IRB Research Plan for New Data Collection—Developed for Maternal And Child Survival Program (MCSP)

Study Title: Generic Protocol for the Evaluation of Knowledge, Practices and Coverage (KPC) through Household Surveys for Planning, Monitoring, and Evaluating Maternal and Child Survival Programs in Middle- and Low-Income Countries

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1. Aims of the Study

Primary Objectives

The primary objective of the Knowledge, Practices and Coverage (KPC) household survey is to guide the implementation of maternal, newborn, and child health interventions countries targeted under the Maternal and Child Survival Program (MCSP), a consortium led by Jhpiego and funded by the United States Agency for International Development (USAID). The KPC survey[1] is designed to help implementers of integrated maternal and child survival programs understand the health situation at a local level, such as a subnational program area (such as districts or regions) and measure progress toward program objectives, including whether intervention coverage varies across different vulnerable groups, thus, serving as input for decision making. It is a planning, monitoring, and evaluation tool. The KPC tool consists of eight modules, each containing questionnaires, indicators, tabulation plans, and instructions. Consent forms will be available for the questionnaires. Implementers select modules and questions that correspond to technical areas and interventions in a program area, thus customizing the survey to the specific needs of the program. The ultimate aim is to contribute to a reduction in frequent, preventable maternal and child deaths through the increased use and quality of known life-saving interventions.

The following modules are available to be administered along with each respondents' background, demographic, and assets information. The data collection tools submitted are referred to as modules in this protocol covering various technical areas as follows:

1. Sick Child Module (including acute respiratory infection, control of diarrheal disease, and community case management)

2. Malaria Module

3. Immunization Module

4. Maternal and Newborn Care Module

5. Pregnancy Spacing and Family Planning Module

6. Nutrition Module

7. Water, Sanitation, and Hygiene (WASH) Module

8. Background

9. Gender[2]

Secondary Objectives

1. To measure changes in knowledge of community members regarding maternal and child health

2. To measure changes in practices and care-seeking behavior of community members regarding maternal and child health

3. To measure changes in coverage of maternal and child health outcomes (which refer to maternal and health interventions, such as at the community level; coverage of maternal and child health outcomes refer to maternal and child health interventions such as DTP3, skilled birth attendance, and treatment of diarrhea with ORS and zinc)

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[1]ICF MACRO (2009), R. Davis, J. Luna, A. Rodriguez-Lainz, and E. Sarriot (2009), *The Rapid Household Survey: How to Obtain Reliable Data on Health at the Local Level* (ICF Macro: Calverton, MD; and Public Health Institute: Oakland, CA), http://www.mchipngo.net/lib/components/documents/MandE/PHI_RapidHealth.pdf.
[2] Currently being developed.

2. Background and Rationale

Poor maternal and child health outcomes are caused by a combination of factors, including lack of access to health services; poor quality of health services (including disrespectful care), and poor health behaviors or choices at the individual, family, or community level. Worldwide, more than 800,000 women die annually from complications related to pregnancy; about 60 percent of maternal deaths occur within the first 48 hours of delivery, primarily in developing countries, with postpartum hemorrhage as the leading cause of death.[3] Other common poor maternal outcomes include infection, uterine rupture dystocia, and eclampsia.[4] Health outcomes for both mothers and their newborns can be greatly improved though access to quality antenatal care, skilled attendance at birth, and postnatal care services. It has been documented that access to high-quality care provided by skilled attendants significantly improves maternal health, because it allows for early detection of problems that could result in adverse pregnancy outcomes.[5] In most sub-Saharan African countries, the rates of skilled attendance at birth are five times higher among the non-poor than among the poor. Inequities are not confined to Africa: in India, nearly 9 out of 10 women in the richest quintile have skilled assistance during delivery while only 2 out of 10 in the poorest quintile do.[6]

Under-five mortality, especially from preventable causes, continues to be unacceptably high. UNICEF estimated that in 2012 nearly 18,000 children died each day. Infectious diseases (such as pneumonia, diarrhea, and malaria), malnutrition, and neonatal complications were responsible for the vast majority of these deaths.[7] Furthermore, disparities exist in mortality rates between regions and across the social strata within each country thus necessitating careful assessment and understanding of the factors involved with a view to addressing them to fit specific situations. For example, Latin America has some of the best overall health statistics, but these numbers mask large inequities. In 2009, the region attained 94 percent average measles immunization coverage; however, the percentage of children vaccinated against the disease in Haiti, Paraguay, and Bolivia was only 60 percent, 71 percent, and 86 percent, respectively.[8] Reliable herd immunity from measles requires that immunization coverage rates for the disease reach at least 90 percent, meaning that the populations in those three countries remain vulnerable. Within countries there are also inequities. For example, in Bolivia overall infant mortality declined from 67 to 54 per 1,000 live births between 1998 and 2003. However, in 2003, the infant mortality rate for mothers without formal education was 87; and among the poorest wealth quintile, 72.9. Another example is the 2011 infant mortality rate in the Brazilian state of Amapa, which was 25.4 per 1,000 live births, more than twice the rate of Rio Grande do Sul of 11.3 per 1,000 live births in the same year.

