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Protocol for biomarker testing in the 2004 Malawi Diffusion and Ideational Change Project

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1. INTRODUCTION

The 2004 Malawi Diffusion and Ideational Change Project (MDICP-3) will collect and analyze biomarkers for sexually transmitted infections (STIs) and HIV. The testing will be conducted for all respondents in the original MDICP sample, plus an additional sample of adolescents that will be added in 2004. This report presents the protocol that will be implemented to collect the STI/HIV specimens.

The rationale for the collection of behavioral information and STI/HIV biomarkers for the same individual in the MDICP-3 is threefold:

- 1) monitoring disease burden and behavior change over time,
- 2) assessing and calibrating self-reported data,
- 3) explicating pathways and elaborating linkages between social environment and health.

The study will provide the first population-based information on trends in prevalence of STIs. Although little is known about the distribution of non-HIV STIs in rural Malawi, the most common are said to be genital ulcer disease, gonorrhea, chlamydia, trichomonas, syphilis, and herpes, in that order (Agabu, personal communication). The focus of the MDICP-3 is on *curable*¹ STIs. For females the biomarkers are for chlamydia, gonorrhea and trichomonas; for males, chlamydia and gonorrhea.² HIV data will also provide an opportunity to validate estimates of HIV prevalence in rural Malawi routinely produced on the basis of data collected among pregnant women in antenatal surveillance clinics.

The testing method that will be used in the MDICP-3 is *not* anonymous. The respondents' unique Biomarker ID will be kept on every specimen that is collected from them, and it will be linked to the person's computerized data. Identifying individuals who were tested is necessary to inform them of their test results. However, we will ensure confidentiality of the respondents who agree to be tested. No personal identifier will be kept on the specimens (like the name of the respondent or the village where he or she lives). In addition, at every stage of data collection (including results'

¹ STIs for which curative treatment exists. Non-curable STIs are, for example, herpes or HIV.

² The diagnosis of genital ulcer disease requires a clinical exam, which is not feasible for a large and relatively dispersed rural sample.

dissemination), only the MDICP biomarker coordinators and selected members of the STI team will have access to the respondent's identifying information.

2. SUMMARY OF TESTING PROCEDURES

2.1 Target sample

The target sample for the STI/HIV testing includes *all respondents who will be interviewed by the MDICP-3*, that is:

- the respondents included in the original MDICP-1 sample (about 1500 married women and their husbands) and the respondents added in the MDICP-2 (i.e. all co-wives of polygamous men, as well as new spouses of respondents who had remarried between MDICP-1 and MDICP-2);
- a sample of adolescents aged 15-24 (approximately 600 males and 600 females);
- a sample of approximately 500 adolescents aged 15-24 in Balaka District that will be included in the ACASI study, carried out by Barbara Mensch and Paul Hewitt from the Population Council.

2.2 Tests

For women, vaginal swabs will be used to test for chlamydia, gonorrhea, and trichomonas. For men, urine will be used to test for chlamydia and gonorrhea. The HIV tests will be done with oral swabs.³

The selection of these tests has been done according to guidelines of the Malawian Ministry of Health and in conjunction with specialists at from the UNC Project based at Lilongwe Central Hospital. The MDICP STI/HIV testing protocol has been approved by the IRB in Malawi as well as in the United States.

2.3 Collection of biomarkers

The team involved in the MDICP-3 data collection will include a group of trained nurses who will be responsible for the collection of biomarkers.

³ Roche PCR will be used for gonorrhea, chlamydia, and trichomonas. ORASURE saliva tests will be used for HIV, and positive results from ORASURE will be confirmed through Western Blot on the same specimen.

Once the biomarkers have been collected, the nurse will take a Polaroid picture of the respondent, write the respondent's ID number on the back of it, and leave it with the respondent, explaining that he/she has to show this picture in order to obtain the results. The nurse will also provide information about when the respondent will be able to receive the results.

In the evening all specimens will be logged and refrigerated. Three times a week the specimens will be transported to the UNC laboratory in Lilongwe for analysis.

2.4 Analysis of biomarkers

The biomarkers will be analyzed by the laboratory run by the University of North Carolina at Chapel Hill (UNC) in Lilongwe Central Hospital (LGH), under the direction of Irving Hoffman and Francis Martinson.

2.5 Results dissemination

Results will be communicated to respondents approximately five to seven weeks after collection of the specimens by the nurses. The approach chosen for results dissemination uses temporary Voluntary Counseling and Testing (VCT) centers set up in each village, staffed by nurses trained in HIV testing and counseling.

Results will be made available throughout each study area in small portable tents, which provide privacy. There will be several VCT (tent) sites in each surveyed area, so that all respondents' homes will be within approximately five kilometers from at least one site. A few days before the results are to be available, the VCT team will visit all respondents in their homes to communicate the location of the tent and the specific week the team will be in their village.

The VCT team will have a list of Biomarker ID numbers with corresponding test results, but without respondents' names or any other identifying information. In order to get their results, respondents will have to present to the nurse the Polaroid picture they had taken when the specimens where collected. The nurse will use the picture to make sure that nobody else other than the respondent is given the test results. These procedures should preserve confidentiality, as the results will only be known to the respondent.

2.6 Treatment

One single-dose treatment for each STI will be provided to all respondents who are

infected.⁴ Infected respondents will also receive treatment for up to two of their sexual partners. All respondents who come to get their test results will receive vitamins. Respondents who test positive for HIV will be offered counseling.

By providing all with some treatment, we hope to preserve confidentiality and prevent speculation about who is infected and who is not. All respondents, whether they are infected or not, will be counseled by the nurses about the symptoms of STIs and encouraged to go to the local clinic should they experience these symptoms.

2.7 Incentives

The MDICP-3 biomarker data collection is linked to a randomized experiment focused on the incentives for VCT uptake.

The MDICP incentives experiment will be carried out at the moment of the collection of biomarkers from the respondents. After the nurse has completed collecting the specimens, the respondents will be asked to choose an amount of monetary compensation randomly from two plastic bags, one for STIs and one for HIV. Each plastic bag will contain bottle tops where a monetary amount is written on the back, with a total value ranging from 0 to 300 Kwacha (approximately \$3.00). Each patient will choose a random amount that he/she will be able to collect conditional on receiving STI and/or HIV test results. The monetary amount will be copied on a voucher, and will be distributed when the respondent comes to get his/her test results at the VCT center. The fact that individuals select the amount of their voucher provides a transparent allocation of incentives given the randomness of the experiment.

⁴ Azithromycin for chlamydia, metronidazole for trichomonas, Ciprofloxacin for gonorrhea. Women who are pregnant and who have gonorrhea will receive azithromycin instead of Ciprofloxacin (see Section 6.4).

⁵ To determine whether having an additional incentive specifically linked to the HIV test had a different effect from a having single incentive linked to receiving either test result, in the third site, Rumphi, only one incentive was given. In that site, respondents received the amount of the incentive if they consented to and received results for either STI or HIV testing.

3. PRE-SURVEY OPERATIONS

3.1 Informing the communities

The collection of biomarkers will be preceded by visits to each of the village chiefs in the sample to inform the community about the coming survey. These visits will be carried out by an experienced supervisor trained specifically for the purpose.

Since the communities are quite familiar with the MDICP, emphasis will be placed upon explaining the reasons for testing for STIs and HIV, the procedures for specimen collection and results dissemination, and the confidentiality of the results. Village heads will also be briefed about the timetable of the survey and STI/HIV testing.

At the end of each visit, the supervisor will fill in a form to keep track of the issues raised, to improve communication and explanations for the succeeding villages and field sites, and ultimately to give back the results of the testing. This short form (presented in Appendix B) has been designed on the basis of those used by the Mali Demographic and Health Survey to evaluate informed consent (Yoder and Konaté 2002).

3.2 Recruitment of nurses

The selection of nurses is important to the project for a number of reasons. First, because the demand for nurses is high in Malawi and health centers are often understaffed, it is important that nurses are not hired away from their professional jobs. In addition, because of the sensitive nature of HIV testing, it is important that nurses are able to speak the local language in each of the study sites but, to preserve confidentiality, who are also outsiders to the community to the extent that it is possible.

Nurses will be recruited before fieldwork begins by Rebecca Thornton with the assistance of personnel from Kamuzu College of Nursing. Two types of nurses will be hired for the project: younger nurses who recently graduated from one of the health science schools with a degree in nursing (from Zomba or Blantyre), and more veteran health professionals who took time off from their job. Because nurses tend to have the same practical training, we will hire on the basis of past research experience, experience in VCT and HIV counseling, as well as personal qualities such as willingness to work in more difficult and rural conditions. In total, approximately 60 nurses will be recruited, including supervisors for the three sites.

3.3 Training of nurses

Nurses' training for the MDICP-3 survey will consist of a combination of classroom training and practical experience that will provide the nurses with the background necessary to perform these tasks during a field survey. The nurses' training will be carried out by the staff of the UNC Project at Lilongwe Central Hospital and by the STI team of the MDICP.

