SPECIAL ARTICLE

An Intervention Involving Traditional Birth Attendants and Perinatal and Maternal Mortality in Pakistan

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ABSTRACT

BACKGROUND

There are approximately 4 million neonatal deaths and half a million maternal deaths worldwide each year. There is limited evidence from clinical trials to guide the development of effective maternity services in developing countries.

METHODS

We performed a cluster-randomized, controlled trial involving seven subdistricts (*talukas*) of a rural district in Pakistan. In three talukas randomly assigned to the intervention group, traditional birth attendants were trained and issued disposable delivery kits; Lady Health Workers linked traditional birth attendants with established services and documented processes and outcomes; and obstetrical teams provided outreach clinics for antenatal care. Women in the four control talukas received usual care. The primary outcome measures were perinatal and maternal mortality.

RESULTS

Of the estimated number of eligible women in the seven talukas, 10,114 (84.3 percent) were recruited in the three intervention talukas, and 9443 (78.7 percent) in the four control talukas. In the intervention group, 9184 women (90.8 percent) received antenatal care by trained traditional birth attendants, 1634 women (16.2 percent) were seen antenatally at least once by the obstetrical teams, and 8172 safe-delivery kits were used. As compared with the control talukas, the intervention talukas had a cluster-adjusted odds ratio for perinatal death of 0.70 (95 percent confidence interval, 0.59 to 0.82) and for maternal mortality of 0.74 (95 percent confidence interval, 0.45 to 1.23).

CONCLUSIONS

Training traditional birth attendants and integrating them into an improved health care system were achievable and effective in reducing perinatal mortality. This model could result in large improvements in perinatal and maternal health in developing countries.

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There are an estimated 4 million neonatal deaths and 500,000 maternal deaths worldwide each year.[1,2] The vast majority of these deaths occur in developing countries, where 43 percent of births are attended by traditional birth attendants, the proportion generally being higher in rural areas. Training traditional birth attendants was a central component of the Safe Motherhood Initiative launched by the World Health Organization, the United Nations Children's Fund (also known as UNICEF), the United Nations Population Fund, the World Bank, and other organizations, but the lack of evidence from randomized, controlled trials to inform decision making has prohibited widespread implementation of such training.[3,4] We present the results of a large cluster-randomized, controlled trial of training traditional birth attendants and integrating them into an improved maternal health care system in rural Pakistan.

Organized data on routine health outcomes do not exist in rural Pakistan. The World Health Organization's estimate of maternal mortality in Pakistan (350 per 100,000 live births in 1995) was modeled from projections of deaths of adult females.[5] In Pakistan, more than 89 percent of deliveries, and 80 percent of maternal deaths, occur at home, and 80 percent of deliveries are attended by only a traditional birth attendant.[6,7] Only 1 in 20 women with complications of pregnancy or childbirth reaches a facility with emergency obstetrical care. Infant mortality is estimated at 82 per 1000 live births.[8]

METHODS

STUDY DESIGN

The study was a randomized, controlled trial. Since the intervention included the training of traditional birth attendants, an individualized, randomized design would have led to contamination between intervention and control care; therefore, cluster randomization was required. Financial and logistic considerations dictated the subdistrict (*taluka*) as the most appropriate unit for randomization.

SETTING

Sindh is one of Pakistan's four provinces. In Sindh's 21 districts, an infrastructure of primary and district-level care serves well-defined geographic areas. Larkana, the study district, is largely rural. The Ministry of Health's Lady Health Workers Programme is an important element in the government of Pakistan's plan to raise the health status of women and children in rural villages and poor urban areas. A cadre of Lady Health Workers based at primary health centers have a mission of delivering primary health care, including maternal-health and child-health services. Although the women are educated (10 years of schooling), they have no medical or nursing degree, but they do receive 3 to 6 months of training in primary health care and family planning. Recruiting and retaining female medical staff is difficult in rural areas, so the quality of primary maternity services is, in general, poor.

STUDY GROUPS

With a simple cluster-randomization sampling scheme, and with a computer-generated procedure, Larkana's seven talukas were allocated to intervention or control groups. All pregnant women were eligible for inclusion. Most of the private medical centers and a public tertiary-level hospital providing specialist obstetrical care are located in Larkana City, where residents have better access to services. The city and its immediate environs were therefore excluded.

