African staff, as was its support for GCM staff in its Delhi, Nairobi, and Washington, DC offices.

PATH did not, at the time, have an office in Europe. GCM, therefore, housed its staff in Brussels by entering into a partnership with like-minded organizations for shared office space. This is another good option if other supportive infrastructural arrangements are not available. The complexity of negotiating leases, supply chains, and (most of all) hiring and employment practices that conform to local employment laws and benefits requirements should not be underestimated. Obtaining knowledgeable support in this, preferably in the form of assistance from a locally based office that does it all the time, is invaluable and results in an advocacy-focused entity being able to spend far more time on fulfilling its mission than would be possible without such support.

These options, however, also involve tradeoffs. While GCM had its own steering committee, it did not have an independent board of directors. As a project of PATH, GCM had less autonomy in some situations than it would have had as a discreet organization. Co-location agreements, for their part, involve joint leases and other commitments that can also reduce an organization's flexibility.

Lesson 5: Leading from behind is a successful strategy for engaging partners and promoting empowerment, but it comes at a cost.

As mentioned, GCM used an approach called "leading from behind" in its collaborations with smaller partner organizations. In competitive funding environments, organizations using this approach do not always fare well. It is easy for donors to lose sight of the impact that such entities have over the long term. Donors wishing to fund the kind of advocacy mobilization that GCM generated sometimes made grants to higher-profile organizations either because they were the most visible in the field or because the donors assumed that actors were working collaboratively across the field. As occurred with Canadian and European funding in particular, donors assumed that their funding would "trickle down," supporting not only the immediate grantee but also GCM, whose work benefitted the field and supported the efforts of the grantee.

GCM's failure to devote enough effort to cultivating its own public profile cost it essential recognition. This became acute when funders' interest in microbicides started to wane in 2007, and other competitors, who were less focused on leading from behind, entered the field.

Lesson 6: Take the time to build a diverse and invested set of donors that will provide longer-term support and flexibility.

GCM's founder took the time to share her passion and vision for GCM's work with its donors in a way that persuaded them of the value of GCM's mission. She also consciously and consistently involved donors in numerous ways, including in-person meetings, serving on advisory or steering committees, and regular phone calls, as well as more formal reporting structures. In its first ten years of existence, GCM had support from more than 15 different foundations and ran a major donor campaign known as "Looking for Mrs. McCormick" (a reference to Katharine McCormick, the philanthropist who funded initial research into the birth control pill).

One of GCM's core attributes was its flexibility to follow the science and the needs in the field. This meant that GCM had to ask donors to support the shifts that GCM's staff determined were necessary to keep its work relevant and most effective. The size and scope of MMCI, for example, exceeded that originally laid out in grant proposals, but GCM was able to convince existing donors to support expansion of the initiative because such crucial need for it emerged in the field. As GCM matured and its scope expanded, it became important for donors to have well-developed relationships with other staff in addition to the director, since her energies were necessarily distributed over a wider area as the organization grew. Anticipating this

and ensuring that at least one or two other staff members are specifically responsible for keeping donors informed and engaged is essential to maintaining the strong and flexible donor relationships that are most likely to weather environmental changes successfully.

Lesson 7: Community involvement in clinical trials is a relatively new concept, not yet widely embraced or fully realized in most settings. When implemented with authentic commitment, it leads to better and more accurate trial data and enhances community receptivity to hosting future trials.

Many people, particularly in the scientific community, could not imagine that microbicide trial participants (most of them women in developing countries with little formal education) could become informed and effective advisors for the processes of clinical trial implementation. In private, some contended that such community involvement had worked in the women's health movement starting in the 1970s and AIDS activism starting in the 1980s because the consumers involved were educated and living in developed countries. The work of GCM and others, however, shows that it is possible to build the capacity of interested people in trial host communities to understand how research works.

Further, it showed that people in trial communities have their own expertise that can benefit the trial. Just as involved community members need research literacy training, so also do researchers need to build their "community literacy"[52] in order to understand the dynamics that shape communication, perceptions, decision-making, and trial protocol adherence in their host communities. When community members are valued as sources of this information and as authentic partners in the process of mounting a trial, the resulting convergence of perspectives benefits the endeavor overall.