The nurses will have five days of training before the beginning of the fieldwork operations in Balaka and Mchinji, during which the various sections of the *Nurse's Training Material* and of this *Protocol* will be reviewed. Two days will be carried out by the staff of the UNC lab and will focus on management of STIs, lab procedures and pre- and post-test counseling. The remaining days of training will be carried out by the MDICP staff and will focus on the survey procedures associated with the collection of biomarkers, with particular focus on the informed consent for STI testing. Nurses will learn how to collect and label the specimens, how to complete the necessary forms, and how to tell the respondents when and where they can get their results.

3.4 Pilot study

A small pilot study of the collection of biomarkers will follow the nurses' training. In order to avoid sample contamination, the respondents included in the pilot study will belong to a village neighboring, but not included in, the MDICP sample. The main aim of the pilot study is to assess:

- 1) the impact of the study on respondents (especially in terms of response rates);
- 2) the acceptability of vaginal swabs among women;
- 3) the consent forms and the overall efficacy of the STI/HIV collection,
- 4) the efficiency of testing done by the UNC laboratory,
- 5) the effectiveness of VCT pre- and post-counseling for HIV.

This assessment will serve as the basis to modify, if necessary, our protocol, in order to achieve higher response rates and smoother procedures.

The pilot study will be carried out in the first site to be surveyed (Mchinji District), with a target sample of 30 respondents (15 men and 15 women). Additional pilots will be conducted prior to the start of fieldwork in the other two sites, in which

⁶ Nurses hired to work in the third site, Rumphi, will attend the Balaka training.

nurses will be grouped together and work closely with nurse supervisors to practice the procedure of biomarker collection. Questions and concerns regarding procedure will be addressed in meetings following these pilots and before additional fieldwork.

3.5 Creation of identifiers for STI/HIV testing

In order to ensure confidentiality, a set of identifiers specific to biomarker data collection (Biomarker ID numbers) will be created for each respondent prior to the beginning of fieldwork. This set of Biomarker IDs will be different from the Survey IDs used for the survey data collection. The Biomarker IDs will be used to label all specimens, so that at no point will it be possible for the survey personnel to link the survey information with the biomarker data. A master file that links this set of Biomarker IDs with the original Survey IDs of respondents in the sample will be kept *only* by the MDICP biomarker coordinators. Only after the end of data collection in each site will the Survey IDs be linked with the Biomarker IDs.

4. COLLECTION OF BIOMARKERS

4.1 STI team

In each survey site, there will be 4 teams (5 in Balaka, because of its larger size) to collect biomarker data. Each team will be composed of 5-6 nurses and 1 nurse supervisor.

In addition to the nurses' team, in each village there will be typically 1-2 'scouts', local villagers hired because of their extensive familiarity with village residents, who will help to identify and locate respondents. In each village, the scout will work first with the MDICP survey team, and subsequently with the STI team. Depending on the logistics of the site, in some locations scouts will be village-specific, whereas in others they will cover multiple villages. In addition to identifying and locating respondents, scouts will make appointments with respondents for future nurse visits.

Bike messengers will aid the STI team by providing transport when households are located far apart.

⁷ Village headmen will assist in identifying potential scouts in each village.

4.2 Data collection design

To reduce confusion amongst team members and respondents, an effort will be made to avoid having both MDICP survey interviewers and nurses working simultaneously in the same village. Respondents will be interviewed first by members of the MDICP survey team. The MDICP interviewers will make the initial contact with respondents and tell them to expect a visit from a nurse in the coming days.⁸

Once all the respondents in a village have been interviewed by the MDICP survey team, the nurses will begin the STI data collection. First, the STI team will meet with the village scout. The MDICP field logs, listing each person in the village who have been interviewed by the MDICP and should thus be approached by the STI team, will be given to nurse supervisors. The experience of the scout and the documentation kept by the MDICP survey team will guide the STI team in finding respondents, to ensure that each team approaches the same people. After arriving in the village and meeting the scout, the nurse supervisor will assign nurses to respondents, and provide each nurse with a set of STI labels for each respondent.

Upon meeting a respondent, the nurse will fill the STI questionnaire, discuss the tests, ask for their informed consent and, if consent is given, collect the STI/HIV specimens. If the respondent has accepted to be tested for HIV, the nurse will also provide pre-counseling. In sum, the primary responsibilities of the nurse include:

- filling the STI questionnaire (see Section 4.4);
- informing eligible respondents about the test and asking for consent (see Section 4.5);
- collecting the specimens—urine samples and oral swabs for men; vaginal and oral swabs for women (see Section 4.6);
- completing the necessary forms (see Section 4.7);
- telling respondents where and when they can go if they want to be given the results.

Following a completed attempt with a respondent, the nurse will go back to the nurse supervisor and be given a new set of ID's and the location of a new respondent from the scout.

⁸ Because the interviewer will obtain the initial consent and conduct the initial interview, he/she will also be responsible for giving respondents the gift (a bag of sugar for each respondent interviewed) that is provided to thank them for their cooperation.

If the respondent is not found, their location has to be determined by questioning family or neighbors, and a follow-up appointment has to be made, if possible. Particular effort has to be made if the respondent is particularly mobile. For example, students should be visited primarily after school hours during the week or on weekends. However, *no attempts* should be made to find respondents who have moved out of the sample area.

4.3 Labeling of STI questionnaire and specimens

The nurse supervisor will be responsible for giving each nurse the labels necessary for specimen collection.

For each respondent there will be two rows of printed labels (i.e. 10) on each label sheet. The first label in the upper-left corner of the three rows of labels contains that respondent's name, Survey ID, and village number. The other 9 labels contain only the corresponding Biomarker ID. The supervisor should give the appropriate labels to the nurse, and retain the first label of the first row (i.e. the label with the respondent's name and Survey ID) to hand in to the STI supervisor at the end of each day. The remaining 9 labels are placed on an HIV sample (1), STI sample (1), consent forms (1 each for HIV and STI), questionnaire (2), testing sheet (1), and incentives (1 each for HIV and STI).

4.4 STI questionnaire

The nurse will administer a short STI questionnaire (Appendix C) to the respondent prior to the specimens' collection. The nurse should administer the questionnaire immediately and regardless of specimen collection.

4.5 Informed consent for STI and HIV testing

In order to ensure that the respondents can make an 'informed' decision about participating in the testing, the STI questionnaire includes separate statements explaining the nature of the STI/HIV tests and requesting respondents' permission to collect urine samples, vaginal swabs, and oral swabs for these tests (these informed consent statements are presented in Appendix D). The consent forms will be translated into the local languages (Chichewa in the Central Region, ChiYao in the Southern Region, and ChiTumbuka in the Northern Region).

The nurse is responsible for explaining the purpose of the testing to the respondents and to obtain their consent before collecting any specimens. Consent for STI and HIV testing will be asked for separately, such that respondents can give (or refuse) consent for any, all, or none of the components.

After filling the STI questionnaire, the nurse will read the appropriate informed consent statement, that is:

- <u>if the respondent is age 18 or over</u>, the nurse should obtain the respondent's consent to the testing before any specimen collection is done. If the respondent agrees to be tested, he/she should indicate consent by signing or inscribing his/her thumbprint in the space provided;
- if the respondent is between the ages of 15 and 17, the nurse will have to first obtain the consent of one of the respondent's parents. If the parent agrees to the test for the adolescent, he/she should indicate consent by signing or inscribing his/her thumbprint in the space provided. After getting consent from the parent, the nurse should also read the consent statement to the adolescent, ask the adolescent whether he/she agrees to the test, and have the adolescent indicate consent by signing or inscribing his/her thumbprint in the space provided. The only exceptions are if the adolescent is married or if the adolescent lives alone or in a household in which there are no adults. In such cases, the consent of the adolescent is sufficient.

Each consent statement begins by describing the objectives of the test and the procedures to be followed. The nurse will emphasize that every effort will be made to protect the confidentiality of the information. The nurse will also make it clear that the respondent has the right to refuse to participate in the study, to withdraw at any time, and to refuse to answer any individual questions. Respondents will finally be told that, when the nurses return to provide the results of the STI testing, they will have only the identification number of the respondent (each respondent who participates in the testing will be given a personal Polaroid picture with this Biomarker ID number on the back).

If consent is given, the nurse will paste a label with the respondent's unique Biomarker ID number at the bottom of each informed consent form and proceed with biomarker collection.

If consent is not obtained for either specimen, the nurse must ask the respondent if he/she would be willing to provide consent if a nurse of the opposite gender instead collected the test. The nurse must then report back to the nurse supervisor the answer

given. If the respondent agrees to being tested by a nurse of a different sex, the supervisor will send a new nurse. If the respondent reports that he/she does not want to be tested regardless of the gender of the nurse, then the supervisor must visit the respondent to ensure that he/she was adequately briefed and counseled by the first nurse. Since nurse supervisors will be selected on the basis of their exceptional expertise and counseling skills, the expectation is that some respondents may consent to testing following discussion with the nursing supervisor.

4.6 Specimens' collection

Nurses will be responsible for refilling their supplies from the stock in the supply room each evening when they return from the field. One nurse will receive a salary bonus for serving in the capacity of the "Nursing Organizer." The duties of the nursing organizer will consist of organizing the supply room each evening, keeping track of supplies, and informing the STI coordinator if any supplies are running low.

