PARTNERING FOR CARE in the HIV Prevention Trials Network

PART I. OVERALL FINDINGS

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CONTENTS

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Summary

In 2004 the Prevention Leadership Group (PLG) of the HIV Prevention Trials Network (HPTN) recommended that the Network strive to improve the standard of care that exists at HPTN sites and to document efforts, activities, and accomplishments towards this end. The PLG charged the Ethics Working Group to develop, with community input, a survey to document alliances already in place and to assess what the HPTN is doing at each site to provide or facilitate HIV-related care and, ultimately, other health-related care partnerships. The Partnering for Care project was undertaken to meet this objective.

A brief email survey was sent to Principle Investigators and study coordinators at all HPTN sites in summer 2004 (33 sites). Respondents were asked whether their sites had partnerships in place to provide care for research participants (yes or no). A second email survey was conducted between June and December, 2005. "No" responders to Survey 1 were asked to complete an abbreviated survey focusing on health care referral options and regulatory requirements or policies regarding provision of care. Survey 1 "Yes" responders were asked the same questions plus others describing their partnerships. Based on responses received and in consultation with investigators responding to Survey 2, seven sites were selected for in-depth case study analysis:

- UNC Project, Tidziwe Centre, Lilongwe, Malawi
- MU-JHU Research House, Kampala, Uganda
- UZ-UCSF Collaborative Research Programme, Harare, Zimbabwe
- MRC, Durban, South Africa
- NARI, Pune, India
- FIOCRUZ, Rio de Janeiro, Brazil
- University of Pennsylvania, Philadelphia, PA, USA

From March through May 2006, FHI social scientists working together with local HPTN collaborators at the seven selected sites visited study clinics, referral sites, and the communities in which research participants lived and worked. Through observations and conversations with study site staff, referral site staff, and community advisory board (CAB) members, they 1) chronicled the efforts of each HPTN site in developing referral systems with healthcare partners, 2) explored how partnerships between the study and referral sites are maintained, and 3) considered the strengths and challenges of developing and maintaining healthcare referral partnerships that benefit research participants.

There are essentially two ways that researchers can meet the health needs of research participants: through direct provision of care or through referrals to hospitals, clinics, or other organizations. All HPTN research includes some combination of direct care and referrals. Several key factors were identified through the case studies that contribute to the balance between direct care and

health care referrals at a research site, as well as the overall quality of the health care that could be made available to research participants.

- *Public health system constraints* were a pervasive influence at all HPTN sites. The syndemic nature of HIV means that people who participate in HIV prevention research often have multiple treatment, care, and service needs. At all sites, clinics that served the neediest members of society had long lines, waiting lists, and restrictive rules about who can access what care and where. Attempts to improve health care for research participants without consideration of the larger health system constraints could have unintended negative consequences.

- *Local community values, attitudes and priorities* were a similarly pervasive influence on HPTN site responses. Since the beginning of the epidemic, HIV has highlighted the importance of cultural sensitivity and respect for community in the way public health responds. This is no less true for the context of HIV prevention research than for the provision of prevention services, treatment, and care more broadly.

- A *public health attitude* on the part of research leadership and staff was important for fostering pro-active efforts to address health care challenges. Elements of this attitude included recognition that HIV prevention research is conducted in a larger context of health care delivery and public health policy, that the research team may identify health care needs that exceed local response capacity, and that researchers must therefore be prepared to respond to health needs that go beyond what is necessary to meet scientific goals. A public health attitude also meant that research teams understood the limits of what they could accomplish on their own and hence the importance of partnering with other public health stakeholders as they sought to meet health care needs identified in the course of research.

- *Referral follow-up* procedures were important for identifying barriers to care, including lack of transportation, program enrollment fees or other costs, long queues, understaffing, and drug stock-outs. Once barriers were identified, steps could be taken to address them. Considerable effort and resources were often needed to do such follow-up effectively and to address the problems identified.

- *Physical proximity* of the research site to the referral clinics, hospitals, and service providers made it easier to address referral challenges as well as to build mutually beneficial partnerships with referral sites.

- The type and extent of *capacity building* efforts reflected the range of local needs as well as the type of research, the nature of the research organization, and the resources available. At times, both community

stakeholders and research staff needed to work through false assumptions and misunderstandings about each other's strengths and weaknesses before effective capacity building plans could be put in place.

- Those research organizations that conducted studies where *people living with HIV/AIDS are enrolled in research*, such as PMTCT trials, tended to have in-house capacity to provide treatment and care directly to participants. Conversely, those organizations that enrolled primarily or only uninfected persons tended to have much more limited clinical capacity and were therefore more reliant on meeting participant needs through referrals.

- *Community engagement* efforts undertaken by the research team enriched and deepened their understanding of the lives of research participants. They gained a clearer sense of the role of their research in assuring the conditions of health for the community as a whole. They also became aware of opportunities where they could substantively contribute to improving those conditions.

- *Partnership-building* efforts undertaken by the research team were crucial to facilitating health care referrals. Some partnerships grew organically from personal contacts among research staff and word of mouth among community-based professionals working in similar areas. Others emerged as specific needs were identified among research participants or related research groups such as CABs. Sometimes a fortuitous event brought people together to fill a need.

The detailed case studies in **Part II** of this report demonstrate the full complexity of the challenges faced by HPTN sites; neither problems nor solutions are simple. Ultimately each site must decide how far down the list of health needs the research team can go without depleting the time, resources, and energy needed to do the research. The dedication, creativity, and initiative of the research teams and community members is a source of inspiration in this regard. Hopefully, this report will help to generate additional resources to support their efforts as well as to address the broader health care access and delivery problems that make such efforts necessary.

PART I. OVERALL FINDINGS

SECTION 1. INTRODUCTION

HIV prevention trials identify a wide range of health needs among study participants, including family planning needs, pregnancy, sexually transmitted infections (STIs), and HIV infection. Some of these needs, such as treatment for bacterial STIs, can be easily addressed at research sites. In other cases, participants must be referred for care.

In the countries hardest hit by HIV, where most HIV prevention trials take place, participants may be referred to a poor and overburdened health infrastructure that is not equipped to address their needs. Despite efforts to expand global access to antiretroviral treatment for HIV, for example, as of December 2005 at least 80% of those in clinical need of the drugs failed to receive them.[1]

Many health needs, and particularly those of people living with HIV, extend well beyond the life of a clinical trial. Sustainability and continuity of care are best ensured if participants can be linked to appropriate health care in their local communities. Successful linkage requires establishing partnerships with local clinics and organizations, verifying that needed care is available, and ensuring that those who are referred actually receive appropriate care.

Direct provision of health care to study participants can be a viable option, especially when the need is acute rather than chronic and the per-participant cost associated with a specific health need is small. However, even for acute needs the cumulative costs for thousands of participants across dozens of trials can quickly become prohibitive. There may be hidden societal costs as well. Direct care provision requires the hiring and training of skilled medical personnel, often in settings where severe staffing shortages exist in community health facilities. Increasing the capacity of the research staff to provide medical care tends to draw off critically needed staff from the public health sector in such situations.

