Global Campaign for Microbicides

Consultation on Operationalizing Access to HIV Treatment and Care

Palomar Hotel, Washington, DC
June 19th and 20th, 2008

Global Campaign FOR Microbicides

Expanding HIV prevention options, especially for women

Executive Summary

For trials of novel HIV prevention methods like microbicides, pre-exposure prophylaxis (PrEP) and vaccines, a key issue that has emerged is ensuring access to long-term treatment and care for participants who become HIV infected during the course of a trial. Most sponsors, researchers, activists and study participants now agree that ensuring long-term access to treatment and care is an indispensable part of the agreement between trial sponsors and participants. Recent international guidance from UNAIDS (2007) on this issue is also quite clear: researchers and sponsors must ensure access to comprehensive care for HIV infection, including access to ART for trial participants who become HIV positive during a trial. However, the pathways for operationalizing access to treatment and care are unclear, particularly in those countries where large-scale public HIV treatment programs are overburdened, underfunded or do not exist.

To develop a concrete proposal for operationalizing durable access to HIV treatment and care for prevention trial participants, the Global Campaign for Microbicides brought together thirty stakeholders – HIV prevention researchers and treatment providers, study sponsors, policymakers, treatment and prevention advocates, as well as experts in health care, financing and insurance – for a two-day brainstorming session in Washington, DC. The goal was to explore past experiences and future plans, and identify some of the challenges associated with ensuring access to treatment and care for HIV-positive trial participants. Different options for providing access to treatment and care were also discussed, including: referral to established public HIV treatment programs; enrollment in on-going HIV natural history and treatment studies; trust funds to provide for care in those countries where public HIV treatment programs do not exist; and partnering with public or private health insurance companies.

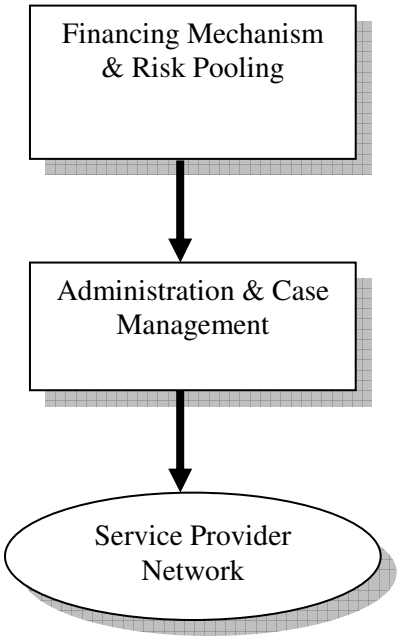
Participants from trials and trial networks underscored that this is a critical area for the HIV prevention field, practically, ethically and politically. International donors, host country governments, and local community members are demanding that trials provide long-term care and treatment for seroconverters. There was a great deal of support for developing a common approach to addressing this challenge. The meeting participants endorsed the idea of empowering a small working group to develop a draft proposal for operationalizing access to treatment and care. As currently envisioned, this proposal will call for establishing a partnership in which publicly-funded research networks conducting HIV prevention trials would pay into an insurance pool that could be used to provide a uniform HIV-specific care and treatment package for trial participants.

One possible approach, developed as an example by a small working group after the main consultation, would have three essential components: 1) A centralized funding mechanism, such as an insurance trust fund to receive payments and pool risks across trial sites; 2) a centralized administration to handle billing, to identify and accredit service provider networks, and to process claims and payment; and 3) a treatment implementation program made up of accredited provider networks, laboratories and pharmacies. Trial sponsors would pay into the insurance fund based either on the number of participants they have enrolled in the trial or the number of seroconversions they expect. The fund would pay for a set package of HIV care for individuals who become HIV positive during a trial.

The diagram below identifies a number of existing entities that may be well positioned to provide such services. A detailed description of each of these companies is provided on page 18. Although based primarily in South Africa, many of these administrative companies and clinical consulting services have relationships with insurance companies and treatment providers in other sub-Saharan nations. It is thus hoped that partnership suggested below, if successfully implemented in South Africa, can be expanded to include private sector partners in other countries where HIV prevention trials are occurring or planned.

Suggested Structure for Partnership

to Ensure Post-Trial Access to HIV Treatment and Care



- HVTN Seattle Fund, managed by Fred Hutchinson
- NIH Foundation
- Discovery Health, South Africa

- Discovery Holdings PTY, South Africa
- Alexander Forbes, South Africa

- Provider Networks
- Trial Sites
- Calibre Clinical Consultants, Ltd., South Africa
- ICAS, South Africa

In designing a shared approach to ensure long-term access to treatment and care for participants in future HIV prevention trials, the following features must be worked out:

1) The nature of the treatment obligation (i.e., who qualifies for treatment, what treatments will be made available, and for how long will services be provided?);
2) How the fund will be capitalized (i.e. will sponsors pay in per participant or per seroconversion?);
3) How will any shared approach be administeed; and
4) How to establish an appropriate provider network, particularly in those countries in which existing public health infrastructure is fragmentary.

Introduction and Background

There has been considerable debate about clinical researchers' moral and legal obligations to respond to the health problems of research trial participants, particularly for trials conducted in developing countries where access to quality healthcare might otherwise be limited (Council for International Organizations of Medical Sciences [CIOMS] 2002; Medical Research Council [MRC] 2004; National Bioethics Advisory Commission [NBAC] 2001; Nuffield Council on Bioethics 2002; Shapiro and Benatar 2005).

For trials of novel HIV prevention methods like microbicides, pre-exposure prophylaxis (PrEP), and vaccines, this debate has focused on a single key issue: provision of antiretroviral treatment (ART) for participants who seroconvert during a trial (e.g., Bass 2003-4; Lo and Padian 2007; Macklin 2006; Schüklenk and Ashcroft 2008; UNAIDS 2003; Weijer and LeBlanc 2006).

Most sponsors, researchers, activists, and study participants now agree that ensuring long-term access to treatment and care is an indispensable part of the agreement between trial sponsors and participants (e.g. Global Campaign for Microbicides [GCM]/International AIDS Vaccine Initiative [IAVI] 2003; Forbes 2006; Macklin 2006; UNAIDS/AVAC 2007). For example, current guidelines from UNAIDS and the World Health Organization on

ethical conduct of biomedical HIV prevention trials maintain that researchers must ensure access to comprehensive care for HIV infection, including access to ART for trial participants (UNAIDS/WHO 2007).

The pathways for operationalizing such access, however, are unclear. In countries where HIV prevention trials are currently taking place, large-scale public HIV treatment programs are often overburdened, underfunded, or do not exist (Fitzgerald et al. 2003; GCM/IAVI 2003; Turner and Slack 2003). In addition, many participants who seroconvert during an HIV prevention trial may not need treatment or care for several years, long after the study has ended and international researchers and trial sponsors may have redirected their attention and efforts. As a result, the often ad hoc approach used by different researchers and sponsors to provide long-term access to HIV treatment and care for trial participants has been varied. .