Health managers at all levels are faced with the challenge of needing contextually meaningful information about the coverage of evidence-based MNCH intervention for program decision making in a relatively short time frame without incurring high costs. It is difficult to plan and implement effective interventions relying solely on data gathered through large national surveys that are done every 5 years such as the Demographic and Health Survey (DHS), or even every 2 years, such as UNICEF's Multiple Indicator Cluster survey (MICS). In order to improve health outcomes for children and mothers it is important to understand what is happening at the community and facility levels and to determine whether community and facility-based services are reaching families, where the gaps are, and whether or not healthy behaviors are being practiced. Just relying on national statistics will not provide accurate information for a local area, given that inequities exist within most countries.

[3]WHO, Maternal Mortality, http://www.who.int/mediacentre/factsheets/fs348/en/.
[4]Luc de Bernis, Della R. Sherratt, Carla AbouZahr, and Wim Van Lerberghe (2003), "Skilled Attendants for Pregnancy, Childbirth and Postnatal Care," *British Medical Bulletin* 67: 39–58, doi: 10.1093/bmb/ldg017.
[5]C. Rosmans and W. J. Graham (2006), "Maternal Mortality: Who, When, Where, and Why," *Lancet* 368: 1189–1200, doi:10.1016/S0140-6736(06)69380-X.
[6]K. A. Grépin and J. Klugman (2013), "Maternal Health: A Missed Opportunity for Development," *Lancet* 381, no. 9879: 1691–1693.
[7]UNICEF, UNICEF Data: Monitoring the Situation of Children and Women: Child Mortality, http://data.unicef.org/child-mortality/under-five.
[8]UNICEF, WHO, World Bank, UN Population Division (2013), Level and trends of child mortality: Report 2013, http://www.childinfo.org/files/Child_Mortality_Report_2013.pdf.

IRB Research Plan for New Data Collection

Knowledge, Practices and Coverage (KPC) Module

The KPC survey is a relatively rapid, low-cost methodology that can provide information quickly, allowing health managers at various levels of the health system to work with other stakeholders such as community members, local authorities, and finance authorities in order to make decisions based reliable information. KPC surveys provide the desired flexibility that allows measurement of differential burden of disease up to the desired level of disaggregation (e.g., district level, community level). Information from a KPC survey provides a basis for tailoring interventions so that they reach the community (coverage) and for assessing their effectiveness toward reducing morbidity and mortality in the long run. These surveys are meant to complement other forms of information collection, such as qualitative studies, to understand why services are not reaching communities or why healthy behaviors are not being practiced. This household survey can be part of a regular monitoring and evaluation system. Questions have been harmonized with the DHS and MICS where appropriate.

We expect to conduct the KPC survey as requests arise in the 24 USAID priority countries (identified by USAID's Office of Health, Infectious Disease and Nutrition) that are the focus of the MCSP.[9] Surveys may also be implemented in additional countries as requested by USAID missions. This protocol focuses on using the KPC modules to tailor household surveys for use in a variety of maternal and child survival programs in different countries.

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[9] The 24 priority countries are Afghanistan, Bangladesh, Democratic Republic of Congo, Ethiopia, Ghana, Haiti, India, Indonesia, Kenya, Liberia, Madagascar, Malawi, Mali, Mozambique, Nepal, Nigeria, Pakistan, Rwanda, Senegal, South Sudan, Tanzania, Uganda, Yemen, and Zambia.

3. Study Design

The study consists of a cross-sectional household survey to collect knowledge, practice, and coverage information on maternal, child survival, reproductive health, and gender interventions from mothers and/or fathers of children under 5 years of age and/or from women ages 15–49 years and/or men ages 15 years and older. These surveys will be done at different time points during project life cycles in order to measure changes over time. Anthropometric information from children under 5 years of age whose mother is interviewed will be collected.

