Obtaining Informed Consent for HIV Testing

The DHS Experience in Mali

Obtaining Informed Consent for HIV Testing: The DHS Experience in Mali

P. Stanley Yoder
Mamadou Kani Konaté

ORC Macro
Calverton, MD

November 2002

This report presents findings from a qualitative research study conducted in Mali in 2001 as part of the MEASURE *DHS*+ project. ORC Macro coordinated this activity and provided technical assistance. Funding was provided by the U.S. Agency for International Development (USAID) through a subcontract with Marikani and Castle, Ltd. in Bamako, Mali. The principal researchers were P. Stanley Yoder, ORC Macro, and Mamadou Kani Konaté, CERPOD, Bamako, Mali.

Additional information about the MEASURE DHS+ project can be obtained from MEASURE *DHS+,* ORC Macro, 11785 Beltsville Drive, Calverton, MD 20705 (telephone: 301-572-0200; fax: 301-572-0999; email: reports@macroint.com; internet: www.measuredhs.com).

This publication was made possible through support provided by the U.S. Agency for International Development under the terms of Contract No. HRN-C-00-97-00019-00. The opinions expressed herein are those of the authors and do not necessarily reflect the views of the U.S. Agency for International Development.

Suggested citation:

Yoder, P. Stanley, and Mamadou Kani Konaté. 2002. *Obtaining Informed Consent for HIV Testing: The DHS Experience in Mali.* Calverton, Maryland, USA: ORC Macro.

CONTENTS

Page

TABLES

PREFACE

The Mali informed consent (MIC) study was implemented through a subcontract with Marikani and Castle, Ltd., a consulting firm based in Bamako, Mali. The study was carried out at the same time and in conjunction with the 2001 DHS survey in Mali, *Enquéte Démographique et de Santé au Mali 2001 (EDSM-III)*. Fieldwork, analysis, and much of the writing was directed by Mamadou Konaté, a sociologist from Centre d'Etudes et de Recherche sur la Population pour le Développement (CERPOD). The work was financed with funds from U.S. Agency for International Development (USAID) Washington under MEASURE *DHS*+.

We wish to warmly thank the research team composed of four persons who proved to be sharp observers, skilled interviewers, and careful notetakers, and who were willing and able to share numerous insights along the way. Their patience and generosity were exceptional. They were Issa Daffé, Djibril Diallo, Assa Konaté and Fanta Djenepo. We also wish to thank the members of the four EDSM-III teams whom we followed around, for generously allowing us to observe the way they worked. Special thanks also goes to Salif Ndiaye, Resident Advisor for the EDSM-III in Mali, for his many efforts to assist the MIC research team.

EXECUTIVE SUMMARY

Introduction

The third Demographic and Health Survey in Mali, *Enquéte Démographique et de Santé au Mali 2001 (EDSM-III),* was a standard national-level DHS survey. It was directed by the Cellule de Planification et de Statistique of the Ministry of Health and the Direction Nationale de la Statistique et de l'Informatique with technical assistance from ORC Macro. In addition to the core questionnaires and several modules, the EDSM-III included taking blood for anemia and HIV testing in a subsample of those interviewed. While anemia testing has become part of the core questionnaire in DHS surveys, this survey marked the first time a DHS survey had included drawing blood for HIV testing.

The EDSM-III was conducted with a sample of 403 clusters nationwide. In urban areas a cluster included about 25 households, while in rural areas most clusters included about 40 households. In one-third of the households, a men's questionnaire was administered to all males age 15 to 59. In these same households, all eligible adults, males and females, were asked to participate in the anemia and HIV testing. With this subsample more than 7,600 adults in the country were asked to give blood for testing.

This first experience of including a blood test for HIV in a subsample of a standard DHS survey raised many issues new to the DHS program: Is it feasible to conduct such tests for biomarkers without interfering in the survey process? What kind of informed consent is appropriate for these blood tests? How well is the consent statement understood? What do people recall about the statement after the tests? How and why would some individuals refuse to participate? In short, how did the consent statement work in the field?

USAID Washington asked ORC Macro to monitor the use of the consent statement and the blood tests in order to shed light on these questions. ORC Macro was specifically asked to focus on how the informed consent statement was presented and what individuals understood when they were asked to give blood for a test for anemia and for HIV.

Background

The practice of requiring informed consent for medical research became common in Europe and North America in the 1970s following much public discussion and the work of several commissions. For medical research sponsored by the U.S. government, informed consent statements are required to mention certain elements (Singer et al., 1992) including the purpose of the study, the possible benefits and the risks entailed, a statement that participation is voluntary, and an offer to answer any questions. In survey research, respondents also need to be told that their answers will be kept confidential.

Some researchers question whether the medical model of risks and benefits should be applied to at all in the nontherapeutic context of population surveys, because the individual risks and benefits are minimal. Drawing a few drops of blood for tests of anemia and HIV in the context of a standard DHS survey does not present a major risk to participants, but one cannot say there is no risk at all. Therefore, DHS survey policy requires that an informed consent statement be read to all respondents who are asked to provide blood for testing for any purpose.

Many studies of the use of informed consent statements have examined the extent to which participants understood or retained the information contained in a written statement of the possible risks and benefits of their participation. The settings for these consent statements have nearly always been medical treatments or clinical trials. Participants generally first have the procedure, risks and benefits explained to them; and then they are given a text describing the risks of the intervention to read and then to sign. Their

signature is used as an indication that they have understood and accepted the risks involved.

Researchers who have examined informed consent studies in medicine, psychology, and the social sciences, have found that the language used is often too complex for easy understanding by an American public (Ogloff and Otto, 1991). Studies of what patients retained from an informed consent statement have shown that a significant proportion did not well understand the risks and benefits of the procedures they had accepted. The lack of understanding may well be linked to the complexity of the language used. If the standard statements of informed consent currently used in English are not easily understood, their use in societies where many languages are spoken offers additional challenges in obtaining an informed consent.

Study Objectives

This study observed the process of obtaining the consent of respondents in giving a few drops of blood for tests for anemia and for HIV in order to see if the statements were properly presented and what the respondents understood from those presentations. The overall objective was to understand just how the process of doing blood tests worked and how it might be made more effective. This goal was achieved through a combination of observations and interviews with respondents following the blood tests.

The research team defined several tasks that should be accomplished in order to understand how the informed consent statement worked in the field. Those tasks of data collection and analysis included the following:

- Observe how the informed consent statement was presented to eligible respondents.
- Ask what these persons understood from the informed consent statement they had just heard.
- Discuss with respondents the reasons for accepting or refusing to participate in the blood testing.
- Observe how the card to be used for obtaining test results was offered and accepted.

Methodology

This Mali informed consent study was designed by the technical director from ORC Macro in collaboration with the consultant hired to direct the fieldwork and the data analysis. The fieldwork team was composed of two men and two women who participated in one week of training in qualitative research methods and the development of research instruments. Three instruments were formulated during the training: 1) an observation form to monitor how the EDSM-III team introduced themselves to local leaders and heads of households, 2) an observation form for observing how the informed consent statement was administered, and 3) a short open-ended questionnaire for obtaining information from respondents on their understanding of the blood tests and the informed consent statement.

Introductions by the EDSM-III teams were monitored by the MIC study team because it was thought that the way the EDSM-III teams presented themselves locally might affect participation in the blood test. The observation form to monitor the presentation of the consent statement provided data on how the field editor presented herself, how she set up the blood test, how the consent statement was presented, and the reaction of the respondents. The brief questionnaire included questions about what the respondents had been told about the blood tests, why they had accepted or refused, what the purpose of the “green card” was, and their knowledge of AIDS. These instruments were pretested for a week and were then revised before fieldwork began.

The MIC study training took place after the EDSM-III teams had been working for six weeks. The EDSM-III teams were made up of five persons: a male team leader, three female interviewers, and a female field editor who also conducted the blood tests. The study team functioned independently from the EDSM-III teams and did not interfere with the teams' activities.

The MIC study was conducted in a small subsample of the clusters in which the EDSM-III was carried out. The clusters were selected to provide some contrast between the central region and the southern region, plus clusters in the capital city of Bamako: 1) two urban and one rural cluster in the Mopti region (central), 2) two urban and one rural cluster in the Sikasso region (southern), and 3) four clusters in Bamako. A total of 196 observations of the presentation of the informed consent statement were conducted in these ten clusters.

The most important aspect of the study was the presentation of the informed consent statement, since it was critical that information be collected on how the statement worked. Also considered were reasons for acceptance and refusal to participate, the passing out of the green card, and respondents' reaction to questions about AIDS. The "green card" was a card that could be taken to a health center and that entitled the bearer to obtain a free HIV test. Researchers had hypothesized that individuals might refuse to participate in the blood test for HIV because they had little knowledge of AIDS or they thought that AIDS was of no concern to them.

Results

The observation form for the presentation of the informed consent statement allowed researchers to monitor what was said to respondents and just how the statement was presented. The consent statement consisted of two parts: a part asking permission to draw a few drops of blood for an anemia test, with results available on the spot, and a part asking permission to use a drop or two of blood do a test for HIV, with the results being anonymous. The two sections were all on one page and were in four languages: French, Bambara, Peuhl (Fulfulde), and Sonrhaï.

In practice, the field editors nearly always combined the two sections, asking for a general permission to draw a few drops of blood rather than asking for two permissions. In the majority of cases observed, the field editor explained the statement without reading the statement verbatim. Most likely, the field editors found the formal language and structure did not fit local language practices, and adapted them to improve understanding. Since the MIC study was conducted after the EDSM-III teams had been in the field for three months, the field editors had time to learn just how to explain the elements of the statement in ways that they could be understood. The statement was actually read, with or without explanation, in 20 percent of the cases.

Nearly everyone had been told the purpose of the blood tests. In the brief interview after the blood tests, respondents were asked about what they recalled from the informed consent statement. A total of 88 percent remembered that there was a test for anemia, and 89 percent recalled a test for HIV. Since these answers were given spontaneously, and it was assumed that a few people were told but forgot to mention the purpose of the blood test, nearly all respondents knew the blood tests were related to anemia and to AIDS. At least 60 percent also mentioned that the HIV test results were anonymous.

Participation in the blood tests was voluntary, and 15 percent of the respondents refused the blood tests in the cases observed. According to the observation forms, 69 percent (N=133) were told directly that their participation was voluntary. In the conversation after the blood drawing, individuals were asked if they knew that participation was voluntary. A total of 135 said yes, they had known, which is virtually the same number who had been told directly. In nearly all cases the individuals in the two groups (observed and reported) were the same individuals. Most importantly, the group of respondents who said they did not understand that participation was voluntary were just as likely to refuse the blood tests as those who had

understood the tests were voluntary.

Although the performance of the field editors in presenting the informed consent statement leaves room for improvement, the ways the statement was presented can be easily understood by examining the social context. First, most people accepted the blood tests because the teams introduced themselves as coming from the Ministry of Health. Second, the conditions known as anemia and AIDS are not familiar concepts to most Malians, yet they accepted nevertheless. The national level of refusal was 11 percent. Third, field editors found ways to explain the consent statement so it could be understood. It seems likely that a simple and conversational consent statement, rather than a formal and complex one, would greatly facilitate this task and make it more likely to be understood.

The study team had hypothesized that individuals might refuse to accept the blood test for HIV because of the way the EDSM-III team introduced itself, the way the informed consent statement was presented, or because of knowledge or concerns about AIDS. No evidence was found to link the actions of the EDSM-III team to acceptance rates. Nor was any evidence found that the way the informed consent statement was presented influenced participation rates. The rate of refusals was not tied to the way the consent statement was presented. It is also important to note that all of the observed refusals but one were in urban clusters.

Some evidence was found linking refusals to individual knowledge and experience with AIDS. In the conversations that followed the blood tests, respondents were asked directly why they had refused the blood test. The answers given generally indicated that the persons knew nothing about AIDS, or that they thought they were not at risk.

During the conversation held after the blood test, the interviewers asked the respondents, “What do you know about AIDS?”

A series of subquestions usually followed, for often the respondent would say, “I don’t know anything.” Interviewers would then ask related questions and the respondent would give information about AIDS they had heard in the media or from their neighbors. Although people’s first response to the question about what they knew about AIDS was most often “nothing,” the majority were able to mention a few things they had heard.

What was most striking about the responses of so many to the question of what they knew about AIDS was that they first said they knew nothing, and then they would say, “Well, I heard on the radio that... or it is said that . . . or some claim that . . .,” and would then explain that AIDS can be transmitted through sexual relations and contaminated instruments. Few individuals came out directly and stated how it was transmitted. Often there was a tentative tone to the response, as though they did not really believe their answer.

Nevertheless, nearly two-thirds mentioned that AIDS is transmitted through sexual relations. Of the 188 conversations about AIDS recorded, 122 mentioned the classic modes of transmission they had heard about through the media or through friends. Another 30 percent simply said they did not know how AIDS is transmitted.