INTERVENTION CLUSTERS

The intervention was designed to facilitate care based on the available infrastructure and to be low-cost and sustainable. In the intervention clusters, a team of obstetricians and female paramedics trained all traditional birth attendants in the taluka who performed at least one delivery per month (Fig. 1). The training lasted three days and involved the use of picture cards containing advice on antepartum, intrapartum, and postpartum care; how to conduct a clean delivery; use of the disposable delivery kit; when to refer women for emergency obstetrical care; and care of the newborn. The traditional birth attendants were asked to visit each woman at least three times during the pregnancy (at three, six, and nine months) to check for dangerous signs such as bleeding or eclampsia, and to encourage women with such signs to seek emergency obstetrical care. Lady Health Workers were trained to support the traditional attendants and record the data.

Because of the difficulties in recruiting full-time female medical staff in primary care centers, obstetrical consultation was also provided by two teams

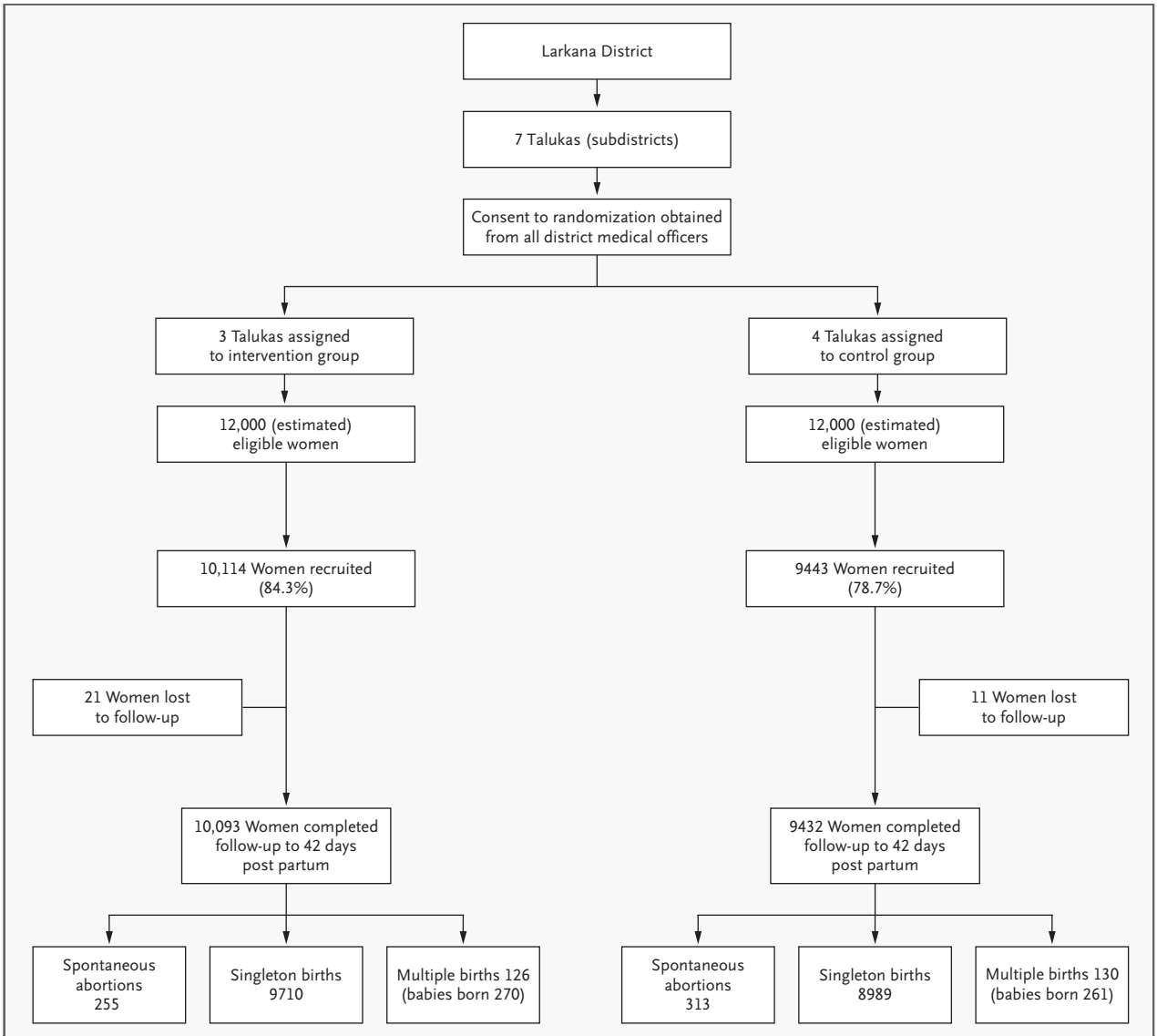

Figure 1. Flow Chart Showing the Enrollment and Status of Women in the Trial.

