

*Misoprostol and the Prevention of Postpartum Hemorrhage in Rural Nigeria:  
Lessons from the field*

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**Background:**

Globally, postpartum hemorrhage accounts for roughly 25% of all maternal mortality. PPH is defined as excessive blood loss (>500ml) after birth. Postpartum hemorrhage (PPH) is one of the major public health challenges facing those working in international health and concerned with safe motherhood. PPH disproportionately affects women of the global south. Not only do women in developing countries experience a greater incidence of PPH, but also high mortality due to the increased prevalence of anemia which makes even modest blood loss life-threatening<sup>1</sup>. The same trend is also seen among women who deliver at home, either alone or in the presence of a traditional birth attendant, and women with little or no access to treatment. As of 2000, the maternal mortality ratio (MMR) in Nigeria was 800 deaths for every 100,000 live births<sup>2</sup>. The majority of these deaths are due to PPH and today this figure is estimated to be higher.

Currently the World Health Organization (WHO) recommends the use of uterotonics to treat PPH. In a controlled hospital or clinic setting this regime is quite effective, however it is not a feasible treatment method for many developing countries. In order to maintain its effectiveness, this medication must be kept cold; making it unstable in the field. It must also be injected. This poses a huge problem for countries in which there is limited access to sterile equipment and a shortage of trained health care professionals. These obstacles are particularly relevant in Nigeria where 52% of the population resides in rural communities<sup>2</sup>. Since the burden of PPH is greatest among women in the developing world, there is a great need for an effective treatment regime that is can be administered given the constraints of the health care system.

Misoprostol is a viable option that has generated a lot of attention among those working in the area of maternal and child health. An already existing drug, misoprostol has been proven safe for use to induce abortion, labor, and treat ulcers. It comes in tablet form and therefore does not need to be injected. Thus misoprostol can be administered orally, vaginally, or rectally. It is also stable in tropical climates. The side effects, which include shivering, sweating, and vomiting, are manageable and last for a short period of time. Misoprostol is also incredibly inexpensive. However, since being considered to treat PPH, the effectiveness of misoprostol is being explored in a series of studies located in various parts of the world.

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[1] Prata N, Mbaruku G, Campbell M, Potts M, Vahidnia F. Controlling postpartum hemorrhage after home births in Tanzania. *Int J Gynaecol Obstet.* 2005 Jul;90(1): 51-5.

[2] UNICEF – At a Glance: Nigeria – Statistics. website: [http://www.unicef.org/infobycountry/nigeria\\_statistics.html#0](http://www.unicef.org/infobycountry/nigeria_statistics.html#0)

## **My Experience:**

In the summer of 2006, I traveled to Nigeria to work on a community-based intervention trial in Benin City, Nigeria. The women most affected by PPH in this area live in rural communities and therefore have very limited access to a hospital or clinic. While there I worked with the agency responsible for managing the study and implementing the intervention, Women's Health and Action Research Centre (WHARC). The intervention aimed to achieve two main goals: assessing the effectiveness of misoprostol as treatment for PPH and training traditional birth attendants to administer the drug. Working with TBAs was a way to provide access amidst a variety of barriers.

Upon arrival I had expected the study to be in its final stages. As far as I knew, enrollment and follow-up were complete and the data had been input into a database. I arrived with a clear understanding of my role. My job was to clean and analyze the data, focusing on the relationship between treatment with misoprostol and the number of TBA referrals to the hospital related to PPH. I was also responsible for carrying out the qualitative aspects of the study by conducting focus groups and interviews with some of the women in the study as well as the TBAs. The final product was to be a paper discussing the results of the study.

I decided to begin with the qualitative work, because I had no idea how long it would take for me to establish a relationship with the community before they felt comfortable letting me ask them questions. Luckily it did not take much time at all. The first day I visited Okokhuo village, the study site, the eldest TBAs were extremely receptive. I went with the research nurse assigned to the project. After she introduced me and discussed the reason for my presence, the TBAs welcomed me with a traditional prayer. They saw no problem with me interviewing them, women in the study, and other TBAs involved. For three weeks I held focus groups and personal interviews with women from the study and several TBAs.

The objective for conducting the qualitative work was to assess any obstacles encountered during program implementation from the perspective of the study participants. Feedback from both TBAs and the women concerning their experience with misoprostol is a critical piece of the project. When thinking about how the results could inform future policy and practices it is important that we have an accurate picture of what is and is not effective and compatible with local practices. The response from both groups was positive all around. As co-facilitator of these sessions it was very powerful to hear the women talk about why they wanted misoprostol available to them. The message was simple and clear; misoprostol worked for them.

When I was not in Okokhuo, I was at the office working with the data and familiarizing myself with the questionnaire. It quickly became clear to me that we had some complications with this data set. First I noticed was that the total number of observations we had was not equal to the target sample size specified in the protocol. We still needed over 200 women to reach our goal. After getting a hold of the hard files, I began to check the quality of the data by cross-checking the files and the data set. I found that a large portion of the data had been entered incorrectly.

