



December 19, 2012

Margo Schwab, Ph.D.
Office of Management and Budget
725 17th Street, N.W.
Washington, DC 20503

Dear Dr. Schwab:

The staff of the NCHS Questionnaire Design Research Laboratory (QDRL) (OMB No. 0920-0222, exp. 06/30/2015) plans to evaluate the Violence Against Children Survey (VACS) in Malawi in partnership with the Malawi Center for Social Research, UNICEF Malawi, and CDC's Center Global for Health under a GenIC. The protocol was developed with the active participation of these partners.

We propose to start advertising for volunteer participants as soon as we receive clearance. Once approval is received, plans are to conduct cognitive interviews in Malawi in January 5-12.

Background Information about Cognitive Testing of Questionnaires

The methodological design of this proposed study is consistent with the design of typical cognitive testing research. As you know, the purpose of cognitive testing is to obtain information about the processes people use to answer survey questions as well as to identify any potential problems in the questions. The analysis will be qualitative.

Proposed project: Violence Against Children Survey (VACS) Evaluation Study - Malawi

Violence against children and young women is a major human rights violation and health problem throughout the world. Generally, this abuse is divided into three major categories: physical, emotional, and sexual, all of which can have significant short- and long-term health consequences for children and young women. These include injury, sexual and reproductive health problems, unintended pregnancy, increased risk of HIV, mental health issues, alcohol and drug abuse, social ostracism, and increased incidence of chronic disease in adulthood. Victims of childhood violence are more likely to engage in risk behaviors as adolescents and adults, and may be more likely to become perpetrators themselves.

Malawi is of particular importance in the study of violence against children and young women. Throughout the last several decades, Malawi has consistently had some of the poorest development indicators in sub-Saharan Africa and has consistently experienced widespread poverty, food insecurity, and high prevalence of HIV, all of which have the potential to increase the vulnerability of all children and young women. In addition, there is a large population of children who are orphans, work in agricultural or domestic settings, and/or do not attend school, which constitutes an unusually large proportion of children who may be particularly vulnerable to violence. Although there have been no nationally

representative data on violence against children in Malawi to date, available studies have uncovered high rates of physical and sexual violence experienced in childhood, particularly among girls and very young children.

The findings from the VACS will be used primarily to better understand the magnitude of violence against children and young women, especially sexual violence, and its underlying risk and protective factors in order to make recommendations to relevant Ministries to the Government of Malawi and national and international agencies and non-governmental organizations on developing strategies to identify, treat, and prevent violence against children and young women. In addition to the primary use mentioned above, the findings of the survey may also serve as a foundation for future research on violence.

Prior to the actual VACS being conducted in Malawi the instrument will undergo cognitive testing and evaluation. This cognitive interview study in Malawi is being conducted in partnership with and facilitated by the Center for Social Research (CSR) at the University of Malawi. CSR was selected as a partner for this project because of their substantial experience conducting social science research in Malawi. CSR received IRB in-country approval on October 18, 2012 from the Malawi National Committee for Research in Social Sciences and Humanities for the VACS cognitive test.

In conducting the cognitive interview study, QDRL Staff will collect information about the processes respondents use to answer survey questions, identify what the questions measure, and pinpoint any potential problems in the questions, e.g. questions which are vague or ambiguous, questions that cannot be answered readily or accurately by the respondent or otherwise contribute to the non-sampling errors of the survey. The VACS survey instrument will be evaluated for optimal design and also provide documentation supporting the validity of survey data. The documentation will guide the redesign of questions and also serve data users, allowing them to be critical users in their approach and application of the data.

As determined by all partners, the purpose of the cognitive interviewing study is to provide understanding regarding:

1. Feasibility of collecting such data given the sensitivity and age suitability of the questions
2. Assurance that meaning of terms and concepts are understood
3. Length of the questionnaire
4. Ordering of sections
5. Length of section introductions
6. Ability of respondents to distinguish between types of violence
7. Ability of respondents to distinguish specific events

The VACS Malawi questionnaire to be evaluated appears as Attachment 1. The testing procedure will conform to the cognitive interviewing techniques described in the generic OMB clearance package.

As many as twenty cognitive interviews may be conducted with 13-24 year old English speaking males and females living in Zomba.