A total of 19,557 women were recruited in the six months from May to October 1998. From March to April 1998, 565 traditional birth attendants, 811 Lady Health Workers in the intervention group, and 819 Lady Health Workers in the control group were trained as appropriate to study group. A spontaneous abortion is defined as loss of a fetus before six months of gestation. For two women in the intervention group, the outcomes of the births were not known.

of obstetricians from the public-sector tertiary care center in Larkana City. These teams offered outreach clinics in two centers (one taluka hospital and one large, rural health center) in each of the three intervention talukas. The teams rotated their visits among the centers, holding eight outreach sessions in each center during the six-month intervention period.

Traditional birth attendants were instructed to register all pregnant women in their catchment areas and to inform the Lady Health Workers about the pregnant women under their care. Subsequently, the traditional birth attendants were issued delivery kits from the primary care centers. The kits included sterilized disposable gloves, soap, gauze, cotton balls, antiseptic solution, an umbilical-cord

clamp, and a surgical blade. We anticipated that these kits would improve the standing of the traditional birth attendants among their clients, and the method of distribution was designed to increase the links between traditional birth attendants and the primary care facilities.

CONTROL CLUSTERS

In the control clusters, Lady Health Workers enrolled and followed up all pregnant women in their catchment area in the course of their normal monthly home visits to women and children. The traditional birth attendants in the control clusters did not receive any training and were not supplied with delivery kits. No outreach clinics were organized in these talukas, and women in these areas received "usual" care.

FOLLOW-UP

Follow-up in both groups involved the collection of information by Lady Health Workers, who asked the women, their families, and traditional birth attendants for details of the progress and outcome of each pregnancy that was registered. In cases of maternal death, the cause was ascertained by Lady Health Workers on the basis of oral reports from relatives, neighbors, or traditional birth attendants.

OUTCOME MEASURES

The primary outcomes were perinatal mortality (stillbirths and live-born babies who died within 28 days after birth) and maternal mortality (deaths during pregnancy and up to 6 weeks post partum, excluding those known to have been due to injury or accident) from any cause, including deaths after spontaneous abortion (loss of a fetus before 6 months of gestation). Only singleton pregnancies were included in the analysis of perinatal outcome.

The secondary outcomes were major complications of pregnancy (hemorrhage, obstructed labor, puerperal sepsis, eclampsia, and abortion), referral by the traditional birth attendant for emergency obstetrical care, type and place of delivery, and delivery attendant. Lady Health Workers who recorded outcomes could not be blinded to the intervention status of the women but were not made aware of the main study objective or the outcome measures for the planned comparison.

STATISTICAL ANALYSIS

The sample size of this trial was limited by the available funding. Local information suggested that there were approximately 70,000 deliveries per year in Larkana district. After excluding urban areas, we estimated that 24,000 pregnant women could be recruited in six months. Randomization below the level of the taluka was not practical. With seven clusters (average size, 4000 pregnant women each) and an intraclass correlation coefficient of 0.001, the study would have 80 percent power (two-sided $P<0.05$) to detect a 23 percent difference in perinatal mortality (estimated at 95 per 1000 live births and stillbirths in the control group) between the study groups. Assuming maternal mortality in the control group of 400 per 100,000 pregnancies, such a sample size would permit us to detect a relative reduction in maternal mortality only as large as 90 percent. However, given the importance of the outcome, and the hypothesis that the outcome would be influenced by the intervention, we included maternal mortality as a primary outcome measure.

The data were entered into a database of epidemiologic information[9] and analyzed with the use of SPSS software, version 10.0. Evaluation was by intention-to-treat analysis. Multilevel modeling to adjust for cluster randomization was performed with the use of MLwiN software, version 1.1.[10] For perinatal and maternal mortality, we used a quasi-likelihood binary-regression model with random intercept to estimate the degree of overdispersion in the cluster-specific death rates. Odds ratios and 95 percent confidence limits were computed for the model coefficients with the use of MLwiN guidelines.[10]

No formal ethics committee exists in this region, but the protocol was discussed and approved after a meeting of Sindh province's secretary of health, director of health services (Larkana Division), and director of the Lady Health Worker Programme (at which Dr. Jokhio was present). These key people acted as guardians of the women's interests.