Building this collaboration requires patience, resource investment, ingenuity, and a commitment on all sides. It involves honest efforts to level the playing field and create the trust required for good-faith negotiations. Research institutions and funders that do not want to invest such time and resources often say that the benefits of such effort are insignificant. But evidence is showing (not just in the HIV field) that authentic community involvement is not only possible and ethically desirable, but that it has significant pragmatic value to the scientific endeavor.[53,54]

Appendix 1: Timeline of the AIDS pandemic and GCM's advocacy activities

IN THE MICROBICIDES FIELD AS A WHOLE	YEAR	ADVOCACY/GCM ACTION
• NIH begins testing current contraceptives to see if any work against HV. One is Nonoxynol-9 (N-9), a common spermicide.	1987	
In sub-Saharan Africa, women and men are living with HIV in roughly even numbers.		
• South African epidemiologist and advocate Zena Stein writes first journal article calling for HIV prevention tools for women.	1990	• U.S. advocates at National Conference on Women and HIV Infection call on government to find "virucides" that women can use for HIV prevention. • GCM contacts NIH and WHO scientists to ask if microbicide development is possible .
• European scientists issue a report urging the UK government to fund microbicide research.	1991	• Women's health advocates convened by WHO and the International Women's Health Coalition identify the need a product that protects against both HIV and pregnancy as a high research priority.
• UK and US governments fund the early research leading to creation of microbicide candidates. • Study among Kenyan sex workers suggests that frequent N-9 use may actually increase HIV risk.	1992	• GCM and Population Council President Chris Elias convene international symposium attended by 55 advocates, policy-makers and scientists who debate the challenges of microbicide research and conclude that it should be prioritized.
• First female condom approved by FDA for sale in the U.S. • Data on N-9 is conflicting as observational studies show it as reducing HIV risk. Research continues.	1993	• Women's Health Advocates on Microbicides (WHAM) is created to provide input on the Population Council's microbicide research program. • GCM publish a Population Council Working Paper on microbicides. • GCM starts presenting a workshop based on the Working Paper at conferences and by request for NGOs.
• 12 microbicide candidates are in pre-clinical research studies and 9 are in clinical (human) trials. • Microbicides are among the top research priorities identified at the International Conference on Pop-ulation and Development in Cairo.	1994	• At the WHO consultation to prepare for the World Conference on Women in Beijing, advocates list microbicides among their six highest priority demands. • At 10th International AIDS Conference, Stein give a plenary speech on microbicides.
• First microbicide-specific research grants are issued by NIH (US).	1995	• US Presidential Advisory Council on AIDS (PACHA) urges that US fund microbicides research after Heise testifies before them.
Women make up and half of all people living with HIV globally and two thirds of all Africans living with HIV.		

IN THE MICROBICIDES FIELD AS A WHOLE	YEAR	ADVOCACY/GCM ACTION
• Triple combination anti-retroviral therapy (ART) revolutionizes treatment for people with HIV. • US puts $100 million over four years into microbicide initiative. • First microbicide clinical trial starts in South Africa and Thailand.	1996	• During US presidential campaign, Mothers' Voices in New York mobilizes a national "Platform to Defeat AIDS" that is widely supported by AIDS activists. It includes a demand for microbicide research funding.
• US death rate from AIDS dropped by 50% in one year due to rising availability of ART.	1997	• WHAM issues report on "Practical and Ethical Dilemmas in the Clinical Testing of Microbicides", then disbands to make way for a broader advocacy network.
• Alan Guttmacher Institute survey shows that 23% of American women ages 18-44 are interested in microbicides. Strongest interest is expressed by women in populations at highest HIV risk.	1998	• Global Campaign for Microbicides (GCM) launched by Heise, Forbes, former WHAM members and other supporters at 12th International AIDS Conference. • PACHA endorses GCM's "Ten Point Plan to Accelerate Microbicide Development".
• American Foundation for AIDS Research (amFAR) joins other private foundations (including Rockefeller, Mellon, and Hewlett) in funding microbicide research. • Society for Women and AIDS in Africa (with offices in 37 countries) begins advocacy for microbicides.	1999	• Advocates and Congressional sponsors draft a "Microbicides Development Act" for the US Congress. The bill proposes to increase microbicide research funding to US$100 million annually by 2013. • With NGO partners, GCM organizes advocacy hubs in ten key legislative districts to mobilize support for the bill.
• Rockefeller Foundation convenes International Microbicides Initiative to map out field-accelerating plans. • Large trial shows that frequent use of N-9 increases HIV risk. Finding contributes to public skepticism about the field as a whole.	2000	• GCM chairs Advocacy Sub-Committee of the Rockefeller Initiative, subsequently publishes its report as "A Call to Action". • GCM staff support for grassroots organizing in North America, India, Thailand and several African countries.