The KPC surveys will be implemented in the 24 priority countries where the USAID-funded MCSP will have a presence as well as other countries where in-country USAID missions buy into MCSP to conduct these studies. This generic protocol will have JHSPH (Johns Hopkins Bloomberg School of Public Health) as the IRB of record; the MCSP consortium partner IRBs (JSI [John Snow International], PATH, PSI [Population Services International]) will receive the final approved version. Country-specific plans detailing the sampling and procedures will be added to this generic protocol as "annexes"; this will be done through submitting amendments of the generic protocol to JHSPH's IRB, reflecting any relevant changes that will be made in order to maintain the annexes added as subsets of the generic protocol.

The KPC is a flexible survey tool that can be tailored for various technical areas and combination of areas while maintaining standards for collection of information for specific interventions. For example, all programs that include control of diarrheal disease will collect information about the percentage of children who had diarrhea in the two weeks preceding the survey, were given oral rehydration solution (ORS), and were given zinc. However, programs that do not focus on diarrhea will not collect information on treatment of diarrhea.

KPC surveys will be repeated at various times during MCSP program implementation in a target country, from annually to every 2–3 years. In most cases surveys will be implemented only in MCSP intervention areas, but if the opportunity exists surveys may also be carried out in comparison areas. Specific details for each country conducting a KPC survey will be added as an annex to this generic protocol.

Justification of Sample Size

In order for the KPC to be adapted to what is needed for specific studies, the design provides for limited choices regarding sampling methodology, household selection, respondent selection, and sample size. Each study amendment will specify which options were chosen to be implemented in the individual study.

Sampling Methodologies

The following are the three options for sampling methodology, each of which can be implemented with or without parallel sampling. All sampling methodologies will include a step of choosing clusters.

1. 30-cluster, with number of interviews conducted per cluster varying from 7–30

    a. Parallel sampling

    b. Without parallel sampling

2. LQAS (lot quality assurance sampling), minimum of 19 interviews per supervision area, minimum of 5 supervision areas

    a. Parallel sampling

    b. Without parallel sampling

3. Stratified random sampling

    a. Parallel sampling

    b. Without parallel sampling

Choosing Clusters

Clusters will be determined by probability proportion to size (PPS). The definition of a cluster may vary country to country. In most cases clusters will be communities in rural areas and neighborhoods in urban areas; however, alternative divisions of populations may be used if appropriate to the country setting. The following are the steps for PPS:

1. Create a list (ordered randomly) of communities (or other appropriate division), the population for each, and the total population of all communities (estimates are fine).

2. Calculate the cumulative population of each community by summing the total population of the community with the combined total population of all the preceding communities on the list.

3. Determine the sampling interval by dividing the total population of the entire program area by the total number of clusters, which is 30 for a 30-cluster survey, a minimum of 95 for LQAS, and a minimum of 96 for stratified.

4. Choose a random number to identify the starting point on the list to begin selecting clusters. The random number must be less than or equal to the sampling interval.

5. Beginning with the random number, use the sampling interval to identify communities for the clusters (30, 96, or 95).

Household Selection (within a Cluster)

The following are options for household selection.

1. In the field, at the time of conducting interviews
   a. "Spin the bottle"
   b. Mapping
2. With a pre-existing list

In all cases larger clusters should be subdivided before beginning household selection. For urban areas in particular, selection rules must be developed ahead of time on how to handle different housing types, such as high rises or multiple families living in a single dwelling. "Spin the bottle" and mapping are applied at the time of data collection, while using a pre-existing list involves household selection before beginning data collection in the field. For "spin the bottle," the interview team selects the center of the cluster and spins the bottle to determine which direction to go for interviews. Households are selected based on a set (kth) interval of households from the center or the nearest neighbor's door.

Mapping involves walking around a community with local leaders, identifying all households, drawing a map, and randomly selecting the first household. Subsequent households are selected the same way as "spin-the-bottle." If a pre-existing list is available, then households can be selected at random before arriving at the cluster.

Respondent Selection (within a Household)

In all cases adult women and men will be interviewed, and in all cases only one eligible women or man will be interviewed per household. They will be asked specifically about their own health experience or, in the case of men, also about the health of their wives or partners. They will be asked about the health experiences of one of their children. Specific studies will first choose from the following adults to interview:

1. Mothers of young children
2. Fathers of young children
3. Women of reproductive age (15–49 years)
4. Men of reproductive age (15 years and older)

For studies that interview parents of young children, adult respondents will be narrowed to parents of children of specific age groups or children who were ill during the previous 2 weeks. Information will only be collected from parents of children younger than 60 months. Information will be only collected about one child per age group per household and only one child per illness group per household. The following are possible age and illness groups:

0–5 months	12–23 months	With fever in previous 2 weeks
0–11 months		With diarrhea in previous 2 weeks
0–23 months	6–23 months	With fast or difficult breathing in the previous 2 weeks
0–59 months	2–59 months	

For example, if a study needs information on excusive breastfeeding of children 0–5 months of age, immunization coverage for children 12–23 months, mothers' decision making regarding immunization, and fathers' decision making regarding immunization, the study would include respondents who are mothers of children 0–6 months of age, mothers of children who are 12–23 months of age, and fathers of children who are 12–23 months of age.

