AVERTING MATERNAL DEATH AND DISABILITY

Prevention of postpartum hemorrhage at home birth in Afghanistan

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ABSTRACT

Objective: To test the safety, acceptability, feasibility, and effectiveness of community-based education and distribution of misoprostol for prevention of postpartum hemorrhage at home birth in Afghanistan. Methods: A nonrandomized experimental control design in rural Afghanistan. Results: A total of 3187 women participated: 2039 in the intervention group and 1148 in the control group. Of the 1421 women in the intervention group who took misoprostol, 100% correctly took it after birth, including 20 women with twin pregnancies. Adverse effect rates were unexpectedly lower in the intervention group than in the comparison group. Among women in the intervention group, 92% said they would use misoprostol in their next pregnancy. In the intervention area where community-based distribution of misoprostol was introduced, near-universal uterotonic coverage (92%) was achieved compared with 25% coverage in the control areas. Conclusion: In Afghanistan, community-based education and distribution of misoprostol is safe, acceptable, feasible, and effective. This strategy should be considered for other countries where access to skilled attendance is limited.

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1. Introduction

Postpartum hemorrhage (PPH) due to atonic uterus (failure of the uterus to contract after delivery of the placenta) is the major cause of maternal mortality in Africa and Asia [1]. Once hemorrhage occurs, the woman’s condition can rapidly deteriorate, requiring rapid resuscitation, blood transfusion, and other costly and invasive measures. In low-resource settings, rapid referral/transport and emergency preparedness at the referral site are often suboptimal. The World Health Organization (WHO) indicates that coverage for effective prenatal care, skilled birth attendance (SBA), institutional delivery, and emergency obstetric care is less than 50% in 75 of the highest mortality countries [2]. The importance of SBA is highlighted because between 60% and 80% of PPH could be prevented if appropriate care were available during labor and childbirth [3]. Unfortunately, while attempts to increase SBA continue, recent WHO figures indicate that only 63% of births worldwide were attended by a skilled provider [4].

When SBA is available, the most effective intervention for preventing PPH is active management of the third stage of labor (AMTSL), which includes using a uterotonic drug after the baby’s birth. AMTSL has been shown to decrease incidence of blood loss of 1 liter or more, decrease need for blood transfusion, and decrease need for additional uterotonic drugs [5]. WHO currently recommends that AMTSL should only be performed by skilled attendants for women giving birth [6].

Three effective uterotonic drugs are potentially available for use during AMTSL in low-resource settings. Oxytocin has minor adverse effects, including nausea, vomiting, and diarrhea. It requires storage in a cool temperature (5–25 °C), although it can be kept outside these temperatures for short durations. Adverse effects with ergometrine are more common; it is also less stable in warm temperatures, requires dark storage, and cannot be used in the 10%–15% of women who have hypertension in pregnancy. Both require a skilled provider trained in safe injection practices and availability of sterile syringes and needles. The third uterotonic drug, misoprostol, is also effective, available in tablet form, and has relatively common but minor adverse effects, such as shivering and transient elevation in body temperature (although adverse effects of misoprostol are lower when administered rectally, rectal administration is less acceptable to women and requires providers). Because of these attributes, orally administered misoprostol has the potential for use in preventing PPH at home births without a skilled provider. Lumbiganon et al. [7] documented that the adverse effects of misoprostol are dose-dependent, and determined that the optimal dose of misoprostol for prophylactic postpartum use is 600 µg.

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1.1. Misoprostol for prevention of PPH

A 2006 joint statement from the International Confederation of Midwives (ICM) and the International Federation of Gynecology and Obstetrics (FIGO) states that: “In home births without a skilled attendant, misoprostol may be the only technology available to control PPH” [8].

Several studies have examined the role of misoprostol in preventing PPH [9–13], Goldberg et al. [14] concluded in their data review that there is good and consistent evidence to support a recommendation for use of misoprostol to prevent PPH when oxytocin is unavailable. Efficacy of misoprostol in preventing PPH was demonstrated most convincingly by a trial in India [13], where either misoprostol or a placebo was given by auxiliary nurse midwives at home and sub-center births. The study demonstrated a reduction in PPH with the use of misoprostol, with a decreased incidence of blood loss of 500 mL or greater (12% vs 6.4%; RR 0.53, 95% CI 0.39–0.74, \( p < 0.001 \)).