RESULTS

A total of 19,557 women were recruited in the six months from May to October 1998. An exact figure for the eligible women could not be obtained, since there are no reliable birth registers. On the basis of the crude estimate of 24,000 deliveries in a six-month period, the 10,114 women in the intervention group and the 9443 women in the control group represented 84.3 percent and 78.7 percent, respectively, of the eligible total (Fig. 1). Follow-up

to 42 days post partum was achieved for 10,093 women (99.8 percent) in the intervention group and 9432 women (99.9 percent) in the control group. Pregnancy ended in spontaneous abortion in 255 women (2.5 percent) in the intervention group and 313 women (3.3 percent) in the control group (Table 1). One hundred twenty-six women (1.2 percent) in the intervention group and 130 women (1.4 percent) in the control group had multiple births.

The baseline maternal characteristics were similar for the study groups and across clusters with respect to all measured variables except years of education, which were slightly greater among women in the control group (Table 2). The size of the clusters ranged from 1966 to 3987 women. Of the women in the intervention group, 9184 (90.8 percent) received care by trained traditional birth attendants, and 1634 (16.2 percent) had at least one antepartum visit with the consulting obstetrical teams. Traditional birth attendants used 8172 safe-delivery kits for the intervention group.

The crude perinatal rate of death among the intervention group was 84.8 per 1000 (823 deaths per 9710 live births and stillbirths) as compared with 120 per 1000 (1077 deaths per 8989 live births and stillbirths) in the control group (Table 3). We used random-effects multilevel modeling to determine that the odds ratio for perinatal death in the

Table 1. Factors Related to Delivery According to Study Group.*

Delivery	Intervention (N=10,114)	Control (N=9443)	Cluster-Adjusted Odds Ratio (95% CI)†	P Value
	number (percent)			
Place				
At home	8373 (82.8)	7614 (80.6)	1.07 (0.79–1.45)	0.65
At public health facility	623 (6.2)	493 (5.2)	1.23 (0.96–1.57)	0.10
At private health facility	783 (7.7)	957 (10.1)	0.82 (0.54–1.27)	0.38
En route	22 (0.2)	18 (0.2)	1.28 (0.56–2.96)	0.56
Other places	36 (0.4)	35 (0.4)	0.97 (0.58–1.64)	0.91
Spontaneous abortion‡	255 (2.5)	313 (3.3)	0.73 (0.55–0.99)	0.04
Type				
Normal	9235 (91.3)	8562 (90.7)	1.05 (0.84–1.32)	0.67
Forceps	399 (3.9)	342 (3.6)	1.10 (0.93–1.29)	0.26
Cesarean section	203 (2.0)	213 (2.3)	0.90 (0.67–1.19)	0.46
Attendant				
Doctor	949 (9.4)	1023 (10.8)	0.93 (0.59–1.47)	0.75
Nurse or midwife	568 (5.6)	497 (5.3)	1.14 (0.85–1.54)	0.38
Traditional birth attendant				
Trained§	7460 (73.8)	—	—	—
Untrained¶	583 (5.8)	7191 (76.2)	0.02 (0.01–0.02)	<0.001
Training status unknown‖	164 (1.6)	269 (2.8)	0.55 (0.33–0.94)	0.03
Relative	103 (1.0)	126 (1.3)	0.81 (0.46–1.42)	0.62
Other	10 (0.1)	11 (0.1)	0.85 (0.36–2.00)	0.71

* In the intervention group, 21 women were lost to follow-up, and for 2 women, the outcomes of the births were not known. In the control group, 11 women were lost to follow-up. Numbers may not sum to totals and percentages may not sum to 100 because of incomplete information about delivery. CI denotes confidence interval, and a dash not applicable.
† Multilevel modeling was performed to adjust for cluster randomization.
‡ A spontaneous abortion was defined as a loss of a fetus before six months of gestation.
§ A trained traditional birth attendant was a traditional birth attendant for the intervention group who was trained according to the study protocol.
¶ An untrained traditional birth attendant was a traditional birth attendant not trained according to the study protocol.
‖ In some cases, the woman was known to have been assisted during delivery by a traditional birth attendant, but it was not possible to ascertain if the traditional birth attendant was trained according to the study protocol.

