PARTNERING FOR CARE
in the
HIV Prevention Trials Network

PART II. CASE STUDIES

Kathleen M. MacQueen and Kerry McLoughlin, Editors

Behavioral and Social Sciences Division
Family Health International
Research Triangle Park, North Carolina

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PART II. CASE STUDY REPORTS

SUMMARY TABLES

Table 1. Basic demographics and health information.

Site	Demographics of the area	ART coverage	ART access	2005 HIV prevalence among adults (15-49) in the country (from UNAIDS 2006)	Health Care system
Kampala	Capital city; Urban; population of 1.2 million.	about 50% of those who need ART are receiving it (UNAIDS 2006)	Free ART available at government hospitals and public, non-profit, and private HIV/AIDS care and treatment centers; PEPFAR country; Global Funds, MAP;	6.7% in Uganda	Government health system is free
Philadelphia	Urban; population is 1,517,550. 42.0% White, 45.% African American, 5% Asian. Hispanic or Latino of any race were 9.9% of the population.		Readily available; ART available at hospitals; public, non-profit, and private HIV/AIDS care and treatment centers; State-government and federal programs to assist with the cost of care and treatments (ex. Ryan White CARE Act; Pennsylvania Drug Assistance Program).	0.6% in US; about 20% of new HIV infections in the US are attributed to IDU	Free care at city-run Health Care Centers
Durban	2nd most populated city in SA; Urban; population of 3.2 million. Largest Indian population in SA; 68% Black Africa; 20% Indian; 9% White; 3% coloured. 68% Christian; 36% completed high school.	Less than 20% of those who need ART are receiving it (UNAIDS 2006)	Free ART available at **all?** government hospitals. PEPFAR country;	18.8% in South Africa	Small fee to access care at government hospitals and local clinics
Rio		170,000 of 209,000 (81.3%) who need ART are receiving it	Free ART available through the government system	0.5% in Brazil	Universal Health Care system [Sistema Unico de Saude (SUS)]

Site	Demographics of the area	ART coverage	ART access	2005 HIV prevalence among adults (15-49) in the country (from UNAIDS 2006)	Health Care system
		(UNAIDS 2006)			
Harare		23,000 of 320,000 (7.2%) who need it are receiving ART (WHO/UNAIDS 2006)	No PEPFAR or Global Funds	20.1% in Zimbabwe	
Pune	Pune is an urban city located east of Mumbai (Bombay) where according to the 2001 census over four million people reside. Pune is located in the western Indian state of Maharashtra. Marathi is the local language spoken in Maharashtra, but Hindi (the national language) and English are also spoken. Hindu and Muslim are the religions practiced most predominately.	Less than 10% of those who need it are receiving ART (UNAIDS 2006)	Free ART available at governmental hospitals in 6 high prevalence states	0.9% in India	
Lilongwe				14.1% in Malawi	Government health system is free; Some private, fee-based wards in govt hospitals

UNAIDS. 2006. "Chapter 2 Overview of the Global AIDS epidemic." 2006 Report on the Global AIDS Epidemic. (pp. 8-50)
US Census. "Factfinder: Philadelphia City, Pennsylvania." Accessed at factfinder.census.gov on July 7, 2006

Table 2. Research activities at HPTN sites participating as case studies as of July 2006.

Location (site)	Active HPTN studies	Study Population	Other non-HPTN Research Activities
Kampala	HPTN 027	HIV positive mothers and HIV negative infants	Yes
	HPTN 046	HIV positive mothers and HIV negative infants	
Philadelphia	HPTN 035	women at risk for HIV	Yes
	HPTN 037	IDUs and members of their sex and drug networks	
Durban	HPTN 035	women at risk for HIV	Yes
Rio	HPTN 052	serodiscordant couples	Yes
Harare	HPTN 039	High risk negative, HSV-2 positive women and men who have sex with men	Yes
	HPTN 035	women at risk for HIV	
	HPTN 052	serodiscordant couples	
	HPTN 046	HIV positive mothers and HIV negative infants	
Pune	HPTN 052	serodiscordant couples	??
	HPTN 059 (pending)		
Lilongwe	HPTN 035	women at risk for HIV	Yes
	HPTN 052	serodiscordant couples	

Table 3. Characteristics of HPTN sites participating as case studies.

	Length of time site has been active	Focus	Type of facility (govt, NGO, university)	Clinic facilities
Kampala	18 years	Research and care programs	University-based	study clinics on-site; most care provided on-site or at nearby hospital
Philadelphia	17 years	Research	University-based	study clinic for 035 on-site; clinic for 037 off-site; no care provided on-site
Durban	37 years (since 1969)	Research	Government sponsored but autonomous	study clinic for 035 off-site; only FP counseling provided on-site
Rio	unknown	Research and care programs	Government sponsored	1 study clinic on-site (at FIOCRUZ) and 2 off-site (within hospitals); most care provided onsite or within hospitals in which clinics located
Harare	unknown	Research	University-based	1 study clinic on-site and other clinics off-site
Pune	14 years	Research and care programs	Government sponsored	1 study clinic on-site and the others off-site; some care provided on-site or within hospitals in which clinics are located
Lilongwe	7 years	Research and care programs	University-based	study clinics on-site; most care provided on-site or at nearby hospital

CASE STUDIES

MU-JHU Research House, Kampala, Uganda

Kerry McLoughlin

HISTORY OF THE SITE

The Makerere University – Johns Hopkins University (MU-JHU) Research Collaboration was established in 1988, largely through the efforts of Laura Guay and Brooks Jackson. The collaboration received permission to build the MU-JHU Research House on the grounds of Mulago Hospital, one of two national referral hospitals in Uganda. The first major clinical trial held at MU-JHU Research House was HIVNET 012 which evaluated the efficacy of two short course ARV drug regimens, Nevirapine and AZT, in the prevention of mother to child transmission (PMTCT). The study showed that Nevirapine given to mothers at the onset of labor and to infants within 72 hours of birth reduced the risk of transmission by about 40% at birth and during breastfeeding up to 18 months. The results have been widely disseminated and the use of Nevirapine, a safe, simple, and inexpensive regimen, has become standard practice for PMTCT in low-income countries.

Entrance to the original MU-JHU Research House in Kampala, Uganda (K. McLoughlin, 2006).

Currently, MU-JHU Research House is a site for two HPTN projects. HPTN 027 is a Phase I Study to Evaluate the Safety and Immunogenicity of ALVAC-HIV vCP1521, an HIV vaccine, in Infants Born to HIV-1 Infected Women in Uganda. The vaccine will be administered postnatally during the breastfeeding period. HPTN 046 is a Phase III Trial to Determine the Efficacy and Safety of an

Extended Regimen of Nevirapine in Infants Born to HIV Infected Women to Prevent Vertical HIV Transmission During Breastfeeding.

At the time of data collection, MU-JHU was the only HPTN site to focus on mothers and children. NIH is the main funder of the site. Mary Glenn Fowler and Philippa Musoke are the site coordinators. Frances Mmiro is the on-site principal investigator (PI). Laura Guay is the HPTU PI.

A Dual Purpose Site

Staff consider the activities at MU-JHU to be 70% research and 30% care and treatment. The site began providing HIV/AIDS care and treatment for participants and community members in 2003. They currently have three programs through which they provide ART: MTCT Plus, the ILA program for children, and TREAT.

The MTCT Plus Program is a pilot program funded by Columbia University through which families with HIV positive members (mothers, fathers, and/or children) receive free care and treatment, including ARVs. About 900 people are enrolled. In 2003, the site received an International Leadership Award (ILA) through the Elizabeth Glaser Foundation. The ILA study has a program component, through which staff can provide ART to about 100 children. Neither program was enrolling during the case study site visit, and both were scheduled to end in 2006.

MU-JHU Research House is also a site for the Timetable for Regional Expansion of Antiretroviral Therapy (TREAT) Program. The TREAT Program is a joint effort between the Joint Clinical Research Centre (JCRC) in Kampala and US AID. JCRC is an HIV/AIDS care and research facility in Uganda. The goal of the TREAT program is to expand access to “high quality, low cost” ART throughout all regions of Uganda. The program supplies low cost drugs to public, private, and faith-based groups, and promotes capacity building in lab services, counseling, and adherence promotion strategies. Through the program, MU-JHU Research House is able to provide ART to HIV positive mothers and children (www.jcrc.co.ug accessed November 13, 2006; US Embassy Kampala, 2006a).

Rationale for proving HIV/AIDS Care and Treatment on-site

The Kampala site is a unique HPTN site in that they enroll HIV+ and HIV- participants, as they are interested in mother to child transmission of HIV. The study staff decided the best option to meet HIV+ participants’ needs was to offer HIV/AIDS care and treatment themselves. In 2003, there were few places to refer participants and most participants could not afford ARVs when and where they were available. Treatment can cost between US$214 to $740 per month (Uganda Ministry of Health, 2006). The two main referral sites for PLWHA who needed ART were JCRC and the Infectious Disease Clinic at Mulago Hospital.

However, both facilities were overburdened with patients. PLWHA were also referred to The AIDS Service Organization (TASO), but they did not offer ART. MU-JHU study staff were seeing numerous participants grow sick and die, and they felt a compelling need to do something about it. So they applied for funding from various sources.

While HIV/AIDS care programs have expanded and multiple facilities in Kampala now offer free or low cost ART, the MU-JHU site plans to continue providing HIV/AIDS care and treatment to study participants and they are currently pursuing additional funding for this purpose.

BRIEF OUTLINE OF HEALTH CARE/SERVICES STRUCTURE IN UGANDA

The health care system in Uganda faces major challenges. Health care facilities are understaffed, overburdened, and under funded. Most facilities lack adequate supplies and equipment. Most trained staff work in the urban areas, although the majority of Ugandans live in rural areas (Garbus & Marseille, 2003).

Hospitals fall into three main categories: government, non-government and private. In terms of government hospitals, people can access basic medical care at district/rural hospitals located in each district of Uganda. Patients are referred to regional hospitals for some specialized care, and national referral hospitals for the most specialized care. There are only two national referral hospitals in the entire country. One is located in Kampala (Uganda Ministry of Health, 2006).

Patients face a number of barriers to accessing care at regional and national referral hospitals. Distance and cost can hamper one’s ability to travel to the hospital. Another barrier is that usually a patient needs to bring one or more family members with him/her to care for him/her while hospitalized. Due to lack of resources and staff in the hospitals, a patient’s family members will be responsible for feeding the patient, bathing them, doing laundry, and other tasks. There is no place for family members to stay while taking care of the hospitalized person except in the same hospital ward or outside. Families may not be able to uproot for a period of time because of responsibilities at home.

As most Ugandans live on less than US $1 per day, they cannot afford health care (Garbus & Marseille, 2003). Thus, government facilities, where care is free or for a low cost, are overburdened, frequently face drug shortages, and lack supplies. Non-profit health care facilities, such as missionary hospitals, relieve the pressure on the government care system to some extent, but are over-burdened themselves and dependent upon donors. For those who are better-off, they can access health care in private hospitals and facilities. However, this is a minority of Ugandans, and generally not those enrolling in HPTN research.

Although rates of HIV/AIDS have declined since the 1990s, Uganda still faces a major epidemic that is overwhelming the health care system and families. The HIV prevalence rate is about 4.1%. By 2000, 1.3 million people had died because of HIV/AIDS. Life expectancy has been reduced by 17%. By 2020, the country will have lost about 14% of its agricultural labor force. Care for over two million children orphaned by HIV/AIDS is a growing concern (Garbus & Marseille, 2003).

Uganda has received funding from a number of international donors to respond to the epidemic. In 2003, Uganda was chosen as a focus country for the President's Emergency Plan for AIDS Relief (PEPFAR). Uganda has been able to expand its HIV/AIDS care, treatment, and prevention activities with PEPFAR funds (90.8 million in 2004 and 148.4 million in 2005) (US Embassy Kampala, 2006b).

Uganda also received about $100 million from the UN Global Fund to Fight AIDS, TB & Malaria, and $47.5 million from the World Bank's Multicountry HIV/AIDS Program (MAP), although some of the Global Funds were misused (Garbus & Marseille, 2003).

Despite the early and focused response by the government to the HIV/AIDS epidemic and international support, only 56% of PLWHA who need ART receive it in 2005 (UNAIDS, 2006). The MOH declared that women and research participants are priority populations, so this makes it somewhat easier for research participants to access care.

WHAT ARE PARTICIPANT NEEDS AND HOW ARE THEY MET?

As the focus of studies at MU-JHU Research Site is HIV/AIDS transmission from mothers to children, perinatally and postnatally, they usually enroll mother/child pairs, in which the mothers are HIV positive and the children are negative. During studies, some study mothers need to start ART or need treatment for opportunistic infections. Some children seroconvert and need monitoring, care and treatment.

As the majority of Uganda's population lives on less than US $1 per day, study staff often encounter participants with a variety of medical and social service needs, besides HIV/AIDS. It is usually not just the participant who needs assistance, but her entire family.

Medical needs of participants include:

- HIV/AIDS care and treatment for adults and children
- Family Planning
- Pregnancy care
- STI testing, care and treatment
- VCT for study participants' partners and other children

- Primary care for the entire family

Social service needs include:

- food
- counseling/social support for families affected and infected with HIV/AIDS
- assistance with paying children's school fees
- employment and job training

During studies, MU-JHU tries to minimize referrals of research participants for both medical and social needs. Study staff provide as much medical care as possible at the research site. Most adverse events, HIV/AIDS care and treatment (including ART), STI care and treatment, VCT, family planning, and primary care are provided on-site to mother/child pairs. MU-JHU has a pharmacy on site and runs a lab at the Institute for Infectious Diseases (IDI), just a short distance away on hospital grounds.

The site seems to be moving to a model of providing holistic care for participants and their families during study participation. To the extent possible, staff will provide primary care and VCT to family members of study participants, if they come to the study site. Staff do not encourage this though as they do not have the capacity to provide comprehensive care for families on a regular basis. Through the MTCT Plus Program, some current and former research participants and their families have been able to receive HIV/AIDS care and treatment on-site. Families have also been able to access social support through the MU-JHU Psychosocial Support Group, which offers activities and counseling for adults and children. Families have also been able to obtain food through the MU-JHU site's World Food Programme. The site is unique because of their focus on families.

Staff believe there are advantages to providing HIV/AIDS care and treatment on site. First, the participants and often their family members are already coming to the study site on a regular basis. It is easier for the participants and their family members to receive care at the same place rather than attend different facilities. One staff member called it "one-stop shopping." Asking families to attend different facilities for care makes it difficult for them.

> *We deal with the poorest of the poor here, and when you start telling them that, 'you go over here to PIDC for your children, you send your husband to TASO, and then you come here', the adherence to scheduled visits does not go as well. (study coordinator 1)*
>
> *Now that ARVs are available, why send her [study mother] somewhere else to sit in another line for 8-12 hours, when you can provide the same service . . .It just doesn't make sense to us. (study coordinator 2)*

Third, the study staff have established relationships with the participants, and this familiarity improves adherence to ART.

> *I think that the relationships that our patients have with the doctors, with the health visitors, with the counselors, is really special. They don't get that anywhere else. That's why we find, a lot of times, and it's not just because we provide transport reimbursement for study visits, or provide medicine. But it is that ability to talk to, that caring, that they come back for more. (study coordinator 1)*

Fourth, as the study staff can provide transportation to the site, it also improves adherence, as participants are less likely to miss visits.

While the site is not obligated to provide care to study mothers or seroconverters, except for adverse events, some staff view providing care to research participants in need as an ethical responsibility:

> *I think it's unfair to have a mother who has volunteered for something and then you are not providing all that you can provide for her. And then send her off somewhere else for it, where she may or may not get it. I think it's our responsibility. The least that we can do is try to help them as much as (we can). (study coordinator 2)*

The site is able to provide outpatient HIV/AIDS care and treatment for several reasons. They have a large facility with their own pharmacy and a state-of-the-art lab. They also have a large staff, with numerous doctors and nurses, to manage the workload.

Psychosocial Support Group

The Psychosocial support group 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 that conduct follow-up with study participants from the time they enroll to study termination. Agnes had gathered some participants together to meet with a visitor. She realized at that time that there was a need for a support group for PLWHA. The participants really enjoyed getting together and sharing their stories. Agnes 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 so that Agnes could officially coordinate the group full-time. She became the "Psychosocial Coordinator". She has also 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 peer support group leaders in their office, next to MU-JHU Research House (K. McLoughlin, 2006).

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 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.

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 told 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. The staff and the leadership at the site 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 - a type of partnership

The Psychosocial Support Group can be viewed as a type of mutually beneficial partnership between the researchers and some of their research/care program participants, and thus community members. The researchers provide the space for the group to meet and a coordinator for the group. They organized a training for 25 members of the group to become peer educators. The researchers benefit because their research participants get social support, counseling, and the opportunity to participate in a variety of social activities. The researchers are dependent upon Mama Agnes and the volunteers to provide these services.

The chairs of the group benefit because they seemed empowered by their volunteer work. Their work is a source of pride for them. When the Music, Dance, and Drama group performed, I could see the enjoyment and pride in their faces. The group also fights stigma and provides a supportive environment for PLWHA and their families. It is a win-win situation.

One challenge that the chair of the group, William Mulindwa, mentioned was that he wished the volunteers were paid for their work. Transportation is expensive. For example, the Friend in Need group pays their own way to travel to funerals for PLWHA, even if they are in rural areas. Also, he felt that their work would be legitimized in the community if they were paid employees. Although they are just expanding into the community, he noted that people tend to question the volunteers’ motives for speaking up about HIV/AIDS and sharing their stories.

Members of the group also face challenges coming to meetings because of transportation costs.

Impressions of the psychosocial support group

The dancers of the MU-JHU Peer Productions Group perform a traditional dance to welcome people and praise God (K. McLoughlin, 2006).

I met with Agnes, the psychosocial coordinator, the chairperson, William, and all of the chairs of the various sub-groups during my visit. I found them to be a very committed, energetic group who are working very hard to improve their own lives and the lives of others. Agnes and the chairs built this group from the ground up. They take their work very seriously. They are all volunteers, but over the week I was visiting, I saw many of the members at the site on a daily basis. They are all very grateful for the care, especially the ART, they have received through the site. Most are enrolled in the MTCT Plus program. As we were watching the Music, Drama and Dance group – known as MU-JHU Peer Productions -- Mama Agnes told me that before receiving ART, many members were so weak. ‘But now look at them’. Many of the groups songs and poems were about their gratitude for ARVs, and their gratitude towards donors who have made it possible for them to live positively.

Margaret, one of the founding members of the Psychosocial support group and a former research participant, told me how the MTCT Plus program has helped her and her family. She said that without the MTCT Plus program, she would have died. At the time she enrolled, her CD count was 1. Half of her body was paralyzed. Now, her CD count is 900. Her three children come to the site every three months for a check-up, and her husband every 6 months. None of them need ARVs at this time. She also brings her children to the site for care when they are sick. Through her volunteer work with the group, she tries to give back to others. She encourages parents to bring their children for testing and to get treatment. Margaret and her daughter also traveled to Washington DC to testify before Congress about HIV/AIDS.

World Food Programme

The World Food Programme at MU-JHU was started by two study coordinators, Jennifer Trizzino and Linda Barlow. The staff were motivated to take action because they saw so many families struggling to feed themselves and their children due to poverty. For example, Trizzino said that she has seen some participants feeding their babies black tea, because they don't have anything else to give them.

The staff also noticed that once patients start ART, their bodies 'wake up' and people become extremely hungry. Patients who have been sick for a long time are often unemployed and have been getting by on little food. Once they start ART, they are starving and they have no means to feed themselves.

While some staff have always tried to help out participants with small donations, Trizzino and Barlow wanted to do more, which they attribute to their "public health backgrounds." Jennifer said, "Because we believe in that holistic approach, Linda and I have gone outside of our job descriptions". The two staff members applied for a World Food Programme award. They received the award and established the program at the research site in 2005. The program will continue until 2008.

Participants are recommended for the WFP by study staff. There are requirements for qualifying for assistance that were established by WFP. If a person qualifies, they can receive food for 12 months. Through the program, the site also provides lunch and porridge to children in the study clinic waiting rooms. The day I observed in the clinic, each child received a hard boiled egg and a cup of porridge. The staff feel the program is successful:

> *We're seeing a big difference in our families. . . .Children are going to bed with tummies that are full instead of hungry. They are starting to have breakfast in the mornings. People are adhering to their ARVS (study coordinator 1)*
>
> *One of our volunteers, G, he looks strong and strappy . . . before WFP, he was on ARVs and he wasn't doing well. He couldn't hold down a job. He was starving. . . . He wasn't doing well, and wasn't adhering to them.*

> *Then he got WFP food. And, you see him now, he's doing great. He's healthy. There's so many stories like that. (study coordinator 1)*

One challenge associated with the WFP is that there is not enough funding to cover staff time. WFP provides a portion of the funds to cover staff time, but the research site has to cover the other portion. This can be difficult because some studies have no funds to spare. One solution is that volunteers from the Psychosocial Support Group help out with the program on a daily basis. There are no funds to cover Trizzino and Barlow's time. They volunteered to get the program up and going, and insure it runs smoothly. Another challenge is that some months the site does not receive all of their needed food supplies.

A challenge that Trizzino and Barlow addressed was that they felt the rations for patients not on ARVs were too small. The cost of transportation to pickup the food was more than the food was worth. They successfully lobbied the WFP and had the rations increased.

Other social service referrals

The same two staff who initiated the WFP on site also raise funds from family and friends to help participants' pay school fees for their children. They also have plans to teach participants about nutrition and how to grow food at home. There is a nutrition center in Mulago Hospital where participants with severe malnutrition issues can be referred. Staff did not mention other referral sites for social services besides these.

Referrals during Study Participation

While the site minimizes the number of referrals, pregnant participants and some women and children with adverse events that cannot be handled on site are referred to Mulago Hospital. Abortion is illegal in Uganda, so the site provides no referral or assistance with unwanted pregnancies.

Participants who are recruited while pregnant or become pregnant during a study are encouraged to deliver at Mulago Hospital as it is safer and they can be sure to receive PMTCT care. The majority of Ugandan women deliver at home (Garbus and Marseille 2003) and it is a challenge to convince women to go to the hospital. But through their study participation, the women's awareness is raised and they are more likely to deliver at the hospital.

If a participant is referred to Mulago Hospital because of an adverse event or to deliver a baby, study staff ensure they receive adequate care in several ways. First, there are study staff stationed in the hospital to care for the research participants in the antenatal clinic, labor and delivery, the Acute Care Unit, and the Special Care Unit.

Second, if a participant (adult or child) is admitted to the hospital, a Health Visitor will visit the ward on a daily basis, talk to the hospital staff about the participant, look over the participant's chart, and ensure they are receiving the needed care. If the participant needs drugs or tests that the hospital cannot provide, the study staff will buy and supply the drugs, or pay for the needed tests.

The site implemented these procedures of stationing staff in the hospital and conducting monitoring during HIVNET 012.

In addition to following up with participants who are hospitalized, health visitors will also be sent to sent to pick up participants who need immediate care or to deliver medicine if a participant needs it, forgot it, or it was not ready/available when she was at MU-JHU.

HIV/AIDS Care and Treatment After a Study Ends

Currently, the site is not able to continue care for research participants after a study ends. As mentioned previously, the MTCT Plus Program and the ILA funded program will end this year. Participants who access care through the TREAT program must transfer to another TREAT site after their study participation ends.

Study counselors ask participants where they would like to go for care and treatment after the study, for themselves and/or their child. According to a study counselor, there are 11 options in Kampala. According to the clinic director, there are three main options for HIV+ children: the Pediatric Infectious Disease Clinic at Mulago Hospital, Mildmay Centre, and the Joint Clinical Research Centre.

