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An integrated approach to improve maternal and perinatal outcomes in rural Guatemala: A stepped-wedge cluster randomized trial

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Abstract

Objective: To evaluate the impact of an intervention package on maternal and newborn health indicators.

Methods: A randomized stepped-wedge non-blind trial was conducted across six sub-districts within two districts in Guatemala from January 2014 to January 2017. Data on outcomes were collected on all deliveries in all 33 health centers. The intervention package included distribution of promotional materials encouraging health center delivery; education for traditional birth attendants about the importance of health center delivery; and provider capacity building using simulation training. Main outcomes were number of health center deliveries, maternal morbidity, and perinatal morbidity and mortality.

Results: Overall, there were 24 412 deliveries. Health center deliveries per 1000 live births showed an overall increase, although after adjustment for secular trends and clustering, the relative risk for the treatment effect was not statistically significant (aRR, 1.04; 95% confidence interval [CI], 0.97–1.11, P=0.242). Although not statistically significant, maternal morbidity (aRR, 0.78; 95% CI, 0.60–1.02; P=0.068) and perinatal morbidity (aRR, 0.84; 95% CI, 0.68–1.05; P=0.133) showed a tendency toward a decrease.

Conclusion: The present study represents one of the few randomized evaluations of an integrated approach to improve birth outcomes in a low-income setting.

ClinicalTrials.gov: NCT0315107.

KEYWORDS

Mortality stepped-wedge design; Package intervention; Severe maternal morbidity

1 | INTRODUCTION

Despite significant global declines in maternal and perinatal morbidity and mortality since 1990, many low-income countries lag behind in reaching global targets, often in regions where fewer births take place in facilities and where the use of routine evidence-based practices and quality emergency response are not standard.[1] In Latin America, Guatemala has the worst maternal and infant mortality rates in comparison with other countries in the region (Table 1).

Within Guatemala, districts where indigenous populations comprise a high proportion of the total population experience higher maternal mortality rates (e.g., 177 and 150 deaths per 100 000 live births in Huehuetenango and Alta Verapaz districts, respectively) and perinatal mortality rates (43 and 35 deaths per 1000 live births in Huehuetenango and Alta Verapaz, respectively).[2–4]

These high rates are partially due to the low proportion of deliveries attended by skilled labor,[5] which in turn is driven by factors on both the demand side (i.e., perception of quality of care and access

TABLE 1 Maternal and infant mortality rate in six Central and South American countries, 2015.[a]

Country	Maternal mortality rate	Infant mortality rate
Costa Rica	27	9
Ecuador	48	18
El Salvador	42	14
Guatemala	113	24
Honduras	74	17
Peru	93	13

[a]Data taken from.[26]

to facilities) and the supply side (i.e., quality of clinical care, treatment during delivery, and cultural sensitivity).[6–8] The aim of the current study was therefore to implement and evaluate the impact of an intervention package on the outcomes of deliveries occurring at the health center level across the districts of Huehuetenango and Alta Verapaz, Guatemala.

2 | MATERIALS AND METHODS

2.1 | Intervention rationale

A 2015 national survey showed that 60.6% of births in Huehuetenango and 43.2% in Alta Verapaz were registered as having occurred at home.[2] For centuries, home births have been delivered by informally trained traditional birth attendants (TBAs), who provide care for women during pregnancy, delivery, and the postpartum period.[9] Qualitative studies in Guatemala suggest that lack of trust in the quality of care is one of the determinants that deter women from giving birth in health centers.[10] Therefore, the first component of the intervention included a culturally relevant social marketing campaign to encourage pregnant women to give birth in their closest health center. Social marketing has been used in a broad number of public health programs as a vehicle to encourage healthy behaviors or behavior change.[11,12] Social marketing has also been used successfully for the promotion of family planning methods, smoking cessation campaigns, youth weight loss programs,[13–15] and delivery in healthcare facilities.[16]

The second component sought to bridge and to bring TBAs and traditional birth practices into the formal healthcare system to increase the likelihood of women choosing a health center to give birth. Because quality improvement interventions focus on maternal and newborn health indicators, the third component included a culturally-sensitive simulation-based training program focused on obstetric and neonatal emergencies for birth attendants in the study facilities.