Table 2. Baseline Maternal Characteristics According to Study Group and Cluster.*

Characteristic	Intervention Group				Control Group				
	Cluster 1 (N=3417)	Cluster 2 (N=3987)	Cluster 3 (N=2710)	Total (N=10,114)	Cluster 4 (N=2796)	Cluster 5 (N=2065)	Cluster 6 (N=1966)	Cluster 7 (N=2616)	Total (N=9443)
Age (yr)	27.0±5.8	26.6±5.8	26.5±6.1	26.7±5.9	26.3±6.3	26.5±6.1	26.9±6.3	26.8±6.0	26.6±6.2
Parity (no.)	3.5±2.8	3.5±2.7	3.4±2.8	3.5±2.8	3.6±2.9	3.6±2.9	3.8±2.8	3.6±2.9	3.7±2.9
Month of pregnancy when recruited	5.0±2.1	4.8±2.1	5.3±2.5	5.0±2.2	4.9±2.2	4.9±2.3	5.0±2.3	4.5±1.9	4.8±2.2
Woman's education (yr)	1.2±3.0	1.0±2.7	1.1±2.8	1.1±2.8	1.4±3.2	1.3±3.1	1.1±2.9	1.6±3.4	1.4±3.2
Husband's education (yr)	4.8±5.5	4.1±5.1	4.2±5.5	4.3±5.3	4.2±5.2	4.3±5.5	4.0±5.2	5.3±5.7	4.5±5.4
Distance from nearest primary health care facility (km)	1.7±2.1	3.7±3.9	2.3±2.0	2.7±3.0	3.1±3.5	2.5±3.2	2.7±2.9	1.6±1.8	2.5±3.0

* Plus–minus values are means ±SD.

intervention group, as compared with the control group, was 0.70 (95 percent confidence interval, 0.59 to 0.82); the results were similar for stillbirths and neonatal deaths (Table 4) and across intervention clusters (Table 3). There were 27 maternal deaths in the intervention group and 34 in the control group, corresponding to respective maternal mortality rates of 268 and 360 per 100,000 pregnancies. The cluster-adjusted odds ratio for maternal deaths in the intervention group, as compared with the control group, was 0.74 (95 percent confidence interval, 0.45 to 1.23).

The intervention group had significantly lower rates of puerperal sepsis and hemorrhage as a complication of pregnancy (Table 4). The frequency of a diagnosis of obstructed labor was significantly greater in the intervention group. The frequencies of eclampsia and of spontaneous abortion with associated morbidity did not differ significantly between groups, but the overall numbers of complications recorded were small. Women in the intervention group were more likely than those in the control group to be referred to emergency obstetrical care for treatment (Table 4).

The cause of maternal death, as ascertained by oral report to the Lady Health Workers, is summarized in Table 4.

DISCUSSION

There was a significant reduction in perinatal mortality of about 30 percent in the intervention group of this large, cluster-randomized, controlled trial. The estimated percent reduction in maternal mortality was similar but was not statistically significant despite the large size of the trial. The large decrease in puerperal sepsis is consistent with the recorded high use of safe-delivery kits by traditional birth attendants. It is likely that much of the reduction in perinatal mortality was mediated through reduced sepsis, but it was not possible to obtain definitive information.

The training of traditional birth attendants included teaching them to recognize serious complications of pregnancy and delivery, and obstructed labor was more frequently recorded for women in the intervention group. Referral to public health services was also encouraged, and correspondingly, a higher proportion of women in the intervention group than in the control group were referred to an emergency obstetrical care facility. To obtain such care, even in publicly funded hospitals, women and their families must arrange for their own transportation and pay for all drugs and equipment. Intervention did not involve changes in the availability of or access to existing emergency care. This may explain why, despite the increased referrals for emergency care, there was no significant increase in the percentage of women who delivered at a public or private health facility. We do not have information on the acceptance or the outcomes of these referrals.

Limited data have been available on the value of training traditional birth attendants and integrating them into a maternal health care system in developing countries. A clear strength of the present study is its cluster-randomized design. It was not feasible for individual patients to undergo randomization, owing to the risk of contamination if trained traditional birth attendants were expected

Table 3. Distribution of Outcome Measures According to Study Group and Cluster.