Two main facilities people attend for HIV/AIDS care and treatment are the Infectious Disease Institute (IDI) and the Pediatric Infectious Disease Clinic (PIDC) at Mulago Hospital. IDI is for adults; PIDC for children and adolescents under 18. IDI and PIDC are located close to the research site, and to each other, and the research staff have close ties with each organization. Dr. Musoke, one of the site PIs, is the head of the Department of Pediatrics which oversees PIDC. She is also on the board of IDI.

Services are free at IDI and PIDC, including ART, although if a participant can pay, they do. However, less than 5% of patients of IDI pay for their ART. IDI is a brand new facility thus the equipment, wait room, and exam rooms are state of the art. IDI has board games, an art table, a canteen (snack bar), and prayer and singing groups that meet in the waiting areas to keep patients entertained and busy. The ward in which PIDC is located was recently renovated with funds from CDC Uganda. The waiting room in PIDC is decorated for children and there is a TV, children's books and games to keep them entertained. Each clinic has its own pharmacy on site.

A weakness of both centers is that they see many patients a day so the wait time is long. Staff at IDI estimated they see 300-350 patients per day. Staff at PIDC estimate 250 patients on most days.

> *Right now, the limiting factor is a lot of patients but limited structure and human resources to deal with all of the patients*. *(head of clinical services, IDI)*

To try to deal with the high load, they have trained nurses to help with ART counseling, moved to an appointment system, and will soon allow patients who only need a drug refill to pick it up without having to see a doctor.

In terms of ART, IDI does not have a limit on the number of patients to whom they can provide free ART. They work under a “push-pull system.” Every 30 days, they estimate the number of people who will be eligible for ART, and share that information with the MOH. The MOH then provides them with the number of slots they need.

A specific challenge IDI staff face caring for referred MU-JHU participants is that many of them need OB/GYN care, and they do not employ a staff member with that expertise. The head of clinical services suggested that the researchers supply one person at IDI to deal with the women they refer with OB/GYN needs, if even one day per week. On the positive side, the doctor noted that the participants referred from MU-JHU usually have a greater understanding of HIV/AIDS care and treatment, and that makes their job easier.

Another weakness of IDI and PIDC is that in general families cannot receive care together. PIDC does offer a family day once a week, but in general, adults go to IDI and children and adolescents go to PIDC. As each clinic has its own pharmacy, a parent needs to go to two separate pahrmacies if both he/she and his/her child need treatment

Another option for families is Mildmay Centre. They treat children and adults. Care for children is free. Adults have to pay for services. They have a support group, a pharmacy, and a chapel on site. However, the site’s location is not accessible to everyone. Mildmay Centre is located far from the city center, on the road to Entebbe. In addition, some adults may not be able to pay for their own care and treatment needs, meaning they would have to seek care in a different place then their children.

Before IDI opened and before the site began offering their own care and treatment programs, The AIDS Service Organization (TASO) was one of the main referral sites for adult PLWHA. TASO is a comprehensive HIV/AIDS care and treatment center. TASO offers primary care and numerous social service programs, including home based care, a drama group, technical training for young people, a youth club, and a “Train the Trainers” Program. TASO began offering ART in 2004, and were given 1000 slots. At the time of my visit, 150 slots were still open.

TASO is located close to the research site. It would probably be a 20 minute walk, but is a short drive. On the downside, TASO has many patients. On the day I visited, the waiting areas were packed with people. They also do not see patients under 18 years of age, so families cannot receive care together.

Other Medical and Social Services After a Study Ends

After a study ends, participants will likely return to Mulago Hospital for primary care, STI care and treatment, and family planning needs.

The psychosocial group is for former and current research participants, so people will be able to continue their involvement after a study ends. However, according to a study counselor, all of the HIV/AIDS care and treatment centers have support groups service programs for patients, if people were not able to continue to come to the study site for meetings and group activities.

CHARACTERISTICS OF SUCCESS IN THE REFERRAL SYSTEM & PARTNERSHIPS

Partnership with Mulago Hospital

MU-JHU Research House’s main partner is Mulago Hospital. MU-JHU has been closely linked to the hospital since the site’s inception in 1988. MU-JHU is housed on hospital grounds. They share staff, and find the relationship mutually beneficial. This partnership will be discussed in more detail.

Mulago Hospital in Kampala, Uganda (K. McLoughlin, 2006).

Shared Leadership

Having people at the top involved in both institutions was noted by several people at MU-JHU and Mulago hospital as one of the key aspects that makes the partnership successful and strong. Dr. Philippa Musoke, one of the site PIs, is the head of the Department of Pediatrics at the hospital. Prof. Mmiro, now retired, was a pediatrician at the hospital for many years and a PI.

Because of their dual roles, the leadership of MU-JHU has intimate knowledge of the hospital -- knowledge which aids in balancing the needs of research with the limits and constraints of a national health care system. It also increases trust, comfort and willingness to cooperate when the research staff are well-known to the organization with whom they are partnering.

MU-JHU site provides support to the hospital (staff and financial support)

The study site stationed MU-JHU staff, such as nurses, in various wards of Mulago Hospital: the antenatal clinic, labor and delivery, the Acute Care Unit, and the Special Care Unit. MU-JHU staff also coordinate the lab at IDI. The study site also provides some funding to the Labor Ward for the nurses.

Having MU-JHU staff in the hospital reduces the burden for hospital staff who are already overloaded with work. For example, hospital staff is not responsible for recruiting women from the Antenatal clinic as there is a full-time recruiter stationed there. Infants who are hospitalized with an adverse event are cared for by MU-JHU nurses. An added benefit is that MU-JHU staff in the hospital can help out the hospital staff when they have time.

Dr. Musoke noted that there can be some tension between the staffs, as MU-JHU staff working in the hospital are paid more than government staff. But overall, they respect each other and share a commitment to their patients.

Good working relationships between staff in the hospital and MU-JHU staff

According to staff in both organizations, the staff from the two partner organizations have good working relationships. Familiarity with one another, respect, and regular communication contribute to good working relationships. Familiarity comes from the fact that most of the researchers and a number of the older nurses on site worked in the hospital. Prof. Mmiro has taught most of the doctors working in the hospital, and Dr. Musoke has also taught a number of them. The two staffs tend to get along. The supervisor of the Health Visitors said the staffs work “hand in hand”.

Respect for the referral organizations’ policies also contributes to a successful partnership. According to the head of clinical services at IDI, where many participants are referred after a study ends, the research staff have respected IDI’s policies for referrals. IDI only accepts patients who have already been tested and sent with a referral letter.

Regular communication also contributes to a good working relationship. Having staff that work in both places makes communication between the hospital and research site easier, especially when a problem is encountered. For example, a doctor in the PIDC, where MU-JHU recruits participants and also refers children, said that if she had a concern or problem she could pass information through the recruiter that visits the site, or she would feel comfortable calling the doctors at MU-JHU. It also makes it easier for the research site to keep up with what is happening at the hospital, something that may occur sporadically when staff are not shared. For example, Dr. Musoke is one of the overseers of IDI, thus she receives their quarterly reports.

Partnership is mutually beneficial

The partnership between MU-JHU and Mulago Hospital is beneficial for both parties. Mulago has benefited from the capacity building that the researchers did in the hospital in order to be able to conduct their research. For example, before HIVNET 012, the study staff felt that key hospital staff needed training, and that the hospital would need certain equipment and supplies. Thus trainings and resources were provided to the hospital. The capacity building was beneficial for MU-JHU as it contributed to the success of the trial and beneficial to the hospital as they received needed training and supplies. The hospital and the community have also benefited greatly from the trial as the results have been widely disseminated and implemented in Uganda and led to a decrease in HIV/AIDS transmission between mothers and children (Bennett Swingle, 2001).

Another example of the mutually beneficial nature of the partnership is the development of VCT services in the antenatal clinic at the hospital. Having VCT is beneficial for the researchers as they need to identify HIV+ pregnant women for their studies. VCT also benefits the pregnant women, as those who are HIV+ can receive the needed care and treatment to prevent transmission to their child. The hospital, the researchers, and the pregnant women benefit.

Besides capacity building, MU-JHU staff are willing to help out hospital staff when they can and when needed. For example, one time the doctors at the hospital went on strike. The hospital staff asked the MU-JHU staff to pitch in by doing additional paperwork for the patients they were referring. MU-JHU staff were willing and able to help out.

MU-JHU staff also share resources with the hospital when possible. For example, if they have an overstock of drugs, or a stock of drugs that are about to expire, they will give them to the hospital. This can be very beneficial for a government hospital where stock-outs are common. MU-JHU also provides needed drugs to the hospital, upon request and when possible, especially for meningitis patients. The site will also invite hospital staff to trainings it holds, and vice versa.

The MU-JHU site benefits greatly from their relationship with the hospital, as all of their participants are recruited there, and they rely on the hospital as a referral site for many of their participants.

Proximity

MU-JHU Research House is located on hospital grounds, in walking distance to the outpatient and inpatient sections of the hospital. The close proximity makes recruitment, referral and collaboration easier than in places where the sites are more spread out.

Shared Goals

The researchers and the hospital staff have a common cause of improving participants' health. Many hospital staff view research participation as beneficial for their patients, a way to improve their patients' health, so they are happy to refer participants to the research site. Two doctors at PIDC said that they know their patients will receive good care, and extra things, like social support.

Partnerships with other organizations

MU-JHU refers participants to other organizations in Kampala besides Mulago Hospital after a study ends. However, these relationships are not as developed as with the hospital. There is little regular communication, no shared staff, and no identifiable mutually beneficial aspects of the relationships.

The study has partnered with the MOH to disseminate the findings of the HIVNET 012 study. Staff have conducted trainings at hospitals throughout Uganda on PMTCT. The CAB has also worked to disseminate information on PMTCT to the community.

Committed Staff

MU-JHU staff have a strong commitment to participants. They do not view the people as merely study participants, but as people who need their help. This view translates into staff taking action to make sure participants' needs are met, whether it means finding a way to provide the care themselves (e.g., by writing grants), providing resources to their partner organizations where participants go for care, or volunteering their time. Staff have great empathy and compassion for their study participants. There is a lot of energy, commitment and desire from research staff to improve the community in which they work and live. The site also has very committed volunteers.

> *Not to deal with these other issues-- why are we doing this? It is solely for the research so we can write papers and say this is effective? Or are we also looking at, on a more micro level, and saying these are actually human beings, and how can I benefit them, you know? (study coordinator 1)*

> *It's really hard to see a baby come in, the mother is sick, the father may have passed away. She doesn't have much money. And the child is failing to thrive. And you keep telling her, 'you got to give the baby this. You got to give the baby this.' I mean you can provide all the words, but if you can't actually help her. . . (I just have a problem with that) (study coordinator 2)*

Catherine Makku, a counselor at MU-JHU clinic (K. McLoughlin, 2006).

CHALLENGES/BARRIERS TO SUCCESS IN THE REFERRAL SYSTEM & PARTNERSHIPS

The hospital has limited resources

Partnering with a national referral hospital and referring participants to it is challenging as the hospital is overburdened with patients, understaffed, and lacking resources. The study staff said that many participants do not want to be admitted to the hospital because of the quality of care and the fact that they need a family member to come and care for them while hospitalized. Participants, and many community members, prefer to be treated as an outpatient.

The study staff deal with this situation in several ways. First, they try to minimize referrals to the hospital. When they do refer participants, the study staff will buy or provide needed drugs or pay for tests that the hospital cannot provide. They also have their own staff in the key units in the hospital where MU-JHU participants are usually referred for care. They closely monitor their study participants' progress while in the hospital. These strategies help ensure that participants get a high level of care while in the hospital, but require a lot of effort and cost. It also does not address the issues around costs to the family while a member is hospitalized.

Higher SOC through Study Site

A number of staff mentioned that some study participants do not want to go to other care facilities when a study ends or even during study participation. The participants like the personalized attention they receive at the study site, and the shorter waits. In addition, the site employs drivers who can provide transportation to study participants to and from the research site. The site also does not face drug stock-outs, which happens at the hospital. Study counselors encourage participants to go for care regardless of these issues. One study counselors tells participants, "there is no place to go with short lines."

No follow-up with participants after a study ends; no formalized partnerships with referral sites for post-study care

The site does not ensure a participant's ability to access care after they leave a research study. The site is not obligated to follow-up on referrals, but it has been recommended that research sites communicate with referral sites, assess their capacity to absorb more patients, and ensure participants receive needed care.

Dr. Awor, the clinic director, said they have tried to establish a feedback loop with their two main referral sites – IDI and PIDC – at Mulago Hospital, but it was not successful. Dr. Maxi said the staff at the referral sites did not have the time or energy to do this work for the research site. There has been no effort to establish a feedback loop with the other HIV/AIDS care and treatment centers in Kampala. It may become important to establish a formal agreement with other TREAT program sites to ensure continuity of care, as participants who begin care on site will have to transition to a new site when a study ends.

Challenges in accessing HIV/AIDS care after a study

There are challenges associated with transitioning participants to another facility. Most HIV/AIDS care centers are overburdened. However, the MOH declared that women and research participants are priority populations, so this assists participants in getting access to care. Participants are also provided with a form, stamped by MU-JHU staff, that contains notes from the study provider on their health status – CD 4 count, etc. The form is put in an envelope for the participant to take. It is their ticket to get care for themselves or their child.

A study counselor noted that transportation is a major barrier for a number of participants. Participants have told her they cannot afford the cost. For HIV/AIDS patients, she said she encourages them to find a way.

Another barrier to accessing HIV/AIDS care that some study participants face is partner resistance. The study counselor told me that she has heard of some male partners ripping up the referral letter. Also, some participants lack child care, and thus find it hard to travel to care centers with young children.

CHALLENGES WITH BEING A DUAL PURPOSE SITE (RESARCH AND CARE & TREATMENT)

As this site provides the majority of medical and social services to participants during their participation rather than refer them elsewhere, they face unique challenges.

Balancing research and care responsibilities

While the study staff see advantages to offering care and treatment to study participants on site, they also noted that it can be difficult to balance research and care responsibilities. Staff energies can be pulled in different directions. Also, there is no funding to cover the extra time some staff spend on care and treatment, fundraising, and working with participants on the weekends. Despite the challenges, comments from the study staff made it clear that they feel a strong obligation and ethical responsibility to help meet their participants' medical and social needs in as many ways as they can.

> *We do get stretched. It's not everybody. Not every coordinator is working on programs . . . it's the people that feel very passionately about it that do stretch themselves, and yet it needs to be done and there's no money. It's not like HPTN really gives money for these kind of services. (study coordinator 1)*

Financial challenges with providing care and treatment

Although the site is providing medical and social care to study participants, there is no money in the NIH study budgets for this. Study staff still take it upon themselves to find the funds to do these things. Research participants and care program/research participants also volunteer their time to provide needed social services for others through the psychosocial support group. Some staff members said they would like money to be able to provide "holistic care for families".

> *The ideal situation is that we would have money to provide holistic care, to provide programs. You know, to really, as people in the public health*

> *profession, to be able to address holistically, the issues that our patients are coming (with), that they deal with. (study coordinator 1)*
>
> *If HPTN doesn't pay for it, you find staff, coordinators, health visitors, it's coming out, money out of their own pockets, because they just can't do it. You just can't say no to a child. You just can't say no to a woman. (study coordinator 1)*

A different financial challenge is that there are never enough funds for care and treatment, even when the site receives funding specifically for that purpose. Dr. Musoke said, 'it is hard to plan a budget for programs as the circle always expands – meaning more and more people need help as the program goes on. You always need more money than what you have for care and treatment.'

Concern with coercion and undue inducement

Staff have to be cautious about people joining studies in order to get access to the care and services available at MU-JHU. To avoid coercion issues or undue inducement, none of the information about the site being a TREAT site, a WFP site, or the psychosocial support group is in the consent forms. None of the information is shared with potential participants before they join a study.

SUSTAINABILITY

The comprehensive medical care and social services that study participants receive during trials is not available to participants after trials end, except the psychosocial support group. Those participants who have been able to continue HIV/AIDS care on site through the MTCT Plus Program and ILA funded program after their participation ended will have to transition to other organizations soon unless additional funding is found, as both programs end in 2006. Those receiving care through the TREAT program will also be asked to transition to another site when their study participation ends. In addition, people can only receive assistance from The World Food Program for one year and the program is scheduled to end in 2008.

The study site is able to do a lot of good for a small number of people for a short period of time. Participants and their family members can benefit greatly during study participation. However, when studies end, most participants and their families must go back to an overburdened health care system and to a situation in which they may not be able to access existing health care services due to poverty and/or transportation issues.

As it has only been a few years since the site's movement into providing care and treatment, it has yet to be seen how the site will handle the challenges that may come with transitioning participants back to community services or whether the site will continue to expand their capacity so that participants do not have to transition back to community services. An additional concern regarding seroconverters and HIV+ participants is that PEPFAR funding is scheduled to end in 2008. PEPFAR funding had a significant impact on Uganda's ability to expand care and treatments. The staff member at TASO said that they tell patients who are going to start ART that the free drugs may only be for a limited time, and not forever, and that they may only be extending their lives by a few years.

What will help make HIV/AIDS care and treatment programs sustainable is more access to cheaper, generic ARVs. Even the PEPFAR program only allows name-brand drugs. Until pharmaceutical companies make generic ARVs available at a low price, it will continue to be difficult for Ugandan patients to get the care they need to stay alive.

UNMET NEEDS

One unmet need I discovered during an interview at one of the referral sites was family planning needs of HIV+ women. The referral site only offers condoms to PLWHA, despite the fact they have had several patients who continue to become pregnant. When I asked the interviewee if she wished the site could offer some other family planning methods to women, she said she hoped microbicides will be available one day---indicating confusion about microbicides and contraception needs. Better understanding about and access to effective forms of contraception is needed for women who do not or cannot use condoms.

Another unmet need is getting male partners of research participants to come in for VCT. According to Dr. Musoke, less than 1% of women's partners have been tested. The site has tried to increase male involvement in VCT. They have sent brochures home with women and letters from a doctor asking the men to come in. They also started a Men's Access Program – couples are invited to come on a Friday night to watch TV, hear educational information, and then get tested together. However, male involvement is still low. Only about 20 members of the psychosocial group are male.

In terms of social needs, staff have made great strides in their efforts to address participants' need for food, income, and social support. Some staff have also tried to provide some financial support to help people send their children to school by raising funds on their own time. However, the study staff cannot meet all or even most of the participants' needs. Poverty is so widespread that only macro level changes in Uganda's economy and political landscape will be able to alleviate most of the people's needs.

> *The participants are so thankful for everything we do. And it's just almost overwhelming. Because you don't feel like you are ever doing enough. (study coordinator 1)*

A specific unmet social need I heard about during a visit at one of the referral sites was HIV/AIDS education for teachers. The interviewee coordinates a support group for HIV positive children and noted that many children have experienced stigma and discrimination from their teachers.

RECOMMENDATIONS AND LESSONS LEARNED

- Not all sites can provide care for research participants themselves, like MU-JHU does. If a site cannot, encourage real partnerships, not “paper partnerships.” To have a real partnership, sites need to be more aggressive about follow-up. A provider can refer someone, document it, and feel good about it, but never know what happened to that person.

> *I: What are paper partnerships?*
>
> *P: There are organizations that you may have an MOU with. Or just say, refer there. Kind of like how it was. I don’t think they were real before. I mean, we’re going to send you to IDI. But it’s really up to the individual to get there and to actually be seen. But if there was actually more aggressive follow-up-- just like the question you asked, how many people actually go to TASO? I don’t know. I don’t think anybody can answer that question. So sending them away just to send them away . . . in your conscience, you’re happy, cause in your file, you wrote down, I referred them to TASO. But really, did that person ever really get there? Are they still taking the (stuff?) that you used to give them all the time? Or are they off it now cause they somehow got stuck in the cracks? Sometimes they may get there and they may get frustrated by the person they first find. And just give it up.*

- Support the referral sites if there are deficits (supplies, medicines, logistics). Offer training to staff at the referral site.

- Improve communication. Inform the site they you will be referring there. “When there are complaints, give them an ear and address their issues” (clinic director).

- Funders should give sites that can provide extra care and services to participants funding to do so.

> *I think its sometimes easy when someone is at a desk to kind of say ‘but, we’re only focusing on research’ when they don’t have to encounter these people on a day to day basis, and just say, ‘Sorry, there’s nothing I can do for you.’ ‘But I’m starving’. Sorry.’ ‘I need*

> *a job, my husband left me for a negative woman.'. . .Or 'my husband left me because he saw the study car drop me off.' Things like that happen. . .. . 'Guess what, I'm living on the streets, I might have to go prostitute myself' . .. How can you just say, 'OK. I'll see you next, Thursday.'   (study coordinator 1)*

CONCLUSION

The MU-JHU site has moved away from partnering with organizations to provide participants care during a trial, and moved toward a situation where they meet most of their needs on site. They have built and continue to build their own capacity to meet participants medical, social, and psychological needs, for example, by applying for grants to offer ART, by becoming a WFP site, and by supporting a psychosocial support group. The site does continue to refer for certain things during a trial, such as pregnancy, labor and delivery, and certain adverse events, to their main and long-term partner – Mulago Hospital. With this partnership, the site seems to be working towards an ideal in which they provide holistic care for participants' and their families on site or at Mulago Hospital.

The site continues to have partnerships with HIV/AIDS care and treatment centers for when a trial ends. Some of these partnerships are stronger than others. The strongest partnerships are with IDI and PIDC at Mulago Hospital. There are no formalized partnerships with other care centers in Kampala. HIV+ participants (adults and children) who transition to other organizations after their study participation are not followed up. The site has tried to institute a feedback loop with IDI and PIDC, but it was not successful. Participants are provided with a referral letter to present at other care and treatment centers.

REFERENCES

Bennett Swingle, Anne. 2001. The Pathologist Who Struck Gold." Hopkins Medical News. Accessed on November 13, 2006 at www.hopkinsmedicine.org/hmn/S01/feature.html

Garbus, Lisa and Elliot Marseille. 2004. "HIV/AIDS in Uganda". San Francisco: AIDS Policy Research Center, University of California San Francisco.

"Joint Clinical Research Centre – Projects." Accessed on November 13, 2006 at www.jcrc.co.ug

Uganda Ministry of Health. "Ministry of Health Online." Accessed at www.health.go.ug on November 13, 2006.

US Embassy Kampala. 2006a. “President’s Emergency Plan for AIDS Relief – Uganda Success Stories” Accessed on November 13, 2006 at http://usembassy.state.gov/posts/ug1/wwwhsuccess.html

US Embassy Kampala. 2006b. “President’s Emergency Plan for AIDS Relief - Country Profile: Uganda” Accessed on November 13, 2006 at http://usembassy.state.gov/posts/ug1/wwwhfaqs.html

UNC Project, Tidziwe Centre, Lilongwe, Malawi

Natasha Mack

HISTORY OF THE SITE

The University of North Carolina Project (UNC Project) is a collaboration dating to 1999 between the University of North Carolina and Kamuzu Central Hospital (KCH), a government hospital operated by the Malawi Ministry of Health (MOH). UNC-Project is located in the Tidziwe Center, a two-story 20,000-square foot building on the KCH grounds completed in 2003. The bottom floor is dedicated to 14 exam rooms, the clinic pharmacy, and a lab. The lab is equipped to conduct sophisticated tests including acute HIV testing, serum and cell separation and storage, and HIV viral load testing. Staff offices, a lecture hall, a conference room, and a library with on-line services are located on the second floor of the Tidziwe Center.

UNC Project Tidziwe Center offices in Lilongwe, Malawi (K. MacQueen, 2004).