The Ministry of Health in Mali chose to conduct unlinked blood tests for HIV but for ethical reasons, wanted to provide everyone with an opportunity to take an HIV blood test and obtain the results free of charge if they so desired. Each person asked to give blood for an HIV test received a green card that could be taken to a medical facility to obtain an HIV test free of charge. In the discussions held with individuals after the blood test, respondents were asked what purpose the green card served. Nearly everyone had understood that it should be taken to a health facility, but only about one-fourth had understood it should be

used to get an HIV test free of charge. However, only several dozen individuals out of more than 6,800 persons tested used their card to get an HIV test, according to reports from the medical centers prepared to conduct HIV tests.

Conclusion

The results of this study contain numerous lessons for conducting large sample surveys that include tests for biomarkers in West African societies. For the Demographic and Health Survey personnel, it is reassuring to find that tests for biomarkers can be added without jeopardizing survey results.

But there are also more general conclusions for survey research that derive from the impact of the social context on fieldwork. First, people will participate in giving blood for tests for unfamiliar conditions, even if they have only a vague idea of the condition in question, if a medical team requests it. In that, they are just like many Americans who give their assent to medical tests they do not understand. In Mali most people have only a vague idea, if that, of what anemia might be, and AIDS is not a disease that concerns many of them personally.

Second, informed consent statements could be formulated in simple and conversational language to increase the probability that the statements will be read or recited verbatim. This requires that members of the ethical or institutional research boards reviewing the statements be convinced that simple language can contain the information they deem indispensable. The reading of a speech in formal language is an unnatural act in these contexts, and the temptation to simplify by explanation should be removed.

Third, the training of interviewers in presenting informed consent statements should emphasize the importance of mentioning a list of key items in the statements presented. Demonstration of the ability to present consent statements that include all these items should be part of the training. If the language is simple and conversational, learning what must be said will not prove difficult, and reading or reciting from a text can be performed by all interviewers.

CHAPTER 1

INTRODUCTION

1.1 Context

The third Demographic and Health Survey in Mali, *Enquéte Démographique et de Santé au Mali 2001 (EDSM-III)* was a standard national-level DHS survey conducted by the Cellule de Planification et de Statistique of the Ministry of Health and the Direction Nationale de la Statistique et de l'Informatique with technical assistance from ORC Macro (CPS/MS, DNSI, and ORC Macro, 2002). In addition to the core questionnaires and several modules, the EDSM-III included taking blood for anemia and HIV testing in a subsample of those interviewed. While anemia testing has become part of the core questionnaire for DHS surveys, this survey marked the first time a DHS survey had included drawing blood for HIV testing.

This first experience for ORC Macro in assisting with HIV testing as part of a DHS survey involved close collaboration with many agencies from within Mali and from elsewhere. Government ministries in Mali, USAID Washington, and the Centers for Disease Control and Prevention (CDC) all had a keen interest in monitoring this process. The government ministries supplied the personnel and took charge of survey logistics; ORC Macro supplied technical assistance; and CDC directed the arrangements for setting up a laboratory for HIV testing and arranging for the ziplock bags to protect and transport the filter paper for HIV testing.

The EDSM-III was conducted throughout the country with a sample representative of all households of the nation. The sample was composed of 403 clusters with about 25 or 40 households per cluster: the urban clusters usually contained about 25 households, while the rural clusters normally had 40 households. It was expected that the survey would contact about 14,500 women from 15 to 49 years old and 4,000 men from 15 to 59 years old. In each household the interviewer filled out a household questionnaire that identified the persons eligible for the men's or women's questionnaires, and then conducted individual interviews with the core questionnaire.

A men's questionnaire was administered to all eligible males in one-third of the households, a subsample often used in DHS surveys. In these same households all eligible adults, males and females, were asked to give a few drops of blood for a test for anemia and for AIDS. Children age five and younger were also eligible for an anemia test. The physical mechanics were simple: prick the end of a finger with a tiny lance; touch a drop of blood with a microcuvette to obtain blood for reading the anemia level; and put a drop or two onto filter paper for the HIV test.

The informed consent statement told the respondents that the result of their anemia test would be given by a machine on the spot; the result would be kept confidential, but they would be told the result. With regard to HIV, the statement declared that the result would not be given to them, but that no name would be attached to their blood. The results of the anemia test were read immediately in a machine (HemoCue) which gave the hemoglobin level upon insertion of the cuvette. The field editor gave the test results for anemia to the respondent (normal or below normal), and then explained that the HIV test results were not available on the spot. Respondents were given a small green card and told that if they wanted to know the results of their test, they could take the card to a medical center to request an AIDS test without cost to them. In order to guarantee anonymity of test results, each sample sent to the laboratory for HIV testing in Bamako was accompanied by a yellow card on which was written only the cluster number, the age, and the sex of the person.

This first experience of including a blood test for HIV in a subsample of a standard DHS survey raised many issues new to the DHS program: 1) What kind of informed consent statement is suitable for these blood tests? 2) How well is the consent statement understood? 3) That is, how well does the consent statement work? 4) What do people recall about the statement after the blood tests? 5) How and why would some individuals refuse to collaborate?

USAID Washington asked ORC Macro to monitor the use of the consent statement and the blood tests in order to answer some of these questions. ORC Macro was asked to focus on investigating the use of the informed consent statement and what individuals understood when they were asked to give blood for an AIDS blood test. Through a combination of observations and interviews following the blood tests, the study sought to specify what people recalled from the consent statement and what they knew about AIDS.

1.2 Objectives

This study was designed and directed to understand how the process of drawing blood for anemia and HIV blood tests occurred in Mali, and how well the informed consent statement worked in the field. Attainment of this objective depended on accomplishing the following tasks:

- Observe how the informed consent statement was presented to eligible respondents
- Ask what these persons understood from the informed consent statement they had just heard
- Discuss with respondents the reasons for accepting or refusing to participate in the blood testing
- Observe how the green card to be used for obtaining test results was offered and accepted.

ORC Macro sought to understand how the informed consent statement worked in the field, not only to monitor this first experience with population-based HIV testing, but to draw lessons for training and use of informed consent for future surveys. Questions that were being asked include the following: 1) How should the legal and ethical issues of informed consent be considered in a survey? 2) To what extent do people realize that their participation is voluntary? 3) What degree of understanding should be considered as "informed"? 4) How does the social context of compounds in Mali, where the head of the household often decides for its members, influence the way the consent statements are presented? These questions were discussed during each phase of the study (design, fieldwork, analysis, report writing).

1.3 Hypotheses

In the process of finalizing the study design and developing a rationale for the study, a large number of assumptions and hypotheses about possible responses to the request for blood tests were discussed among the research team members in Bamako. Also discussed at length were reasons that individuals would accept or reject the blood tests, for the group was unsure about how people would respond. Eventually the group chose five hypotheses to explore, each one related to the way individuals would react. Individual responses were to be measured by whether they accepted or refused the blood test, and how well they understood elements of the informed consent statement and the purpose of the green card.

The research team identified the following hypotheses:

1) Publicity regarding the DHS survey team might influence the way individuals respond to the team. A clear understanding of the identity of the DHS survey team would make a positive response more likely.

2) The identity of the field editor might influence the reaction of the population to the survey. If a field editor identifies herself as a medical person, chances of a positive response increase.

3) The manner in which the field editor presents the informed consent statement influences the response of the population. Consent statements read slowly and clearly are more likely to be understood than those briefly explained.

4) The images individuals hold about AIDS might influence their reactions. Persons very afraid of AIDS who don't want to talk about it might tend to refuse a blood test.

5) Questionnaire fatigue might influence respondents' reactions. That is, for those who had just completed a long individual questionnaire, they may refuse a blood test because they have already spent time with an interviewer.

These hypotheses, as well as implicit assumptions, guided the research team in formulating and revising the observation and questioning instruments during training.

CHAPTER 2

STUDIES OF INFORMED CONSENT

The literature on the investigation of the use of informed consent in data collection refers to three types of contexts: medical contexts involving interventions or clinical trials, surveys of a general population, and ethnographic research. The literature related to medical contexts emphasizes the importance of disclosure of risks and benefits to patients, but includes only a small number of studies on the readability of texts. Studies of survey data collection have focused on the relationship between various forms of introducing the survey and the refusal rates. Researchers have experimented with longer versus shorter introductions, and with more or less emphasis on the confidentiality of the results, to see which approach produces the lowest rate of refusal. Discussions among anthropologists feature ways of explaining the purpose of research and maintaining confidentiality of results in a context in which a researcher spends long periods of time with the same population.

The situation of this study in Mali does not correspond closely to any of these three types of contexts, although it seems similar to studies of survey data collection. The variation observed by the study team was in the way the informed consent statement was presented rather than in the way the survey was introduced.

2.1 Development of Informed Consent

The practice of requiring informed consent for medical research became common in North America and Western Europe in the mid 1970s following much public discussion and the work of several commissions. Robert Levine (1991) outlined the contents of the Nuremberg Code that first formalized ethical standards for research on humans. In order for individual consent to be considered valid and appropriate, it must have four attributes: participation must be voluntary, and the individual must be legally competent, informed, and comprehending. These elements have endured and are considered as fundamental to consent.

The Privacy Act of 1974 from the U.S. Department of Health, Education and Welfare set standards for informing subjects of the risks and benefits of research, and the Belmont Report of 1978 linked the obligation to obtain informed consent on the ethical principle of "respect for persons" (Singer, 1993; Ijsselmuiden and Faden, 1992). According to the Belmont Report, the informed consent process was designed to protect individual autonomy and the personal dignity of research subjects.

Although various versions of the elements that are considered indispensable have been published, the original formulation stated that informed consent statements should always include the following elements (Singer, 1993):

- A fair explanation of procedures and their purpose
- A description of discomfort and risks
- A description of benefits
- A disclosure of alternative methods
- An offer to answer any questions
- A statement that the person is free to withdraw at any time without prejudice.

These elements can be recombined and adapted to a survey context to leave us with four basic elements that must always form part of an informed consent:

- a fair explanation of the purpose of the procedures

- a description of the risks and benefits involved
- an offer to answer any questions and explain further
- a declaration that participation is voluntary.

A note about the confidentiality of the survey results must be added to this list. The level of understanding of these elements that should be expected is addressed later in the text.

In their comprehensive study of the history and development of the concept of "informed consent," Ruth Faden and Tom Beauchamp reviewed the various meanings ascribed to informed consent (Faden and Beauchamp, 1986). They noted that the legal definition has sometimes been limited to disclosure. That is, a potential subject must be fully apprised of the risks and benefits of the procedure envisioned. As the U.S. Supreme Court noted in 1976, "One might well wonder . . . what 'informed consent' if a patient is . . . We are content to accept, as the meaning, the giving of information to the patient as to just what would be done and as to its consequences." (Faden and Beauchamp, 1986:275). Such a definition resembles the ones physicians favor, one that emphasizes full disclosure without mentioning understanding. Just what constitutes "informed" in giving consent remains a subject of much debate.

2.2 Studies of Informed Consent in Medical Settings

Most studies of the informed consent process have examined consent obtained for medical interventions. The relative dominance of medical studies can be seen in the bibliography of studies of informed consent statements assembled by the Hastings Center in 1999 (Sugarman et al., 1999). Of the 377 abstracts presented, all but 18 were studies of some aspect of a medical intervention or clinical trial. Thirteen of these 18 were studies of the relative readability of informed consent statements, studies that sought to determine if many or most patients would be able to read and understand the statements. In addition, there were two studies of how Institutional Review Boards (IRB) work, two of hypothetical situations with nonpatients, and one study of how medical students were taught the use of informed consent.

Many studies of the use of informed consent statements have examined the extent to which participants understood or retained the information about the possible risks and benefits of their participation (Fortney, 1999; Lynöe et al., 1991). These are studies in which participants were asked questions about a procedure a week or a month or two after it occurred. Such information could have come from explanations given by medical personnel or from the informed consent text they were asked to sign indicating that they had understood and accepted the risks involved.

The informed consent statements of medical studies have been careful to cover the elements set out in government documents. Researchers have accepted the importance of full disclosure of the risks and benefits of procedures and see that these elements are mentioned in texts. A review of the medical studies has shown that they emphasize disclosure and worry little about understanding (Byrne et al., 1988). But is it sufficient to have told participants of the risks? Is it not necessary to verify that the risks are understood before consent is given? What if disclosure is done in a language not understood by patients?

In their review of several dozen studies of the use of informed consent statements, Ogloff and Otto (1991) found that most informed consent statements from medicine, psychology, and the social sciences were written in a language too complex for most patients to understand. They argue strongly that if the reading level is inappropriately high, patients will not understand and, thus, informed consent is not obtained. They point out that researchers have a legal and ethical obligation to ensure that their statements can be understood. That may mean simplifying the terms used. A number of the readability studies mentioned above showed that most consent materials in the U.S. require college reading level, and that simpler language is more easily understood and retained.

