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CLINICAL ARTICLE

Feasibility and acceptability of clean birth kits containing misoprostol for self-administration to prevent postpartum hemorrhage in rural Papua New Guinea



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ABSTRACT

Objective: To determine the feasibility and acceptability of providing clean birth kits (CBKs) containing misoprostol for self-administration in a rural setting in Papua New Guinea. *Methods:* A prospective intervention study was conducted between April 8, 2013, and October 24, 2014. Eligible participants were women in the third trimester of pregnancy who attended a prenatal clinic in Unggai Bena. Participants received individual instruction and were then given a CBK containing 600 µg misoprostol tablets for self-administration following an unsupervised birth if they could demonstrate their understanding of correct use of items in the CBK. Data regarding the use and acceptability of the CBK and misoprostol were collected during postpartum follow-up. *Results:* Among 200 participants, 106 (53.0%) had an unsupervised birth, and 99 (93.4%) of these women used the CBK. All would use the CBK again and would recommend it to others. Among these 99 women, misoprostol was self-administered by 98 (99.0%), all of whom would take the drug again and would recommend it to others. *Conclusion:* The findings strengthen the case for community-based use of misoprostol to prevent postpartum hemorrhage in remote communities. Large-scale interventions should be planned to further evaluate impact and acceptability.

1. Introduction

Most maternal deaths occur in low-resource settings [1], primarily in remote and rural communities when births are not assisted by skilled attendants. Globally, postpartum hemorrhage (PPH) is the leading cause of maternal mortality [1], but this complication can be prevented by the use of uterotonic agents, such as oxytocin [2]. However, oxytocin requires intramuscular administration and refrigerated storage, making this potentially life-saving intervention unavailable for the millions of women who experience unsupervised delivery. Misoprostol has been suggested as a substitute to oxytocin in lowresource settings [3,4]. The safety and efficacy of 600 µg orally administered misoprostol to prevent PPH in community settings has been documented in several countries [3,5–14]. Distribution of misoprostol has been undertaken by community health workers, including traditional birth attendants [5–8,13]. In some settings, this drug has been distributed to women for self-administration [9–12,14]. Such distribution is frequently undertaken in conjunction with training and education about birth preparedness, the importance of supervised births, recognizing danger signs (including PPH), the correct timing for taking misoprostol, and common adverse effects [3,6,8–12,14].

In 2012, in recognition of the limited evidence to support distribution of self-administered misoprostol, WHO and the International Federation of Gynecology and Obstetrics called for research to evaluate the inclusion of misoprostol in effective, locally appropriate, and comprehensive

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community-based interventions [15]. The distribution of clean birth kits (CBKs) to support hygienic birth practices is one such intervention that has been frequently used in low-resource settings [16]. The potential benefit of including additional items in these kits, such as misoprostol, has been suggested [17], although this advice has not been formally evaluated in such settings.

Papua New Guinea (PNG) is a low-to-middle-income country in the Asia–Pacific region. Access to skilled health care in this country is limited as a result of geographic, infrastructure, and logistical challenges. The majority (87%) of the 7.2 million residents of PNG live in rural areas [18]. Furthermore, PNG has one of the highest maternal mortality ratios in the world, with 594–733 maternal deaths per 100 000 live births [1,19]. Although 78% of women in PNG attend a prenatal clinic at least once during their pregnancy, only 44% experience supervised births within a health facility [20]. Many women give birth in the community, either alone or with a female relative to support them. In PNG–as in many low-resource settings–PPH and sepsis are the leading causes of maternal mortality [21].

The aim of the present study was to evaluate the distribution of misoprostol as part of a comprehensive community-based strategy to prevent PPH and to describe the feasibility and acceptability of CBKs and misoprostol among participants in a remote rural setting in PNG.

2. Materials and methods

A prospective community-based intervention study was conducted between April 8, 2013, and October 24, 2014. Women in the third trimester of pregnancy (on the basis of clinical assessment) who attended a prenatal clinic at government health facilities in Unggai Bena were eligible to participate. The eligibility criteria limited the time between receiving the intervention and the estimated delivery date. Exclusion criteria were a history of mental illness and age younger than 16 years. Ethical approval was provided by the Institutional Review Board of the PNG Institute of Medical Research, Goroka; the Medical Research Advisory Committee, PNG National Department of Health, Port Moresby; and the Human Research Ethics Committee, University of Queensland, Brisbane, QLD, Australia. Women willing to participate completed written informed consent procedures. For women unable to sign owing to illiteracy, a witness signature confirmed that the participant had understood the consent process and was providing informed consent. All women were assigned a unique study identity number.

