Ethical Issues in the Collection, Analysis and Dissemination of DHS Data in sub-Saharan Africa*

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Abstract

When the Demographic and Health Surveys (DHS) program collected data primarily through structured interviews with consenting adults, very few ethical issues arose. However, in recent years, increased demand for detailed data needed for monitoring and evaluating health programs such a HIV and malaria has led to the collection of biomarkers and geographical information systems data. The collection and storage of these new data required that attention be paid to ethical issues of informed consent, confidentiality, and privacy when working with sensitive biomarker data, especially when making provision for follow-up for those who test positive to easily treatable conditions. This paper discusses these ethical issues as they relate to the collection of serum samples for HIV, syphilis, and anemia testing and the handling of geo-referenced data. The procedure for maintaining strong ethical standards under the DHS is discussed. Thorny questions with which the program grapples are also presented.

Introduction

Although the discussion of ethical issues in general social science research is becoming prominent among researchers and funding agencies, those issues that arise in the collection, handling and distribution of international population and health survey data deserve more attention. In this paper, we present the experience of the US Agency for International Development (USAID or the Agency), an organization that has been a major sponsor of large-scale social science data collection efforts over the past 40 years. In telling this story, we focus specifically on one program of international survey data collection that is sponsored by the Agency – the Demographic and Health Survey (DHS) Project. We describe what is done both within and without the Agency to maintain high ethical standards and what lessons have been learned, particularly in the context of sub-Saharan Africa. As a funding agency, USAID's role is one of collaborating with host country partners and implementing agencies to define the initial objectives of the data collection effort, providing technical guidance based upon the experience we have gained in countries around the world, directing survey activities in particular countries, and providing funding. The responsibility for data collection is then delegated to the implementing agencies and host country counterparts. USAID's perspective, therefore, is one step or two removed from direct survey implementation in the field. Although the experience of the agency as a sponsor of cross-nationally comparable surveys spans over three decades, the focus of this paper is on more recent experience, particularly the variety of experiences we have had over the past five years under the DHS.

The Demographic and Health Surveys is one of the five component activities of MEASURE (an acronym that stands for Monitoring and Evaluation to Assess and Use Results). DHS is managed within the Bureau for Global Health (GH) at USAID, and implemented under a contract with Macro International Inc. (now ICF Macro), a private company based in Calverton, Maryland. It is the main source of nationally representative and cross-nationally comparable population and health data for the Bureau and the Agency. Other donors have also contributed to the DHS, often through support for local costs. [1] The DHS program, which is now in its sixth contract cycle since 1984, has conducted more than 260 surveys and special studies in over 80 countries across Africa, Asia, Latin America/Caribbean, and Central Asia and Eastern Europe. One of the main objectives of the DHS is to provide useful information to decision makers in participating countries and to help them make informed policy and program choices, especially in the area of population, health and nutrition.

Over the years, the DHS has emerged as one of the best sources of nationally representative and cross-nationally comparable data on population, family planning and maternal and child health in the developing region. In its initial phase, DHS was largely focused on family planning and reproductive health, but with a significant maternal and child health component: information was collected on antenatal care, immunization, recent experience of diarrhea and fever, and their treatment, and childhood anthropometry. However, the focus has widened over the years to cover an expanded set

[1] Support from non-USAID sources has increased significantly for the Demographic and Health Surveys (DHS) program since its inception in 1984. Donors who have supported DHS activities in-country include UNICEF, UNFPA, World Bank, DFID, UNDP, IDB, PAHO, WHO, World Food Program, Ford, Packard

of health issues, and more recently has included collection of biological specimens in some surveys. The project has collected serum specimens to test for anemia, HIV sero-status, and vitamin A in some countries. Many other sensitive data are also gathered, including some geo-referenced information collected by global positioning systems. The collection of such information requires adherence to certain ethical standards. Such ethical standards are discussed below.

However, before proceeding to that discussion, it is necessary to highlight some broad parameters under which DHS operates, particularly as far as the protection of human research subjects is concerned. First, DHS is an open data collection activity. Its aims and goals are clear to the government that requests the survey and to all stakeholders participating in its contents and design. The data collection instruments are, to large extent, standardized and are widely accepted. The broad goals of the exercise are explained to the respondents by fieldworkers during their introduction in the household. There is no deception of respondents. No attempt is made to cajole respondents into agreeing to something to which they may not have otherwise agreed. Moreover, information that may compromise anonymity of respondents is not retained on record. Data collected are coded and analyzed, and the final report of survey findings is released for dissemination only after it has been approved by the host-country government. With the consent of the host-country government, standard recode data files for these data are made publicly available to researchers free of charge. The instruments used for data collection are made publicly available at no charge. Since these surveys have the backing

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of host-country governments, the results are used for program and policy development, which ultimately benefits the citizens of participating countries.