For surveys that include anthropometry (specifically, weight of children 0–59 months, height of children 24–59 months, and length of children 0–23 months), children 0–59 months whose mothers are interviewed will be weighed and have their height or length taken.

For studies that interview women and/or men ages 15–17 years, consent will be obtained from an adult in the household to conduct the interviews or, in the case of emancipated minors (according to local legal definition), they will give their own consent.

Households within each sampled cluster will be visited by the data collectors. Interviewers will ask to speak to an adult (18 years of age or whatever the local legal age of majority is), and if available the interviewers will ask screening questions (and fill out a screening form) to determine whether an eligible mother or father is present in the household. The screening form will be destroyed at the end of the fieldwork. If the answer is yes, and he or she is home and he or she agrees to participate following an informed consent/assent process, then he or she is interviewed. If he or she is not home but expected back within 30 minutes, the interview team will return to the house no more than three times before finishing all the interviews in the area. If unavailable, he or she will be counted as "Non-response" and substituted with someone from another household.

When no eligible mother or father is available in a household, then the interview team proceeds to the next house selected to be visited. If a mother has more than one child age 0–59 months, normally they will be asked about the youngest child. However, for some countries, it can be predetermined to select one of the mother's children at random.

Sample Size Determination

Specific sample sizes will vary from country to country. However, sample sizes will be calculated to provide estimates with confidence levels of 95 percent and precision of 10 percent for key indicators. For stratified random sampling and LQAS the design effect is 1. For 30-cluster sampling a design effect of 2 will be assumed. For all cases, if indicators are to be disaggregated, the total sample size must be multiplied by the number of disaggregation categories; if parallel sampling is needed the sample size must be increased to ensure adequate sample sizes for all indicators collected. Final sample sizes will be powered on the most important indicators, which may result in wider confidence intervals for a few of the other indicators.

For individual studies, decisions will be made regarding the most important indicators for which to collect information. The sample size will be powered for these indicators. After this the study will use the

appropriate sample size formula based on the chosen sampling methodology. The value of p (proportion) should be .5 (50%) given that these surveys collect information from a variety of indicators with varying proportions in a population, many of which may not be known before the survey is implemented. A p value of .5 gives the maximum sample size needed to estimate any level.

The sample size for a single survey designed to estimate levels at one point in time (not compared with another group) will be determined by the following:

For stratified sampling, simple random sampling, and LQAS:

$$N = Z\alpha^2 \, pq \, / \, d^2$$

- $Z\alpha = 1.96$ corresponding to a confidence level of 95%
- $p = 0.5$ (maximum sample size)
- $q = 1 - 0.5 = 0.5$
- d = accuracy desired = 10% = 0.10
- $N = (1.96)^2 \times 0.5 \times 0.5 \, / \, (0.10)^2 = 96$

For 30-cluster sampling, samples size collected from the preceding formula will be multiplied by 2:

$$N_C = N \times \text{deff}$$

Thus, $N_C = 192$

The number of households visited will be calculated based on estimates of the percentage of families expected to have children in the needed age groups. For example, if it is estimated that 45 percent of households have children 0–23 months and 166 eligible mothers must be interviewed, then survey teams may have to visit $N_1 = 166 \times (100 \, / \, 45) = 369$ households.

Sample sizes for comparison of two phases or groups will use the following formula for stratified random sampling or simple random sampling:

$$N_1 = N_2 = [Z\alpha_{/2} + Z\beta]^2 \, [2pq] \, / \, (p_1 - p_2)^2 = [1.96 + 1.28]^2 \, [2(.5)(.5)] \, / \, (.2)^2 = 131$$