Overall, therefore, the intervention included (1) a social marketing campaign to increase the demand for health center deliveries; (2) outreach activities by professional midwives to improve the link between TBAs and the formal healthcare system; and (3) a simulation and team training program to improve clinical skills and team function among providers.

2.2 | Study design rationale

After promising results from a pilot project that built interest among local stakeholders, a prospective trial aim to implement and evaluate the impact of an intervention package at scale, was launched across the two rural districts of Huehuetenango and Alta Verapaz.[17] Given the nature of the intervention package, health centers and the municipalities were chosen as clusters and serve as the unit of delivery of the intervention and randomization to assess the impact of the intervention on the outcomes of all births occurring at the health center level. A stepped-wedge design was chosen because there were limited resources to roll out the intervention to all health centers simultaneously.

2.3 | Study design and population

The cluster randomized stepped-wedge trial to evaluate the package of three interventions on health center delivery volume and maternal and perinatal morbidity and mortality in the districts of Huehuetenango and Alta Verapaz, Guatemala, was conducted from January 1, 2014, to January 31, 2017. Pregnant women, fetuses, and indigenous communities are considered vulnerable populations; the study strictly adhered to ethical principles and guidelines and was approved by University of California, San Francisco's Committee on Human Research, (#14-13057) and the Institutional Review Board of the Guatemalan Ministry of Health (#47-2014). All activities in the study were voluntary and the participants did not receive compensation. The providers who participated in training gave written consent to participation at the beginning of each training session. The study was registered at ClinicalTrials.gov under NCT03151070.

The intervention package was implemented in 33 health centers (15 in Alta Verapaz and 18 in Huehuetenango) and their surrounding municipalities, representing all secondary-level healthcare centers in these regions. The health centers are all open 24 hours, 7 days a week, and are staffed by medical personnel. They all provide basic emergency obstetric and neonatal care but do not perform cesarean, vacuum- or forceps-assisted delivery, or blood transfusions.[18]

The study involved three populations: (1) mothers who delivered at 28 gestational weeks or later during the trial period and their newborns (including stillbirths and neonates who died prior to discharge for whom outcomes were available); (2) TBAs and community members living in the proximity of the study health centers who were contacted by the social marketing campaign and the professional midwifery liaison; (3) clinic providers attending births in the study health centers who were invited to participate in emergency obstetric and newborn care simulation training.

2.4 | Roll out of the implementation

The 33 health centers were grouped into six subdistricts of 4–6 adjacent centers, which each received and implemented the intervention in a step-wise fashion (Fig. 1). Randomization consisted of random allocation of the six subdistricts to one of the six study sequences with two restrictions: (1) the subdistrict allocated to the first sequence was

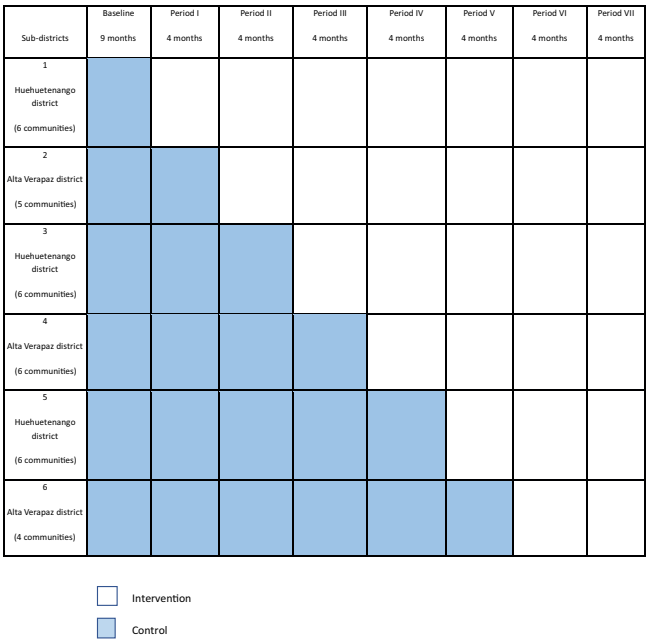


FIGURE 1 Diagram outlining the stepped-wedge study design.

pre-specified and not randomly allocated; (2) the subdistricts selected for subsequent sequences alternated between the two districts to create a balance of the roll out across the districts. This increased the acceptability of the trial design and mitigated against any large imbalances between the two districts. These limitations reduced the possible orders of intervention for sub-districts to 12 possibilities from which one was randomly chosen.

