NO TIME TO WAIT:

Fourteen years of demanding safe, effective HIV prevention options for women

The Global Campaign for Microbicides
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Between 1998 and 2012, the Global Campaign for Microbicides led an unprecedented international effort to give women safe, effective tools to protect themselves from HIV.

Over 14 years, it built a powerful global advocacy network, dramatically increased political will and investment, supported more ethical and effective clinical trials, and paved the way to introduce products when they become available.

Along the way, GCM gave women and communities an authentic voice in research, policy, and practice, and built a foundation of approaches that continue to inform global health advocacy today.
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.

“"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
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 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. Following extensive stakeholder consultation and analysis of the evolving scientific, political and financial environment, PATH (which served as the institutional home for GCM) announced its decision 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.

In the late 1980s, activists in women’s health, contraceptive research and development, and HIV/AIDS coalesced around a powerful public health goal: ensuring that women had effective tools to protect themselves from HIV. They saw escalating but often overlooked evidence that women were more vulnerable to HIV infection from sex than men, along with a clear lack of effective, woman-controlled protection. Male condoms were not enough.

This aim dovetailed with an increasing focus on personal rights. Advocates, patients, and others argued that people should have a voice both in their own care and in the policy, research, and trials that shaped their future health options. This was especially true for participants in research trials, who were often left out of a process that relied on their very bodies to succeed.

The Global Campaign for Microbicides (GCM), founded in 1998, grew out of this movement. For 14 years, GCM served as a nexus of advocacy and action to speed the development of woman-controlled HIV prevention tools. It focused primarily on microbicides, products designed to be used vaginally or rectally to reduce the risk of HIV infection from sexual exposure.

From 1998 until its close in 2012, GCM worked in two categories of countries: those with the resources to serve as major research donors, and those where large-scale microbicide trials were occurring or scheduled to occur. It collaborated with partners in these countries to build a global movement for microbicides, mobilize political will and funding, support ethical clinical trials, and pave the way to introduce products. Working first from the office of a small nongovernmental organization (NGO), and
later from a home at PATH, an international health nonprofit, GCM grew into a global movement with staff in Africa, Asia, and Europe.

Along the way, GCM gave women and communities an authentic voice in scientific planning and research, and contributed to changing the way the work of global health is done.

Building a movement

GCM built a global advocacy network for woman-controlled HIV prevention options by reaching out to allies, strengthening their capacity, and responding to their needs. Together, this network built the awareness and political will to dramatically increase investment in HIV prevention research.

Mobilizing grassroots allies

When GCM began, there was strong but untapped public demand worldwide for effective, woman-controlled alternatives to the male condom. Still, public health need does not always translate into political will. Despite clear evidence that women were more vulnerable to HIV than their male peers, few politicians, communities, and researchers were aware of this risk, willing to accept it, or ready to translate their knowledge into action.

GCM knew that increasing political will and funding would require wide-reaching advocacy and nuanced engagement with many different governments and systems. Yet GCM itself was small and had only modest funding. Rather than build a network from scratch, its small group of professional activists reached out to NGOs and other natural allies, such as women’s health advocates, family planning organizations, and HIV activists. These groups were uniquely able to mobilize local constituencies and effectively lobby their own governments.

Understanding that most organizations already had heavy workloads, GCM invited them to participate at whatever level they could, and offered simple ways to help, such as circulating a petition or distributing information on their websites. Over time, GCM acquired 348 “endorser” worldwide through this approach, dozens of which also took a more active and labor-intensive role as partners.

To give advocates the understanding and tools to lobby effectively, GCM created user-friendly educational materials and talking points on the science of HIV and HIV transmission, the role microbicides could play in protecting women worldwide, and the status of research. It also circulated the “Petition for Greater Investments in Microbicides,” which gave advocates worldwide a common goal and provided an easy way for them to open discussion with women and stakeholders in any setting. By 2004, the petition had garnered more than 200,000 signatures and sparked discussion worldwide.

Generating political will and investment

Pharmaceutical companies, which often drive the development of new products, have not traditionally seen microbicides as profitable enough to warrant investment, or have been put off by the complexities of their development. For this reason, public funding is crucial to microbicide research. To ensure sustained and sufficient funding, GCM raised interest in microbicides among resource-rich governments, including the United States, Canada, and European nations.