Based on these and many other studies, WHO has recommended that “in the absence of AMTSL, a uterotonic drug (oxytocin or misoprostol) be offered by a health worker trained in its use for prevention of PPH” [6].

1.2. PPH in Afghanistan

The maternal mortality ratio in Afghanistan is 1600 per 100 000 live births [15], one of the highest in the world. Hemorrhage is the most common cause of maternal mortality, responsible for about 38% of maternal deaths. Given that only an estimated 19% of women deliver with an SBA, the Government of Afghanistan’s goal to reduce its maternal mortality ratio by 50% by 2015 presents an enormous challenge [16]. Since much of the country is snowbound during winter, even if SBA was available, providers would not be able to reach many rural women. In short, although substantial effort is underway to increase the number of births attended by skilled providers, providing skilled professional care to all women in Afghanistan is still many years away. Therefore, any maternal survival strategy to reduce PPH at home births must consider what can be achieved at the community level, beyond the reach of skilled professional providers.

The purpose of this study was to test a strategy for community education about PPH prevention accompanied by provision of misoprostol directly to women for self-administration post partum. The study sought to assess whether community-based distribution of misoprostol was: (1) safe and not likely to be misused; (2) acceptable to women and their families; (3) feasible; and (4) programmatically effective. Afghanistan has a growing community education and health outreach program, and in the last 3 years most districts have achieved the target of having at least 1 community health worker (CHW) per 100–150 households. These CHWs, who are generally semi-literate, are widespread and accepted in the community. CHWs are already identifying pregnant women in the community and distributing hematinics. Moreover, infrastructure and supervision systems already exist to manage them and keep them supplied. It is therefore reasonable to expect that a strategy for prevention of PPH at home births in Afghanistan can be implemented using a community-based distribution model that relies on CHWs.

2. Materials and methods

2.1. Study design and methods

The study protocol used a nonrandomized experimental control design approved by the Afghanistan Ministry of Public Health (MOPH) Technical Advisory Group, Essential Drug Board, and Ethical Review Board (no. 358322, MOPH Afghanistan, February 23, 2006). Although we recognize the limitations posed by nonrandomized trials, several logistical reasons prevented use of a randomized design. The two districts used for the study were selected because they receive existing support from the U.S. Agency for International Development (USAID), have established and functioning CHWs, and were not in insurgency areas.

CHWs routinely identified pregnant women and recorded them on household maps. We measured safety (including correct dose, correct timing, and recovery of unused misoprostol) during postpartum interviews conducted by trained, literate interviewers. We studied acceptability (including adverse effects, and willingness to use and recommend misoprostol to others) also through postpartum interviews, as well as through focus groups. Feasibility was measured through qualitative interviews with CHWs regarding willingness and motivation to take on the task of reaching all pregnant women with the message and drug. Finally, we measured program effectiveness through postpartum interviews to determine coverage of pregnant women who had taken uterotonic drugs (misoprostol or an injection by a skilled provider presumed to be oxytocin).

In both the intervention and comparison areas, CHWs made 3 home visits to pregnant women and their families: when they were first registered, during their eighth month of pregnancy, and within a week after birth. All women who agreed to participate in the project and provided verbal informed consent were interviewed by CHWs using a pictorial data form. During each visit, CHWs provided one-on-one education of the women and household support members. CHWs used pictorial flipcharts to provide education on birth preparedness and complication readiness; recognition of danger signs—especially PPH—during pregnancy, childbirth, and postpartum; the role of SBA; and what to do in the event of a complication, including where and from whom to seek care. In addition, women and their support persons in the intervention areas received education on the purpose, correct timing, and use of misoprostol to prevent PPH; the risks of taking misoprostol before the birth of the baby; common adverse effects and what to do in case they occurred; and what to do if PPH occurred despite taking the medication. At the second visit, women in the intervention group who agreed to accept misoprostol were given a package containing 3 tablets of 200 µg of misoprostol, as well as pictorial and written educational materials with instructions on correct and safe use of misoprostol. Demonstration of understanding was required prior to handing over the drug. Women who chose to give birth with a professional midwife at home had the option to take misoprostol unless the midwife chose to override the protocol. CHWs visited the participants within 1 week of giving birth and informed the community health supervisors, who then administered a structured questionnaire during the postpartum interview.