Outcome Measure	Intervention Group				Control Group				
	Cluster 1 (N=3253)	Cluster 2 (N=3835)	Cluster 3 (N=2622)	Total (N=9710)	Cluster 4 (N=2686)	Cluster 5 (N=1947)	Cluster 6 (N=1879)	Cluster 7 (N=2477)	Total (N=8989)
Singleton births*									
Perinatal deaths — no. (no. per 1000 live births and stillbirths)†	232 (71)	361 (94)	230 (88)	823 (85)	266 (99)	296 (152)	224 (119)	291 (117)	1077 (120)
Stillbirths — no. (no. per 1000 live births and stillbirths)‡	130 (40)	227 (59)	126 (48)	483 (50)	149 (55)	178 (91)	143 (76)	168 (68)	638 (71)
Neonatal deaths — no. (no. per 1000 live births)§	102 (33)	134 (37)	104 (42)	340 (37)	117 (46)	118 (67)	81 (47)	123 (53)	439 (53)
	Cluster 1 (N=3408)	Cluster 2 (N=3980)	Cluster 3 (N=2704)	Total (N=10,092)	Cluster 4 (N=2794)	Cluster 5 (N=2061)	Cluster 6 (N=1965)	Cluster 7 (N=2612)	Total (N=9432)
Women									
Maternal deaths — no. (no. per 100,000 pregnancies)¶	6 (176)	15 (377)	6 (222)	27 (268)	11 (394)	8 (388)	7 (356)	8 (306)	34 (360)

* Perinatal outcomes are for singleton births only.
† Perinatal deaths were defined as stillbirths or live-born infants who died within 28 days after birth. (It was not possible to separate early and late neonatal deaths.)
‡ Stillbirths were defined as fetuses born after six months that never showed signs of life.
§ Neonatal deaths were defined as live-born babies who died within 28 days after birth.
¶ Maternal deaths were defined as death of the mother during pregnancy, delivery, and up to six weeks post partum, excluding deaths known to have been due to injury or accident. In addition to these maternal deaths, one woman in the intervention group died of viral hepatitis, and one in the control group was murdered.

to deliver two different forms of care. The small number of clusters of very large size is a limitation of the trial design.[11] The administrative and training costs of delivering alternative forms of care to a larger number of smaller geographic clusters were prohibitive, and the risk of contamination would have been increased.[12] No major organizational or demographic differences were anticipated among the talukas, and the baseline characteristics of women in different talukas were similar. The effect of intervention on perinatal mortality seemed consistent across intervention clusters, and adjusting for cluster had no material effect on the estimated risk reductions.

We have no data to ascertain the accuracy of the reports of death or of the reported causes of maternal death. Although the traditional birth attendants and Lady Health Workers could not be blinded to the intervention, observer bias is unlikely to have affected the reporting of the primary outcomes of perinatal and maternal mortality. Lady Health Workers, who collected data on the primary outcomes in both groups, were not aware of the purpose or comparative nature of the study.

The method of providing safe-delivery kits to traditional birth attendants improved their contact with primary care centers and with the Lady Health Workers linked to the attendants. The standing and confidence of traditional birth attendants may also have been improved by their authority to refer women to outreach clinics for antenatal care, although we did not directly assess this.

In the 1990s, it became widely accepted that training traditional birth attendants was likely to cause only a small reduction in maternal mortality.[4,13] A recent review suggested that training may improve the knowledge, attitudes, and behaviors of traditional birth attendants,[14] but effects on neonatal mortality could not be adequately assessed owing to incomplete reporting and the inadequate quality of available studies.[15] Only 4 of the 63 studies compared outcomes in the study group before and after traditional birth attendant training with those in a control group, and the key features of the study were often not reported.

A recently reported cluster-randomized trial in Nepal showed a 30 percent reduction in neonatal mortality per 1000 live births (similar to our find-

Table 4. Odds Ratios for Primary and Secondary Outcomes.