Consensus now exists that HIV treatment arrangements need to be defined during protocol design[2], but many researchers and other stakeholders are struggling to identify strategies to meet participants' needs without undermining local health systems, jeopardizing the conduct of trials, or detracting from the goal of identifying critically needed new HIV prevention technologies. The experiences of established research sites in this regard are a valuable but largely untapped resource. The HIV Prevention Trials Network (HPTN) Partnering for Care Project was undertaken to document this experience. We describe the variety of healthcare partnerships in the Network's research sites and strategies developed to meet the health needs of research participants under variable conditions.

[1] UNAIDS. 2006 Report on the Global AIDS Epidemic. May 2006. Geneva: UNAIDS.
[2] UNAIDS. Creating effective partnerships for HIV prevention trials: report of a UNAIDS Consultation, Geneva 20-21 June 2005. *AIDS* 2006;20:W1-W11.

SECTION 2. METHODS

This study was reviewed by Family Health International's institutional review board and determined to be exempt under 45 CFR 46.

A brief email survey was sent to Principle Investigators and study coordinators at all HPTN sites in summer 2004 (33 sites). Respondents were asked whether their sites had partnerships in place to provide care for research participants (yes or no) and who to contact for further information about such partnerships. Twenty-five responses were received, providing information on 22 research sites. Of these, 20 sites noted one or more partnerships. No survey was returned for 11 sites.

A second email survey was conducted between June and December, 2005. "No" responders to Survey 1 were asked to complete an abbreviated survey focusing on health care referral options and regulatory requirements or policies regarding provision of care. Survey 1 "Yes" responders were asked the same questions plus others describing their partnerships.

Survey 2 was sent to staff at eligible sites, defined as those with an active or pending HPTN protocol between May 2004 and May 2005. With one exception, sites that did not complete Survey 1 were excluded from Survey 2. Follow-up surveys were sent on June 30 to investigators and study coordinators at 17 sites. Follow-up phone calls and emails were conducted in order to encourage survey completion. During follow-up, one site became ineligible. As of December 2005, completed surveys were obtained from each of the 16 remaining eligible research sites.

Four criteria were established for selecting a subset of sites for in-depth case study analysis:

- Unique aspects regarding referral systems, referral follow-up, and capacity building
- Geographic diversity with at least one site from Africa, Asia, Latin America, and the U.S.
- Adequacy of detail provided in the survey and in follow-up emails/phone calls.
- Willingness on the part of the site research team to be a case study.

Based on these criteria and in consultation with investigators responding to Survey 2, seven case study sites were selected:

- UNC Project, Tidziwe Centre, Lilongwe, Malawi
- MU-JHU Research House, Kampala, Uganda
- UZ-UCSF Collaborative Research Programme, Harare, Zimbabwe

- MRC, Durban, South Africa
- NARI, Pune, India
- FIOCRUZ, Rio de Janeiro, Brazil
- University of Pennsylvania, Philadelphia, PA, USA

Between March and May 2006, social science researchers from FHI, working together with local HPTN collaborators at the seven selected sites, visited study clinics, referral sites, and the communities in which research participants live and work. Through observations and conversations with study site staff, referral site staff, and community advisory board (CAB) members, the FHI team chronicled the efforts of each HPTN site in developing referral systems with healthcare partners, explored how partnerships between the study and referral sites are maintained, and described the strengths and challenges of developing and maintaining healthcare partnerships to benefit research participants. A minimum of 5 days was spent at each site, and additional information was sought as needed through follow-up phone calls and emails.

Table 1. Survey 2 respondents.

Research Site	Place of Central Coordination	Performance sites
Kampala, Uganda	MU/JHU Research House, Mulago Hospital/Makerere University	MU/JHU Research House, Mulago Hospital
Chiang Mai, Thailand	Research Institute for Health Sciences (RIHES)	Research Institute for Health Sciences (RIHES)
Rio de Janeiro, Brasil	FIOCRUZ	Fiocruz; Nova Iguacu General Hospital; Servidores do Estado Hospital
Porto Alegre, Brasil	FIOCRUZ	Hospital Nossa Senhora da Conceicao
Lusaka, Zambia	CIDRZ	George, Matero, Kamwala, and Chilenje Clinics
Hlabisa, South Africa	Medical Research Council	Medical Research Council
Durban, South Africa	Medical Reseach Council	RK Khan Hospital, Chatsworth
Philadelphia, PA, USA	University of Pennsylvania HIV Prevention Research Unit	Market St. Office and RAP office
Dar es Salaam, Tanzania	Harvard-MUCHS Collaborative Research Projects Building	Muhimbili Medical Center (Makuti clinic) and Temeke District Hospital
Lilongwe, Malawi	UNC Project	Kamuzu Central Hospital
Pune, India	NARI	multiple performance sites
Chennai, India	YRGCare	YRGCare
Miraflores- Lima, Peru	Asociacion Civil Impacta Salud y Educacion	Asociacion Civil Impacta Salud y Educacion
Pucallpa, Peru	Asociacion Civil Impacta Salud y Educacion	Asociacion Civil Cayetano heredia (Centro Medico Cayetano)
Blantyre, Malawi	JH/Malawi COM Project	Queen Elizabeth Central Hospital
Zimbabwe	UZ/UCSF Collaborative Research Programme, Harare	7 performance sites

SECTION 3. EMAIL SURVEY RESULTS

Table 2 summarizes the types of policies and requirements in place at the 16 sites responding to the survey as of December 2005. Considerable variability existed across the sites in this regard.

Table 2. Policies and other requirements regarding provision of health care for research participants reported by Survey 2 respondents (n=16 sites).

Type of Policy or Requirement	Number of Sites Reporting Policy or Requirement	Examples of Policies or Requirements
Regulatory requirements	9	Researchers required to provide the government standard of care to research participants (Chiang Mai, Porto Alegre, Rio de Janeiro, Lilongwe, Blantyre, Dar es Salaam) Researchers are required to include information about care for research participants in the informed consent (Chiang Mai, Rio de Janeiro) Informed consent must include information on types of indemnity to cover possible injury resulting from the research (Rio de Janeiro)
IRB/EC policies	12	Care and treatment of participants with HIV required (Dar es Salaam) Researchers must provide information about the availability of referrals for participants who are screened out, seroconverters, and participants who become pregnant during a trial (Durban) Researchers encouraged to provide health care as part of their studies (Lusaka) Issues related to care and support are discussed with the lead investigators of each protocol reviewed (Pune)

Type of Policy or Requirement	Number of Sites Reporting Policy or Requirement	Examples of Policies or Requirements
Institutional and other policies	9	Provide support for care and treatment not available through the research site via networking and partnering with other government facilities (Pune) SOPs for clinical management of study participants (Pune) Institutional policies developed in alignment with regulatory and/or IRB/EC policies (Rio de Janeiro, Blantyre, Dar es Salaam) Formal Care Plan developed for research participants (Durban)

Similar variability existed with regard to partnerships, collaborations, agreements, and other efforts aimed at facilitating the ability of HPTN research participants to access health care. At the 14 sites reporting partnerships, most were made in order to be able to refer participants for care that the research site did not or could not provide. A few partnerships were made for technical or laboratory support. Some sites also reported the development of partnerships in order to recruit participants at the partner's site.