In 16 African countries, at least 10% of the population is living with HIV. In 16 African countries, at least 10% of the population is living with HIV.

• 50 microbicide candidates are in research pipeline, 7 in large-scale clinical trials. • Three major foundations start funding advocacy for microbicides. • NIH convenes first scientific meeting on the development of microbicides for rectal use.	2001	• GCM secretariat moves to PATH, a global NGO with 19 offices in 13 countries. • 60 advocates from 28 countries attend GCM's International Advocates Meeting. • With GCM's support, the Microbicides Advocacy Groups Network (MAGNet) forms to call on the Canadian government to join in funding of microbicides research.
• International Partnership for Microbicides (IPM) created as result of the Rockefeller Initiative . • UK grants £16 million (US$20 million) to microbicide research. • GCM and London School of Hygiene and Tropical Medicine produce first mathematical model on potential impact of microbicides.	2002	• In collaboration with International Family Health, GCM uses European Commission funding to establish GC Europe. • GCM initiates sub-grants to NGO partners in India and, Africa and southeast Asia. • Endorsed by 85 leading scientists and health groups, GCM launches campaign to remove N-9 from condoms and lubricants, due to danger to rectal tissue.

IN THE MICROBICIDES FIELD AS A WHOLE	YEAR	ADVOCACY/GCM ACTION
• IPM raises start-up budget of nearly US$!00 million, including $60 million from Bill and Melinda Gates Foundation . • First Canadian Microbicides Symposium held, primarily organized by MAGNet members.	2003	• Indian Council for Medical Research and GCM co-host founding meeting of INational Microbicides Working Group. • Nigerian HIV and Vaccines and Microbicides Advocacy Group founded. • GCM holds 12-country consultation on "Rethinking the Ethical Road Map for Clinical Testing of Microbicides".
Globally, approximately 14,000 people infected with HIV daily. Half of them are women.		
• First five novel (post-Nonoxynol-9) microbicide candidates are in large-scale effectiveness trials . • US microbicide investment triples from 1999 level to US $92 million . • Canada makes first microbicides research grant, $15 million to IPM. • IPM announces collaboration with Tibotec, first major pharmaceutical company to participate in the field.	2004	• African Microbicides Advocacy. • Group (AMAG) formed by Africa-based advocates to create African agenda. GCM helps fund staff and partnership activities. • GCM launches documentary film and walk-through photo-exhibit used by partner organizations to raise awareness. 800 copies of film are ordered globally and exhibit is displayed in 70 venues. • GC Europe, IPM and other partners brief European Parliament members.
• The G8 issues a Gleneagles Communique on Africa that cites the urgent need for microbicides . • International Rectal Microbicides Advocates (IRMA) founded.	2005	• GCM initiates Microbicides Media and Communication Initiative (MMCI). • GCM leads field-wide debate on ethically acceptable standard of care for those who sero-convert during a clinical trial.
• Savvy trial closed due to futility (data unlikely to show clear result). • Canada becomes first country with national Microbicides Action Plan that parallels its HIV Vaccine Plan. • At 16th International AIDS Conference, support for microbicides reach a "tipping point". Concept is enthusiastically endorsed by plenary speakers, including Bill and Melinda Gates.	2006	• After five years of working with local consultants, GCM hires its first local staff in Africa and India. • GCM Southeast Asia Microbicides Chat Group (SAM-Chat) fosters dialog among members in Australia, China, Thailand, Indonesia, the Philippines and Malaysia. • GCM begins development of an electronic course -- a virtual textbook to build research literacy among clinical trial staff, advocates and other stakeholders.
• Cellulose Sulfate trial stopped, as product may increase HIV risk. • Microbicides Trials Network plans to complete 14 trials by 2013. • The European Developing Countries Clinical Trial Partnership is building clinical trial capacity in several African countries, as is IPM.	2007	• GCM publishes Standard of Care mapping exercise, documenting care now provided to microbicide trial participants and recommending enhancements. • GCM Steering Committee decides to transition GCM's focus to working in South Africa, Kenya and Zambia exclusively – three trial-hosting countries where community involvement and advocacy capacity are urgently needed.