- N_1 = baseline sample size
- N_2 = final evaluation sample size
- $Z\alpha_{/2}$ is the Z value corresponding to the chosen level of risk α. ($Z\alpha_{/2}$ should be used in two-sided tests, and $Z\alpha$ should be used in one-sided tests.)
- $Z\beta$ is the Z value corresponding to the chosen level of risk β (it directly relates to the "power" of the test as power = $1 - \beta$; ($Z\beta = 1.28$ for a power of .9)
- p_1 is the expected coverage at baseline (can be set to .5 for maximum sample size)
- $q_1 = 1 - p_1$
- p_2 is the expected final coverage (can be set to .5 for maximum sample size)
- $q_2 = 1 - p_2$
- $p = (N_1 \, p_1 + N_2 \, p_2) \, / \, (N_1 + N_2)$
- $q = 1 - p$

For 30-cluster, the final value calculated from the preceding formula is multiplied by 2 (design effect) for a sample size of 262. If it is estimated that 45 percent of the households will have eligible mothers, then the total number of household that must be visited is $N_{1t} = N_{2t} = 262 \times (100 / 45) = 582$

Next, if cluster sampling methodology is used, a decision will be made to either to increase the total number of interviews in order to disaggregate into the needed age and illness groups of the children or to use parallel sampling. For example, if information is needed on exclusive breastfeeding of children 0–5 months of age and immunization coverage of children 12–23 months, the sample size as determined by the formula could be multiplied by 4 in order to have enough children 0–5 months to provide exclusive breastfeeding estimates with confidence levels of 95 percent and precision of 10 percent. So, if the original estimate is 210 then the actual sample size will be 840 (4 × 210). However, if parallel sampling is used, then 210 mothers of children 12–23 months and 210 mothers of children 0–5 months should be interviewed for a total of 420 mothers interviewed. In this case it is only necessary to multiple the *n* calculated from the sample formula by 2.

Parallel sampling is especially useful for cluster sampling when information is needed about indicators with different denominators, such as for the following:

Indicator	Denominator
Exclusive breastfeeding of children 0–5 months	Children 0–5 months
Immunization coverage of children 12–23 months	Children 12–23 months
Decision making of mothers	Mothers
Decision making of fathers	Fathers

If LQAS or stratified random sampling methodologies are used, parallel sampling must be used if information is collected for indicators from different age and illness categories of children.

Specific studies will arrive at sample sizes though the following steps. Decisions made will be part of individual study protocols. The steps are as follows:

1. Decide on most important indicators.
2. Choose appropriate sample size formula.
3. Use $p = .5$.
4. Calculate sample size based on appropriate formula.
5. If using cluster methodology, decide between inflating the total sample size to allow disaggregation into appropriate age and illness groups or using parallel sampling.
6. Adjust the calculated sample size number by needed disaggregation or to collect parallel samples.

For Anthropometry

Weight and height will be taken of children either 0–59 months or 0–23 months only where the mother was interviewed; where the father was interviewed; anthropometric measurements will not be taken. The same six steps will be followed for children. Only one child will be measured for households. Thus, for surveys that include anthropometry, the sample size will be calculated for them separately from the sample size calculated for the adult respondents.

Participants

Study participants will be from areas where MCSP is implementing programs and in some cases from control areas where MCSP is not working. Participants will be from the following groups:

1. Mothers of young children

2. Fathers of young children

3. Women of reproductive age (15–49 years)

4. Men of reproductive age (15+ years and older)

5. Children 0–59 (for anthropometry, specifically weight and height) of mothers who are being interviewed

Respondents will be adult women and men. However, for surveys that focus on child health or maternal and newborn care (MNC) a subset of women and/or men will be interviewed who have children of specific age groups, illness categories, or, in the case of MNC women (or wives/partners) who have delivered in the last 2 years, 1 year, or 6 months.

If anthropometry is collected from children, then children 0–59 months whose mothers are interviewed are also participants. Only one child per household will be measured. Amendments for specific studies will describe methodologies used to train data collectors on anthropometric measurement.

Inclusion or Exclusion Criteria

Only one adult woman and/or one adult man will be selected in a household where there are multiple eligible participants. Anthropometric data (length, height, and weight only) will be collected from only one child of the mother being interviewed. Study participant women and men will provide oral consent and will be informed that they do not have to answer all questions and can end the interview at any time. Mothers will provide oral consent for anthropometric measurements to be taken from the chosen child.

See section on selecting the respondent in a household for additional details.

4. Study Procedures

Recruitment Process

Before beginning field work, the research team will contact national and regional or county level authorities in writing, describing the study and seeking permission to carry out the KPC survey. The relevant authorities will communicate to the community leaders about the study through their usual channels such as letters introducing the research team to them. Next the research team will approach community leaders and local administrative authorities and describe the study to them. Once local leaders and authorities give permission for the study to proceed, they will then inform their communities about the study through public notices, gatherings, and other fora. Thereafter the research team will commence with recruitment of individual study participants.

