

HPTN 052 Retention Workshop
June 7, 2010
Washington, D.C.

Challenges and Solutions

Lilongwe, Malawi

- **Challenge:** The couple needs a child but the negative partner is afraid of contracting the virus. He wants to marry a new uninfected wife but doesn't want the new wife to know that he was associated with an HIV POSITIVE person and wants this first wife to go away from his house/town to be getting drugs elsewhere for fear of her coming to see him. If anything he will be assisting her wherever she is going to stay without the knowledge of the new wife.

Solution: Study staff discusses with the couple about the risk of indulging in unprotected sex, at the same time information is given to the couple about PMTCT PROGRAMMES. Staff also stresses the importance of the couples to participate in the study.

What do you mean by PMTCT PROGRAMMES? What about counseling them that 052 is a discordant couples study and reminding the uninfected partner that by consenting to the study it means he/she is part of the study?

- **Challenge:** The partner male participant comes alone to the clinic for an interim visit because he is sick. A visit is conducted and he goes home telling the wife that the study staff has sent him to tell her (the index case) that she should stop her participation in the study and leave the house to stay away from the husband. This is because whenever they have sex with condoms they make him sick, therefore, she must leave immediately to avoid sexual contact and desires. This information was collected from the index during tracing from her.

The participant says, "The consent form says I can stop the study at any time," therefore he wants to stop.

Solution: The study staff explores other reasons for her intention to stop participation. Explanation is done about the importance of his/her study participation. His/her concerns are addressed and a way forward is discussed.

- **Challenge:** The index case (female) is having an extra marital affair to the extent that the new husband has moved in the house whilst the first husband is gone to the first wife. On the study visit day, there are two husbands and a wife. The wife intends to enroll the new husband and divorce the old husband. He cries to continue the study but the wife refuses his participation in the study as her partner.

Solution: The study staff counsels the couple about the importance of their participation in the study. However, the couple is referred to their marriage counselor and to come back after they resolve their marital issues.

- **Challenge:** The negative partner discloses the spouse's status to the parents/relatives. The relatives force their uninfected child to divorce and stop coming to the study because he has no virus.

Solution: The study team counseled the couple about the importance of coming to the clinic as a couple and on confidentiality issues among themselves. The couple was reminded about the issue of window period, an emphasis was put on the negative partner that there is a possibility of becoming infected though negative today. Partner advised to cling to an already known status partner than thinking about someone with unknown status. Lastly couple referred to their marriage counselors and encouraged to report together for their next scheduled visit.

- **Challenge:** The index participant is a second wife to a husband who has an uninfected first wife. She wants the husband to leave the first wife to prove his love for her. She thinks he may be discussing her HIV status with this first wife if he continues to be with his wife. The husband refuses to leave his wife. She decides to divorce him and stop coming to the study with him. The husband continues to attend study visits and willing to continue.

Solutions: The clinic counseled them individually since they are separated and they come to the clinic differently. The partner promised to continue participating so too the index case. Individually they were all reminded on the importance of reporting as a couple for couples counseling and not differently.

Locator not collected or lost. Difficult to trace.

- **Challenge:** Couple reported together for a visit and when it came to blood draws, the partner refused blood draws saying it was too much.

Solution: Despite the study clinic giving all the important information on sample collection, the client still refused; the study clinic did not collect blood for the visit, the client refused and wrote to SCHARP telling them about this situation to be alert in case we come across another same scenario. The couple encouraged to continue reporting for their study visits

- **Challenge:** Couple refuses to come back for the study because of blood draws.

Solution: The tracer nurses visited the couple to convince them about the importance of blood draws in the study and reminded them about all procedures and tests to be done as indicated in the consent form which they previously signed

Harare, Zimbabwe

- **Challenge:** An Index case was temporarily attached to a sister company in SA for skill upgrading. The participant's work schedule was not flexible enough to allow him to attend clinic visits as scheduled, during the week days. The participant showed concern since he was quite willing to adhere to his scheduled visits

Solution: Since the above scenario was a threat to our retention, the site opted to offer weekend clinics for the index case and any other couples who cannot afford attending clinic visits during working days.

- **Challenge:** Couple resides 140Km away from the clinic site (Extended outreach) and experiences high transport costs plus long distance. Sometimes gets to the clinic by midday for quarterly procedures and will have difficulty in getting transport back home. Couple tries by all means not to default but sometimes it's in vain.

Solution: Transport tickets for 140Km radius are reimbursed plus the normal 4USD reimbursement. Couples who stay 140KM radius from the clinic site are ferried back by study, if procedures exceed working hours

- **Challenge:** An Index Case in (Arm 1) experienced inability to report to the clinic for a scheduled clinic visit due to ill health. The Index informed the clinic through the phone.