2.2. Packaging, distribution, and provision of misoprostol

Three 200-µg tablets of misoprostol in foil packets were packaged together in sealed paper packets and labeled with pictorial messages about correct use. All packets were numbered and each CHW’s initial stock of 5 packets was replenished during monthly supervisory meetings. CHWs provided misoprostol to women in their eighth month of pregnancy only after the woman demonstrated understanding of use and prevention of misuse of the drug. Unused doses were collected during the postpartum visit from women who did not take the medication.

2.3. Field implementation

The study was conducted between June 2005 and August 2007 in 3 phases: (1) proposal development and advocacy; (2) preparation; and (3) implementation. In Phase 1, a national PPH Technical Advisory Group was established to provide a high-level forum where stakeholders from the MOPH and implementing partners could be integrally involved in oversight of the study. Advocacy for the study...
involved a series of sensitization meetings with stakeholders (from national level to community level) to promote understanding of the study and garner support. During Phase 2, provinces serving as implementation sites were selected by the PPH Technical Advisory Group, and the study was approved by the Ethical Review Board. Provinces were selected based on security, accessibility, and existing support from USAID. Districts within these provinces were then selected based on availability of baseline data on maternal health status; existence of a CHW network and nongovernmental organizations supporting CHW work; availability of a functioning health center or hospital within 2 hours travel time; presence of other community activities on which to build, such as birth preparedness; and a low rate of SBA. Women in these areas were generally nonliterate. Districts chosen were: Qarghan, Qaramqul, Qarzin, Khamab, Qarabagh, and Guldara from Faryab, Jawzjan, and Kabul Provinces, totaling a population of 177 300.

2.4. Data collection and analysis

Quantitative data collection focused on recall of critical information, use of drug, experience of adverse effects, and pregnancy outcomes. Qualitative data, which were gathered from a subgroup of all acceptors, focused on acceptability of the intervention, tolerance of adverse effects, and reasons for non use.

All data collection forms were manually reviewed for completion and accuracy. Data entry and preliminary analyses were conducted at the Jhpiego/ACCESS Program office in Kabul using Microsoft Access. Further analysis was conducted in Baltimore, Maryland, and at the University of California, Berkeley, using Stata 10.0 (Stata Corp, College Station, TX, USA). Results were summarized using frequency distributions and cross tabulations. Bivariate analyses according to study area (intervention and comparison) were used to assess differences between indicators. Two-tailed student t test for comparison of two proportions or two means was estimated, and statistical significance was established at \( P \leq 0.05 \).

3. Results

3.1. Characteristics of the study population

A total of 3187 women participated in the study. Table 1 shows the characteristics of the study population. For the indicators assessed, no significant differences existed between women in the comparison and intervention areas.

Each implementation district had at least one health facility e.g., Basic Health Center (BHC), Comprehensive Health Center (CHC), or district hospital. The estimated time to access the health facility from the women’s homes ranged from 15 minutes to 1.5 hours. Since some of these BHCs and CHCs did not have qualified midwives, prenatal care was often provided by any health worker. Primary care services in the study areas were provided by nongovernmental organizations. In the intervention group, 16% of women received prenatal care from a midwife, and of this group 79% received prenatal care at a local health facility. In the comparison group, these numbers were 21% and 71%, respectively.

As shown in Table 2, the majority of births in both groups occurred at home. Only 21% and 18% of births were at health facilities in the intervention and comparison areas, respectively. Nearly 8% and 2% of births were at midwives’ homes in the intervention and comparison areas, respectively.

3.2. Safety

Of the 2039 women in the intervention group identified as pregnant during community mapping, 2021 (99%) were offered the drug; the other 18 women were either not found at home during the visit or their visits at eight months’ gestation were missed for other reasons, or had already given birth (Table 3). Of the 2021 women who were offered misoprostol, 1970 (97%) accepted the drug; the 51 women who did not accept misoprostol had planned to deliver at a health facility, or had firm plans for delivering with a skilled provider. Of all the women who were identified as pregnant, 1421 (70%) women used the misoprostol. No woman took the misoprostol before the birth of the baby. There were 20 twin deliveries and among this group all of the women took the drug after delivery of the second baby. All women who took misoprostol did it at the correct time. Three women did not take the full dose of 3 tablets because one pill had been dropped/lost. The misoprostol was taken immediately after delivery of the baby and before the placenta was delivered by 96% of the women.