Reaching leaders

In each country, GCM worked with local networks to cater its approach to national political structures, norms, and resources. In the United States and Canada, it asked networks to raise public interest in microbicides and pressure political leaders to prioritize research. At the same time, it built

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

~ HIV prevention activist, 1998
meaningful relationships with policymakers. This “inside/out” approach amplified public demand while building GCM’s influence in budget and policy discussions.

In Europe, GCM established a distinct campaign with two local staff. As in other regions, it connected key advocates and allies, translating and adapting educational materials to support their efforts. GCM also benefitted from close collaborations with regional microbicide and HIV advocacy groups, and from the momentum generated by microbicide initiatives from the United Kingdom Department for International Development and the US-based Rockefeller Foundation.

Together, these efforts dramatically increased global funding for microbicide and prevention research. In the United States, investments nearly tripled between 1999 and 2004, growing from US$28 to US$92 million, and then almost doubled again between 2004 and 2009. Canadian funding increased from CA$0 in 2000 to CA$2.7 million in 2007. In Europe, funding rose from US$0.7 million to US$59 million between 2000 and 2007.

Getting the word out

Beginning with these efforts, and throughout its lifecycle, GCM harnessed the power of media to draw attention to microbicides and other HIV prevention options for women. Articles and radio interviews engaged a wide audience at little cost. In low-resource countries, where NGOs must often buy coverage, GCM worked with a community-based journalism program to get the word out. It also created several traveling photo exhibits, which provided an emotional window into the promise and urgency of GCM’s work.

Supporting ethical clinical trials

GCM supported ethical microbicide and prevention clinical trials by increasing civil society involvement in trials, resolving ethics, policy, and communication dilemmas that hindered progress, and laying the groundwork for continued improvement.

Accelerating progress toward new HIV prevention options requires not only funding and interest, but effective research and development. Clinical trials are key to this effort.

Researchers generally conduct large-scale microbicide trials in areas with high rates of new HIV infection, where they are most able to demonstrate impact. When GCM began its efforts, most trials were being conducted in sub-Saharan Africa, where these conditions were present. Some research was also being conducted in, or planned for, India and Southeast Asia.

“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?”

~ Activist, Uganda, 1990
GCM IN THE COMMUNITY: NAVIGATING NONOXYNOL-9

In 2000, study results showed that nonoxynol-9 (N-9), a popular contraceptive that had shown some promise as a microbicide, might instead have increased HIV risk among trial participants who used it frequently. Many saw this as signaling that microbicides were dangerous. Some also felt that researchers should have foreseen and prevented this result.

GCM urged patience, noting that many other promising microbicide candidates were in development and that trials have protective measures to reduce participants’ risk. It also explained that N-9 had not been developed as an anti-HIV agent, but that because it was being used by millions of women to prevent pregnancy, it was important to evaluate its safety within the context of HIV.

Nevertheless, N-9 remained a prominent concern for African organizations. GCM’s sensitivity in responding to their skepticism was critical to its ability to support new prevention options for women.

GCM worked with advocates, communities, and trial sponsors in these regions to improve ethical practices and address challenges. In particular, it prioritized stronger civil society involvement, arguing that it is not only ethically mandatory but also crucial for success. It also responded to ethical, policy, and communication dilemmas that could impede progress.

GCM faced several challenges. Although community involvement was crucial to trials, there was little or no tradition of such participation, and research networks often saw it as unnecessary. Trials also operated in the shadow of a long history of human rights abuses in medical research. This was compounded by the frequency with which successful products, once complete, were unaffordable or unavailable to the very people on whose bodies they had been tested. Many communities did not trust researchers’ intentions. In addition, trials in some countries, particularly South Africa, were occurring within the context of devastating HIV epidemics, accompanied by stigma, denial, and violence against people living with HIV. In these regions, it was difficult even to broach the topic of HIV, particularly HIV among women.

GCM’s success relied on its ability to build rapport with, and foster discussion between, diverse and opposing groups. It also required GCM to respond effectively and diplomatically to events that aggravated sensitivities, such as disappointing trial results.

