

The Realities of Conducting Reproductive Health-based Studies in the Developing World: Cases from Mali & India

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This field notes article provides an overview of two reproductive health research studies previously conducted in Mali and India and the methodological lessons learned. The lessons learned from these studies were: 1) to effectively emphasize the protocol for the study and the specific timeline to which all study coordinators/partners will adhere; 2) to obtain both written and oral agreements from all the partners to abide by the protocol; 3) to ensure the study tools are approved for use by all study coordinators; 4) to ensure adequate resources are available for use prior to the beginning of data collection; and 5) to provide adequate training to all interviewers and personnel who will be interacting and working with study participants. By following these steps, study investigators in the future will be able to effectively carry out international public health research.

Social science research is essential to understanding and describing the nature, magnitude, determinants and consequences of reproductive health-related behavior and their associated morbidities and mortalities.¹ According to the World Health Organization (WHO), in order to understand the nature of behaviors and illnesses associated with reproductive health, the consequences of reproductive health problems in social, cultural and economic terms should be explored and understood.¹ The need for qualitative research with a particular focus on exploratory methods is especially necessary when attempting to describe the factors that influence women's health specifically.^{2,3} Various sampling approaches, such as location sampling, snowball sampling and respondent-driven sampling, have all been used and explored for the purposes of understanding reproductive health-related behaviors and sexual health.¹ The purpose of this paper is to add to the limited existing literature on methods previously used for the purpose of learning more about women's reproductive-related health behaviors in both Ségou, Mali and Karnataka, India. Furthermore, this paper will provide specific examples of methodological limitations that arose throughout these two studies and how they may be addressed in the future.

Background & Previous Research:

The overall maternal mortality ratio (MMR) globally has dropped 45 percent since 1990, largely due to public health initiatives driving to reach the United Nations Millennium Development Goal (MDG) of helping improve maternal health globally.^{4,5} However, this decrease in overall MMR still lies far off from the goal of decreasing by 75 percent by 2015.^{4,5} Every day, approximately 800 women around the world die from preventable causes related to pregnancy and childbirth, 99 percent of which occur in low- and lower-middle income

countries.^{4,6} The rates of MMR in these developing regions are approximately fourteen times higher than those of higher income nations with the highest rates seen in Sub-Saharan Africa (510 per 100,000 live births) and Southern Asia (190 per 100,000 live births).^{4,6} Most of these maternal deaths are preventable through the use of common medical practices such as antenatal care, skilled birth attendance and educational services for vulnerable populations.^{4,6}

Utilization of antenatal care services has been recommended by the WHO as a means to ensure the well-being of mothers and newborns along with the use of skilled care during and after childbirth.^{4,6} The utilization of these services along with educational and preventative programs, such as handing out cost-effective educational brochures and community education, has been proven to be effective in preventing detrimental conditions and even death.⁷ Previous studies have shown that strong determinants of antenatal care service utilization are religion, traditional or cultural beliefs, women's autonomy or decision-making capability, exposure to media or healthcare messages and the presence of social groups.⁸⁻¹⁵ These determinants for antenatal care service utilization were the foundation and justification for conducting both of the studies in Mali and India detailed in this paper.

The need for identifying and sharing the most effective practices to help strengthen health systems has been identified in the Global Health Strategy of the United States Department of Health and Human Services (HHS).¹⁶ HHS states that by promoting the global exchange of the best practices and lessons learned, we will ensure that the evidence supports decisions and program implementation.¹⁶ In a recent study conducted in Mali in 2011, researchers from Emory University aimed to identify and address underlying social determinants of poor maternal health in rural areas through the use of in-home interviews and surveys of other members in the household.¹⁷ While

the study successfully established the importance of mothers-in-law in determining the utilization of maternal health care, the cross-sectional design placed limitations on the study. Some of these limitations were the inability to determine causality (due to being carried out at one point in time and giving no indication of the sequence of events) and also the possibility of recall and social desirability biases due to self-reporting.^{15,17-19} In a similar study conducted by UK-based researchers, they stated that the most effective way of understanding social processes and the beliefs they form and influence is through the use of qualitative research.³ Another study stated that incorporation of cognitive interviewing and in-depth qualitative research allow for the development of scales that capture the element of agency in maternal care seeking.¹⁷