For recruitment in a selected household, data collectors will introduce themselves and the study, then seek permission to interview from an adult present (18 years and older or according to the local age of majority). The interviewer will follow the steps outlined in the household screening form to first, seek permission to ask screening questions, and then, if permission is granted, determine the number of eligible participants.

If there is an eligible participant, informed oral consent will be obtained before interviewing can commence (see the following section on consent procedure). If he or she is not home but expected back within 30 minutes, the interview team will return to the house no more than three times before finishing all the interviews in the area. If unavailable, he or she will be counted as "Non-response" and will be substituted with someone from another household.

Refer to the country-specific annex for recruitment details.

Consent Process

Members of interview teams, including supervisors and data collectors, will be trained using the JHSPH Human Subjects Research Ethics Field Training Guide. They will also be oriented on the study protocols, data storage procedures, recruitment and consent forms, and data collection tools. Additional training will be provided on interviewing techniques. MCSP Program, Technical, and M&E staff will supervise the interview team during the data collection process. Throughout field-based activities, the data collected will be reviewed daily to identify any potential issues with the interview tools or interviewers. No personal identifiers will be collected, and participants will be assigned study IDs.

Women and men will provide oral consent to be interviewed. Study participants will be asked individually to consent to being interviewed. Data collectors will explain the purpose of the study, how the household was selected, interview procedures, risks, and benefits. The participants will be informed that they can stop the interview at any time. Emancipated minors (according to local legal definition) who are 15–17 years will provide their own consent as participants. Mothers will provide oral consent for anthropometric measurements to be taken of their children. Adult respondents will be asked to suggest a private location in the homestead or close by where an interview can be conducted in private; all interviews will be conducted at locations that assure audio privacy. Privacy and confidentiality will be maintained during interviews and handling of data obtained. Mothers and fathers with small children may be permitted to participate in the interview in the presence of the child.

We are requesting a waiver of signed consent. The KPC studies will be conducted primarily for the purposes of program learning around integrated service delivery and health systems issues in order to inform national and international programs. A participant's signature on a consent form would, by definition, be a record of the identity of participants. By not having the participant sign or mark a consent form, we can avoid collecting or keeping any identifiers. Study participants will learn about the study and have ample chance to ask questions about the study through use of the enrollment and consent script.

Study Implementation

1. Participants will be recruited (approximately 5 minutes) and consent will be obtained (approximately 5 minutes) and then the questionnaire will be administered.

2. Each household will be visited no more than three times in an attempt to locate a selected respondent. The interview will take about 60–75 minutes depending on the number of modules included for that country. Interviews will take place in or near the home, in a private location where the interview is unlikely to be overheard.

3. Each individual respondent will be asked to spend about 60–75 minutes with the interview team, including introductions, description of privacy measures, consenting, and responding to interview questions. Respondents will *not* be followed up for additional information. The majority of the studies will be cross-sectional of 1–4 months' duration per each data collection period.

4. The interview team will provide a brief data analysis plan and a description of variables to be derived. Each survey module contains indicator definitions and tabulation plans. Analysis will generally focus on generating frequencies and occasionally on cross-tabulations. (See modules for details.) For example, the on the data tabulation plans for selected key maternal indicators is based on data collected through the Maternal and Newborn Care Module. Any statistical software or hand tabulation procedure may be used as long as standardized tabulation plans are followed. In addition, for LQAS, decision rule tables will be used to assess whether or not a supervision area has reached expected results. However, care will be taken not to prematurely remove resources from any supervision area

The following are examples of indicators and tabulation plans from the MNC module.

Illustrative Key Maternal Health Indicators	
Indicator 1.2	Antenatal Care (4+ visits)
Indicator 1.13	IPTp (3+)
Indicator 1.14	LLIN Use
Indicator 2.1	Skilled Attendant at Birth
Indicator 2.2	Facility Birth

Data Tabulation Plans[10]		
1.2, 6.2 Antenatal Care (4+) Percentage of mothers of children ages 0–23 months who had four or more antenatal visits while pregnant with their youngest child	Number of mothers of children ages 0–23 months who had four or more antenatal visits while pregnant with their youngest child **$4 \leq MN105 < 98$** ——————————— Total number of mothers of children ages 0–23 months in the survey	$\times 100$

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[10]These tabulation plans and indicators are examples from one of the current modules (Maternal and Newborn care). Target populations (denominators) for these indicators may vary, depending on the specific survey. Variations will be explained in amendments submitted for specific surveys.

