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Women's Health in Women's Hands: A Pilot Study Assessing the Feasibility of Providing Women With Medications to Reduce Postpartum Hemorrhage and Sepsis in Rural Tanzania

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In rural Africa, deaths from childbirth are common and access to health care facilities with skilled providers is very limited. Leading causes of death for women are bleeding and infection. In this pilot study, we establish the feasibility of distributing oral medications to women in rural Tanzania to self-administer after delivery to reduce bleeding and infection. Of the 642 women provided with medications, 90% of the women took them appropriately, while the remaining 10% did not require them. We conclude that is it feasible to distribute oral medications to rural women to self-administer after delivery.

Context of Maternal Mortality in Africa

Death from childbirth is one of the largest challenges facing African women today, particularly in rural communities. The United Nations' fifth Millennium Development Goal addressed this concern with the aim to improve maternal health and reduce by two-thirds by 2015 the enormously high numbers of

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women dying while giving birth (United Nations, 2013). Although, several African countries have made some progress toward this goal, there are still many thousands of women dying as a result of childbirth annually. In 2010, an estimated 164,800 women lost their lives while giving birth in Africa—56% of the number of women dying globally of childbirth (African Union Commission, Economic Commission for Africa, African Development Bank Group, & United Nations Development Program, 2013). In Tanzania, with a maternal mortality ratio of 454 per 100,000 (National Bureau of Statistics Tanzania & ICF Macro Tanzania, 2011), this reality equates to one woman dying in childbirth almost hourly (Ministry of Finance and Economic Affairs, Republic of Tanzania, 2009).

Two of the largest causes of maternal mortality are bleeding and infection, causing 25% and 15% of maternal deaths globally, respectively (Sullivan & Hirst, 2011). In Africa, 34% of maternal deaths are attributed to hemorrhage (Haeri & Dildy, 2012). Women who deliver outside of a health care institution are most at risk, as they do not have access to life-saving medications or skilled attendants. More than 50% of women delivering in sub-Saharan Africa lack a skilled birth attendant at their delivery, and there is evidence that this concerning statistic is unlikely to change soon (Crowe, Utley, Costello, & Pagel, 2012). In addition to increasing access to health care services for rural women, strategies are urgently needed to provide women with alternative methods to reduce their risks at the time of delivery that are not dependent on the presence of skilled health care workers.

Postpartum Hemorrhage

Saving mothers' lives from the risks of childbirth does not always involve costly interventions. The recommendations for the period immediately after delivery of the baby, referred to as the third stage of labor, are to provide injectable uterotonic medications such as oxytocin or ergometrine to prevent bleeding. Unfortunately, for women delivering in the villages or on the way to a facility, this is not possible as these medications require refrigeration and a skilled provider to administer them. Six hundred micrograms of oral misoprostol has been shown to be an effective alternative to injectable uterotonics in low-resource settings (Gülmezoglu, Forna, Villar, & Hofmeyr, 2011; Sheldon, Blum, Durocher, & Winikoff, 2012). The World Health Organization (WHO) and the International Federation of Gynecology and Obstetrics (FIGO) have both endorsed the use of misoprostol for the prevention of postpartum hemorrhage (PPH) in settings where oxytocin in not available, although only when administered by a skilled or lay health care provider (FIGO Safe Motherhood and Newborn Committee, 2012; WHO, 2012a). The United Nations Commission on Life-Saving Commodities for Women and Children has listed misoprostol for the prevention and treatment of PPH as

one of 13 key commodities to reduce deaths of women and children (Every Women Every Child, 2012).

Community distribution of misoprostol for PPH prevention through various providers has been demonstrated to be effective in India (Derman et al., 2006), Afghanistan (Sanghvi et al., 2010), Nepal (Rajbhandari et al., 2010), Bangladesh (Nasreen, Nahar, Al Mamun, Afsana, & Byass, 2011), and Pakistan (Mir Wajid, & Gull, 2012), as well as several other countries in Africa and Asia (Smith, Gubin, Holston, Fullerton, & Prata, 2013). In Tanzania, there have been two studies of misoprostol for PPH prevention. In the first (Prata, Mbaruki, Grossman, Holston, & Hsieh, 2009), misoprostol was successfully distributed through traditional birth attendants (TBAs). Unfortunately, this is no longer feasible as the Tanzanian government has officially restricted the work of TBAs, and while women still attend these caregivers, it is unlikely that TBAs would be permitted to engage in misoprostol distribution. In the second study, the intervention entailed dispensary nurses delivering misoprostol at the antenatal visits after 32 weeks gestation (Ifakara Health Institute, Venture Strategies Innovations, Bixby Center for Population, Health and Sustainability, Population Services International [PSI]/Tanzania, 2011); however, the researchers found that many women did not receive the medications because they did not attend antenatal care during the latter weeks of their pregnancy. The WHO has recognized that task shifting needs to occur in maternal and child health in order to optimize care, but, they have stopped short of promoting misoprostol distribution to pregnant women for self-administration to prevent PPH (WHO, 2012b).