DHS is systematic collection of relevant data, but it is slightly different from the type of research that sets out to test a set of hypotheses. Its aims are to collect relevant information that would help to understand the perspectives, knowledge, attitudes and practices of individuals, households and communities that impinge on specific demographic and health outcomes, and to describe respondents' socioeconomic, physical and environmental circumstances. In some sense, therefore, DHS purports to play the role of a measurement tool – almost in the order of a thermometer or a gage – that seeks to objectively reflect what is happening to demographic behavior of men and women, and health of mothers and their children.

Ethical Issues under DHS

In this section, we present measures that are taken to maintain high ethical standards under the DHS program: protecting survey participants, obtaining informed consent, ensuring privacy and maintaining anonymity, and reconciling differences when Western ethical standards are at odds with locally approved procedures. A summary of these issues and responses under DHS is presented in Table 1.

1. Protection of Survey Participants

Often, the people from whom data are collected in household surveys have little or no education, may not fully understand why certain information is being collected, may be obliging, shy, vulnerable, and may not have the confidence to ask questions to clarify their understanding. Such people may tend to cooperate with official-looking interviewers, such as representatives of the Ministry of Health, Central Statistical Agency, or the Census Bureau. Under the ethical principle of beneficence, participants should be protected from known or foreseeable harms that could result from their participation in research (Belmont Report, 1979). In household surveys, much of the information collected is innocuous. However, some of the information gathered from individuals is of a sensitive nature. When surveys involve the collection of biomarkers, the potential for risks is further increased. Any biomarker collection involves some risks related to potential infection, unless certain clinical procedures are carefully followed. In addition, illnesses such as HIV/AIDS may be detected through biomarker components, thereby increasing the importance of maintaining the anonymity of the participants.

Identifying the "harms" that might result from participation in research, determining how to protect participants from them, and ensuring that respondents understand the potential risks is not straightforward. The Bureau of Global Health of USAID has technical staff who works closely with the contractor as well as host country agencies to help minimize the risk of any known harm. This is done by emphasizing careful planning and attention to detail, keeping up to date with the state of the art and current best practices, multiple

vetting of survey protocols by Institutional Review Boards (IRB), and satisfying of US Government regulations.

2. Obtaining Informed Consent

Often, the people from whom data are elicited may not be familiar with formal language contained in standard consent forms. Frequently, finding the right words in local lexicons is challenging. In addition, it is difficult to judge whether what the respondent finally understands through the informed consent process truly reflects what was intended by the original designers of the consent form. This is a fundamental ethical issue in research in developing countries, especially in settings where the level of formal education is low.

USAID promotes the use of simple local language for better understanding among potential participants and to help them make an informed decision about whether or not to participate. In some cases, funds are set aside to ascertain if people in such studies are properly informed and whether participation is truly voluntary. A study of informed consent in an HIV seroprevalence survey in Mali found that formal language used in Western consent forms was inappropriate for use in local interview settings as demonstrated in the following case study.

Informed Consent when Blood is Collected:

The Mali Case Study: For the first time under the DHS program, serum sample was collected to assess prevalence rates for HIV and anemia in the 2001 Mali DHS. The protocol indicates that respondents who consent to HIV testing will have capillary blood drawn by means of a finger prick made with a small retractable blade. The first two drops would be placed on a special filter paper and sent to the laboratory for HIV testing. The serum samples for HIV testing were not linked to the main DHS data set, but each respondent who wished to know his/her sero-status was given a green card to present at a district health center where he/she would receive counseling and testing.

Before implementing this protocol in Mali, there were concerns about the process of obtaining respondents' consent, particularly with regard to whether the application of US Government rules about the use of informed consent statements was appropriate for such a population with low levels of literacy. There was ambiguity about how to determine whether respondents were "informed" and whether decisions to participate were voluntary. Therefore, the voluntary consent form prepared by Macro and CDC was vetted by the Ministry of Health in Mali and by technical advisers at USAID Washington and USAID Mali.