The collaborative partnership between UNC and KCH involves significant contributions on the part of UNC to KCH, including staff time, lab use, medical and office supplies, pharmaceuticals, facilities, funding, and technical support. The partnership is monitored by the UNC-Project clinical director, who attends KCH management meetings and verifies staff fulfillment of time commitments to KCH. UNC clinical staff contribute 20% time effort to patient care, providing staff for the KCH Admissions Room, Medical Ward, Lighthouse HIV/AIDS clinic, and STI Clinic. UNC lab staff contribute up to 10% effort through occasional support and testing of KCH patients. UNC also funds a competitive salary (equivalent to private sector rates) for one KCH lab technician skilled in blood transfusions. It funds the salary of one clinician at Lighthouse, plus nurses and a receptionist. In addition, UNC purchases office supplies like paper and stationery; equipment such as blood pressure gauges, thermometers, and furniture; and on an "emergency" basis medications and medical supplies including gloves and antiseptic. In actuality, UNC fills orders for KCH supplies on a fairly regular, ongoing basis due to the chronic shortage of drugs and supplies at KCH. The UNC-Project conference rooms, lecture hall, library, and internet services are available to KCH staff free of charge. Funding assistance includes an annual contribution to KCH as rental compensation for the study clinic location on KCH grounds, and payment of KCH communication expenses, including telephone bills and the annual internet subscription. Technical assistance is also offered as needed, such as when they provided a computer consultant to set up the KCH web site (currently no longer in operation).

Current HPTN studies at UNC Project are 035 and 052. HPTN 035 is a Phase II/IIb Safety and Effectiveness Study of the Vaginal Microbicides BufferGel and 0.5% PRO2000/5 Gel (P) for the Prevention of HIV Infection in Women. HPTN 052 is a randomized trial to evaluate the effectiveness of antiretroviral therapy plus HIV primary care versus HIV primary care alone to prevent the sexual transmission of HIV-1 in serodiscordant couples. UNC-Project has study activities unrelated to HPTN at Bottom Hospital, also a government facility located in Lilongwe, including the Breastfeeding Antiretroviral and Nutrition (BAN) study.

Health care and treatment in the government health system is free in Malawi, including clinic visits, hospitalization, tests, and medication. Some "private", fee-paying wards are available at government hospitals. Their advantage is a more private hospital room involving fewer beds and patients per room, but there is typically no difference in care in the free versus fee-paying wards. The standard of care at government institutions is hindered by chronic shortages in qualified medical personnel (doctors, nurses, medical officers) resulting from Malawi's professional "brain drain", and in basic supplies such as gloves, sutures, antiseptic, and paracetemol.

PARTICIPANT HEALTH CARE AND TREATMENT NEEDS

UNC-Project study participants and their children receive routine, outpatient medical care from clinicians at the UNC study clinic. This care is provided at scheduled study visits and between visits as necessary. Transport reimbursements are not provided for the non-scheduled visits. Both current HPTN studies have standard operating procedures (SOPs) for referral that specify the forms required, whom to contact on the KCH ward, and how to document referrals for the study. The referral form consists of a standard UNC triplicate book. One copy remains in the book, a second goes in the study file, and the third is sent with the participant to the referral site.

Most study participant referrals for care are to clinics within the KCH system. As with all government health facilities, care at KCH is free whether for study participants or non-participants. The exception is the fee-paying wards, but these are always optional. Study participants do, however, have the advantage of expedited access to KCH services and facilities, and sometimes to treatments, lab tests, and medications provided by UNC that are not available to non-participant KCH patients. Some study participants admitted as patients receive primary medical attention from the study clinician rather than the KCH ward clinician. This occurs in an unofficial capacity rather than through formal agreement.

Below are listed the most common study participant care and treatment needs and how these are met, whether at UNC Project clinics or at referral sites.

SEXUAL HEALTH

Antenatal and maternity care

Pregnant women are not eligible to participate in current HPTN studies. For those women screened out as pregnant prior to enrollment or who become pregnant during a trial, referrals for antenatal and maternity care are made to Bottom Hospital (free), or to KCH for the more private, fee-paying ward. Women found HIV+ and pregnant at screening or during the study are referred to Call to Action, a PMTCT program funded by the Glaser Foundation and operated out of Bottom Hospital. Subsequent to giving birth, women are then referred from Call to Action to the UNC Project's BAN (Breastfeeding Antiretroviral and Nutrition) study. Call to Action is not a UNC effort, but UNC is helping to finance the opening of two hospital centers for PMTCT programs. The government health system will eventually take over management of these programs once they are in operation.

Family Planning

Family planning services for hormonal methods (depo provera and oral contraceptives) are available to study participants at the UNC clinic. All participant FP clients undergo an initial pelvic exam, including women already on hormonal methods and who want to continue, and women new to FP. For other FP methods such as Norplant or IUD, participants are referred to Bottom Hospital. They are not tracked formally but pregnancy rates for these participants indicate that women do not always follow through with referrals to outside FP services. Participants may obtain condoms (for dual protection against pregnancy and STIs) at the UNC Project FP clinic (HPTN 052) or at their study visits (HPTN 035), depending on the study.

Gynecology

UNC contracts services with an ob/gyn from Bottom Hospital labor ward for non-routine gynecological exams and procedures that a medical officer or nurse would not be qualified to perform, such as colposcopies. The ob/gyn comes to UNC Project one day each week for this purpose.

STI

STIs require no referrals because they are treated at the study clinic. The STI clinic does however frequently refer patients to UNC Project studies. The STI clinic is technically part of KCH, but at this time the hospital is unable to staff the clinic. UNC therefore provides a full-time clinician and 3 or 4 nurses. The government system provides the drugs for the clinic, but UNC acts as a buffer in the event of potential stockout. As a government facility, the clinic also serves as an occasional training institution for students training in the health field. UNC and MOH management meet quarterly to discuss any issues that arise from the partnership.

Condoms

Upon study exit, participants are advised that male condoms are available at the National AIDS Commission, MANET, and District AIDS Support Organization. Interest in female condoms has been expressed at study and community support groups, but they are currently unavailable for free distribution.

GENERAL AND EMERGENCY

TB Testing and Treatment, Malaria, X-rays and scans

Participants in need of TB testing and treatment, malaria treatment, x-rays, and scans are referred to KCH.

Adult Hospital Care

In general, study participants in need of care are encouraged to come to the study clinic before going to KCH. If clinicians determine that inpatient hospital care is needed, they refer the participant to KCH Admissions for the medical ward.

The admissions room for the KCH medical ward was set up with UNC-Project funds and is staffed by one UNC clinician two full days each week, a full-time nurse Monday through Friday, and a full-time clinic aid who cleans and stocks the room and runs errands within the hospital. All drugs administered in admissions are purchased by UNC. The medical ward itself is severely understaffed but does not benefit from the regular presence of a UNC clinician.

Study clinicians often come to attend to their referral patients, but this does not typically involve after-hours care or non-participants.

The medical wards face a continuous shortage of supplies, including gloves, antiseptic, paracetemol, and qualified medical staff. There are currently no plans to increase UNC staff contribution to the medical ward. However, in the event of new studies having a large hospital component and potential impact on the hospital, such as a study involving early or late-stage TB, a more substantial presence of UNC clinicians on the ward would be needed. Under the current arrangement, there has been interest on the part of both medical ward and UNC clinicians to engage in more collaboration, such as a weekly consultants round in the ward. This would be an opportunity for UNC to offer services like lab tests and medications for non-participants, and for all parties to share and benefit mutually from their combined experience and expertise.

Many UNC-Project referrals are seen in the medical ward, but estimates of how many are unavailable. The ward receives no referral paperwork specific to UNC. Verbal communication regarding participant referrals may take place, but this occurs informally and at each clinician's own initiative. For example, a UNC-Project clinician may call the ward clinician to say that a participant is being referred and to describe the participant's medical case. However, there is no standard referral form or written communication between study staff and the medical ward staff concerning participant referrals. UNC nurses may however copy source document files to send to KCH. Sometimes UNC study staff are themselves unaware of a participant's admission to the hospital because the person went straight to the hospital rather than coming first to the study clinic.

Medical ward staff sometimes become aware that particular patients are study referrals when a UNC clinician comes to the ward to see the patient. Once medical ward staff see that the patient is being attended to, is receiving special treatment and perhaps special drug treatments from a UNC clinician, they consider him/her to be the UNC clinician's patient. It is normal protocol to respect the jurisdiction of any clinician with special interest in a particular patient. (In this case, medical ward staff consider the ward to be in essence providing the space, and UNC the clinician and medications.) Given the staff shortage in the wards, this could potentially be an effective arrangement. As an informal process, however, it can unclear who is responsible for providing the ongoing, regular care.

HIV/AIDS

Children (of participants) suspected or found to be HIV+ are referred to the KCH pediatrics HIV clinic [see ***Pediatrics***]. All adults who screen out as HIV+ prior to study enrollment or who seroconvert during study participation are referred to Lighthouse for HIV/AIDS care and treatment. Lighthouse is the outcome of a local government initiative launched in 1999 to relieve congestion in the KCH wards of patients with HIV/AIDS-related illness. Located a few minutes walk from UNC Project on the KCH grounds, it is currently the only referral option for HIV/AIDS care and treatment in Lilongwe and has the highest standard of HIV care in Malawi. Services include the ARV clinic, training for home-based care, and VCT. VCT is also available at multiple district health centers throughout the country. The National AIDS Commission, in an effort funded through support from the Global Fund, has set up all government hospitals to begin offering ART in the near future. At the time of referral, most study participants do not yet need ART. By the time ART does become an issue for them, access is likely to be more feasible than it is currently.

Entrance to Lighthouse, the HIV/AIDS care and treatment center in Lilongwe, Malawi (N. Mack, 2006).

UNC shares a close relationship with Lighthouse. Directors and other high-level staff meet formally two to three times per year. Staff from each organization communicate informally regarding day-to-day management, patient, and staff issues. UNC provides the equivalent of one full-time study clinician to work at Lighthouse by means of staff time contribution. Most UNC clinicians contribute one day or one half-day per week.

Until 3 years ago, all Lighthouse patients were required to pay for ART and CD4 counts, but these are now provided free of charge. CD4 counts are not conducted routinely. If the person meets the criteria for WHO stage 3 or 4, CD4 counts may be done and the person started on ART. Guidelines are in the process of being revised to begin a patient on ART if their CD4 count is below

250 rather than below the current limit of 200. A person at WHO stage 1 or 2 is followed in primary care.

Capacity at Lighthouse is of great concern, with many more potential clients appearing on any given day than the facility can accommodate. Only 180 patients may be seen per day, a maximum of 20 of whom can be new patients. These quotas were implemented because the clinic was running too late, up to six or seven o'clock each evening. The specific numbers chosen for the quota reflect the number of people for whom Lighthouse can guarantee continuous ART within the constraints of its current budget, supplies, and staff. It is preferable for the majority of Lighthouse patients to be eligible for or already on ARVs rather than those in stage 1 who only need primary care. To alleviate the problem of people waiting all day to be seen and then not making the quota, patient registration for each day ends at noon. Those not on the list must return another day. ARVs are provided for a 32 day-supply. Once patients are considered to have stable adherence, they are given a two-month supply to reduce the number of visits they have to make.

UNC-Project study participants referred to Lighthouse have priority for receiving care. This priority status is evident in practice only; that is, it is not advertised to study participants as a benefit, nor is it specified in any contractual agreements. However, priority access to care is a distinct advantage for participants over non-participants. This advantage is illustrated in that people camp out overnight to ensure their place in the following day's quota, so great is the demand. People with the ability to camp tend to be those healthy enough to do so, usually in stage 1 or 2. Despite the disparity between supply and demand, Lighthouse staff do not consider UNC-Project study participants to affect non-participant access substantially because studies actually refer very few participants to Lighthouse at any given time.

Since 2005, Lighthouse has seen 250 people who were clearly UNC-Project referrals. There may also be additional people not identifiable as referrals. UNC is currently setting up new procedures to systematically track the date the referred person presented at Lighthouse and whether the person was seen. Lighthouse in turn routinely refers clients to UNC-Project studies when appropriate, but these number few. More frequent are Lighthouse referrals to Call to Action for women in need of PMTCT.

Once a UNC referral is made, all available clinical research data on the person is forwarded from UNC to Lighthouse. Study staff often follow up referees informally during their staff contribution hours at Lighthouse. It is possible that UNC studies involving participants on ART may feature a different drug regimen from the government first-line regimen. In such a case, UNC would modify the person's treatment to the government ART regimen after the completion of study follow up.

A second Lighthouse location is planned to open in 2007 at Bottom Hospital. It will be connected to the TB registry, which constitutes a great improvement. Transport to get to Lighthouse (at KCH) is double the cost of transport to Bottom Hospital, where the TB treatment takes place. Patients therefore typically delay going to Lighthouse until they complete the TB treatment at Bottom Hospital first. The new location will alleviate this issue. Approximately 75% of TB patients are also HIV+.

PEDIATRICS

Participants often bring sick children to their study visits. Those children requiring outpatient care are seen by study clinicians. Clinicians refer children in need of hospitalization to the KCH pediatrics ward. Children infected with HIV are referred to the pediatrics HIV ward. In both cases, they receive priority in the queue. The rational for treating children as part of UNC study participant care is that if sick children were not treated at the study clinic, women could wait several hours to be seen for their study visit, then have to go to the pediatrics clinic afterwards and wait again for many hours. This may not be feasible in terms of women's time and transport arrangements. In addition, the clinician shortage at KCH can sometimes mean that not everyone receives same-day care.

A new, state-of-the-art HIV facility for children, called the Baylor Clinic, is being built with a trust from Baylor University. Plans are for the KCH pediatrics HIV ward to be subsumed within this clinic. Eventually, the Baylor Clinic will have a family focus and will be the main HIV referral institution for HIV/AIDS care in the region.

As with other KCH services, pediatric care is provided free of charge. Clients may pay for a more comfortable room for their child, but care is identical for paying and non-paying patients.

Many referrals from UNC study participants are seen in the pediatrics ward, but there is no system in place to track the exact number of participant children referred versus how many actually make it to the pediatrics clinic. Pediatrics staff estimate only a small percentage of daily admissions to be study referrals. Of the 30 to 40 children admitted to the pediatrics ward per day, 2 or 3 of these may be referrals. Children referred from UNC studies are typically intended for admission. Although referral documentation is not provided, if the referring clinician thinks the child should be admitted, admission papers are prepared and sent with the child to pediatrics. This documentation consists of the regular admissions forms rather than a separate document recognizable as a referral.

PHARMACY

Study participants obtain prescriptions and medications free of charge at the UNC-Project clinic pharmacy located on the same floor as the examination rooms. The pharmacy keeps a daily supply of study products and commonly prescribed medications, such as flu mixtures, paracetomol, and antibiotics. It is open to study participants exclusively. Participants (or their children) who have been admitted to KCH wards often also benefit from medications in the UNC-Project pharmacy supply not available at KCH. These medications may be provided to the participant by a study clinician continuing to see to care in the ward.

SUPPORT GROUPS

While UNC Project research studies are ongoing, participants attend study-specific HIV/AIDS support groups. For the BAN study and Call to Action program, participants were responsible for instigating and organizing support groups among themselves once the study/program began. Support groups are likely to remain study-specific because participants of different studies/programs may not have the same HIV status. The support groups serve as a forum for discussion of issues relevant to their particular situations. Participants are also helped to access small bank loans that will allow them to start up income-generating activities.

Upon study exit, participants are referred by study staff to community-based organizations for HIV/AIDS support groups and home-based care. Community-based groups in Lilongwe include NAPHAM, KASO, and Catholic organizations open to people of all faiths. Participants do not typically join community support groups prior to study exit, but during individual counseling sessions health staff encourage them to begin considering the available groups. The goal is for the participant to select a specific group by the end of the study. Once the participant has chosen a group, at study exit, study staff provide the participant with a referral letter to that specific organization. Proximity to the person’s residence is usually the deciding factor in support group selection. Advice from friends can also play a role.

NAPHAM has been a UNC-Project referral site since 2002. It has also been active in the CAB and has contracted with UNC’s drama group for community sensitization activities. NAPHAM has locations in two districts, Lilongwe and Kasungo. Activities and services include multiple group meetings per week, a children’s support group, pre- and post-test counseling, VCT referral, individual/couple/family counseling, HIV/AIDS community sensitization, and home-based care. Counselors include one salaried staff member and volunteers trained in psychosocial counseling. Registration in NAPHAM is required for membership. Currently, there are over 400 registered members. The referring organization for each person is indicated on the registration form. However, there has been no systematic tracking of the number of people UNC has provided with referral letters versus how many have registered with NAPHAM.

KASO holds weekly support groups with a mixture of men and women. They discuss positive living, ARV adherence, discrimination and stigma, home and family issues, sexuality, condom use, the need for community sensitization, and poverty. All counselors are volunteers.

KASO volunteer staff members in Lilongwe, Malawi persevere despite difficult conditions. At the time this photo was taken, the organization did not have the means to provide a meal for support group members to share after meetings. One member stated that the worst challenge in the PLWHA community was not having any food to take with ARV pills, which are not supposed to be taken on an empty stomach (N. Mack, 2006).

Until recently, there has not been a system in place to track whether referees attend the support groups for which they have referral letters. Some community educators associated with the study do phone clients to check up on them, but this happens of their own volition rather than according to a policy. Lack of feedback from those referral sites was regrettable, but staff considered that it would be impracticable to burden support group staff with UNC referral tracking responsibilities. The new referral box collection system is expected to improve this situation.

UNC has been referring study participants to NAPHAM upon study exit since 2002. NAPHAM itself began in 1993, and has support groups in Lilongwe (205 members) and Kasungo (208 members). Its main sources of clients, in addition to UNC, include Lighthouse, Macro FP Association of Malawi, and government hospitals. Group meetings are held once weekly on different days of the week. There is also a Saturday general meeting attended by 100-150 members. Childcare for both HIV+ and negative children aged 3-13 years is provided during support groups. It includes a combination of recreation and information on positive living, how to care for sick parents, psychosocial support, and fighting stigma. It is typically attended by 30-45 children. All but one counselor are volunteers who have gone through counselor training.

Home-based care

Referrals for home-based care, specifically, are generally not made at UNC because study participants are not sick enough to require this service. Nonetheless, because home-based care is provided by community support groups, participants referred to those groups at study exit will have access to home-based care support groups should they need it in the future. NAPHAM, for example, offers home-based care in addition to support groups.

Home-based care typically functions such that a support group counselor might learn that a group member is need of aid, for example if the person does not attend the weekly support group due to being ill. The support group counselor then goes to the person’s home to perform light housework, get water and firewood, and work with guardians on the importance of adherence and other care issues.

CHARACTERISTICS OF SUCCESS AND BARRIERS TO EFFECTIVE REFERRAL SYSTEMS

The keys to success in the UNC Project referral relationship with KCH include:
- Ongoing communication
- Collaboration between the study and referral site personnel
- Resource sharing
- Direct access to referral site—liaisons, escorts, handovers, and follow-up
- Documentation
- Community liaisons such as CAB members

Success of referral processes can be attributed largely to cooperative relationships personnel at the HPTN and referral sites develop and maintain. These cooperative relationships are characterized by frequent telephone communication regarding individual referral cases, periodic regular, scheduled meetings of staff from each organization to express and address issues of concern, and informal discussion occasioned by fortuitous meeting of relevant personnel. Some referral cases will call for more communication than others.

Effort at the levels of individual staff members and the organization management emerges as fundamental to a successful referral process. Cooperative relationships involve communication, a mutual recognition of each organization’s needs, and a willingness to share resources within reasonable limitations in order to meet these needs. Resource sharing might consist of personnel time, labs, pharmaceuticals, supplies, beds, etc.

Liaisons whose role is to accompany referred participants to referral sites and do “handovers” to a direct contact can be essential for ensuring that participants arrive at the referral site and receive medical attention without delay. This is particularly true if the participant has been recommended to go to the referral site the same day for medical reasons. It is also important for participants referred to sites located at greater than walking distance and may involve provision of transport. For people unable to go directly to the referral site due, for example, to household obligations, follow-up with the person is needed, as well as a way to identify them as a study participant referral when they do present. The benefit of priority in the queue tends to be lost in the absence of same-day escorts and when participants delay in going to the referral site. In addition, clinicians may not learn that the person was a study participant until after the person has spent several hours waiting to be seen.

CAB members can greatly facilitate the referral process when there are things going on in the community that might affect participants’ willingness or ability to follow through with referrals. Their work could include community sensitization activities for individual studies and particular health needs, encouraging follow-up of referrals, and dispelling rumors in the community.

Imprecise tracking procedures render it difficult to tell how much referrals are being utilized. Documentation and tracking of referrals are therefore essential. An effective system will include:

- Templates indicating all essential information (participant ID#, date of referral, date of presentation at referral site, referring source, referral site)
- Copies of referral documents for referral and referring sites
- Minimal action required at the referral site
- Minimal time on the part of clinicians
- Procedures for tracking whether individual participants have presented at the referral site
- Procedures for comparing the number of people referred versus how many have presented

Barriers to success include:

- Lack of communication
- Conflicts related to disparities in resources, staffing, and work conditions
- Transport between study clinic and referral site
- Participant poverty

Lack of communication between the HPTN and referral sites prohibits the referral process from running smoothly. This is sometimes the result of interpersonal conflict or a spirit of competition stemming from a larger issue—disparities in resources and working conditions at UNC Project versus referral sites.

Disparities include higher numbers of qualified nurses and clinicians at research sites; better salary levels offered in research clinician versus government positions; and more opportunities to go on leave to prevent staff burnout. In addition, research clinics have the ability to counter the brain drain by hiring staff from abroad through attractive salary packages. Opportunities for further training and educational advancement are greater for research clinicians than government employees. There are significant differences in the medical supplies and facilities available to each, affecting standard of care. The workload is more manageable for research clinicians than referral site clinicians. Working hours differ: research clinicians do not work night shifts. Researchers have the luxury of working towards running efficient study clinics, but this goal is impossible in the government system due to scarcity of resources. All of these factors affect morale.

From the participant perspective, issues of transport and poverty affect the extent to which they can take advantage of referrals. If referrals are made to a location not within walking distance of the clinic, transport costs can be difficult to cover. For example, there is no direct public transport going from Bottom Hospital (where UNC's BAN study is located) to KCH. The trip requires two bus rides and walking nearly a kilometer through the city center, where there is danger of being attacked by thieves. Recognition of the impact of poverty on people's ability to follow through with referrals is important.

VIGNETTES ILLUSTRATING PROBLEMS OVERCOME, OUTSTANDING CHALLENGES

Escorts

Referral issue

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" 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 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.

Solution

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 prevent them from 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.

Outstanding obstacles

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.

Referral boxes

Referral issue

UNC refers participants out for care to the KCH medical, pediatrics, and maternity wards, Lighthouse, Bottom Hospital antenatal and maternity services, and community-based support groups. Individual referral cases may be followed up at the personal initiative of study staff, but overall counts of how many people are referred versus how many present to the referral site were not being conducted systematically. This created a communication gap that precluded opportunities for getting/giving feedback from/to referral sites. Participants who may have decided to use the referral with some prompting from an outreach worker may slip through the cracks.

Solution

In order to systematically track how many referrals report to the referral site and identify which specific participants do and do not report to the referral site, UNC is implementing the use of referral form boxes. This system involves minimal paperwork and time effort. UNC staff have created a new referral form template in triplicate book format: one copy for the participant file, one copy to remain in the referral book, and the third sent with the participant to the referral site. UNC staff will place a referral box at the reception of each referral site and return on a monthly basis to collect it. In the meantime, staff from the referral site will fill in the date on the referral form the participant has brought and deposit the form into the box. Indicated on the form are the UNC study, the participant ID number, date of referral, and reason for referral. The referral site could also write down any additional information, such as whether the person was admitted or started on ARVs, as feasible. Similar tracking systems have worked well for area support groups.

Outstanding issues
It remains to be seen how much of a burden these procedures will place on UNC and referral site staff. UNC had not been using a referral form at all for many of the sites. Once participants who do not present at the referral site are identified, decisions regarding follow-up will have to be made.

