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RESEARCH

Effect of training traditional birth attendants on neonatal mortality (Lufwanyama Neonatal Survival Project): randomised controlled study

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ABSTRACT

Objective To determine whether training traditional birth attendants to manage several common perinatal conditions could reduce neonatal mortality in the setting of a resource poor country with limited access to healthcare.

Design Prospective, cluster randomised and controlled effectiveness study.

Setting Lufwanyama, an agrarian, poorly developed district located in the Copperbelt province, Zambia. All births carried out by study birth attendants occurred at mothers' homes, in rural village settings.

Participants 127 traditional birth attendants and mothers and their newborns (3559 infants delivered regardless of vital status) from Lufwanyama district.

Interventions Using an unblinded design, birth attendants were cluster randomised to intervention or control groups. The intervention had two components: training in a modified version of the neonatal resuscitation protocol, and single dose amoxicillin coupled with facilitated referral of infants to a health centre. Control birth attendants continued their existing standard of care (basic obstetric skills and use of clean delivery kits).

Main outcome measures The primary outcome was the proportion of liveborn infants who died by day 28 after birth, with rate ratios statistically adjusted for clustering. Secondary outcomes were mortality at different time points; and comparison of causes of death based on verbal autopsy data.

Results Among 3497 deliveries with reliable information, mortality at day 28 after birth was 45% lower among liveborn infants delivered by intervention birth attendants than control birth attendants (rate ratio 0.55, 95% confidence interval 0.33 to 0.90). The greatest reductions in mortality were in the first 24 hours after birth: 7.8 deaths per 1000 live births for infants delivered by intervention birth attendants compared with 19.9 per 1000 for infants delivered by control birth attendants (0.40, 0.19 to 0.83). Deaths due to birth asphyxia were reduced by 63% among infants delivered by intervention birth attendants (0.37, 0.17 to 0.81) and by 81% within the first two days after birth (0.19, 0.07 to 0.52). Stillbirths and deaths from serious infection occurred at similar rates in both groups.

Conclusions Training traditional birth attendants to manage common perinatal conditions significantly reduced neonatal mortality in a rural African setting. This approach has high potential to be applied to similar settings with dispersed rural populations.

Trial registration Clinicaltrials.gov NCT00518856.

INTRODUCTION

Although mortality rates for children in resource poor countries have declined,[1] those for neonatal mortality have not. Neonatal deaths now account for greater than 40% of deaths in children aged under 5,[2] with about 75% occurring in the first week of life.[3 4] Birth asphyxia and neonatal infections account for about half of all neonatal deaths.[2 3] Globally, at least 10% of otherwise healthy newborns have inadequate respiratory effort at birth,[5 6] a problem often compounded by hypothermia from failure to immediately dry and warm newborn infants.[7] If neonatal mortality is not reduced, achieving the Millennium Development Goals reduction in childhood mortality of two thirds by 2015 will not be possible.

In resource poor countries, particularly in rural settings with limited access to healthcare, traditional birth attendants are an essential source of obstetric care. Although traditional birth attendants have also proved successful as community health educators and breastfeeding counsellors,[8 9] their proximity to the newborn infant suggests that they could have a more direct role in reducing neonatal mortality. Several recent reviews concluded that training traditional birth attendants to manage birth asphyxia and neonatal sepsis using basic skills and equipment seemed feasible even in low resource countries and had the potential to reduce neonatal mortality rates by up to 50%.[10-12] However, these authors also cautioned that the evidence basis supporting these conclusions was limited.

The Lufwanyama Neonatal Survival Project (LUNESP) was a community based field effectiveness study carried out in rural Zambia. We tested the hypothesis that providing traditional birth attendants with skills targeting birth asphyxia, neonatal hypothermia, and sepsis could significantly reduce neonatal mortality in a population whose access to even basic healthcare was limited. The primary end point was the proportion of liveborn infants delivered by intervention compared with control traditional birth attendants who died by day 28 after birth.

METHODS

Lufwanyama is a vast, sparsely populated and underdeveloped rural district located in Zambia's Copperbelt province (estimated population 63 185, size 3803 square miles (9849 km^2), density about 6.4 people/km^2).[13] During the study, Lufwanyama had 12 government supported rural health centres staffed by nurse midwives or clinical officers; the district had no resident doctors and no hospital.