Most of the partnerships stemmed from long-standing relationships between the research site and other organizations. For example, the partnership between the Research Institute for Health Sciences (RIHES) and Chiang Mai University Hospital has existed since 1978. The Malawi College of Medicine and Queen Elizabeth Central Hospital have been in partnership since 1989. In 2001, CIDRZ in Lusaka made an arrangement with the district health board to allow all of their research projects to be conducted within the district health clinics.

Personal contacts between research staff and providers in the community also were important for partnership development. For example, the Manager of Research Projects in Philadelphia used her connections in the nursing field to find contacts within referral sites where participants could be sent for care.

A few sites described a formal process of establishing partnerships when the need arose. For example in Hlabisa and Pune, an organization, clinic or hospital would be identified as a potential partner and then a study staff member would go to the organization to make a presentation and ask for a formal partnership to be formed. In Pune, memos of understanding were then signed.

In a few sites, a staff member was hired specifically to build and sustain partnerships. For example in Durban and Hlabisa, a Community Liaison Officer was hired to facilitate the partnerships and visit referral organizations to see if the care that was agreed upon was being provided to participants. In Pune, the site employs community educators, health outreach workers, community coordinators, and health visitors to work in the community and with the NGOs that are partners with NARI. More commonly, however, the building and sustaining of partnerships is incorporated into existing research staff work. In Lilongwe, the UNC Project Country Director is responsible for maintaining the partnership with Kamuzu Central Hospital, and UNC clinical staff contribute 20% of their effort to KCH patient care. In Chiang Mai, most staff provide time and effort in the partner hospital as needed. In Blantyre, clinic managers, the PI, and the study coordinators are responsible for building and maintaining partnerships. In Pune, the PI and the community programs supervisor contribute substantial time to building and sustaining the partnerships with local NGOs.

Nine of the 14 sites reporting partnerships stated that they contributed resources to their partner organizations including staff time (n=8), infrastructure or supplies (6), training (5), and funding (2). The amount of staff time provided varied from 20% (as in Lilongwe) to occasional help. Examples of infrastructure and supplies provided included renovations to clinics (Lusaka, Blantyre), provision of lab equipment (Lusaka), supplying drugs when needed (Kampala), installing a generator (Lusaka), providing a garden hose (Harare), and printing or copying materials for partners when needed (Durban). Examples of training topics included ethics, VCT, study procedures, and bioharzard waste disposal.

Two sites reported providing funding to partner organizations. In Lusaka, funding is provided for pap readings and Western blot kit readings at partner organizations. In Pune, NARI provides funds for services provided by the hospitals they refer participants to and to the National AIDS Coordinating Organization which provides ART care. NARI also provides funding in the form of honorariums for NGO staff for NGO partners who work with them, as well as monetary support for meetings and transportation to the same.

Thirteen of the 16 responding sites reported that they use referral sites. The number of referral sites reported by research organizations ranged from 1 to 7, with most referral sites also listed as partner organizations. Few problems were reported with regard to referrals; those reported included waiting lists and overcrowding (3 sites), lack of required medications (3 sites), unaccompanied participants getting lost in the system or not showing up (3 sites), and difficulty in locating clinic records (1 site).

Several sites have a convenient situation with regard to referrals as they are located within a complex, center, or compound that houses multiple health care facilities where participants are referred. Others reported at least one referral site

within walking distance, and several have partnerships with clinics throughout the cities where they are located which helps participants access care close to where they live.

A total of 40 referral sites were described by the 16 HPTN sites responding to Survey 2. Of these, 23 were open during business hours 4 to 5 days a week; 8 were open 24 hours a day, 7 days a week; and 4 had emergency and in-patient care available at any time combined with outpatient care during business hours 4 to 5 days a week. Of sites without 24/7 accessibility, 10 had weekend and/or evening hours at least one day a week.

Staff at all 13 sites using referrals reported they did some form of follow-up. Two sites reported that staff accompany participants to a referral site. A number of sites reported they follow-up with participants at their next study visit to find out if they went to a referral and what their experience was like. Some sites noted they try to follow up with screened-out participants, either with participants directly or by asking referral sites if participants attended visits. Two sites reported that follow-up is facilitated as a result of research staff who work in the referral site as well (Lilongwe and Blantryre); close proximity of the research and care facilities also facilitated follow-up. Two sites reported using referral slips to track follow-up but with mixed success.

For virtually all referral sites, someone from the research staff had made a visit in the six months preceding the survey. Six sites reported at least one CAB member who was affiliated with a referral site.

SECTION 4. CASE STUDY HIGHLIGHTS

HIV prevention research takes place within the context of local communities. Those communities, in turn, exist within a larger social, political, and economic context that can constrain or enrich health care options (Figure 1). The HPTN sites who participated as case examples in this study represent a broad range of HIV prevention research contexts. These case studies demonstrate the full complexity of the situation; neither problems nor solutions are simple. Ultimately each site must decide how far down the list of health needs the research team can go without depleting the time, resources, and energy needed to do the research. The case studies often exemplify what Weijer and LeBlanc[3] have called "moral negotiation," that is, a process where increasingly empowered local communities and host countries negotiate with researchers and sponsors to achieve meaningful and substantive benefits from biomedical research.

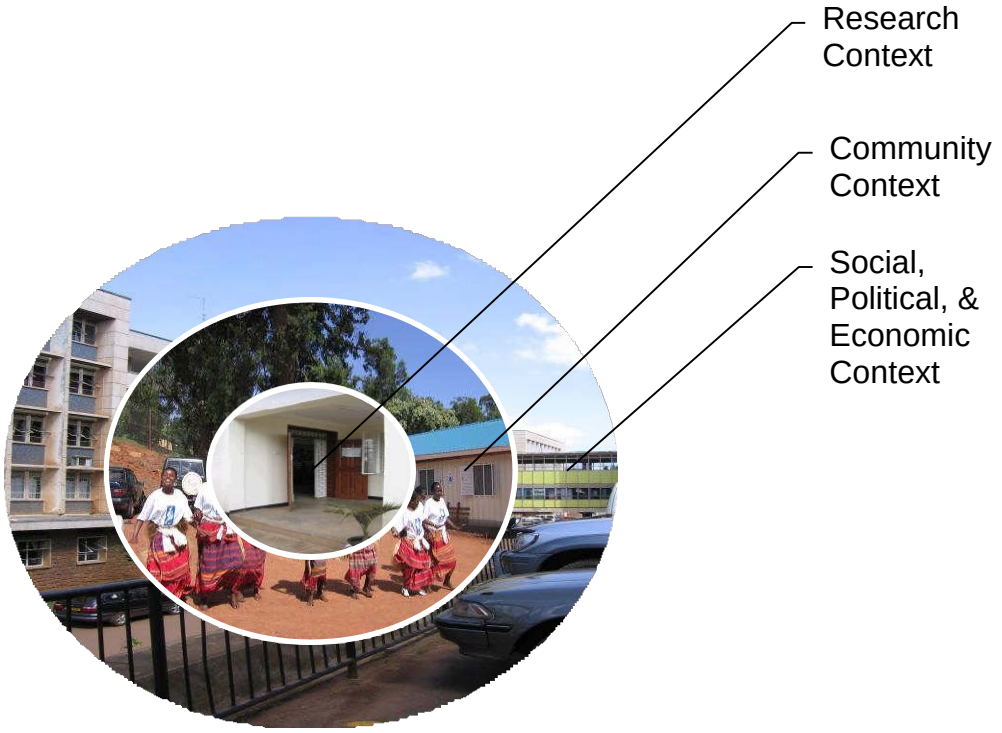


Figure 1. HIV prevention research influences and is influenced by the larger context within which it takes place.