Resource sharing

Local hospital issue
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 at KCH. 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.

Solution
A new collaborative arrangement between the UNC Project pharmacy and the KCH medical ward commenced in April 2006. In this arrangement, the UNC Project pharmacy supplies a small stock of drugs for the male and female medical wards of KCH. This is kept in a small, 24-hour “pharmacy” in the medical ward itself rather than in the UNC-Project pharmacy or the KCH pharmacy. The initial stock was based on need estimates made by the ward clinicians who collaborated on the project. Quantities will be re-evaluated after 3 months. Thereafter, the medical ward will place an order with UNC-Project every 3 months according to a fixed budget. UNC will continuously finance this effort.

Resource Sharing

Local hospital issue
The STI clinic is part of KCH, 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.

Solution
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 then UNC provides the remainder of the drugs and supplies needed.

MRC, Durban, South Africa

Kerry McLoughlin

HISTORY OF THE SITE

The Medical Research Council (MRC) in Durban is a non-profit research organization. Through their HIV Prevention Research Unit (HPRU), they coordinate several studies on microbicides. Gita Ramjee is the principal investigator of the PTN site, and also the unit director of the HPRU. Neetha Morar is the Senior Scientist and Research Manager at the HPRU, and coordinates community related activities for the HPTN studies. Mark Pillay is the community liaison officer (CLO) for HPTN studies. His main duties include building and maintaining community partnerships and coordinating the referral system. Dr Roshini Govinden is the project manager of the HPTN 035 trial and Nicola Coumi is the project leader of the trial for the Durban site.

Outreach clinic at RK Khan Hospital in Durban, South Africa. Located next to the study clinic on hospital grounds, primary care, VCT, and ART care are provided in this building by nurses (K. McLoughlin, 2006).

The site is currently coordinating HPTN 035. 035 is a Phase II/IIb Safety and Effectiveness Study of the Vaginal Microbicides Buffer Gel and 0.5% PRO2000/5 Gel (P) for the Prevention of HIV Infection in Women. HPTN 035 is conducted at the Chatsworth study site. Chatsworth is about 20 minutes outside of Durban. The study site is located on the grounds of RK Khan Hospital, a district regional hospital, run by the government. The site also conducted HPTN 055 at the Chatsworth site. 055 was a prospective cohort study conducted to prepare sites for HPTN 035.

MRC first established a presence at RK Khan Hospital in 2000 during HIVNET 020 (HPYN 020). They had a study office in the hospital itself. In 2002, the HPRU secured research space from the hospital and they moved the study staff into two pre-fabs located on hospital grounds, next to the Primary Health Clinic and VCT/ARV clinic. The study clinic is located far enough from the main hospital building to insure some privacy for study participants coming to the study site.

BRIEF OUTLINE OF HEALTH CARE/SERVICES STRUCTURE

South Africa is the only high income country in Africa. Despite this, about half of the population lives in poverty and the unemployment rate is almost 40% (www.southafrica.info accessed on November 13, 2006). Durban is the second most populated city in South Africa with a population of 3.2 million. Durban has the largest Indian population in South Africa. The racial/ethnic breakdown for Durban is as follows: 68% Black African; 20% Indian; 9% White; 3% coloured. The majority of the Durban population is Christian (68%) and about a third (36%) completed high school. Chatsworth is a suburb of Durban, and where the 035 study clinic is located. Chatsworth was developed as a township for Indians in the late 1960s and early 1970s, and still has a large Indian population (http://en.wikipedia.org/wiki/Chatsworth%2C_Durban accessed on November 13, 2006).

South Africa has a large public health sector, which was expanded and revamped after the 1994 democratic elections. The public sector provides mainly basic care to low-income members of the population, and has moved away from providing tertiary care. The public sector is overburdened, understaffed and lacking resources as it serves about 80% of the country's population. Public facilities charge patients for services who earn an income, but not indigent patients. Primary health care is provided through clinics run by provincial health administrations. Health care is free for children under six, pregnant women, and breastfeeding women at local clinics (http://www.doh.gov.za/docs/reports/2002/inquiry/sahs.pdf accessed November 13, 2006; http://www.southafrica.info accessed November 13, 2006).

The public health system is moving to a district-based health system. Primary health care clinics will be controlled by district authorities while public hospitals will be managed from the provincial level. There are nine provinces and 162 health districts throughout the country.

South Africa has a small, growing private sector, which first expanded after desegregation of the health care faculties in the early 1990s. The private sector mainly serves middle and high income citizens, about 20% of the population.

Specialized and advanced health care services are available through the private sector. About 18% of the South African population are members of a medical scheme (health insurance plan) and mainly access care through the private sector (http://www.doh.gov.za/docs/reports/2002/inquiry/sahs.pdf accessed November 13, 2006; http://www.southafrica.info accessed November 13, 2006).

South Africa has a major HIV/AIDS epidemic. The 2005 prevalence rate among adults 15-49 was 18.8% (UNAIDS 2006). Despite being a PEPFAR country, providing HIV/AIDS care and treatment in South Africa has been a struggle due to resistance from the President Mbeki, the Health Minister, and AIDS denialists. The ARV rollout finally began in 2004, after a legal battle which forced the government to allow the rollout (Nattrass 2006). Now, ART is available free to citizens through at least one health care facility in each district of the country (http://www.avert.org/aidssouthafrica.htm accessed November 13, 2006). However, less than 20% of those who need ART are receiving it (UNAIDS 2006). The shortage of health care professionals due to a brain drain is a challenge, as there are not enough staff to care for HIV/AIDS patients (http://www.irinnews.org/print.asp?ReportID=43334 accessed November 13, 2006).

What are participant needs and how are they being met?

HIV/AIDS

The participants in HPTN 035 are HIV- women at-risk for HIV infection. The major endpoint for the study is HIV infection. As of March 2006, the site had only a few seroconverters. They had identified136 women out of 500 during screening who were HIV+. Seroconverters are invited to continue their study visits and receive counseling from study staff. HIV + screened ineligibles are offered 3 follow-up counseling sessions. Counselors will make a courtesy phone call to seroconverters and screened ineligibles to find out if she has accessed the referral centre, and if she has run into any issues. However, courtesy calls are up to the counselors' discretion and also based on counselors' availability of time, whether participants have contact telephone numbers and can talk privately on the phone, and needs assessment by counselors. Not all participants are called for these reasons. Seroconverters and screen failures are provided an official referral form to take to the HIV care and treatment centre in the area.

The VCT/ARV clinic at RK Khan Hospital is the only referral option for most seroconverters and HIV+ screen failures who live in the Chatsworth area. While there are other government hospitals throughout Durban, patients are only allowed to access care at the hospitals in their area of residence. This is based on the district health care system and public health referrals process. Most participants cannot afford to pay for care, so the public clinics are their only option.

The lack of options is a problem for some patients because of fear of stigmatization. The VCT/ARV clinic does not offer much privacy. While it is located away from the main hospital, the waiting areas are not enclosed and are open to the parking lot. According to staff, some women are fearful of seeing anyone they know at the clinic. For those with limited means, they have two choices: go to the clinic in their area, or do not go at all unless they are able to gain access to other clinics if staying with relatives and family in those areas. Some staff feel that fear of stigmatization may lead some women to choose the latter.

A major strength of the VCT/ARV clinic is that it is part of the government ARV program. Through the government ARV program, seroconverters and screened ineligibles can access care and treatment free or at minimal cost. Proximity to the study clinic is also a strength; the clinic is located next door to the study clinic. The VCT/ARV clinic provides some social support, as they provide nutritional supplements to some patients in need.

A major challenge for the clinic is that it has many patients, is understaffed, and lacking space. There are three doctors, and two nurses. The hospital is in the midst of a nursing shortage, and two of the nurses have been pulled from the PHC to the hospital. Nurses in the PHC also have to make rounds in the main hospital each day. According to the nurse in charge, they see 200 patients a day.

For the staff and patients they have, they have little space. The ARV offices were created by taking space from the PHC. The PHC is on one half of the building, and the VCT/ARV clinic on the other half. The hospital had just begun construction on a larger building to be used as a VCT/ARV clinic. When completed, this will improve the quality of care and lead to less cramped quarters, but it is not known when the building will be completed.

The clinic faces a challenge because it does not have its own lab. The clinic must send out for CD 4 tests to be conducted. It can take up to 4 weeks for the results to come by mail. The clinic does not have internet access in order to check results online.

On the positive side, stockouts of drugs are not common. Also, none of the staff at the hospital felt that caring for study participants is a burden, since they live in this area anyway and would come for care there whether they were in the study or not.

MRC has a Memorandum of Understanding for Referral of Helath care for Clinical Trial Participants with the Hospital. The MOU states that the RK Khan HIV clinic will “absorb participants” who live in their catchment area.

Study staff also refer seroconverters and screened ineligibles to two studies: the SPARTEC study and a CAPRISA study**.** SPARTAC is a multicentre trial looking at short pulse ART treatment in early seroconverters. It is a three arm trial with a long, short and no treatment arm. The CAPRISA research study is a follow up of early seroconverters where women are monitored over a period of time. Extensive immunologic tests are conducted to detect early markers (maybe) for progression to AIDS and participants receive treatment for opportunistic infections and given ARVs if they qualify for them. The CAPRISA staff provided MRC staff with a short info sheet of the study that they provide to seroconverters. According to one of the study coordinators, most participants choose to pursue the SPARTEC study, as the staff come to Chatsworth. Participants must travel to the MRC office in Westville for the CAPRISA study, which is about 20 minutes from Chatsworth.

It may be challenging to transition seroconverters to community services. At this point, study staff only know for sure that one seroconverter regularly attends the VCT/ARV clinic. Some of the women have become attached to the study counselors.

Medical Needs

Most Adverse events are handled at the study clinic. For AEs that are very serious, participants are referred to RK Khan Hospital. For example, one woman was bleeding heavily, so they brought her to the hospital in a wheelchair.

The most common referrals for study participants are to the Gynecological Department in the hospital. One of the doctors in the department is a consultant with MRC. The study staff feel that this makes communication with the department easier. Also the doctor said he makes sure participants do not get lost in the hospital system. The waiting queues are long at the hospital. He helps move them through the system faster. He sees them the same day the clinic contacts him about a participant, or schedules them to come to the GYNE clinic the next day he is working there.

The study staff test women for two STIs - gonorrhea and syphilis. Women who test positive are treated on site. Study staff also treat participants if a woman is symptomatic for other STIs. Patients with a viral STI would be referred to the hospital. If staff have questions about STIs, they contact the MRC consultant in the hospital, and/or refer the participant to him if necessary.

Participants receive family planning (FP) counseling from study counselors. Participants in 035 who become pregnant must discontinue their use of the study product. As this is undesirable for the study, staff take steps to reduce the likelihood of participants becoming pregnant by providing FP counseling and products. Initially, study staff referred women to the RK Khan Family Planning clinic for the initial counseling session, and then received follow-up counseling on site. As the FP clinic is located next to the study clinic, this was convenient.

Beds awaiting patients in a hallway at RK Khan Hospital in Durban (K. McLoughlin, 2006).

However, the site is currently in the process of training study staff to provide comprehensive FP counseling of site. Despite the close proximity, some women did not go for FP counseling. Participants are offered oral contraceptives and injectables. All participants receive condoms. To facilitate adherence to FP, the staff try to schedule participants' study visits to coincide when they need a FP visit. For example, the study visit is scheduled close to the day they need their next depo shot.

Part of the study procedures is to conduct colposcopy at some follow-up visits. However, as staff have limited experience in this area, when the results are difficult to interpret, they ask for assistance from the consultant at RK Khan.

Pregnant women are referred to local government clinics or the municipal clinics. They offer antenatal care (ANC). The ANC at the hospital is for when women near their delivery date and complex cases. Most women do go for ANC in the Chatsworth area. However, the study staff find that the clinical team have to keep reminding participants to access the ANCs as they have a tendency to leave it to the last possible minute.

PMTCT is also available at municipal clinics. However, the Chatsworth community clinic, one of the most commonly used clinics, has not received formula for the HIV positive mothers to use in place of breast milk for about 6 months. Infant formula was also unavailable at the time of the Standard of Care assessment conducted at potential 035 study sites in 2002 by FHI staff

(MacQueen 2003).

Abortion is legal in South Africa. Some women request a referral for a Termination of Pregnancy (TOP). TOPs are available at another government hospital, King Edward Hospital. The procedure is free. However, according to one study staff, women cannot make appointments, and must arrive early in the morning. According to study staff, the referral letter does not help women “jump the queue.” The letter does assist the over-burdened public clinics by providing the woman’s last pregnancy test result and any other information that may be of importance in caring for her.

There are several options for primary medical care. There is the Gateway clinic at RK Khan, next to the study clinic. It is part of the PHC in which the VCT/ARV clinic is located. Participants can also attend the municipal or local clinic they normally do.

For participants who need immediate medical care, members of the study staff will provide transportation for participants. If the participant cannot be reached by phone, study staff will conduct home visits. For example, a participant had an abnormal Pap smear result, and had been referred to the Gynecological Department at RK Khan. However, the woman did not attend her appointment. The outreach staff was sent to find the woman as she could not be reached by phone to let her know she needed to return to the clinic for care.

Social Service Referrals

According to study staff, few participants request referrals for social services. Study counselors said some participants have relationship problems. Relationship issues come to light in the research context mainly because women develop a trusting relationship with the study counselor and other study staff such as field team members. In addition, some participants know that staff are a resource and can refer them to appropriate organizations for help. Some counselors refer women to Chatsworth Child and Family Welfare for marital counseling. One counselor mentioned referring women to the Family and Marriage Association of South Africa (FAMSA) for counseling. However, study counselors agreed that most participants prefer not to take the referral for counseling, but to talk to the study counselor about their relationship issues.

Based on the resource guide and discussions with staff, there are a number of social service organizations in the area, if issues do come up. The CLO and one of the study counselors favored Child and Family Welfare as a referral site for social services, as they worked there for many years. They know the quality of services is high and participants referred there will receive good care. The center is part of government system. They can therefore screen people for disability grants and child support grants to see if they qualify. They place children (in foster homes/adoptive homes). The services are free.

An HIV counselor at Chatsworth Child and Family Welfare, a referral site (K. McLoughlin, 2006).

When asked why participants do not request more assistance with social problems, staff also pointed out that some participants do not request assistance because they are able to access that assistance on their own and/or are already accessing such assistance. Staff noted that community members are aware of the social services available in the area. However, one staff member also noted that many participants feel that just talking to the clinic staff is a help and do not fully understand the possible implications if they do not seek help from the social services to which they are referred. As a result it is a constant struggle to “convince” participants to access the help available.

Partnership with Community Organizations

MRC has built a network of partners with community organizations in Chatsworth over the past six years. The site reached out to community organizations in order to build public support for their research studies and increase research literacy. If awareness, understanding and support for research are high, then it is easier to conduct their research, recruit, and retain participants.

To develop the partnerships, study staff completed a situational analysis and community profile of the community and then contacted local community groups in the community and in areas in which they wanted to recruit, and offered to give presentations on the research. Through this process, the community groups learned about the research study and were able to ask questions. Staff also use the time to dispel rumors and misperceptions about research. For example, there was a rumor they were selling the blood they collected. They showed them exactly how much blood would be taken to combat the rumor. Some people also thought staff were taking pictures of vaginas to sell because they were going to do pelvic exams.

Community members also learned the eligibility criteria for studies, and thus were able to refer clients, patients, or friends to studies. For example, study staff presented at the VCT/ARV clinic of RK Khan Hospital and the nurses said they were able to refer patients who were eligible to the study clinic.

The study staff now work to maintain the partnerships they have developed and ensure that they continue to network with new community groups. One way is by hosting community feedback meetings in Chatsworth twice a year. The community feedback meetings are an opportunity for the Director/PI of the HPRU to provide an update of the research, introduce new studies, and address questions and concerns. Partnerships are also maintained through the activities of the CLO. The CLO visits partner organizations in the area on a regular basis in order to keep the communication lines open. The CLO's visits are informal.

Study staff at the HPRU feels that they have made an impact in raising research understanding in the community. They find that community members ask more complex questions about the research now (ex. Why should we use a condom when trying to test a new product? Vs. What is HIV?). This tells MRC that understanding has increased, and will continue to do so.

Staff at MRC who work with the community organizations admitted that partnering with community organizations can be frustrating at times. For example, community partners ask for help that MRC cannot provide, such as funding. At the same time, staff feel that community partners are not taking advantage of the resources MRC can provide, such as education. For example, MRC offered to talk about substance abuse issues with the male involvement group but no meeting has been organized. The CLO wants the community groups to take responsibility for planning such things, so they do not become dependent upon MRC. On the flip side, MRC staff know that they can work with community groups to organize a meeting, but it takes time and effort. Another frustrating aspect of working with the community is when few representatives from partner organizations turn out for MRC sponsored meetings. For example the last community feedback meeting had only 5 attendees.

In a few interviews with staff from partner organizations, it was clear that partnering with researchers can also be frustrating. Two interviewees felt that the partnership between the researchers and the community is not mutually beneficial. One interviewee, who has worked with the research group for many years, said that he feels that the community organizations are saying 'we support you' but they are not getting all the support they need from researchers. He noted they get moral support from researchers but they need financial support. He said that if partners (community groups) got financial help, 'we will go the extra mile. We will be more supportive of the researchers'. His ideal partnership would be a joint initiative between MRC and his community group with the expenses underwritten by MRC.

Another interviewee felt that the community has not benefited from the research. She said it seems like ‘research is an end in itself’ and ‘we are used as guinea pigs.’ She also said she feels like researchers and community groups work in isolation. She argued for more networking between the two groups and chances for community input into the research.

Study staff that work with the community were aware of these complaints from community partners. The CLO said he knows they have to give something to their partner organizations so they do not get frustrated. Study staff have offered to provide space for meetings and the use of their phone to make fundraising calls. They allow the VCT/ARV clinic to use one of their pre-fabs for group counseling sessions. Staff who live in the area have also volunteered with partner organizations, for example on World AIDS Day and at an advice and information desk one partner organization coordinates at the large mall in the area.

One of the areas in Chatsworth where study staff recruit participants (K. McLoughlin, 2006).

Study staff also try to explain that they do not have funds to share with partner organizations. They emphasize what they can provide: education and training. They also emphasize the partnership should be mutually beneficial. Meaning the research group cannot afford to underwrite partner organization activities unless the activities also benefit the research group.

Study staff are also prepared to deal with the critique that they treat participants like guinea pigs. Staff emphasize the possible future benefits of the research and how the research may help their children be safe. However, the staff recognize it is a constant challenge to maintain a positive image in the community.

The Referral system

The site is unique in that they have a specific person responsible for upkeep of the referral system. The Community Liaison Officer (CLO) contacted community groups, health facilities, and care programs during HPTN 055 and at the start of 035 to inform them of the study, to share information on the study with them, and establish that participants will be referred and/or recruited from there.

The CLO is also charged with communicating regularly with the referral site staff to insure that referrals are not overburdening the site, and that participants are receiving the care they need. There are challenges with this system though. First, even though some referral sites are overburdened, there is no where else to refer participants. Second, it is not clear that organizations “remember” that they are a referral site. For example, at one municipal clinic that women use for antenatal care, the nurse interviewed did not know participants were being referred there. Study staff think that women may not always present their referral slips because they do not want others to know they are in the study.

The site has developed a resource guide for counselors that lists many different types of community organizations in the area, the services they provide, and contact information. Counselors can share information with participants as needed. The CLO updates the information when the need arise, but it is not done in a systematic way. For example, if a staff member calls an organization and the number no longer works, the guide is updated at that time.

Except during study visits with enrolled participants and courtesy calls, there is no easy way to verify referrals. To protect confidentiality, staff cannot ask referral sites if a participant has come for a referral. Some participants do not want others to know they are in a study. As a solution - staff verify referrals in an indirect way by asking if the number of patients have increased and if clients tend to have some knowledge of HIV/AIDS or whatever the issue is when they arrive.

Participants receive a referral slip when they are referred. Study staff reported that participants will use the referral slip to be able to access care at the hospital rather than at the PHC. Some participants prefer to see doctors at the hospital rather than the nurses at the clinic, and will wait for their next study visit before going for primary care in order to get a referral slip. Study staff pointed out that participants can usually skip the line if they have a referral slip. They also get faster appointments, and they may not be asked to pay for services. However, according to the public relations officer interviewed at the hospital, participants are treated like anyone else, and do not receive special privileges.

Study staff keep notes on participant referrals. The notes are kept in the front of participant files, in order to make follow-up easier for study staff. Study staff see the notes during each participant visit, and ask follow-up questions at that time.

STRENGTHS OF PARTNERSHIPS/REFERRAL SYSTEM

- Close proximity to most commonly used referral sites; 5-10 km to referral sites off the hospital grounds.
- Government ARV Program
- Handling of HIV+ screened ineligibles at research site they receive three counseling sessions
- Ongoing communication with referral sites
- Resource guide for counselors to use when participants need a referral
- Efforts to increase research literacy
- Consultant within the hospital to whom most participants are referred for adverse events, and to provide guidance regarding STI treatment and colpos.
- Study counselors willing to counsel participants on non-study related problems, as they often do not want to be referred for counseling (ex. Relationship issues).

CHALLENGES WITH PARTNERSHIPS/REFERRAL SYSTEM

- The main referral sites are short staffed and short on resources, such as equipment and supplies, according to referral site staff. (ex. PHC at the hospital, Chatsworth community clinic, the hospital).
- Some stigma attached to RK Khan Hospital. It is known as a hospital for the poorest of the poor. Some people do not want to be seen there.
- Participants may not go for HIV/AIDS care and treatment because they fear stigmatization. Few other options for participants to access care.
- Community partners ask for help that MRC cannot provide, such as funding.

- Community partners are not taking advantage of the resources MRC can provide, such as education.

- Representatives from community partners not turning out for MRC sponsored meetings. For example the last community feedback meeting had only 5 attendees.

- Except during study visits with enrolled participants and courtesy calls, there is no easy way to verify referrals.

- Relationships with referral sites, beside the Hospital, are not formalized with a Memo of Understanding, but the site does engage in a process to introduce the study to partner organizations and notify sites that participants will be referred there.

Unmet Needs

The Chatsworth area lacks a strong support group for PLWHA. According to a study staff member, most of the “support groups” are more educational about HIV/AIDS than supportive. However, there is a support group at Child and Family Welfare, a non-profit organization. A staff member in the HIV unit there said they the group provides food and clothes to PLWHA. But the group tries to protect the identity of members and does not seem to advertise its services.

RK Khan Hospital must refer TB patients for care, as they do not have the capability to care for them on-site.

Sustainability

As the government ARV program expands, care for PLWHA should remain stable. At RK Khan Hospital in particular, they have begun construction on a new VCT/ARV clinic. Study staff will have to ensure that seroconverters are transitioned to the hospital clinic at the end of the study, as most are currently not attending it.

In terms of social services, the government welfare programs are stable. While the main referral organization, Chatsworth Child and Family Welfare, does partly depend on donations, they also receive 60% of their funds from the government.

One staff member at a referral organization suggested that guidelines on how to carry on the care that research leaves behind be provided to community groups. Community groups need to know if they will need training to be able to provide the services researchers have been providing. For the Chatsworth site, it seems that a strong support group and counseling services for PLWHA are needed in the community to fill the void the study counselors will leave when the study ends.

Recommendations

- Keep the referral notes in patients' files near the front/visible.
- Communication between referral and study staff needs to be ongoing.
- Use established, trustworthy referral sites
- To build partnerships with community organizations spend time talking to community group and be visible in the community

References

"Chatsworth, Durban." Accessed on November 13, 2006 at http://en.wikipedia.org/wiki/Chatsworth%2C_Durban

"Durban." Accessed on November 13, 2006 at http://en.wikipedia.org/wiki/Chatsworth%2C_Durban

"Health care in South Africa." Accessed June 14, 2006 at http://www.southafrica.info

"HIV & AIDS in South Africa" Accessed June 30, 2006 at http://www.avert.org/aidssouthafrica.htm

MacQueen, Kathleen. 2003. HPTN 035 Standard of Care Assessment: Email Survey Results. Family Health International.