In a 2006 mapping exercise, for example, the Global Campaign for Microbicides examined existing practices across six different Phase IIB/III microbicide trial sites and networks (GCM 2008). Most of these trials were planned before access to ART was widely expected, and they worked to address this issue as expectations about access to treatment and care changed dramatically. At every trial site visited, research participants theoretically had access to free or inexpensive public treatment services, and seroconverters were provided with 'assisted referrals' to these public HIV services. The level of assistance, however, varied greatly and most sites did not provide funding to the participants or to the public programs to ensure continued care after the trial was over. In addition, as seen in this and other mapping exercises (e.g. GCM 2008; HIV Prevention Trials Network [HPTN] 2006; Population Council 2008), HIV-positive trial participants referred for care often did not seek or access care and treatment programs for a number of reasons, including stigma, competing economic and social priorities, because they were not yet ready to accept their diagnosis, or because they did not feel ill.

Given this backdrop, coupled with the urgency and political necessity of establishing clear mechanisms for ensuring access to treatment services for trial participants, the Global Campaign for Microbicides brought together a diverse group of researchers, clinicians, economists, and advocates to explore ways to provide a uniform HIV-specific care and treatment package for individuals who seroconvert while participating in an HIV prevention trial.

Opening Remarks

Ms. Lori Heise, Director of the Global Campaign for Microbicides, began the discussion by providing a historical overview of the Global Campaign for Microbicides, explaining that it serves as a platform for activism. GCM is an advocacy organization whose mission is to create a new model of HIV prevention research that involves greater communication and partnership between researchers and the communities in which trials take place. The Global Campaign works with partner groups to support community outreach and capacity-building activities, and to ensure that community and user perspectives inform research. In particular, Ms. Heise focused on the role that GCM has played in the evolving debate around a range of practical and ethical issues in HIV prevention trials, including provision of treatment and care in HIV prevention trials. This process started with an international consultation co-sponsored with the Population Council in 1993 and has continued with consultations around access to antiretroviral treatment (ART) in 2002 and the ethics of HIV prevention trials in 2003.

She pointed out that since these early meetings, the way the HIV prevention field thinks about providing access to treatment and care has evolved. At a 1997 GCM-hosted meeting on the ethics of HIV prevention trials, for example, although the issue of providing access to treatment and care was raised by several participants, it wasn't part of the original agenda. At that time, there were no viable government-run ART programs in countries where trials were occurring. Trial participants who seroconverted were referred for counseling, but there were no plans to refer or provide these individuals with antiretroviral treatment. Over the last ten years, however, a lot has changed, including increased political and financial commitment on the part of developed and developing countries to provide antiretroviral treatment (e.g. licensing arrangements to allow developing countries like India and South Africa to produce generic versions of many ARTs, and the roll out of well-funded treatment programs supported by the Global Fund or the President's Emergency Plan for AIDS Relief [PEPFAR]). There has also been increased pressure from advocates. Part of the controversy surrounding the 2003 Cameroon PrEP trials, for instance, was directly related to plans (or lack thereof) to provide adequate access to treatment for trial participants.

As mentioned previously, this evolution in thinking is also reflected in changing international guidance on this topic. Early guidelines from the Council for International Organizations of Medical Sciences (CIOMS 2002), for example, describe the provision of antiretroviral treatment for HIV prevention trial participants who seroconvert as morally praiseworthy but not ethically obligatory. Newly revised guidelines from UNAIDS and the World Health Organization, in contrast, argue that researchers and trial sponsors have an obligation to ensure access to state-of-the-art treatment for all seroconverting trial participants. As Guidance Point 14 of the 2007 UNAIDS/WHO guidance document states

> Participants who acquire HIV infection during the conduct of a biomedical HIV prevention trial should be provided access to treatment regiments from among those internationally recognized as optimal. Prior to initiation of a trial, all research stakeholders should come to agreement through participatory processes on mechanisms to provide and sustain such HIV-related care and treatment.

The UNAIDS/WHO guidance document, however, does not provide clear guidance on operationalizing access to treatment and care in resource-poor settings where many HIV prevention research trials take place.

Ms. Heise closed by summarizing the goals of the meeting, emphasizing that the focus of the consultation was "not on the 'whether' but rather on the 'how.'" In particular, the consultation will focus on key operational questions around post-trial provision of antiretroviral therapy – whether via referral to existing public treatment programs, establishing trust funds to provide for care in those countries where public treatment programs do not exist, or by partnering with public or private health insurance companies – with the hope that the meeting participants can help identify a way forward for operationalizing durable access to treatment and care in future HIV prevention trials.

Reports from the Field (1): Standards of Care of Past and Present Microbicide Trials

Dr. Sean Philpott, Science and Ethics Officer of the Global Campaign for Microbicides, presented the results of the Global Campaign's recent standard of care mapping exercise, presented at the Microbicides 2008 in New Delhi, India. Focusing on provision of treatment for HIV-positive trial participants, Dr. Philpott summarized the approaches used by each of nine Phase IIb/III microbicide trial sites – two Family Health International (FHI) sites in Ghana and Nigeria, two Microbicide Development Programme (MDP) sites in South Africa and Tanzania, two Population Council sites in South Africa, one CONRAD site in Benin, one HIV Prevention Trials Network (HPTN) site in Zimbabwe, one MIRA site in Zimbabwe – to ensure access to HIV treatment and care for seroconverters.

For study participants who seroconverted in the course of the trial, all studies but one allowed them to stay in the trial and receive trial related care. All study sites also offered ongoing counseling for positive living, and referral to ART programs with some monitoring of uptake. Some sites also offered prophylaxis for opportunistic infections (OIs), CD4 counts, and baseline laboratory studies; most women did not need these services during the study. The sites that were co-located or partnered with existing government care facilities were able to provide the broadest range of HIV services to the most women.

The approach taken by two networks was highlighted. The CONRAD Benin site provided complete HIV care for everyone, including counseling, screening and treatment for sexually transmitted infections (STIs), CD4 cell counts at diagnosis and biannually thereafter, viral load monitoring, and prophylaxis and treatment of OIs. This high level of care was possible because the study site was run out of an established community clinic where most of the women had been seen regularly before study screening and continued to access services as usual after testing HIV positive. Familiarity with study providers and ongoing peer support in their communities (from peer educators supported by the study) helped to maintain regular visits.

At the two Population Council sites in South Africa, seroconverters and those who tested HIV-positive at screening were referred to nearby Department of Health-run clinics that offered integrated HIV care, including diagnosis and treatment of OIs, tuberculosis (TB), and STIs. The level of care varied at the different sites, however. The township of Gugulethu, outside of Cape Town, benefits from multiple research projects that involve its public health clinics; HIV/ART services are more advanced than at other South African sites. Because of stigma, the desire to seek care anonymously, and the lack of an established relationship between the study site and the referral clinics, however, it was unclear how many women sought care. In contrast, women at the Shoshanguve site outside of Pretoria were referred to a clinic with which the Population Council had a formalized

relationship via a memorandum of understanding. However, women often did not seek care as it was provided at a large hospital approximately 18 km. away from the study clinic; this clinic had a waiting list, and transport was difficult for many participants.

The most interesting aspect of the Population Council's approach was that each site was given a lump sum (~$100,000 US) to assist in the care of seroconverters. At the Gugulethu (Cape Town) site, researchers discussed with the Department of Health how to best use this money, electing to support an additional HIV clinic every week at the busiest public health center. At the Shoshanguve (Pretoria) site, in contrast, the money was used to finance medical services and an HIV support and care group for seroconverters and women who screen out as HIV-positive; this support group was transitioned to a local NGO when the study closed and there are discussions underway about continued funding of the group through PEPFAR.