[3] Weijer C, LeBlanc G. The Balm of Gilead: Is the provision of treatment to those who seroconvert in HIV prevention trials a matter of moral obligation or moral negotiation? *Journal of Law, Medicine &Ethics*. 2006;Winter(in press)

There are essentially two ways that researchers can meet the health needs of research participants: through direct provision of care or through referrals to hospitals, clinics, or other organizations. All HPTN research includes some combination of direct care and referrals. For example, in a PMTCT trial where the research clinicians may have advanced training in a broad range of PLWHA health needs, they will nonetheless make referrals for things like cervical cancer or major trauma requiring surgery. In a microbicide trial enrolling uninfected and largely healthy women, direct care is likely to be limited to a set of easily treated ailments such as STIs and malaria.

While referrals are a necessary option, they may be more or less effective. Even in well-resourced settings such as Philadelphia, the people who enroll in HIV prevention research may confront multiple barriers to accessing those resources. In severely impoverished countries such as Malawi, Zimbabwe, and Uganda referral barriers are often combined with an overwhelming lack of health care resources. The case studies explored how each site sought to improve the effectiveness of referrals given both strengths and weaknesses in the local systems.

Figure 2 summarizes the key factors and relationships that emerged from a cross-site analysis of the case studies. Public health system constraints and local community values, attitudes and priorities represent pervasive influences on the identified factors and relationships. From the case studies, it is clear that many factors contribute to the balance between direct care and health care referrals at a research site including:

- A *public health attitude* on the part of research leadership and staff at the site
- *Referral follow-up* procedures in place at the research site
- *Physical proximity* of the research site to the referral site
- *Capacity-building* efforts on the part of the research site that benefit the referral sites
- The implementation of studies where *PLWHA are enrolled in research*
- *Community engagement* efforts undertaken by the research team
- *Partnership-building* efforts undertaken by the research team to facilitate health care referrals

Each of these factors is described in detail below, with illustrative examples drawn from the case studies. The factors are synergistic, that is, they are mutually reinforcing in their effects. In Section 5 several vignettes are presented to illustrate some of this synergy at work. Ultimately, however, the full complexity of the partnering processes can only be understood via rich descriptions of the cases themselves. To this end, Part II of this report includes detailed reports of the seven case studies.

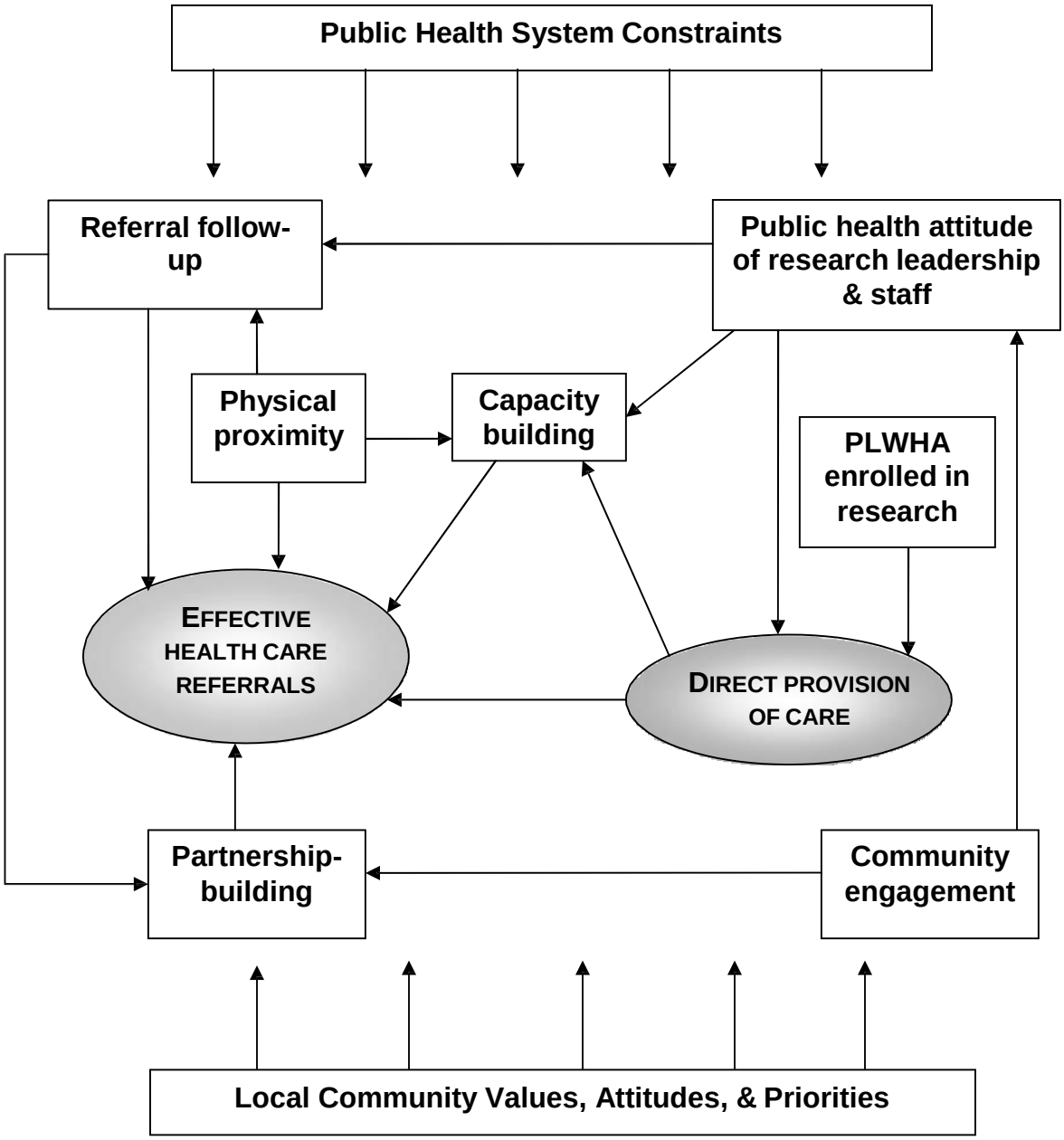


Figure 2. Factors that contribute to improved health care for research participants.