Indicator	Intervention Group (N=10,093)	Control Group (N=9432)	Odds Ratio (95% CI)	P Value	Odds Ratio (95% CI)	P Value
			Unadjusted for Cluster		Adjusted for Cluster*	
	no. (%)					
Perinatal death†	823 (8.47)	1077 (11.9)	0.68 (0.62–0.75)	<0.001	0.70 (0.59–0.82)	<0.001
Stillbirth†	483 (4.97)	638 (7.10)	0.69 (0.61–0.78)	<0.001	0.69 (0.57–0.83)	<0.001
Neonatal death†	340 (3.50)	439 (4.88)	0.71 (0.62–0.82)	<0.001	0.71 (0.62–0.83)	<0.001
Maternal death‡	27 (0.27)	34 (0.36)	0.74 (0.45–1.23)	0.24	0.74 (0.45–1.23)	0.24
Complications of pregnancy§						
Hemorrhage	174 (1.72)	259 (2.75)	0.62 (0.51–0.75)	<0.001	0.61 (0.47–0.79)	<0.001
Obstructed labor	571 (5.66)	449 (4.76)	1.20 (1.06–1.36)	0.005	1.26 (1.03–1.54)	0.025
Puerperal sepsis	78 (0.77)	400 (4.24)	0.18 (0.14–0.22)	<0.001	0.17 (0.13–0.23)	<0.001
Eclampsia	23 (0.23)	29 (0.31)	0.74 (0.43–1.28)	0.28	0.69 (0.36–1.31)	0.25
Spontaneous abortion	47 (0.47)	54 (0.57)	0.81 (0.55–1.2)	0.3	0.71 (0.38–1.34)	0.29
Referral to emergency obstetrical care¶	1008 (9.99)	654 (6.93)	1.49 (1.34–1.65)	<0.001	1.50 (1.19–1.91)	<0.001

* Multilevel modeling was performed to adjust for cluster randomization.
† Percentages for perinatal deaths, stillbirths, and neonatal deaths were calculated from a total of 9710 singleton births in the intervention group, and 8989 in the control group.
‡ Of the 27 maternal deaths in the intervention group, 7 (25.9 percent) were attributed to hemorrhage, 5 (18.5 percent) to obstructed labor, 8 (29.6 percent) to eclampsia, 3 (11.1 percent) to spontaneous abortion, and 4 (14.8 percent) to other causes. Of the 34 maternal deaths in the control group, 15 (44.1 percent) were attributed to hemorrhage, 9 (26.5 percent) to obstructed labor, 3 (8.8 percent) to eclampsia, 6 (17.6 percent) to spontaneous abortion, and 1 (2.9 percent) to other causes.
§ A Lady Health Worker recorded a complication of pregnancy if she ascertained that any of the complications listed had occurred to the woman at any stage of pregnancy or post partum. The training of Lady Health Workers and traditional birth attendants included oral descriptions and pictorial representations of the complications listed. Hemorrhage was defined as excessive bleeding from the genital tract after 28 weeks of gestation owing to complications of pregnancy, delivery, or the puerperium. Labor was defined as obstructed when it lasted longer than 18 hours. Puerperal sepsis was defined as fever or foul-smelling lochia or both. Eclampsia was defined as maternal seizures before, during, or after delivery. Lady Health Workers recorded spontaneous abortions (loss of the fetus before six months of gestation) that were complicated by excessive bleeding, for example, as complications of pregnancy.
¶ Referral to an emergency obstetrical care facility included referral of the woman to any such facility for any complication during pregnancy, delivery, or the postpartum period.

ings) and a 78 percent reduction in maternal mortality in clusters exposed to different community-based interventions.[16] The interventions did not involve traditional birth attendants but, rather, involved the convening of women's groups to identify local perinatal problems and formulate strategies to address them; resulting changes included more clean-delivery practices and better links with improved primary care services. The results from that study and the current trial confirm the possibility of large improvements in perinatal and maternal health from interventions at the community level.

Experts from several centers have pointed out the lack of evidence that interventions are effective in reducing maternal and perinatal mortality in developing countries.[17-20] Ethical and practical constraints have limited the study of potential interventions — for example, the large sample size needed to detect differences in maternal mortality.[17] Despite the large number of women in our study, it was not adequately powered to detect a meaningful change in maternal mortality. Although results from the study in Nepal are encouraging, it would be unwise to use the large risk reduction in maternal mortality in that study to form the basis for estimates of sample size for future trials.[16] Some people have proposed the use of perinatal mortality as a proxy for maternal mortality, but this suggestion is controversial[21,22]; in the present study, the change in maternal mortality appeared to mirror closely that in perinatal mortality.

We tried to capitalize on an infrastructure that is already in place but fails to meet women's needs.

Our results show that substantial improvement in outcomes is achievable and sustainable within this infrastructure. These data should inform policy decisions directed toward reducing neonatal and maternal mortality in developing countries.[17,18]

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