IN THE MICROBICIDES FIELD AS A WHOLE	YEAR	ADVOCACY/GCM ACTION
• Carraguard trial results show that product is safe but not effective. • Annual global investment in microbicides tops out at US$244 million – 84% from governments, 14% from philanthropies and 2% from the commercial sector.	2008	• In its three target countries, local GCM staff provide Prevention Research Literacy Trainings in seven local languages, as well as in English. • GCM invited to join governmental committees and participate in drafting of National HIV Strategic Plans.
UNAIDS reports that fewer that half of all countries are funding HIV-related programming targeted to women and girls.		
• US government funding = $178 million (600% increase from 1999). • Canadian government funding = US$178 million (from 0 in 2000). • In Europe, 11 governments and the European Commission are funding microbicide research. • Trials of BufferGel and Pro2000 find both safe but neither effective. • Zambian press reaction to PRO-2000 results is sensational and inaccurate. Government threatens to ban further trials in Zambia. MMCI's public education response and GCM's meeting with Health Ministry reverses their stance.	2009	• To hire additional African staff, GCM ends staff positions in Europe, Asia and North America. At time of closing, GC Europe has hubs in ten European countries and puts out materials in five languages . • GCM Steering Committee is reconfigured to better reflect the field's policy, advocacy, and research leadership in sub-Saharan Africa. • South African government holds Inaugural Women's HIV Prevention Summit, organized by GCM in collaboration with South African Health Ministry and other partners. To build up governmental involvement, GCM organizes a 2011 South African summit and similar co-sponsored summits in Kenya (in 2010) and Zambia (in 2011).
• Proof of concept! Tenofovir gel shown to reduce HIV risk by 39% percent overall and by 54% among women using it regularly. • Confirmatory trial (called FACTS) launched, results due in 2014. • Pre-exposure Prophylaxis (PrEP) trial shows that oral PrEP taken consistently can reduce HIV risk.	2010	• GCM shifts focus from prevention research literacy to preparing for product introduction. Recruits African professional women (nurses, midwives and teachers) to serve as educators and early adopters when a microbicide becomes available. • GCM staffing reconfiguration completed with 2 staff based in Washington DC and 8 across South Africa, Kenya and Zambia.
• VOICE trial's Tenofovir gel arm stopped due to futility (data unlikely to show clear result). • Gates Foundation reduces its investment in microbicides by 42%. Field-wide, global funding for microbicides drops by 24%, from US $244 in 2009 to US$186.	2011	• GCM launches second travelling exhibit at the Fifth South African AIDS Conference – subsequently displayed at two International AIDS Conferences and at Microbicides 2012, among other venues. • GCM works with USAID to establish a Microbicide Access Working Group to inform issues related to the introduction of the first microbicide in Africa.
72% of all youth (15-24 years old) living with HIV in sub-Saharan Africa are female.		
• Effectiveness trial of vaginal ring starts – first topical product designed to provide continuous protection through time-released microbicide. Results due in 2015. • HPTN 052 trial shows that consistent ART use can reduce risk of HIV transmission, affirming "treatment as prevention" strategy.	2012	• Role of GCM director is eliminated in April. • GCM closes in September 2012.

Appendix 2: Global Campaign for Microbicides staff and steering committee

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Precious Pilane
Zoe Ruhf
Jui Shah
Katie West Slevin
Stephanie Stuart
Ananthy Thambinayagam
Rebekah Webb
Sydney West
Gary Wolnitzek
Anandi Yuvraj

STEERING COMMITTEE

Keith Alcorn, 2010-2012
Deborah Arindell, 2001-2009
Manju Chattani, 2004-2009
Ennie Chipembere, 2010-2012
Susan Chong, 2006-2009
Paddy Connelly, 2002-2005
Martine de Schutter, 2001
Dazon Dixon Diallo, 2001-2012
Kim Dickson, 2002-2008
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Geeta Rao Gupta, 2001-2003
Nohkwhezi Hoboyi, 2010-2012
Scott Jackson, 2006-2012
Mayowa Joel, 2007-2011
Elly Katabira, 2010-2012
Monruedee Laphimon, 2007-2009
Marc-André LeBlanc, 2004-2006
Zinhle Makatini, 2010-2012
Sheena McCormack, 2004-2009
Promise Mthembu, 2004-2007
Margaret Muganwa, 2005-2007
Nelly Mugo, 2010-2012
Vimla Nadkarni, 2004-2007
Salimata Niang, 2001
Gita Ramjee, 2001-2003; 2010-2012
Cory Richards, 2001-2004
Zeda Rosenberg, 2001-2003
Caroline Sande, 2006-2009
Shira Saperstein, 2001-2010
Balwant Singh, 2003
Laurie Novick Sylla, 2001-2005
Joan Tallada, 2004-2005
Kanokwan Tharawan, 2001-2007
Moniek Van der Kroef, 2005-2011
Janneke Van Wijgert, 2004-2010
Francoise Welter, 2006-2008

Endnotes

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