PERVASIVE INFLUENCE: Public Health System Constraints

The syndemic nature of HIV means that people who participate in HIV prevention research often have multiple treatment, care, and service needs: STIs, unintended pregnancies, substance abuse, domestic violence, TB, malaria, cervical cancer, and even hunger and malnutrition afflict HPTN research participants. When care is sought, long lines and waiting lists are the norm. Stock-outs of even the most basic medicines are common.

Nurses at Sassoon Hospital in Pune (H. Burke, 2006).

Given this reality, one of the more valued benefits of research participation is the ability to "jump the queue." This benefit does not translate as "cutting in line." It is most likely to occur when the research team includes medical staff who can conduct initial screenings and evaluations that are then forwarded to the referral clinic with the research participant. The medical information saves time and money at the clinic, which can then be devoted to other clients in the queue who need screening and evaluation prior to accessing treatment. The factors that come together to make it possible to jump the queue can be complex, especially in contexts where health care systems are severely strained as in Malawi, Zimbabwe, and Uganda. The advantage gained from research-related screenings and evaluations may be lost if other barriers are allowed to intervene, such as lack of transportation or stigma.

The availability of HIV treatment, care, and services varied widely across the sites, and challenges existed in all settings. The complexity of HIV-related care, the life-long need for care and treatment, and the fact that spouses and children of research participants are often infected meant that health care needs extended well beyond what most research organizations were equipped to handle. Where available, funding by PEPFAR, the Global Fund, and others for meeting HIV-related care needs is counterbalanced by the uncertainties of the same. Sustainability of HIV-related care is probably the most difficult challenge faced by all sites. At many African HPTN sites, PEPFAR funding is scheduled to end in 2008. Nor is this an issue solely for the developing world. It is a continual challenge to provide care and services to uninsured and underinsured patients in the US, as is the case with a number of trial participants in Philadelphia. In fact, some providers in this area refer patients to clinical trials as a means of gaining free HIV/AIDS care and treatment as well as other types of medical care.

At all sites, clinics that served the neediest members of society had long lines, waiting lists, and restrictive rules about who can access what care and where. Circumstances sometimes changed for the worse rather than improving. Zimbabwe's public health structure was once the aspiration of many other African countries. However, years of political mismanagement have led to severe overall economic shortages across all sectors of society. The shortages have directly impacted the health system in terms of human and material resources. Many health professionals have left Zimbabwe for positions in other African countries and Europe. Currently there is a two to three month wait for screening for potential ARV access, and another one to two month wait period for initiation of ARVs. Hopefully the availability of Global Fund grant money to supply ARVs to 25,000 patients in January 2007 will help somewhat alleviate the strain on the existing government ARV system.

FACTOR: Public Health Attitude

".. why are we doing this? Is it solely for the research so we can write papers and say this is effective? Or are we also looking at things, on a more micro level, and saying these are actually human beings, and how can I benefit them?" (MU-JHU study coordinator)

One of the most important factors that emerged from the case studies entails a *public health attitude* on the part of the research team. Elements of this attitude include recognition that HIV prevention research is conducted in a larger context of health care delivery and public health policy, and that the research team may identify health care needs that exceed local response capacity. Therefore researchers must be prepared to respond to health needs that go beyond what is necessary to meet scientific goals. A public health attitude also means that research teams understand the limits of what they can accomplish on their own and hence the importance of partnering with other public health stakeholders as they seek to meet health care needs identified in the course of research.

Staff attitude is important in overcoming obstacles, creating solutions for difficult problems, and building effective partnerships with providers and service organizations in the community. Often, a "can-do" attitude grew from a stated sense of moral responsibility for the well-being of research participants that in turn created a willingness to invest personally in building relationships, identifying resources, and creating solutions.

At MU-JHU in Kampala, Uganda staff took direct action to make sure participants' needs were met: they generated resources to provide care directly to participants by writing grants for this purpose, they provided resources to partner organizations where participants went for care, and they volunteered personal time and money. The site also has committed volunteers from the

community who have stepped forward to help meet the many pressing needs of participants.

The UNC Project in Lilongwe, Malawi institutionalized a volunteer ethic: medical staff each devoted one day a week in the hospital or clinics. The collaborative partnership between UNC and Kamuzu Central Hospital involved other significant contributions on the part of UNC, including lab use, medical and office supplies, pharmaceuticals, facilities, funding, and technical support.

In Philadelphia, partner organizations and the HIV Prevention Research Unit staff have developed a foundation of mutual trust and respect. This trust stems from the long-standing relationships and personal connections between the Center for Studies of Addiction and their partner organizations, and from the fact that both shared a common philosophy and commitment to patients and participants. The partners and researchers saw themselves as on the same team.

A nurse and two patients in the waiting area at the VCT/ARV clinic at RK Khan Hospital in Durban (K. McLoughlin, 2006).

At the Chatsworth research site in Durban the research team were sensitive to not only the referral needs of women being screened for microbicide trials but also the health care system within which those referrals must function. Free referrals for HIV-related care are only available in a woman's home community, and some women express concerns about confidentiality and stigma. To help ease the referral process the team instituted two extra counseling sessions and a follow-up phone call if desired for women identified as HIV+ during screening. In parallel with such transitional support from research setting to community health setting, the Chatsworth team reached out to local partners to learn how site resources and staff expertise could be used as a resource for local capacity building.

As stated by one researcher at UZ-UCSF in Harare, the "Zimbabwe [health] system is there, water tight on paper, but with so many potential holes." The success of the Harare HPTN research site in providing an elevated standard of care for participants included a committed research team who took responsibility to cover the 'holes' with research resources and through collaboration with other organizations who collectively addressed HIV prevention and care for the population.

In Pune, the NARI staff strove to educate everyone in the community about HIV/AIDS and be a resource to their community because they felt a moral responsibility to help people. The partners had good rapport with one another and are "not working for themselves or NARI, but for the patient." NARI and its partners shared a common goal "to help clients only" and felt that it was their responsibility to help their community and people with HIV.

The relationship between the research sites in Rio de Janeiro and the impoverished slums they neighbor was based on a shared appreciation and respect. As one of the Rio Principle Investigators expressed it, "we are only involved in research projects that we believe in [with both] heart and head." The researchers and their teams believed that ethically they must help patients deal with their "life demands and thus improve their adherence to the study demands." This attitude reached beyond a sense of responsibility for study participants to the surrounding slums. For example, at Fiocruz they helped the neighboring *favela* to establish a community association, and in turn hired the association for maintenance at the institute, i.e., gardens and housekeeping. The Fiocruz campus included an adult education school where neighboring residents earn secondary equivalence degrees or take preparatory technical courses.

In summary, though the specifics vary, the research teams embody the mission of public health by collectively seeking through their partnerships to create the conditions in which study participants and others in the community can be healthy.