A second issue is one of competence. Researchers in the U.S. assume that participants are literate and autonomous, able to understand their own situation and decide for themselves. In studies involving the elderly or the mentally ill, however, the competence of participants to comprehend what was being asked of them has arisen and has been examined in a number of studies. In such studies it is not unusual to find that one-fourth to one-third of participants did not really understand the risks they were taking.

A few studies have questioned whether consent statements for Western countries are appropriate for developing nations (Ekunwe and Kessel, 1984; Hall, 1989; Levine, 1991). They point out that Western assumption of individual autonomy and responsibility may not apply to African societies where the images of self and autonomy are more social and less individual. Ijsselmuiden and Faden (1992), however, argue that these objections are based on outmoded images of African societies and that the same rules of autonomy and individual decisions can be applied in African societies.

The principal lesson to be retained from the medical intervention literature is that informed consent statements in many clinical studies are currently far too complex and difficult for the average person to understand, and that simplifying the language itself improves comprehension.

2.3 Informed Consent Forms in a Survey Context

It is also necessary to question whether the medical model of risks and benefits should be applied at all in nontherapeutic contexts such as population surveys. Survey research has sometimes been exempt from the IRB requirements because the individual risks and benefits are minimal or nonexistent. Drawing a few drops of blood for tests in the context of a standard DHS survey does not present a major risk to participants, but one cannot say there is no risk at all. Thus DHS survey policy is to employ an informed consent statement prior to any collection of blood in DHS surveys.

A search of the social science literature on informed consent did not reveal any studies of the use of informed consent statements used in survey research in developing countries (Presser, 1994). This may be due in part to the fact that general population surveys are often exempt from informed consent requirements, since the risks to individuals appear to be minimal or nonexistent. It may also be due in part that in cases where informed consent is required in surveys, the way that consent statements are presented is not judged to be of great research interest (Groves et al., 1992).

Although not the equivalent of studies of informed consent, a number of studies of introductory statements for social science surveys have examined the effect on various formulations of the introduction on rates of participation (Sobal, 1984). These scholars seek to identify the type of introduction— cursory or detailed, emphasis on confidentiality or not—that will maximize participation (Singer, 1978). In a review of 113 quantitative studies published between 1975 and 1992, Singer, Von Thurn and Miller (1995) tested the hypothesis that detailed assurances of the confidentiality of answers would increase participation in research projects. They found that for cases of studies that did not involve sensitive issues, detailed assurances did not increase participation, but that in studies involving sensitive issues such detailed presentations did, in fact, increase participation. In other reviews of research the provision of details about the purpose and administration of surveys did not increase participation.

Discussions of the use of informed consent in anthropology have focused on how populations that participate in ethnographic research can be informed of the goals of the research while maintaining their privacy and confidentiality. The code of ethics of the Society for Applied Anthropology (SfAA) does not discuss the use of an informed consent statement, but stresses the responsibility of the researcher to act in a way that corresponds to the spirit of informed consent concerns. The code does state that "participation . . .

shall only be on a voluntary and informed basis" (SfAA 1983). However, the situation of an ethnographer

living in the same area for a year or two bears little resemblance to that of an interviewer just passing through.

Nevertheless, the difficulty of evaluating the comprehension of participants remains, whether part of medical treatment, a population survey, or in ethnographic research. Scholars who study informed consent for medical treatment or clinical trials are concerned about both comprehension and competence to make knowledgeable and rational decisions (Taub, 1986). In population surveys, it is assumed that participants are competent to decide to participate or not, but the importance of comprehension and ways of evaluating understanding remains of enduring concern.

In designing the study of the use of informed consent for anemia and HIV testing in Mali, the issue of individual comprehension of the informed consent statement was often discussed. Concern from USAID Washington focused on the degree to which participants understood the purpose of the blood tests; whether they understood that participation was voluntary; reasons for accepting or refusing to participate in the blood tests; and what was understood about the purpose of the green card given to all participants. This study collected data on these issues.

The question of how much and how well the presentations for obtaining consent were understood may involve at least four elements: the complexity of the language itself, the form of the statement framed as a speech rather than a conversation, whether or not the respondents were familiar with anemia and with AIDS, and whether or not they had any experience with getting their blood tested for something. An examination of the consent statement shows that the language is relatively complex, and that the ideas are framed formally in language suitable to a speech rather than a conversation. English and French versions of the informed consent statement are found in Appendix D.

The idea of taking a blood test for diagnostic purposes may be familiar to some, but no information is available about what proportion of the population would understand what a blood test provides. Anemia is not a concept familiar to the population in Mali, for it is not an illness diagnosed in local systems of knowledge. In the translations of the informed consent statement into local languages, anemia was translated as the equivalent of "bad" blood, "low" blood, "light weight" blood, "too much" or "too little" blood, or the result of a poor diet. In some health centers it may be a condition diagnosed by health care agents who prescribe iron tablets or changes in diet. Nor have many individuals in Mali had experience in seeing individuals with AIDS. These issues will be further dealt with in the section on study results.

CHAPTER 3

METHODOLOGY

Just as the drawing of blood for HIV tests as part of a national DHS survey was new, so were the research questions posed in the Mali informed consent study. The study used traditional data collection techniques, such as observation and open-ended interviews, to monitor the response of the population to a request to give blood for an HIV blood test, with a particular focus on the presentation of an informed consent statement. This was to be done without interfering in any way with the work of the EDSM-III teams.

3.1 Preparations for Data Collection

Preparations for this study began with the writing of a research proposal by ORC Macro for review in Bamako. One week was spent with a team of four experienced interviewers in discussions of the methodology of qualitative research, the content of the proposal, and the formulation of the study instruments. Three main instruments were formulated during the training: 1) an observation form to monitor how the DHS survey team introduced themselves to local leaders and heads of households; 2) an observation form for observing how the informed consent statement was administered; and 3) a short open-ended questionnaire in French and in Bambara for obtaining information from respondents on their understanding of the blood tests and the informed consent statement.

Since it was anticipated that the presentation of the team leader to the village chief and then to heads of households would influence the participation of the population in blood tests, an observation module to monitor these presentations was prepared. This module featured four elements: 1) the introduction of the survey by the team leader to the head of household; 2) the response of the person addressed; 3) a description of the conversation between the two persons; and 4) an evaluation of the nature of this conversation. The forms provide a combination of checklists for items mentioned and extensive commentary on the event. Discussion in the text of the way the EDSM-III teams introduced themselves draws on information from this module. The module is found in Appendix A.

A second module was developed to monitor the presentation of the informed consent statement, the taking of blood, and the handing over of the green card. The sections of this form included the following: 1) the preparations for the blood test; 2) the explanations given by the field editor; 3) the way the consent statement was presented; 4) the reaction of the respondent to the consent statement; 5) the handing over of the green card and the explanation that accompanied this act. The module is reproduced in Appendix B.

The guide used in interviewing respondents just after the blood test consisted of a few simple questions about what had just occurred. Individuals were asked about: 1) what they had heard about the EDSM-III before the arrival of the survey team; 2) the informed consent statement, the blood test, and the green card; 3) knowledge of AIDS; 4) the process of being interviewed by a EDSM-III interviewer. These brief interviews were tape-recorded, translated into French, and then typed. The answers follow the questioning categories quite closely, which facilitates their reading, but it also shows how critical subquestions were in persuading people to say anything at all about AIDS. The sections of the report that discuss respondents' reaction to the invitation to take a blood test are based on these data. English and French versions of the interview guide are reproduced in Appendix C.

The instruments were pretested for five days in two areas that were not part of the sample to be used for the MIC study. Two EDSM-II teams were included in the pretest. The pretest allowed the study team to refine the instruments and develop a strategy for interacting with the EDSM-III teams in a fieldwork setting.

This was also an opportunity for the study team to practice tape-recording conversations and making notes on the forms provided.

The commentaries from the second module were typed out in French and entered into *Ethnograph,* a software program for the analysis of text. The checklist data and yes/no answers were recorded and entered into SPSS for analysis. Some of the data in the tables draw on this source, while others draw on the answers given in the interviews.

3.2 The Sample

The sample was chosen by the technicians in charge of the EDSM-III along with the technical advisor from ORC Macro. The fact that three months of fieldwork had already been completed limited the number of clusters that could be visited. Yet the group wanted representation from both urban and rural clusters, thinking that urban residents might be better informed about AIDS. Since it is presumed that exposure from AIDS comes from the south, namely from Côte d'Ivoire, they also wanted to make a north-south comparison. The capital city was of special interest, so four clusters had already been set aside in Bamako for this study. It was decided to do two urban clusters in Sikasso (south) and Mopti (north) plus one rural cluster in Mopti and one in Sikasso. That provided the study with a total of ten clusters.

In discussions with the EDSM-III personnel and then with the MIC study personnel, two conclusions were reached:

1) The study would examine all of the households eligible for blood tests in the selected urban and rural clusters, and

2) Estimating that 8 or 9 men and 12 or 13 women would be eligible in urban clusters, and that about 13 men and 18 women would be eligible in rural clusters, the study would observe approximately 200 cases for opportunities to take a blood test in this study.

The sample ended up being 196 persons, reduced slightly because of the households that had moved since the household listing months earlier. The following urban clusters were retained:

Bamako : four urban clusters
Mopti : two urban clusters
Sikasso : two urban clusters

The two rural clusters were specified in the field. In Mopti, however, because of scheduling confusion, one of the clusters had already been completed before the arrival of the research team. Thus the team substituted a rural cluster for this urban one.

Table 1 shows the distribution of respondents who were invited to participate in the AIDS test by region, cluster, and sex.

Table 1 Distribution of respondents who were invited to participate in the AIDS test, by region, cluster, and sex

Region	Cluster (Ward)	Women	Men	Total
Mopti	Cluster 1	15	10	25
	Cluster 2	8	7	15
	Cluster 3	5	2	7
	Total	28	19	47
Sikasso	Cluster 1	11	10	21
	Cluster 2	15	12	27
	Cluster 3	10	16	26
	Total	36	38	74
Bamako	Cluster 1	14	13	27
	Cluster 2	12	7	19
	Cluster 3	7	10	17
	Cluster 4	4	8	12
	Total	37	38	75

The study observed four EDSM-III teams: one team that worked in the Mopti region, one that did the three clusters in Sikasso, and two teams in Bamako. In Bamako, one team worked in clusters 1 and 2, while the other team worked in clusters 3 and 4.

3.3 Data Collection and Analysis

Each of the 25 EDSM-III teams was composed of five persons: a male team leader, three female interviewers, and a female field editor who also conducted the blood collection. Most of the team leaders had been team leaders in earlier DHS surveys in Mali (EDSM-I and EDSM-II) surveys or had participated in the recent household listing exercise. The EDSM-III team leader introduced the survey to village and neighborhood leaders as well as to many household heads, placed interviewers in eligible households, interviewed men, and weighed and measured children. The interviewers did the household interviews and then the individual interviews with women. The field editors checked over the questionnaires and collected blood for testing. Most of the field editors were practicing nurses or persons working in some medical context. They received special training in conducting the blood tests for anemia and HIV and in obtaining informed consent.

The MIC study team was composed of two men and two women. It focused primarily on the work of the EDSM-III field editor, since she was supposed to take the blood for testing. The two women spent their time with the field editor, taking notes and translating the conversations recorded. The two men observed team introductions and the blood tests of eligible males. The MIC team followed the work rhythm of the EDSM-III team without interfering or changing any aspect of their work.

Modules 1 and 2 (see Appendix A and B) were used to observe and monitor 1) the introduction of the EDSM-III team to heads of households, and 2) the process of obtaining permission and doing the blood tests. Notes on what was observed were written down to accompany the observations. These notes were typed in French and then entered into Ethnograph for analysis.

The analysis was guided by several concerns. First, what evidence can be found for supporting the hypotheses generated at the start of the research? Second, how was the consent statement presented most often? Third, were the cases of failure to present a consent statement alike or different from the other cases? How were cases of refusal of a blood test different from other cases? Was there a link between understanding that participation was voluntary and accepting or refusing the blood test? What did respondents understand about the green card?

Relevant sections of the interviews were read several times and then summarized along with specific examples. Comments on the presentation of consent statements were read for added insight into those events. Cases of refusal of blood tests were identified and examined separately, as were cases of blood tests performed without presentation of a complete consent statement. The respondents quoted are identified only by cluster and sex to assure confidentiality.

CHAPTER 4

INTRODUCTION OF THE EDSM-III TEAM IN HOUSEHOLDS

4.1 Respondent Awareness of the EDSM-III

The Mali informed consent study sought to explain both how the informed consent statement functioned in the field and how and why individuals accepted or refused to participate in the blood tests. It was hypothesized that individuals who had heard about the coming survey might be more likely to participate than those who had not. Thus individuals were asked if they had heard about the EDSM-III before the arrival of the survey team and if so, how had they heard about it. The MIC team had expected that most people would have heard about the survey through the media or from the team that had done the household listing a few months earlier.