Each health center was informed of the date that they would be exposed to the intervention 4 months before the start of the intervention to allow time to embed the intervention into practice. Baseline data were collected at all facilities from January 1 to September 30, 2014, during which time no health center was exposed to the intervention. The intervention package was then rolled out sequentially, every 4 months, until all centers in all subdistricts had received 4 months of intervention exposure. Data collection continued in all facilities until 4 months after the final group of health centers had completed the 4-month intervention (January 31, 2017). Trained field monitors visited each center once a month beginning at baseline and continuing until 4 months after the intervention ended in the last subdistrict (January 31, 2017).

2.5 | Outcomes and measurements

The outcomes measures were (1) numbers of health center deliveries (≥28 gestational weeks); and cases of (2) severe acute maternal morbidity, defined as conditions related directly to maternal mortality (severe postpartum hemorrhage, eclampsia, pre-eclampsia, and sepsis) prior to discharge; (3) perinatal morbidity, defined as a neonate (≥28 gestational weeks) with either an Apgar score of 7 or less at 5 minutes or respiratory difficulties who required use of positive pressure ventilation or cardiac massage as reported on the outcome form prior to discharge; (4) perinatal mortality, defined as stillbirth or death of newborn (≥28 gestational weeks) occurring at the health facility before the mother and/or neonate were discharged or referred; and (5) perinatal mortality before discharge, defined as health center newborn deaths excluding stillbirths. The last outcome was added post-hoc to evaluate the improvement in quality of care for women delivering in health centers.

Data were extracted from health center records by using an adapted 30-question tool previously used in a pilot phase of the study.[17] Field workers were trained in data collection procedures including data protection and privacy. Data were initially collected on a paper form and then entered into an electronic database. On extraction of data from the paper form, all individual identifiers were removed, leaving only unique codes designating health center and patient to maintain

TABLE 2 Summary of intervention components and exposure.

Intervention component	Realized exposure
PRONTO training	3-d training on obstetric and neonatal emergencies using simulation and team training 544 providers trained in obstetric and neonatal emergencies and teamwork and communication 162 simulations performed at health centers
Professional midwife liaison	1089 TBAs contacted 450 workshops with pregnant women 260 obstetric and neonatal emergency simulations with TBAs
Social marketing campaign	1611 posters distributed 11 124 posters distributed 25 000 silicon bracelets distributed 122 119 stickers distributed 301 269 flyers distributed 4236 baby beanies distributed 2119 CDs and DVDs distributed 20 115 calendars distributed

Abbreviation: TBA, traditional birth attendant.

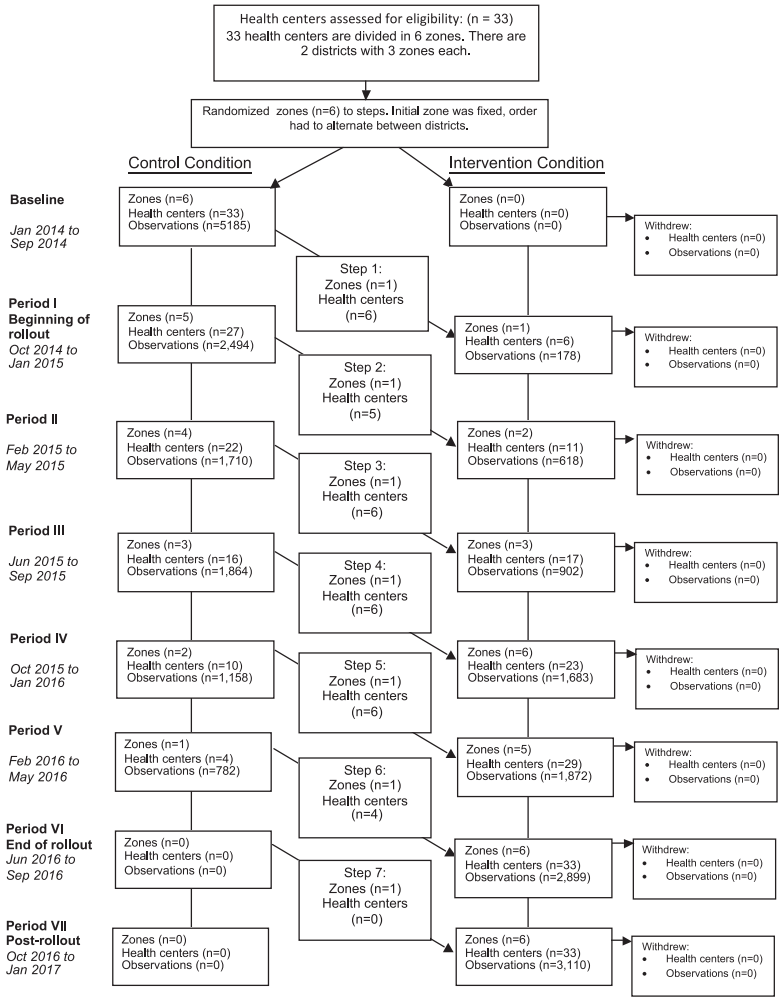
anonymity and confidentiality. Owing to the nature of the intervention, neither patients nor healthcare practitioners were blind to the intervention. Data analysts were not masked to intervention exposure owing to the sequential roll out of the intervention. Data collection included the total number of health center deliveries, and individual maternal and perinatal morbidity and mortality outcomes.