Solution: Study assigned project vehicle to collect the index. This is currently practiced to all those couples who are unable to report to the clinic due to ill health.

- **Challenge:** Couples, mostly in a cohabiting relationship, are presenting with multifaceted marital discords which threaten or result in separation, hence creating a decline in the retention rate for partners

Solutions:

Thorough pre-screening procedures to ascertain willingness to continue as a couple for the duration of the study are conducted.

Continuous and intensive couple counseling sessions at quarterly visits

Couple counseling sessions conducted despite the presents of either the Index or the Partner (Sessions can be done with the part of the couple present)

Engaging couples in HIV discordant support group meetings whereby various psychosocial issues are addressed.

Systematic Referral Procedure of intense marital issues to respective psychosocial organizations

- **Challenge:** A handful of HPTN 052 Couples engage themselves in self sustainable projects in order to cater for their basic needs, (e.g. food) since they are not employed. Time spent in such projects sometimes forces the couples to default their clinic visits.

Solutions:

The study conducted a survey on the social welfare programmes in the community offering food AID in order to assist these couples.

The study networked intensively with local food AID organizations e.g. Christian Care and Rokpa.

A thorough assessment of the 052 couples was conducted by the 052 team basing on the degree of need.

Participants were classified according to their vulnerability.

Registrations for Food AID conducted.

Food is currently being distributed to couples in need on monthly basis.

Food contains high protein and caloric content.

This has tremendously controlled the trend of defaulting scheduled visits.

Chiang Mai, Thailand

- **Challenge:** Couples who live a long distance from the clinic have difficulty traveling for study visits.

Reasons: Problems with public transportation – by the time they return to their hometown, it is late at night, and there is no vehicle to take them the rest of the way home.

Solutions:

After receiving permission from the participants, the site rents a local van to pick up participants in groups of 2-3 couples (who live nearby each other). This allows them to travel to clinic and back home within one day. The participants are very appreciative that they no need to stay overnight and have the opportunity to meet new friends.

For motion sickness, our study physician prescribes anti-motion sickness drug in advance for them to take before traveling.

If participants cannot find someone to take care of their kids, we ask them to bring their kids with them and our nurse-aid provides babysitting services which include milk powder, a snack and toys.

- **Challenge:** One member of the couple must travel and live outside of Northern Thailand for work, and must travel a long distance for study visits.

Solution: The site provides reimbursement for long distance bus or train travel for study visits.

- **Challenge:** Couples are unable to come to clinic during work hours.

Solution: Several couples prefer to come around 5-6 pm in the evening after finishing their work. The site assigns staff to work over-time so that the couples can continue to be in the study.

Soweto, South Africa

- **Challenge:** Index participant who is on immediate arm reports that he cannot take his ARV's well because he is not employed and does not have food.

Solutions:

The social worker intervened in order to discourage dependency syndrome displayed by the participant.

The social worker challenged the participant to continue whatever part time job that was generating income for him before joining the study.

The social worker also emphasized to the participant how important it is for him to resume his normal life.

In addition, with the resistance from the participant, the social worker attempted to arrange food parcels for the participant and, unfortunately, discovers that HIVSA organization no longer offer food parcels.

- **Challenge:** Index participant on immediate arm is not adhering to her study drug because she claims that she does not have any reminder tools. The discussion with the participant reveals further that there is also a history of alcohol abuse, which makes it harder for her to properly adhere to ARV's when intoxicated. Further discussion with the participants reveal that she is intentionally not taking her drugs because she wants to fall ill and qualify for the Disability Grant.

Solution: One counselor has been assigned for this participant to do follow ups, random and scheduled home visits. Counselor will review reminder strategies on every visit. Counselor will discuss with participants dangers of not adhering to the drugs. Counselor will discuss with participant the dangers of taking ARV's with alcohol or when intoxicated

- **Challenge:** Index participant on immediate arm not adhering to her study drug. Partner participant mentioned that index is smoking dagga. The index is unstable; she moves around from one residential area to another due to unemployment, which hampers her adherence to the drugs.

Solution: One counselor assigned for participant to do follow ups with random and scheduled home visits. Counselor will review reminder strategies. Counselor will discuss barriers to non adherence with the participant, tracking down participants at all given addresses. Having one counselor seeing the same participants will help with consistency and participants will not be able to change stories at each visit.

Kisumu, Kenya

- **Challenge:** Participants move out of their rural home that is within the study area to live in an urban area (Kisumu town) that is 50km away. The couple has no contact phone number or person to be contacted in their new home in Kisumu. The family at the rural home had no idea where they relocated to in Kisumu Town.