Nattrass, Nicoli. 2006. AIDS, Science and Governance: The battle over antiretroviral therapy in post-apartheid South Africa. Unpublished manuscript.

South African Department of Health. 2002. "South African health system: a review" in Inquiry into the Various Social Security Aspects of the South African Health System. Accessed June 14, 2006 at http://www.doh.gov.za/docs/reports/2002/inquiry/sahs.pdf

UNAIDS. 2006. "Chapter 2 Overview of the Global AIDS epidemic." 2006 Report on the Global AIDS Epidemic. (pp. 8-50)

UN Office for the Coordination of Humanitarian Affairs. September, 24, 2004. "South Africa: A health system under pressure." Accessed June 14, 2006 at http://www.irinnews.org/print.asp?ReportID=43334

NARI, Pune, India

Holly McClain Burke

HISTORY OF THE SITE

National AIDS Research Institute (NARI) is the implementing agency for the HIV Prevention Trial Network (HPTN) in Pune, India. NARI, a governmental agency, was established in 1992 under the aegis of Indian Council of Medical Research (ICMR), Ministry of Health. (http://www.nari-icmr.res.in/about.html accessed November 13, 2006). NARI main campus is located in Bhosari, Pune and has its own clinic and laboratory. In addition, six other NARI clinics are located throughout the city of Pune. Four of these clinics are located in hospitals (Sassoon, Talera, Gadikhana, and Jehangir) and one is located in the National Institute of Virology (NIV) which is another ICMR institute. The seventh NARI clinic, Arogya Kendra, is located in the red-light area of Pune. NARI has completed two HPTN protocols (034 and 047), and currently has one active (052) and one pending protocol (059).

Entrance to NARI main campus in Pune, India (H. Burke, 2006).

Pune is located in the western Indian state of Maharashtra. Marathi is the local language spoken in Maharashtra, but Hindi (the national language) and English are also spoken. Hindu and Muslim are the religions practiced most predominately. Pune is an urban city located east of Mumbai (Bombay) where according to the 2001 census over four million people reside (http://censusindia.gov.in/Census_Data_2001/Census_Data_Online/Population.html accessed November 13, 2006). Pune is considered one of the most historic cities in India. It is also known by locals as the “city of knowledge” because of the numerous teaching institutions, and science and technology industries located there which attract people from all over India (http://www.punecity.com accessed November 13, 2006). Pune is also referred to as the “cultural capital” of India due to its relatively progressive stance on women’s rights and the plethora of music, literary works, exhibitions, museums and sports events that can be enjoyed there (http://www.punecity.com accessed November 13, 2006).

HEALTH CARE STRUCTURE

There are three types of hospitals in Pune: private, public and charitable trust. The private hospitals have the highest fees and most modern facilities and the public hospitals have the lowest fees (or are free of cost) and have the least modern facilities. The charitable trust hospitals are funded through donations and lie between the private and public hospitals in terms of fees and the condition of the facility.

The India government formed a National AIDS Committee in 1986 in response to the HIV pandemic (http://www.nacoonline.org/about.htm accessed November 13, 2006). By 1987 the committee launched a National AIDS Control Programme. Today, the National AIDS Control Organization (NACO) provides anti-retroviral therapy (ART) treatment free of cost at governmental hospitals in six high prevalent states including Maharashtra (http://www.nacoonline.org/directory_arv.htm accessed November 13, 2006). HIV prevalence of over 1 % of pregnant women has been found in Maharashtra. HIV is spread in this state primarily through unprotected sex and a large proportion of new infections are occurring among married women who are infected by husbands who visit or visited sex workers (http://www.unaids.org/epi/2005/doc/EPIupdate2005_pdf_en/epi-update2005_en.pdf accessed November 13, 2006).

Several non-governmental organizations (NGOs) in Pune are active in the field of HIV/AIDS. They provide a range of services to People Living with AIDS (PLWA) and their families including medical examinations, dispensing medicines, nutritional meals, awareness, legal advice and advocacy. The services offered by the NGOs are typically free of charge or provided at minimum cost.

PARTICIPANT NEEDS

Transition from descriptive epidemiological studies to clinical trials created the need for community involvement and building partnerships with the existing health care system. NARI is a research institute with excellent facilities for conducting HIV/AIDS research in various fields, still there was a need to involve local service providers for anticipated hospitalizations and specialist services.

Within the clinical trials, the shift from conducting Phase I to Phase III studies increased the number of participants NARI needed to recruit. Clinical trials require greater community involvement as members of the community participate in these trials. Additionally, the type of participant required changes from Phase I to Phase III studies. A Phase I study recruits healthy people at little or no risk for HIV who need to be convinced to participate. A Phase III study, on the other hand, requires participants at-risk of HIV. Recruiting volunteers for any phase of a trial is a challenge especially in a developing country setting where there are gaps including lack of awareness, poverty and lower literacy. NARI recognized the need of community involvement and hence the ensuing partnership-building with Non Governmental Organizations (NGOs). Therefore, they formed partnerships with local NGOs who were actually working in the community. The NGOs helped in bridging the gap between NARI researchers and community at the grass-roots by involving and training a team of people from the community.

HOW PARTICIPANT NEEDS ARE BEING MET

NARI works closely with their Community Advisory Board (CAB) to identify and meet participant needs. NARI provides standard medical care and treatment to anyone attending the NARI clinics spread geographically across the Pune city. Finally, NARI meets the needs of their participants through forming partnerships with local hospitals, governmental programs, and NGOs.

Community Advisory Board

NARI has had a CAB since 1992, but they faced problems such as how to fund the CAB activities (transport, meeting space, etc), how to find the optimal mix of people to be part of the CAB, and what would be their role on the research studies. It was new concept. In HPTN, since clinical trials were to be conducted the role of CAB became clearer and it became more “dynamic”. Today NARI CAB has 36 volunteer members from diverse backgrounds including: NGO staff, PLWA, men who have sex with men (MSMs), teachers, doctors, ethicists, philanthropist, commercial sex workers, public health personnel and social scientists. The members meet once every three months or more if needed.

The CAB provides advice to NARI on a variety of health topics to meet the needs of the community, not solely HIV research. Specifically, the CAB participates in protocol and consent form development, as well as, reviews case report forms and interview guides. Sometimes CAB members suggest additional questions to ask in studies. One of the most important functions of the CAB is to help NARI develop and translate consent forms into the local language. The CAB helps the consent forms “maintain transparency” by using non-technical words. CAB members attend protocol conference calls along with the international protocol team and their counterparts. They also attend HPTN full group meetings and actively participate in CAB meetings that are conducted under Community Working Group (CWG) of HPTN. The CAB members also sent for national and international training for ethics.

The CAB also organizes meetings in the communities and writes newspaper articles. The CAB is never directly involved in participant recruitment because if they were the community would perceive the CAB member to be a “NARI person”. However CAB members may help in developing recruitment plans for a particular study. This would include identifying target groups, discussing issues pertaining to specific communities in reference to the study protocol.

Another important function of the CAB is to advise NARI on the preferred referral sites in the community. The members know the community’s likes and dislikes. Individual CAB members have visited the referral sites NARI uses for their research participants.

> *“Today’s CAB is the result of a process over a decade. It has been a process of learning.” - NARI’s HPTN Principle Investigator*

NARI clinics

NARI has seven clinics throughout Pune where community members can get voluntary counseling and testing, receive safer behavior counseling, receive basic medical care and investigations, treatment for opportunistic infections, be screened for study participation, attend follow-up study visits, and receive free condoms. The basic medical care services and HIV testing are free and open to anyone in the community.

In 1993, NARI opened their clinic at the National Institute of Virology (NIV). Later HPTN funds helped to improve the clinic facilities. The NIV clinic is the oldest referral center for HIV testing in Pune and currently one of the NACO centers providing ART treatment and care to all participants of NARI studies (national and international studies). The NIV clinic is special because it is located within a virology center and participants feel comfortable there because it is not labeled as an “STD clinic”. In addition, all NARI clinics are located on public hospital premise and are not identified as “AIDS” clinics. One NARI clinic, located in the red-light area, has been carefully named “Arogya Kendra” meaning “Centre for Health”. These efforts help to reduce stigma among participants attending the clinics. All NARI clinics have basic ambience and infrastructure in terms of laboratory and personnel (physician, counselors, lab technician and attendant). The clinic at National AIDS Research Institute (main centre) has additional facilities including radiology and ultrasonography. The NARI clinic at Jehangir Hospital is equipped with colposcope.

Referral Network

The referral process is viewed as “a two-way process” at the Pune HPTN site. First, research participants are referred to partner hospitals and NGOs for medical and/or social services they may need. Second, hospital staff and NGO staff refer community members to NARI clinics for HIV testing and to be screened for research studies.

NARI staff and community partners view the referrals to NARI clinics as beneficial to all the members of the community even those who may not be eligible for the studies because at the NARI clinic all persons receive information about HIV, counseling, testing, and general medical care.

Hospital referrals

Research participants are referred to five hospitals in Pune: Sassoon, Talera, Jehangir, Gadikhana, and Sanjeevan. NARI also refers participants to Anandpur Medical Diagnostic Center for radio-imaging services. All referral hospitals are within 5 km of the NARI clinic that the participant attends. Participants are referred to the hospital that is closest to where they reside. NARI has a Memorandum of Understanding (MOU) with each hospital that clearly outlines the services that NARI will pay for their research participants. NARI, being a governmental organization, can only reimburse the hospitals for their services up to the Center Governmental Hospital Scheme (CGHS) rates. The CGHS prices are lower than the fees charged at private hospitals.

Typical adverse events (AEs) and health concerns experienced by research participants at the NARI clinic included fever, vomiting, headache, pneumonia, gastroenteritis with dehydration, and sever anemia. When patients require admission, IV fluids, spinal tests, or any other specialized investigation the clinic doctors will refer the participants to the MOU hospitals.

Outside Talera Hospital in Pune, India (H. Burke, 2006).

Sassoon and Talera hospitals are public, government hospitals. Sanjeevan Hospital is a charitable trust hospital. Jehangir is a private hospital. Participants are referred to Sassoon Hospital for a broad range of services, including:

virology outpatient delivery (OPD), tuberculosis (TB) OPD, ophthalmology OPD, obstetrics and gynecology (OB/GYN), skin and venereal disease (VD) OPD, pediatric OPD and inpatient care. Participants are referred to Jehangir and Sanjeevan Hospitals for inpatient care (CCU), as well as, OB/GYN OPD and other medical OPD. Participants are referred to Talera Hospital for TB OPD, outpatient and inpatient care. Talera serves as the main TB center or the 'City TB Center' (CTC).

According to NARI clinic staff there is no stigma against research participants who are referred to the MOU hospitals. The staff in all MOU hospitals have been trained in the management of HIV patients. To evaluate this, the NARI clinic staff ask participants and their relatives about the care they received at the referral hospitals. Staff admit, however, that stigma against HIV positive persons is not 100% gone and hospital staff, in rare occasions, were afraid to bathe and draw blood from HIV positive research participants. When these problems occur the NARI clinic staff contact the physician in-charge of the particular hospital ward to discuss and resolve the problem.

If participants become pregnant, a confirmatory pregnancy test is conducted at the NARI clinic and counseling is provided depending on the HIV status of the participant and his/her partner. Counseling for HIV positive persons includes medical termination of pregnancy (MTP), continuing pregnancy and prevention of mother to child transmission (PMCT) therapy, and infant feeding options. Advantages and disadvantages of all options are discussed during counseling and the final decisions are made by the participant. All participants are referred to a MOU hospital for delivery, PMCT, or termination. According to NARI staff the patients are not stigmatized by the hospital staff for being a study participant, for being HIV+, or if they chose to terminate the pregnancy.

The number of referrals from NARI clinics to MOU hospitals has been lower this past year. Most likely this is the result of increased access to ART which mean that few people require admission for opportunistic infections.

Doctors referring to NARI clinics

Doctors in MOU hospitals will refer their patients to a NARI clinic if the patient does not have the money for HIV testing and for confirmation tests to those who test positive for HIV at the hospital. NARI provides free HIV testing.

NGOs and local doctors refer patients to NARI because they think that NARI performs the best possible lab evaluations for their patients. NARI is perceived to have good equipment and people in the community trust the lab results.

In fact, many partnerships with MOU hospitals started because doctors treating HIV patients at the hospitals referred their patients to NARI for testing and participation in research studies. NARI would ask the participants where they were referred from and the participants would give the name of the doctor, hospital or NGO. Participants also expressed interest in returning to their referring doctors for care. NARI used this referral information to approach hospitals about forming MOU partnerships.

Partnership with governmental programs

NACO has been providing NARI with HIV diagnostic kits since 1993-1994. Through this program, NARI has provided 8000-9000 HIV diagnosis investigations. Currently, NACO has approved one ART center at NARI's NIV clinic. Under this program, 500 of NARI's HIV positive research participants, who meet the national requirements, are able to receive ART for free. The national eligibility requirements are a CD4 count of less than 200 or clinical signs of AIDS as determined by the clinician. The participants come once a month to the NARI clinic to receive medical examination, necessary investigations, adherence and risk behavior counseling, treatment for opportunistic infections, condoms and ART.

NGO referrals

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 two exploratory meetings with several NGOs, NARI provided information about NARI's research and determined which NGOs were willing to help with research. Most NGOs have a health service and program implementation agendas. NARI explained the public health significance of research on a local, city and country level in an effort to help the NGOs realize that research will enhance their service agenda.

Each NGO partner helped develop and sign a MOU with NARI. The MOU explains the scope of services offered, and privacy/confidentiality requirements.

NARI currently has partnerships with six different NGOs in Pune. Some of the NGO directors are also members of the CAB. The MOU NGOs are:

- Child Aid and Sponsorship Program (CASP)
- Deep Griha
- John Paul Slum Development Corporation
- Snehdeep Jankalyan Sanstha
- Jagruti Seva Sanstha
- Pathway Project

The **Child Aid and Sponsorship Program (CASP)** has services for children in urban India. CASP provides education sponsorships, health services (including basic medicines) and health education. CASP also provides food to pregnant women through a community kitchen. Some topics CASP covers during community awareness include: leprosy, geriatrics, youth empowerment, and community empowerment. Another program called the CASP Plan works in rural India.

Deep Griha was established in 1975 and strives to improve the lives of people living in the slums of Pune. An independent charitable organization that serves more than 30,000 people provides education, nutrition and health programs to families. The clinic and dispensary provides general medical care to families for minimal charge. There are also day care programs for children at the facility which enable mothers to work. Other services provided include: evening classes for children, youth development programs, non-formal training for school drop-outs, and community awareness programs.

Outside Deep Griha, a charitable organization in Pune, India (H. Burke, 2006).

While ART is not provided at the clinic, Deep Griha's Integrated Service for HIV/AIDS (DISHA) was started in 2005 to provide care for PLWA in the community. The services provided include: medical treatment, Direct Observation of Tuberculosis Services (DOT) treatment, daily nutritious food, counseling, and home visits. The organization has a second site in rural area outside of Pune that provides a safe home for destitute women and children.

John Paul Slum Development Corporation (JPSDP) is a NGO that provides HIV/AIDS awareness and services for PLWA in Pune. It has served more than 1,500 since 1995. Specifically, JPSDP provides HIV/AIDS awareness programs for the community, home-base care for PLWA, a Community Care Center for PLWA, a counseling center for STD/HIV, nutritious food program for PLWA, and a DOT center.

In 1997, JPSDP opened the first STD clinic in the slum community which provided services especially to women. ARTs are not provided by JPSDP, only medicines to treat opportunistic infections. JPSDP provides nutritious cooked meals to the family of PLWAs. Currently, the organization provides meals seven days a week for 50 persons. JPSDP also provides cremations of bodies of those who die of AIDS and do not have family members to make arrangements.

In 1998 JPSDP staff started providing supplement care in a local hospital that was not able to provide adequate care for PLWA. Specifically, they provided meals (2 meals per day per person, including relatives of patient). JPSDP realized that it was not enough to just give PLWA medicines, but they needed basic nutrition for these medicines to improve the health of the patients. They also quickly learned that if they just gave the PLWA the food that this person would give the food to their family members, especially the children. JPSDP, therefore, expanded their service to provide food for the entire family.

JPSDP provides technical and financial support to a community group of HIV+ persons called "Route Plus". The organization also runs a beauty parlor that trains girls who have dropped out of school. To date they have trained 600 girls who earn $3-4 per day cutting hair in home-based settings. The John Paul Hospital, funded by USAID, currently has 10 beds. In the next couple of months they will have 40 beds ready for PLWA.

Cook preparing food at John Paul Slum Development in Pune, India. Currently, the organization provides cooked food for 50 persons per day, 7 days a week. The picture demonstrates the challenges NGOs in this environment face to provide a basic services to numerous people in need, given few resources (especially space and supplies) (H. Burke, 2006).

Snehdeep Janakalyan Foundation, established 22 years ago, focuses on health issues, education, day care, and nutrition of malnourished children. The NGO serves eleven communities in Pune. The NGO has 3 offices and 6 one-room centers throughout the community, providing free antenatal care, check-ups for infants, and contraceptive methods to the community. The contraceptive methods they provide are oral contraceptive pills, condoms, and the copper T to people aged 18-35 years living in the community.

The organization also helps the community members get their children enrolled in school and obtain important documents such as birth certificates and ration cards. They provide counseling for alcoholism, mental health, HIV/AIDS, and economic stability. Snehdeep Janakalyan Foundation has an income generation program where they train community members as beauticians, or teach them how to make handy crafts, or provide skills so that they can care for patients. The NGO also provides small loans for people who want to open a small fruit/vegetable store and has a sponsorship program that will pay half of school fees and provide books for talented children. The NGO also works with affected families to help them be aware of government schemes and provides assistance with obtaining and completing the required forms.

Jagruti Seva Sanstha is a NGO working in women and adolescent empowerment. They have a library, study room, and teachers to help the adolescents in the community. They also conduct a sewing class to teach woman and adolescents how to sew. They have a small community clinic with a small laboratory that provides basic medicines, blood pressure, and diabetes screening. They refer patients to NARI clinics for HIV testing.

Pathway is a community based organization (CBO) that provides home-base care for HIV+ people. The provide food and medicines (just started providing ART). They have eight community based clinics and a mobile clinic van. They also have a small savings group where everyone contributes a small amount to the pot and the money can be used for small loans for medicines, to open a business, or provide school fees for children.

Community referrals to NARI clinics

NARI asked each MOU NGO to identify two trainers within their organization to implement NARI projects and train grass level workers living in the community called ‘peers’. The trainers are called Trainers of Trainers (TOTs).

NARI provided a formal two-week training program for the TOTs which covered:

- General HIV/AIDS information and care
- Research methodology
- Current NARI research projects
- Future projects that would require the community’s help

- Ethics

Each NGO was asked to identify 10-20 literate people with a commitment to the wellbeing of the community. These 'peers' needed to be willing to volunteer 1-2 hours per day to work in the field. The TOTs and NARI staff provided 60 hours of training for the peers over two months time. In total, 150 peers have been trained and 75 are currently active working in 80 communities in Pune. The peers' work entails:

- Administering a household roster/health care needs assessment survey
- Providing health education in community meetings called "corner meetings"
- Providing risk assessment and health education at couples meetings
- Identification and treatment of common ailments in the community
- Identification of volunteers for NARI studies
- Providing referrals for counseling, investigations and care
- Providing referrals for social needs, including self-help groups

The peers, typically housewives or unemployed youth, are expected to spend 15 days per month conducting door-to-door visits to complete 'baseline' survey forms which collect household composition data (number, age, sex of those living in household) and the health care needs of the household. They also provide AIDS awareness education during this process.

The other 15 days in the month, the peers are expected to conduct 'corner' meetings in the community. The peers have discussions about HIV, STDs, and the importance of research during the corner meetings. At this stage the peers can start to identify eligible participants which make the recruitment process proceed more efficiently when a specific protocol is begun.

During couple meetings the peers have discussions with individual couples about safe sex practices, sexual health, partner communication, HIV and STD education, risk assessment, and referrals to the clinic for HIV testing. The couples are identified by the peers and through the surveys that the peers fill out.

The peers and TOTs receive an honorarium for their work. The amount is decided by the NGOs and written in the MOU. While NARI gives the NGOs the money for the honorarium, the NGOs distribute the money themselves to their volunteers. In the past the honorarium was around $10 per month, but as of April 2006 the amount was increased to around $17 per month.

NARI community staff and a JPSDP peer at the NARI community office in Pune, India (H. Burke, 2006).

NARI monitors the peers' work by interviewing a randomized selection of households in the community once a year. During these interviews NARI staff asks the community members questions including "Where is the NARI clinic located?" and "What services are provided at the NARI clinic?" The staff then reviews the evaluations with the peers to help them improve their work.

The most frequent referrals to NGOs vary depending on the specific neighborhood. In additional to referrals to the MOU NGOs, peers also make referrals for:

- residential care home for people experiencing isolation and unemployment (referred to Sahara)
- ART (before the NACO program started in December 2005)
- Nutritious food (referred to Pathway, National Maharashtra Pune Plus (NMP Plus)
- TB and herpes (referred to Sassoon, DOT centers)
- Malaria (referred to NARI clinics)
- Opportunistic infections (referred to NARI clinics)
- Domestic violence (refer to Sofosh)

Community Outreach Office

NARI's Community Outreach Office is located in the city of Pune and has 15 full-time staff members. Thirteen of the staff have master degrees in social work and conduct a variety of activities in the community including corner and couple meetings with the trained peers from the NGOs. This office is accessible to all CAB members, peers and NGO partners.

NARI community staff provide weekly refresher meetings with the peers. During this meeting they review the previous week's work, discuss any problems encountered, have time for experience sharing and role playing exercises, discuss any rumors that may be unfolding in the community, and submit the completed baseline surveys to the NARI staff member. The surveys are stored at NARI.

During this meeting the peers discuss if they identified any couples that might want to be tested for HIV or may be eligible for a study. The peers later return to the couple and ask if they would like to meet a NARI staff member and schedule an appointment for the testing. If the couple agrees, the NARI staff member then goes to the home and provides awareness education, discusses specific studies (if the couple is eligible), and provides referrals to the clinics for testing. The peers and NARI staff members are willing to escort participants to the clinic if the participants want them to.

If issues arise during the visits the NARI staff also provide referrals for adverse events (AEs) to NARI clinics or for social services to NGOs. The staff provide referrals for other community members even if they are not part of a NARI study. In the community, the NARI community staff are seen as “social workers” working for the good of the community.

When a clinic referral is made the participant is given a piece of paper with the clinic address and the doctor’s name written. The NARI community staff members record the appointment information in a diary and develop a follow-up plan with the participant. The NARI community staff will place reminder calls to the couple a few days before the scheduled appointment. The staff will also follow-up with a couple to see if they went to the clinic. When the person has made it to the clinic the work of the community staff member stops to maintain confidentiality of the participants.

The NGO peers assist the NARI community staff with the follow-up efforts and play a key role because they live in the community. The NARI community staff and NGO peers work closely together in the community. Outreach in the community is important because staff can remind participants of their appointments, provide follow-up and increase the retention rates in the studies.

SUSTAINABILITY

Since NARI and many of its partners are governmental organizations the partnerships have been and appear to be sustainable. As a result, the level of care provided to research participants during the clinical trials also appears to be sustainable.

One concern NARI and their partners have in common is the long term care of research participants after the trial ends. For example, through NACO, NARI can provide ART to participants after the trials; however, most participants are not eligible now because their CD4 count is above 200. While the CD4 requirement might be changed to 350 in the future, according to study staff, most of participants still will not be eligible for ART until a latter time. Unfortunately, the long-term funding of ART through NACO or other sources is unknown.