As discussed below, both of these examples focused on strengthening existing ART services at local referral sites and did not restrict the use of those funds to the provision of care for individuals who seroconverted while participating in an HIV prevention trial.

Reports from the Field (2):What Are HIV Prevention Networks Planning to Do?

Representatives from eight HIV prevention networks or studies were invited to present their network's policies around securing access to care and treatment for trial participants who become HIV positive during the trial, including how (or if) they have been put into practice and the implementation challenges experienced or anticipated.

1. CONRAD

Drs. Lut Van Damme and Fernand Guedou presented a case study of the CONRAD cellulose sulfate trial.

Dr. Van Damme began the discussion by talking about her experiences in running the COL-1492 trial of nonoxynol-9 (N-9), which had marked impact on her perception of researcher responsibility to provide care to trial participants. At that time, treatment was not widely available and there was little funding, so the COL-1492 investigators relied upon a passive referral mechanism. After it became apparent that use of N-9 put some participants at greater risk, however, Dr. Van Damme concluded that all future HIV prevention trials should have a plan in place for treatment and care of seroconverters.

At Dr. Van Damme's insistence, the cellulose sulfate trial was designed to provide trial participants with access to HIV treatment and care, and funding was set aside at the beginning of the trial to provide five years of antiretroviral treatment (based on the local cost of care and the number of seroconversions expected at each site). Recognizing that the investigators could not be held responsible for the treatment funds, nor could the funds be given directly to trial participants, Dr. Van Damme and her colleagues concluded that the best option would be to give the money directly to the referral clinics. When the cellulose sulfate trials were unexpectedly closed due to DSMB concerns, CONRAD delegated care of seroconverters to the local study team, who were responsible for obtaining written agreements with the referral clinics, transferring the money, and following up to see that the money was appropriately spent. CONRAD also retained the right to do financial audits of the referral sites. Although this approach did not address some of CONRAD's concerns – such as confirming that the participants will access care or that the treatment funds will be spent for the participants' benefit – Dr. Van Damme concluded that there must be some trust as well as some recognition that the local study and referral sites are better positioned to prioritize funds based on local needs.

Dr. Guedou then gave an overview of the HIV care program in Benin, where treatment and care is controlled by the national AIDS program (PLNS) that provides and oversees HIV treatment and care distribution to all who need it. This treatment package includes all lab tests, antiretroviral treatment, OI prophylaxis, nutritional support, and psychosocial counseling and is supported by the Global Fund.

The CONRAD cellulose sulfate trial in Benin co-located with two public treatment clinics – DIST and Waly Diop. Since 2005, DIST has been a PNLS-designated center for HIV care. As part of the cellulose sulfate study, the local study team met with PNLS authorities to discuss HIV treatment and care for trial participants, and signed a letter of agreement with them. In exchange for a lump payment to the clinic – enough money to

cover five years of ART for 10 seroconverters at an estimated cost of $136 US per person per month ($81,600 US total) – PNLS committed to take care of these seroconverters after the study ended. Setting up this agreement proved challenging, however, as the local Director changed twice during the process, and the PNLS team preferred that responsibility of care be "shared" rather than transferred. PNLS officials were

concerned that they might face claims for treatment and care that far exceeded what they had agreed to, both in terms of cost and in the types of services requested, and asked that CONRAD share responsibility for meeting such claims. There also was reluctance on the part of the PNLS to agree to an approach in which individual trial participants were given formal letters or vouchers that listed the types of care and services available to them. Local treatment providers and clinics, however, strongly recommended the use of such letters or vouchers, and the local study team was reluctant to threaten their existing relationships with these local providers by opposing their use. Dr. Guedou believed that these difficulties could have been avoided, however, if the PNLS had been more actively involved in the research process. Dr. Guedou and others also expressed some concern about the transfer of responsibility, worrying that there were few mechanisms in place to ensure that the trial participants will be able to access care five or ten years from now and suggested that a relationship with a private provider (with government support and oversight) might be more stable and secure.

2. HIV Vaccine Trials Network

Dr. Margaret Weckler from the HIV Vaccine Trials Network (HVTN) summarized the basic organization and structure of the HVTN, a cooperative vaccine trials network that operates with US National Institutes of Health (NIH) funding. Currently, the HVTN has 14 domestic and 14 international sites. Although there is some coordination with PEPFAR, research sites and PEPFAR-funded treatment clinics do not always overlap. Peru, for example, hosts an HVTN research site but is not one of the 15 priority countries currently targeted by PEPFAR.

In a 2003 article in *The Lancet*, the HVTN promised that "participants who become infected during HVTN funded trials will be provided with long term ART" (Fitzgerald et al. 2003, 993). Because US policy prevents the use of NIH funds for monitoring, testing, and provision of ART outside of the clinical trial context, the HVTN set up a private trust fund to ensure HIV-positive trial participants access to treatment if they meet treatment guidelines, but only until a local plan to provide publicly-funded care and treatment is in place. It is conceived of as a fund of "last resort" to provide ART for trial participants who lack other avenues to comprehensive HIV treatment and care. The trust fund, known as the "Seattle Fund", will purchase antiretroviral drugs, and pay for CD4 counts, viral load testing, and all other monitoring necessary to manage care associated with ART. To date, the HVTN has had a total of 79 seroconversions among trial participants. Twenty-four of these seroconverters live in countries that do not have publicly-funded care and treatment services. Two seroconverters are currently on treatment, both in Peru.

The fund, established by soliciting donations from vaccine developers and with a current endowment of approximately $500,000 US, is managed by the Fred Hutchinson Cancer Center in Seattle where HVTN is based. Each individual HVTN site, however, has responsibility for arranging and providing care for trial participants. For example, each site identifies gaps in existing treatment and care services, and provides the fund managers with treatment cost estimates, revised as necessary to reflect changes in national HIV care plans. This provides considerable flexibility but several challenges remain, including limited funding, shifting need patterns, and challenges associated with implementation (e.g., knowing if and when a trial participant qualifies for assistance, particularly once a trial has ended).

3. International AIDS Vaccine Initiative

Mr. Prince Bahati of the International AIDS Vaccine Initiative (IAVI) started by giving a brief overview of IAVI, IAVI-funded trials and partnerships, and its policy concerning provision of ART to trial participants. Currently, the policy is to guarantee ART to trial participants for 5 years after the start of treatment, if publicly-funded treatment and care programs are not otherwise available. IAVI also has a follow-up protocol for seroconverters (both those who acquire HIV during a vaccine trial, and those who seroconvert once a trial has ended). Finally, IAVI has ensured that referral systems are in place for volunteers who screen out, and

IAVI continues to advocate and leverage support at a national and international level for continued investment and improvement of local healthcare services.

To date, over 900 volunteers have enrolled in IAVI-funded vaccine studies, of whom twelve have seroconverted. Six of these seroconverters live in Africa, and all of these have been referred to treatment programs to be monitored. As more participants enroll in IAVI-funded studies, however, anticipated challenges include follow-up of large numbers of HIV-infected volunteers, ensuring the availability of treatment and care at referral sites in countries with public ART programs, and overcoming likely participant resistance to accessing care through referral.