Respondents will be recruited through flyers distributed by the Center for Social Research (CSR) to students at primary and secondary schools in Zomba and the surrounding area as well as at Chancellor College in Zomba (Attachment 2). Additionally, CSR will provide flyers to non-governmental organizations (NGOs) who work with children in the area around Zomba to recruit students who may not currently be enrolled in school. CSR will recruit, determine eligibility, and schedule

eligible respondents. During the recruitment process potential respondents between the age of 13 and 17 will be informed that a parent or primary caregiver must accompany them to the interview in order to provide consent (See Appendix 4 of the approved NCHS Ethics Review Board (ERB) Package, Attachment 3, for the full recruitment script). Additionally, “child headed households” and emancipated minors will not be eligible to participate in this study.

Cognitive interviews will be conducted by QDRL staff members in a private room arranged by the CSR with an individual participant for approximately 90-minutes each. Interviews will not be recorded.

Before beginning interviews with a potential respondent under 18, QDRL staff will obtain verbal consent from the respondent’s parent or caregiver as well as verbal assent from the child, and for interviews with respondents age 18 and older QDRL staff will obtain verbal consent. QDRL has requested a waiver of written consent due to the fact that data indicate that approximately 19 percent of women and 11 percent of men in Malawi have no formal education. As such, it would be inappropriate to expect those who are illiterate to read and sign a consent form. In addition, a signed informed consent would be the only document linking a respondent to the study. Consequently, each respondent will be read the consent form that addresses their rights and welfare as a respondent in the study and given time to ask questions and then will provide verbal consent if they agree to participate in the study. Additionally, due to the fact that the parent or primary caregiver being asked for consent could be a perpetrator of sexual, physical, or emotional abuse, QDRL requested a waiver of the requirement to inform parents of youth 13-17 years of age of the purpose of the research. The World Health Organization (WHO) guidelines recommend that the only person in a household who should be aware of the nature and contents of the survey is the selected respondent. Accordingly, for the protection and safety of the participants, parents/caregivers will be informed that the study concerns young peoples’ health, educational, and life experiences and only mentions “community violence” as part of a list of broad topics, such as access to health services and education, that are included in the survey in order to obtain permission to speak with the study participant (See Appendices 5 and 6 of the ERB Package for copies of the consent and assent forms). See Attachment 3.

The interview will begin with a brief introduction about the VACS. Interviewers will explain how the cognitive testing is aimed to gain an understanding of how respondents answer questions – what thought process they use, how they comprehend questions, and how they calculate dates and numbers of events to reach their chosen responses and that the objective of the study does not focus on what study participants/respondents answer. Because of the nature of the study, it is possible that children or adult respondents could disclose that they are (or have been) victims of violence. Regardless of whether or not such circumstances are disclosed in the interview, respondents could experience psychological discomfort given the subject matter of the questionnaire. Given both of these scenarios, a response plan which includes a referral process has been put in place. (See Appendix 1, Cognitive Interview Response Plan for more detailed information). See Attachment 3.

The study will be conducted anonymously. A unique identifier known only to the interviewer will be assigned to each study participant. No personal data (names, addresses, and phone numbers) will be collected or recorded on a questionnaire. The completed questionnaire will not contain any identifying information.

All data, including questionnaires, interviewer’s notes, and any other information collected as part of this study, will be stored in secure travel cases while in route to the QDRL at which point they will be transferred to secured locked storage cabinets. All data, including questionnaires, interviewer’s notes, and any other information collected as part of

this study, will remain the property of the QDRL.

Individuals (13-24 years of age) participating in the cognitive interview will be remunerated MK3500, which is approximately \$11 USD, for the 90-minute interview to cover the study participants' transportation and token for their participation. CSR and QDRL will attempt to recruit children who live in rural areas outside of Zomba to ensure a balance of participants from urban and rural households. This remuneration will allow respondents to travel to the interview location, which otherwise might not be possible to recruit. Importantly, all interviews must take place in 5 days when QDRL interviewers are in Malawi, requiring an incentive that would generate a prompt recruitment. Given the sensitive nature of the interview and the limited window of time, CSR and QDRL believe that an incentive is necessary for the successful completion of this project.

In total, for this project, the maximum respondent burden will be 30 hours of interviewing in addition to travel time. The burden is already accounted for in the generic clearance. An updated burden table for this genIC project is shown below:

Projects	Number of Participants	Number of Responses/ Participant	Average hours per response	Response burden
QDRL Interviews				
2) Other questionnaire testing	20	1	1.5	30

Attachments (3)
cc:
M. Moien
T. Richardson
DHHS RCO