Solution: Made three visits to the same rural home. Clinic staff alerted Kisumu staff and gatemen of possibility of this couple turning up at the Kisumu office. Coincidentally, the partner (male –heterosexual relationship) is spotted at a busy area in town by one of our staff and agreed to an appointment made with him for the study visit schedule. Participant honored the appointment one day to closure of allowable window period. Female partner said to have moved within 100km away to her paternal home. Staff was sent to obtain locator information and schedule appointment with her and to offer counseling to sort out marital issue that led to them staying apart. This is yet to be accomplished but the participant has agreed to come to the clinic.

Johannesburg, South Africa

- **Challenge:** Index is very ill and can not able to come to the clinic; partner called and reports that they can not able to do their visit.

Solution: The Unit will need to provide transportation to bring them to the clinic and take them back.

- **Challenge:** Partner not able to attend due to work commitment

Solution: Allocate dedicated staff to accommodate patient's visits to performed either before or after hours.

- **Challenge:** A couple is leaving in communal yard sharing almost every thing e.g. food, water and other source of things like refrigerator, they randomized to immediate arm were her medication will be kept in the fridge the one she is sharing with neighbors

Solution: To create a mini box and put ace bags to keep treatment inside.

- **Challenge:** Participants believe more on their culture and that affect compliance and retention.

Solution: Family involvement to give more understanding on study basis and give treatment support.

Rio de Janeiro, Brazil (IPEC)

- **Challenge:** Couple started both a new job and was in the training period; therefore they could not miss a working day, nor arrive late.

Solution: The site then asked them to come early in the morning to collect blood, then they went to work, and in lunch time (same day) the site sent a cab to get them and bring to the site for their visit, where staff were waiting for them;

- **Challenge:** Index had a small business and he had to set the bar, so he was the first to get on the working place and the last to leave.

Solution: The site then asked the couple to come early in the morning to collect blood, and then he went to work, and at night, after working hours, the site staff waited for them to complete their visit on that same day.

- **Challenge:** During a holiday when the site closes at noon the couple that lives very far was unable to get to site in time for blood collecting in the morning.

Solution: Site sent a car to pick up the couple.

- **Challenge:** Couple does not have someone to take care of their 3 children while they come to study visit. They always bring the children and cause great disorder in the whole clinic.

Solution: To solve this problem the site bought some toys and delegated someone from the staff to babysit the children while the parents were doing their study visit procedures.

A question for the retention workshop: What can we do to avoid that some participants keep rescheduling with no reason?

Gaborone, Botswana

- **Challenge:** Five couples had social problems and decided to break up and felt that there is no need of participating in the study anymore;

Solution: Counseling have been scheduled for couples who have social problems One day a week has been designated for one member of staff to provided couples /social counseling

- **Challenge:** Three index participants were not willing to start HAART one participant felt her CD4 is high the other was because of religion and the third participant was afraid of side effects.

Solution: Two were counseled however one does not want to come to study clinic because he does not want to be 'convinced'

- **Challenge:** One couple stated that study visit so frequent that they end up losing valuable time

Solution: Couple was counseled on the importance of study visits

- **Challenge:** Two participants stated that their supervisors are not happy with the hours they miss while attending study clinic

Solution: A letter was written to the supervisors explaining the situation, but still the problem persisted.

- **Challenge:** One index participant on the immediate arm was not happy that they may have to stop HAART at the end of the study

Solution: Counseled that it is a preventive study, thus it will be safe even when quitting

Question: The participant would like a social event and/or support group to be organized by the study clinic- what are the implications?

Blantyre, Malawi

(No Solutions were submitted from Site)

- Challenges:

Rumors. There are different rumors spreading in the communities concerning the study and study participants, such as satanic practices and blood sales. Participants' sudden monthly, quarterly trips to the hospital in town arouse suspicions.

Participants agree to be traced but give false locator information to get larger reimbursements. Consequently, you fail to locate them when you attempt to trace for missed visit or AE management.

Confidentiality. Study participants disclose to other members of their community about another couple's participation in the trial.

One participant decides to withdraw from the study and forces their partner to withdraw against their will.

Family members. Senior members of couples exert pressure on participants to stop participation despite couple's willingness to participate.

Relocation of study participants outside the catchment area. Some participants have relocated to far places including surrounding countries for different reasons despite there assurance that they don't plan to relocate during the study period.

Participants withdrawal from study without giving reasons, this has been difficult to the study staff since the cause is unknown.

Marriage break ups. Partners to index cases are increasingly reporting separations from their respective partners

Fear of blood draws: Some participants have withdrawn from the study giving blood drawing as the reason. They have stated that they are no longer happy to have their blood withdrawn despite thorough explanations before entry and during the study.