Going into the field, each nurse will carry one *lunch-size cooler bag*, containing:

- 3 ice packs;
- 1 'dirty' pen (i.e. a pen to be used only when handling specimens).

In addition, the nurse should carry the following equipment and supplies in his/her *backpack*:

- 1 'clean' pen;
- 1 marker;
- 1 clipboard, with:
 - 8 STI questionnaires (4 men and 4 women), with corresponding consent forms;
 - 1 Umoyo scale;
 - 1 STI/HIV Testing Sheet;
 - the *Step-by-Step instructions*.
- 1 large plastic bag, containing:
 - 4 urine cups, pre-marked at 20 cc (for men);
 - 4 vaginal swabs (for women);
 - 8 oral swabs (for men and women).

- 24 Ziploc plastic bags, of which 16 to individually seal the specimens and 8 to put the respondent's Polaroid picture and the voucher(s);
- 16 pairs of plastic gloves;
- 1 timer for the HIV test, to verify that the respondent keep the oral swab between his/her cheek and gum for at least 2 minutes.
- 1 biohazard bag for disposal of wastes;
- 1 Polaroid camera, with 1 extra film and 1 extra battery;
- for incentive experiment:
 - 2 small plastic bags containing bottle caps (pink and blue);
 - 2 voucher books (pink and blue);
- 1 First-aid kit (including condoms).

Each *nurse supervisor* will carry in his/her backpack:

- 1 Clipboard with the village lists;
- 1 plastic document holder containing labels;
- 1 Typex (white-out);
- 1 pair of scissors;
- Spare (blank) labels for new spouses;
- Spare batteries;

To aid with identification and legitimization of the project staff, nurses and nursing supervisors will wear their project T-shirts when in the field. They should also prominently display their photo project ID. Specific details for the collection of urine samples and oral swabs are described below.

After the respondent has given his/her informed consent to participate in the STI and/or HIV testing, the nurse will take his/her picture by using the Polaroid camera. The nurse will then paste a label with the respondent's unique Biomarker ID onto the back of the Polaroid picture, and will instruct the respondent to present this picture to collect the results of the test(s).

If a male respondent has agreed to be tested for STI, the nurse will take a urine cup, paste a label with the respondent's Biomarker ID on the side of the cup (*not* on the cap) and give it to the respondent. The nurse will instruct him to go in a private place and fill the cup to the pre-marked line (20cc) and then to tighten the cap. When the

respondent returns with the cup, the nurse will write the date and time on the label, place the urine cup in a Ziploc plastic bag and then transfer it into the cooler.

If a female respondent has agreed to be tested for STI, the nurse will take a vaginal swab, paste a label with the respondent's ID on the tube and give the swab to the respondent, instructing her about its use. When the respondent returns with the swab, the nurse will put the swab into the culture tube, break the stick, and cap the tube. The nurse will place the tube in a Ziploc plastic bag and transfer it into the cooler. If a woman has agreed to be tested for STIs but the vaginal swab specimen is bloody because she is menstruating, the nurse should also collect a urine sample from her.

If the respondent (male or female) has also agreed to be tested for HIV, the nurse will take an oral swab, paste a label with the respondent's ID on the tube and give the swab to the respondent. The nurse will tell the respondent to place the swab between his/her gum and cheek until moist, for at least two minutes. The nurse will use the timer to check that the respondent keeps the swab at least 2 minutes between his/her cheek and gum. After this time has elapsed, the nurse will put the swab into the culture tube, break the stick, and cap the tube. The nurse will place the tube in a Ziploc plastic bag and transfer it to the cooler.

4.7 Recording specimens taken

When the nurse has finished collecting the specimens, he/she should fill the necessary sections in the STI/HIV Testing Sheet (Appendix E). *Each nurse will carry only one Testing Sheet*, as there is enough room for the maximum number of specimens a nurse can collect each day.

The following summarizes the procedures for recording information on the Testing Sheet:

- **Column 1.** The nurse should paste here one label with the respondent's ID number.
- **Column 2.** The nurse should fill the code for the administered STI test in this column.
- **Column 3.** The nurse should fill the date and time of collection of the STI specimen.
- Column 4. The nurse should fill the code for the administered HIV test in this column.
- **Column 5.** The nurse should fill the date and time of collection of the HIV specimen.

If a respondent is not found after 3 call-backs, no STI/HIV Testing Sheet should be filled, since the failure to contact the respondent will be noted on the supervisor's field log.

4.8 Incentives experiment

The MDICP-3 biomarker data collection is linked to a randomized experiment focused on the incentives for VCT uptake.

It is widely assumed that the spread of HIV will be reduced if people know their HIV status. However, a significant proportion of individuals who get tested for HIV do not return for their results: the proportion of those who return for their results ranges from 8 to 95 percent. The literature suggests that factors associated with uptake of VCT services are not only perceived or actual HIV status¹⁰, but also time, distance and work obligations. Previous studies, primarily in the US, suggest that small monetary incentives to receive results might overcome these barriers. For example, monetary incentives have been shown in the US to increase respondents' participation in a multisession HIV/STI risk reduction trial, to increase follow-up visits after STI treatment, and to support parents' investment in the education of their children. ¹¹ The literature on incentives also emphasizes the importance of design, monitoring and ethics: in particular, great care is needed to avoid any possible association of incentive payments with coercion or violations of human rights.¹² If it is important for individuals to learn their HIV status, it is therefore important to learn to what extent financial compensation increases return rates. Moreover, by randomizing the amount of the financial compensation, it is possible to determine how return rates vary and what the optimal compensation will increase returns. This will be of use in budgeting for scaling up VCT uptake.

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⁹ Cartoux M, Meda N, Van de Perre P, et al. (1998): Acceptability of Voluntary HIV Testing by Pregnant Women in Developing Countries: An International Survey; *AIDS* 12:2489-93. In a population-based study conducted by the Africa Research Centre in KwaZulu-Natal, South Africa, of the 13,124 persons tested only 8 percent returned to special VCT clinics to receive their results (M. Bennish, personal communication).

¹⁰ Main DS, Iverson DC, McGloin J (1994): Comparison of HIV-risk behaviors and demographics of adolescents tested or not tested for HIV infection; *Public Health Reports* 109:699-702. Nyblade LC (1998): *HIV counseling and testing in a rural Ugandan population*; PhD Dissertation, Graduate Group in Demography, University of Pennsylvania.

¹¹ Kamb ML, Rhodes F, Hoxworth T, et al. (1998): What about money? Effect of small monetary incentives on enrollment, retention, and motivation to change behaviour in an HIV/STD prevention counselling intervention; *Sexually Transmitted Infections* 74:253-255. Kissinger P, Kopicko JJ, Myers L, et al. (2000): The effect of modest monetary incentives on follow-up rates in sexually transmitted disease studies; *International Journal of STD & AIDS* 11:27-30. Behrman J, Segupta P, Todd P (2001): *Progressing through Progresa: An impact assessment of a school subsidy experiment*; University of Pennsylvania, Pier Working Paper No. 01-033.

¹² Hartman B. (1995): Reproductive Rights and Wrongs: The Global Politics of Population Control; Boston, MA: South End Press

After the specimens have been collected, the MDICP nurse will offer respondents an opportunity to receive monetary incentives. The nurse will explain that the project will compensate respondents for their time if they choose to come to the VCT clinic. The nurse will also explain that, in order to ensure a fair process, the respondent will be able to pick randomly the amount of compensation that they will receive for going to the VCT tent and obtaining STI and/or HIV results. The nurse will carry two bags containing bottle caps. The respondent will reach into each bag (into the pink bag for the HIV test and into the blue bag for the STI test). He/she will choose one bottle cap from each bag. Written on the back of each bottle cap will be assigned a monetary amount, that provides a total monetary incentive ranging from 0 to 300 Kwacha (approximately \$3.00). 14

After the respondent has picked the cap from each of the two plastic bags, the nurse will copy the amount written on the back of each cap onto the Testing Sheet, indicating which amount is to be given for HIV and which for STIs. The nurse will then write the amount on a voucher and the voucher number (found on the voucher form) from the corresponding voucher book (blue or pink), and will paste the label with the respondent's unique ID in the space provided. The voucher will be stapled to the respondent's Polaroid picture that was taken at the beginning of the biomarker collection to ensure that it will not get lost. The picture and the voucher will be put in a Ziploc plastic bag and given to the respondent to keep. The nurse will emphasize that voucher forms must be presented at the VCT in order to receive monetary compensation.

4.9 Delivery of specimens to the nurses' supervisors

At the end of each day, when the nurses come back from the field, the nurses' supervisors will collect all STI questionnaires, all informed consent forms, and all Testing Sheets. The nurses will put the specimens in the study fridge. As they do so, the nurse supervisors will check the testing sheets against the samples collected. The nurse *must* initial the bottom of the Testing Sheets and questionnaires before giving

¹³ As noted previously, the procedure changed for the last site, Rumphi. Specifically, only one incentive was used rather than two.

¹⁴ To put this amount in perspective, the average daily wage in the 2001 MDICP sample is 120 Kwacha. We estimate that respondents who return for their results will 'spend' about 315-450 minutes of their time (30-45 minutes round trip from home to mobile VCT clinic, 4-6 hours waiting, 45 minutes for the

them to the supervisor. The nurse supervisor must then initial that the samples have been checked against the Testing Sheets.