2.6 | Intervention

The intervention package involved three components. First, PRONTO provider training, a low-cost simulation and team training program utilizing the low-technology birth simulator PartoPants[19] was used to teach birth attendants maternal and perinatal emergency management, teamwork and communication skills, and provision of culturally sensitive care.[20] Second, a social marketing campaign, "Qué Vivan Las Madres!" (Long Live the Mothers!), lasting the whole of the 4-month intervention period, was used to distribute promotional material in the intervention community in seven native languages including radio and TV adverts, posters at health facilities and other public places, calendars, flyers, bracelets, stickers, and baby beanies. The campaign aimed to encourage pregnant women to choose to give birth in the nearest health center rather than at home. Third, four professional midwives conducted outreach activities in the communities and with TBAs to promote health center delivery. Professional midwives were asked to raise awareness among clinic providers on the importance and benefits of integrating midwifery-based care and traditional midwifery practices into the formal sector (Table 2). The project emphasized the cultural factors at play and included activities to bridge the cultural divide.

2.7 | Data analysis

All analyses were conducted in STATA versions 13 and 15 (StataCorp, College Station, TX, USA). Mixed-effects Poisson regression was used with a log link and clustering by health center (henceforth referred to as clusters), using robust variances to allow for inflated variances and analysis of binary outcomes. Treatment effects were therefore reported as a relative risk (RR) with 95% confidence intervals (CIs).



Note: 1 health center was excluded from analysis due to missing outcomes for several months. This implied the exclussion of 43 cases.

FIGURE 2 Study flowchart showing roll out of the intervention and data collection across each of the six subdistricts (zones).

TABLE 3 Baseline characteristics of health centers in each subdistrict of the trial.[a]

Characteristic	Subdistrict 1	Subdistrict 2	Subdistrict 3	Subdistrict 4	Subdistrict 5	Subdistrict 6
No. of deliveries per month	48 ± 9	88 ± 9	45 ± 9	135 ± 20	71 ± 7	182 ± 15
Severe maternal morbidity[b]	76 ± 55	85 ± 35	86 ± 89	61 ± 18	122 ± 105	58 ± 44
Perinatal mortality[b]	0 ± 0	14 ± 8	27 ± 27	21 ± 11	69 ± 110	5.0 ± 2.4
Perinatal morbidity[b]	64 ± 42	69 ± 21	46 ± 33	88 ± 30	93 ± 76	58 ± 40
Perinatal mortality before discharge[b]	0 ± 0	2.0 ± 2.7	5.0 ± 7.7	1.7 ± 3.8	19 ± 37	1.0 ± 1.4

[a]Values are given as mean ± SD.
[b]Cases per 1000 live births per month.

Time trends were incorporated by including number of months as a fixed effect categoric variable in all analyses. Heterogeneity across clusters in time trends was incorporated by including a random interaction between cluster and month. Treatment effect heterogeneity across clusters was incorporated by including a random interaction between cluster and intervention.