Competition with other health facilities: Some projects within the study's catchment area supply their clients with different food stuffs. Some of our participants have asked for the same.

Weather? Rainy season/gardening activities, poor transport system.

Rio de Janeiro, Brazil (HGNI)

- **Challenge:** A couple has moved a significant distance away from the clinic, but is still willing to participate in the study. They have no means of paying for transportation to and from the site for scheduled visits.

Solution: The site decides to provide bus tickets for transportation so that the couple can continue in the study.

- **Challenge:** Important enhance on drug abuse by partner, who started using crack, which led to problems of family violence and abuse, losing the guard of their child and being homeless for a period of time.

Solution: Acionado social work that provide referrals to a shelter. Was also provided referrals to support groups specialized on drug active use.

- **Challenge:** Difficulties on being absent/leaving their job (formal/informal) to come to the visit.

Solution: The team provided scheduled visits on Saturdays and out of business hours.

- **Challenge:** Difficulties on the relationship with the partner.

Solution: Offer to them the possibility of having the couples counseling separated or provide their schedule visit on different days.

- **Challenge:** We lost contact with the couple for almost one year. When they returned, told us they were living in another state (São Paul) because the partner got a job there when they were visiting their family. The couple denied having any problems with their participation on the study and make sure they will were willing to continue.

Attempts of Solution: When they were missing, the team made several an unsuccessful telephone calls, and sent unanswered telegram. We contacted the social worker who has gone to the couple's address. When they arrived at the site, the team offer holder and we have emphasized how it is important to attend the visits and complete the procedures to the study.

- **Challenge:** Ambivalent behavior in relation with their participation on the study.

Attempt of Solution: The team is trying to identify the real reasons that the couple is acting that way. We think that the couple was having some problems about the diagnosis and the treatment because they were never absent or had any adherence problems before.

Pune, India

- **Challenge:** An Index has stopped ART medicines and subsequently the couple stopped coming for study follow up visits. On contacting them, couple informed their disinterest in continuing study participation. On probing, couple informed that they are undergoing a “spiritual intervention” which is giving the Index a feeling of well being.

Solutions:

1. Site decided not to terminate the couple and continue with some retention efforts at each study visit per site Standard Operating Procedures.
 2. It was also decided not to pressurize them in any way in order to allow them an opportunity to find their way back to study clinic if they get dissatisfied with spiritual intervention or needs medical care.
- **Challenge:** The couple was moved a significant distance away from their original place due to a “charge of theft” made on Index participant. Couple was not contactable over phone and when site tried home visit, site found that the address updated by the participant at his last follow up visit was incorrect. Site was unable to trace the couple.

Solution:

1. Site decided not to terminate the couple but wait for the couple to contact on their own.
 2. Continue retention efforts at each study visit by telephone.
 3. Site team is in process of initiating a procedure of verification of address provided by all participants. Site is planning to send a plain post card message on participant’s address and asking the participant to inform the site team over phone whenever he/she receives the card and to get it back to clinic at his/her next follow up visit
- **Challenge:** The couple experienced marital difficulties and had then separated. Index and Partner were staying separately since then. Index who was on ART was coming regularly for follow up visits however partner was coming intermittently.

Solutions:

1. Multiple discussions were held with index and partner individually by the clinic team and seniors. During the discussion study team realized that index and partner still had feelings for each other and was not planning for any legal separation. Site hence decided not to terminate the partner and to follow both participants [index and partner] individually at each visit.
2. Site decided to give some time to the couple to come out of their marital difficulties.
3. Couple decided to stay together after one year and is coming regularly for follow up.

Porto Alegre, Brazil

- **Challenge:** A partner who is a sailor cannot attend the clinic on working days.

Solution: Taking advantage of the window for visits, we schedule his attendance to happen on a Saturday when he is off duty and we open the clinic to see him.

Chennai, India

- **Challenges:**

Coming to site as a couple is a challenge

Spouse of female Index is not willing to bring her to the site

Participants travel a very long distance

Couple's separation is the greatest challenge

Change in participant mobile numbers and contact persons numbers

Contact person does not help to contact the participant

Some participants do not have a mobile phone

Solutions:

Linkages with local NGO, CBO and positive networks help ensure retention is high

Linkages with private and public medical providers (offering participants continued medical education or other technical inputs as required)

Offering psychosocial support and other social or medical linkages to PLHIV in the catchment areas

Developing sufficient rapport with family members or personal care givers (this is on a case by case basis depending on a participant's willingness to introduce personal care givers to retention staff)