4. International Partnership for Microbicides

Ms. Pam Norick of the International Partnership for Microbicides (IPM), a non-profit partnership that focuses on the development and testing of vaginal microbicides, began by highlighting that most of IPM's current donors, public and private, are concerned about access to treatment and care for seroconverters and expect to see some provisions put in place for all IPM-funded studies.

Currently, IPM has only funded safety and acceptability studies, with no seroconversions to date. Two larger IPM-funded safety trials are scheduled to start in Africa in the next year, however, and IPM is currently developing a seroconverter protocol to deal with the issue of access to care. As currently envisioned, this protocol will rely upon guided referrals for care and support via pre-established partnerships with local and national treatment services. IPM is also in negotiation with its donors to obtain funding for direct provision of treatment and care for trial participants in those countries where publicly-funded ART programs are not available. Anticipated challenges to ensuring access to ART, however, include: establishing a dedicated funding mechanism that is sustainable regardless of IPM's future business and financial status; ensuring that the political will exists to sustain existing treatment programs (including continued support from donors like the Global Fund, the Clinton Foundation, PEPFAR, and host country governments); and tracking and monitoring trial participants to ensure they can access care when they need it.

5. Microbicide Trials Network

Dr. Patrick Ndase gave an overview of the Microbicide Trials Network (MTN), an NIH-funded network conducting studies of both topically-applied (vaginal and rectal) and orally-administered microbicides. As he pointed out, the reliance on NIH funding means that the bulk of the MTN's research funds cannot be used to provide HIV treatment and care. Although the MTN had considered setting up a fund similar to the HVTN's "Seattle Fund," they were not able to obtain sufficient commitment from outside donors to establish a private trust.

Currently, the MTN relies on a referral mechanism, with seroconverters actively referred to publicly-funded treatment clinics with which the network has an established relationship (i.e. formalized through a memorandum of understanding). They have also developed a protocol to look at disease progression and response to treatment among trial participants who seroconvert while enrolled in an MTN-funded prevention study. This seroconverter protocol, currently funded through 2013, will provide a number of monitoring tests (e.g. CD4 cell counts, viral load, and HIV drug resistance testing) but will not provide antiretroviral treatment; ART will continue to be provided through the referral clinics.

Dr. Ndase felt that this approach is more flexible and has greater sustainability, particularly given the variable time frame of need for access to treatment and care. This assumes, however, that current and planned public health programs are sustainable even in the face of economic and political instability. This is unlikely. In addition, this approach also fails to address the problem of disparate access to ART in different countries and different contexts.

6. MIRA

Ms. Elizabeth Montgomery from Research Triangle Institute presented an overview of the MIRA (Methods

for Improving Reproductive Health in Africa) diaphragm study, conducted at two sites in South Africa and one site in Zimbabwe.

At the start of the trial, seroconverters were offered counseling and referral to treatment studies but no there was no plan in place to ensure access to treatment and care services, particularly as there was no public treatment program in Zimbabwe at that time. With the introduction of a national ART program in Zimbabwe, however, the trial sponsor – the Bill and Melinda Gates Foundation – pushed for some provision of care.

MIRA researchers spent the last nine months of the study trying to re-contact all 309 seroconverters to inform them of various treatment options available in their communities. Each of the three research sites was allowed to develop its own strategy, ranging from simple memoranda of understanding to referring seroconverters to publicly-funded clinics co-localized with the research site. There was no assumption that the study sponsors would assume responsibility for ensuring access to treatment and care; instead, the overall goal was to transition seroconverters into existing national programs.

One of the key challenges of this approach included a reliance on overburdened public treatment programs, particularly in Zimbabwe. Often, women referred to public clinics in Harare faced a six to twelve month wait to get the baseline tests necessary for enrollment. In response, MIRA investigators began to provide some of these tests (e.g. CD4 cell counts and WHO staging) to help some women "jump the queue." There was also considerable variation in access across the different sites, ranging from 74% of HIV-positive women accessing care in Harare, Zimbabwe, to only 37% accessing care in Durban, South Africa. Without a mechanism for monitoring and tracking these referrals, however, it is unclear if this difference is due to the refusal of participants to access care, administrative barriers to access, or differential need for treatment at the different sites.

7. Population Council

Dr. Louise Pedneault provided an organizational overview of the Population Council, and then described the results of the Carraguard trial. Conducted at three research sites in South Africa, the Carraguard trial began enrolling participants in 2004, at which time there was no well-established public ART program in South Africa. Over 27% of volunteers screened-out as HIV-positive at enrollment (a seropositivity rate ranging from 18% in Cape Town to over 40% in Durban). An additional 285 women seroconverted during the study. Both screen-outs and seroconverters were referred to local counseling and treatment services, with each research site responsible for establishing and maintaining relationships with referral clinics. Although women who seroconverted were discontinued from the study, the Population Council later offered follow-up monitoring visits at which CD4 cell counts, HIV viral load, and Pap smears were performed. Between 80-100% of all seroconverting women were contacted during the six to twelve months after the study ended, but less than half of these came for the monitoring visit. Most of the women who refused were uninterested, had relocated, or were already receiving care elsewhere.

The Population Council also evaluated empirically the HIV care and treatment services provided to trial participants through the referral process. This study, consisting of 50 in-depth interviews of seroconverters at the three research sites, was used to identify barriers to access. Key barriers to access included individual concerns about confidentiality and stigma, and a lack of direct assistance during the referral process.

8. US Military HIV Research Program

Dr. Nelson Michael of the US Military HIV Research Program (USMHRP) gave an overview of the US Military's interest in AIDS research, particularly its interest in reducing the toll of HIV and other infectious diseases as a key US security policy goal.

USMHRP was established in 1986 to develop globally effective vaccines and evaluate public health interventions, and currently has five HIV vaccine development sites (one in Nigeria, one in Thailand, and three in Eastern Africa) and 20 international surveillance sites.

At each research site, an effort is made to build local health infrastructure prior to study initiation. With the help of PEPFAR, for example, the USMHRP works to develop local capacity to provide integrated

prevention, care and treatment in the community, working to develop local staff capacity to provide ART and palliative care at USMHRP sites. The goal is to build a sustainable, locally-run network of care and treatment sites within the same communities where the USMHRP recruits research trial participants. Using a combination of NIH, Department of Defense, and PEPFAR funds, the USMHRP has trained over 2,200 local staff to provide treatment, established 617 palliative care and 300 ART clinics, and provided antiretroviral treatment to 41,000 individuals in four African countries.

The successes of the USMHRP approach, many meeting participants felt, highlight the need to develop, in consultation with the community and local stakeholders, a comprehensive plan to provide access to treatment and care for trial participants. However, Dr. Michael pointed out that this is a time-consuming process; at every USMHRP research site, community consultation and local capacity building efforts involved several years of sustained effort before the research trial began.

Reports from the Field (3): How Are Network Plans and Policies Put Into Practice?

Representatives from four HIV prevention networks, research sites, and treatment clinics were invited to present their individual experiences in providing for treatment and care of trial participants. The goal of this session was to help meeting participants appreciate some of the different perspectives, issues and challenges faced by researchers working in countries like South Africa, Uganda and Zimbabwe.