Table 4 shows the proportion of women who took misoprostol, according to where they delivered. Ninety-four percent of women who gave birth at home used misoprostol.

Table 5 shows the symptoms reported after delivery by women in both groups to assess the rates of any adverse effects. Rates of each of the 6 commonly reported symptoms were higher in comparison areas than in intervention areas.

| Table 1 | Characteristics of the study population. * |
|---|---|---|
| Characteristics | Participants | P value |
| | (n = 2039) | (n = 1148) | |
| Talked to any health worker during pregnancy | 88.7 | 87.5 | 0.31 |
| Multiple births | 1.0 | 1.2 | 0.60 |
| Cesarean section | 0.9 | 0.4 | 0.08 |
| Gravidity 1 | 15.2 | 14.3 | 0.49 |
| Gravidity >1 | 84.8 | 85.7 | 0.49 |

* Values are given as percentage.

| Table 2 | Delivery information.* |
|---|---|---|
| | Intervention (n = 2039) | Comparison (n = 1148) | P value |
| Place of delivery | | | |
| Woman’s home | 70.6 | 80.1 | 0.001 |
| TBA’s home | 0.3 | 0.1 | 0.26 |
| Midwife’s home | 7.8 | 1.8 | 0.001 |
| Health facility | 21.4 | 18.1 | 0.001 |
| Assistance during delivery | | | |
| Doctor/midwife | 29.9 | 27.6 | 0.17 |
| TBA | 46.9 | 41.9 | 0.01 |
| Friend/relative | 20.7 | 28.9 | 0.001 |
| CHW | 2.1 | 0.9 | 0.01 |
| No one | 0.3 | 0.7 | 0.10 |

Abbreviations: TBA, traditional birth attendant; CHW, community health worker.* Values are given as percentage.

3.3. Acceptability

Ninety-two percent of all women, regardless of whether they actually took the misoprostol or not, said they would recommend misoprostol to their friends and use it in their next pregnancy. Approximately 88% said they would be willing to pay to receive misoprostol in the future. The women who said they would be willing to pay for misoprostol, 88% were willing to pay at least 50 AFG (equivalent to approximately $1 USD). In addition, results from focus group discussions suggested that misoprostol was acceptable by the women’s husbands and mothers-in-law.

3.4. Feasibility

Fig. 1 shows the steady recruitment of women observed throughout the study period. The population estimates used in the denominator were the expected number of new pregnant women per month based on population census data and crude birth rates. The CHW target was to reach every such woman. On average, each CHW conducted 9 home visits per month in the intervention areas and 13 in the comparison areas. This difference is partly because the duration of the visit was longer in the intervention areas. On average, each CHW looks after 3 pregnant women per month, and each skilled attendant (midwife) attends 8 births per month. CHWs reached almost 94% of the expected births in the intervention areas and 80% in the comparison areas.

Study recruitment ended in February 2007, with identification of pregnant woman and the first educational message completed for 94% of the expected population. Misoprostol distribution paralleled the recruitment of women (although delayed by 4–5 months since most women were recruited mid-pregnancy but provided the medication in the eighth month) in that almost every woman identified as pregnant received misoprostol. The use of misoprostol also showed a steady increase, reaching a plateau at nearly 70%.

3.5. Program effectiveness

Since the efficacy of misoprostol in PPH has already been demonstrated [6,13], the purpose of this study was not to determine incidence or prevalence of PPH, but to demonstrate that community-based distribution could reach nearly every woman in need. We did, however, ask women in postpartum interviews to describe the quantity of blood loss and characterized perceived hemorrhage as 2 soaked cloths. Using this criteria, we demonstrated that women who used misoprostol were more than 6 times less likely to report excessive bleeding than women who did not take misoprostol. Of the 2039 women in the intervention group, 1366 (67%) women took only misoprostol, 540 (27%) received only an injection (presumed to be oxytocin), 54 (3%) took the misoprostol and received an injection, and 78 (4%) received neither misoprostol nor an injection (see Table 6). In the comparison area, 295 women (26%) received only an injection (presumed to be oxytocin) immediately after birth of the baby, and 853 (74%) did not get any drug.