Puerperal Sepsis

In addition to PPH, puerperal sepsis, or life-threatening infection associated with childbirth, is another major cause of death for mothers. Puerperal sepsis has been estimated to contribute to 75,000 deaths per year, mostly in developing countries (Hussein & Fortney, 2004). It has been proposed that the provision of antibiotics to prevent life-threatening sepsis and oral misoprostol to prevent postpartum bleeding could augment facility strengthening in Africa to reduce deaths from childbirth by one-third (Pagel et al., 2009). There is evidence that prophylactic antibiotic use prevents sepsis in elective and nonelective caesarian sections and in women at high risk of sepsis (van Dillen, Zwart, Schutte & van Roosmalen, 2010). In a study of prophylactic antibiotics at delivery in HIV-positive women, researchers have also documented a reduction in postpartum infections (Sebitloane, Moodley, & Esterhuizen, 2008), although a study of HIV infected and noninfected women was unable to demonstrate a positive effect of prophylactic antibiotics given during the antenatal and intrapartum periods to women in urban health care facilities in Malawi, Tanzania, and Zambia (Aboud et al., 2009).

Purpose and Objectives

In order to address the problem of maternal mortality for rural women living in Rorya District, Tanzania, we conducted a 6-month study in 2012. The purpose of this research was to assess the feasibility of misoprostol and erythromycin distribution to rural Tanzanian women to prevent PPH and puerperal sepsis. Our objectives were to demonstrate that the community provision of these medications was both acceptable to the community and safe for the women, in preparation for a later scale-up to the larger Mara Region.

METHODS

Research Design

This research used a mixed method design composed of both quantitative and qualitative methods. After receiving the study medications, the women were surveyed by the research assistants about their demographic information and the facts of their delivery experience (quantitative results). The results of the survey are the focus of this article. In addition, interviews were conducted with women, traditional birth attendants, and dispensary nurses; these results are reported elsewhere (Webber & Chirangi, n.d.).

Research Setting

Rorya District is bordered by Lake Victoria to the west, Serengeti National Park to the east, and the Kenyan border to the north. Mara Region has one of the highest nonfacility birth rates in Tanzania, with more than 60% of women delivering in their villages where no skilled attendants are available (Ministry of Finance and Economic Affairs, Republic of Tanzania, 2009). We chose to conduct the study in the villages serviced by 12 rural dispensaries in Rorya that were located farthest from the district hospital.

Ethics and Data Collection

Ethical approval for the study was obtained from the Ottawa Hospital Research Ethics Board in Canada and the National Institute of Medical Research in Tanzania, which is responsible for ethical approval of all medical research in Tanzania.

In this study, research assistants and dispensary nurses distributed misoprostol and erythromycin to rural women for self-administration after delivery (i.e., the women could take the medication themselves or designate a family member or TBA to administer it to them). We used a misoprostol dose of 600 micrograms because this is the recommended dose for prevention of

PPH (WHO, 2011). We included 500 mg of erythromycin, an antibiotic that is used to treat Group A streptococcus, historically a common cause of puerperal sepsis (Hussein & Fortney, 2004). It is important to note that in order to maximize distribution, we provided these medications to women during their pregnancy for self-administration after delivery and we attempted to include all willing women in the catchment area, not just those who attended antenatal clinics for prenatal care, unlike some previous studies (Smith et al., 2013).

From February to July 2012, the research assistants visited the study villages and with the assistance of local health workers, they met with women who were currently pregnant and due to deliver before August. In addition to distributing the medications directly from the research assistants, the dispensary nurses were provided with the study medications and were instructed how to enroll women in the study. The research assistants and dispensary nurses explained the study to the women in the local language of Swahili or Luo, and they provided an information letter in Swahili to the women. The women were asked to sign a consent form indicating their agreement to participate in the study. The consent form was read to women who lacked the literacy skills to read it themselves. Women who consented to be part of the study were provided with a small bag containing three tablets of misoprostol (200 micrograms each) and two tablets of erythromycin (250 mg each). The women were instructed to store the medication in a safe location, to take it with them wherever they chose to deliver, and to swallow the medications immediately after the birth of the infant and not before. The women were also warned about the possible side effects of the medications, particularly shivering and an upset stomach. We sought ethics permission from the Canadian ethics committee to include only women 18 years and older; hence younger women are not represented in this report.