1. Putting Policy Into Practice at MTB trial sites in Eastern and Southern Africa

Dr. Patrick Ndase, MTN regional physician, spoke at length about MTN's plans and policies for ensuring sustainable and equitable access to treatment and care for trial participants. As he noted in his previous presentation, the MTN originally considered establishing a separate fund to pay for treatment (i.e. similar to the HVTN's "Seattle Fund").

A separate fund could have a number of advantages, such as the timely provision of high-level (international best standard) care for seroconverters without additionally burdening already-challenged public treatment clinics. There are, however, a number of distinct disadvantages to this approach, including sustainability, equitability (i.e., providing care only for seroconverters versus care for seroconverters and screen-outs), stigma, co-enrollment of "street smart" participants in MTN- and other network-funded studies, financial abuse, and the need to establish separate administrative and monitoring systems to ensure that participants access the care they need. The issue of confidentiality and stigma was of particular concern to the stakeholders involved in community involvement and outreach. At the community working group, for example, it was noted that the MTN's seroconverter protocol (MTN015) has had considerable difficulty recruiting HIV-positive trial participants because the nature of this study makes it clear that enrolled participants are HIV-positive. Finally, coordination with existing health insurance mechanisms, Dr. Ndase argued, also could present a challenge as most trial participants in developing countries like Kenya and Uganda have little experience with private health insurance.

Instead of developing a separate fund, the MTN chose to focus on developing effective linkages with existing, publicly-funded ART sites. Such an approach, it was felt, was more sustainable and equitable. However, this approach also has a number of disadvantages. Most notably, it relies upon referral to often overburdened clinics and assumes that funding and other resources for treatment programmes will continue into the future. Although many of these clinics are funded by PEPFAR or the Global Fund, the busiest clinics can only provide about 70% ART coverage for those who need it. Some clinics also have caps on enrollment, resulting in long waiting lists. At other clinics, increasing numbers of clients often require tough budgetary decisions (e.g. a key clinic in Uganda recently reduced the amount of resources devoted to nutritional support services). The MTN has devoted some resources to help these overburdened clinics, including staffing support at the key clinic in Lilongwe and capacity-building efforts incorporated the seroconverter study, but there is some concern that these efforts amount to little more than "a drop in the ocean".

2. How Do Participants Access Referrals at the MDP Africa Centre Site in South Africa?

Ms. Hlengiwe Ndlovu, clinical coordinator of Africa Centre for Health and Population Studies, presented an overview of the Africa Centre's role in the design and conduct of an MDP-funded Phase III study of topically-applied PRO2000/5 gel for the prevention of vaginally-acquired HIV infection.

The Africa Centre, located in Mtubatuba, South Africa, serves a large and predominantly rural catchment area. In this area of KwaZulu-Natal province, HIV prevalence is almost 50% among women aged 25-29, and 45% among men aged 30-40. The Centre is co-located with a government-run public health clinic and, beginning in 2003, began a program to roll-out ART services across the catchment area by using a combination of government and PEPFAR funding. There are now 15 ART clinics in the sub-district, with 5000 people receiving treatment.

To date, 1662 women have volunteered for the MDP study, 461 of whom tested HIV-positive at screening. These HIV-positive screen outs were given counseling and offered CD4 testing. 100% of these women accepted the offer of CD4 testing, but a smaller number actually returned to the clinic to receive their results (the actual percentage of participants returning to the clinic is unclear due to monitoring errors). Those who returned were referred by letter for HIV care and treatment to the local public health clinic. Referrals occur immediately if the woman's CD4 cell count is equal to or less than 250 cells/mm^3, otherwise the referral is delayed. A total of 37 women have met the criteria for immediate referral and treatment. For women not needing immediate treatment, the Africa Centre has also established a pre-treatment cohort which provides a variety of services, including psychosocial counseling and nutritional support.

There is no formal procedure in place to deal with women who seroconvert while enrolled in the MDP study, but the expectation is that these women will also be referred to local ART clinics for care and treatment.

Although the Africa Centre's approach has the benefit of helping build local capacity for HIV treatment and care, it faces a number of challenges. In particular, women who test HIV positive often do not seek treatment and care at the referral clinics. The reasons are many and include stigma, traditional health seeking attitudes (e.g. reliance upon traditional healers until extremely sick), and mixed messages from politicians at the local and national level concerning HIV treatment and care. In a recent phone survey of 18 women referred for immediate care, for example, only six had started treatment. Of those who did not access services, many reported that they did not feel sick and so did not need treatment, that they had moved out of the area, or that they simply lacked the time to go. Unfortunately, the exact number of women seeking care at the referral clinics is unknown. Not only do these women rarely submit their referral letters, but many of the rural ART clinics do not keep a good central record of referrals.

One of the current debates at the Africa Centre is the question of 'if and when' to provide CD4 cell counts to HIV-positive women. Of the women who receive CD4 cell counts at the Africa Centre, many either do not return for their results or do not take their results to the referral clinic. As a result, referral clinics often repeat these tests – a redundancy that burdens the clinic in terms of both time and resources. Offering these tests to women who screen-out or seroconvert, however, could familiarize them with regular CD4 testing and could reduce the burden on local ART clinics by identifying and referring only those women who need immediate treatment. It was also noted that other settings in sub-Saharan Africa, such as in Zimbabwe, CD4 cell counts are an important step in the process of accessing care and treatment through public health clinics.

3. Impact of the MIRA Trial on Referral Services in South Africa and Zimbabwe

As previously mentioned, HIV-positive participants in the MIRA trial were referred for treatment and care to existing publicly-funded ART clinics, although research investigators at some sites did facilitate the referral process by providing baseline CD4 cell counts and WHO staging.

Ms. Elizabeth Montgomery presented the results from a recent study to evaluate the impact of MIRA's referral system on treatment and care sites. This study looked at 13 sites overall, including sites that offered counseling and social support services, as well as those that provided antiretroviral treatment. At nine of these sites, semi-structured interviews with clinical managers, physicians, doctors, nurses and administrators were conducted. A total of 13 such interviews were conducted.

In general, referral site staff members were positive about their relationship with the MIRA research trial, although only a minority of staff were aware that this relationship had been formalized through a written memorandum of understanding. The majority of referral site staff (10/13) also thought that the clinic benefited from this relationship, through financial support, capacity building, or through educational outreach to staff. However, staff at two sites felt that the clients benefited but the clinic did not, and at one site it was believed that neither the clients nor the staff benefited. There was also some concern about the added burden from the referrals (i.e. the total number of clients increased – as a result of both the referral process and increased awareness of clinic services overall – and these clients were more educated about HIV and thus needed more extensive counseling). Finally, several referral site staff felt that MIRA could have provided more in the way of financial support for the clinics.

The conclusions that can be drawn from this study are limited by the small number of respondents and may reflect personal biases of staff, but these results suggest a need for greater communication between the research trials and the treatment clinics, as well as a need to consider the impact of prevention trials on local public health clinics in terms of staff workload and financial burden. Although the referrals process can be beneficial to the local clinics and the community they serve, there is a need for greater dialogue and more direct involvement of the referral sites in the research process.