Involving civil society in trials

As in donor countries, GCM mobilized and connected local and national NGOs, women’s health groups, and civil society organizations in trial host countries. To do this, it established regional staff in India, Kenya, and South Africa. Together, GCM and these networks amplified existing but often unvoiced demand for HIV prevention options for women, advocated for communities’ roles in research agendas and clinical trials, and pressured leaders to ensure

EXAMPLES OF ETHICAL CONSIDERATIONS FOR MICROBICIDE CLINICAL TRIALS

- Whether researchers must include ongoing access to antiretroviral treatment for participants in low-resource settings who acquire HIV during the study.
- What the appropriate ethical parameters should be around enrolling adolescent girls in trials.
- What role male partners of women in trials should have.
that products resulting from trials, if effective, would be accessible and affordable to local residents.

A hallmark of GCM’s approach was to “lead from behind.” Rather than directing activities, it built sustainable and self-reliant local networks by emphasizing shared decision-making, building partners’ capacity to lead projects, and distributing public credit for success.

To prepare advocates to work knowledgeably with trial staff, researchers, and others, GCM translated and adapted advocacy training materials into local languages. It also created a comprehensive online course, Microbicides Essentials, to equip advocates, trial staff, and others with basic HIV prevention research literacy. The course, which provided talking points and information on microbicide science, development, safety, and acceptability, eventually reached 600 stakeholders worldwide.

In tandem with these efforts, GCM catalyzed productive discussion between scientists, communities, advocates, and leaders in trial host countries. It convened or participated in national and regional conferences, built communities of practice, and created platforms, such as listervs, to foster discussion. This work sparked powerful local initiatives, including the African Microbicides Advocacy Group, dedicated to supporting a microbicides advocacy agenda for Africa, and the Indian National Working Group on Microbicides, which placed a new focus on prevention options for Indian women.

Addressing ethics, policy, and communication challenges

Microbicide research raises complex ethical questions, and charges that research is conducted unethically can stop trials and destroy public and political support. Most microbicide trials are publicly funded, and are held to greater scrutiny than privately funded studies, making them more vulnerable to inaccurate media coverage. In 2002, GCM established an effort called the Research Ethics Initiative to support ethical conduct, mitigate the risk of false or sensationalized charges, and address emerging challenges.

The Initiative combined several approaches. First, GCM helped to build consensus among investigators, advocates, ethicists, and others in the microbicide community around the ethical issues that might arise during trials. Among other activities, it convened an international consultation to identify ethical issues, obligations, and other concerns.

In addition, it developed a participatory ethics training course to prepare advocates from many backgrounds to engage effectively in debates on ethical reasoning and HIV prevention trials.

“I can see a 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
Community participation

The Research Ethics Initiative also facilitated meaningful community engagement in trials, and demonstrated to trial sponsors that authentic partnerships can be well worth the investment. Strong relationships encourage ethical practice, help trials run more smoothly, and improve participant adherence and reporting. They also build trust, which can prevent or mitigate anger or sensationalized media coverage if study results are disappointing.

GCM found that in many cases, neither trial staff nor communities were sure what meaningful participation would look like or how it could be achieved. Further, trial sponsors did not always prioritize funding to ensure true engagement. To overcome this challenge, GCM convened community outreach personnel and other trial staff from sites in four countries. After several consultations, it established an ongoing community of practice to support meaningful and authentic community partnerships. At its height, this group included 65 members from civil society groups, HIV prevention trial sites, and research networks, as well as trial sponsors from 14 countries.

Crisis communications

Sensationalized or misleading media coverage also can halt trials or block current and future support. GCM and its partners established the Microbicides Media and Communications Initiative (MMCI) to help members of the microbicides field anticipate and respond to the communication challenges they might face during large-scale trials, particularly in Africa and other resource-limited settings.

In collaboration with other advocates and experts, GCM charted a strategy to help trial sponsors improve stakeholder outreach, media relations,
Focus on African countries

GCM intensified its outreach efforts in Kenya, South Africa, and Zambia. It provided advocacy, research, and ethics materials and training to partners and strengthened their capacity to conduct outreach activities. These efforts brought continued attention to women’s HIV prevention needs, facilitated the inclusion of prevention options for women in the national HIV and AIDS strategic plans for Kenya and South Africa, and built strong governmental support for microbicide trials in all three countries.

At the same time, the rate of scientific progress suggested that microbicides were closer than ever to becoming widely available. GCM began to lay the groundwork to successfully introduce microbicides if they became available. It prepared advocates and communities for product introduction, gathered opinions and impressions from potential users, and reached out to influential women’s groups, such as nursing organizations, to prepare members as advocates.