A dilemma faced by doctors treating study participants is that medication costs are only covered during the duration of the protocol, despite the fact that some conditions require longer treatments. This causes a moral dilemma of whether to start treatment during the study knowing that it will have to end in the next couple of months or not to treat at all.

NARI is currently working on developing a private trust fund with community partners to address the challenge of sustainability of care after trials end. The goal of this trust fund is to make funds available to participants during the gaps in care and will provide follow-up care of trial participants, as well as food and support for the children of participants.

UNMET NEEDS

Coordination of NGO activities and services

Many NGOs are working in HIV/AIDS and other health issues in Pune. Some efforts are duplicated, while other services are not covered by any NGO. Moreover, NARI and NGO staff does not know all of the services being provided by all of NGOs working in Pune.

Currently, NARI is making a directory of NGOs that can be used by NARI staff and the NGOs to help participants find the help they need. Another suggestion is to assign a coordinating agency on the city level to bring together all the organizations working in Pune.

Surgery costs

The MOUs with hospitals do not cover surgeries for research participants. If a participant can not pay for a surgery the process to get provisions for surgery requires extensive paperwork. This requires extra time and may delay the surgery. Many doctors at the MOU partner hospitals feel that there should be no restrictions on medical procedures covered in the MOU. NARI is brainstorming on the process of modifying the MOUs to include surgery.

Domestic violence assistance

Many women in India are the victims of domestic violence. Indeed, of ever-married women in Marharashtra, 18% were ever beaten or physically mistreated since the age of 15 and almost 17% were beaten by their husbands. In the past 12 months, 7.3% were beaten or physically mistreated (IIPS and ORC Macro, 2000).

Surprisingly, NARI clinic staff do not have many instances of providing treatment or referrals for women experiencing domestic violence. Moreover, staff believe that women would not come to the clinic if they were being abused as the family usually intervenes in these circumstances. NARI staff recognized that it is difficult for women to tell their husbands that they are HIV positive. According to clinic staff however, with the help of their families, women usually can convince their husbands to be tested. In general, people in the community are aware of the seriousness of HIV and so they normally do not object to being tested.

If a woman can not convince her husband or is afraid to tell her husband then the NARI counselor will help the woman identify someone in the family who might have influence on her husband. One example occurred three to four years ago when a female participant in the PMTC program was beaten by her husband. The NARI clinic staff made an assessment of the woman and the clinic doctor talked to the husband telling him that it was not fair that he beat her. Multiple counseling sessions where conducted with the husband. In these situations, if the condition does not improve the clinic staff can make referrals to an NGO that provides shelter for abused women. Unfortunately, there are not many NGOs in Pune working on domestic violence issues.

Family planning services

NARI, its partners, and participants consider NARI an “AIDS research” organization. As a result, men mostly ask for condoms during their visits at NARI clinics. The clinic staff does not receive many requests for other family planning methods. Occasionally participants seek advice on tubectomy/vasectomy or other methods (IUD or pills) and they are referred to governmental hospitals for these services. NARI does not follow-up for family planning.

According to some interviewees, family planning is controlled by husbands and in-laws in Indian culture. Furthermore, family planning recipients must be 18 years old. Sixty-one percent of currently married women living in urban areas of India have ever used any modern method of contraception and 51% are currently using a modern method (IIPS and ORC Macro, 2000). The most prevalent method is female sterilization (36%) followed by condoms (7%, current use). Few women are currently using the pill (3%) and IUD (4%). A relatively large percentage of urban Indian women (6.7%) are using traditional methods.

Family planning is clearly a need among Indian women, and NARI sits in a good position to provide family planning counseling to its participants. Since NARI counselors are already discussing sexual behavior with regards to HIV it would be a natural transition to discuss contraceptive issues with the participants. With the upcoming HPTN 059 microbicide study approaching, ensuring that there are no missed opportunities to discuss family planning options may reduce unintended pregnancies among participants, benefiting both the participant and the research study.

Services for men

There are not many services for men in the community in terms of social empowerment, economic empowerment, emotional support, legal information, skills training, and STD/HIV camps. NARI provides technical support for training of doctors, counselors, and laboratory staff for various organizations. These camps are conducted in the community halls and the services are usually free or very inexpensive. Camps are currently offered for females only, but they could be extended to couples so that men could also benefit from the services.

Another challenge is male involvement in research and awareness activities. The working hours for NARI staff (9:00 AM-5:30 PM) are also the working hours for most men in the community. NARI addressed this challenge by learning through experience as well as utilizing participatory methods. One of the first strategies employed was to ask the women to talk to their husbands about HIV. NARI staff then tried asking the women to ask their husbands to attend meetings in the evening. When this strategy did not work, couple seminar strategy was implemented. Unfortunately, the sensitive nature of the discussions hampered the effort because no one wanted to talk or ask questions about sex or HIV in front of others. Finally, the individual couples meeting strategy was initiated and has been working to reach both men and women in the community.

CHARACTERISTICS OF SUCCESSFUL PARTNERSHIPS

NARI views their relationship with the community as long term

NARI staff strive to educate the community about HIV/AIDS and be a resource to their community because they feel a moral responsibility to help people. Additionally, NARI recognizes that those community members who may not be eligible for the current study, but may become eligible in the future. Finally, NARI understands that people in the community can influence the decision of other people to join or stay involved in research studies. To this end, NARI staff address rumor control proactively by educating the entire community and not just those who are eligible for participation.

Community partners feel that NARI values community involvement in research. This is evidenced by the way NARI spends resource in terms of time and personnel to communicate with the community in “plain, simple words” and listens to the CAB’s suggestions within the constraints of the research.

The partnership is beneficial for both partners

NARI provides the NGOs resources and support for the services they perform for NARI, specifically they provide:

- Honorarium to NGO for the NARI peers and their supervisors
- Periodic training of NGO staff and peers and cost of training materials
- Survey forms and educational materials used by peers
- Organizational and refreshment expenses during community meetings
- Transportation to the NARI clinics for peers and community members
- Financial support for logistics and refreshments for community-based social programs
- One NARI community staff member for each community served by the partner NGOs
- Providing technical resources to the partner NGOs especially helping them to develop projects and train their staff

Furthermore, the NGOs gain visibility from working with NARI and enjoy increased confidence from the community because of the information NARI provides. The supervisors and peers value the information and trainings NARI provides. In addition, through the partnership the NGO staff becomes aware of different projects NARI is working on.

Doctors at the MOU partner hospitals also feel that they benefit from the partnership. Doctors who treat research participants can conduct more investigations for these patients and have fewer restrictions on treatment because the costs are paid by NARI. In the end, they feel that the partnership enables them to provide better treatment to their patients.

NARI also provides much needed HIV information, slides, booklets, and other materials to their partners. Working with NARI also provides opportunities for partners' self development such as participating in HPTN meetings, attending HIV-related courses, and developing research posters for conferences.

NARI and the NGOs expanded their respective agendas

The NGOs wanted to partner with NARI because they view the partnership of value to the community. NARI took steps to ensure that NGOs made a voluntary decision to join the partnership through continuous discussions.

According to the HPTN Principal Investigator in Pune, “NARI would have to bring service agenda to their agenda” for the partnership to work. In other words, NARI needed to show a willingness to provide services to the community. 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. NARI took a broader approach to health, not just HIV.

Research is still NARI's primary agenda and service is another agenda of the organization. The NGOs have the opposite agenda. Both partners view the partnership as a "give and take relationship". Furthermore, they work synergistically together to help each other's agendas.

NARI allots larges amounts of human resources and time to community involvement

The HPTN Principal Investigator at NARI and the Community Program Supervisor each spend 30% of their time on community involvement. Similarly, the NARI clinic staff spends approximately 20% of their time on community involvement. NARI also has a Community Outreach Office located in Pune where 15 full-time staff work to develop and foster the partnership between NARI and the community organizations.

Additionally, the individual NARI clinics have the same working hours as the MOU hospitals with whom they work most closely. If NARI main campus is closed, but the MOU hospital is open, then the NARI clinic will be open. This provides a continuity of care for the patients.

NARI and its partners have a shared goal

Before the partnership with NARI the NGOs were already working in the field and identified HIV as a problem in the community. NARI wants the NGOs to be the face of the work and receive credit for the work. According to the Community Program Supervisor at NARI, "the community is moving forward because of the good work of the NGOs and NARI reaped the harvest that the NGOs sowed."

The partnerships between NARI and local NGOs work well because NARI is respected and known for "doing things right". The partners have good rapport with one another and are "not working for themselves or NARI, but for the patient." Moreover, the partners have a common goal "to help clients only" and feel that it is their responsibility to help their community and people with HIV.

Indeed, the peers agree to volunteer for NARI because they believe it is their "moral responsibility to help their community". They feel that their community does not know about HIV/AIDS and they want to inform their community.

NARI and their partners have open communication and work as a team

Communication and teamwork among the partners are important when helping the community interpret their HIV reports. For example, sometimes confusion and misunderstanding arises among participants when a person feels healthy and receives an HIV positive report; or when a couple does not understand how one of them can be HIV positive while the other remains negative; or when a participant receives a report saying his CD4 count has improved and yet he still has HIV. When misunderstandings occurs the NARI community staff, the NGO staff and peers, and the clinic staff all work together to help participants interpret their reports. In the NARI Community Coordinator's words "Everyone works in a team. If there is no teamwork then things will stop."

Intensive Care Unit at Sanjaveen Hospital in Pune, India (H. Burke, 2006).

NARI clinic staff and doctors at the MOU partner hospitals have good communication with each other. Indeed, the partner doctors have the cell phone numbers of the NARI staff and feel free to call them anytime, day or night. Many of the doctors at the partner hospitals have a long standing relationship with the NARI doctors, and have "mutual trust and friendship". One partner doctor expressed, "Both partners want to provide the best possible care. Beyond research and economics it is the human aspect. HIV is a great teacher. It teaches many things. When you see someone walking in sick you should help them. We are all concerned about the health of people."

Doctors at the MOU partner hospitals gain advice, information and supplies from NARI staff. NARI clinic doctors will cover the partner doctor's duties during absences and vice versa. The NARI clinics are willing to share their medicines with the hospital if the hospital experiences stock-outs.

Coordination happens at many levels: management, clinicians, and counselors. NARI makes appointments for specific times at the referral sites for their participants. This step reduces the wait time experienced by the participants. NARI clinic staff also provides detailed information on the participant's condition to the department within the hospital that they are referred.

There is good communication between the NARI clinics; the NARI clinic doctors can call each other and the MOU hospitals any time. The NARI doctors also provide their cell phone numbers to the participants' relatives so they can call for information.

The communication between the partners is considered good because they have "direct communication with each other and do not relay medical information via the participant." Moreover, the partners talk directly to each other in addition to sending written notes. Similarly, there is good communication between the NARI nurses and the nurses in the hospital wards. The nurses met face-to-face with each other, developed rapport and a good relationship before the research studies begin. Face-to-face communication is also evidenced in the community as NARI staff members come to the peers meetings each week.

Senior management is involved and supportive

NARI staff and partners believe that the partnership is successful because NARI's HPTN Principle Investigator (PI) is involved in community activities and day-to-day operations of the referral partnerships. The PI is described as an "excellent leader" and staff feels that he is available anytime to provide support. The doctors at the MOU partner hospitals, NGO staff and volunteer peers describe the PI as "approachable" and "supportive". One peer recounted a story of when the PI participated in a peer meeting and "sat together [with the peers] on the ground". Furthermore, peers feel that the senior NARI staff respects their work and feels that they are part of a team effort.

MOUs make expectations, roles and responsibilities clear

NARI and their partners develop MOU agreements together that outline the roles and responsibilities of each partner. The partners feel a sense of "assurance" in the partnership because the MOUs are written and signed by both partners. Some of the challenges faced before the MOU was in place include:

- Where to admit participants needing care? Before the MOU, participants were admitted to Sassoon Hospital, but this government hospital did not have the space to handle the referral load.
- The NARI physician could not intervene in the care provided in Sassoon.
- NARI physicians had relationships with HIV specialists practicing at private hospitals, but if they referred the participants to the private hospitals the participants could not pay the fees.

- How would NARI pay the fees at the hospital? What would be the mode of payment delivery?
- If a participant had an emergency he/she would be admitted to a local hospital and the NARI physician could not follow-up. This increased the lost-to-follow-up rate for the studies.

The MOU is specific and provides clear answers to these questions. The MOU also provides a system that channels participants' care through the NARI physician. After seeing the NARI doctor the participant is then referred to the MOU hospital for care. The on-call mobile numbers for the NARI doctors are displayed at the NARI clinics.

Indeed, doctors at the MOU partner hospitals believe that NARI's research participants might receive better treatment than non-research participants because doctors are less restricted in prescribing medicines and conducting investigations because the NARI has agreed to pay for the treatment of their participants in the MOU.

BARRIERS TO SUCCESS IN PARTNERSHIPS

Addressing NGO expectations

One of the biggest challenges faced during the partnership was how to address the expectations of NGOs. The NGOs wanted the partnership to strengthen their organizations through the provision of office buildings and salary support. NARI handled these expectations by reminding the NGOs that they already had a standing in the community and that they need to give to the partnership in addition to taking. During discussions, NARI made a commitment to provide technical support to the NGOs, but explained that the NGOs needed to take the lead in securing future funds for their organizations.

Misunderstandings about research

Another challenge faced was how to handle the community's misunderstandings about research and the research process. For example, confusion and disappointment may arise when a person is screened out or becomes ineligible for a study. In these cases the NARI clinic counselors and community peers visit the affected people and try to explain the eligibility criteria again. Staff also remind the community members that they can receive care from the clinic even if they are not part of a research study.

Peers spend substantial time identifying participants and bringing them to the clinic for screening. Sometimes peers may not understand why some of their recruitments are screened out of a study. On some occasions the peers may expect the health information of participants to be shared with them. NARI clinic staff, however, can not share health information about participants because it is up to the participant to disclose their own information. This highlights the importance of ensuring that the peers and community are well informed about particular study eligibility criteria and confidentiality requirements.

NARI also has the challenge of explaining “research versus treatment” to the community. “Treatment” in the Pune community context means that as soon as symptoms are over the person can stop taking medicines. However, when participating in “research”, participants need to continue taking medicine whether or not symptoms are present. This distinction needs to be explained to the community to ensure adherence.

Another misunderstanding in the community is differentiating between HPTN studies and the other studies conducted by NARI. The MOU covers the treatment costs for HPTN participants, but not the costs associated with treating non-HPTN participants who participant in other NARI studies. This situation creates confusion among the participants because they do not understand why some participants are getting free treatment while others have to pay.

Differing opinions on course of treatment

On occasions, the NARI doctors and the doctors working in the MOU hospitals differ in their opinion on how to treat research participants experiencing border-line illnesses. Participants may feel confused if, for example, the NARI doctor refers them for admission for dehydration, but the doctor at the MOU partner hospitals does not admit this patient because of the high patient load the hospital. In these cases, the NARI doctor discusses the difference of opinion with the partner doctor and then explains the situation to participant.

Over-working and losing trained volunteers

The peers were initially asked to volunteer for 2 hours per day, but they actually work 4-6 hours per day to perform the required tasks. Peers’ days are especially long when they wait for couples who are getting tested at the clinic. Moreover, peers must return to houses multiple times in an effort to gain the family’s trust and slowly introduce the sensitive topic of HIV.

Despite long work hours the peers feel a sense of responsibility to help their community and in the words of one peer “if her life is used for a noble purpose then she is satisfied.” The peers take pride in knowing that their role as volunteers for NARI and their NGOs is helping their community.

Peers are sometimes overtaxed when there are multiple trials going on simultaneously. To alleviate the situation NARI community staff helps the peers determine where they are lagging. During the peer meeting the group decides to pair peers who have high efficiency of recruiting study participants with peers who have a lower efficiency. The peers are asked to work together so that they can learn from each other.

Losing trained peers is identified as a challenge in the partnership. Over time, the peers find employment and no longer are able to volunteer for NARI. NARI has addressed this challenge by being flexible with the peers' work schedule and allow them to work at nights or all on one day of the week or during holidays. This flexibility increases the NARI staff workload because they need to provide assistance and supervision at separate times to the peers working flexible schedules, but reduces the turnover of peers.

Finding funding for care and support

Securing funds for community-wide care and training is challenging. In the past, NARI found it challenging 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.

In more recent experience funding agencies are becoming more receptive to the idea of providing care for clinical trial participants. NARI has been able to create a budget for community work including funds for the CAB, community involvement and support for health care. The size of the budget needed in India to provide care 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.

CONCLUSION

Findings from the Pune case study demonstrate that the process of involving the community and developing referral partnerships takes time, money and commitment. Partners need to be flexible with their agendas and willing to give to the partnership. Partners need to work together to develop written memorandum of understandings which make expectations, roles and responsibilities of the partners clear. They need to communicate effectively and routinely to proactively handle potential problems and misunderstandings. All those involved in the partnership need to have a shared goal and feel like an important part of the team. Finally, forming linkages with governmental agencies for political motive may increase sustainability.

REFERENCES

Census of India (2001) accessed November 13, 2006 at http://censusindia.gov.in/Census_Data_2001/Census_Data_Online/Population.html

International Institute for Population Sciences (IIPS) and ORC Macro. 2000. *National Family Health Survey, (NFHS-2), 1998-99: India*. Mumbai: IIPS.

National AIDS Control Committee (NACO) accessed November 13, 2006 at http://www.nacoonline.org/about.htm

National AIDS Research Institute (NARI) website accessed November 13, 2006 at http://www.nari-icmr.res.in/about.html

Pune City website accessed November 13, 2006 at http://www.punecity.com

UNAIDS and WHO. 2005. *AIDS epidemic update: December 2005: Asia*. Accessed November 13, 2006 at http://www.unaids.org/epi/2005/doc/EPIupdate2005_pdf_en/epi-update2005_en.pdf

FIOCRUZ, Rio de Janeiro, Brasil

Patty Alleman

The Brazilian context

Rio de Janeiro has an undeniable life pulse that is felt from the beaches of Copacabana and Ipanema to their neighboring favelas (slums). In a land of extreme diversity, this almost indescribable passion of existing is at the core of not only every individual, but also the professional organizations. The HPTN Rio site is extremely proud of the standard of care for their participants, which is based on the belief that, in the words of human rights activist Herbert de Souza (Betinho), “AIDS has to be viewed as a social issue and not an individual problem.”

Favela Fiocruz community in Rio de Janeiro, Brazil (P. Alleman, 2006).

In order to understand the standard of care for research participants in Brazil it is important to appreciate the underlying cultural foundation of the universal health care system and the special synergy of factors that surrounded the emergence of HIV. The Brazilian universal health system (Sistema Unico de Saude, SUS) is based on equity, universality, and holistic care for patients. Theoretically all Brazilians have access to free health care that is centered at a municipal level and managed by community representative health councils. The social reality is that limited human and financial capital often challenges the SUS system, particularly in regard to accessing specialized care. Yet despite the challenges, SUS forms a strong foundation of care which is based in ardently held cultural principals.

In the early 1980s HIV emerged in Brazil alongside the political uprising against dictatorship. Solidarity of the people for the freedom to meet and express themselves allowed voices of the communities most impacted by HIV, alongside emerging non-governmental organizations and an extremely committed professional community to be heard by the government. The resulting policy of HIV care includes not only access to antiretroviral (ARV) treatment as part of the SUS system, but as classified chronic disease patients, free transportation and housing if needed. In addition, the Brazilian government has strongly supported HIV prevention messages and testing services.

HPTN RIO: MODELING AND ENHANCING THE HEALTH SYSTEM

Research sites

The Rio de Janeiro research site includes three government clinical locations: Fiocruz, Nova Iguacu General Hospital (Nova Iguacu), and Servidores do Estado Hospital (Servidores). Fiocruz and Servidores are both located within the city of Rio de Janeiro. Nova Iguacu is located outside Rio city, in the poorest section of Rio state where 90% of the population lives in slums and the commute to the city is one hour by bus.

The Fiocruz clinic- Evandro Chagas Clinical Research Institute- is part of the Ministry of Health. It is located on a large, beautifully manicured campus alongside a small hospital and other research offices. Servidores is a federal hospital located in the center of Rio city, convenient to the transportation hub. Historically the hospital served federal employees and thus has a reputation for specialized services and high quality of care. Nova Iguacu is a regional hospital that alone serves its very populated area, and averages 1,500 visits to the emergency room daily. The overall research site is managed by Fiocruz and includes all data and lab management. The research site’s centralized administrative structure works well to logistically implement protocol requirements (e.g., storage and disposal), as well as efficiently meet the linguistic capacity to communicate with the United States staff. Currently there is one active HPTN study, 052, with approximately 100 serodiscordant couples in the cohort. However, there are numerous non-HPTN funded clinical studies with adults and children being implemented at the clinical locations.

The slums of Rio de Janeiro are infamous in Latin America and it is important to note that all three clinical sites neighbor such communities. The relationship between the clinical sites and these impoverished neighborhoods is based on a shared appreciation and respect. 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. Additionally, there is also an adult education school on the Fiocruz campus where neighboring residents can earn their secondary equivalence degree or take preparatory technical courses.

Research teams

The principal investigators (PI) of the Rio de Janeiro HPTN site have worked together since the early 1990s, and share an understanding that the purpose of their research is to benefit their communities. As expressed by one PI, "we are only involved in research projects that we believe in heart and head." These researchers and their teams also believe that ethically they must help patients deal with their "life demands and thus improve their adherence to the study demands." As explained by one researcher, research studies are "responsible, at least in part, of what will happen to this individual;" therefore, there is a need to try and make the life of the individual a little easier.

As expressed by one member of the site team, although the Brazilian health system supports multidisciplinary health provider training, often specializations such as counseling and psychology are seen as "accessories of the system, not part of the system." However, the HPTN clinical sites are not only multidisciplinary, but interdisciplinary. There are weekly meetings of provider staff to discuss "collaboratively and with compassion" the needs of the patients. Each clinical team has medical doctors, nurses, psychologists, counselors, lab staff and administrators. And although according to one member of the medical team, every member of the team "doesn't need to understand the science, they do need to understand humans," and it is the role of the team, according to a staff member, to help patients "live, with their rights and be happy."

MEETING THE NEEDS OF PARTICIPANTS: EQUAL WITH BENEFITS

The three clinic locations of the HPTN Rio site exemplify the best of the government system, i.e., patients of these clinics have immediate access to some of the highest quality care in Rio. These sites epitomize the assessment, provision and follow-up components of the referral process, particularly in regard to medical and psychological/counseling needs of their participants. However, when it comes to addressing patients' social needs, it becomes evident that Rio struggles alongside other sites with finding a balance between what one PI states as the real world referral context of "helping a participant come to the clinical visit and adhere to advice," and the ideal world context that would "help him get educated, earn money, and live a better life."

Within the Brazilian health system infrastructure, the referral process is quite systematic, with distinctions between primary, secondary and tertiary care centers. Additionally, there is philosophy of humanized care, i.e., making a relation between patient and provider. In order to aid the referral process between government sites, within the SUS system there are social workers who serve as patient advocates. However, these social workers are often burdened with a large patient load, making humanized care a difficult challenge.

Similarly at the HPTN clinics there is a strong belief in providing fair access to care for all patients at the site, regardless of participation in clinical trials. Yet undoubtedly, there is a distinction of being a clinical study participant. In a clinical study, participants benefit from being part of a system where the staff to patient ratio allows each patient to be seen as an individual case. Exemplifying the Brazilian ideal of humanized care, as staff members express, patients feel “like being part of a family,” “safe” and “like human beings” as they are able to express themselves and get their needs covered. Further, as expressed by one site staff member, “study participants receive help, and don’t have to ask for it.”