Initially, all analyses allowed for unstructured covariance so that random intercepts and random intervention effects could be correlated; however, perinatal mortality, neonatal mortality, and perinatal morbidity analyses did not converge under this assumption. Therefore, an independent covariance structure was used. Owing to expected differences between the two districts, district was initially included as a covariate in all analyses; however, analysis of neonatal mortality did not converge when the district covariate was included.

For outcomes other than the number of deliveries per health center, treatment effects were reported as time-adjusted risk ratios (aRRs) with 95% CIs. For the outcome health center deliveries, numbers were standardized by including an offset of the log of estimated number of live births for that district based on the number of births registered. These denominator data were available for years 2014

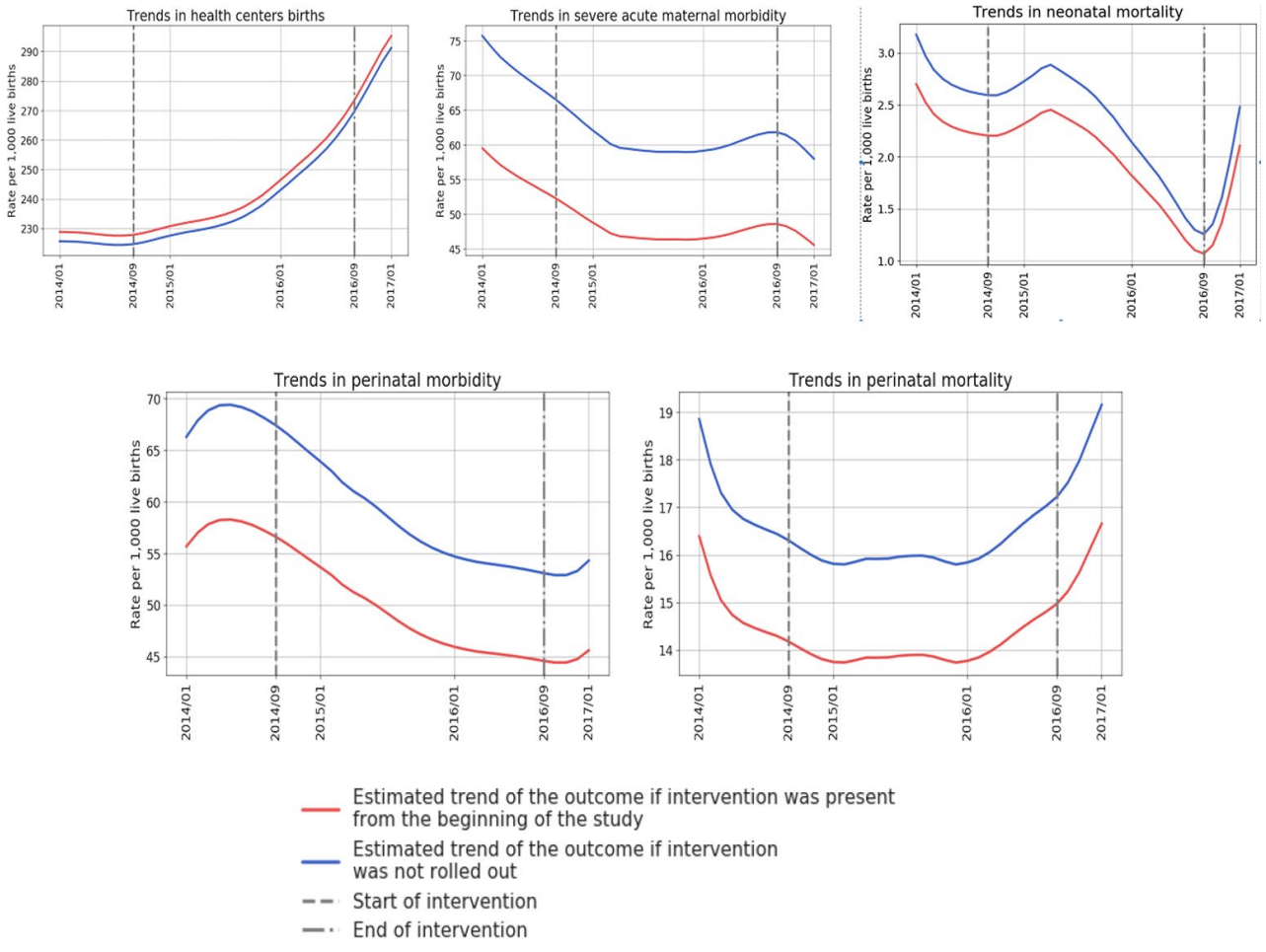


FIGURE 3 Trends in outcomes from January 1, 2014, to January 31, 2017.