After the women delivered, the research assistants returned to survey them about their birth experience. The research assistants collected demographic information on the women (including age, parity, and distance living from the hospital and dispensary), in addition to details about the delivery (location, attendance at delivery, whether study medications were taken, whether the woman would consider taking the study medications in future deliveries, side effects, and the health of the baby).

Analysis and Validity

All data were entered into an Excel spreadsheet by the principal investigator or a research assistant, and 20% of the data entries were double-entered for accuracy. All errors were corrected. The data were then analyzed using SPSS for descriptive statistics.

RESULTS

A total of 642 women were surveyed after they used the study medications. The results of the survey are provided in Table 1.

Demographic Information

The mothers' ages ranged from 18 to 47, with a median age of 26. The women's parity also had a wide spread, from 1 to 14 with a median parity of fou children. The median distance from the hospital for the women was 34 km, although the farthest was 90 km. The median distance from the dispensary was 4 km, while the range extended from 0.25 km to 57 km.

Experience of Delivery

Most of the women surveyed delivered in their own home (47.9%) or the TBA's home (21.1%). A further 3.4% delivered en route to a health facility. Thus 72.4% of this cohort of women delivered outside of a health care facility. The remainder of the women delivered in a variety of health care

TABLE 1 Survey Results ($n = 642$)

Survey item	Results
Age of mothers (years; $n = 642$)	Range 18–47 (median 26)
Parity of mothers ($n = 642$)	Range 1–14 (median 4)
Distance from hospital (km; $n = 642$)	Range 2–90 (median 34)
Distance from dispensary (km; $n = 640$)	Range 0.25–57 (median 4)
Place of delivery ($n = 641$)	Home: 307 (47.9%) TBA's home: 135 (21.1%) Dispensary: 83 (12.9%) Hospital: 79 (12.3%) On the way: 22 (3.4%) Health center: 12 (1.9%) Pharmacy: 3 (0.5%)
Attendance at delivery ($n = 642$)	TBA: 244 (38.0%) Family/neighbors only: 195 (30.4%) Dispensary nurses: 97 (15.1%) Hospital staff: 78 (12.1%) Alone: 22 (3.4%) Others: 6 (0.9%)
Number who took study medications ($n = 642$)	Yes: 578 (90.0%) No: 64 (10.0%)* *All received injection at institution.
Number who would take study medications again in future pregnancies ($n = 642$)	Yes: 640 (99.7%) No: 2 (0.3%)* *One wanted tubal ligation, one had not used meds.

facilities: dispensary (12.9%), hospital (12.3%), health center (1.9%), and local pharmacy (0.5%).

More than two-thirds of the women were not attended by a skilled health care provider for their delivery. About one-third was either alone (3.4%), or only with family or neighbors (30.4%), or with others (0.9%). More than one-third (38%) were attended by a TBA. The remaining women had the skilled attendance of a dispensary nurse (15.1%) or hospital staff (12.1%).

When asked about whether they took the study medications, 90% of the women stated they did. The remaining 10% who did not take the medications all received an injectable medication at a health care institution, and thus they did not require the study medications. Of note, some of the women who delivered in an institution where injectable medication was available still insisted on using the study medication, despite the instructions of the health care staff to accept the injectable medication. All the women except for two, including those who had not used the medication, stated they would take them in a future pregnancy. Of the two who declined, one had not used the medications, and the second did not intend to have more children.

The women were asked if they sought medical attention for bleeding ($n = 641$). The vast majority (99.4%) stated they did not. Of the four women who admitted to requiring further attention for bleeding, two women had bleeding after using the misoprostol. One of these women got assistance from a health care provider and received injectable medication, while the other received local medications. The other two women who bled had received injectable medications first, and subsequently they decided to take the study medications.

When asked if they sought medical attention for infection, 636 of the 642 women surveyed (99.1%) stated that they did not. The six women who did seek medical attention for infection just reported on side effects. One of the six had not received misoprostol. Of the five women who had used the misoprostol, three reported abdominal pain, while one each reported palpitations and lack of energy. Two women stated that they subsequently used traditional medicine.

The women were also asked if the baby was born healthy ($n = 641$). For 631 women (98.4%), they agreed that the baby was healthy. For the remaining 10 women (1.6%), the responses follow: death of baby for seven (from prematurity, cord around neck, convulsions), spontaneous abortion (one), prematurity at 7 months (one), and no reason given (one).

DISCUSSION

About half of the women surveyed lived more than 30 km from the hospital and more than 4 km from the dispensary, and most had no access to

transportation. A total of 72.4% of this cohort delivered outside of a health care facility. This percentage is higher than the average for the region (Ministry of Finance and Economic Affairs, Republic of Tanzania, 2009). Such a statistic is not surprising, however, as we chose to conduct this project in the most rural dispensaries in the district. There are many barriers to women in this region reaching a facility for delivery, including geographic distances, lack of affordable transportation, and insufficient time to undertake the trip before delivery.