Medical Referrals

Specialists that are most often needed for clinical trial participants are psychologists, nutritionists, and dermatologists. As each team has psychologists and counselors, most of the psychological/counseling needs of patients are handled at the sites. The biggest counseling problem for 052 is the promotion of condom use of the couples. According to a counselor, the counseling message focuses on sex not being “down there, but in the mind,” and promoting the use of condoms as a method of eroticism in the sexual encounter. Counseling methods include individual, couple and group sessions. Importantly, the counseling for clinical trial participants is of more advanced quality than at SUS primary health and VCT centers, due to more availability of time as well as specialized expertise of staff.

Reception area at Servidores Hospital in Rio de Janeiro (P. Alleman, 2006).

Many of the other medical needs of patients are also handled on site at Fiocruz, Nova Iguacu and Servidores. Yet as such, each site must also deal with the existing limitations of the government system. For example, gynecological exams are routinely done on clinical trial patients, but currently contraceptives on site are limited to the injectable and condoms. Therefore, if participants want to access oral contraceptives they must visit their local health centers. Although there is no need to make an appointment at the local health center, there are limitations such as restricted service hours and federally controlled prescription availability. Further, certain types of medical services have a very long wait period (e.g., family planning sterilizations), and at all hospital sites there is always a need for more and enhanced services, e.g., x-rays and CTs.

Since the onsite hospital at Fiocruz is small and only treats infectious diseases, certain types of needs must be referred to a neighboring larger hospital, e.g., MRIs and surgery. Although there is a formal agreement between the hospital and Fiocruz, making these specialized appointments for patients are usually accomplished through the professional and personal connections of staff, thus patients are given a helping hand to navigate and sometimes bypass the long waiting periods of getting medical services. Importantly, even if these special connections do not materialize into an appointment at the government hospital, the funds of the clinical trials allow emergency access to services through the private health system. For example, there was once a patient who had HIV and TB and needed an urgent MRI, and the cost to do it at a private clinic was covered by the trial. Further, participants benefit from study funds that can help cover medication costs that are suggested by a doctor outside of the clinical trial setting, e.g., cardiologist, but are not part of national drug list that are available free through the SUS system.

At Fiocruz internal referrals are documented in the computer patient data system which includes a listing of referrals and ability to electronically generate a referral notice. This system also allows the referral site/specialist to review the patient history and immediately note the outcome of the referral visit in the electronic patient file. For the referrals that are referred outside of Fiocruz, e.g., at the neighboring large SUS hospital, it is the responsibility of the research team to, in the words of a research nurse, “always stay with their antennas,” i.e., follow-up to make sure the participant accesses and is satisfied with the referred services. For all clinical sites, members of the research teams routinely visit the hospital wards if participants are admitted for in-patient care.

Social referrals

According to many of the research team staff, in reality, a person’s HIV status or risky sexual behavior is usually not in their top three problems of life. Other types of needs that are often identified with participants include limited transportation, alcohol and drug abuse, lack of food, school costs of children, and unemployment. In regard to transportation costs, if the participant is part of the trial, they do receive transportation vouchers. If the person is HIV+, they are eligible for a permanent transportation pass. For alcohol and drug abuse, participants are referred to local Alcohol Anonymous or Narcotics Anonymous groups; no treatment programs are available.

HIV+ Support Group at Servidores Hospital, Rio de Janeiro (P. Alleman, 2006).

In an effort to address the multitude of social needs, different approaches are implemented at the three clinical sites. At Nova Iguacu, there is a social service office that is managed by a small staff that attempts to address many needs through long-standing community connections. For example, they serve as the distribution site for community donations (e.g., clothes from the Catholic church) as well as the infant formula provided by the government for HIV+ mothers. Additionally, they organize a monthly support group for HIV+ women which includes peer support as well as presentations from professional and community groups.

At Servidores, for the general patient population, outreach nurses sometimes go the patients' houses and give them material goods, e.g., cooking gas and food staples. In this example, again each person is treated as an individual case to be managed as identified. Also at Servidores is a HIV+ support group, Grupo Viva a Vida, that manages a small office in part of the hospital. As discussed by the group's founder, in the beginning they had very few services to offer other than the staple food donations, e.g., rice and beans. Over time the group has received media coverage which has increased individual donations and they also sell small handmade items for donations. As many of the group's volunteers are HIV+, the motto of the group is 'in order to help ourselves we need to help the group.' The funds of the group help provide gift bags for new HIV+ moms, conduct social activities and HIV awareness events. There is a similar group at

Fiocruz, Friends of IPEC, that also serves as the distribution site for food donations and donated clothing for HIV+ patients. The group is primarily supported by staff donations, but as the current waiting list of over one hundred indicates, the demand is often greater than the availability of assistance.

SUCCESS, BARRIERS AND RECOMMENDATIONS

The characteristics of success in providing care to participants in the Rio example undoubtedly benefits from having, in the words of a site staff member, “a health system that even if bad, allows access to care.” Further, participants are accessing the SUS system from the vantage point of clinical sites that are model examples of the Brazilian health system. However, these sites are model examples not only in terms of service availability, but also in exemplifying the pillars of the SUS system: equity, universality, and holistic care. As such, 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 advanced counseling and psychological management provided to patients is impressive.

Another characteristic of success within the Rio system is acknowledging the available health system for its advantages and limitations. The research team views the external funds of clinical trials as mechanisms to enhance the existing system. For example, many of the serodiscordant couples of HPTN 052 are referred from local government funded HIV voluntary counseling and testing (VCT) centers. Using study funds, the research site developed an enhanced lab capacity and is now able to offer affiliated VCT centers quick confirmatory HIV testing results. This allows patients to receive their HIV results from the VCT locations in about two weeks compared to accustomed 3-4 month wait period. The research sites benefit from the identification of possible participants for their study protocol.

These research teams believe strongly in the concept of solidarity; that is doing something that might benefit oneself, but will definitely benefit others. Another example is their passionate commitment to research for the benefit of the community. As such, the sites value and work hard to maintain strong relationships with their community bases. A current proposal of the Rio Community Advisory Board is for the research sites to collaborate with a large, localized non-governmental organization (NGO) with established offices and community workers in many of Rio’s most difficult neighborhoods. By supplementing the salaries of the existing community workers, the HPTN site and NGO would work collaboratively to get HIV prevention and study recruitment messages into the communities. The research sites will perhaps benefit from reaching a wider potential recruitment audience, while the communities will benefit from enhanced health information delivery.

Participants do benefit from the external funding of clinical trials, as compared to the availability and quality of care in the SUS system. For example, the study staff is able to more adequately provide humanized care because of their low provider to patient ratio, as well as availability of an interdisciplinary staff. Having the ability to use external funding to enhance an already strong staff base allows patients to benefit greatly from someone helping them individualize their care and navigate the system.

Yet it is important to realize that the Rio site also faces the same barriers of other sites to work within a health system that in practice is not perfect, and to address the overwhelming social needs of the participants. For example, to access specialized care within the SUS system, the Rio team must often rely on their personal and professional connections. The overwhelming amount of need within the community as well as the complexity of social issues is not unique to the Rio site, but it is a barrier to achieving the level of patient care success that is idealized by many in the Rio clinic teams.

Appreciating the model of care being provided by the Rio HPTN site, there are factors that might serve as recommendations to other sites aspiring to improve their level of care for participants. First, reaffirm that research is to benefit the community, thus sustain mutually beneficial community relations. Secondly, it is important that providers from all health disciplines work collaboratively, as a true interdisciplinary team, to address the holistic needs of the participants. Finally, appreciate the concept of solidarity in recognizing the importance of government, non-governmental organizations, and the individuals themselves in addressing the issue of HIV and AIDS as a collaborative social responsibility.

University of Pennsylvania, Philadelphia, PA, USA

Kerry McLoughlin

HISTORY OF THE SITE

The HIV Prevention Research Unit at the University of Pennsylvania Center for Addiction Studies has been a research site since 1989, first as a HIVNET site and now a HPTN and HVTN site. The main research focus is enrolling subjects at risk for HIV due to their drug use and sexual pratices. Dave Metzger is the site PI, began the HIV Prevention Research division. Annet Davis-Vogel, Manager of Research Projects of the HIV Prevention Research Unit, and the Project Director for HPTN 037. She has worked there for 10 years.

The site is currently home to two HPTN trials: 035 and 037. This case study focused on HPTN 037, as staff from 035 were not available at the time of the case study visit. The study site for 037 is the RAP office, located in North Philadelphia.

Entrance to the HPTN 037 study clinic in Philadephia, PA, USA (K. McLoughlin, 2006).

PARTNERSHIPS/REFERRAL RELATIONSHIPS

In Philadelphia, the referral system grew organically over time. The researchers have been referring to these facilities for years, but initially, the Manager of Research Projects drew on her personal contacts with others who work in the field of HIV/AIDS and substance abuse to identify key contacts and referral sites. She also identified referral sites through word of mouth.

Of the relationships with referral sites, she said they are not study dependent. “I will refer to these places wherever I am working.” She noted the relationships she has with referral sites were developed before HPTN and will go on after HPTN. The researchers and their partners are part of a community working to promote harm reduction among injection drug users.

Referral System for the Study

The two Harm Reduction Counselors at the study site make the referrals for study participants. If study interviewers identify the need for a referral, they usually tell the participant to speak with the counselor. However, the recruitment and retention staff have provided referrals to individuals while in the field. No medical care is provided at the study clinic, and no funding is available to cover medical or social care costs for participants

BRIEF OUTLINE OF HEALTH CARE SERVICES/STRUCTURE IN PHILADELPHIA

Philadelphia has one of the strongest health care structures in the US. The number of medical practitioners and facilities per person is higher than the national average (Grande et al, 2005). There are four major medical schools (Temple, Jefferson, UPENN, Drexel) and about 40 public and private hospitals.

Philadelphia has a number of health care facilities specifically for low-income populations, including eight Health Care Centers (HCC) run by the Philadelphia Department of Health and a number of federally qualified healthcare centers (FQHC). FQHCs are non-profit organizations that receive federal funds to provide primary health care to an underserved population. The HCCs and the FQHCs provide services such as family planning, STI care and treatment, HIV/AIDS care, dental care, and immunizations on a sliding fee scale. The HCCs refer patients for specialty care to designated hospitals, and offer patients a social worker’s assistance in applying for medical insurance and when referred (www.phila.gov/health accessed November 13, 2006; Grande et al, 2005).

While Philadelphia has many options for the uninsured or underinsured, the system is strained. Half of patients at the Health Care Centers wait at least 3 weeks to get an appointment, or many hours if they walk-in (Grande, et al, 2005). As the number of people in Philadelphia without insurance is growing, this problem will continue (Grande, et al, 2005).

Philadelphia offers a wide array of HIV/AIDS services through the AIDS Activities Coordinating Office (AACO) of the Department of Health. The AACO is funded though the Ryan White CARE Act, the CDC, and the city of Philadelphia.

Services include medical care, financial assistance to purchase medications, case management, home health care, dental care, psychosocial services, food banks, transportation to care services, day and respite care, client advocacy, and assistance with housing expenses.

There are several state programs available to assist HIV/AIDS patients cover their drug costs, including the Pennsylvania AIDS Drug Assistance Program (ADAP), the Special Pharmaceutical Benefits program, and Medical Assistance One program is sponsored by pharmaceutical companies: The Patient Assistance Program.

In terms of HIV/AIDS care and treatment facilities, almost 50 facilities have physicians who are experienced in HIV/AIDS in the Philadelphia area (CHOICE, 2006). About 40 facilities provide HIV/AIDS care and treatment to people without health care insurance (AIDS Library, 2005; CHOICE HIV, 2006). Most facilities have sliding fee scales (AIDS Library, 2005; CHOICE HIV). The clinics that offer free care range from university hospitals (Drexel, HUP, Temple); to city-run health care centers; to non-profit and private facilities. Many receive federal funds through the Ryan White CARE Act to care for HIV+ uninsured and underinsured patients.

There are a wide variety of social services available in Philadelphia, including homeless shelters, halfway houses, domestic violence services, and in-patient and out-patient drug rehabilitation services.

> *"Philadelphia is fortunate. We have a number of care options." (Project Director)*

WHAT ARE 037 PARTICIPANTS NEEDS AND HOW ARE THEY MET?

HPTN 037 is a Phase III randomized study investigating the effects of a behavioral intervention on HIV prevention among Injection Drug Users and members of their drug and sex networks. The majority of participants are male. The study is housed in the RAP office, a small office in North Philadelphia. The study is scheduled for early closure on June 30, 2006.

HIV Care and Treatment

The major endpoint of the study is whether a participant seroconverts. The staff test for HIV/AIDS during screening and at each study visit. The site has identified a small number of seroconverters (n=8) and 62 people who were HIV positive during screening.

At the time of the case study site visit, eight subjects had seroconverted while enrolled in the study. Seroconverters continue with follow-up visits to receive counseling and support, but staff move to link seroconverters into community services immediately. Study counselors ask seroconverters to choose where they would like to go. They can choose the clinic most convenient to them geographically, or for confidentiality reasons, they can choose a clinic in another part of the city. Study counselors then call the clinic that the person chooses and sets up an appointment for the person, sometimes putting the participant on the phone with the clinic staff.

Waiting room at Infectious Disease Clinic at Presbyterian Hospital, a referral site in Philadelphia, PA, USA (K. McLoughlin, 2006).

Counselors follow up with seroconverters by telephone and/or at the next study visit to see if they have gone for their referral or encountered any problems in trying to access care and services. Counselors encourage those who have not gone for care/services to go. All seroconverters are being contacted and reminded that the study will end June 30, 2006, and to insure they are connected to care. HIV positive screen failures were given verbal information on care options at the post-test counseling session, but no follow-up is conducted.

> *Recently, Ruthie, a study participant, tested HIV positive. At first, she did everything she was supposed to do. But then, she stopped going for help. She had been going to a support group on Wednesdays at Lax Center. She also missed a few follow-up visits. When Khadeja, the Harm Reduction Counselor, talked to the woman on the phone, she found out that the woman felt depressed. She had been working a lot and she was trying to stay strong for her children.*
>
> *Khadeja kept calling her, or “stalking her”, as she puts it jokingly. She talked to her about the importance of “going to group.” Khadeja reported to me with a big smile on her face that Ruthie called the other day from*

> *outside the Lax center to say she was going to the support group meeting. The follow-up worked. (fieldnotes, 4/28/06)*

While there are about 47 facilities which provide HIV/AIDS care and treatment in Philadelphia, the main referral sites for HPTN 037 participants are the ID clinic at Presbyterian Hospital, the ID clinic at Hospital of the University of Pennsylvania (HUP), and the Jonathan Lax Center. All three facilities offer case management services, and treat patients with no insurance and/or little income. Lax Center and the ID clinic at HUP offer support groups for women and men; the ID clinic at Presbyterian Hospital has a support group for men (the women's group fizzed out). Lax Center has a psychologist, nutritionist, and acupuncturist on staff.

Patients of Lax Center can also access services through Philadelphia FIGHT, the center's parent organization located in the same building. FIGHT, a non-profit organization focused on HIV/AIDS, offers a program called "Project TEACH" for HIV positive people. Through classes, participants learn how to navigate in the health care system and to advocate for themselves. They also discuss disclosure issues, provide moral support to participants, and recently added a job training component. The Project Director for 037 has referred research participants to Project TEACH for years.

> *Annet told me about some women she referred to Project TEACH in 1995. Before going, they had never told anyone they were HIV positive. After joining Project TEACH, 'they went through a metamorphosis.' They attended a conference and talked about their status. They started becoming AIDS activists. She said prior to their experience and training in Project Teach these women 'barely went out of their houses!' (fieldnotes, 4/26/06)*

The clinic at Presbyterian Hospital is especially friendly to IDUs, as they have experience working with drug users, accept walk-ins and do not punish patients when they miss appointments.

> *Jody told me that some clinics will ask a patient to not come back or to pay if they miss an appointment. She said she was charged $50 for missing a dental appointment recently. This clinic does not do those kinds of things. "It's bullshit," she said. (fieldnotes, 4/25/06)*

The 037 Project Director has high regard for the clinic at Presbyterian:

> *We can't provide the care, but we know that we can refer the participants here (Presbyterian Hospital), to a caring, patient-centered clinic. (Project Director)*

The key contact (a nurse practitioner) at Lax Center has experience working with IDUs, and is willing to accommodate patients who may come to an appointment high, miss appointments, or show up unscheduled, although this may mean skipping lunch or juggling a heavy workload.

> *I tell patients 'you don't have to be clean to get care. It's OK.' They can still come. (nurse practitioner, Lax Center)*

The key contact noted that not all providers are willing to care for such patients, and the receptionists do not appreciate unreliable patients.

Lizzie Schmidt, a nurse practitioner at Jonathan Lax Center, a referral site in Philadelphia, PA, USA (K. McLoughlin, 2006).

The ID Clinic at HUP is the least friendly to IDUs, as they do not accept walk-ins, and are located on the University campus, which can be hard to navigate. The HUP ID clinic does have a program to provide a number of free visits to HIV/AIDS patients with no insurance and also provides excellent health care.

Another aspect of all three referral sites is that they try to link patients into other research studies or use research studies as a resource. HUP and Lax Center house their own research studies. All three facilities are recruitment sites for a variety of research studies. One provider said he will refer HIV positive patients with little income to an ACTG clinical trial; if they become participants, they can receive care through the trial. Another provider said she will send patients who cannot afford certain tests to a study to get them done for free. Then the study provides her the results. A third provider said she sees research as a resource for her patients as studies can go "above and beyond" - they can provide cutting edge treatments, transportation, personalized attention, and compensation. For example, she has referred a number of depressed female patients to a study of depression, as they do not have enough psychologists on staff to help the great number of depressed patients they see. She said, “I will use research to get clients extra care.”

Primary Care

As the study is behavioral, the staff do not have to contend with providing care for participants with adverse events. The staff do not test participants for any STIs besides HIV/AIDS, nor do they perform pregnancy tests. However, participants do ask study staff for advice on where to seek medical care, and at times, staff notice that a participant needs medical care. Medical needs for participants include:

- STI testing and treatment (the majority of IDUs have Hepatitis C)
- primary care (including vein care)

According to study staff, family planning and pregnancy needs have not been an issue. One reason is that the majority of participants enrolled in the study are men. As for the women, many women who regularly use heroin experience alterations with their menstrual cycle, ranging from irregular periods to not having periods. While study counselors and interviewers did not mention female participants requesting advice or referrals for this issue, if it did come up, study counselors would refer participants to family planning & health care providers. All participants are provided condoms during study visits.

For general medical care, and STI testing, care and treatment, counselors first ask participants if they have a primary health care provider. If so, they are advised to seek care there. According to the study counselor, many participants have jobs and a primary care provider.

If a person has no primary care provider, the study counselor will give the participant verbal information on several options. The study staff have compiled a resource guide on health care and social service facilities in Philadelphia. They reference this guide when referring a participant, but also draw on the internet, and their own experience and knowledge of options in the area.

> *During counseling with study participants, we ask them what their needs are. We go through the (resource) guide to identify places. If we can’t find it in the guide, we will go online. (study counselor)*

For study participants without health care insurance the HIV Harm Reduction Counselors use two main options when referring a participant for primary health care: the city-run Health Care Centers (HCC), and the Streetside Health Project of Prevention Point Philadelphia (PPP). The HCCs offer free health care to Philadelphia citizens, and are located throughout the city. In fact, there is one located a few blocks from the study clinic. However, it can take several weeks to get an appointment at a district clinic, or many hours, if one walks-in. According to the director of programs at PPP, there is currently a four month wait for mammogram and a six month wait for a Hepatitis C test.

The Project Director said the wait is so long at HCCs, she advises participants to bring a snack, something to occupy their time, and if still using drugs; not to go "dope sick" due to the long wait on the day of your visit. She also tells them, "Pay attention so you don't miss your name getting called because they are not going to call it again."

Another issue is that the HCCs require identification and proof of residency to access care. According to the Project Director and the PPP director of programs, some IDUs have lost their IDs, and do not have the correct paperwork or money to get a new one Also, HCC staff are not necessarily trained to work with IDUs. While the HCC near the study site treats IDUs respectfully as they are located in an area with high drug use, other centers may not. According to study staff, most participants would rather not go to a HCC for care.

A room for use by clients at Prevention Point Philadelphia, a referral site (K. McLoughlin, 2006).

A better option for many HPTN 037 participants is The Streetside Health Project. The Project is coordinated by PPP, a non-profit organization aimed at providing care and services for Injection Drug Users. Through the Streetside Health Project, IDUs can access primary health care through mobile care units Thursdays through Saturdays. People do not need ID to access care, and registration is anonymous (only basic demographics and drug history is collected). Medical students staff the mobile care units, and provide wound care, care for respiratory infections, Hepatitis A and B vaccinations, flu shots, prescriptions, free birth control, and STI testing. They also make referrals for medical care and social services. PPP also coordinates syringe exchange sites. Staff offer free supplies, including condoms and bleach kits, and provide information on PPP's other services (legal advocacy, medical assistance social worker services, support groups, VCT, and case management).

According to a study counselor, there are other facilities and programs where participants can access STI testing and/or treatment that have shorter wait times than the HCCs, including Covenant House, the Youth Health Empowerment Project (Y-HEP) for people under 25 years old, and Blacks Educating Blacks About Sexual Health Issues (BEBASHI). These clinics may also be a good option for those participants who are not IDUs, as they may not be comfortable at the Streetside Health Project.

Study staff have referred participants with Hepatitis C to a clinical trial at Hospital of Pennsylvania. However, as a number of participants do not have phones it has been difficult for them to enroll, as people wishing to enroll must leave a phone message and are called back at a later time. In addition, the trial requires participants to come for follow-up visits on specific days at specific times. For many 037 participants, this is not possible as their lives are not very stable.

Psychological Services

General counseling is a need that participants have that they tend to get through the study visits. One study interviewer said that interview sessions often go “outside of the box” and that participants are walking round with a “big weight on their shoulders”, and when they come in for visits, it is like they “dump” the weight off here. Another study interviewer noted that many participants do not have stable relationships, so may not have someone they can talk to about their problems. Interviews can become ‘a therapy session.’

When I asked if interviewers and the study counselor were trained for that or expected to be doing psychosocial counseling, they said they were not and did not, but it is part of their job. Two retention staff members said that, “we may be the only people they can talk openly to about their problems” since injection drug use is stigmatizing and illegal.

The Project Director does not provide counseling training to staff because she does not want to encourage the development of a therapeutic relationship between study staff and participants. Such a relationship is not sustainable, and she also believes “it is a disservice (to participants) and may border on unethical . . . especially if medications may be needed.” She believes that the study staff's responsibility is to refer participants who need psychological counseling to trained specialists, and assist them with the referral process. She emphasized that “we are a research site and not (a) treatment (site).”

Social Services

Study staff said that HPTN 037 participants have expressed a variety of social service needs:

- housing
- domestic violence
- clothing needs
- food
- employment
- legal services
- a place to shower and wash clothes.
- incarceration

There are a variety of social services in Philadelphia. Staff usually consult the resource guide in order to find a service that is conveniently located for the person. For example, a participant came in asking for help finding clothing, and Emma, part of the retention team, consulted the resource guide and found a place to refer him.

Street scene in the neighborhood where the Philadelphia HPTN 037 study site is located (K. McLoughlin, 2006).

Prevention Point Philadelphia provides a number of services and is a major referral site for study participants' social needs, as they have a support groups, a drop-in center with a shower, and will soon have a washer and dryer. They have a social worker who can help people register for Medical Assistance (Medicaid) or get benefits reinstated if they are canceled, or get a new ID card so they can get benefits. They recently started a legal advocacy program. According to the director of programs, many IDUs have outstanding bench warrants which prevents them from accessing state services. The Legal program will help people clear their records so they can move on with their lives. Prevention Point Philadelphia and Pittsburgh offer syringe exchange sites, and are the only places in the country that do so legally.

