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CLINICAL ARTICLE

Cost-effectiveness of two interventions for the prevention of postpartum hemorrhage in Senegal

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ABSTRACT

Objective: To compare, at the community level, the cost-effectiveness of oxytocin and misoprostol for the prevention of postpartum hemorrhage (PPH). *Methods:* The present cost-effectiveness study used data collected during a randomized trial that compared the prophylactic effectiveness of misoprostol and oxytocin for the prevention of PPH in a rural setting in Senegal between June 6 and September 21 2013. The two interventions were compared, with referral to a higher level facility owing to PPH being the outcome measure. The costs and effects were calculated for two hypothetical cohorts of patients delivering during a 1-year period, with each cohort receiving one intervention. A comparison with a third hypothetical cohort receiving the current standard of care was included. A sensitivity analysis was performed to estimate the impact of variations in model assumptions. *Results:* The cost per PPH referral averted was US$ 38.96 for misoprostol and US$ 119.15 for oxytocin. In all the scenarios modeled the misoprostol intervention dominated, except in the worst-case scenario, where the oxytocin intervention demonstrated slightly better cost-effectiveness. *Conclusion:* The use of misoprostol for PPH prophylaxis could be cost effective and improve maternal outcomes in low-income settings.

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1. Introduction

Postpartum hemorrhage (PPH) is a major cause of maternal mortality. WHO estimates that 27% of all maternal mortality is due to PPH [1]. The incidence of maternal mortality is concentrated overwhelmingly in low- and middle-income countries—WHO estimates that, out of 289 000 maternal deaths that occurred worldwide in 2013, 286 000 were in low- and middle-income countries. In this respect, the maternal mortality ratio in Senegal (320 deaths per 100 000 live births) is fairly typical of Sub-Saharan Africa [2]. Tragically, while PPH is a manageable condition in high-income countries, it can be life-threatening and often fatal in countries similar to Senegal, where access to adequate obstetric care and blood transfusions are limited.

Prophylactic administration of either misoprostol or oxytocin immediately after delivery has been shown to be effective in preventing PPH [3,4]. Both have been recommended by WHO for the prevention and treatment of PPH, although oxytocin remains the drug of choice [5–8]. However, oxytocin requires cold-chain logistics because it degrades at room temperatures or higher; additionally, it must be administered parenterally. These requirements make oxytocin more difficult to use in situations where trained practitioners and medical infrastructure are relatively scarce. Conversely, misoprostol is thermostable and available in tablet form, making transportation, storage, and administration easy.

Whereas several clinical studies have demonstrated superior efficacy for oxytocin compared with misoprostol in the prevention of PPH [9], to the best of our knowledge no studies have examined the relative merits of these two drugs in a community-level setting, under sub-optimal conditions where many deliveries take place (i.e. either at patients' home or at sub-centers with only traditional birth attendants to assist during deliveries) [10–13]. The aim of the present cost-effectiveness analysis was to compare the use of oxytocin and misoprostol for the prevention of PPH in a community-based setting.

2. Materials and methods

The present cost-effectiveness analysis used data from a cluster randomized trial conducted at the community level in three predominantly rural districts of Senegal between June 6 and September 21, 2013 that compared the effectiveness of misoprostol (600 μg administered orally) and oxytocin (10 IU administered intramuscularly via the Uniject system [Instituto Biologico Argentina S.A.I.C., Buenos Aires, Argentina]) for the prevention of PPH during the third stage of labor [14]. The present cost-effectiveness analysis was approved by the National

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Council on Health Research, National Ethical Committee, Ministry of Health and Prevention, Senegal as part of the cluster randomized trial [14]. No specific patient data was used in the present analysis so it was not necessary to obtain informed consent.

The study protocol for the randomized trial has been described in detail elsewhere [14] and will only be summarized briefly here. The study was conducted by auxiliary midwives (matrones) at 28 village "health huts" (maternity huts with a delivery table but no instruments or medications), with 14 huts included in each treatment arm. All patients attending the health huts for delivery who consented were included in the trial. The primary outcome measure was the change in hemoglobin level, measured at a prenatal visit before delivery and again within 48 h of delivery. Referral to health centers or hospitals for treatment for PPH was recorded in the study as a secondary outcome measure, as were drops in hemoglobin of 20 g/L or more.

There was no significant difference in the change in hemoglobin level between the two study arms. No significant difference was observed in the mean decrease in hemoglobin count pre- and post-intervention between the two arms. The referral rates owing to PPH were 0.0% (95% confidence interval 0.0–1.2) in the misoprostol arm and 0.2% (95% confidence interval 0.0–2.0) in the oxytocin arm. There were no PPH-attributed deaths in the trial and no serious adverse events occurred in either arm, although shivering was more common in the misoprostol arm [14].

Utilizing the data and findings from the randomized trial, the present cost-effectiveness analysis was conducted to compare misoprostol and oxytocin (administering via Uniject) for the prevention of PPH at the community level. The primary outcome was referral to a health center or hospital for PPH. This measure was a proxy variable for PPH because the main study did not measure PPH directly (i.e. postpartum blood loss ≥500 mL).