The purpose of this article is to add to the existing literature on methods that have and have not worked in both low and lower-middle income countries. This paper will present background information on each of the previously conducted studies and their methodologies followed by a discussion of the methodological challenges faced in each of the studies. The study conducted in Mali was discontinued due to its limitations. Both of these studies were conducted and chosen by the author, as they provide ideal examples of methodological challenges international researchers may face. When conducting global health research, specifically in countries like Mali and India, investigators must be tactful in their approach. Sensitive topics such as sexual history, the discussion of miscarriages or abortion, having a history of sexual assault, as well as the level of autonomy or power from familial influence are often considered taboo to discuss, especially with a foreign/external study investigator. This paper will discuss two studies that were conducted and the challenges faced while working with these sensitive subject matters in two different cultures.

Studying Vesicovaginal Fistula (VVF) in Mali

The World Health Organization has called VVF “the single most dramatic aftermath of neglected childbirth.”²⁰ Vesicovaginal fistula is a condition seen most commonly in women under the age of 25 in low and lower-middle income nations.^{21,22} It occurs when there is pressure necrosis from the fetal head on the vagina and bladder tissues during prolonged and obstructed labor.²³ As a consequence, perforations develop on the walls of the vagina and the bladder, causing a constant and uncontrollable flow of urine from the vagina.²³ VVF is seen in low income nations due to biological, social and economic factors.²¹ The main biological factor that affects the development of VVF is the predisposition of African women for having dystocia, or physical blockage during childbirth, due to the relatively narrow structure of the pelvis.²¹ This condition is worsened when women are undernourished throughout their childhood and adolescence.²¹ In many African countries, girls are married at a very young age due to social pressures resulting in pregnancies that antecede pelvic maturity.²¹ Although the occurrence of obstructed labor is most common in younger women, a woman at any age could develop VVF due to an array of factors including large fetal size, malpresentation and intervening diseases.²¹

In most low-income nations, women have little or no access to antenatal or obstetric care, and once they develop VVF, nearly all women go untreated, even though surgery could easily correct the obstetric fistulas.^{20,24,25} Due to the smell of urine on their body and clothes, as well as their inability to have more children, the women are often cast out from their communities and left to fend for themselves.²⁰ By understanding the factors that affect women in the medically under-served populations of rural Africa, treatment and educational programs that address the socially stigmatizing consequences

of the disease could be developed in the hopes of one day eradicating VVF from the developing world.

Methodology used for Vesicovaginal Fistula Study among Malian Women

This study was a qualitative case-control study based on information collected via personal interviews from VVF patients in Ségou, Mali. This study aimed to determine the possible factors that affect the development of VVF in women at reproductive age. The study population consisted of women who were in Mali and had undergone the VVF correctional surgery through an organization called Physicians for Peace prior to the time of the study. Physicians for Peace is an organization that was established on the premise of working with the underserved populations of developing nations by building long-term, sustainable medical education and training to care for local communities.²⁶ With this understanding, determining effective means of treatment and prevention education for local communities is critical to the successful eradication of VVF in low income nations. The case group consisted of women in the rural regions of the Tiby cluster in Mali who had undergone the surgery after the creation of the program. The control group consisted of healthy women who were from this particular locality and had not undergone the correctional surgery. There were two surgical missions carried out by Physicians for Peace in 2009, both of which acted as the population base for the case group in this study.

The questionnaire that was to be administered in Mali was developed in collaboration with Physicians for Peace. The goal was to cover 50 percent of the women who received the surgical intervention, which were approximately 30 individuals in the case group and a similar sample size for the control group. Two sets of questionnaires were formulated and sent to the health workers employed by the Millennium Cities Initiative (MCI) and the Millennium Villages Project (MVP) in Mali to determine if the questions were appropriate for the study populations. Once finalized by Physicians for Peace and the workers of MCI and MVP, the questions were to be sent to Mali to be translated into the local dialects.