An earlier study also documented multiple barriers facing Tanzanian women seeking a facility delivery (Women's Dignity and CARE International in Tanzania, 2008). In this study, women noted that in addition to distance and cost of delivery at a health care facility, the negative attitudes of health care providers and the lack of qualified staff and supplies were other barriers to seeking a health care facility for childbirth. Despite the existence of multiple barriers, Mbaruku and colleagues have demonstrated that many Tanzanian women would prefer a facility birth over birthing with a TBA if they had the choice because they are aware of the need for a skilled birth attendant to ensure a safe delivery (Mbaruku, Msambichaka, Galea, Rockers, & Kruk, 2009).

Only about a quarter of women in our cohort were attended by a trained health care provider, and a third of the women delivered without even the presence of a TBA. Interventions to help these women will be most effective if they can be easily administered by the women themselves or by those who are with her at the time of delivery. While the challenges for women to attend health care facilities for delivery are significant, the women who participated in our study were very positive about the availability of oral medications for them to take. All the women who took the study medications would use them again. Indeed, almost all of the women who did not take them would also use them in another pregnancy, as the word had spread about how effective the medications were. In future studies, more education about available drugs and their effectiveness is needed as some of the participating women chose to use misoprostol even when the superior medication oxytocin was available at a health care facility. Community distribution of misoprostol will help ensure that women have access to a uterotonic drug at the time of delivery for prevention of PPH, as the lower-level health care facilities (e.g., dispensaries) often do not have oxytocin in stock (Plotkin, Tibaijuka, Makene, Currie, & Lacoste, 2010).

There is not enough evidence to warrant including an oral antibiotic for sepsis prevention currently, and this will be abandoned in future research. Instead, in our scale-up project we intend to provide rural women with 600 micrograms of misoprostol in combination with a birth kit. How to effectively deliver these kits containing misoprostol to the most women has yet to be determined (Smith et al., 2013) and will be a focus of future research.

Limitations

There were several limitations to the research. It was not feasible to randomize the population; therefore, a convenience sample of women was used. Unfortunately, we were unable to include the TBAs in the distribution of the misoprostol as current government policy has prohibited them from practicing (although many still service the rural population). We did not record the number of women who declined to participate and the reasons for this; however, the participating dispensary nurses could only recall one woman who actively declined taking the study medications. Future research should capture this data, including which family members are making the decision for women to access care. We relied on self-report of the women about using the medication, which could elicit some bias. In addition, we did not confirm the timing of when the medication was taken; this oversight will be addressed in the scale-up study. Finally, in the future we will seek ethics approval to include younger women in the study (obtaining parental consent for their participation), as it is not uncommon for women aged 14 to 17 to become pregnant in this region, and excluding them from access to this important intervention because of age would be unethical.

Conclusions

Investment in maternal health is a human right, and results in improved health for the whole family as mothers are the main caregivers for children. It also makes economic sense, for every dollar spent on maternal health has the potential to multiply twentyfold in economic benefits (The Partnership for Maternal, Newborn and Child Health, 2013). Like thousands of women living in rural Africa, many women in rural Tanzania lack the resources and time to access health care providers at the time of their deliveries. Until there is sufficient resources to construct and staff health care facilities in the most rural areas of the country, there is a role for provision of oral medications for home deliveries. Women are both willing and able to safely take oral medications provided to them in pregnancy at the time of their deliveries, even when delivering at home with a TBA, family member, or alone. Through this study we conclude that it is feasible to distribute misoprostol to women for self-administration for PPH prevention, and in fact this is confirmed by a recent review of the literature (Smith et al., 2013). Qualitative data from interviews with participating women, TBAs, and dispensary nurses demonstrate that this program is very acceptable to women, their health care providers, and their communities (Webber & Chirangi, n.d.). As noted earlier, the benefits of misoprostol in preventing PPH are well established (Derman et al., 2006; Guülmezoglu et al., 2011; Sheldon, Blum, Durocher, & Winikoff, 2012) and it is now recommended that misoprostol be provided at all deliveries where access to injectable uterotonic medications is limited (FIGO, 2012; WHO,

2012a). While the WHO has not yet endorsed the distribution of misoprostol for self-administration for PPH prevention (WHO, 2012a, 2012b), we would argue that there is an imperative to undertake larger studies demonstrating the safety and effectiveness of this. Hundreds of thousands of women could be saved by access to this inexpensive medication: the time for further research is now.

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