In addition, a qualitative study was designed to assess whether respondents fully understood the formal informed consent procedure and whether the level of understanding influenced their participation. The results of the qualitative study suggest that interviewers followed the informed consent procedure in most cases. However, it

was observed that the formal presentation of informed consent forms did not flow with the normal conversational interview procedure. Therefore, interviewers in many cases were adding informal wordings to aid understanding and flow. This practice is actually consistent with US Government regulations on informed consent because informed consent is a process of understanding.

The qualitative study also found that how the information contained in the informed consent had little effect on the decision of respondents to give blood for the tests. The acceptance rate among the 7600 respondents was 89% (92% for women and 86% for men). Decisions not to participate tended to be for reasons such as "I don't know anything about HIV", or "I do not want to see my blood flow" (Yoder and Konate, 2002).

3. Anonymity and Confidentiality, and Protecting Privacy

In general, information collected from respondents under the DHS is anonymous. Every effort is made to ensure the confidentiality of the informant. This is done through various means. First, survey data are transformed and coded to protect anonymity and privacy of respondents. No names and addresses are retained in DHS data files. Over the years, there has been no case of a reported violation of privacy of confidentiality of information. In fact, whenever DHS staff makes a determination that respondent's privacy would be compromised, they try to address the concern even if it means postponing the interview. For example, there was a case encountered in the field in the Dominican Republic in 2002 when one eligible household was occupied by an eligible woman, her three children

and a helper. The woman was deaf and unable to speak. The question was whether to allow the helper to serve as translator (by sign language) for the woman. However, the DHS staff determined that a translator was not appropriate for some of the questions in the questionnaire because of privacy protection concerns. Thus, DHS fieldworkers were instructed not to interview the woman.

In other cases where anonymity might be compromised, a more elaborate formal procedure was called for. One such example was the case of geo-referenced data collected under the DHS or the geographic information system (GIS) data, which is described below.

GIS Data and Anonymity: DHS began the collection of geo-referenced data or the GIS in some countries in 1996, and today, about 102 geo-referenced DHS data sets are available from about 50 countries[2]. Each of these data sets contains the longitude and latitude coordinates recorded near the center of each DHS cluster using recreational grade hand-held GIS equipment. DHS recognizes that through these GIS data, chances are that the clusters where specific respondents lived could be located. The possibility of being able to locate respondents is much higher under the service provision assessment (SPA) that surveys health facilities than ordinary household surveys. This is because, while there would be several households and respondents within a cluster in an ordinary DHS, the number of health facilities surveyed per cluster in a SPA is usually small – making it easier to identify them through GIS than in standard household surveys.

Using the data to locate individual facilities and respondents would violate the principle of anonymity under which the DHS is conducted. Therefore, for years, careful deliberations were held to determine whether and under what conditions the GIS data should be made available to researchers. A Working Group of GIS professionals was established and has developed guidelines for handling this issue so that respondents' identities are protected. To date, data are released only after a careful review of the research for which the information is requested, and after potential users of data have signed privacy protection clauses. Even then, the possibility of adding random errors to the original GIS coordinates is being considered to further protect respondent's identities.

Before leaving this section, it important to point out that privacy protection, although an important ethical consideration in social science research, has multiple dimensions, and researchers often do not agree on its meaning (Pinkard, 1982). However, most agree that privacy is an important right and that invasion of privacy should be avoided. Such an invasion of privacy includes unwanted public disclosure of private facts. This is why under the DHS, results of interviews are stripped of information that would make respondents identifiable to others: there are no names or addresses retained.

4. Reconciling Western Ethical Standards with Local Laws

For several years, social science has struggled with the extent to which there is cultural relativity in ethics, and if so, whose ethical standards is upheld. This question becomes very important when international data collection or research is involved. The concern

[2] Of the 102 datasets, only 90 datasets from 45 countries are available for distribution.

ultimately is to prevent researchers from abusing the rights and dignity of human subjects in other cultures. Under the DHS, the goal is to adhere to ethical standards and obey the rules of the US Government as they apply to research. However, there have been situations under the DHS where the ethical review board in a surveyed country is more liberal about what they allow than are IRBs in more developed countries. Under such circumstances, the DHS program applies the Western standards, but sometimes has to accommodate local laws.