TABLE 4 Estimated impact of intervention on outcomes.

Outcome	Total no. of cases	No. per 1000 live births	aRR (95% CI)[a]	*P* value
Health center-based vaginal deliveries[b]	24 412	214	1.04 (0.97–1.11)	0.242
Maternal morbidity	1322	54	0.78 (0.60–1.02)	0.068
Perinatal morbidity	1214	50	0.84 (0.68–1.05)	0.133
Perinatal mortality	345	14	0.87 (0.65–1.17)	0.355
Perinatal mortality before discharge	52	2	0.85 (0.45–1.62)	0.622

Abbreviations: aRR, adjusted risk ratio; CI, confidence interval.
[a]Intervention effects are adjusted for temporal trends and clusters (see Materials and method).
[b]Excluding deliveries at less than 28 gestational weeks (n=52) and cases from the outlier health center (n=43).

to 2016, but not for the last month of the study, January 2017, for which the values from January 2016 were imputed. For this outcome, treatment effects were reported as time-adjusted RRs with 95% CIs. Transition periods were not included because it was expected that the effect of the intervention would begin to be seen after the first month of intervention.

The estimated rates for each outcome were plotted by first generating marginal estimates for each observation with the intervention arm covariate turned on (intervention) or off (control). These estimates were then summed over all observations at each time point for each arm and smoothed lines were plotted by arm.

3 | RESULTS

The flow chart describing in detail each step of the study from baseline to the post-roll-out period shows how all subdistricts (zones) started in the control condition and moved to the intervention condition sequentially (Fig. 2). Overall, there were a total of 24 412 health center deliveries between the beginning of intervention roll out and the end of the study (September 1, 2014, to January 31, 2017). This equated to a mean ± SD of 690 ± 78 combined births per month in participating health centers and 21 ± 20 births per month per health center. There were 982 cases of severe and acute maternal morbidity, 912 cases of perinatal morbidity, and 309 cases of perinatal mortality (Table 3).

Overall, during the trial period, the number of health center deliveries increased by 26% from about 230 per 1000 live births at baseline to 290 per 1000 live births at the end (Fig. 3). After adjustment for temporal trends and clustering, the estimated effect of the intervention on institutional births was increasing but was not statistically significant (aRR, 1.04; 95% CI, 0.97–1.11; *P*=0.242) (Table 4).

Maternal morbidity decreased over the study period (Fig. 3). After adjusting for temporal trends and clustering, the estimated effect of the intervention was a reduction of 22.0% in risk (aRR, 0.78; 95% CI, 0.60–1.02; *P*=0.068) (Table 4).

Perinatal morbidity showed a decreasing trend over the study period (Fig. 3). After adjusting for temporal trends and clustering, the estimated effect of the intervention on perinatal morbidity was a 15.6% reduction in risk (aRR, 0.84; 95% CI, 0.68–1.05; *P*=0.133) (Table 4).

Perinatal mortality decreased over the study period (Fig. 3). After adjusting for temporal trends and clustering, the estimated effect of the intervention on perinatal mortality was a 13.1% reduction in risk (aRR, 0.87; 95% CI, 0.65–1.17; *P*=0.355) (Table 4).

Lastly, for the outcome perinatal mortality before discharge (Fig. 3), the estimated effect of intervention on neonatal mortality was a 15.0% reduction in risk (aRR, 0.85; 95% CI, 0.45–1.62) (Table 4).

4 | DISCUSSION

The present study successfully implemented and evaluated the impact of an intervention package across all second-level health centers in Alta Verapaz and Huehuetenango districts in Guatemala. A significant association was not observed between the social marketing campaign or liaison with TBA activities and number of health center deliveries. However, the PRONTO simulation-based training program was close to showing a statistically significant reduction in maternal morbidity. There was no significant association between the PRONTO simulation-based training program and the other outcomes (perinatal morbidity and mortality, and perinatal mortality before discharge). To our knowledge, this is the first cluster randomized stepped-wedge design study to measure the impact of this type of intervention package, including a social marketing campaign, liaison with TBAs, and obstetric and perinatal emergency simulation and team training, on maternal and perinatal health indicators in a rural setting.