The EDSM-III was conducted from January through May 2001, during a time when other national surveys were also being conducted. With assistance from the World Bank, the Ministry of Economy was conducting a study on poverty. The Ministry of Administration and Local Communities was conducting a population survey in order to establish an electoral registry for the coming elections. Each of the three surveys was the focus of television announcements that were broadcast one after the other before the evening news, as well as numerous radio announcements about the surveys. The broadcasts did not, however, ensure that the majority of the population had heard about a survey. For example, according to the EDSM-III, about one-half of women in the Mopti region and one-third of women in the Sikasso region listened to the radio or watched television less frequently than once a week or they did not tune in at all (CPS/MS, DNSI, and ORC Macro 2002).

In this context of multiple surveys, it also seems easy to understand that individuals might confuse the identity of survey teams when they arrived. Table 2 shows the number of persons (aggregated by cluster and sex and grouped by region) who stated that they had heard about the EDSM-III survey before the team's arrival.

Table 2 Distribution of respondents who heard information about the EDSM-III, by cluster and sex

	Women		Men	
Cluster	Yes	No	Yes	No
Mopti				
Cluster 1	4	9	6	2
Cluster 2	5	4	4	3
Cluster 3	1	2	3	1
Total	10	15	13	6
Sikasso				
Cluster 1	2	10	2	6
Cluster 2	2	10	2	6
Cluster 3	2	7	8	7
Total	6	27	12	19
Bamako				
Cluster 1	5	9	6	7
Cluster 2	5	4	3	9
Cluster 3	2	5	2	8
Cluster 4	3	1	1	7
Total	15	19	12	31
Grand total	31	61	37	56

The table shows systematic contrasts in the numbers who had heard of the EDSM-III survey by sex and region. The three or four clusters in each region seem similar, suggesting that the use of media for advertising the survey was done regionally. About one in three women had heard of the EDSM-III while about two in five men had heard of the survey. Those totals hide the fact that about half the people interviewed in the Mopti clusters had heard of the survey, but relatively few in Sikasso or in Bamako had heard of the survey. A total of 68 men and women had heard about the visit of the EDSM-III team while 117 had not. Overall, about one-third of the persons interviewed had heard about

the EDSM-III before the survey team arrived.

4.2 Media Sources

The people who heard about the EDSM-III said they had heard news from the radio, from the team doing the household listing, or from some other source. The examples below show the kinds of responses that occurred most often.

Sometimes, interviewers asked several times whether the respondents had heard about the EDSM-III on the radio. In one household in Bamako, a man insisted that he had not heard anything on the radio or seen anything on television, as observed in this exchange:

Respondent: *No, I was not informed.*
Interviewer: *Was the news not on the radio and the television?*
Respondent: *No, I don't know anything about that.*

One of the 11 persons in the same cluster among 27 who were offered a blood test was well informed. She answered this way:

> *We see a program on the television every day that announces the arrival of the DHS teams. Those same people came by here to write numbers on the household walls and saying that their team of doctors would visit in about three months.*

It should be recognized, however, that after three months of publicity and of implementation of the survey in one of the most densely populated neighborhoods of Bamako, more than half of the persons interviewed had not heard of the EDSM-III survey.

Sometimes, announcements about the EDSM-III were heard but not understood. People heard that a survey team had arrived in their area, but they did not know which survey it was. This reaction was seen in the response of a woman from Mopti when she said:

> *Yes . . . I heard on the radio that people would be coming to do a health survey. I don't know if they were talking about this team or about others.*

In one of the households in rural Mopti, the respondent explained that he had heard about the EDSM-III team when the household listing team was in the area:

> *I had already heard about the survey . . . the team leader of Team C had come by here several months ago to write numbers on the doors. He then said that people from the Ministry of Health would come by to ask questions. In fact it was that same team leader who returned.*

Other sources of information about the EDSM-III were generally unofficial ones, most often someone living in the neighborhood. The following quote from Mopti illustrates such responses:

> *I learned a month ago along with the other women from the village that health workers would be coming to our village asking questions, but I did not know what kinds of things they would be asking about.*

The interviewer then followed up with:

> *So you heard about the DHS survey only in talking with other women in the village?*

Yes, of course we learn a great deal from each other when we women talk together.

In a few cases individuals reported having heard about the survey from the village chief:

Yes we had heard the news . . . We were informed by the village chief after the visit of a health team who came to check each household and write numbers on all the doors.

Or again:

Yes, I knew . . . at the house of the chief.

Differences in the proportion of those who had heard of the EDSM-III by region can be seen more clearly in Table 3. The table shows that the proportion of people who had heard about the survey was smallest in Sikasso where only 16 of 62 respondents had heard of the survey, and largest in Mopti where 23 of 44 respondents had heard of the survey. Perhaps the group in charge of publicizing the survey did a better job of choosing the most effective channels of communication in Mopti, with fewer channels of communication available, than in Sikasso or Bamako, where the population had access to far more radio and television stations.

Table 3 Distribution of respondents who had heard about the EDSM-III, by sex and region

	Women		Men		Total	
Region	Yes	No	Yes	No	Yes	No
Mopti	10	15	13	6	23	21
Sikasso	6	27	12	19	18	46
Bamako	15	19	12	31	27	50
Total	31	61	37	56	68	117

The MIC team asked respondents if they had heard about the EDSM-III and paid careful attention to how the EDSM-III team was introduced. They had hypothesized that publicity regarding the EDSM-III might influence the way individuals responded to the team. It was thought that a clear understanding of the identity of the EDSM-III team would make a positive response more likely. The MIC team assumed that the reactions of respondents would be conditioned by the information they had received (or not received) about the survey.

The analysis found no evidence that knowing about the survey beforehand influenced individual responses to participate in the blood test. Other factors proved to be more important in the response to being asked to give blood for a test.

CHAPTER 5

PRESENTATION OF THE INFORMED CONSENT STATEMENT

5.1 Background

Training for the EDSM-III survey teams included special training for the field editors and the team leaders. They were trained how to present the informed consent statement, how to draw blood, how to read the anemia levels, and how to explain the green card. The field editor had the main responsibility for drawing blood, but the team leader was also expected to be available for this task. In most of the cases observed during the MIC study, the field editor performed the blood test operation.

Field editors and team leaders were trained to read an informed consent statement to obtain the respondent's consent before drawing any blood. The exact form and formulation of the informed consent in English was the subject of much discussion among ORC Macro, USAID Washington, and CDC. The informed consent had to be approved by the IRB at ORC Macro as well as the Ethics Committee for Mali based in Bamako. The statement consisted of three parts: 1) a part saying that anemia is a serious health problem caused by a poor diet; asking permission to draw a few drops of blood for an anemia test; and promising the results on the spot; 2) a part explaining that HIV causes AIDS, that AIDS is usually fatal, and asking permission to do a test for HIV with a few drops of blood, with the results being anonymous; 3) an explanation of the purpose of a small green card given out to everyone permitting them to have an HIV test performed free of charge. After each section the respondent is asked: "Do you have any questions?" The three sections were all on one page and were in four languages: French, Bambara, Peuhl, and Sonrhaï. Field editors were expected to read the page and explain the text as necessary (see Appendix D).

This study focused on the HIV part of the testing rather than the anemia part, but the two tests were usually described together before permission to draw blood was requested. The term in French used in Mali to translate "informed consent" was *consentement volontaire,* which evoked the voluntary nature of the permission to draw blood. Other scholars working in Francophone West Africa might translate informed consent as *consentement éclairé*, or *consentement libre et éclairé*. The translation used here *(consentement volontaire)* seemed simple and sufficient. The term *éclairé* refers to "informed," and thus draws attention to the issue of whether the population is properly informed or understands what is being asked.

In seeking to estimate how well informed the respondents were, the research team sought evidence about their understanding that: 1) the tests were for anemia and for HIV; 2) participation was voluntary; 3) the results of the HIV test were anonymous; and 4) the green card allowed them free test results at a later date.

5.2 Local Knowledge

It was easy to assume that a simple request like asking permission to draw blood for anemia and for an HIV test would be generally understood anywhere, including Mali. A reading of the recorded introductions, the questions asked, and the conversations that followed the blood tests indicated otherwise.

Consider the following exchange in a Bamako neighborhood:

Field editor:

> *We are doing two kinds of blood tests. One is for having lots of blood (anemia), and we want to know how many people have anemia in Mali. We give the results on the spot. The other one is for AIDS, and that too is to know how many people have AIDS. For the AIDS blood test you will go*

pick up the results at the laboratory and no name will be attached to your blood. The blood test is free. You might accept or you might refuse. What do you think about the blood test?

Respondent:
If I have a great deal of blood, are you taking it to give to those who don't have enough?

Field editor:
No, it's not that way, and if it were I would have told you.

Another man in the same neighborhood responded:

Field editor:
Do you have an questions about the anemia test?

Respondent:
I would like to ask a question, that is, what is anemia?

Field editor:
Anemia is a lack of vitamins and iron in the blood. It can be caused by malaria, etc.

Respondent:
After the survey is over, are you going to treat these sick people?

A man in a different neighborhood of Bamako had another question:

Field editor:
Do you have any questions about the blood test?

Respondent:
That second blood test, to know if the blood is working well or not, is that a good thing or something else?

From such exchanges and from the conversations with respondents after the blood was taken, it seemed clear that these Malians did not have an understanding that anemia might be an illness or a serious health problem. Some people certainly understood that people might have weak blood because they did not eat well, but that did not correspond closely with anemia. The EDSM-III field editors tried to describe anemia in various ways—little blood, light weight blood, weak blood, bad blood, a poor diet— but it was unclear what people understood.

5.3 Setting Up for the Blood Tests

The process of drawing blood as well as any conversations with respondents was monitored by the MIC team using an observation form that included both checklists and space for notes (Module 2). More often than not, the field editor did not introduce herself, but when she did, she usually said, *"We are people sent by the Ministry of Health*." EDSM-III team members often spoke of themselves as *dogotolo* (a cognate of *docteur* in French) in Bambara. As seen below, this identification was often cited as a reason for cooperating with the team. The field editor often said that the survey included a blood test. Thus, the interaction between the EDSM-III team and the respondents was framed as contact with medical experts, and the blood test was simply a continuation of the general survey process.

In the notes from the observation of drawing blood, similar descriptive phrases are found repeatedly:

1) the field editor opens her bag, spreads out her things . . . and 2) the field editor [had] all of her things spread out on the ground.

In this way, the respondent learned that something was about to happen just by seeing the instruments displayed in front of the field editor. This process of setting out the instruments seemed to work well, except for the HemoCue machine used for anemia testing, which sometimes failed to function. Failure of a HemoCue machine sometimes forced the EDSM-III team to return to a cluster simply to do the blood tests.

5.4 Presentation of the Informed Consent Statement

The research team followed the field editor around in order to observe how she presented the informed consent statement and drew the blood. There were three sources of information available. Module 2 had a section for noting in checklist form the elements that were mentioned in the presentation of the informed consent as well as a section for comments on the procedure. The comments were typed out in Microsoft Word and indexed to the respondents, while the elements mentioned (or not) were entered into SPSS. In addition, after the drawing of blood, one of the research team members asked a series of questions about what had just transpired and about AIDS.

The timing of the drawing of blood was discussed at least briefly during the training of the EDSM-III teams. The teams were instructed to draw blood after the individual interviews. For that reason, the MIC study plan included questions about what the respondent thought of the individual interview. In practice, the field editors usually began asking individuals to participate in the blood tests right after the interviewer had completed the household questionnaire. Since the household questionnaire identified who was eligible for blood tests in the household, the field editors found it easy and efficient to conduct the blood tests at this time. Although this procedure facilitated the work of the field editor, it sometimes caused confusion in the work of other members of the EDSM-III team.

The observations recorded in Module 2 showed that 116 of 188 cases (8 missing cases) of blood tests were conducted before the individual interview and 48 cases were done after the interview. Sixteen individuals also gave blood during the individual interview. While there were benefits as well as drawbacks in taking blood before or after the individual questionnaire, doing blood tests during an interview—stopping an interview to draw blood—could not be recommended.

Table 4 shows the distribution of respondents by the way in which the informed consent statement was presented, according to sex. For three cases, the information was missing. The table shows no difference by sex of the respondent. The field editors were trained to read the text in a "lively manner" rather than in a monotone. The table shows that in 80 percent of the cases, the field editor explained what the informed consent meant with or without reading the text. They might well have learned the information by heart after three months of survey work.