The nurses' supervisor should first check that the STI questionnaire is filled out correctly (i.e. that all fields are completed, that the skips have been used properly, and so on). If complete, the supervisor will then place the questionnaire in the appropriate box for data entry. If the STI questionnaire is not completed correctly, the supervisor should ask the nurse to clarify and, if not satisfied, should request a call-back to be carried out the following day by the same nurse.

The nurse supervisor must also check that all people who have been tested have been given a voucher and the amount recorded on the Testing Sheet. If the number of tests recorded on the STI/HIV Testing Sheet does not correspond to the number of urine cups, vaginal swabs and oral swabs placed in the fridge by the nurse, or the appropriate consent forms or VCT information are not complete, the supervisor will ask the nurse to explain and, if necessary, will send the nurse for a call-back.

After placing all of the specimens in the fridge, the nurse will remove the cold packs from the coolers and place them in the study freezer, where they will be kept frozen until the next day.¹⁵ The supervisor *must* lock the fridge and the freezer after all specimens and all cold packs have been stored. *For security reasons, the supervisors are also responsible for making sure that, whenever the storage room is not in use, the door is locked.*

4.10 Delivery of Testing Sheets to the survey staff

The nurse supervisors will give the initialed Testing Sheets to the Biomarker Coordinator at the daily supervisors meeting that will be held each evening. The Biomarker Coordinator will use the information recorded on the Testing Sheets to log the tests performed during the day on the Transfer Sheet. After each transfer to the lab, the Biomarker Coordinator will place the completed Testing and Transfer Sheets in the appropriate boxes for data entry.

4.11 Logging

Nursing supervisors will be responsible for keeping track of their own Village Lists,

counseling session). The imputed value of the time spent by respondents is approximately 79-112 Kwacha.

¹⁵ The cold packs have to be replaced with newly frozen ice packs each morning.

labels, and Field Logs for the villages in which they are working. However, periodically they will be asked to lend their Field Logs to the data entry clerk for logging purposes. These episodes will be timed so as not to interfere with fieldwork. Similarly, the nursing supervisors will receive a plastic document holder to assist with keeping track of their unused labels. To ensure confidentiality, it is imperative that any unused labels be disposed of properly and far from the villages.

When data collection in a village is complete, the nursing supervisors will place their completed field logs in the appropriate box. The data entry clerk will then check to ensure that all the information has been logged. All completed and logged field logs will be stored in approximate chronological order in a series of Field Log binders for each site.

Prior to logging each questionnaire, the data entry clerk will check to make sure that it is complete. Any questionnaires found to be incomplete will be returned to the supervisor responsible, and a computerized record made of the problem to assist with nurses' evaluation. After logging completed questionnaires, the data entry clerk will place them in boxes in preparation for shipment to Suntec¹⁶.

Finally, the data entry clerk will be responsible for logging the Testing Sheets. Unlike the questionnaires, for which only coversheet information will be entered, the data entry clerk will enter into the database all the information recorded on the Testing Sheets and Field Logs.

4.12 Call-backs

If the STI/HIV specimens get lost or damaged after they are collected from the respondent and the survey team is still working in the same area¹⁷, a call-back has to be conducted. Call-backs will not be carried out if the specimens are lost or damaged during shipping to LCH.

 Suntec is the company responsible for data entry of all MDICP survey and STI questionnaires.
 This limitation is mandated by the costs associated with sending the survey team to collect the specimens a second time.

5. ANALYSIS OF BIOMARKERS

5.1 Delivery of specimens to Lilongwe Central Hospital

Specimens will be delivered for analysis to the UNC laboratory in Lilongwe Central Hospital (LCH) *three times a week*. Large sealed coolers containing cooler packs will be used to transport the specimens, accompanied by a trained "Transfer Nurse". Because of the varying distance of the survey sites from Lilongwe, the following describes the specific delivery procedures.

In Mchinji (the first site to be surveyed), which is one hour away from Lilongwe by car, delivery of specimens to LCH will be made by a designated driver and vehicle hired for the purpose three days a week. Because of the greater distance between the other two sites (Balaka and Rumphi) and Lilongwe, additional transfer nurses will be trained (one in Balaka and two¹⁸ in Rumphi) and alternate delivery of the samples. Additionally, during the fieldwork in Rumphi, the driver and nurse will stay in Lilongwe overnight after the specimens' delivery instead of returning to the survey site.

In all cases, the transfer nurse will log the specimens and pack the transfer cooler. He/she will also be responsible for the delivery of the specimens to the lab technicians and return of the signed Transfer Sheet and related transfer materials. Lab protocols require that samples be fixed within 72 hours of being transferred. When samples will be collected on Fridays, it is essential that these specimens are transported to be lab by Monday at noon. To ensure that the lab team is ready to receive and catalog the samples when they arrive, the transfer nurse must keep the lab director apprised by phone of the estimated arrival time of the specimens.

Prior to the transfer, the Biomarker Coordinator will generate a Transfer Sheet from all Testing Sheets (which will be logged daily), and give it to the Transfer Nurse. The Transfer Nurse will use the Transfer Sheet to catalog all samples due to be delivered to the lab, providing another layer of data cross-checking. To avoid biohazard contamination of the Transfer Sheet, a second person¹⁹ will assist the Transfer Nurse by logging the samples as the nurse packs them in the cooler. To ensure accuracy, all samples will be checked twice against the Transfer Sheet prior to transfer. At the lab,

¹⁹ In Mchinji and Balaka, this task will be performed by the data entry clerk. In Rumphi, the second transfer nurse will perform it.

¹⁸ The particularly long distance from Lilongwe to Rumphi requires a rotation of drivers and transfer nurses, so as not to overburden any one nurse or driver.

the technician accepting the samples will perform a third check while unloading the samples. Upon completion of the transfer, the lab staff must initial the Transfer Sheet and make a photocopy for the lab's records. The Transfer Nurse is responsible for returning the signed Transfer sheet to the Biomarker Coordinator.

Prior to the transfer, the Biomarker Coordinator will also provide the Transfer Nurse with five additional ID labels per specimen. To increase recording accuracy, these labels will be delivered along with the specimens and will be used by lab personnel to track the samples at various stages in the process of analysis.

5.2 Delivery of results to survey staff

The UNC lab will keep a record of all test results by Biomarker ID and district, so that no names will be associated with the samples. Test results will be given to the Biomarker Coordinator at the end of fieldwork in each site.

6. DISSEMINATION OF RESULTS TO RESPONDENTS

6.1 Voluntary Counseling and Testing (VCT) centers

Results will be communicated to respondents approximately five to seven weeks²⁰ after collection of the specimens by the nurses. The approach chosen for results dissemination uses temporary Voluntary Counseling and Testing (VCT) centers set up in each village, staffed by nurses trained in HIV testing and counseling.

Results will be made available throughout each study area in small portable tents, which provide privacy. There will be several VCT (tent) sites in each surveyed area, so that all respondents' homes will be within approximately five kilometers from at least one site. A few days before the results are to be available, the VCT team will visit all respondents in their homes to communicate the location of the tent and the specific week the team will be in their village.

6.2 Identification of respondents

In order to identify the respondents and to give them their test result and their monetary incentive (if any), VCT nurses will use the VCT Sheet (Appendix F). The VCT Sheet

²⁰ This is the average lab processing time estimated on the basis of our sample size, which will allow the UNC Project at LGH to coordinate the analysis of our samples with their other ongoing tasks.

will contain a list with the ID numbers of the respondents, the village they live in, the results of their test, and the amount of the incentive to be paid if they get the results. *The list will not contain names or any other identifying information* of the respondents. This procedure should preserve confidentiality, as the results will be known only to the individual.

In order to obtain their results, respondents have to present to the nurses their picture that was taken at the time of the collection of the specimens. The nurse will receive the picture and first verify that the individual depicted in the picture is the same asking for the results. If there is a match, the nurse will look up the ID number written on the back of the picture in the VCT Sheet.

The nurse will first provide the results for the STI test and the appropriate treatment (see Section 6.4 below). The result of the HIV test will be communicated after the STI test results, and will be followed by post-counseling.

After the respondent has been given the test results (and post-counseling for HIV), the nurse should give the indicated monetary incentive. *Under no circumstance respondents should be given the monetary incentive if the test results were not communicated.*

6.3 Treatment for STIs other than HIV

After the STI test results are communicated to the respondents, the nurse will give them the appropriate treatment if infected. We will give Azithromycin (Azithral) for Chlamydia, Metronidazole for Trichomonas, Ciprofloxacin for gonorrhea in <u>non-pregnant</u> woman, and Azithromycin for gonorrhea in <u>pregnant</u> woman. All treatment will be administered to the respondents on the spot.