Costs and effects were calculated for two hypothetical cohorts, each consisting of 150 000 patients delivering during a 1-year period. Each cohort was assumed to have received either misoprostol or oxytocin. This number was chosen to approximate the annual number of non-institutional births that presently occur in Senegal [15,16]. A third cohort of the same size was assumed to use the current standard of care practices.

Costs were calculated in 2013 US dollars. A health-system perspective was adopted so costs incurred by the patient, their family, or society, including losses in productivity and income, or other social, psychological, and intergenerational costs were not included.

For each intervention, the total cost per delivery was calculated as the sum of the commodity cost (misoprostol or oxytocin), the cost of training matrones to administer the drug, distribution and administration costs, cold-chain costs, and wastage costs (Table 1). The commodity cost of oxytocin per delivery (US$ 1.44) was derived directly from invoices collected during the randomized trial [14] and included shipping and insurance fees, as well as a handling fee for refrigeration. The commodity cost for misoprostol (US$ 0.42) was obtained from local organizations based on the costs of recent purchases.

Table 1
Prophylactic PPH intervention costs, Senegal, 2013.[a]

Cost component	Intervention	
	Misoprostol	Oxytocin
Matrone training	1.68	1.86
Commodity	0.42	1.44
Wastage	0.02	0.17
Cold-chain logistics	NA	0.84
Distribution/use	0.09	0.06
Total	2.21	4.38

Abbreviations: PPH, postpartum hemorrhage; NA, not applicable.
[a] Intervention costs are given in 2013 US dollars.

The time taken to train matrones to be able to competently administer the study drugs was used to calculate the training cost. The per-delivery training costs were US$ 1.86 for oxytocin and US$ 1.68 for misoprostol.

It was estimated that the cost of distributing and using the two drugs contributed little to the total cost per delivery; these costs were US$ 0.06 for oxytocin and US$ 0.09 for misoprostol. The computations required various assumptions but the measurement errors that these assumptions could have introduced to the overall cost calculation were slight (computational details in Supplementary material S1).

The cost of wastage in the logistics of supplying the two drugs was also calculated. It was not possible to find an estimate of wastage for misoprostol tablets in the public drug supply system. The wastage rate for misoprostol in the randomized trial was less than 1% [14]. However, this rate was from a controlled study and so could be unrepresentative of typical wastage rates; consequently, a commonly used wastage rate of 5% was included. For oxytocin, the wastage rate from the randomized study [14] was used; of the Uniject devices, 12.1% were discarded owing to breakage, being compromised by heat, or having passed the expiration date. Consequently, the estimated cost of wastage per delivery was US$ 0.17 for oxytocin and US$ 0.02 for misoprostol.

Finally, a per-delivery cost of maintaining a cold chain for oxytocin was estimated; this estimate considered that the cold chain only extends to the health center/rural hospital level (oxytocin in Uniject form was not kept refrigerated at the health-hut level). Data regarding annual outlays for existing cold-chain logistics were obtained from the ministry of health (computational details in Supplementary material S1). The cold-chain component was estimated to add US$ 0.84 to the total per-delivery cost of oxytocin.

The two outcomes recorded in the randomized trial that were available for the present cost-effectiveness analysis were decreases in hemoglobin of at least 20 g/L and patients referred to health centers or hospitals owing to PPH. The methodological challenges in measuring PPH have been widely acknowledged [17], and the relationship between hemoglobin decreases and blood loss are not well established; some studies have reported a positive correlation and others have found none [18–22]. In view of this uncertainty, this measure of effectiveness was not included in the present analysis, which used the rate of PPH referrals.

The effects of the two prophylactic interventions were compared to the current standard of care in rural Senegal. In such areas, individuals often undergo delivery at home or in a health hut with no equipment or drugs to provide basic emergency obstetric care and no trained professional to deliver such care; consequently, the standard of care in these areas is the referral of patients to a higher-level facility for PPH. It was assumed that the rate of PPH referrals under standard of care would be equivalent to the incidence of severe PPH (blood loss >1000 mL); this was based on the assumption that all referrals reached higher-level facilities. A published estimate of 3% of deliveries among rural populations was used [23]; consequently, under standard of care, a PPH-referral rate of 3% was assumed.

Incremental costs were calculated as the difference between the cost of providing misoprostol or oxytocin to a cohort of 150 000 patients undergoing delivery versus the cost associated with applying the standard of care to the same cohort. The incremental outcomes were the difference between the number of PPH referrals in the two intervention arms and the same outcome under the standard of care. Incremental costs and incremental outcomes were used to calculate incremental cost-effectiveness ratios (ICERs). ICERs represent the incremental change in costs of an intervention divided by the incremental change in outcome following the intervention. Statistical significance (or lack of significance) in the randomized study was assumed to carry over to the cost-effectiveness analysis.

A univariate sensitivity analysis was performed to examine how uncertainty in several of the parameters that fed into ICER calculations could affected the study findings, and to determine which variables

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