As part of retention activities, the study sends letters to incarcerated participants. The letter reminds the participants to return for study visits upon release. The letter also provides the address for Books Through Bars, a service which provides free books to prisoners. The study will also supply stamped envelopes to incarcerated participants.

I asked two staff members if doing social service referrals is extra work for them, as one described making phone calls to find a place to get clothing. They said this part of their job is just as important as the other aspects of their job.

Drug Treatment

All of the index participants in 037 are IDUs. The study recruits members of the index participant’s drug and sex networks. Once in the study, index participants do not have to continue their drug use to be eligible for the study. A number of participants have expressed the desire to go to rehab or detox.

While there are a number of in-patient and out-patient drug treatment centers in Philadelphia, study staff mentioned two main programs they refer participants to: the Behavioral Health Special Initiative (BHSI) and the Community Behavioral Health (CBH) program. Both are city-run programs. CBH is for Medicaid patients, BHSI is for patients ineligible for Medicaid. Patients call the programs, their needs are assessed, and ultimately placed in an appropriate substance abuse program.

While the BHSI and CBH programs are free, a person can ‘max out’ their use of the programs. A person can only receive treatment a certain number of times per year. Some people will go for detox, relapse, and need to go to detox again. But if they have used all their chances for the year, and cannot afford services, they cannot get treatment. A few staff members described people facing this situation who go to an ER and say that they are considering suicide. Then they will be placed in detox, no matter if they have maxed out their services.

A barrier to accessing the services in the first place is that signing up is a two step process. One has to call the BHSI or CBH program and request help, then wait for the program staff to call back with treatment placement information. One staff member said a participant had to wait around the study office all day fro the return phone call, as he did not have his own phone.

Sustainability

In terms of the partnerships, the relationships with key staff in the referral sites stem from the Project Director's personal connections. However, the Project Director states she has turned these relationships over to the study staff, and the relationships would not fall apart if she were to leave. She "turned them over" by training the harm reduction counselors on how to make referrals. The counselors were provided the names of contact persons in the referral agencies. As counselors needed to refer participants, they established their own relationship and learned how to navigate through the systems. If they confronted obstacles, The Project Director would work with or coach the staff, and they would observe how she handled barriers to referral. In addition, all the information about referral agencies and contact names was recorded in the resource book staff use when making referrals.

Seroconverters in Philadelphia should be able to access care and treatment for HIV/AIDS long after the trial is over. Unlike people in developing countries, the clinics are not dependent upon PEPFAR funds, they do not face stockouts or shortages of drugs, and they are pretty well staffed. Seroconverters are not dependent upon the study staff for care and treatment. While seroconverters do receive counseling through the trial, most of the HIV/AIDS care and treatment clinics/centers offer support groups, so study participants will still be able to access counseling services after study termination.

However, it is a continual challenge in the US to provide care and services to uninsured and underinsured patients, as a number of 037 participants are. Some providers refer patients to clinical trials to get free HIV/AIDS care and treatment, and other types of medical care. This may increase if funding for the Ryan White CARE act, Medicaid, Medicare, and/or other sources of funding for low-income populations are cut. However, relying on research studies to cover costs for people with little money is not sustainable, as studies are short-term, and creates ethical issues, as people may only be joining studies to access needed care. More sustainable solutions, such as universal health care for US citizens, are needed.

One of the main referral sites for 037 participants is Prevention Point Philadelphia. While the organization is well-established, they are facing increasing challenges in funding their syringe exchange program. As syringe exchange programs are illegal at the state and federal level, the funding is very restricted. In addition, funding from private donors is declining.

UNMET NEEDS

- Two study staff noted that most drug users have multiple issues. They felt programs could do a better job of addressing co-occurring problems (ex. addiction and depression).
- There is nowhere specific to refer someone looking for employment.
- One provider noted that most of her female HIV positive patients are depressed, and there are not enough services for them.

CHARACTERISTICS OF SUCCESS IN THE REFERRAL SYSTEM AND PARTNERSHIPS

- Personal contacts in the referral sites
  - Having a key contact within the referral site means study staff can call that person and give the staff information about the participant who is being referred. It may also lead to improved quality of care - two providers at referral sites said that out of professional courtesy, they will give a referred patient extra special care. Study staff have also used their connections to get research participants earlier appointments, if they believe it is necessary, although they do not abuse those connections.

  "I will treat the (referred) patient like a VIP." (nurse practitioner, Lax Center)

- Referral sites that are sensitive to the study population, share a common philosophy about patients, and a common goal.
  - In general, the study staff refer to places that have experience dealing with IDUs, and believe in the Harm Reduction Model.

- Strong health care system to plug participants into.
  - Philadelphia has one of the strongest health care systems in the US.

- Multiple high quality HIV/AIDS care and treatment options
  - All of the HIV/AIDS clinics offer support groups and case management services.
  - Having multiple HIV/AIDS clinics in Philadelphia prevents any one clinic from being burdened. It is also allows participants choice.

- Options for the uninsured and underinsured for primary care and HIV/AIDS care.

  - Many facilities receive funds through the Ryan White Care Act, aimed at covering HIV/AIDS related expenses for people without insurance, and/or low incomes. Many have sliding fee scales.

    - There are a number of state and city programs to cover costs of prescriptions related to HIV.

- Committed Staff
    - Staff are willing to go the extra mile to find the right option for participants. They see it as part of their job.

- “I scratch your back, you scratch mine” mentality (mutually beneficial)
    - The partners do favors for one another when they can. This mainly occurs between Prevention Point Philadelphia and the study staff. The site PI has advocated for PPP when their funding was threatened. Study staff manage the data from their syringe exchange site. Study staff developed the anonymous registration format that the syringe exchange sites use. The Project Director passes on information to PPP about studies that might be of interest to clients.
    - The Manager of Research Projects pointed out that referrals themselves can be beneficial for HIV/AIDS clinics, as the more patients a clinic has, the more federal funds they are eligible for.

- Mutual Respect and Trust

Partner organizations clearly trust the HIV Prevention Research Unit staff and respect the work they are doing. The Research staff feel that same way about their partners. Trust stems from the long-standing relationships and personal connections between the Center for Studies of Addiction and their partner organizations. Trust also stems from the fact that the researchers and partners share a common philosophy and commitment to patients/participants. The partners and researchers see themselves as on the same team.

> *“We are on the same page and have the same level of commitment to clients” (director of programs, PPP).*

Staff interviewed saw research as another resource for their clients. For example, one staff member said ‘we see the research staff as an extension of the social service network’. The partners viewed research as beneficial for their clients and the community.

Some partners do have a healthy level of caution when referring someone to a research study. One provider said she always wonders if patients are participating for the money, or if this study will be good for him/her. But in general, all the staff interviewed felt that research participation and their partnership with the research site is positive.

BARRIERS TO SUCCESS IN THE REFERRAL SYSTEM AND PARTNERSHIPS

- No formal tracking or follow-up regarding non-HIV related referrals to ensure participant received needed care.
- The study staff do not accompany referred participants, including seroconverters, to care facilities and cannot provide transportation. They will give participants subway tokens on occasion.
- Partnerships with referral sites are not formalized.
- Strained system for low-income populations. One HIV/AIDS clinic – Lax Center – has recently lost staff.
- Working with research studies is extra work for partners – either as a recruitment site or as a referral site.
    - One provider suggested that research sites could provide small incentives to providers to motivate them to help out. Also, one provider thought it would be nice if the research site could make some sort of contribution – ex) donate subway tokens to give out to patients. In contrast, one provider thought that they are doing what they should be doing for patients; researchers do not owe them money for taking referrals.
- The resource guide with information about referral organizations in the community that is used by study staff is needs to be updated. The HIV Prevention CAB took on the task of updating, but has not had time to complete it. An MSW student from UPENN who will be working at the site for a year will take on the task.

RECOMMENDATIONS

- Become familiar with services that each facility or organization provides
- Get a sense of which facilities will be sensitive to your study population
- For HIV referrals, find clinics that offer case management services.
- Identify key staff in each referral site who you can work with when referring a participant.
- Maintain a dialogue with referral sites/partners.

References

CHOICE. (2006). CHOICE HIV/AIDS Resource Guide, HIV-Experienced Physicians. Philadelphia, PA. Accessed November 13, 2006 http://www.choice-philadelphia.org

Grande, David, Rebekah Cook-Mack, Adrienne Corpuz Joyce, Joshua DuBois, Jessica Goldberg, and Alexis Smokler. (2005). Decent health care for all in Philadelphia: Local leadership and action. Woodrow Wilson School of Public and International Affairs, Princeton University. Accessed November 13, 2006 from www.phila.gov/Health

AIDS Library. 2005. Guide to HIV clinics in the Philadelphia area. Accessed November 13, 2006 from www.aidslibrary.org

UZ-UCSF Collaborative Research Programme, Harare, Zimbabwe

Patty Alleman and Marge Chigwanda

HARARE CONTEXT

Zimbabwe's public health structure was once the aspiration of many other African countries. However, years of political and economic turmoil has led to severe overall economic shortages across all sectors of society. Currently Zimbabwe has the distinction of having the highest inflation rate in the world at nearly 1,000 percent, thus making life even difficult for people gainfully employed. The economic shortages have 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. Compounding the problems further is the government's lack of foreign currency needed to purchase many of the medications that support their health programs, e.g., antiretroviral drugs (ARVs) for the treatment of AIDS patients.

Appreciating the current political and economic context in Zimbabwe, the public health system that remains is a direct result of the dedication of those health professionals who have stayed. According to many of these health professionals, as expressed by one principal investigator (PI), "Zimbabwe is doing very well under very difficult circumstances." Further, as expressed by another PI, "Zimbabwe has an excellent health system framework for a developing country." Undoubtedly, there does still remain a 'framework'; however, that framework is under much strain in the current economic environment. In the past the government policy was to provide treatment to any person in difficult circumstances and earning below the minimum wage, yet under the current economic strain this is a difficult policy to maintain. Thus many of those who are involved in research view part of their work as strengthening the government health system in terms of financial and human resources. For example, providing required diagnostic testing for study affiliated patients needing to start ARV treatment, and offering to help develop national guidelines from research findings.

As indicated by many staff members of current HPTN research projects in Harare, the most needed referrals are for psychosocial services and access to ARV treatment for participants who are screened out HIV positive during the recruitment process for the HIV prevention trials and hence fail to meet the eligibility criteria, and those who seroconvert during the trials. It is important to note that the existing ARV program in Zimbabwe does not currently benefit from the major sources of external funds, i.e., PEPFAR or Global Fund, that support ARV programs in many of the neighboring countries. Provision of care for research participants is a response to the current standard of health care available in Harare, dedication of a committed local research community, and reliance upon the careful coordination between the government and nongovernmental groups that remain in the health service provision sector.

MEETING THE NEEDS OF STUDY PARTICIPANTS: MEDICAL HEALTH AND SOCIAL REALITIES

Currently in Harare there are four HPTN studies (039, 035, 052, 046), albeit in different stages of activation. Additionally, there are other externally funded studies also being conducted at the University of Zimbabwe-University of California San Francisco (UZ-UCSF) research site. Although the studies focus on different sections of the population, e.g., HIV positive mothers and prevention of transmission to babies in 046, and HIV negative women in 035, the standard of care for all research participants is very similar. However, as the needs and access to ARV care for screened out potential participants and seroconverters are unique, they will be discussed separately below.

Medical needs

According to a member of the counseling core team at UZ-UCSF, there is a set package of services that is part of all research trial protocols and available on site for research participants. These services provide most of the primary health care needs of research participants. Therefore, research participants are benefiting from study participation in that a lot of their primary health care services are covered by the study funds, e.g., contraceptives, and there is a reduced need to access fragmented government services for primary care.

For medical needs of participants that cannot be met at site, i.e., specialized health care such as advanced testing or treatment, they are referred to local government clinics and hospitals. Undoubtedly, these health settings are very impacted by the current economic reality of Zimbabwe, which leads to often insufficient service availability. Yet again the research participants do benefit from their study participatory status as they often are provided a referral letter from the study, thus service access is enhanced.

However, in addition to limited service availability, other potential barriers to participants accessing these external referrals include not having bus fare and not being able to pay the clinic administration fee. The administrative fee is in constant flux, e.g., within the last month it increased from .50 cents $US to 10 dollars $US. In only extremely dire medical circumstances is the administrative fee paid from study funds. In non-emergency medical referral situations participants can be referred to a Social Welfare Station to access a medical treatment order (AMTO) that covers investigations, treatment and the basic administrative costs at government clinics. However, the application process is lengthy. Thus there is a significant gap in the government referral site access, particularly in regard to immediate medical care needs, because many people are not able to pay the amount of the administration fee.

Psychological and counseling needs of research participants are assessed by study counselors, and any needed psychological/counseling referrals, including domestic violence and family therapy, are provided. However, as in the case of medical referrals, the existing referral network for psychological and advanced counseling services is extremely limited. The most often used referral organization is New Life. New Life has support groups called ‘post test clubs’ that offer nutritional counseling, psychosocial support counseling, and informational sessions to any person who has been tested for HIV. Currently there are two New Life offices, one in Harare city center and one in the suburban area of Chitungwiza. The research site has been able to strengthen the relationship with New Life by buying emergency purchases, e.g., a hose pipe to provide water for the clinic, and documenting the referral process through an official referral form, thus aiding both organizations in providing evaluation data applicable in reports for funders. Importantly, New Life has an extensive referral network that includes access to Opportunistic Infection (OI) clinics which are the sites for ARV treatment.

In an effort to meet the needs of participants from another suburb of Harare, Epworth, UZ-UCSF has just begun a relationship with an organization called Connect (Zimbabwe Institute of Systemic Therapy). As a means to assist Connect, the research site has assisted the organization in acquiring needed office space and desks. As described by a member of the counseling team, the maintenance of these referral relationships is because the organizations “need each other,” that is, the research site gets funds to provide a certain standard of care for participants, and these referral sites get funds to provide psychosocial and counseling services to people infected and affected by HIV. Therefore, the UZ-UCSF project is able to provide funding for very basic infrastructure needed to allow organizations such as Connect to provide the care.

In addition to counseling available on-site by research staff and through referrals, some of the existing HPTN studies have also started support groups as a means to enhance the psychosocial support for participants. For example, in 052 there is a support group that meets once a month, and invited guests, e.g., medical providers, give informational talks. In the 046 study, anticipating that depression of mothers may be a potential concern, they anticipate modeling an existing mentorship program of a similar mother to child transmission study currently being conducted in Harare. These mentors are paid women who have completed their time as a study participant, and are trained to address certain psychosocial and knowledge needs, such as, adherence to ARVs and partner communication.

As mentioned, an important part of ensuring the medical referral network for participants is the consistent monitoring of referral sites by a dedicated staff at the research site. Yet as stated by a counseling staff member, the “challenge for most organizations is lack of resources to deal with patients, not quality of services." Additionally, there remain other barriers for participants wishing to access referral services that are not aided by their research participation status, e.g., transportation costs to referral sites. Also, certain types of referral services, e.g., a training program on how to be a caregiver to a HIV positive individual, are not available within the current government or nongovernmental organizational structure in Harare.

Social needs

Among the many, many social needs of participants, availability of food is the most needed referral. For patients who are HIV positive, there are a few organizations that receive special funding to provide food for this population. However, for all participants who are HIV negative, there are very limited sources of referral. Historically, participants needing food supplements have been sent to the Red Cross. Yet currently the Red Cross does not have enough food to meet the demand. Additionally there is one local NGO that also currently has some food for distribution, and access to this service is enhanced with a UZ-UCSF referral letter.

In regard to meeting other social needs, the research staff builds formal and informal relationships with local non-governmental organizations. In the example of the local NGO with limited food supply, an arrangement has been made that formalizes the referral process. That is, this organization is part of the master referral list that is constantly updated and shared among UZ-UCSF research teams, and all referrals are implemented through the official referral form from UZ-UCSF. Yet, other organizations ask not to be part of the official referral process as they feel they will be overwhelmed and not be able to handle any needs in the community. For such organizations UZ-UCSF counselors are informally provided the contact information and limitations of referral.

MANAGEMENT OF SEROCONVERTERS AND POTENTIAL PARTICIPANTS WHO SCREENED HIV+

Among HPTN community advisory board (CAB) members, the biggest referral concern is for those individuals 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. However, according to a few study PIs, a good number of the participants who get screened out due to their HIV positive status already knew they were positive, and decided to get screened for the study because of the "perceived benefits" of confirmatory HIV testing, access to other studies that need participants who are HIV positive, or at the very least, enhanced access into the government ARV programs.

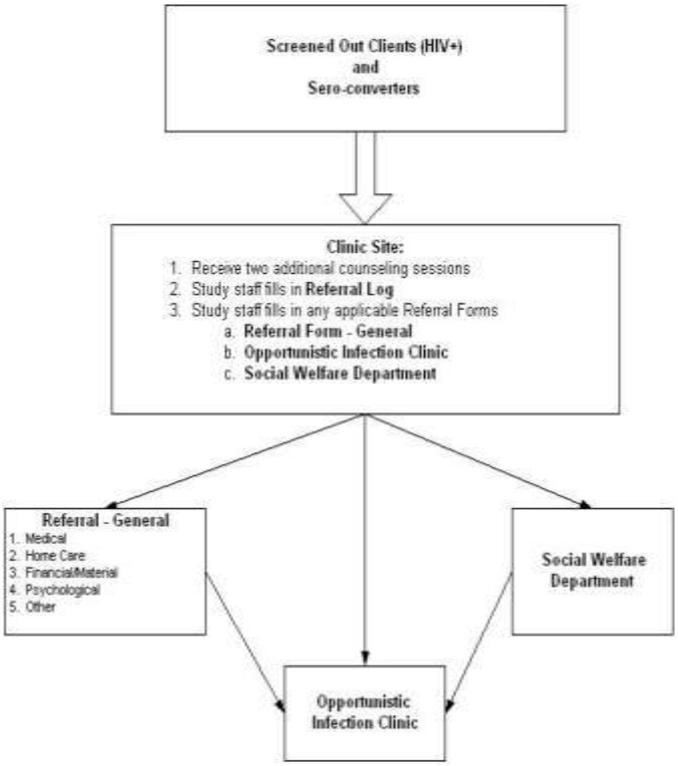
In many of the current HPTN studies, seroconverters have access to ancillary studies that are recruiting participants who are HIV positive, e.g., in one study all the seroconverters have been referred to an ancillary study. However, in response to the CAB concerns and the current needs at the UZ/UCSF research site, the counseling team has proposed a standard operation procedure (SOP) that specifically addresses the referral needs of HIV positive screened out clients and seroconverters. As illustrated in the flow chart below, the SOP proposes to provide 'guidelines for providing direct care and referral services to both current and potential participants 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 other service providers in government and those in the community.'

As indicated on the flow chart, there are services that are directly provided at the research site and those that are referred out. Similar to current research participants, the direct care that is available for these particular clients include 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 study until the end of the study, 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 due to HIV positive status, they receive two additional counseling sessions at the research site and referral to services as needed, i.e., general referrals, OI referrals and social welfare referrals. The partners of these screened ineligible potential participants are also offered HIV testing.

In regard to the referrals for these clients, they are most often referred to New Life for psychosocial needs and a mix of organizations for other referral needs. For Opportunistic Infection (OI) clinic access, these clients are referred to one of four ARV access points in the Harare area. Although ARVs are theoretically free at government clinics, it costs about 100 US$ for screening testing costs before ARVs can be initiated. Considering the bus fare to attend a clinic appointment is often a major economic burden to patients, undoubtedly paying for these tests is unrealistic. There is an option to apply have the costs paid by government social welfare services, however, this process is lengthy and adds additional time to accessing ARV care. Currently there is at least a 2-3 month wait for screening testing for potential ARV access, and another 1-2 month wait period for initiation of ARVs. Having CD4 counts and other relevant laboratory investigations attached to the referral letter from a UZ-UCSF research project does shorten the time to access ARV treatment considerably.

There is not enough ARV availability to meet the high demand, and further, only first line ARV drugs are currently available. Therefore, for those participants who seroconvert during the study and have access to the screening tests provided with study funds, it is, according to one study medical director, "a privilege for the government clinics to get a referral from a research site because the patient comes to clinic with all screening tests completed and are ‘ready’ for ARVs.” However, these patients are often in the least need for ARV initiation due to their viral and immunity counts. Potential participants who screen ineligible for HIV prevention trials due to being HIV+ are not considered participants, thus are not provided the pre-screening tests for ARV initiation. The provision of screening tests needed for ARV initiation for all screened HIV+ individuals would greatly impact their timely access to ARV care.

REFERRAL FLOW CHART:
Screened Out Clients (HIV+)
and
Seroconvertors in Enrolled Studies



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. Identification and collaboration with existing organizations is very important to ensure that, according to a member of the research staff, “competent care is provided in the community after the research project is finished.” As part of the proposed SOP, the referral form expands upon the existing form that is currently only used with referrals for research participants to New Life. This form will be used with all referrals and includes 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.

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. For the referral sites that are most often used by the UZ-UCSF research teams, i.e., New Life, OI clinics and the Social Welfare Department, the counseling department has recently started an enhanced collaborative evaluation system that uses a referral log that is maintained at each referral site. This enhanced system is in response to many past referrals only being evaluated by word-of-mouth from participant upon return, as sometimes the slips from the referral form got lost in the referral organization. On a monthly basis the counseling team from UZ-UCSF will visit these high-demand referral sites and examine the log to systematically document the referral process.

SUCCESS, BARRIERS AND RECOMMENDATIONS

As stated by one research PI, the “Zimbabwe system is there, water tight on paper, but with so many potential holes.” The success of the Harare HPTN research site in providing a standard of care for participants includes an extremely committed research team taking responsibility to cover these ‘holes’ with research resources and collaboration with other organizations who collectively are addressing HIV prevention and care for the population. Undoubtedly, research participants benefit from their participation in studies as they are provided primary care and referrals for specialized care that are not easily accessible as part of current government health infrastructure. However, the access to primary care is limited to those who classify as study participants, albeit active or serocoverters, and does not include the many potential participants who are found HIV+ during the screening process.

UZ-UCSF recognizes the need to seek additional funding to support their desired referral system. In particular the priority lists includes funds for capacity building and direct patient assistance. In regard to capacity building, the UZ-UCSF team believes there is a need for a designated psychosocial counselor who can coordinate and maintain linkages with referral agencies, and also to have ongoing training of personnel to understand and maintain the functioning of the referral system. For direct patient assistance the priority is for funding to provide ARV initiation testing and investigations to all individuals who screen out for HIV prevention trial participation due to their HIV+ status. Additionally, there is a need to supply bus fare and money for the administrative fee at referral organizations for those individuals (screened ineligibles and research participants) who cannot afford the costs and have yet to receive assistance from the social welfare system.

One staff member states that ideally competent care for participants is “not only physical, but is described holistically to include physical, psychological, social and mental well-being.” However, the economic and political reality in Harare makes even provision of specialized physical, psychological and social care a challenge. The need for ARV treatment is great. One researcher recommended that research institutes need to budget for ARVs and not only rely on the government system, especially in economically challenged environments like Zimbabwe. 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.

The Harare site has a very strong CAB that mobilizes stakeholders in their communities to support the research protocols. However, as discussed by one CAB leader, there is a need for the CAB to be further appreciated as an integral part of the research team, and “not only a window dressing.” Additionally, as stated by a few study members, there is a need to realize the importance of interdisciplinary approach in research teams, thus being able to provide more comprehensive services at the research clinic site. It is important for the research fraternity to continue to strengthen the referral agencies with any identified resources in order to assist in the creation of a sustainable referral treatment service network. Considering the extremely difficult circumstances of Harare currently, the commitment of the existing research teams to strive for holistic, high quality care for participants deserves to be recognized as a model of standard of care delivery through passion and partnerships.