The dosage for the treatment to administer in each case is indicated in the table below:

Treatment	Number of Pills	Dose per Pill	Total Dosage
Ciprofloyagin	1	500 mg	500 ma
Ciprofloxacin	1	500 mg	500 mg
A with not	4	250 ma	1 anom
Azıtnrai	4	230 mg	1 gram
Azithral	4	250 mg	1 gram
Metronidazole			2 grams
	Ciprofloxacin Azithral Azithral	Ciprofloxacin 1 Azithral 4 Azithral 4	Ciprofloxacin 1 500 mg Azithral 4 250 mg Azithral 4 250 mg

If a woman has tested positive for gonorrhea, *before administering the treatment* the nurse should ask her whether she is pregnant, and give her the appropriate treatment. If a pregnant woman has tested positive for both gonorrhea and Chlamydia, she should be given only *four pills* of Azithral (not eight pills). The nurse should indicate the treatment administered on the VCT Sheet.

The respondent will also receive an envelope containing treatment for up to two of his/her sexual partners. Because we will not know the pregnancy status of the female partners of those husbands who tested positive for gonorrhea, these female partners will receive Azithral instead of Ciprofloxacin. In the event that the respondent has more than two sexual partners, he/she will receive two packs of medicines to take with him/her to treat the first two sexual partners; the nurse will then tell the respondent that the additional sexual partners should go seek care at the local clinic. If husband and wife come separately to get their test results, they potentially might be exposed to a chance for double-treatment (i.e., one set of drugs ingested at the clinic and another set brought home by the spouse as partner-treatment). The nurses will have to stress that the treatment should not be taken twice, as it might be harmful.

All respondents, whether they are infected or not, will receive vitamins and will be counseled by the nurses about the symptoms of STIs and encouraged to go to the local clinic should they experience these symptoms.

6.4 Counseling for HIV

After communicating results to respondents who have resulted HIV positive, the nurse will provide counseling. The nurse should stress that the Government of Malawi plans to expand access to ARVs to District Hospitals. The nurse should also advise HIV-positive respondents to go to the nearest District Hospital for a second, confirmatory test and to be informed by health official as to when ARVs will be available.

APPENDIX

APPENDIX A PERSONNEL LIST

COORDINATORS

Principal Investigators:

Susan Watkins (University of Pennsylvania) Hans-Peter Kohler (University of Pennsylvania) Jere Behrman (University of Pennsylvania) Alex Weinreb (Hebrew University)

Biomarker Coordinators:

Simona Bignami-Van Assche (Harvard University) Kirsten Smith (University of Pennsylvania) Georges Reniers (University of Pennsylvania) Philip Anglewicz (University of Pennsylvania)

Incentive Experiment and VCT Coordinator:

Rebecca Thornton (Harvard University)

MANAGEMENT STAFF

Pre-fieldwork operations:

Simona Bignami-Van Assche (Harvard University) Li-Wei Chao (University of Pennsylvania)

Questionnaire design:

Kirsten Smith (University of Pennsylvania) Simona Bignami-Van Assche (Harvard University)

Nurses recruitment:

Rebecca Thornton (Harvard University) Flora Nankhuni (University of Pennsylvania) Agnes Chambiri (Kamusu College of Nursing)

Site coordinators:

Kirsten Smith (Mchinji) Georges Reniers¹ (Balaka) Philip Anglewicz (Balaka & Rumphi)

Site staff:

Flora Nankhuni (Mchinji) Francis Onyango (Balaka & Rumphi)

ADMINISTRATIVE STAFF

Project accountant:Davie Chitenge

Data entry clerk: Rita Moyo

NURSING STAFF

Nurse supervisors:
Faith Teleka
Naloli Mukiwa
Bright Mukhuna
James Mkandawire
Aaron Jere-Rumphi
Rose Mataka- Balaka

Transfer nurses: Grant Macheso Bright Mkhuna Virginia Thonyiwa Falesi Kachale

STI collection nurses:

Mchinji	Balaka	Rumphi
Aaron Jere	Annie Chirwa	Grace Makina
Bettina Pweshiwa	Annie Chitimbe	Vinjeru Lungu
Chrissy Banda	Bridget Mangoche	Innocent Luwanda
Christopher Mgunda	Chrissy Banda	Chrissy Banda
Dalitso Mandala	Cliven Kasalu	Winasi Boma
Doreen Chalulu	Dalitso Matala	Charity Zimba
Dorice Lungu	Doreen Chalalu	Cliven Kasalu
Elizabeth Kelanga	Edith Makuluni	Evelyn Nyirongo
Grant Macheso	Eunice Kangunga	Nyaniwe Tembo
Lyson Makumba	Evelyn Nyirongo	Winnie Useni
Mbumba Munthali	Falisi Kachala	Moses Tambala
Mike Kavina	Grace Makina	Maggie Kanyenda
Moses Tambala	Haleema Mbutuka	Falesi Kachala
Noel Chimpeni	Hilda Lungu	Miriam Gausi
Patrick Stevens	Jene Ngosi	Doris Lungu
Phillimon Phiri	Lawrence Kambale	Lucy Kalonga
Precious Hajison	Lucy Kalonga	Nelson Chirwa
Ruth Namboya	Lydia Kaduya	Moses Chilombe
Sostin Chambankuya	Maggi Kanyenda	Mbumba Munthali
Stonny Makunganya	Mary Ndutaya	Jane Ngosi
Virginia Thonyiwa	Mike Kavina	Sosten Chambankuya
Winnie Useni	Mphatso Mtata	Virginia Thonyiwa
	Ruth Mkhola	Ruth Mkhola
	Ruth Namboya	Luciana Simwaka
	Tabu Chirwa	
	Virginia Thonyiwa	
	Winnie Useni	

LILONGWE CENTRAL HOSPITAL/UNC LABRATORY STAFF

Director:Project manager:Irving HoffmanDavid ChilongoziLab director:Lab consultant:Topia BandaRob KysiakNurses' facilitator:Lab consultant:Agatha BulaGeorge Jowaki

APPENDIX B

2004 Malawi Diffusion and Ideational Change project				
Supervisor's form to evaluate contact with the community				
IDE	IDENTIFICATION			
Traditional Authority				
Village name				
Village number				
Name of village head				
Sex of village head	_ Male _ Female			
Language used				
Date (day/month/year)				
Supervisor's initials				
REACTIONS OF VILLA	AGE HEAD TO STI/HIV TESTING			
Please mo	ark when appropriate			
	COMMENTS			
_ Had already heard about the survey (specify)				
☐ Reacted positively to the idea of testing (specify)				
_ Reacted negatively to the idea of testing (specify)				
_ Asked questions about the testing (specify)				
_ Gave suggestions about the testing (specify)				
DESCRIPTION OF THE INTE	RACTION WITH THE VILLAGE HEAD			
EVALUATION OF THE CONV	ERSATION WITH THE VILLAGE HEAD			

APPENDIX C

STI QUESTIONNAIRE

(Female and Male STI Questionnaires on pages following)

THE ROLE OF INFORMAL CONVERSATIONS ON HEALTH AND AIDS BEHAVIOR IN MALAWI, 2004 MINI-QUESTIONNAIRE ABOUT HEALTH AND STIS -- WOMEN

Date (de	d/mm/yy) [_]/[]	Time begun (hh:mm) [_	_]:[]
NO.	QUESTION	RESPONSE	SKIP
B1	How old are you?	YEARS OLD	
	•	DON'T KNOW 88	
B1b	IF RESPONDENT DOESN'T KNOW HIS AGE, ESTIMATE IT	YEARS	
B2	Are you currently married?	YES	
В3	How old were you when you had your first period?	YEARS OLD CAN'T REMEMBER	
Hla	In general, would you say your health now is: (READ OPTIONS)	EXCELLENT	
Н1Р	Overall, how would you rate your health now?	RECORD CLOSEST NUMBER ON THE UMOYO SCALE:	
	SHOW THE RESPONDENT THE UMOYO SCALE AND EXPLAIN: For example, if the end of this line [SHOW#1]		
	means lots of health problems like serious diarrhea	DON'T KNOW 88	
	and really bad fevers and this end [SHOW #2] means no problem at all, where would you place yourself?	DOESN'T UNDERSTAND	
H2	In the last 12 months, have you had TB or shingles?	NO TB and NO SHINGLES	
H3	Some women experience an unusual (often foul smelling) discharge from the vagina, or pain in the bottom of their stomachs that is not related to their periods. During the last 12 months, have you noticed any such discharge or pain?	YES	
H4	Some women experience sores or ulcers in the genital area. During the last 12 months, have you noticed any such sores or ulcers?	YES	IF "NO" TO H3 & H4, SKIP TO H6
H5	Did you take medicine to cure these symptoms, or did you do nothing and wait for the symptoms to go away on their own?	TOOK MEDICINE	
H6	In the last 24 hours, did you have any unusual discharge from the vagina?	YES	
H7	At present, do you have any sores or ulcers in the genital area? If yes, are they painful?	NO	
"Now I	would like to ask you about your own experiences with S	Tls, excluding HIV."	