Table 4 Distribution of respondents by the way in which the informed consent statement was presented, according to sex

	Explained without reading	Read with explanations	Read only	Read by respondent	Not presented	Total
Women	70	11	5	0	14	99
Men	62	14	6	1	10	93
Total	132	25	11	1	24	192

The

field editors for the four EDSM-III teams observed in the MIC study differed in their practice of presenting the consent statement. For example, 16 of the 24 cases of no presentation occurred in the clusters of the Mopti region. The field editor of this team did not read the consent form during the study at all. On the other hand, the team working in Sikasso read the statement with or without an explanation in 27 of 74 cases, or one-third of the time.

These results raise the question of what was said if the field editors spoke without referring to the paper. According to observations, a total of 88 percent of respondents were told about the test for anemia and 89 percent about the HIV test. Thus nearly everyone had been told about the purpose of the blood test. About 60 percent were told that the HIV test results were anonymous. Perhaps most important, 69 percent (N=135) were directly told that their participation was voluntary. In the conversation after the blood drawing, individuals were asked if they had understood that they could refuse to participate. A total of 138 said that they had understood, which is virtually the same as the number who were told directly.

Table 5 shows the number of individuals who said they understood that their participation was voluntary, with data taken from the conversations held right after blood was drawn. It should be noted that three-fourths of those interviewed said it was voluntary, despite the prior approval of the head of the household in most cases, and the fact that the team members identified themselves as medical care agents. In a comparison of cases where the text was read versus explained, no difference was found in the proportion of persons who had understood the voluntary nature of the blood text.

The table shows marked variation by cluster in the number of respondents who said they understood that taking a blood test was voluntary, suggesting that the differences may be due to variation in the performance of the EDSM-III teams. One team operated in Mopti, another in Sikasso, and two teams in Bamako. Table 6 shows more clearly the team effect. The team in Mopti did not communicate the voluntary nature of taking blood tests as well as the other teams.

Table 5 Distribution of respondents by whether they understood that participation in the AIDS test was voluntary, by cluster and sex

Cluster (ward)	Women		Men	
	Yes	No	Yes	No
Cluster 1	3	10	5	3
Cluster 2	3	6	2	5
Cluster 3	1	2	3	1
Cluster 1	11	1	8	0
Cluster 2	9	3	8	0
Cluster 3	7	2	14	1
Cluster 1	13	1	11	2
Cluster 2	6	3	12	0
Cluster 3	5	1	8	2
Cluster 4	3	1	6	1
Total	61	30	77	15

Table 6 Distribution of respondents by whether they understood that participation in the AIDS test was voluntary, according to EDSM-III team

EDSM-III team	Women		Men		Total	
	Yes	No	Yes	No	Yes	No
Mopti (3 clusters)	7	18	10	9	17	27
Sikasso (3 clusters)	27	6	30	1	57	7
Bamako (2 clusters)	19	4	23	2	42	6
Bamako (2 clusters)	8	2	14	3	22	5
Total	61	30	77	15	138	45

Also relevant to what was communicated were cases where the informed consent was not presented at all, was partially presented, and the attention with which the respondents followed the presentation.

5.5 Incomplete Presentations of the Consent Statement

In some households with several persons eligible for the blood test, the EDSM-III field editor presented the informed consent statement to one person, often the household head, but did not repeat the consent statement to all the other household members. In some instances a husband would be the first to give blood for the tests, and he would then ask his wives and/or servants to participate as well. Or it was understood that the others would follow the example shown. In such situations it became easy to offer the blood test to the others without a full presentation of informed consent.

The other type of situation where a blood test was done without a statement presented to the respondent was in the case of a guardian in charge of a minor (age 15-17), or sometimes several minors. Field instructions said that the guardian, not the minor, had the right to give permission for a blood test.

A few examples will clarify the situation.

In a compound of Sikasso, the notes from the observation went as follows:

> *The statement was read to the guardian since she* [the respondent] *was only 17...*
> *After the first presentation the field editor did not present the statement to the two maids, since their guardian who should hear the statement had already heard it and asks that it not be repeated, and orders that they be tested.*

In the same neighborhood, three blood tests were done on minors after presentation of the statement to the guardian:

> *The statement was read to the guardian since the child is 16 years old. The field editor did not introduce herself. The guardian accepts and the child as well.*

In a similar case, the minor was only 15 years old. The statement was read to the guardian for her own test, and then it seemed just too strange to repeat it to the same person for each of the others.

Such situations accounted for a good number of the cases recorded as "not presented," since they would be recorded as such in the observations. Yet cases were also observed where instructions to participate were not followed. In the testing of a fourth minor from the household observed above, a young man, the commentary showed:

> *The statement is read to the guardian. The field editor does not introduce herself, she just read the statement... the guardian accepts but the child refuses. So the blood test is not done.*

This example showed the dangers of generalizing to say that minors or wives who were asked to participate simply acquiesce. Sometimes they refused despite instructions to accept.

Occasionally respondents wanted to discuss an issue with others before they participated in a blood test. Though it may be unusual, it seemed significant since it served as an example of people consulting each other to arrive at a decision for all. This case was observed in a situation where the informed consent statement was presented and people were told that all those eligible in the household would be tested. In one of the urban clusters of Sikasso, one of the women responded:

You would like to draw the blood of everyone here? Can't you give us some time to talk it over?

These examples all showed that the interaction leading up to the informed consent and the blood tests often occurred in public with several persons listening to what was being said and done. Such situations contrast with an image of each person privately hearing the statement and thinking about whether to participate or not, which are conditions that favor autonomy and voluntary consent in Western terms.

A total of 24 cases were observed where a blood test was done without a presentation of the informed consent statement. Sixteen of those cases occurred in the Mopti clusters where the team sometimes had communication problems. In a cluster north of Mopti, where the field editor was absent and the team worked through interpreters, the team leader did four blood tests without presenting the informed consent statement. In a compound on the edge of Mopti, where the team leader was working through an interpreter, the following dialogue was recorded:

Team leader:
Tell her that blood tests are part of this survey.

Interpreter:
She has been told.

Team leader:
Did you tell her that the blood test is for anemia?

Interpreter:
No, but she knows.

In another compound of the same cluster, the following scene was observed and noted:

> *The equipment was spread out because the husband had just been tested . . . she* [field editor] *gave no explanation except that she remarked to the interviewer: - since she does not understand Bambara and her husband agrees . . . - I'll go ahead with drawing blood; since the consent statement was presented to the husband, that is enough... The informed consent statement had been presented to the husband who accepted, and the woman did not understand Bambara and was thus tested without getting her consent.*

In yet another household of the same cluster another form of failure to present the statement was observed:

> *The field editor seated opposite the respondent, opens her bag, spreads out her equipment and puts on her gloves . . . the interviewer tells the field editor that she had already spoken to the respondent about the blood tests and that she had accepted . . . let me have your hand* [she says] *so I can draw your blood.*

Most of the situations where a blood test was done without clear consent of the individual were those in which consent was required of a parent or a guardian, or where a husband or head of household had ordered a wife or servant to be tested. Although it is easy to understand why the field editor does not present a statement, such situations need to be directly addressed in training so that those drawing blood make a maximum effort to allow each individual to decide to participate or not.

Three cases were observed where a respondent refused without the chance to hear the consent statement. In this example the field editor had a discussion with the respondent (a minor) in which she said:

> *I need to present a statement for permission to your mother. If you can go ask for her permission and come back, I'll draw your blood for the test. Since the respondent had not agreed, he did not return. We waited with the field editor in vain. No consent statement was presented, for the respondent left without asking any questions. We consider this as a case of refusal since the team leader said he asked the respondent if he wanted to do a blood test for AIDS and he said, "No."*

5.6 Contents of Presentations of Informed Consent

Table 4 showed that most of the time the field editors explained the informed consent statement whether they read it or not. Whether read or explained, it was critical to know what was said in order to comply with IRB regulations. About half of the presentations were recorded and translated into French.

A study of those translations showed that the elements mentioned consistently were the association with the Ministry of Health, the fact that blood tests were a part of the survey, that the blood tests were for anemia and for AIDS, and that participation was voluntary. The following example shows hesitation on the part of the respondent:

Field editor:

> *Tell her that we are coming to draw blood for two tests: one to see if she has a lot or a little of blood. For that one we give the result right away. There are cases of anemia in Mali these days and we want to know how many people have anemia. The second blood test is for AIDS. We want to know how many people have AIDS. No name will be attached to the sample of blood. You will go to the laboratory to get the results. She should understand also that we do these blood tests in her own interest. She can accept or she can refuse; it's voluntary.*

Respondent:

> *If you see me hesitating, it's because I had not understood. One should not accept something before trying to understand it.*

Field editor:

> *You are absolutely right in trying to understand. We agree, so before we do anything we explain so you understand.*

Sometimes the abbreviated nature of the consent statement led to questioning by the respondents. A conversation in a household in Sikasso went like this:

Field editor preparing for the blood test:

> Notes: *The field editor, seated on a mat, opens her bag and spreads out her equipment.*

Field editor:

> [I am] *Djénèba Diarra sent from the Department of Health. We work for the Ministry of Health and the survey is taking place all over the country. The survey is about the improvement of health in Mali. In addition to interviews, we also do blood tests*.

Respondent:

> *Have you finished speaking?*

Field editor:

If a farmer leaves his house to go into the bush, what did he go look for? Is he looking for food or what? We all get sick, don't we?

Respondent:

Well, it's this way. I don't really refuse the blood test, but I don't accept it either. Why? Can one accept to give blood without knowing what will be done with it? Do you draw blood and then sell it later on? What will you do with it?

Field editor:

The blood tests are something we do in addition to the interviews, that's all. We take several drops of blood and put it on this paper here. We keep the paper in a plastic bag very carefully. The drops of blood will be analysed for AIDS in a laboratory once they arrive in Bamako. But we cannot give you the results here. The other drop we'll put into this machine for the anemia test and we will give you the results on the spot.

Field editor (green card):

You can take this card to a hospital if you wish and get a free AIDS test and get all the information you need about the illness as well as all the advice you need.

CHAPTER 6

RESPONSES TO THE REQUEST TO GIVE BLOOD FOR AN HIV TEST

6.1 Reactions to the Consent Statement

The observation instrument included a question for recording the degree of attention paid to the field editor when she presented the informed consent. The researcher classified the respondents' reaction, according to visible signs of attention or questions asked, into three categories: follows closely, followed somewhat, and did not follow at all. More than two-thirds of the respondents appeared to closely follow the presentation, and more than one-third asked questions of the field editor. A larger proportion of men paid closer attention than did women.

Most of the individuals who were asked to participate in the blood test accepted with little hesitation, although some accepted after an explanation or after consultation with someone else. Table 7 summarizes the numbers of men and women who accepted or refused the blood test.

Table 7 Distribution of respondents by response to presentation of consent statement and gender

Reaction	Women	Men	Total
Accepted right away	66	46	112
Accepted after explanations	10	18	28
Accepted after consultation with another	15	8	23
Refused the blood test	11	21	32

Three aspects of this table are worth noting. First, more than one half of respondents accepted immediately and another one-fourth accepted after discussions or explanations. Second, women seemed a bit more likely than men to accept a blood test right away than were men. Third, men were more likely to refuse the blood test than were women. Fifteen women accepted after consulting someone, usually their husband.

The observation form recorded whether the respondent asked a question after the consent form was presented. About one- fourth of the women (27 of 100) asked a question and one-half of the men (45 of 93) asked at least one question. Questions were asked about the identity of the team: "Are you government or private?" or about the green card, "If I take this care to the doctor, what do I do if they ask for money?" but most were about the process of drawing blood. "What is anemia? Will you use a syringe? That machine that you put the blood in, is it cleaned afterwards? Is this the same needle you used earlier?"

At times, respondents were not really given much chance to ask questions. In one of the households in Sikasso, the man was asked why he had refused the blood test. He replied,

> *No, I did not refuse. Your woman* [field editor] *was very nervous when she asked people to give blood. They should ask you questions, talk with you, but as soon as you want to ask, she says, "Well, if you don't want to give blood, that's OK." Actually I did not refuse.*

The experience of doing blood tests for anemia and HIV in Mali has one element in common with

students of informed consent statements in medical contexts: in both cases medical personnel ask for cooperation, and they get it. Individuals sometimes accept a doctor's request simply because it is the doctor who asks. Evidence from the study indicated that Malians accepted the blood tests for that same reason. Because of their unfamiliarity with taking blood tests, because anemia was unknown, and because so few really understood what AIDS is about, many individuals accepted the blood tests without clear knowledge of its implications.

6.2 Refusal of the Blood Test

There are two types of reasons for refusal to consider: refusals linked to the performance of the EDSM-III team and the field editor, or to knowledge and concerns of the respondents. The MIC team had hypothesized that refusals might be related to prior knowledge of a visit by the EDSM-III team or to whether the field editor identified herself as a medical person. Neither of those explanations proved valid. That is, no relation was found between having heard of the EDSM-III and rates of acceptance; and the field editors always identified themselves as medical personnel.