The final two questionnaires that were developed covered the following topics: social and family life, economic status, social expectations and cultural norms, sexual and reproductive history and medical history. The questions that pertained to sexual assault under the sexual history section were developed as a means to determine if there is a link between the prevalence of sexual assault and the development of VVF, as suggested by previous literature. If a link were observed between the prevalence of sexual assault and VVF, it would have provided justification for additional studies in the future to examine the correlation.

Trained community workers who worked with MCI and/or MVP and resided locally in Ségou were to assist in the interviews of the women selected to participate in the study. Women being interviewed were required to sign an informed consent form in the language they could understand. For the purposes of this study, individuals under the age of 18 were not included in the study as there are many socio-cultural factors, such as power dynamics within the home or limited autonomy, which may have prevented these women from receiving parental or guardian approval. The interview required four categories of information from their participants: information on their social, cultural and economic standing and on their sexual practices.

Once the questions were translated, the health workers of MCI and MVP were to be administered the surveys to the study popu-

lation. After all the interviews were completed, the data was to be sent to the Physicians for Peace headquarters in Norfolk, VA to be translated to English by their employees. Only Physicians for Peace and the health workers in Mali would know the identity of each of the individuals in the study as the interview manuscripts were to be de-identified before being provided to the study investigator. This was to ensure that the identity of the study participants and their private medical history would be protected. The interview manuscripts were then to be sent to the study investigators for further analysis and dissemination of results.

Utilization of Maternal Care Services during pregnancy in Karnataka, India

In India, approximately 28 million pregnancies take place with 67,000 maternal deaths and one million women left with chronic ill health each year.²⁷ Maternal mortality and morbidity in India are the result of a confluence of factors, some of which are potentially harmful social norms, attitudes and practices as well as a lack of basic health knowledge.^{27,28} As a result of public health initiatives within communities across India, maternal mortality rates have been on the decline since the early 1990s from 560/100,000 live births to 190/100,000.^{29,30} However, several of the community-based programs and solutions available have extremely low rates of utilization.^{27,28} These programs have not always been scientifically developed to methodically target specific risk factors and address social and structural barriers to behavioral change.²⁸ There have been several studies conducted in these communities to determine the beliefs and values which act as the basis of their behavior.²⁸ These studies, however, did not follow the study participants and understand the progression of decisions made during the woman's pregnancy and/or post-delivery. This study aimed to understand women and their immediate family member's views on practices during the pregnancy period; mother-in-laws/mothers as well as husbands were included. There were also new individuals who had not been previously studied: potential mothers. The study of this group provided insight into what women perceive as sociocultural norms prior to becoming pregnant. As previously mentioned by Darmstadt and Tarigopula, the "timely publication of key findings from the formative studies will not only help in disseminating knowledge on behavior change in India, but is also aimed to generate further discussion and research on questions that remain unanswered and thus impede progress in this area globally."²⁸

Methodology Used for Maternal Service Utilization Study in Northern Karnataka

Individuals from three districts in Northern Karnataka—Gulbarga, Bellary and Bagalkot (N=76)—were interviewed about their sociocultural practices, risky behaviors and the prevailing safe practices (practices that women take part in during their pregnancy time period to care for themselves, i.e. attending ANC checkups, taking the necessary prenatal medications, etc.) during the pregnancy period. There were five categories of individuals who were being investigated in this study under which there were four social classes. The five categories were: 1) women who were pregnant; 2) post-delivery (PD) women; 3) potential mothers (PM) as well as their families; 4) mother-in-laws (MIL)/mothers; and 5) husbands. There are four distinct social classes/groups in the three districts of interest: 1) the Kurba's (the farming and shepherding class/caste); 2) schedule castes/schedule tribes (SC/ST; historically disadvantaged people); 3) upper classes (including Lingayats and Brahmins); and 4) single women. Due to the different

social classes potentially having different behavioral practices, two individuals were selected per social class. The only social class that had four less than the rest was the "single women" category as the women did not have husbands to question.

This study used an exploratory research approach and a systematic approach to categorize the data. This allowed the study investigators to make scientifically supported conclusions on the findings and to develop evidence-based interventions appropriately. The data collected from the interviews were used to help guide communication strategies for Behavior Change Communication (BCC) in the field of maternal, neonatal and child health, specifically in Northern Karnataka.