The findings are consistent with other studies reporting that simulation-based training programs can be effective in reducing maternal and perinatal and perinatal morbidity in low-resource settings. For example, a hospital-based cluster randomized trial in Mexico found that simulation and team training increased the number of evidence-based practices at delivery, contributing to quality of care.[21] Another cluster randomized trial in Ghana found that a training program using simulation and skill stations resulted in a sustained decrease in facility-based newborn mortality and intrapartum stillbirth and in retained knowledge among birth attendants after 2 years.[22]

Even though the number of health center deliveries showed a notable increase over the study period, the difference between

control and intervention groups was negligible. One possible explanation for this was contamination between the adjacent subdistricts as a result of the social marketing campaign spilling over to adjacent districts. Furthermore, previous studies suggest that the decision to give birth at home is partially driven by social and cultural traditions where TBAs provide not only obstetric but also social and spiritual care.[23] These traditions have prevailed for millennia. An intervention package to further influence the decision to deliver at a health center may require interventions that are more focused on addressing cultural birthing norms and other structural and economic barriers (i.e., mother's educational attainment, decision-making power in the household, and fear of cesarean) that prevent women giving birth at health centers. These underlying issues were not within the scope of the intervention and will require further consideration.

Although not statistically significant, the magnitude of the intervention effect was similar across the outcomes perinatal morbidity and mortality, and perinatal mortality before discharge. These positive trends are consistent with those of other quality improvement programs that employed resuscitation training in low-resource settings to address these problems.[24] The non-significance of the result might indicate that either the intervention does not work or there is a lack of statistical certainty. Budget constraints prevented the inclusion of additional health facilities, but larger studies will be needed to accurately assess the effect of the intervention on these indicators. Importantly, any further studies must have a rigorous design and not simply be before and after studies.

The study has several limitations. First, the geographic proximity of the health facilities and the communities that they serve created the potential for contamination between control and intervention groups with women crossing between subdistricts. Second, owing to the heterogeneity of the study population (indigenous population with diverse languages, traditions, and beliefs) and low literacy level in Huehuetenango and Alta Verapaz, the generalizability of these results is unclear. Third, few cases of perinatal mortality were seen in the health centers, resulting in wide confidence intervals and large *P* values for the effect estimates. In addition, data collection on perinatal morbidity and mortality was limited to pre-discharge events. Because no follow-up or referrals were captured, these two outcome measures included only cases that occurred in the health centers, usually during a 24-hour stay. The morbidity outcome indicators were limited to diagnoses that were perceived to be accurately captured by providers. Furthermore, as has previously occurred in similar stepped-wedge design studies, no sample size or power analysis calculations were performed because all second-level health facilities and all women delivering in the health facilities who met the eligibility criteria were enrolled in the study.[25]

Despite these limitations, the data suggest that, in a predominantly indigenous region in Guatemala, an integrated approach to encouraging women to deliver at health facilities and simultaneously training providers in obstetric and neonatal emergency management may have an impact on maternal and perinatal health outcomes. Although the results were not statistically significant, from a public health standpoint, a 20% decrease in maternal and perinatal morbidity and mortality—if repeated in future studies—would be meaningful. This type of intervention package deserves further investigation with lessons learned from the present trial to modify the intervention (particularly the demand side) and improve data collection on morbidity. Qualitative research would also be a valuable addition to better understand the various drivers that motivate women to deliver in a health facility and inform future innovations and designs.

AUTHOR CONTRIBUTIONS

EK was the principal investigator, conceived the trial, and wrote and reviewed the manuscript. GA contributed to data analysis and manuscript writing and revision. KH contributed to data analysis and interpretation, and manuscript writing and revision. JPH contributed to study design, data analysis and interpretation, and manuscript writing and revision. JM contributed to data interpretation and manuscript revision. MM contributed to data interpretation and manuscript revision. SM contributed to literature review, data interpretation, and manuscript writing. DW was the co-principal investigator, conceived the trial, and wrote and revised the manuscript.

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CONFLICTS OF INTEREST

The authors have no conflicts of interest.

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