4. Providing HIV Care and Treatment in a Referral Center

Dr. Ian Sanne, Chief Executive Officer and Managing Director of Right to Care, spoke about the approach his organization – a Johannesburg-based organization specializing in HIV management and treatment – uses to provide comprehensive treatment and care for over 65,000 HIV-positive clients.

Established in 2001 as a PEPFAR-funded non-profit, Right to Care provides treatment and care services for almost 150,000 private-sector employees, as well as their family members and communities. Right to Care's clinical service uses the same approach of all the large treatment and medical schemes in South Africa, namely a capitation fee model which is used to provide services through private network of clinical, laboratory and research sites.

Currently, Right to Care can provide comprehensive pre-ART and post-ART care for an annual cost of $1,000 to $1,400 US per person (including all necessary overhead and administrative expenditures) (Rosen et al. 2008). This comprehensive approach, which can work even in rural settings like Lesotho, has three essential components:

1) A centralized funding arrangement, similar to either the needs-based HVTN Seattle Fund (although not as a fund of "last resort") or a South African medical scheme;
2) Centralized administration to handle billing, to identify and accredit service provider networks, to handle contracts and memoranda of understanding, to process claims and payment, and to handle financial reporting; and
3) A treatment implementation program made up of accredited provider networks, accredited laboratories and pharmacies, and accredited prevention trials.

This approach has been particularly successful, however, in that it is closely tied with PEPFAR funding and capacity-building efforts. It may thus be necessary, in Dr. Sanne's opinion, to conduct HIV prevention trials in those countries and areas where PEPFAR-funded clinics exist. This could pose a significant challenge, however, as many prevention research sites (i.e. vaginal microbicide trial sites, which require a large number of at-risk women living in areas of high HIV incidence and prevalence) cannot be selected solely on the basis of a PEPFAR-funded clinic being present. Nevertheless, a useful first step might be to map existing research sites and PEPFAR-funded treatment clinics.

Reports from the Field (4): What Might Be Done and What Cannot Be Done in the Future?

1. South African Health Insurance Plans

Ms. Elaine McKay, Head of HIV Strategy for Discovery Health, gave a brief overview of health insurance plans in South Africa. Known as "medical schemes", these private insurance plans are required by law (under the Medical Schemes Act [No 131 of 1998]) to provide a compulsory minimum package of health benefits, and cannot discriminate on the basis of age, race, gender, health or medical history. Thus, not only do private health insurance plans like those offered by Discovery Health provide a better standard of care than is available through most publicly-funded clinics in South Africa, they are also required to provide comprehensive care and treatment for HIV-positive individuals.

Ms. McKay then presented three ways in which HIV treatment and care could be provided to trial participants through partnerships with private companies: 1) coordinating with existing insurance companies like Discovery Health to provide health insurance; 2) creating a trust fund and contracting with existing health care services to provide treatment; or 3) providing disability insurance for trial participants.

Focusing on Discovery Health's efforts to provide comprehensive health insurance, Ms. McKay distinguished between the "open" scheme available to all individuals and the "closed" schemes managed by Discovery Health but limited to the employees of particular corporations who have contracted with the insurance company. These closed schemes have separate benefit packages and management systems, and an insurance company like Discovery Health would be willing to work with an organization or research trial network to develop a plan to provide an HIV-specific package of treatment benefits. Ideally, this would be a capitated arrangement, with risk pooling across different HIV prevention networks to provide a uniform package of services independent of the trials. The efficiency, effectiveness and cost of this approach would be determined by the size of the risk pool and the expected number of beneficiaries, and it would have the advantage of being easily managed. However, while a country like South Africa has a well developed health insurance industry, established medical scheme providers do not exist in some other countries.

An alternative approach for providing private insurance would be for the trial networks to create their own fund for risk pooling, or to register with an existing fund like PharmAccess. This could be an individual network fund like the HVTN Seattle Fund or a joint fund across the different trial networks and donors. Not only would this approach raise money for the development of health care systems where they do not currently exist, it could also allow the provision of a wider range of services, including case management, antiretroviral treatment, drug resistance monitoring. The disadvantages with this approach are the challenges of indentifying and contracting with credible health care providers, particularly in rural areas, and the added administrative costs associated with managing such a fund.

Finally, although providing disability coverage to all trial participants would be an option, it is prone to misuse. As the money is paid out to the individual trial participant rather than a service provider, there is no guarantee that the insurance money would be used for HIV-related care and treatment.

2. Low-Income Insurance Plans in Namibia and Nigeria

Dr. Emily Gustafsson-Wright, a fellow at the Brookings Institution and the Amsterdam Institute for International Development, discussed a novel partnership to provide health insurance coverage for low-income individuals in Namibia and Nigeria. Supported by the Dutch government and the Health Insurance Fund, PharmAccess introduced a low-cost health insurance program in Namibia in 2004. Established at the behest of private employers in Namibia, who were frustrated by economic costs and lost opportunities associated with the inability of their workers to access care through existing public health clinics, in 2006 the existing program was expanded to create a shared risk pool for the provision of HIV treatment and care. 40,000 low-income Namibians are covered under the existing program, 2,000 of whom are currently receiving comprehensive HIV treatment and care.

Similarly, in 2007 PharmAccess received a 100 million Euro grant from the Dutch government to create a similar insurance program in Lagos and Kware, Nigeria. Unlike the Namibian employer-based program, the

Nigerian insurance plan focuses on individuals employed in the informal sector (e.g., farm workers, market women and their families). This program also includes a quality improvement plan to help build local clinic and hospital capacity.

In both Namibia and Nigeria, these programs focus on creating a risk pool of low-income groups and individuals, with services provided by local insurance companies and health care providers. At a cost of less than $100 US per year plus a small (5-10%) co-pay by individuals, these plans provide a comprehensive primary-care package, with some limited coverage of secondary care and medications (including antiretrovirals).

3. Reaching Out to the Corporate Sector

Dr. Neeraj Mistry, formerly Vice President of the Global Business Coalition on HIV/AIDS, TB and Malaria, suggested that the HIV prevention field could learn some valuable lessons by looking at how the corporate sector – using a consumer marketing approach – has responded to the challenge of HIV among the global workforce. In particular, he noted, the challenge in developing a comprehensive approach to ensuring access to HIV treatment and care for trial participants has focused on three issues: advocating for these services, paying for these services, and delivering these services.

Historically, corporate interest in HIV/AIDS arose out of concerns for declining economic productivity. Many companies in hard-hit regions like sub-Saharan Africa, for example, began to experience declining productivity and reduced profits as a result of HIV-related morbidity and mortality among their employees. Recently, however, corporate interest in HIV/AIDS has expanded to consider consumer and political expectations, as well as social responsibility.

Corporations grappling with this challenge have used a variety of approaches to deal with HIV in the workplace. Some companies, including GTZ and DeBeers, have developed their own comprehensive HIV programs by expanding pre-existing employee health care plans. Other companies have contracted with health insurance providers like Discovery Health to develop comprehensive and integrated workplace programs. Since 2003, for example, Volkswagen South Africa has contracted with a private health care provider to provide its employees and their families with HIV counseling, testing and treatment (including the provision of antiretroviral therapy). Outsourcing approaches like this work best in countries like South Africa and Botswana where there are plenty of providers and insurance companies already in place. It might be possible, however, to use an outsourcing approach even in less-developed countries by working with existing health care providers, including faith-based organizations and NGOs.