Syphilis testing in Zambia is the best example of a clash of ethical standards over the past few years. We present a fuller account of what happened to provide some insight into the processes under the DHS program. In 2001, a request was made by the government of Zambia through USAID/Lusaka to include blood tests for HIV and syphilis in the DHS. At first, the request was to link the HIV and syphilis test results to broader personal demographic and socioeconomic data collected in the survey. The justification was that the linked data would be richer for program planning and that giving results to respondents would provide an opportunity for counseling to respondents in the comfort of their homes. After a careful review of the ethical implications of disclosure of HIV test results and the logistics required for providing counseling, the request for a linked HIV-DHS data was rejected. In addition, there was a concern about interview teams giving results of HIV tests to individuals because of the possible compromise of privacy and the implication of that for stigma and other negative socio-psychological consequences for those who test positive.

However, in the case of syphilis – for which treatment was available – the preferred approach was to adopt a method (i.e., Rapid Plasma Reagin or RPR) that could provide instant results to respondents and that would allow treatment of those who tested positive after confirmatory (Determine) tests. The fieldwork began with the implementation of this protocol and positive syphilitic cases were treated at home with antibiotics. Those who did not want to be treated at home were given referral for a free treatment at the nearest health facility. However, the Central Bureau of Health in Zambia decided after fieldwork had started that the local legal framework opposed the use of a procedure (the Determine test) as it had not been validated or officially approved for use in Zambia. Therefore, a more cumbersome procedure of blood collection for laboratory analysis was adopted: all RPR reactive sera were collected in cryo vials, frozen in liquid nitrogen tanks and transported to a central laboratory for confirmatory testing using Treponema Pallidum Haemaglutination Assay. This is a clear situation where local laws prevailed over Western standards. Nevertheless, DHS still adopted procedures that prioritized the needs of those who tested positive to syphilis: providing referral letters to all who tested positive to syphilis, counting up the number of RPR positive cases and dropping off sufficient antibiotics at designated health centers for use in those positive cases.

Discussion

We have presented a case that seems to suggest that the DHS program takes care to maintain good ethical standards. That is indeed the case. However, it is important to highlight several factors that work together to make maintenance of high ethical standards feasible. First, there is the operation of checks and balances and the presence

of multiple "eyes" that observe the DHS process. These watchful "eyes" operate at various levels. One level includes the presence of Washington-based as well as field-based technical and procurement officers who ensure adherence to US laws. At another level are the watchful eyes of several national and international stakeholders, including researchers and advocacy groups. Then, there is the contractor (currently ORC Macro), which has an independent IRB that is properly constituted according to US Government standards. That IRB reviews DHS protocols to ensure that they conform to US laws. Yet another level is the host country IRB or ethical review committee that reviews the DHS protocols on behalf of host-government before government approval. This multi-layer review process also makes possible the detection of any major ethical violation.

In addition to the regulatory requirements, the DHS contractor recognizes that maintenance of acceptable ethical standards is in its interest, given that the goodwill of the local implementing agencies and fieldworkers as well as the cooperation of respondents are essential for the success and quality of the surveys. To gain the cooperation of respondents, it is necessary to ask questions in a culturally sensitive way, follow local customs, avoid lengthy interview sessions and protect privacy. These surveys are typically not a one-time event – they are often repeated at regular intervals in the same countries, and often the same local implementing agencies are used. The contractor is, therefore, interested in leaving good impression with the people with which it works. Host country governments, local USAID missions as well as other donors and stakeholders need to be happy about the performance of the contractor as well. Missions are provided an alternative source of meeting their data needs from DHS-type surveys if

the contractor does not perform satisfactorily. At regular intervals, the contractor is evaluated on its performance by USAID technical office in Washington DC and the proportion of the contractor's award fee earned is based on how well it performs on various indicators including customer satisfaction.

Thorny issues

In spite of this series of extensive procedures that ensure adherence to high ethical standards under the DHS, there are still some emerging questions that need to be addressed. In this section, we provide a few examples. The first concerns whether or not intervention is appropriate when a health problem is identified that the DHS team could address in the field. Should DHS interview teams intervene in the field in cases where such intervention might be feasible? For example, in some households where DHS data are collected, survey teams often encounter clear cases where early intervention might make a difference or where ignorance is simply the reason for the condition: vitamin deficiencies that could be corrected by simply providing a low-cost supplement or by changing food habits. In cases where the teams identify reported gender-based violence, should pamphlets be distributed to provide information, education and communication to women on that issue? How much service delivery can realistically be supported under the DHS, which has data collection and analysis as its primary objectives, and whose staff is not typically trained in medical interventions? So far, if DHS interview teams see medical emergency in remote locations and their vehicle could be used to transport someone to a nearby medical facility, it is usually difficult to say no. If DHS teams see cases where they think a person in an eligible household should seek medical help, should they say it?