The MIC team had expected that refusals would be linked to the way the informed consent was presented, and that the more clearly the statement was presented, the more likely the respondent would accept. Table 8 shows the acceptance numbers aggregated by the way the statements were presented. The table does not support these two assumptions, for the way the statement was presented did not affect the rates of refusal.

Table 8 Distribution of respondents by acceptance or refusal of informed consent statement and percentage who refused, according to way in which statement was presented

Presentation of statement	Number of respondents			Percentage who refused
	Accepted	Refused	Total	
Not presented	21	3	24	12
Explained	109	23	132	17
Read with explanation	20	5	25	20
Read	10	1	11	10

In the cluster with the most refusals—12 in an urban cluster of Sikasso—the informed consent statement was usually read with an explanation. In that cluster the presentations were more comprehensive than elsewhere. It was also important to note that all refusals but one were in urban clusters.

That left us with explanations of refusals related to the knowledge and experience of the respondents. In the conversations that followed the blood tests, respondents were asked directly why they had refused the blood test. The answers given generally indicated that the subjects knew nothing about AIDS, or that they thought they were not at risk. The following are some examples:

I don't have AIDS.
I have confidence in myself.
I don't know anything about AIDS.

Two people in the region of Sikasso replied in the same vein. The husband said,

There are no other reason; it's just that I don't have AIDS.

His wife responded,

Because there are no people with AIDS around here.

But there were also a number of reasons given that were not directly linked to AIDS. A few talked about not wanting to see blood, or not giving blood. A man from Bamako replied:

No special reason, but I don't like to give blood, I don't like to see my blood flow.

A woman in Sikasso region said:

No special reason, but I don't like the business of giving blood.

One of the women who refused in Bamako had a different take:

I never like to give blood, that's why I did not accept the blood test ... It's against my religious principles.

A man from Sikasso region used his own logic in responding:

Simply because she cannot give me the result of the AIDS test. So I prefer to go to a health center as she suggested and I'll have the results.

In general, the response "AIDS happens only to other people" influenced many of the answers. Sometimes this answer was linked to fear of AIDS. In one recorded conversation the respondent from a household in Sikasso region invoked family names in the context of a joking relationship to avoid using the word AIDS. His conversation with the interviewer showed this approach:

Interviewer:

What did they tell you about giving blood"

Respondent:

She said two things: one is for anemia, and the other is for that thing of the Diarras.

Interviewer:

What is "this thing of the Diarras?"

Respondent:

Only the Diarras know.

Interviewer:

What is the green card used for?

Respondent:

She said that if I want, I can go to the health center with this card for the result of the thing of the Diarras, however, it's voluntary.

Finally, it is worth noting that of the twelve individuals who refused in a cluster in Sikasso, six explained that they knew nothing about AIDS. These answers, as well as most of the others, were somewhat vague and improvised rather than thought out. The interviewers were asking someone to justify something they had just done, so the answers remained superficial. Understanding how these individuals came to refuse would involve a much longer conversation and would be far more complex.

CHAPTER 7

THE GREEN CARD

7.1 Handing Out the Green Card

An important element of the HIV blood test in the context of the EDSM-III was providing those who were asked to take the test an opportunity to be tested free of charge at a health facility. After asking respondents to take the HIV test that was part of the survey, the field editor passed out a small green card along with an explanation of how to use the card to be tested for HIV at a health facility. To be successful, this exercise depended on having the purpose of the green card clearly explained. That process was closely monitored in the MIC study.

The Ministry of Health in Mali chose to conduct unlinked blood tests for HIV but, for ethical reasons, wanted to provide everyone with an opportunity to take an HIV blood test free of charge, if they so desired. The CDC assisted in setting up the testing laboratory and the ways to assure anonymity of test results. A ziplock bag containing filter paper, a yellow card, and a green card was prepared for each respondent. The cluster number the age, and the sex of the person tested were written on the yellow card. The yellow card was sent to the lab accompanying the filter paper with absorbed drops of blood. The green card, labeled *Conseils et test gratuit* (Advice and free blood test) was given to nearly everyone who was asked to give blood for the test, whether they accepted or refused.

The green card was given to 175 of the 195 persons asked to have a blood test, and two individuals refused to accept the card. Fifteen of the 20 people who did not receive the card were from two clusters in Bamako that were interviewed by the same team. Similarly, 45 cases (out of 195) were observed in which no explanation was given at all with the card. However, 39 of those 45 were found in those same two clusters of Bamako. The failure to pass out the green card and the failure to provide any explanation can be linked to the poor performance of one of the four field editors observed.

7.2 Information Given with the Green Card

At the bottom of the informed consent page, instructions for the field editor asked that she say the following [translation]:

> *This card will allow you to get a blood test for HIV and advice free of charge. If you would like to be tested, take this card to an appropriate health facility where you will be told about HIV and advised on how to avoid HIV. In addition, they will take a few drops of blood from you and will let you know the results of the HIV test. Do you have any questions about the card or about the place to go?*

The MIC team observed the handing out of the card and made notes about the explanations provided. The team also asked the respondents directly about what they had been told about the card. Although the messages might have been misunderstood from time to time, the respondents' accounts of what they had been told fit closely with what had been stated by the field editors. Nearly all of those who heard an explanation understood that the card was to be taken to a health facility for some reason. What would happen at the health facility was not well understood by respondents.

7.3 Understanding of the Use of the Green Card

Almost all of the explanations for the purpose of the card fell into four categories:

- To get an AIDS test
- To take the card to a doctor
- To obtain free health care at a health center
- Don't know.

7.3.1 Get a free AIDS test

About one-half of the respondents who had heard an explanation of the use of the green card said, more or less, that the card would allow them to get a free AIDS test in a health facility. A man in Sikasso said,

> *I can go get a free blood test for HIV at the health center with this card, and at the same time, I'll be able to know whether I have the AIDS microbe in my blood or not.*

A woman in Mopti:

> *I told you that the card will allow me, according to what she said, to get free blood tests to find out if I have small ailments or AIDS.*

A woman from rural Sikasso:

> *She said that we needed to take the card to the hospital in Sikasso, and if you have AIDS, they will be able to treat you. And if you wait and go beyond the deadline for getting it done, you will have to pay.*

7.3.2 Take the card to a doctor

A woman from Sikasso:

> *She said that at the health center they will look at your blood to see what's there.*

A man from Sikasso:

> *I can go show them (health care agents) the card and they will give me lots of advice.*

A woman from Mopti:

> *She said that I could take the card to the health center and be told what illness I had.*

A man from Mopti:

> *The card is useful because one can take it to the hospital; the doctors know where it comes from and they can tell what illness I have.*

A man from rural Sikasso:

> *It allows me to check on my health in Sikasso. I think it's very good, for this way if you get sick, you can find out what you have with this card.*

7.3.3 Obtain free health care at a health center

A woman from Sikasso:

> *If I were to become sick and need to go to the hospital, I should take the card along to give to the doctor to facilitate the visits and treatments.*

A man from rural Sikasso:

She said that if you ever were to have AIDS, you could take the card to the hospital in Sikasso and get free treatment.

A woman from Mopti:

I was told that if I get sick and go to the hospital, I should show the card to the doctor so he can easily treat me.

A man from Mopti:

They told me that I should take my card with me if I went to the hospital; that way I would not have to pay anything.

A woman from Mopti:

She told me that if I take this card to the health center, they will examine me and tell me what's wrong, and then will give me the right treatments.

7.3.4 Don't know

Some of the cases in which individuals said they did not know the purpose of the green card were those of respondents who had not been given an explanation. A woman from Bamako said,

I really don't know; she just gave me the card without saying anything. I will keep the card which will show that one day people from the health department came by here to ask me questions about health.

Another example comes from Mopti where the EDSM-III team worked through an interpreter and without a field editor. The question was, "What is the card good for?"

Respondent:

I don't know

Interviewer:

What did they tell you about its use?

Respondent:

They said that my blood was no good and that I should go to the hospital with the card.

Interviewer:

What will you do when you arrive at the hospital?

Respondent:

I don't know anything about that; it's you who should know about that.

Interviewer:

They did not tell you anything when they gave you the card?

Respondent:

They explained things to my husband, but I did not follow their conversation.

A woman from rural Mopti responded,

I don't know what the card is for. They did not tell me about it... I don't even know what to do with it. They gave me the card and I took it. So now, I'll just keep it.

Overall, about one-fourth of those interviewed said the purpose of the card was to do a blood test for AIDS and get the results at a health center or hospital. Several people thought the card was to get the results from the anemia test. Nearly everyone thought the card had to do with going to a health facility for something: information, free treatment, or a blood test.

A summary of the types of answers given to the question, "What is the green card used for?" is found in Table 9. Respondents who mentioned going to a health facility for the results of an AIDS test were placed in the first category whether they understood they needed to give blood again or not. The table shows the variability in the performance of the EDSM-III teams. The reason more people in the Sikasso clusters understood the purpose of the green card might be because in those clusters, the field editor most often read the informed consent, and the information about the green care was printed on the page. Some of the communication problems visible in this discussion could be corrected through careful selection of field editors and improved training.

Table 9 Distribution of respondents by their understanding of the use of the green card

Cluster (ward)	Get an AIDS test	Present the card to a doctor	Receive free health care	Don't know	Did not receive green card	Total
Cluster 1	8	4	7	1	1	7
Cluster 2	1	0	13	1	2	18
Cluster 3	3	1	1	2	0	21
Total	12	5	21	4	4	
Cluster 1	13	2	4	0	2	21
Cluster 2	13	0	6	0	6	25
Cluster 3	15	4	3	0	1	23
Total	41	6	13	0	9	
Cluster 1	0	5	0	11	8	24
Cluster 2	1	2	1	9	10	23
Cluster 3	9	4	1	1	3	18
Total	20	13	2	21	21	

It should be noted that nearly everyone in one Mopti cluster understood that the green card gave them access to free medical care. Although the EDSM-III team had questionnaires in *Fulfulde,* which was spoken by some in the cluster, none of the team members spoke the language. They worked, therefore, with interpreters who seem to have failed in communicating the right messages. In two of the clusters in Bamako the majority of respondents received either no card or no explanation.

Special workshops were held around the country in February 2001 to train health care personnel on how to receive the green cards and conduct the proper tests free of charge. The Ministry gave the population until the end of June to take their green cards to a medical facility. When that failed to bring people out, television announcements were created to inform people that the deadline for testing had been extended.

Despite the efforts exerted to make it possible for individuals to obtain a free HIV test, very few

persons availed themselves of this opportunity. According to the Ministry of Health, of the more than 6,800 acceptors of the HIV blood test nationally, fewer than 50 people presented a green card at a health facility in the six months following the survey.

Three possible explanations for the lack of participation are considered. First, although this study did not address this aspect directly, we had reasons to believe that most people were unfamiliar with the idea of taking a blood test to see what illness they had. Also relevant was the fact that very few people knew what AIDS as an illness might be. It was not a familiar concept in Mali. Second, it was not clear where people were expected to go for their tests. The destinations varied: the health center, the hospital, or a government facility. And third, very few individuals in Mali have had any experience with persons with AIDS; overall prevalence is less than 2 percent. Despite hearing about the condition in the media, there seemed to be little understanding of what constituted AIDS.

CHAPTER 8

KNOWLEDGE OF AIDS

AIDS has been the subject of great attention in the Malian media during the past few years. With the aid of donors, the Malian authorities launched a ten-year health program, *Le Programme de Développement Sanitaire et Sociale* that has HIV/AIDS prevention as one of its major themes. Estimates of the prevalence of HIV at the national level have been based on the collection of routine statistics from health service facilities. The Ministry of Health, with assistance from ORC Macro and CDC, decided to use the opportunity offered by EDSM-III to conduct blood tests for HIV in a subsample of survey households.

During the conversation held after the blood test, the interviewers asked the respondents:

"What do you know about AIDS?"

A series of subquestions usually followed, for often the person would say, "I don't know anything." Interviewers would then ask related questions and the person would give information about AIDS they had heard in the media or from their neighbors.

8.1 General Knowledge about AIDS

Although the first response of individuals to the question about knowledge of AIDS was most often "nothing," the majority were able to mention a few things they had heard. The following example from Sikasso shows what a more talkative person declared after a few follow-up questions:

Interviewer:
What do you know about AIDS?

Respondent:
Actually I don't know anything.

Interviewer:
Might you have heard anything about AIDS on the radio, television, or in casual conversations?

Respondent:
I heard on the radio and on TV as well that there were lots of AIDS cases in Mali and in other countries. It seems that AIDS has been particularly destructive in African countries. Personally, I don't know how to tell the difference between someone who has AIDS and someone who does not.

Interviewer:
How can one get AIDS?

Respondent:
Through contaminated objects such as razor blades, needles, circumcision knives, and sexual relations.

In the process of asking these questions, the research team discovered that saying they knew nothing was not merely a negative response; it was, rather, a way of indicating they had no personal experience with AIDS. The follow-up answers tended to be accounts of what they had heard more than what they actually knew from experience. Most had heard that AIDS was an incurable disease, and some had ideas about transmission.