As the corporate experience has shown, however, there are challenges to both of these approaches. Although it may be possible to work with companies like DeBeers to enroll trial participants in existing employee health care plans, it is unclear whether these services will be available in those regions of Africa where research trials are currently underway or are likely to take place. Outsourcing health care delivery to service providers and insurance companies, however, can be time consuming, particularly in those countries and regions where the existing health care infrastructure is poor or lacking.

4. Tracking Study Participants Once a Trial Ends

Dr. Joshua Kimani, Clinical Research Director at the University of Nairobi, spoke about the challenges of tracking trial participants once a study ends. Although some research trials have had considerable success re-contacting study participants, such as in the MIRA trial, anecdotal evidence from other studies suggests that rates of participant follow up, particularly among migratory high-risk populations like informal laborers and female sex workers, can be exceedingly low.

Dr. Kimani presented data from three cohorts of female sex workers living in shantytowns and slums in and around Nairobi, Kenya. Although these women are particularly marginalized and vulnerable, with a high-level of migration, 95% of those who need antiretroviral treatment are currently receiving them. Retention in these three treatment and natural history cohorts is due primarily to peer-led outreach and cohort cohesion programs. For example, researchers use cell phones and text messaging to remind participants about clinic

appointments and medication. There is also a dedicated nurse counselor whose sole job is to maintain peer networks.

5. Donor Expectations and Limitations: A Case Study of the US National Institutes of Health

Dr. Liza Dawson, from the NIH Division of AIDS (DAIDS) Human Subjects Protection Branch, was invited to discuss post-trial access to antiretroviral treatment in NIH-funded treatment trials. Dr. Dawson described the NIH Office of AIDS Research (OAR) guidance on the provision of antiretroviral treatment after the end of a research trial. In particular, she highlighted the fact that the policy describes restriction on use of funds by US Congressional Statute, 42 USC 284, limiting the authority of the NIH to use funds solely for research purposes. There have been special circumstances in which NIH funds have been used to provide insurance to cover harms that might occur to a trial participant during the course of the study, but this coverage is limited to research-related injury claims associated with trial participation itself.

However, NIH-funded researchers and NIH staff recognize that the continued need for ART at the conclusion of a clinical trial is an important ethical concern, and in 2005, the NIH released guidance document NOT-OD-05-038: Guidance for Addressing the Provision of Antiretroviral Treatment for Trial Participants Following their Completion of NIH-Funded HIV Antiretroviral Treatment Trials in Developing Countries (available online at http://grants.nih.gov/grants/guide/notice-files%5CNOT-OD-05-038.html). Developed by a group of HIV researchers, bioethicists and legal experts from several NIH institutes, this document requires that all NIH-funded HIV treatment trials include a description of treatment services available to study participants at the end of the trial. The NIH recommends further dialogue to ensure continued provision of ART to trial participants following trial completion, but it is not a requirement for project approval. Thus, NOT-OD-05-038 is a procedural requirement that requires that researchers provide a statement as to whether continued treatment will be made available, and if so, through what mechanism.

Recently, Seema Shah and Christine Grady, faculty of the NIH Clinical Center Department of Bioethics, completed a study looking at how this guidance has been implemented in NIH-funded treatment studies. Looking at 18 studies conducted in 14 developing countries, Dr. Grady and Ms. Shah found that the vast majority of studies referred trial participants to existing treatment and care services, including publicly- and PEPFAR-funded treatment clinics. Some studies also mentioned external sources of funding and support, including networking with NGOs and philanthropic organizations or seeking to enroll participants in other HIV treatment trials.

6. The President's Emergency Plan for AIDS Relief (PEPFAR)

No one from the Office of the U.S. Global AIDS Coordinator (OGAC) was able to attend the consultation to talk about PEPFAR. However, many of the meeting participants had considerable experience with PEPFAR.

PEPFAR does not fund clinical research trials, but they are one of the largest funders of HIV treatment and prevention programs in Africa (12 of the 15 PEPFAR "focus countries" are African, along with two countries in the Caribbean and one in Asia). Many of the research and treatment organizations represented at the meeting were recipients of PEPFAR grants. In addition to conducting a phase III microbicide research trial funded by the MDP, for example, the Africa Centre (represented at the meeting by Ms. Hlengiwe Ndlovu) provides ART to 5,000 HIV-infected individuals across a wide catchment area by using a combination of Government of South Africa and PEPFAR funding. Similarly, using a combination of NIH, Department of Defense, and PEPFAR funds, the USMHRP (represented by Dr. Nelson Michael) has trained local staff, established palliative care and ART clinics, and provided antiretroviral treatment to 41,000 individuals in four African countries. Finally, in addition to conducting numerous HIV prevention trials in West Africa, Family Health International (represented by Dr. Lut Van Damme) is also one of the largest providers of treatment and care in Nigeria, provided with funding support from PEPFAR and USAID.

In those regions where there is direct overlap between HIV prevention trial sites and PEPFAR-funded clinics, coordination between prevention researchers and treatment sites has enabled a rapid expansion of ART programs. Establishing additional linkages between research trials and PEPFAR-funded clinics in order to ensure post-trial access to treatment and care, however, faces a number of obstacles. In some countries where

HIV prevention trials are planned or currently taking place – in Peru, for example – PEPFAR-funded treatment programs do not exist. In other countries, such as South Africa, those regions in which PEPFAR-funded clinics exist often are research-saturated regions where HIV incidence is declining; future prevention trials are more likely to be conducted, by necessity, in regions of higher HIV incidence where PEPFAR-funded programs have yet to be rolled out. What is needed, most meeting participants believed, is greater coordination between OGAC and agencies funding HIV prevention research like the NIH and the CDC, starting with an effort to map existing PEPFAR sites with current and planned HIV prevention trials.

Discussion, Wrap-Up and Next Steps

Ms. Heise led an open discussion with the following goal: to develop a process for ensuring long-term access to treatment and care for HIV prevention trial participants that seroconvert. Participants from trials and trial networks underscored that this is a critical area for the HIV prevention field, practically, ethically and politically. International donors, host country governments, and local community members are demanding that trials provide long-term care and treatment for seroconverters. There was a great deal of support for developing a common approach to addressing this challenge, and for GCM to spearhead the next steps. As was discussed over the past two days, there are several mechanisms that have or can be used to ensure long-term access to HIV treatment and care for those who seroconvert in prevention trials, including:

- Enrolling participants in other trials (e.g. seroconverter protocols or treatment trials);
- Developing active referral systems to existing programs, with improved methodologies to evaluate and assist access;
- Establishing or expanding trust funds that can be used to pay for treatment and care for participants in countries where public HIV treatment programs do not exist or are overburdened;
- Transferring responsibility and funding for care and treatment to local trial sites which are better positioned to tailor strategies to suit local needs; or
- Working with private insurance companies or brokers to provide treatment and care.

In designing a shared approach to ensure long-term access to treatment and care for participants in future HIV prevention trials, it is essential to have broad consensus within the prevention field about: 1) the nature of the treatment obligation (i.e. what treatments will be made available to seroconverting trial participants, and for how long?); 2) how to fund the provision of HIV treatment and care; 3) how any shared approach will be administered; and 4) how to establish appropriate delivery mechanisms, particularly in those countries in which existing public health infrastructure is fragmentary.