Seventy-eight women in the intervention group (or less than 4%) did not take misoprostol when oxytocin was not available to them for reasons including fear of adverse effects; belief that it would not work or was not needed; forgetting where the drug had been placed; and/or providers, husbands, or family members deciding it was not needed. All unused misoprostol tablets were collected by project personnel, as per protocol.

4. Discussion

While the procedure and drug of choice for preventing PPH remain AMTSL and injectable oxytocin where there is SBA [6], there is currently no evidence-based means of preventing PPH in the 63% of world births not attended by skilled professional providers. In Southeast Asia and Sub-Saharan Africa, where the proportion of SBA has hardly increased in 15 years, few countries are on track to achieve Millennium Development Goal 5 [4].

Our findings show that providing community-based education and distribution of misoprostol by semi-literate CHWs is a safe, acceptable, feasible, and effective strategy for prevention of PPH in low-resource
settings where women do not have uniform access to SBA. Moreover, this approach does not discourage use of skilled care. On the contrary, because educational messages included significant emphasis on identifying and using a skilled provider, births with skilled providers (either in health facilities or homes of midwives) were actually higher in intervention areas than in comparison areas. We believe this result is because during each of their visits, CHWs emphasized and re-emphasized the message that the woman’s first choice should be to have a skilled provider at birth, and misoprostol should only be used if they could not access SBA or if a skilled provider could not reach them. Nor did this approach discourage women who received care from a midwife from receiving injections (assumed to be oxytocin since recently-graduated midwives had been newly posted in these areas in the last 1–2 years and are skilled in AMTSL). Because the study design encouraged midwives to use AMTSL if they had the skills for this procedure and oxytocin was available and had been properly stored, ultimately more women in the intervention group received injections than the comparison group (29% vs 26%, respectively).

This study also demonstrated that involving mothers-in-law, sisters-in-law, husbands, and mothers in the educational process reinforced the messages and ensured that at least one support person knowledgeable about PPH and misoprostol was present at nearly all births in the intervention area. This ability to provide the same educational message to women and their support persons is difficult at crowded prenatal care clinics because all support persons rarely attend clinics with pregnant women, and most health workers in low-resource nations have too many clients to provide sufficient one-on-one education. Other issues related to the health education component include the importance of counseling messages on correct timing of use of misoprostol (i.e., after the birth of the last baby), particularly given the 1% rate of multiple births observed.

In this study, we chose to distribute misoprostol to the pregnant women themselves rather than provide misoprostol to traditional birth attendants (TBAs) to administer. One reason for this decision is that in remote areas, it is sometimes difficult for women to reach TBAs, and vice versa. Additionally, in some countries, many births occur with “occasional” TBAs, e.g., a neighbor or an aunt who happens to be there and does not provide birth assistance on a regular basis. However, Prata et al. [17] have shown that in Tanzania TBAs can also safely use misoprostol for treatment of PPH, demonstrating that local communities can be empowered to use lifesaving medications responsibly and safely. In settings where skilled providers are present, AMTSL (which requires uterotonic administration and controlled cord traction to deliver the placenta) is usually done. In our study, misoprostol was taken after the birth of the baby and before the placenta was delivered. Delivery of the placenta was then allowed to occur on its own, i.e., “expectant,” in the same way as was done in the Indian study [13], except that misoprostol was not “administered” by the nurse but just taken by the woman.

The community component of this study resulted in higher rates of recruitment and education visits by CHWs in both the comparison and intervention areas than would have been achieved through the existing facility-based delivery system. Importantly, home visits occurred even during severe winter months when much of the study areas are snowed in and access to formal healthcare services becomes more limited.

At a ratio of 1600 per 100 000 live births, the expected number of maternal deaths among 1348 births would be 22. This ratio, which is from the Barlett study and the only one available for Afghanistan [15], may not necessarily reflect the current situation since Afghanistan is in a tremendous stage of transition. In the present study, only 1 maternal death occurred in the intervention area, in February 2007. Unused misoprostol was recovered from the family and a verbal autopsy suggested postpartum eclampsia as the cause of death. Every woman was visited in the postpartum period by the study supervisor and a postpartum interview was conducted. Only 4 women were not interviewed postpartum: the woman who died and 3 who had gone to Pakistan to have their babies. We are certain that this reflects the true maternal mortality in the study area, and recognize that even in the very short period of time almost 25% of births are with skilled providers who have only recently been posted in such areas. In addition, all the study areas now have the basic package of health services available, conditions that were not present when the Bartlett study was done.