According to a female student in another Sikasso cluster:

We learned at school that AIDS is a fatal disease with no cure.

In order to emphasize the seriousness of the disease, a man from Sikasso, using Creole French *(français de Moussa),* said, *"It's a disease like no other!"*

Another man from Sikasso region said it this way:

AIDS is a very fatal disease if I can put it that way. Since Sikasso lies between Côte d'Ivoire and Burkina [Faso], we are very vulnerable, and thus I would like to get my blood tested.

8.2 Transmission of HIV/AIDS

Discussion of the modes of transmission of AIDS suggested that individuals were reporting what they heard in the media, rather than speaking from personal knowledge. Consider this example from rural Mopti:

Interviewer:

What do you know about AIDS?

Respondent:

I know that it is a serious disease and I am even afraid to hear the word.

Interviewer:

Is that all you know about AIDS?

Respondent:

I also heard on the radio that when you have sex with someone who has AIDS, you will catch it right away, or if you have been pricked with a tool that has already been used to prick someone with AIDS, you will be contaminated.

Here is an example from Mopti:

Interviewer:

What do you know about AIDS?

Respondent:

I don't really know anything about AIDS.

Interviewer:

You've never seen or heard anything about AIDS?

Respondent:

I've often seen images on the TV screen showing condoms, but I did not learn anything particular from that.

Interviewer:

What do they say on television?

Respondent:
They show condoms saying that people can use them.

Interviewer:
Use them how?

Respondent:
They show condoms to people.

Interviewer:
Do they say what condoms are used for?

Respondent:
Yes, they show them saying that people can use condoms to protect themselves against AIDS. They say that people who use condoms will not get AIDS.

What is most striking about the responses of so many respondents to these questions is that they first said they knew nothing, and then they would say, "Well, I heard on the radio that . . . or "it is said that . . . or "Some claim that" . . , and would then explain that AIDS can be transmitted through sexual relations and contaminated instruments. Few individuals came out directly and stated how it was transmitted. Often the respondents cast their answers in a tentative tone, as though they did not really believe their answer.

Nevertheless, nearly two-thirds mentioned that AIDS was transmitted through sexual relations. Of the 188 conversations about AIDS recorded, 122 mentioned the classic modes of transmission they had heard about through the media or through friends. Another 30 percent simply said they did not know how AIDS was transmitted. Only eight persons mentioned ways of transmission that would be regarded as unrelated to biomedical knowledge. In only one cluster, in Sikasso, were there more people who did not know how AIDS was transmitted than who gave a classic answer.

These answers suggested that while the media campaign of the national AIDS prevention program has succeeded in diffusing messages about how AIDS is transmitted, the population was not convinced that it concerned them. Several individuals maintained that AIDS did not exist, and one of them knew what the media said about transmission.

8.3 Knowledge of Ways to Avoid AIDS

Most people who had ideas about how to avoid AIDS mentioned one of two strategies: being faithful to one partner or using condoms during sexual relations. As one of the women in rural Mopti said:

You must be faithful to your husband. As for him, God knows if he is faithful or not. In any case, one has to be satisfied with only one's husband.

A woman from Bamako remarked:
The best way to avoid AIDS is to be serious, avoid contaminated instruments, and have a faithful husband.

A student from Sikasso said:
To avoid AIDS, you have to be serious, you have to avoid knife blades, razor blades, and boys.

A man from the same cluster thought that:

To avoid AIDS, you have to be very careful, be faithful, stop running around. If you have doubts about a woman, then use a condom.

A small number of respondents also mentioned that one should avoid contaminated objects, but they expressed concern about that being always possible. A woman from Bamako, after mentioning the importance of being faithful, added:

For everything else now it's rather complicated: syringes, needles, and all those things used in hospitals; only God can protect us.

A similar fatalistic approach was expressed by a man from rural Sikasso. He explained that:

Some people say that one can get AIDS from mosquitos. If that's true, then only the good Lord can protect us from AIDS, since I don't see any solution.

A man from Bamako referred to a philosophical strategy. He was convinced that he could avoid AIDS by "staying away from any type of anxiety possible." The term "anxiety" in the local slang of youth usually referred to temptations, suggesting that one could avoid AIDS by strength of character, which most likely meant abstinence.

There were far fewer suggestions about how to avoid AIDS than comments about how AIDS was transmitted. Efforts to teach the population about how to protect themselves against AIDS have a long way to go to convince people of the danger of AIDS and of ways to prevent AIDS transmission.

CHAPTER 9

CONCLUSION

The MIC team found that the field instruments designed for the study were able to identify relevant indications of how the EDSM-III was introduced, how the consent statements were presented, how the blood tests were conducted, and how the respondents reacted to the request to be tested for anemia and HIV. The results of the study supported two of the five hypotheses originally formulated.

9.1 Evidence for Hypotheses and Team Performances

One of the study hypotheses had suggested that a clear knowledge of the purpose of the EDSM-III as communicated by the media and reinforced by the team leader's introduction would make positive reactions to the team more likely. That might have been true, but the number of refusals (15 percent) compared with the types of introductions did not permit a claim for such a relationship by statistical association of categories.

However, other evidence of peoples' reasons for cooperating with the survey and the blood tests comes from observations of the introductions and the presentation of the consent form. The team was introduced as a group from the Department of Health doing work for the department. A number of respondents mentioned that it seemed like a good thing to be collaborating with such persons. The field editor for the clusters in Sikasso consistently began her contact with those eligible for a blood test by stating:

My name is Bintou Diallo,
I work for the Department of Health
This work includes doing blood tests.

People were simply expected to accept the survey team and respond to their requests. In a few of the observed introductions, the team leader mentioned the health services offered by the government to situate the team within a health-service context. The Bambara word *dogotolo* borrowed from the French *docteur* was often used in the introductions. The fieldwork team became convinced that medical identity was the key to soliciting the cooperation of the respondents. That same power dynamic is evident in the process of obtaining informed consent in medical settings in the USA.

The study proposal had hypothesized that ideas and knowledge about AIDS might influence reactions to a request for an HIV test. An indication that this hypothesis might be correct was the two reasons cited for refusing an HIV test: 1) total ignorance of AIDS, and 2) belief that AIDS does not concern them, i.e., does not touch them. Respondents were asked directly why they had refused a blood test. Though reasons for actions were always more complex than how they are explained, the conversation around these explanations lent them some credibility.

Conversations were held with respondents just after the blood tests, partly to find out what they had retained from the presentation of the consent statements. Those conversations revealed that nearly everyone, about 90 percent, understood they were being asked for a blood test for anemia and for AIDS. That is, people were able to repeat the terms, but it was not clear that either of those conditions had meaning for them. This was especially true of anemia, which was not a condition familiar to Malians. Field editors tried various ways of describing anemia (little blood, light weight blood, weak blood, bad blood, or a poor diet), but it is not clear what people understood.

In addition, about 30 percent said several times that they knew nothing about AIDS at all. However, about two-thirds knew what the media had been saying about ways of transmission— sex and contaminated instruments. There is direct evidence that at least two-thirds knew that participation was voluntary, and some of the rest knew as well, since they refused to participate.

Evidence for variations in the response according to gender was found. More men than women were likely to refuse a blood test, to ask questions after the presentation of the consent form, and fewer men than women accepted the request for a blood test right away. No differences were found in matters related to having heard about the EDSM-III or understanding certain points in presentations.

The study found no evidence that adding a pair of biomarkers (blood tests for anemia and HIV) interfered with the normal performance of the EDSM-III teams. Clearly, biomarkers could be successfully added to the standard DHS survey. Confirming that this was possible was one of the study's objectives. It remained true that adding these blood tests to the responsibilities of the field editor took time away from checking on questionnaires and observing interviewers at work, but it was not possible to evaluate the impact of the added tasks on the performance of the field editors.

Finally, evidence was found of weaknesses in the process of presenting the informed consent statement. Part of the problems stems from the contrast in language between the original consent form and what local linguistic conditions may impose. The formal language of an IRB does not lend itself to be easily spoken, and even if it is were more or less read, a change in language toward spoken rhythms and simple sentences would make the task much easier. There is ample evidence in the studies of informed consent in medical settings to show that using the language of respondents increases comprehension, as well as sounding natural.

9.2 Lessons for the Future

The results of the Mali informed consent study identify lessons for conducting tests for biomarkers as part of large sample surveys in West African societies. For DHS survey personnel, it is reassuring to find that tests for biomarkers can be added without jeopardizing the quality of the survey results.

There are also more general conclusions for survey research that derive from the impact of the social context on fieldwork. First, people will participate in giving blood for tests for unfamiliar conditions, even if they have only a vague idea of the condition in question, if a medical team requests it. In that, they are just like many Americans who give their assent to medical tests they do not understand. In Mali, most people have only a vague idea, if that, of what anemia might be, and AIDS is not a disease that concerns many of them personally.

Second, informed consent statements could be formulated in simple and conversational language to increase the probability that the statements will be read or recited verbatim. This requires that members of the ethical or institutional research boards reviewing the statements be convinced that simple language can contain the information they deem indispensable. The reading of a speech in formal language is an unnatural act in these contexts, and the temptation to simplify by explanation should be removed.

Third, the training of interviewers in presenting informed consent statements should emphasize the importance of mentioning a list of key items in the statements presented. Demonstration of the ability to present consent statements that include all these items should be part of the training. If the language is simple and conversational, learning what must be said will not prove difficult, and reading or reciting from a text can be performed by all interviewers.

Fourth, social situations where presenting a full informed consent statement seems problematic should

be anticipated in training. They include situations such as the following: 1) the head of household asks everyone to give blood, 2) family members listen to a presentation made for another household, or 3) the guardian approves and asks the minor to give blood.

It is important to recognize that local patterns of authority may give the household head the right to decide for others. Whether it is then feasible to present the information to each person eligible will be decided at the time of the interview. Through focused training and regular supervision, DHS survey teams will be prepared to make those decisions.

The proper use of an informed consent statement involves legal, ethical, and practical considerations. Whether we are directing or advising in survey research, our role should be one of conscious and transparent compromise on all three considerations. Somehow we need to balance the legalistic obligations we may inherit from our funding sources; our own ethical concerns about equality and not imposing ourselves on others; and the social conditions of fieldwork.

REFERENCES

Byrne, D.J, A. Napier, and A. Cuschieri 1988. How informed is signed consent? *British Medical Journal* 296(6625):839-840.

Cellule de Planification et de Statistique du Ministère de la Santé (CPS/MS), Direction Nationale de la Statistique et de l'Informatique (DNSI) and ORC Macro. 2002. Enquête Démographique et de Santé au Mali 2001. Calverton, Maryland, USA: CPS/MS, DNSI and ORC Macro.

Ekunwe, E.O and R. Kessel. 1984. Informed consent in the developing world. *The Hastings Center Report* 14:22-24.

Faden, Ruth R. and Tom L. Beauchamp. 1986. *A History and Theory of Informed Consent.* New York: Oxford University Press.

Fortney, Judith A. 1999. Assessing recall and understanding of informed consent in a contraceptive clinical trial. *Studies in Family Planning* 30(4):339-346.

Groves, Robert M, Robert Cialdini, and Mick P. Couper. 1992. Understanding the decision to participate in a survey. *Public Opinion Quarterly* 56(4):475-495.

Hall, A.J. 1989. Public health trials in West Africa: Logistics and ethics. *IRB* 2:8-10.

Ijsselmuiden, C.B. and R.R. Faden. 1992. Research and informed consent in Africa: Another look. *New England Journal of Medicine* 326:830-833.

Levine, R.J. 1991. Informed consent: Some challenges to the universal validity of the Western model. *Law, Medicine and Health Care* 19:207-214.

Lynöe, Niels et al. 1991. Informed consent : Study of quality of information given to participants in a clinical trial. *British Medical Journal* 303(6803):610-613.

Ogloff, J.R.P. and R.K. Otto. 1991. Are research participants truly informed? Readability of informed consent forms used in research. *Ethics and Behavior* 1:239-252.

Presser, Stanley. 1994. Informed consent and confidentiality in survey research. *Public Opinion Quarterly* 58:446-459.

Singer, Eleanor. 1978. Informed consent: Consequences for response rate and response quality in social surveys. *American Sociological Review* 43:144-162.

Singer, Eleanor. 1993. Informed consent and survey response: A summary of the empirical literature. *Journal of Official Statistics* 9(2):361-375.

Singer, Eleanor, Hans-Jurgen Hippler, and Norbert Schwartz. 1992. Confidentiality assurances in surveys: Reassurance or threat? *World Association for Public Opinion Research.*

Singer, Eleanor, Dawn R. von Thurn, and Esther R. Miller. 1995. Confidentiality assurances and response. *Public Opinion Quarterly* 59:66-77.