A changing landscape

During GCM’s later years, the political, research, and financing landscape around HIV prevention shifted drastically. New tools to prevent HIV in large populations had emerged, and funding for female-specific interventions was reduced. And, due to the success of HIV activists, many new players had joined the HIV prevention sphere. Through extensive consultation, HIV leaders expressed nearly unanimous support for the transformative role that GCM had played in creating a movement in support of HIV prevention tools for women, but felt that the time for GCM’s greatest impact had passed and that other partners were well suited to move the field forward. In many ways, GCM had accomplished what
it had 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.

**Lessons learned**

Today, it is more important than ever to ensure that the health needs of women are at the top of the global health and development agenda. There is also an ethical imperative to involve communities in research discussions. Several lessons from GCM in these areas may be useful to advocates and others pursuing similar goals.

**Set forth a clear vision and invite people to join it.**

GCM presented a clear vision: effective, woman-controlled HIV prevention options. It invited those who supported that vision to join its efforts. GCM stuck to this agenda, even when influential partners wanted to expand or revise it in light of changes in the evolving landscape of HIV prevention tools. This required discipline and diplomacy, but it preserved clarity and trust by assuring supporters that shared goals would not change.

**Engage a diverse set of constituents from across various perspectives.**

GCM created a platform where multiple stakeholders were able to make their voices heard. By reaching out to natural allies in the women’s health, family planning, and HIV communities, GCM was able to engage diverse groups uniquely positioned to mobilize local constituencies and effectively lobby their own governments.

**Meet advocates where they are by providing simple, appropriate, easy-to-use tools.**

GCM engaged a broad group of natural allies by including “easy” options for advocacy, such as putting information on a website or circulating a petition. It also provided support to ensure that any partner effort, at any level, would be successful. This allowed partners to participate successfully even if they had conflicting obligations, and often led to expanded participation as their time or resources opened up.

**Provide educational opportunities for advocates to increase their investment in the cause.**

By arming advocates with the information they needed to have a true understanding of the needs and potential solutions to problems, GCM enhanced advocates’ investment and long-term engagement.

**Give partners visibility and credit to maintain strong engagement.**

GCM was quick to distribute credit for success. Partner advocacy campaigns worked well in part because participants felt that they were part of a valued, credible, and effective network.

GCM also balanced visibility with grassroots success. NGOs working at the grassroots level must balance their need for visibility and ownership against the...
need to cultivate and promote the work of their partners. GCM generally preferred to lead from behind, extending visibility and credit to partners.

Promote mechanisms for meaningful engagement by those most affected.

GCM drew on partners’ expertise to create objectives and timelines that were realistic and achievable within the local context. Their insight and candid input allowed GCM to focus on those efforts that were most likely to succeed in each region.

Focusing on transparency and communication can overcome significant challenges.

GCM established an ongoing community of practice to support meaningful and authentic community partnerships and ethical conduct in clinical trials, and to mitigate the risk of false or sensationalized charges and address emerging challenges.

Build an invested group of donors.

GCM’s leaders built close, personal relationships with a core group of donors, and consistently involved them in efforts. Close relationships with donors allowed GCM to weather the changing science and needs of the microbicides field. In particular, close engagement helped donors to confidently fund new activities to keep work relevant and effective, even when this exceeded original funding parameters.

Conclusion: Household hope

Over the course of 14 years, GCM brought HIV protection for women into the global spotlight. Microbicides went from being, in many people’s minds, an unpronounceable and even unnecessary idea to a scientific reality poised to move from the laboratory to household use. In the process, GCM built new foundations for advocacy and progress in sexual and reproductive health.

_GCM demonstrated that it is possible to build an international, rights-based movement to improve the lives of women and communities._ Working from a small base and with limited resources, GCM created a powerful grassroots network and strengthened the capacity of hundreds of partners worldwide. It brought people together from across sectors and borders, many for the first time, to reach common goals.

Drawing from this base, _GCM gave women and communities a new voice in the prevention research agenda, clinical trial planning, and practice._ When GCM began, many in the microbicide community could not imagine that trial participants, particularly women in low-resource countries, could become informed and engaged advisors. GCM demonstrated that authentic participation was possible and highlighted its value to trial sponsors, opening new doors for ethical research.

Although much remains to be done to make women’s health a priority on the HIV prevention research agenda, GCM put women’s needs on the map. In the process, it carried out one of the first, and certainly one of the largest, global prevention and social health movements in history.