Data Tabulation Plans[10]		
1.13.Intermittent Preventive Treatment for Pregnant Women of Malaria (3 doses) Percentage of mothers of children age 0–23 months who received three or more doses of Intermittent Preventive Treatment for pregnant women (IPTp) for malaria while pregnant with their youngest child	Number of mothers of children age 0–23 months who received three or more doses of Intermittent Preventive Treatment (IPTp) for malaria while pregnant with their youngest child **MN127 ≥ 3** <hr>Total number of mothers of children age 0–23 months in the survey	× 100
1.14 Long-Lasting Insecticidal Net (LLIN) Use Percentage of mothers of children ages 0–23 months who slept under an LLIN all of the time or most of the time while pregnant with their youngest child	Number of mothers of children ages 0–23 months who slept under an LLIN all of the time or most of the time while pregnant with their youngest child **[(MN129 = 1 OR 2) <u>AND</u> (MN130 = 1 OR 2)]** <hr>Total number of mothers of children ages 0–23 months in the survey	× 100
2.2, 7.2 Facility Birth Percentage of last-born children ages 0–23 months who were born in a health facility	Number of last-born children ages 0–23 months who were born in a health facility (excludes mobile clinic) **MN201 = Any response [A–C, F, G]** <hr>Total number of children ages 0–23 months in the survey	× 100

5. Describe whether you are collecting or storing personal identifiers; if yes, describe why you need them and when and how you plan to dispose of them. Signatures on consent forms are considered to be identifiers. Privacy and confidentiality will be maintained during the interviews of participants by ensuring that records are kept in safe storage and that interviews will be conducted privately. Personal identifiers will not be collected and oral consent will be obtained unless the in-country regulations require otherwise; the US-based IRB will be informed and concurrence sought. Interviews will be anonymous. In situations where signed consent forms are used (e.g., if that's a requirement by a local IRB), the consent documents will be stored in a locked cabinet separately from the completed data collection forms; the only link will be the study IDs, which will also be stored in a locked cabinet, accessible only by select members of the study team. In these cases the consent form will be located in a tear-off sheet that will be separated from the rest of the survey form. (If a survey collects data using mobile devices or tablets, specific electronic data storage precautions will be included in an amendment protocol specific to that survey.)

5. Data Custody, Security, and Confidentiality Protections

The information in this section has been taken from a standard IRB form. This section serves as a guide for understanding additional information that will be needed when submitting a specific KPC survey protocol for IRB approval.

Data Storage

Mark with an X all that apply. If not applicable, write N/A.

1. Hard Copies of Data Collection Forms	
	This activity will not involve receiving and/or accessing hard copies of data.
	Data collection forms RECORD NO PERSONAL IDENTIFIERS connecting study participants, and there are no codes providing a link. Data are anonymous.
	Data collection forms INCLUDE IDENTIFIERS. The forms are locked in a secure cabinet or room with limited access by authorized individuals. Forms will be kept in study team's possession during transport and will not be left unattended in a vehicle. When possible, de-identified copies will be used for coding and analysis.
	Data collection forms ARE CODED with study participants' random study ID numbers. Codes/links between study IDs and identifiers are stored securely in a separate place (locked storage cabinet or secure electronic database.)
	Other:
2. Electronic Data	
	The data do not contain personally identifiable information
	These data are stored on a secure server protected by limited access and strong password systems. Data are coded when possible. Portable electronic devices will not contain identifiable information unless encrypted.
	Other:
3. Other Identifiable Data Storage, Retention, and Destruction (audiotapes, videotapes, photographs, etc.) will be retained and stored securely (locked in cabinet or room) until:	
	Transcription is complete, then will be destroyed.
	Analysis is complete, then will be destroyed.
	Study is complete and file is closed.
	Indefinitely. Provide justification for indefinite retention:
4. Existing Biospecimens to Be Used in this study:	
	HAVE NO PERSONAL IDENTIFIERS.
	INCLUDE IDENTIFIERS AND ARE CODED; the PI *will not have access* to the link or code connecting the identifiers to the specimens.
	INCLUDE IDENTIFIERS, and the *PI has access* to those identifiers or to the link/code connecting specimens to individuals. The identifiers and/or code will be stored securely until the study is complete.

For the household survey, no personal identifiers will be collected and thus they will not be included in the electronic database. Paper versions of the completed survey forms will be kept at MCSP office for 3 years after the completion of the study then shredded thereafter; the electronic database will be archived.