Resource persons (RP, or community health workers employed by the study sponsoring organization) in the local villages of Gulbarga, Bellary and Bagalkot were the primary means of data collection. Brief training was provided to the RPs to ensure they could administer the questionnaires developed by the study investigators. There were a total of five questionnaires developed to address the five different categories of individuals in this study. The RPs identified eight to ten persons from their local region to participate in the study. As the RPs were the points of contact at the individual village level, they were able to identify individuals in their areas accordingly. Each RP was provided a certain inclusion criteria to follow per category. This was to ensure that there were no replications in the type of study participants being used.

Once all 76 individuals were selected, the RPs were provided with a schedule in which they met with each of their study subjects a total of three times with a fifteen day interval between each visit. The initial consultation consisted of an in-depth interview, after which the two following visits served as a check-in and wrap-up session. After each round of interviews, the data was transcribed and sent back to the head office to be coded and entered into the database. At the conclusion of data collection, the data was coded for overarching themes and reported to the community.

Discussion

There were several aspects of both studies conducted that yielded valuable information for consideration in future studies. In this section, some of the lessons learned from both studies (Figure 1) and how they may be resolved in the development of future studies are discussed. Some of the issues were: 1) communication problems with international partners; 2) social and cultural norm barriers; 3) a truncated timeline to conduct the study; 4) lack of substantive training for RPs; 5) language barriers; and 6) interview tool discrepancies.

Communication Problems

There were several components in the Mali project that required cooperation from the international partners including Institutional Review Board approval by the government of Mali for the purpose of data collection. Partnering with in-country organizations presented challenges due to language barriers, limited or restricted access to technology and physical barriers between the subjects and the study investigators. The partnering organizations consisted completely of non-English speaking individuals, which slowed down the process of communication in each step required to conduct the study. The time restraints that were put in place by the study investigators were also not effectively conveyed due to communication difficulties. Translating everything from English into French initially seemed menial, but as the study progressed, resulting in large documents and detailed emails, it took extensive periods of time to translate to and from En-

glish. Access to technology in Mali was also an issue, as the partnering organizations did not always have access to email or computers. Additionally, the primary method of communication used during the study was email, which presented challenges in coordinating a project discussed only remotely rather than in person. The absence of interpersonal communication contributed to the delay in achieving project milestones.

Social and Cultural Barriers

Social and cultural norms may have played a role in the delay and/or prevention of obtaining detailed responses in both of the studies. The questionnaires and interview tools were developed specifically for the purposes of these studies. They covered subject matters of a sensitive nature and required close consideration and patience to work with the study participants. In the Mali study, questions regarding reproductive health history, sexual assault and cultural practices may have prevented the organizations from agreeing with the methodology of the study, as in many cultures these subjects are rarely discussed. In the India study, this may also have been the case with some of the families, as families often do not disclose power dynamics in the household and women's reproductive health history. Also, husbands in the India study often were reluctant to share or were unaware of the practices and services their wives availed during visits with a medical professional.

Timeline Restraints

Working with a condensed timeline to conduct the study in Mali also played a role in limiting the ability to collect data. At the beginning of the study, a timeline was developed to ensure all activities required to complete the study were given ample time to be carried out. But as the study progressed, issues began to arise, and the timeline was not followed. In order to allow data collection to begin, Institutional Review Board approval was required from both the Malian government as well as from the institution the author was a part of at the time. This step was in the original timeline but as the international partners presented an ambiguous protocol on the process of Mali IRB submissions, problems arose. The process of determining the exact IRB protocol took five months for study investigators to uncover during which time the proposed timeline was completely offset. Therefore, an executive decision was made by Physicians for Peace and all the study investigators to discontinue the study at the time, resulting in no collection of data.