FACTOR: PLWHA Enrolment in Research

Not surprisingly, those research organizations that conducted studies enrolling PLWHA, such as PMTCT trials, tended to have in-house capacity to provide treatment and care directly to participants. Conversely, those organizations that enrolled primarily or only uninfected persons tended to have much more limited clinical capacity and were therefore more reliant on meeting participant needs through referrals. This factor, in turn, affected the type of capacity building that a research organization could do. Obviously, if the research staff included several clinicians who were highly trained in HIV treatment and care, they could potentially transfer those skills and even staff time to help treat others in the community. They sometimes were also able to provide drugs, laboratory tests, and supplies such as gloves. The

Young Positives Group in Kampala (K. McLoughlin, 2006).

organizations employing clinicians with specialized skills were also in a position to apply for programmatic treatment funding, either on their own or in partnership with other organizations in the community. MU-JHU in Kampala and UNC Project in Lilongwe are good examples of this type of capacity building.

As previously noted, however, there is also a risk that research sites that provide substantial health care directly to participants will draw staff away from already-stressed health care facilities, thus inadvertently undermining local capacity. Here again, a public health attitude can go a long way toward minimizing unintended negative consequences. For example, the UNC Project in Lilongwe has met with the Ministry of Health and developed strategies to ensure their hiring practices do not exacerbate the effects of an on-going "brain drain" of medical personnel from Malawi.

FACTOR: Capacity Building

Capacity building as a strategy for meeting research participant health needs requires willingness on the part of research and community stakeholders to engage in a long-term mutual learning process. Stakeholders tended to view researchers as having a wealth of resources---which is often true, relative to the resources otherwise available to care and service organizations. Researchers, however, were keenly aware that the funding they received for research had strict rules governing how it could be used. They also knew that they needed to meet the same standards established for wealthy nations in the implementation of research protocols funded by those nations; if not, the research would be shut down and resources withdrawn. Thus the relative "wealth" of research funding was subject to restrictions and stringent accountability.

The case studies highlighted the role of open dialog, creativity, and willingness to seek solutions despite obstacles to capacity building. The type and extent of capacity building efforts reflected the range of local needs as well as the type of research, the nature of the research organization, and the resources available. At times, both community stakeholders and research staff needed to work through false assumptions and misunderstandings about each other's strengths and weaknesses. For example, efforts by the Durban MRC to develop partnerships with community stakeholders in Chatsworth have required an on-going dialog about community needs as well as MRC funding realities.

The Fiocruz research team in Rio recognized these realities but also viewed clinical research funding as a mechanism to enhance the existing health care system. For example, participants in one HPTN study were referred from local government-funded HIV voluntary counseling and testing (VCT) centers. Using study funds, the research site developed an enhanced lab capacity that enabled them to offer affiliated VCT centers quick confirmatory HIV testing results. As a result, patients received their HIV results from the VCT locations in about two weeks compared to the previous 3-4 month wait period. The use of research

funds for this purpose was justified because the research sites benefited from the identification of potential participants for the study protocol.

FACTOR: Physical Proximity

Not surprisingly, research sites in close proximity to clinics, hospitals, and service providers were generally better able to address referral challenges. When research participants were referred to a clinic down the hall from the research site or in a building on the same grounds, it reduced the impact of barriers such as poor transportation and time spent traveling. It also made it easier for study staff to follow up on referrals, either by accompanying participants or by subsequently meeting with health care staff. At sites like Lilongwe, Kampala, and Rio that are situated either in hospitals or on the same campus, medical research staff are able to follow up directly in the care of participants who are admitted to their partner hospitals. The Durban study clinics in Chatsworth are on hospital grounds and steps away from the VCT/ARV clinic.

Physical proximity also facilitated capacity building. Researcher teams were more likely to know what kinds of resources their partners needed, and therefore provide support on an ad hoc basis. **Vignette 3** below provides an example from the UNC Project in Lilongwe.

FACTOR: Referral Follow-up

The implementation of formal procedures to follow up on referrals emerged as an important strategy at all of the sites to ensure that health care needs were being met. Referral follow-up was important for identifying barriers to care, including lack of transportation, program enrollment fees or other costs, long queues, understaffing, and drug stock-outs. Once barriers were identified, steps could be taken to address them. For example, the research team may be able to provide transportation directly to the site, provide medical documentation that will reduce referral site burdens, maintain basic medicines in the research pharmacy, or generate funding to cover program fees. Sometimes it just takes the persistence of counselors to get participants to go for follow-up. For example, in Philadelphia a counselor learned that one participant had stopped attending her HIV support group despite clearly needing the support. The counselor continued to encourage her in person and on the phone and eventually succeeded in getting her to attend again.

As with everything else, effective referral follow-up sometimes required considerable effort and resources on the part of researchers. At the same time, procedures that proved burdensome for research participants or for the referral site were potential obstacles to effective follow-up. Developing an effective strategy generally required someone from the research team making in-person visits to the referral site to learn what happens when a client enters the system, and then exploring options for documentation and follow-up that would place a

minimal burden on the referral site, the research team, and the participant. **Vignette 4** below describes some of the challenges as well as strategies developed to address them in Lilongwe.

Vignette 5 describes a standard operations procedure (SOP) developed by the UZ-UCSF research team in Harare, working closely with the community advisory board. In response to the CAB concerns and the current needs at the UZ/UCSF research site, the counseling team proposed a SOP that specifically addresses the referral needs of HIV positive screened out clients and seroconverters.

FACTOR: Community Engagement

Within public health, community engagement has been defined as "the process of working collaboratively with and through groups of people affiliated by geographic proximity, special interest, or similar situations to address issues affecting the well-being of those people."[4] As such, it refers to efforts made by public health practitioners to engage community stakeholders in their work, thereby building a foundation for collaboration and partnership.

Neighborhood surrounding one of the Philadelphia HPTN research clinics (K. McLoughlin, 2006).

As members of the research team interacted with community members, they enriched and deepened their understanding of the lives of research participants. They gained a clearer sense of the role of their research in assuring the conditions of health for the community as a whole. They also became aware of opportunities where they could substantively contribute to improving those conditions.

The community engagement process can be facilitated in a number of ways. Formative research including qualitative assessments such as focus groups and in-depth interviews and quantitative surveys can be used to identify the diversity of stakeholder groups and the range of perspectives about HIV prevention broadly and research specifically. Community advisory boards (CABs) provide a mechanism for on-going engagement and collaboration with community stakeholders. For example, the Philadelphia CAB helped to create a series of videos to educate the public on HIV vaccine research. Information, education, and communication (IEC) strategies can be developed to foster not only dissemination and sensitization about research but to ensure that researchers are informed about and engaged with communities in a substantive way.

[4] CDC/ATSDR Committee on Community Engagement. *Principles of Community Engagement.* Centers for Disease Control and Prevention, Public Health Practice Program Office, Atlanta, GA, 1997.

Vignette 2 below describes the process used by NARI to engage community in Pune, which included many of these strategies.

FACTOR: Partnership Building

The process of seeking out partners among health care institutions and organizations is an obvious step in improving referrals. Some partnerships grew organically from personal contacts among research staff and word of mouth among community-based professionals working in similar areas. Others emerged as specific needs were identified among research participants or related research groups such as CABs. Sometimes a fortuitous event brought people together to fill a need (see **Vignette 1** below).

Counselor at NARI community office in Pune, with community map (H. Burke, 2006).