As described earlier, misoprostol has known and predictable adverse effects. We noted that rates of all reported symptoms were actually higher in the comparison areas than the intervention areas (60% vs 19%, respectively). In-depth interviews with recently-delivered women revealed that in the comparison areas women were more likely to use herbal products (such as yellow fat mixed with herb and eggs, herbal root, or molasses mixed with opium extract) during labor and delivery and post partum. These herbal products frequently produce similar symptoms to those commonly associated with uterotonic drugs, such as shivering and nausea. Thus, one possible explanation for this finding is that women were more likely to use herbal products if they did not have a method to protect themselves against PPH. This issue deserves further investigation.

When considering whether misoprostol should be given to all women at childbirth to prevent PPH if an alternative uterotonic or AMTSL is not available, three decisions need to be made. First, does the prevalence and morbidity/mortality associated with PPH justify a preventive approach rather than solely a treatment approach? Given that up to 15% of women will suffer PPH, and even short delays in initiating treatment can result in worsening PPH requiring uterotonics, blood, intravenous fluids, and potentially major surgery, it seems appropriate to prevent as much PPH as feasible. However, given that most births occur far from facilities, a deferral-for-treatment-of-PPH strategy using misoprostol poses significant challenges. Low-literate women would have to make a more complex decision of when to take misoprostol, i.e., decision-making on suspected PPH, as well as having the drug available at the time of birth. It may be easier/more feasible to proactively prevent PPH.

Second, what is the level of adverse effects and their predictability? The dose of 600 µg used in this and other trials resulted in transient chills, nausea, and elevation in temperature. These adverse effects did not affect acceptability negatively; as mentioned previously, rates of symptoms were lower in the intervention group than the comparison group. While a lower dose may reduce adverse effects, there is currently insufficient evidence for the efficacy of a 400-µg dose in preventing PPH.

Third, is distribution of misoprostol for PPH prevention through community-based workers feasible in low-resource settings? Ensuring a robust educational message—delivered by community volunteers who are well-trained, supervised, and supported—requires significant investment. Fortunately, CHWs are now a norm in many low-resource nations, including Kenya, Ethiopia, Tanzania, and Indonesia. It is preferable for CHWs to provide, as in Afghanistan, a package of care that includes both health education and community distribution of some commodities. Such a package of interventions could include birth preparedness and complication readiness education; pregnancy and birth registration; distribution of hematinsics, micronutrients, and anti-worm treatment; distribution of intermittent preventive treatment for malaria, bed net vouchers, clean birth kits, and misoprostol; basic postpartum and newborn care education including support for breastfeeding; and family planning education and distribution. Such a package would address most key maternal and newborn healthcare needs in areas unreachable by skilled providers.

An additional concern is keeping CHWs motivated as volunteers. Two types of incentives were provided to the CHWs in this study. The first was provided by the project and consisted of providing transport to the CHWs to and from training courses and monthly meetings for bringing in data. These costs did not exceed US $15 annually per CHW.
The second type of incentive was provided by the community. Community leadership found creative ways of rewarding CHWs, including providing free power from neighborhood generators, or identifying young men to prepare CHW houses for the winter. For sustainable programs, strategies can and should be devised for creative and appropriate incentives that societies can afford.

A final concern of policymakers and health managers is whether investments in community approaches might detract from providing skilled care at childbirth or whether women who have access to misoprostol will decide not to seek care from skilled providers. As stated previously, our study demonstrated that this concern is unfounded. Women and their families understand that protecting themselves from PPH at home birth using misoprostol is a “plan B” used only for home births when women and their families are unable to reach a skilled provider.

Semi-literate community health workers can reach a high percentage of women, successfully educate them about prevention of PPH, and provide them with misoprostol for self-administration post partum. Women find misoprostol acceptable and are able to safely and correctly use it to protect their own health where there is limited access to skilled birth attendance. For the many countries where universal access to skilled care at birth is a distant reality, this approach offers the possibility of mortality reduction today.

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