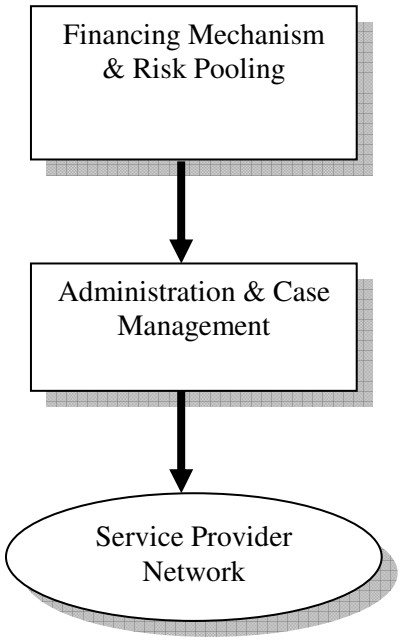
Given these constraints, meeting participants felt that the best solution to ensure long-term access to treatment and care for participants in future HIV prevention trials would be to establish a partnership with private insurance companies and treatment providers to provide a uniform care and treatment package for trial participants. Unlike the HVTN's "Seattle Fund", however, this would not be a fund of last resort. Rather, it would be a centralized fund that all prevention trial networks could contribute to, with each trial sponsor making a clear financial commitment during the trial design process. Each trial would pay a set amount per participant up front – kept relatively low through risk pooling across research networks - and the resulting fund capitalized to form an endowment used to pay for HIV-specific insurance. The corporate sector could also be asked to provide matching funds. The fund could be managed by existing insurance brokers or health delivery companies like Discovery Health, and these private brokers or companies would be responsible for administering the fund and arranging for delivery of HIV-specific treatment services.

Shortly after the main consultation, Lori Heise, Elaine McKay and Ian Sanne met in Johannesburg, South Africa, to draft the initial sketch of the centralized insurance fund. As they envision it, this fund would have three essential components: 1) a centralized funding and risk pooling arrangement; 2) centralized administration to handle billing, to identify and accredit service provider networks, and to process claims and payment; and

3) a treatment implementation program made up of accredited provider networks, laboratories and pharmacies. This structure and its constituent components are outline below, for consideration and additional refinement by the Working Group on Operationalizing Access to HIV Treatment and Care.

Suggested Structure for Partnership

to Ensure Post-Trial Access to HIV Treatment and Care



- HVTN Seattle Fund, managed by Fred Hutchinson
- NIH Foundation
- Discovery Health, South Africa

- Discovery Holdings PTY, South Africa
- Alexander Forbes, South Africa

- Provider Networks
- Trial Sites
- Calibre Clinical Consultants, Ltd., South Africa
- ICAS, South Africa

Description of Potential Private Sector Partners

Company	Role	Description
Discovery Health	Risk Pooling and Financial Management	A subsidiary of South Africa's biggest health and life insurance company, Discovery Health administers 12 medical schemes that provide private health insurance for 2.1 million beneficiaries in South Africa, the UK, and the US.
Discovery Holdings PTY	Administration and Case Management	The parent company of Discovery Health, Discovery Holdings PTY administers and provides managed care services to medical and life insurance schemes in South Africa, the UK, and the US.
Alexander Forbes	Administration and Case Management	Based in South Africa and the UK, Alexander Forbes provides a range of services, including risk and insurance programme management and consulting, insurance broking, and claims management for private companies and individuals in Europe and Africa.
Calibre Clinical Consultants, Ltd.	Care and Treatment Services	Based in South Africa, Calibre Clinical Consultant provides, either directly or via its network of service providers and partners, integrated HIV/AIDS management services for companies in 11 Eastern and Southern African countries.
ICAS	Counseling Services	ICAS is one of the world's leading providers of well-being, employee assistance programs, occupational health services, and behavioral risk management in over 18 countries worldwide, including South Africa and India.

There are still a number of challenges that must be addressed in order to operationalize this approach. First, there will need to be buy-in from most of the HIV prevention networks, requiring broad outreach to all prevention researchers and donors. In addition to advocacy among the various networks and donors, this may require action at a legislative level. There may be legislative- or policy-level barriers, for example, that preclude a donor like the NIH from contributing to a centralized insurance fund. It will also be important to reach out to policymakers, both within key donor countries as well as in those countries in which future HIV prevention trials are likely to take place. There are also a number of unanswered questions, including: 1) capacity-building challenges in the countries where the trials are currently taking place (particularly local capacity to provide laboratory tests like CD4 cell counts, viral load, and HIV drug resistance); 2) what the package would provide (e.g. a full range of treatment and support services - including psychosocial counseling, nutritional support, ancillary care, and contraception and family planning - or a more limited package of HIV-specific treatment and care; and 3) coordination with Global Fund- and PEPFAR-supported treatment programs.

Before these challenges can be addressed, however, the meeting participants felt that it was necessary to develop a draft proposal that can be presented for consideration by a broader audience. To achieve this, the following steps need to be taken:

1) Establish a working group to develop a 'straw man' proposal

A small working group, coordinated by the Global Campaign for Microbicides, will hold regular conference calls to develop a 'straw man' proposal that details the structure and function of the centralized insurance fund.

Apart from GCM staff, participants in this working group include Ian Sanne (who will look into different health care delivery mechanisms in developing countries like South Africa), Elaine McKay (who will consider private health care insurance mechanisms in developing countries like South Africa), Neeraj Mistry (who will look into corporate partnerships, as well as develop the funding model), Margaret Weckler (who will provide information on the operation of a privately-run treatment fund like the Seattle Foundation established by the HVTN), Pam Norick (who will help with legislative strategy and provide information on the needs of local research sites like those set up by IPM), and Liz McGrory (consultant to GCM).

2) Map existing policies and legislative barriers in key priority countries.

In addition to developing a tentative proposal, the working group will also look at a few priority countries like South Africa and Kenya to get sense of potential barriers, such as policies and insurance regulations.

The working group will also work with the legislative group in the United States to see if any policy barriers exist that would prevent key donors like the NIH from contributing to the treatment fund.

3) Examine donor expectations about provision of HIV treatment and care.

The working group will also explore the Gates Foundation's interest in this issue and discuss mechanisms for funding this proposal with Foundation support.

In addition, the working group will explore the role that USAID and PEPFAR may be able to play, including the question of a paired research and treatment plan, and whether the NIH Foundation may be a potential avenue of funding.

4) Seek broader input and support.

Once a draft proposal has been developed, the working group will work with meeting participants to identify mechanisms to vet the proposal with various stakeholders, including national and international policymakers, donors, activists, as well as international and site-level HIV prevention researchers.

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Participant List

The Global Campaign for Microbicides hosted the Consultation on Operationalizing Access to HIV Treatment and Care on June 19th and 20th, 2008, in the Phillips conference room of the Hotel Palomar, 2121 P Street NW, Washington, DC 20037. Thirty stakeholders – HIV prevention researchers and treatment providers, study sponsors, policymakers, treatment and prevention advocates, as well as experts in health care, financing and insurance – were invited to participate in these closed discussions. A full list of meeting attendees is included below:

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