What happens if the household cannot afford treatment cost and so does not want to go – how far should they go to potentially save a life? If DHS teams start doing such humanitarian acts, has a data collection project become an intervention program?

The second set of emerging questions concerns giving of token gifts to households. If a DHS interviewer sits with a woman for over one hour or brings activities in a household to a halt for hours because of the interview, biomarker collection and other procedure, is that enough justification for giving respondents some token of appreciation? In some countries, interviewers are uncomfortable imposing upon respondents without giving them something. If a token gift is given, how much will that act bias the samples or responses? If no token is given (as currently is the case), does it matter?

Does participation as a respondent in DHS interviews put them at any risk – such as domestic violence if a woman's report of extra-marital affair is overheard by her husband? Although the DHS program staff is not aware that this happens, the possibility of its occurrence is taken into consideration when making decisions about protocols at the household level.

As of the time of writing this report, the idea of implementing of a home-based voluntary counseling and testing (VCT) as a part of HIV testing in a DHS is still being debated. The question is whether it is appropriate to use the event of a DHS to implement a program of VCT that should be directed at whole communities. Implementing such a DHS-linked VCT in the household raises other issues such as what would be done for many couples

that will be sero-discordant (which would have multiple consequences, especially if a wife is the one that tests positive) knowing that VCT groups cannot possibly stay with each respondent as much as needed; and they have privacy protection concerns including chances that sero-status will be known by others.

Conclusion

The DHS program has taken appropriate steps to implement ethical standards in its data collection practices. USAID has also supported these steps by encouraging adherence to US Government regulations, identifying ethical issues and developing guidelines that address them; funding studies to determine the effectiveness of informed consent procedures; and monitoring the objectives, methodologies, and procedures for handling the data sets of research efforts to check whether ethical standards are maintained. In addition, the DHS contractor that implements the data collection project has its own autonomous Institutional Review Board with members who have been certified by the US Government that review instruments and testing procedure for the project. There are ethical review committees in host-countries that vet DHS protocols on behalf of their governments before such protocols are approved. This multiple review process appeared to have worked well. Nevertheless, important issues remain about building local capacity of IRB members in developing countries to contribute to and adapt rigorous international ethical standards in research involving human subjects as well as how to handle situations where simple interventions at DHS household could make a difference between life and death.

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Table 1: Selected Examples of Ethically-Relevant Situation in Sub-Saharan Africa and How USAID Works with the Contractors to Respond

Situation in developing countries	**Relevant Principle**	**USAID GH and Contractor's response**
The population • Many are poor and shy • Many are illiterate • May be highly obliging • May tolerate much personal inconvenience to help others	Protection of vulnerable population	• Vetting of instruments and procedure through Institutional Review Boards (IRB). Requirement that IRB members be properly trained. • Work closely with local implementing agencies to pretest survey instruments and field procedures. • USAID monitors implementation to protect the vulnerable population and ensure adherence to US government standards and contracting laws • Ensure careful planning before survey implementation
Weak legal structure and non-litigious population	Do no harm	Adherence to international ethical standards and principles guiding research involving human subjects.
Lack of capacity among members of local Institutional Review Boards (IIRB)	Do no harm	• Agency supports individual and institutional capacity building, and implements only what conforms to rigorous ethical standards. • Develop guidelines.
Multi-ethnic and multi-linguistic settings: • Presents the challenge of ensuring informed consent	Ensuring informed consent	• Interviews are conducted in local language. • Questionnaires are translated to major languages in each country. • Emphasis is placed on ensuring that respondents understand that participation is voluntary. • Local elders and officials are approached first to explain research purpose before approaching households. • USAID sets money aside to investigate respondents' understanding of the informed consent process.
Often local people are	Protect the	• Adherence to international ethical standards

trusting and may not fully understand the extent to which modern technology could compromise anonymity, confidentiality and privacy.	vulnerable; ensure anonymity and privacy	guiding data collection and handling. • Agreements stating the purpose of the research and procedures for handling the data sets are developed and maintained. • Data sets are distributed only on the understanding that respondents' privacy is protected