NO.	QUESTION	RESPONSE	SKIP
Н8	Apart from HIV/AIDS, have you heard about other infections or diseases that one can get through sex? I mean the ones that are treated in health clinics, such as Chlamydia, gonorrhea, syphilis and bubos.	YES	
Н9	If a man has a sexually transmitted infection other than HIV, what symptoms might he have? And what about a woman, what symptoms might she have? (DO NOT READ LIST - MORE THAN ONE ANSWER POSSIBLE) A. Abdominal pain B. Discharge from penis/vagina C. Itching in genital area D. Burning pain on urination E. Pain/pelvic pain during intercourse F. Genital ulcers or open sores G. Swellings in the genital area H. Blood in urine I. Failure to pass urine J. Loss of weight K. Impotence/Inability to conceive L. Other (SPECIFY M. Don't know N. Weakness	MAN WOMAN A 1 1 B 1 1 C 1 1 D 1 1 E 1 1 F 1 1 G 1 1 H 1 1 I 1 1 J 1 1 K 1 1 K 1 1 K 1 1 M 1 1 N 1 1	
H10	Do you think it is possible for a man to have a sexually transmitted infection (other than HIV) but not have symptoms?	YES	
H11	Do you think it is possible for a woman to have a sexually transmitted infection (other than HIV) but not have symptoms?	YES	
H12	If you found out that you had an STI other than HIV, what is the chance that you could be cured with the right treatment (such as getting treated at a hospital)?	NO LIKELIHOOD 0 LOW 1 MEDIUM 2 HIGH 3 DON'T KNOW 88	
H13	Have any of the following people told you that they had a sexually transmitted disease other than HIV? (READ LIST AND MARK ALL THAT APPLY)	SPOUSE/LIVE-IN PARTNER	
H14	In the past 12 months, do you think you had an STI other than HIV?	YES	→ H16 → H16

NO.	QUESTION	RESPONSE	SKIP
H15	How did you know? (MARK ALL THAT APPLY)	KNEW SYMPTOMS FROM PAST EXPERIENCE	
H15A	What did you do? Did you: (READ LIST - MORE THAN ONE ANSWER POSSIBLE) A. Take medicine from a clinic, hospital or private doctor? B. Take medicine from a traditional healer? C. Take medicine from a shop or pharmacy? D. Take medicine you had at home or made themselves? E. Do nothing and wait for the symptoms to go away on their own?	A 1 B 1 C 1 D 1 E 1	
H16	In your opinion, what is the likelihood (chance) that you are infected with an STI other than HIV now?	NO LIKELIHOOD 0 LOW 1 MEDIUM 2 HIGH 3 DON'T KNOW 88	
H17	In your opinion, what is the likelihood (chance) that you will become infected with an STI other than HIV in the future?	NO LIKELIHOOD. 0 LOW. 1 MEDIUM. 2 HIGH. 3 DON'T KNOW. 88	
H18	In your opinion, what is the likelihood (chance) that any of your current or previous sexual partners are infected with an STI other than HIV?	NO LIKELIHOOD. 0 LOW. 1 MEDIUM. 2 HIGH. 3 DON'T KNOW. 88	
H19	Do you suspect or know that your husband has had an STI other than HIV in the past 12 months?	YES, KNOW	
H20	How worried are you that you might catch an STI?	NOT WORRIED AT ALL 1 WORRIED A LITTLE 2 WORRIED A LOT 3 DON'T KNOW. 88	
H21	If we took a group of 10 people from this area—just normal people who you found working in the fields or in homes—how many of them do you think would now have an STI (other than HIV)?	NUMBER [_ _] DON'T KNOW	

NO.	QUESTION	RESPONSE	SKIP	
H22	If we come back after 5 years and take a group of 10 people doing the same sort of daily activities, how	NUMBER [_ _] DON'T KNOW		
	many of them do you think would have an STI (other than HIV)?			
H23	In your opinion, what is the likelihood (chance) that you are infected with HIV now?	NO LIKELIHOOD. 0 LOW. 1 MEDIUM. 2 HIGH. 3 DON'T KNOW. 88		
H24	In your opinion, what is the likelihood (chance) that you will become infected with HIV in the future?	NO LIKELIHOOD. 0 LOW. 1 MEDIUM. 2 HIGH. 3 DON'T KNOW. 88		
H25	In your opinion, what is the likelihood (chance) that any of your current or previous sexual partners are infected with HIV?	NO LIKELIHOOD. 0 LOW. 1 MEDIUM. 2 HIGH. 3 DON'T KNOW. 88		
H26	Do you suspect or know that your husband has HIV?	YES, KNOW		
H27	How worried are you that you might catch HIV?	NOT WORRIED AT ALL 1 WORRIED A LITTLE 2 WORRIED A LOT 3 DON'T KNOW 88		
H28	How scared would you be to know your HIV status?	NOT SCARED AT ALL. 1 A LITTLE SCARED. 2 A LOT SCARED. 3 DON'T KNOW. 88		
H29	If we took a group of 10 people from this area—just normal people who you found working in the fields or in homes—how many of them do you think would now have HIV?	NUMBER [] DON'T KNOW		
H30	If we come back after 5 years and take a group of 10 people doing the same sort of daily activities, how many of them do you think would have HIV?	NUMBER [_ _] DON'T KNOW		
Н31	Do you think most people infected with HIV now in your area are going to die in the next 5 years?	YES		
H32	Do you think treatment for HIV (ARV) will become available to most people in your area in the next 5 years?	YES		
H33	Do you think most people in your area protect themselves against HIV, for example by using condoms or by having fewer sexual partners?	YES		
Time er	nded (hh:mm) [_ _]:[_ _] Langua	age (1=Tumbuka; 2=Yao; 3=Chi	chewa) []	
NOV	NOW USE THE ANSWERS TO B1 AND B2 TO IDENTIFY THE CONSENT FORM (OR SET OF CONSENT			

THE ROLE OF INFORMAL CONVERSATIONS ON HEALTH AND AIDS BEHAVIOR IN MALAWI, 2004 MINI-QUESTIONNAIRE ABOUT HEALTH AND STIS -- MEN

Date (d	d/mm/yy) [_]/[_ _]	Time begun (hh:mm) [_	_]:[]
NO.	QUESTION	RESPONSE	SKIP
B1	How old are you? →	YEARS OLD DON'T KNOW	
B1b	IF RESPONDENT DOESN'T KNOW HIS AGE, ESTIMATE IT	YEARS	
B2	Are you currently married?	YES	
Hla	In general, would you say your health now is: (READ OPTIONS)	EXCELLENT 1 VERY GOOD 2 GOOD 3 FAIR 4 POOR 5	
H1b	Overall, how would you rate your health now?	RECORD CLOSEST NUMBER ON THE UMOYO SCALE:	
	SHOW THE RESPONDENT THE UMOYO SCALE AND EXPLAIN: For example, if the end of this line [SHOW#1]	L	
	means lots of health problems like serious diarrhea	DON'T KNOW 88	
	and really bad fevers and this end [SHOW #2] means no problem at all, where would you place yourself?	DOESN'T UNDERSTAND	
H2	In the last 12 months, have you had TB or shingles?	NO TB and NO SHINGLES. 0 TB ONLY. 1 SHINGLES ONLY. 2 BOTH (TB and SHINGLES). 3 DON'T KNOW. 88	
НЗ	Some men experience pain or burning during urination, or have a discharge from the penis. By discharge I mean anything coloured or clear other than urine or semen that drips or oozes from the penis. During the last 12 months, have you noticed any such pain or discharge?	YES	
H4	Some men experience sores or ulcers on or near the penis. During the last 12 months, have you noticed any such sores or ulcers?	YES	IF "NO" TO H3 & H4, SKIP TO H6
H5	Did you take medicine to cure these symptoms, or did you do nothing and wait for the symptoms to go away on their own?	TOOK MEDICINE	
H6	In the last 24 hours, did you have any unusual discharge from the penis?	YES	
H7	At present, do you have any sores or ulcers on or near the penis? If yes, are they painful?	NO	
"Now I	would like to ask you about your own experiences with S	Tls, excluding HIV."	

NO.	QUESTION	RESPONSE	SKIP
Н8	Apart from HIV/AIDS, have you heard about other infections or diseases that one can get through sex? I mean the ones that are treated in health clinics, such as Chlamydia, gonorrhea, syphilis and bubos.	YES	
Н9	If a man has a sexually transmitted infection other than HIV, what symptoms might he have? And what about a woman, what symptoms might she have? (DO NOT READ LIST - MORE THAN ONE ANSWER POSSIBLE) A. Abdominal pain B. Discharge from penis/vagina C. Itching in genital area D. Burning pain on urination E. Pain/pelvic pain during intercourse F. Genital ulcers or open sores G. Swellings in the genital area H. Blood in urine I. Failure to pass urine J. Loss of weight K. Impotence/Inability to conceive L. Other (SPECIFY M. Don't know N. Weakness	MAN WOMAN A 1 1 B 1 1 C 1 1 D 1 1 E 1 1 F 1 1 G 1 1 H 1 1 I 1 1 J 1 1 K 1 1 K 1 1 K 1 1 M 1 1 N 1 1	
H10	Do you think it is possible for a man to have a sexually transmitted infection (other than HIV) but not have symptoms?	YES	
H11	Do you think it is possible for a woman to have a sexually transmitted infection (other than HIV) but not have symptoms?	YES	
H12	If you found out that you had an STI other than HIV, what is the chance that you could be cured with the right treatment (such as getting treated at a hospital)?	NO LIKELIHOOD 0 LOW 1 MEDIUM 2 HIGH 3 DON'T KNOW 88	
Н13	Have any of the following people told you that they had a sexually transmitted disease other than HIV? (READ LIST AND MARK ALL THAT APPLY)	SPOUSE/LIVE-IN PARTNER	
H14	In the past 12 months, do you think you had an STI other than HIV?	YES	→ H16 → H16