Lack of Training

In the India study, the RPs who conducted the interviews did not have adequate training in how to execute the interview process. The interview manuscripts made it evident that the style of interview conducted by the RPs did not address the type of information needed for the purpose of creating communication tools for the community. In order to create effective communication tools, the study investigators needed to have more insight into the individuals' lives, meaning more in-depth interviews. However, the RPs did not inquire about all the categories determined by the investigators as important indicators for communication tools. The information obtained from each of the interviews varied in the type of information collected, as there was no standard set among the group of interviewers. The style of questions asked by the interviewers was also a source of response bias in the interview process. It was clear the RPs were looking for specific answers and were therefore asking leading questions to obtain those answers from the respondents. After reviewing the interview manuscripts, it

was also evident that the interviews consisted more of the RPs speaking and the respondent providing short answers rather than providing in-depth responses. The style of the interview was not a narration from the respondent but rather just a simple question and answer session with no in-depth explanations or descriptions for some of the key questions. There was also a lack of fluidity in the information provided and it appeared more as broken thoughts.

Language Barriers

As mentioned previously, communication was a major influence on the success of our studies. In the Mali study, having only one translator resulted in the reduced momentum of data collection. We also relied heavily on this individual to ensure that study methodology, timelines and study milestones were explained in detail to the international partners. This was a limitation as this individual did not have any formal research background and was solely responsible for conveying all the information regarding the study. Language differences were also a limitation in the India study due to dialect differences and interview manuscript translations. RPs were responsible for interviewing individuals in their local regions to help assist with language differences. This, however, posed as a challenge for transcribers as not all of the individuals were familiar with different dialects and their underlying meanings. Therefore, English transcription was very poor and the contexts of the answers were not clear in many instances. This also led to the interview analysis process becoming very tedious, caus-

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ing it to take much longer to analyze than anticipated.

Tool Discrepancies

The last major issue that arose was due to discrepancies and difficulties in inquiry about sensitive issues with the interview tools. In the Mali study, there were issues when developing the interview tool due to the sensitivity of the inquired information. The main concern and comment made by the Malian IRB was how we were determined to inquire about incidences of sexual assault among these women and the inappropriateness of asking about such subject matters. This was also one of the main reasons we had much difficulty obtaining IRB approval in Mali. In the India study, many members of the research team who developed the interview tools were unsure what the real expectations of the study were. The questions were extremely broad and had no real direction.

Future considerations

A major future consideration for researchers who wish to conduct studies in low and lower-middle income countries which focus on reproductive health is allowing ample time to conduct such in-depth studies. There are many components that need to be considered and accomplished before data collection can begin. Therefore, planning for delays in the execution of data collection will benefit study investigators. Revisions of the interview tools may also need to be considered due to the sensitive nature of the questions that may be asked. If researchers are able to pilot the interview instrument, it will benefit them in the long run, as it will allow for study investigators to determine the nature of the responses that they may obtain. Variation may occur in the types of responses which are obtained based on different interviewing styles, therefore piloting the tool may assist in understanding areas which may need improvement.

Hiring individuals in the locality where the study is conducted and providing training on the interview/survey tool to these individuals will also help with carrying out the necessary tasks in the local region. This may also be an effective strategy to adhere better to the overall timeline. This strategy would be more effective rather than assigning work to individuals who may not or cannot devote the time needed to execute each step. Since international study designs often call for the help of organizations who partake in other programs, it is difficult to demand that their time be spent solely on conducting just one

study. Therefore, reliability and accountability are essential to carrying out international projects with a sensitive nature such as the studies mentioned in this article. Consequently, working with partnering organizations that not only have a reputable name but also have been recommended by other individuals within their own country is essential to the success of a study.

Conclusion

This article provided an overview of two reproductive health research studies previously conducted by the author in Mali and India and the lessons learned. The author chose both of these studies as they provide ideal examples of methodological challenges international researchers may face. Some of the lessons learned from these studies were: 1) provide direct emphasis of the study protocol and the specific timeline to all individuals working on the study; 2) to obtain both written and oral agreements from all the partner organizations to abide by the protocol; 3) to ensure the study tools are approved for use by all stakeholders; 4) to ensure adequate resources are available for use prior to beginning of data collection; and 5) to provide adequate trainings to all interviewers and personnel who will be interacting and working with study participants. This being said, qualitative research is essential to understanding reproductive health-seeking behaviors in women in low and lower-middle income countries. As one of the two studies detailed in this paper was unable to be carried out as a result of several of these challenges, utilizing the lessons learned from this study and remembering that communication is crucial to the success of any international study, and study investigators in the future will be enabled to effectively carry out international public health research.

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