The study was conducted within Unggai Bena, one of eight administrative districts in the Eastern Highlands Province of PNG. Coverage of maternal health care in this predominantly rural area is low, with only 68% of women attending a prenatal clinic on at least one occasion; the supervised birth rate is just 38% [20]. The present study site of Upper Bena is accessible by one unsurfaced road, often impassable after heavy rain. Many villages are located in steep mountainous terrain and accessible only by bush tracks. Four government health facilities in the area (three aid posts and one health center) offer a range of preventive and curative services, including weekly prenatal clinics. The health center is equipped to manage uncomplicated births, which are conducted primarily by nurses. There is one midwife at the health center.

Review of the available provincial-level maternal health data for 2012 (the year in which the present study was planned) indicated a supervised birth rate at the study site of approximately 7%. The proportion of women who attend the provincial hospital, or other facilities, for a supervised birth is not systematically recorded; however, previous research in the area suggested that most women give birth unsupervised in the community, either alone or supported by family [19,22].

Visual teaching aids were designed using nationally available safe motherhood teaching aids and messages, and piloted by a research team from the PNG Institute of Medical Research, Goroka. The research team comprised a health extension officer (E.W.) (a professional health worker with 4 years of formal training), a midwife (P.H.), and two community liaison officers (M.M. and M.T.), supported by the principal investigator (L.M.V.). All team members were experienced in the conduct of community-based field research. The teaching aids, which highlighted key messages relating to birth preparedness (Box 1), were used to disseminate information through community sessions at both informal and formal gatherings, including at village markets, after church services, and at participating prenatal clinics.

Pictorial flipcharts for the CBKs and misoprostol, including correct use of each item, were also designed and piloted. Each CBK contained a piece of soap, a pair of gloves (non-sterile), a plastic sheet, a scalpel blade, two cord ties, and a sealed packet containing three misoprostol tablets (600 µg in total) to be taken orally after the birth of the infant. The misoprostol tablets were repackaged by the research team and labeled "safer afterbirth" tablets before inclusion in the CBK to comply with a requirement from the ethics committees in PNG following concerns that misoprostol could be used inappropriately (e.g. to induce abortion).

At enrollment, women received one-to-one education using the pictorial flip charts, before being provided with the CBK. Educational activities were undertaken by the health extension officer or research midwife. Women were advised about the risks of taking the misoprostol tablets too soon (i.e. before delivery) and about common minor adverse effects. Using a study-specific checklist, participants were required to demonstrate their understanding of the correct use of each item in the CBK, specifically the use of misoprostol, before the CBK was provided. Women who did not demonstrate the correct knowledge did not receive the CBK at enrollment. These women were asked to return to the prenatal clinic the following week to receive further instruction and to be reassessed regarding their knowledge before provision of the CBK. A pictorial insert on the use of each item (Fig. 1) and a birth notification card (to enable postpartum follow-up) were also included in the CBK.

Sociodemographic data and obstetric history were collected using a study-specific case record form that had previously been tested in this setting (unpublished data). Locator information, including distance from health facility and road access, was collected to enable the research team to visit participants in their villages, communicate key messages to their community (Box 1), and to facilitate postnatal follow-up.

Participants were visited in the community by the research team during the postpartum period. A semi-structured questionnaire was used to collect information relating to birth experience (including location of birth) and the use of each item in the CBK. Probing questions were used where necessary. Unused CBKs, including misoprostol tablets, were collected by the research team and disposed of in accordance with study-specific standard operating procedures.

Box 1

Key messages communicated during community information sessions.

Part 1: Normal process of safe childbirth

- · Childbirth can be dangerous
- Planning for safe childbirth
- · Recognize the signs of labor
- · Help a woman when she is in labor
- Recognize when the child is ready to be born
- · Care for the mother immediately after childbirth
- Care of the mother and newborn from birth to 6 weeks
- Plan for and space pregnancies

Part 2: Danger signs in mothers and newborns

- · Know the danger signs and act quickly
- Danger signs in labor
- Danger signs in the mother after childbirth
- · Danger signs in the newborn
- · Be prepared and plan for a supervised birth

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