NO.	QUESTION	RESPONSE	SKIP
H15	How did you know? (MARK ALL THAT APPLY)	KNEW SYMPTOMS FROM PAST EXPERIENCE	
H15A	What did you do? Did you: (READ LIST - MORE THAN ONE ANSWER POSSIBLE) F. Take medicine from a clinic, hospital or private doctor? G. Take medicine from a traditional healer? H. Take medicine from a shop or pharmacy? I. Take medicine you had at home or made themselves? J. Do nothing and wait for the symptoms to go away on their own?	A 1 B 1 C 1 D 1 E 1	
H16	In your opinion, what is the likelihood (chance) that you are infected with an STI other than HIV now?	NO LIKELIHOOD 0 LOW 1 MEDIUM 2 HIGH 3 DON'T KNOW 88	
H17	In your opinion, what is the likelihood (chance) that you will become infected with an STI other than HIV in the future?	NO LIKELIHOOD 0 LOW 1 MEDIUM 2 HIGH 3 DON'T KNOW 88	
H18	In your opinion, what is the likelihood (chance) that any of your current or previous sexual partners are infected with an STI other than HIV?	NO LIKELIHOOD 0 LOW 1 MEDIUM 2 HIGH 3 DON'T KNOW 88	
H19	Do you suspect or know that your wife has had an STI other than HIV in the past 12 months?	YES, KNOW	
H20	How worried are you that you might catch an STI?	NOT WORRIED AT ALL 1 WORRIED A LITTLE 2 WORRIED A LOT 3 DON'T KNOW. 88	
H21	If we took a group of 10 people from this area—just normal people who you found working in the fields or in homes—how many of them do you think would now have an STI (other than HIV)?	NUMBER [_ _] DON'T KNOW	

NO.	QUESTION	RESPONSE	SKIP	
H22	If we come back after 5 years and take a group of 10 people doing the same sort of daily activities, how many of them do you think would have an STI (other than HIV)?	NUMBER [_ _] DON'T KNOW		
H23	In your opinion, what is the likelihood (chance) that you are infected with HIV now?	NO LIKELIHOOD. 0 LOW. 1 MEDIUM. 2 HIGH. 3 DON'T KNOW. 88		
H24	In your opinion, what is the likelihood (chance) that you will become infected with HIV in the future?	NO LIKELIHOOD. 0 LOW. 1 MEDIUM. 2 HIGH. 3 DON'T KNOW. 88		
H25	In your opinion, what is the likelihood (chance) that any of your current or previous sexual partners are infected with HIV?	NO LIKELIHOOD. 0 LOW. 1 MEDIUM. 2 HIGH. 3 DON'T KNOW. 88		
H26	Do you suspect or know that your wife has HIV?	YES, KNOW		
H27	How worried are you that you might catch HIV?	NOT WORRIED AT ALL 1 WORRIED A LITTLE 2 WORRIED A LOT 3 DON'T KNOW. 88		
H28	How scared would you be to know your HIV status?	NOT SCARED AT ALL		
H29	If we took a group of 10 people from this area—just normal people who you found working in the fields or in homes—how many of them do you think would now have HIV?	NUMBER [_ _] DON'T KNOW		
H30	If we come back after 5 years and take a group of 10 people doing the same sort of daily activities, how many of them do you think would have HIV?	NUMBER [_ _] DON'T KNOW		
H31	Do you think most people infected with HIV now in your area are going to die in the next 5 years?	YES		
H32	Do you think treatment for HIV (ARV) will become available to most people in your area in the next 5 years?	YES		
H33	Do you think most people in your area protect themselves against HIV, for example by using condoms or by having fewer sexual partners?	YES		
Time ended (hh:mm) [_ _]:[_ _] Language (1=Tumbuka; 2=Yao; 3=Chichewa) [_]				
NOV	NOW USE THE ANSWERS TO B1 AND B2 TO IDENTIFY THE CONSENT FORM (OR SET OF CONSENT			

APPENDIX D

INFORMED CONSENT FORMS

1. INVITATION TO PARTICIPATE IN <u>STI TESTING</u>

Male respondents (If adolescent male, obtain consent from parent first)

After the survey interview is completed, the nurse will say:

To understand more about the health of people in Malawi, we are conducting free tests for sexually transmitted infections that have been known in Malawi for a long time: gonorrhea, chlamydia and trichomonas. In addition to the discomfort of the diseases itself, leaving these infections untreated may lead to infertility or may endanger the child if the mother is pregnant. All of these can be cured, and if you have any of these we will provide you with free medication.

If you agree to participate in this test, I will ask you to put some urine in a cup. I will give you the cup, and wait here while you go somewhere private to put the urine into the cup. When you are finished, please put the cap on the cup and give it back to me. The research team will send all the urine cups from this village to a laboratory at Lilongwe General Hospital. They will test it. In order to ensure complete confidentiality of the test results, your name will not be on the cup, only a number. Therefore, no one will be able to trace it to you. Let me emphasize that if you become uncomfortable or do not want to participate in the tests, you can stop at any time.

When we have the results from the tests, a nurse from our team will come to your village. If you want to know the results and receive medicine you can get your results from her. The nurse will have a list of the numbers (not the names) of all men who have provided urine, so even the nurse will not know your name. If you agree, I am going to take your picture and I will write on the back of the picture your number. If you want to get the results of your test, you have to show this picture to the nurse. The picture will help the nurse to make sure that you yourself come to get the results of your test. If you have an infection, the nurse will provide you with free medication to cure it. She will also answer your questions, and give you advice on how to avoid getting infected again.

Do you agree to be tested for STIs?	_ yes _ no	
Interviewer signature:	. <u></u>	
Respondent signature or thumb print: _		
Respondent's Riomarker ID number		

Do you have any questions?

2. INVITATION TO PARTICIPATE IN STI TESTING

Female respondents (If adolescent female, obtain consent from parent first)

After the survey interview is completed, the nurse will say:

To understand more about the health of people in Malawi, we are conducting free tests for sexually transmitted infections that have been known in Malawi for a long time: gonorrhea, chlamydia and trichomonas. In addition to the discomfort of the diseases itself, leaving these infections untreated may lead to infertility or may endanger the child if the mother is pregnant. All of these can be cured, and if you have any of these we will provide you with free medication.

If you agree to participate in this test, I will ask you to give us a few drops of liquid from your vagina. I will give you a little stick with a piece of cotton on it, and wait here while you go somewhere private to put it in your vagina. When you have done this I will put the stick and cotton into a small bag. The research team will send all cotton sticks from this village to a laboratory at Lilongwe General Hospital. They will test it. In order to ensure complete confidentiality of the test results, your name will not be on the cotton stick, only a number. Therefore, no one will be able to trace it to you. Let me emphasize that if you become uncomfortable or do not want to participate in the test, you can stop at any time.

When we have the results from the tests, a nurse from our team will come to your village. If you want to know the results and receive medicine you can get your results from her. The nurse will have a list of the numbers (not the names) of all women who have been tested for STIs, so even the nurse will not know your name. If you agree, I am going to take your picture and I will write on the back of the picture your number. If you want to get the results of your test, you have to show this picture to the nurse. The picture will help the nurse to make sure that you yourself come to get the results of your test. If you have an infection, the nurse will provide you with free medicine to cure it. She will also answer your questions, and give you advice on how to avoid getting infected again.

Do you agree to be tested for STIs?	_ yes _ no	
Interviewer signature:		-
Respondent signature or thumb print: _		
Respondent's Biomarker ID number:		

Do you have any questions?

3. INVITATION TO PARTICIPATE IN HIV TESTING:

All respondents (If adolescent respondent, obtain consent from parent first)

After the STI test is completed, the nurse will say:

Do you have any questions?

A part of our study is to learn how much HIV there is in this area. As you know, HIV is the virus that causes AIDS. The research team is conducting free tests to try find out how common the virus is, so that the government and NGOs can develop programs to prevent AIDS and care for those who have it.

If you agree to participate in this free test, I will ask you to put this little stick with a piece of cotton on it in your mouth. When you have done this I will put the stick and cotton into a small bag. The research team will send all cotton sticks from this village to a laboratory at Lilongwe General Hospital. They will test it. In order to ensure complete confidentiality of the test results, your name will not be on the cotton stick, only a number. Therefore, no one will be able to trace it to you. Let me emphasize that if you become uncomfortable or do not want to participate in the test, you can stop at any time.

When we have the results from the tests, a nurse from our team will come to your village. If you want to know the results you can get your results from her. The nurse will have a list of the numbers (not the names) of all people who have been tested for HIV, so even the nurse will not know your name. If you agree, I am going to take your picture and I will write on the back of the picture your number. If you want to get the results of your test, you have to show this picture to the nurse. The picture will help the nurse to make sure that you yourself come to get the results of your test. As you know, there is no cure for AIDS, but if you are infected the nurse will answer your questions and talk with you about ways in which you can take care of yourself and protect your relatives from getting infected.