At this point the project still seemed salvageable for a few reasons. If need be, I could have just gone through and reentered all of the data from the questionnaires. WHARC had also maintained its relationship with the TBAs, therefore it was

conceivable to begin a “second round” of enrollment. However, during one of the TBA interviews we discovered that the wrong dose of misoprostol had been given. Everyone involved felt that this project was extremely important, so we decided to start the study over again.

Before we could move on to “Phase II of the TB-Misoprostol Study” it was important to understand what went wrong the first time and what could be done to prevent us from making the same mistakes. So I tried to identify some of the main oversights, or sources of error, from “phase I”. One of the major issues was poor project management. Communication between the in-country principal investigator and the project staff needed to be better established. Unfortunately, the two main staff members assigned to the project left WHARC mid-project. Again, the status of the project was not clearly communicated to incoming staff which resulted in poor continuity of the study. Additionally, poor data management and data entry led to files being lost, incomplete, mis-numbered, and incorrectly entered. Most detrimental to the study was the divergence from the protocol. Proper adherence could have prevented the study from being closed out early and possibly the wrong dose being given as well. It was also important to understand any barrier experienced by the project officers. After contacting one of the women who initially worked on the study, I found out that she was working on other projects in addition to the TBA-misoprostol study and was unable to go to Okokhuo every two weeks. The infrequent visits made collecting questionnaires, ensuring that they were completely filled out, and keeping track of misoprostol difficult. Lastly, the person who goes to Okokhuo needs to understand the culture and speak the local dialect, Bini.

When restructuring the protocol for phase II of the study the above mentioned issues were taken into serious consideration. The first step was to assess whether or not the TBAs would be willing to participate the second time around. After telling them the truth, fortunately they still wanted to be involved and agreed to be retrained to administer the correct dose of misoprostol. Second step was to hire a project coordinator who could dedicate all of his/her time to the project. With the help of WHARC staff, I placed an advertisement in the paper for a new project officer position and interviewed applicants. In the end, we hired a young man with a background in statistics and experience conducting field research, collecting data, using Microsoft Excel, and writing reports. He was also a Benin man and spoke the local language!

We realized that we needed to find a new control site for the study. In phase I, Okokhuo contained both the control and intervention site because there were plenty of TBAs available. However, for various reasons we needed to find a new control site. It was important to find a community that was comparable to Okokhuo in order to minimize confounding as much as possible. Although I was unable to secure a control site in my time there, I was able to visit the Local Government Area (LGA) office and speak with the public health officer for the region. After I left, the project coordinator worked with the LGA, found a new control site and trained the TBAs. Fortunately, I was involved in re-training the TBAs from Okokhuo before I returned home.

It was important to make sure that they understood and were willing to adhere to the new treatment regime. All of the TBAs needed to measure blood loss the same way so we conducted training for that as well. The main concern was that the method be compatible with current practices and thus sustainable. The TBAs already used a cloth to

keep track of blood loss, so we trained them to recognize excessive blood loss using their traditional methods. The events from phase I of the study highlighted the need for ongoing monitoring. So we created log books to keep track of the misoprostol tablets, visits to the village, referrals, and identification numbers assigned to each study participant. We also wanted to keep record of each adverse event, so referral audits and oral autopsies were to be carried out for each case of PPH and/or death. Lastly, we arranged for bi-weekly updates to be sent from Nigeria to the US to facilitate improved communication.

### **Lessons learned:**

As a Bixby intern I was introduced to some of the issues confronting those working on PPH in international health. I gained first hand experience working in Nigeria and applying skills I had learned in the classroom. It quickly became clear that the practical application of epidemiologic methods was going to be a challenge. Regardless, I learned some valuable lessons that could have only come from experience.

First, it can be difficult to inspire the same passion that you have about an issue in others. Someone may understand the severity of PPH, but they may not be as invested in the project as the principal investigator. Therefore it is important to hire people you trust will do a thorough job. There is also a need for continual monitoring and evaluation. If we keep track of our progress, we are more likely to catch ourselves before we stray too far from protocol. Obtaining informed consent is another issue that is much more complicated in the developing world. In areas where literacy rates are low, we must be very careful about how we inform people about the risks and benefits of participation. Special care must be taken to ensure that people are fully informed of the risks, benefits, and their rights as study participants. Most importantly, support from local leaders and community members are critical.

This project would not have been able to continue if we had not gotten the buy-in from community and government leaders, the women, their husbands, and the TBAs. It was important that the intervention be sustainable. This was accomplished by working with traditional practices. I felt that the study valued local knowledge and showed respect for the traditional healers and women by creating an intervention which complimented the existing practices. Finally, any study done needs to be relevant to the community involved in the study. While there, it was clear to me that Nigerians feel that maternal mortality is a serious health concern in their country and that PPH is a recognized health issue. Hopefully the results of this study and others alike will inform health policy addressing collaborations and partnerships with traditional birth attendants to improve access to treatment of PPH to the woman who need it most.