Sobal, J. 1984. The content of survey introductions and the provision of informed consent. *Public Opinion Quarterly* 48:788-793.

Society for Applied Anthropology (SfAA). 1983. *Professional and ethical responsibilities*. Washington, D.C.:SfAA.

Sugarman, Jeremy, Douglas McCrory, and Donald Powell. 1999. Empirical research on informed consent: An annotated bibliography. *The Hastings Center Report* supplement 29(1)S1-S42.

Taub, H.A. 1986. Comprehension of informed consent for research: Issues and directions for future study. *IRB* 8:7-10.

APPENDIX A

MODULE D'OBSERVATION N°1

Observation de l'introduction de l'enquête par _____

NUMÉRO DU QUESTIONNAIRE…… ☐

L'incorporation du test du VIH dans le contexte d'une EDS standard : L'expérience du Mali	
IDENTIFICATION	
Nom de la localité :_____	
Numéro de grappe……	☐
Numéro de concession……	☐
Nom du chef de ménage et **N° du ménage**_____	☐
Région……..	☐
Cercle……	☐
Langue utilisée……	☐
Date……..	☐
Enquêteur…….	
Bamako, Autres Villes, Autres Communes, Rural…… (Bamako=**1** ; Autres Villes=**2** ; Autres Communes=**3** ; Rural=**4**)	☐
Nom et **N° de ligne enquêté(e)**_____	☐
Sexe de l'enquêté(e)_____ Féminin=**1** ; Masculin=**2**	☐

L'incorporation du test du VIH dans le contexte d'une EDS standard : L'expérience du Mali		
THÈMES	ÉLÉMENTS DE RÉPONSE	COMMENTAIRES
1 **Introduction**	**1 -** Mention de son identité (écrire en commentaires ce qu'elle exactement dit) **2 -** L'identité de la contrôleuse **3** - Les objectifs de l'enquête EDS **4 -** Le prélèvement sanguin **5 -** Le consentement volontaire **6** - Le test pour l'anémie **7** - Le test VIH/sida **8 -** La carte verte	
2 **Réaction du chef de ménage ou de son représentant** _____ **CM présent** ☐ **Ep. CM** ☐ **Enft CM** ☐ **Autre** ☐	**A -** Il a déjà entendu parler de l'enquête **B -** Il a l'air suivre caractère volontaire **C -** Il suit bien **D -** Il accepte l'enquête dans le mênage **E -** Il pose des questions **F -** Il donne des instructions **G -** Autres **(Ecrire et documenter**)	

3

Description de l'entretien avec le chef de ménage

(Si espace insuffisant, écrivez au verso en reportant le numéro du thème)

4

Évaluation de la conversation avec le chef de ménage ou son résentant

(Si espace insuffisant, écrivez au verso en reportant le numéro du thème)

APPENDIX B

MODULE D'OBSERVATION Nº2
(Le prélèvement sanguin par la contrôleuse)

NUMÉRO DU QUESTIONNAIRE…… ☐☐☐☐☐

L'incorporation du test du VIH dans le contexte d'une EDS standard : L'expérience du Mali	
IDENTIFICATION	
Nom de la localité :_____	
Numéro de grappe……	☐☐☐
Numéro de concession……	☐☐☐
Nom du chef de ménage et **Nº du ménage**_____	☐☐☐
Région……..	☐☐
Cercle……	☐☐
Langue Utilisée……	☐☐
Date……..	☐☐
Enquêteur_____	
Bamako, Autres Villes, Autres Communes, Rural…… (Bamako=**1** ; Autres Villes=**2** ; Autres Communes=**3** ; Rural=**4**)	☐
Nom et **Nº de ligne enquêté(e)**_____	☐☐
Sexe de l'enquêté(e)_____ Féminin=**1** ; Masculin=**2**	☐
Prélèvement effectué : Avant=**1** ; Pendant=**2** ; Après=**3**	☐

L'incorporation du test du VIH dans le contexte d'une EDS standard : L'expérience du Mali		
THÈMES	ÉLÉMENTS DE RÉPONSE	COMMENTAIRES
1 **Préparatifs du prélèvement par la contrôleuse**	**1 OUI** (Mentionnez ce qu'elle a fait) **2 RAS**	
2 **Explications données par la contrôleuse**	**1 -** Mention de son identité (écrire en commentaires ce qu'elle a exactement dit) **2 -** Caractère volontaire **3 -** Anonymat **4 -** Le test pour l'anémie **5 -** Le test VIH/SIDA **6 -** La carte verte	
3 **La façon de présenter le consentement volontaire**	**A -** Le consentement **pas présenté** **B -** Le consentement **expliqué sans lecture** **C -** Le consentement **lu avec explication** **D -** Le consentement **lu** **E -** Le consentement **lu par l'enquêté**	

4 LA RÉACTION DE L'ENQUÊTÉ(E) À LA PRESENTATION DU CONSENTEMENT VOLONTAIRE		
THÈMES	ÉLÉMENTS DE RÉPONSE	COMMENTAIRES
4.1 **L'enquêté(e) suit la présentation avec :**	**1 – Beaucoup** d'attention **2** – **Peu** d'attention **3** – Ne suit **Pas du tout**	
4.2 **L'enquêté(e) pose une ou plusieurs question(s)**	Oui…… **1** Non…… **2** (Si **Oui** enregistrez l'essentiel de la ou des questions en regard – Reportez le Nº de la question et poursuivez au verso si pas assez d'espace)	
4.3 **L'enquêté(e) :**	**1 –** Accepte **tout de suite** **2** – Accepte **après des explications** **3** – Accepte **après une confirmation de quelqu'un d'autre** **4** – **Refuse** le prélèvement	

5 LA CARTE VERTE		
THÈMES	ÉLÉMENTS DE RÉPONSE	COMMENTAIRES
5.1 **La contrôleuse explique à quoi sert la carte verte**	Oui…… **1** Non…… **2** (Notez en commentaires en quels termes – Reportez le Nº de la question et poursuivez au verso si pas assez d'espace)	
5.2 **La contrôleuse donne la carte verte à l'enquêté(e)**	Oui…… **1** Non…… **2** (Notez en commentaires comment et quelles sont les réactions ou commentaires de l'enquêté(e) – Reportez le Nº de la question et poursuivez au verso si pas assez d'espace)	
5.3 **L'enquêté(e) accepte la carte verte**	Oui…… **1** Non…… **2** (Notez de quelles manières en commentaires – Reportez le Nº de la question et poursuivez au verso si pas assez d'espace)	

APPENDIX C

Question Guide for Individuals Asked to Give Blood

A. Information about the DHS survey

1. Had you heard about the DHS survey before the team arrived at your home?
2. How did you hear about it?

B. Informed consent statement and the blood test

1. What were you told about the blood test?
2. Did you know that the blood test was voluntary?
3. Were you given a green card?
4. Did you accept it?
5. What is the green card used for?
6. How do you plan to use the green card?

C. Blood test and AIDS

1. What do you know about AIDS?
2. Why did you accept/refuse the blood test?

D. DHS interview

1. What did you think of the interview with the DHS interviewer?
2. What did you learn during the interview?

Guide d'Entretien Individuel avec les Personnes Prélevées

A. Information sur l'enquête EDS

1. Est-ce que vous étiez informé du déroulement de l'enquête EDS avant l'arrivée de l'équipe?

2. Comment avez-vous été informé?

B. Consentement volontaire et prélèvement

1. Qu'est-ce qu'on vous a dit à-propos du prélèvement sanguin?

2. Est-ce que vous saviez que le prélèvement n'était pas obligatoire?

3. Est-ce qu'on vous a donné une carte verte?

4. L'avez-vous acceptée?

5. A quoi sert-elle?

6. Quel usage comptez-vous en faire?

C. Prélèvement et sida

1. Qu'est-ce que vous savez sur le sida?

2. Pourquoi vous avez accepté/refusé le prélèvement?

D. L'interview

1. Comment vous avez trouvé l'interview avec l'enquêteur?

2. Qu'est-ce que vous avez appris pendant cette interview?

APPENDIX D

Informed Consent Testing for Anemia and for HIV

Anemia testing

In this survey, we are studying anemia among children, men, and women. Anemia is a serious health problem that comes from, among other things, a poor diet. This survey will assist the government to develop programs to prevent and treat this disease.

We are asking that you (and your children) participate in this test for anemia testing by giving a few drops of blood from a finger. For this test we use sterile and disposable instruments that are clean and completely safe. The blood will be analyzed with a new machine and the results will be kept confidential. The results of the test will be given to you right after the blood is taken.

Do you have any questions?

Can I ask you now to participate in the anemia test, you and your children? However, if you decide to refuse, please understand that you have the right and that we will respect your decision.

Now, can you tell me if you are willing to participate in the anemia test, you with your children?

HIV test

In this survey we are also studying HIV among men and women. HIV is a virus that causes AIDS, and AIDS is usually fatal. This survey will assist the government in developing programs to prevent this disease.

We are asking that you participate in the test for HIV in the framework of this survey by giving a few drops of blood from a finger. Just as for anemia, for this test we use instruments that are completely safe. For the HIV results, the blood will be analysed later on in a laboratory. In order to ensure complete confidentiality of the test results, no names will be attached to the blood samples. Therefore, we will not be able to give you the results of your HIV test, and no one will be able to trace the test back to you.

Do you have any questions?

May I now ask you to participate in the HIV test? However, if you decide to refuse, please understand that you have that right and that we will respect your decision.

Now, can you tell me if you agree to participate in the HIV test for yourself?

BE SURE TO GIVE EACH ELIGIBLE PERSON, WHETHER OR NOT THEY ACCEPTED THE TEST, THE "FREE HIV COUNSELING AND TESTING" CARD. TELL HIM/HER: This card gives you the chance to have counseling and an HIV test free of charge. If you would like to take an HIV test, take the card to an appropriate health care facility. In this facility you will be told what HIV is and how to avoid it. In addition, they will take several drops of blood for an HIV test, and they will give you the results. Do you have any questions about this card and where to take it?

Consentement Volontaire pour le test d'anémie et de VIH

Test d'anémie

Dans cette enquête, nous étudions l'anémie chez les enfants, les hommes et les femmes. L'anémie est un sérieux problème de santé qui est dû, entre autre, à une alimentation pauvre. Cette enquête permettra d'aider le gouvernement à développer des programmes pour prévenir et traiter cette maladie

Nous demandons que vous (et tous vos enfants/ceux dont vous avez la charge) participiez au test d'anémie en donnant quelques gouttes de sang d'un doigt. Pour ce test, on utilise des instruments stériles et non réutilisables, qui sont propres et complètement sans risque. Le sang sera analysé avec un équipement neuf et les résultats resteront confidentiels. Pour l'anémie, les résultats du test seront communiqués immédiatement après la prise du sang.

Avez-vous des questions?

Puis-je vous demander de participer au test d'anémie vous (et tous vos enfants/ceux dont vous avez la charge? Cependant, si vous décidez de refuser, sachez que vous en avez le droit et que nous respecterons votre décision.

Maintenant, pouvez-vous me dire si vous acceptez le participer au test d'anémie vous (et tous vos enfants/ceux dont vous avez la charge)?

Test de VIH

Dans cette enquête, nous étudions également le VIH chez les hommes et les femmes. Le VIH est le virus qui cause le sida, qui, habituellement, est mortel. Cette enquête permettra d'aider le gouvernement à développer des programmes pour prévenir cette maladie.

Nous demandons que vous participiez au test du VIH dans le cadre de cette enquête en donnant quelques gouttes de sang d'un doigt. Pour ce test, on utilise, comme pour l'anémie, des instruments complètement sans risque. Pour le VIH, le sang sera analysé plus tard dans un laboratoire. Pour assurer la confidentialité des résultats du test, aucun nom se sera attaché à l'échantillon de sang; ainsi, nous ne pourrons pas vous donner les résultats de votre test de VIH et personne ne sera en mesure de vous identifier à partir de ce test.

Avez-vous des questions?

Puis-je vous demander de participer au test de VIH? Cependant, si vous décidez de refuser, sachez que vous en avez le droit et que nous respecterons votre décision.

Maintenent, pouvez-vous me dire si vous acceptez de participer au test VIH?

ASSUREZ-VOUS DE REMETTRE A CHAQUE PERSONNE ÉLIGIBLE, QU'ELLE AIT ACCEPTÉ OU NON LE TEST DE VIH, UNE CARTE « CONSEILS ET TEST VIH GRATUITS ». DITES-LUI: « Cette carte vous permet de bénéficier de conseils et de test gratuits de VIH. Si vous désirez vous faire tester, adressez-vous, muni de cette carte, à une structure de santé appropriée. Dans cette structure, des informations sur le VIH et les moyens de l'éviter vous seront fournies. Par ailleurs, quelques gouttes de sang vous seront prélevées, ce qui vous permettra de connaître le résultat de votre test. Avez-vous des questions sur cette carte et l'endroit où aller? »