Partnership-building is also an outcome of effective community engagement. For example, in 2001-2002 NARI began identifying NGOs to partner with by compiling a list of the different NGOs working in health and HIV/AIDS in Pune. During a one day meeting with NGOs, NARI provided information about their research and determined which NGOs were willing to help with research. According to the Principal Investigator in Pune, "NARI would have to bring service agenda to their agenda" for the partnership to work. That is, NARI needed to show a willingness to provide services to the community as well as engage in research. To this end, NARI started making Voluntary Counseling and Testing (VCT) centers accessible in the community. They also started providing counseling to patients, PMCT, and treatment for STDs.

PERVASIVE INFLUENCE: Local Community Values, Attitudes and Priorities

Since the beginning of the epidemic, HIV has highlighted the importance of cultural sensitivity and respect for community in the way public health responds. This is no less true for the context of HIV prevention research than for the provision of prevention services, treatment, and care more broadly. One example illustrates how unique historical, cultural, and political factors come together to influence the context of research in a given community.

HIV+ support group at Servidores Hospital in Rio (P. Alleman, 2006).

In the early 1980s HIV emerged in Brazil alongside political uprisings against dictatorship. Solidarity of the people for the freedom to meet and express themselves supported the emergence of voices from the communities most impacted by HIV. Alongside emerging non-governmental organizations and a committed professional community, these voices were heard by the government. As a result of this history, HIV prevention research in Rio exists in a context of successful activism and community empowerment. The HPTN Rio site has approached the issue of establishing a standard of care for their participants based on the belief of Brazilian AIDS activist Herbert de Souza ("Betinho") that, “AIDS has to be viewed as a social issue and not an individual problem.” There is a strong commitment within the Rio clinical sites to have teams that are interdisciplinary, thus available for on-site management, screening, and provision of care for participants. The end result---an array of advanced counseling and psychological management---is an important supplement to the government-supported treatment access program.

SECTION 5. VIGNETTES: PARTNERSHIP IN PRACTICE

The following vignettes are examples of how specific partnerships and referral procedures evolved at several of the sites participating as case studies. They were selected to illustrate the creativity and synergy that are hallmarks of success. Much richer detail is contained in the case studies themselves in **PART II** of this report.

Vignette 1: MU-JHU Psychosocial Support Group, Kampala, Uganda

The peer support group leaders in their workshop, where the Maama income-generating group makes crafts to sell (K. McLoughlin, 2006).

Factors at work:

- Public health attitude of research leadership & staff
- PLWHA enrolled in research
- Community engagement
- Partnership-building
- Capacity-building
- Referral follow-up

The Psychosocial support group at MU-JHU was started by a Health Visitor, Agnes Ssendege, and several participants of the MTCT Plus Program in 2003. Health Visitors are a team of nurses and midwives who conduct follow-up with study participants from the time they enroll to study termination. Agnes had gathered some HIV-positive participants together to meet with an outside visitor. The participants really enjoyed getting together and sharing their stories and Agnes realized that there was a need for a support group for PLWHA. She went

to the site leadership and shared her idea. They agreed to allow her and the participants to develop the group. Within a year, the group grew from 5 couples to 200 members. Within a few years, the site leadership created a new position (Psychosocial Coordinator) so that Agnes could officially coordinate the group full-time. She has come to be known as "Mama Agnes" by the group members and staff at the site because of her work. One staff member said, "she is one of our angels here."

The psychosocial support group offers a variety of services to current and former research participants including:

- Loan Scheme Program which provides small loans to members who want to start a business.
- Friend in Need Group which provides grief counseling to families.
- Handcraft Group, also known as the Maama group; members are taught how to make crafts, and then the group sells their crafts to visitors and overseas. The purpose of the group is income generation.
- About 25 members of the group serve as Peer Educators. They go to the study clinic waiting rooms on a daily basis to counsel participants, share their own stories about living with HIV, and advise participants on drug adherence. Peer Educators also assist in serving food from the World Food Programme to participants waiting in the study clinic, and supervising children in the waiting areas.
- Young Positives Generation group for HIV+ children
- Music, Drama and Dance group, called MU-JHU Peer Productions. They perform for visitors and promote awareness of HIV/AIDS through poems, dance, and song.
- Net ball (sports) group
- Discordancy group for couples
- Pre&Post Test Club

The group has helped its members in various ways. For example, through the Loan Scheme Program, a widow with children was able to buy charcoal to re-sell. Now she is able to send her children to school. An HIV+ woman was "chased" away by her husband. The group helped her rent a house, and paid her rent for three months. Now the woman sells tomatoes and is able to pay her rent herself.

One of the volunteers explained how the group helped her. When she disclosed to her husband she was HIV+, her husband became abusive. He blamed her for infecting him. The woman and her husband, participants in MTCT Plus, joined the psychosocial support group. After hearing other members' stories, her husband changed his ways. Being in the group helped him accept the situation and stop abusing her.

The growth and success of the psychosocial group has been made possible by the study staff and the leadership at the site who are very supportive of the

group. Many staff members volunteer to help out the group with activities, such as the Maama Group that meets two Saturdays of the month to make crafts. Some staff also helped the group obtain funding from the Doris Duke Foundation to purchase a pre-fab building to use for the Maama Group.

The psychosocial support group plans to expand into the community, by starting a community outreach sub-group. Group members want to raise awareness, promote VCT, and share their own stories so that others can learn from them.

Vignette 2: NARI Community Partnership, Pune, India

Role-playing during a peers meeting in Pune (H.Burke, 2006).

Factors at work:

- Community engagement
- Public health attitude of research leadership & staff
- Partnership-building
- Capacity-building

NARI recognizes that those community members who may not be eligible for current research studies may become eligible in the future. NARI also understands that people in the community can influence the decision of other people to join or stay involved in research studies. NARI staff therefore proactively seek to educate the entire community and not just those who are eligible for participation.

NARI allots large amounts of human resources and time to community involvement. The HPTN Principal Investigator and the Community Program Supervisor each spend 30% and clinic staff approximately 20% of their time on community involvement activities. NARI also has a Community Outreach Office with 15 full-time staff to work on developing and fostering the partnership between NARI and community organizations. NARI's community partners believe that the partnership is successful because NARI's HPTN PI is involved in community activities and day-to-day operations of the referral partnerships and is "approachable" and "supportive". Community partners feel that the senior NARI staff respects their work and that they are part of a team effort.

Securing funds for community-wide care and training is challenging however. In the past, NARI found it difficult to convince funding agencies to pay for diagnostics and treatment of opportunistic infections and ART. NARI addressed this challenge by forming partnerships with public hospitals which can provide services at lower costs which are affordable for the study participants. More recently they have found that funding agencies are more receptive to the idea of providing care for clinical trial participants. NARI's community work budget now includes funds for the community advisory board, community involvement, and support for health care. The size of the budget needed to provide care in this Indian setting has been relatively small and has not been an issue for funding. The challenge remains, however, how to continue providing care and support to participants long after the clinical trials end.

Vignette 3: UNC Project Resource sharing, Lilongwe, Malawi

UNC Project pharmacy in Lilongwe (N. Mack, 2006).