Do you agree to be tested for HIV?	_ yes	_ no	
Interviewer signature:			
Respondent signature or thumb print: _			
Respondent's Biomarker ID number:			

4. INVITATION TO PARTICIPATE IN STI TESTING

Parent of unmarried male adolescents age 15-17

After the survey interview is completed, the interviewer will then say:

To understand more about the health of people in Malawi, we are conducting free tests for sexually transmitted infections that have been known in Malawi for a long time: gonorrhea, chlamydia and trichomonas. In addition to the discomfort of the diseases itself, leaving these infections untreated may lead to infertility or may endanger the child if the mother is pregnant. All of these can be cured, and if your son has any of these we will provide free medication.

We would like to ask your permission for your son to participate in this test. If you agree, I will ask him to put some urine in a cup. I will give your son the cup, and wait here while he goes somewhere private to put the urine into the cup. When your son is finished, he should put the cap on the cup and give it back to me. The research team will send all the urine cups from this village to a laboratory at Lilongwe General Hospital. They will test it. In order to ensure complete confidentiality of the test results, the name of your son will not be on the cup, only a number. Therefore, no one will be able to trace it to your son. Let me emphasize that if your son becomes uncomfortable or does not want to participate in the test, he can stop at any time.

When we have the results from the tests, a nurse from our team will come to your village. If your son wants to know the results and receive medicine he can get the results from the nurse. The nurse will have a list of the numbers (not the names) of all people who have provided urine, so even the nurse will not know the name of your son. If you agree, I am going to take a picture of your son and I will write on the back of the picture your son's number. If your son wants to get the results of the test, he has to show this picture to the nurse. The picture will help the nurse to make sure that your son himself comes to get the results of his test. If your son has an infection, the nurse will provide him with free medicine to cure it. She will also answer his questions, and give him advice on how to avoid getting infected again.

Do you agree that your son is tested for STIs?	_ yes _ no	
Interviewer signature:		
Parent's signature or thumb print:		
Respondent's Biomarker ID number:		

Do you have any questions?

5. INVITATION TO PARTICIPATE IN STI TESTING

Parent of unmarried female adolescents age 15-17

After the survey interview is completed, the nurse will say:

To understand more about the health of people in Malawi, we are conducting free tests for sexually transmitted infections that have been known in Malawi for a long time: gonorrhea, chlamydia and trichomonas. In addition to the discomfort of the diseases itself, leaving these infections untreated may lead to infertility or may endanger the child if the mother is pregnant. All these infections can be cured, and if your daughter has any of these we will provide free medication.

We would like to ask your permission for your daughter to participate in this test. If you agree, I will ask her to give us a few drops of liquid from her vagina. I will give your daughter a little stick with a piece of cotton on it, and wait here while she goes somewhere private to put it in her vagina. When she has done this I will put the stick and cotton into a small bag. The research team will send all cotton sticks from this village to a laboratory at Lilongwe General Hospital. They will test it. In order to ensure complete confidentiality of the test results, the name of your daughter will not be on the cotton stick, only a number. Therefore, no one will be able to trace it to your daughter. Let me emphasize that if your daughter becomes uncomfortable or does not want to participate in the test, she can stop at any time.

When we have the results from the tests, a nurse from our team will come to your village. If your daughter wants to know the results and receive medicine she can get your results from the nurse. The nurse will have a list of the numbers (not the names) of all people who have been tested for STIs, so even the nurse will not know her name. If you agree, I am going to take a picture of your daughter and I will write on the back of the picture your daughter's number. If your daughter wants to get the results of her test, she has to show this picture to the nurse. The picture will help the nurse to make sure that your daughter herself comes to get the results of her test. If your daughter has an infection, the nurse will provide her with free medicine to cure it. The nurse will also answer her questions, and give her advice on how to avoid getting infected again.

_ c y co can c and queenous.		
Do you agree that your daughter is tested for STIs?	_ yes	_ no
Interviewer signature:		
Parent's signature or thumb print:		
Respondent's Biomarker ID number:		

Do you have any questions?

6. INVITATION TO PARTICIPATE IN HIV TESTING

Parent of unmarried adolescents age 15-17

After the STI test is completed, the nurse will say:

Do you have any questions?

A part of our study is to learn how much HIV there is in this area. As you know, HIV is the virus that causes AIDS. The research team is conducting free tests to find out how common the virus is, so that the government and NGOs can develop programs to prevent AIDS and care for those who have it.

We would like to ask your permission for your son/daughter to participate in this test. If you agree, I will ask that he/she puts this little stick with a piece of cotton on it in his/her mouth. When he/she has done this I will put the stick and cotton into a small bag. The research team will send all cotton sticks from this village to a laboratory at Lilongwe General Hospital. They will test it. In order to ensure complete confidentiality of the test results, the name of your son/daughter will not be on the cotton stick, only a number. Therefore, no one will be able to trace it to him/her. Let me emphasize that if your son/daughter becomes uncomfortable or does not want to participate in the test, he/she can stop at any time.

When we have the results from the tests, a nurse from our team will come to your village. If your son/daughter wants to know the results he/she can get your results from the nurse. The nurse will have a list of the numbers (not the names) of all people who have been tested for HIV, so even the nurse will not know the name of your son/daughter. If you agree, I am going to take your picture of your son/daughter and I will write on the back of the picture his/her number. If your son/daughter wants to get the results of the test, he/she has to show this picture to the nurse. The picture will help the nurse to make sure that your son/daughter himself/herself comes to get the results of the test. As you know, there is no cure for AIDS, but if your son/daughter is infected the nurse will answer his/her questions and talk with your son/daughter about ways in which he/she can take care of himself/herself and protect his/her relatives from getting infected.

Do you agree that your son/daughter is tested for HIVs?	_ yes _ no
Interviewer signature:	
Parent's signature or thumb print:	
Respondent's Biomarker ID number:	

APPENDIX E

2004 Malawi Diffusion and Ideational Change Project STI/HIV TESTING SHEET

		STI		HIV		
LABEL	SAMPLE RESULT DATE AND TIME INCENTIVE 1=VAGINAL SWAB REMEMBER TO COPY TIME AND VOUCHER 2=URINES TAKEN DATE ON AMOUNT 3=REFUSED SPECIMEN'S LABEL (KWATCHA)		VOUCHER AMOUNT	SAMPLE RESULT 1=ORAL SWAB TAKEN 2=REFUSED 3=OTHER (SPEC.)	DATE AND TIME REMEMBER TO COPY TIME AND DATE ON SPECIMEN'S LABEL	INCENTIVE INCENTIVE VOUCHER AMOUNT (KWATCHA)
(1)	(2)	(3)	(4)	(5)	(6)	(7)
DO NOT WRITE HERE		DATE			DATE	
		TIME			TIME	
DO NOT WRITE HERE		DATE			DATE	
,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,		TIME			TIME	
DO NOT		DATE			DATE	
WRITE HERE		TIME			TIME	
DO NOT		DATE			DATE	
WRITE HERE		TIME			TIME	
DO NOT WRITE HERE		DATE			DATE	
WRITETIERE		TIME			TIME	
DO NOT WRITE HERE		DATE			DATE	
		TIME			TIME	
Total number o	f STI samples			Total nun	nber of HIV sam	ples
Nurse initials	Supervi	sor initials	Logger	initials		

APPENDIX F

2004 Malawi Diffusion and Ideational Change Project VCT SHEET

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	(12)	(13)	(14)	(15)	(16)
				TEST RE	SULTS		WAN	NTED	TREATMI	ENT ADMII	NISTERED	INCE	NTIVE	INCENTI	VE PAID?
LABEL	VILLAGE	SEX		0=NEGATIVE;				TS FOR:	(0=NONE; 2=AZITHRAI	1=CIPROF			AMOUNT (0=NO; 1=YES) RESPONDENT		1=YES) NDENT
	NAME	(M=1; F=2)		2=INADEQUA	ΓE SAMPLE)	Ī	(0=NO;	1=YES)				(KWATCHA) SHOULD INITIA			
			CHLAMYDIA	TRICH	GONORRHEA	HIV	STI	HIV	CHLAMYDIA	TRICH	GONORRHEA	STI	HIV	STI	HIV
DO NOT WRITE HERE															
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DO NOT WRITE HERE															
DO NOT WRITE HERE															

Biomarker collection:	Date _ _ _ _	Nurse supervisor initials
VCT:	Date _ _ _ _	Nurse supervisor initials

APPENDIX G STI/HIV TRANSFER SHEET

2004 Malawi Diffusion and Ideational Change Project TRANSFER SHEET

SQQNUM	TYPE 1= VAGINAL SWAB 2= URINE 3=ORAL SWAB	DATE OF COLLECTION	STAFF MEMBER INITIALS	TRANSFER NURSE INITIALS	LAB TECHNICIAN INITIALS	COMMENTS
Total vaginal swab Total urines Total oral swabs	os	- - -				
Date: _ _ _ _ _	_					
LAB TECHNICIA	N COMMENTS	: 				

INSTRUCTIONS FOR TRANSFER NURSE: THE LAB TECHNICIAN WHO RECEIVES THE SPECIMENS HAS TO MAKE A COPY OF THIS TRANSFER SHEET AND GIVE IT BACK TO YOU.