5. Risks of the Study

Describe the Risks

There are no anticipated physical risks for participation in this study. The potential nonphysical risk for recent mothers and health workers include their personal information being shared with the study personnel, Ministry of Health personnel, or community members. This can be considered minimal risk, as little or no information of a confidential nature will be collected. All information collected during the assessment will be treated as confidential. Some participants might feel a bit uncomfortable discussing some of the topics. This will be mitigated by assuring the participants of confidentiality of information provided. Furthermore, no personal identifiers will be collected through the data collection tools or entered into the electronic database, further ensuring confidentiality.

Describe the anticipated frequency and severity of the harms associated with the risks identified above; for example, if you are performing "x" test/assessment, or dispensing "y" drug, how often do you expect an "anticipated" adverse reaction to occur in a study participant, and how severe do you expect that reaction to be?

Expected harm as a result of participating in this study is minimal. Respondents only participate once in the survey. There is no intervention, therefore adverse events are not relevant.

Describe steps to be taken to minimize risks. Include a description of your efforts to arrange for care or referral for participants who may need it.

Interviews will be administered in a private area within the homestead or nearby; respondents will not be required to travel away from their homes in order to participate. The respondents will assist in identifying a suitable location.

Describe the research burden for participants, including time, inconvenience, out-of-pocket costs, and so on.

The only burden for respondents is up to 75 minutes of time spent during the household visit, including the interview. There will be no payments or monetary compensation of study participants since the interviews will be done at their homes.

Describe how participant privacy will be protected during data collection if sensitive questions are included in interviews.

Private locations will be located for interviews to project participant privacy. No sensitive questions, such as HIV status, will be asked.

6. Direct Personal and Social Benefits

Describe any potential direct benefits the study offers to participants ("payment" for participation is not a direct personal benefit).

There will be no direct benefits to individual study participants; they will not receive any payment or other compensation.

Describe potential societal benefits likely to derive from the research, including value of knowledge learned.

It is expected that through the survey information, community level coverage of healthy behaviors and health-seeking practices will improve at the same time that health interventions will be more effectively targeted to the health situation in the community.

7. Payment

No payment or other means of compensation will be made to study participants.

8. Study Management

Oversight Plan

Describe how the study will be managed.

An MCSP studies steering committee will be constituted at the MCSP headquarters comprising the investigators listed in this protocol and other MCSP staff at managerial positions who provide oversight. The committee will meet at least once a quarter to review the status of each in-country KPC study.

What are the qualifications of study personnel managing the project?

The members of the "core team" are as follows: *add specific names and qualifications here.*

How will personnel involved with the data collection and analysis be trained in human subjects research protections? (Use the JHSPH Ethics Field Training Guide on our website).

All investigators who are members of the Core team have completed CITI training or the equivalent for their organization (ICF International). The local co-investigators and field staff will train in human subjects research protections, by one or more members of core team. The training will follow JHSPH Ethics Field Training Guide and conform to the in-country requirements.

If the PI will not personally be on-site throughout the data collection process, provide details about PI site visits, the supervision over consent and data collection, and the communication plan between the PI and study team.

In situations where the PI is not in a position to visit a study site, one of the core team will visit each site at least twice: once to plan the assessment with the MOH, Jhpiego, USAID, and local counterparts at the start of the assessment for training and to supervise data collection to ensure quality procedures and adherence to human subjects research protocol, and a second time toward the end of data collection to ensure data are

completed and entered and to supervise preliminary analyses and reporting to MOH and counterparts. During interim periods, the research team will conduct teleconferences or email updates every 2 weeks with in-country teams, Jhpiego, and in-country co-investigators.

Recordkeeping

Describe how you plan to ensure that the study team follows the protocol and properly records and stores study data collection forms, IRB regulatory correspondence, and other study documentation.

Safety Monitoring

N/A

Other IRBs/Ethics Review Boards

Approval will be sought from local IRBs in countries that have them. In countries without a local IRB, a letter of approval will be sought by the local Ministry of Health.

Collaborations with Other Institutions

Insert Name of Institutions in Partner column(s); add additional columns if necessary.

	Partner 1	Partner 2	
Primary grant recipient			
Collaborator			

For the following, indicate "P" for "primary" and "S" for "secondary" as appropriate to role and level of responsibility. Add additional items if useful.

1	Human subjects research ethics training for data collectors			
2	Day-to-day management and supervision of data collection			
3	Reporting unanticipated problems to the JHSPH IRB/sponsor			
4	Hiring/supervising people obtaining informed consent and/or collecting data			
5	Execution of plan for data security/protection of participant data confidentiality, as described in Section 5.			
6	Biospecimen processing, storage, management, access, and/or making decisions about future use			