Factors at work:

- Public health attitude of research leadership & staff
- Referral follow-up
- Capacity-building
- Partnership-building

At Kamuzu Central Hospital (KCH) in Lilongwe, drugs to treat patients had to be ordered to be sent from the main hospital pharmacy because there was no drug supply kept in the medical ward. This system created a challenge for efficient treatment of patients in an already understaffed environment. In addition, pharmaceuticals could only be obtained during normal working hours, including medications needed for emergency admissions during the night. Even during the day, when a medication was needed to treat a given

patient, medical ward staff had to walk that patient's file to the pharmacy, get the order filled, then return to the ward with the medication. This could take up to half a day or sometimes be delayed until the next morning.

A new collaborative arrangement between the UNC Project pharmacy and the KCH medical ward began in April 2006. Through this arrangement, the UNC Project pharmacy supplied a small stock of drugs for the KCH male and female medical wards. The stock is kept in a small, 24-hour "pharmacy" in the medical ward itself rather than in the UNC-Project pharmacy or the KCH central pharmacy. The initial stock was based on need estimates made by the ward clinicians who collaborated on the project, with quantities to be re-evaluated after 3 months. The medical ward would then place an order with UNC-Project every 3 months according to a fixed budget, with UNC continuously financing the effort.

A similar challenge emerged with referrals to the sexually transmitted infections (STI) clinic. The clinic is part of KCH and therefore government subsidized and run. However, UNC is currently staffing the clinic. Although the government is theoretically responsible for supplying all STI drugs to be dispensed there, the drug supply is erratic. UNC Project began supplementing the clinic with drugs and equipment, such as speculums. The current procedure is that on a weekly basis, the STI unit orders the drugs it needs from the dispensary at the hospital. The hospital dispensary is usually out of stock on numerous items. The clinic then advises the UNC Project of the deficiencies and UNC provides the remainder of the drugs and supplies needed.

Vignette 4: UNC Project Referral Escorts, Lilongwe, Malawi

Factors at work:

- Referral follow-up
- Partnership-building
- Community engagement

If a study clinician suspects that the sick child of a participant needs inpatient care, the clinician will refer the child to KCH pediatrics. The study clinician or staff completes admissions paperwork for the child and calls to advise the pediatrics clinician of the child's imminent arrival. That child then has priority for being seen before the other children waiting. Oftentimes, however, a woman whose sick child has been referred for care "absconds"

Entrance to UNC Project study offices at Bottom Hospital in Lilongwe (N. Mack, 2006).

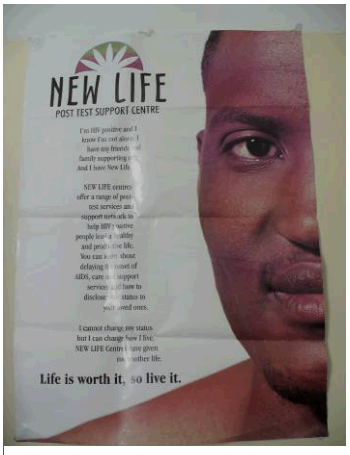
between the clinic and the pediatrics ward. This is typically due to the need to make arrangements to be away from her household should the child be admitted. If the child stays in the hospital overnight, the mother will presumably stay also.

The problem is that once a woman returns home, she may not return to the hospital with the sick child for several days. This could be due to transport issues, difficulty making arrangements to cover household responsibilities, or other personal business. When they do return, the pediatrics clinician is no longer awaiting their arrival and they are not recognized as having UNC study referral status. Therefore, they no longer have priority to be seen first and must endure the long wait, which can easily be an entire day. Such participants often complain about the long wait time, but had they presented at the time of the referral they would have had priority over other patients. There are also health implications for the child when treatment and care is delayed. Study clinicians and staff are less likely to follow up on the child with the pediatrics clinician because they will not be aware of the date the participant returned to the pediatrics clinic.

In HPTN 035, a new procedure was implemented to partially address this problem. Participants referred from the study are escorted to pediatrics by a study nurse to forestall "absconding." There is also an agreement in place for UNC studies at Bottom Hospital that their referred participants are escorted to KCH pediatrics in transportation provided by UNC.

Although the escort system helps to get child referrals into care in a timely and efficient manner, it cannot resolve the personal problems that require women to return home before a hospital stay. Possible measures to mitigate that impact are for outreach workers to contact the women and arrange for transport back to the hospital.

Vignette 5: UZ-UCSF Referral Standard Operation Procedure, Harare, Zimbabwe



Poster for UZ-UCSF referral site in Harare (P. Alleman, 2006).

Factors at work:

- Community engagement
- Partnership-building
- Public health attitude of research leadership & staff
- Referral follow-up
- Capacity-building

Among UZ-UCSF community advisory board (CAB) members, the biggest referral concern is for people who are ineligible for the studies due to their HIV

positive status, and those who seroconvert during the trials. CAB members feel strongly that it is the responsibility of the studies to provide medical and social care for these individuals as their recruitment and screening for the study "initiated the process" of discovery.

In response to the CAB concerns and the current needs at the UZ/UCSF research site, the counseling team has proposed a standard operation procedure (SOP) for providing direct care and referral services to persons who screen out because of a positive HIV result or those who seroconvert during the course of the study. Services depend on the facilities and capabilities of providers in government and in the community.

In preparation for the proposed SOP, the counseling department conducted an inventory of organizations with similar aims in the Harare area. CAB members were also involved in the referral site identification process, particularly identifying sites in their geographical and professional areas. As one member of the research staff noted, identification and collaboration with existing organizations is very important to ensure that "competent care is provided in the community after the research project is finished." As part of the proposed SOP, the referral form expands upon an existing form currently used with referrals to a single social support organization. This form will now be used with all referrals. It has been amended to include a slip at the bottom that will be collected monthly by the research site for evaluation purposes. Additionally, the referral forms are being carbonated so a copy will remain at the research site. For the referral sites that are most often used by the UZ-UCSF research teams, the counseling team from UZ-UCSF will make monthly visits and systematically document the referral process.

As indicated on the flow chart below, there are services that are directly provided at the research site and those that are referred out. Similar to current research practices, the direct care that is available includes assessment of medical and psychosocial needs through counseling sessions. However, there is an important distinction between those clients who screen out and those who seroconvert during the trial. The latter remain part of the research until the end of the study, and thus have standing clinical visits every three months where medical and counseling care is continually provided. For those who are screened ineligible for the study because they are HIV-infected, they receive two additional counseling sessions at the research site and referral to services as needed, i.e., general referrals, opportunistic infection (OI) referrals, and social welfare referrals. The partners of these screened ineligible potential participants are also offered HIV testing. Referrals for these clients are most often for psychosocial and general referral needs. For OI clinic access, they are referred to one of four ARV access points in the Harare area.

All referral relationships are built on personal and professional connections of the UZ-UCSF counseling and medical teams. For example, the UZ-UCSF counseling

staff talked to a local OI clinic and learned their biggest need was more clinical staff and nutritional drinks for patients on ARV treatment. In response, UZ-UCSF has now loaned two clinicians and one counselor with the OI clinic.