Randomisation and training

We used an unblinded, cluster randomised and controlled study in which traditional birth attendants were randomly allocated to receive training and equipment to render them proficient in a set of skills targeting common causes of neonatal mortality (intervention group), or to continue with their existing standard of care (control group). Each cluster was defined as all of the births delivered by a given birth attendant.

Because the interventions were applied at district level, we used an effectiveness study building on an existing infrastructure for healthcare delivery. Beyond provision of training and essential equipment and creating a system by which to document the outcomes of deliveries by the birth attendants, the study minimised oversight and contact with the birth attendants so as not to interfere with their routine delivery of obstetric care.

Before the study, traditional birth attendants had been trained in basic obstetric and newborn care (including mouth to mouth assisted breathing) and clean delivery techniques, and used clean delivery kits for every delivery. They were required to refer all high risk pregnancies to be delivered at a health centre. The birth attendants maintained a link to the formal health sector through the Lufwanyama rural health centre and were supported by the Lufwanyama District Health Management Team. Although the study was carried out with the approval of the Lufwanyama District Health Management Team, no formal link existed between the study and the healthcare sector.

After enrolling in the study, the birth attendants received additional training on basic record keeping, the reporting aspects of the trial, and the importance of maintaining regular contact with the mother and infant pair, even after the delivery. Subsequently the birth attendants were randomly allocated (1:1) to intervention or control groups. Randomisation was done by generating 120 allocation slips (60 intervention and 60 control), which were placed in an opaque container. During a public ceremony, witnessed by all the birth attendants and study staff, the participants individually took a slip from the box and the group allocation was announced to the whole group. Using a public ceremony to carry out randomisation was consistent with local customs. After randomisation, the control birth attendants returned to their villages and continued their existing standard of care; the intervention birth attendants remained to receive further training.

Intervention birth attendants each took part in two, one week training workshops, carried out in June and August 2006. The trainers, members of the study team, used a variety of techniques, including interactive lectures, demonstrations, small group sessions, and skills practice using infant manikins. To be judged competent, each birth attendant had to satisfactorily complete a one on one skills assessment with one of the trainers. After the initial training, both intervention and control birth attendants took part in refresher workshops every three or four months throughout the study, again with one to one skills assessments for each intervention birth attendant.

During the baseline and subsequent refresher training, the birth attendants were compensated for their travel costs and provided with food and lodging while attending the workshops. None of the participants received salary support or other incentives for their participation in the study.

The intervention had two components: training in a modified version of the neonatal resuscitation protocol, and single dose amoxicillin coupled with facilitated referral of infants to a health centre.

Neonatal resuscitation protocol

The neonatal resuscitation protocol, a modification of that endorsed by the American Academy of Pediatrics and American Heart Association,[5] aimed to reduce mortality from neonatal hypothermia and birth asphyxia. The resuscitation protocol consists of a series of standardised procedures, some of which are to be carried out at every delivery and some of which are done only as needed. The resuscitation protocol is not synonymous with positive pressure ventilation but rather is a continuum of interventions that may culminate in ventilation. In fact, if the early steps of the protocol are used effectively, positive pressure ventilation should only be required in a few deliveries.

In our adaptation of the resuscitation protocol, the birth attendants were trained to rapidly dry and warm the newborn, clear airways, and evaluate respiratory effort, colour, and tone. The use of supplemental oxygen, adrenaline (epinephrine), or other drugs, and training in chest compressions, endotracheal intubation, and other advanced steps were beyond the resource potential for the rural community studied, so were not used. The sequence of steps in the resuscitation protocol as adapted for Lufwanyama traditional birth attendants included immediately drying the infant and swaddling in a second dry blanket to avoid hypothermia, suctioning the infant's mouth and nose with a soft rubber suction bulb, and optimally positioning the infant's airway, followed by an assessment of the infant's breathing. Intervention birth attendants were also trained to stimulate the infants, when indicated, by gently rubbing their back or feet[5] and to provide positive pressure ventilation for infants with inadequate or absent respiratory effort by using a reusable, resuscitator mask (Laerdal, Pediatric Pocket Resuscitator; Laerdal, Wappingers Falls, New York; see web extra on bmj.com). Stimulation was continued briefly when infants were not vigorous, but if there was absent or poor respiratory effort the birth attendants were trained to immediately begin positive pressure ventilation.

Antibiotics with facilitated referral

Although the birth attendants were expected to maintain regular contact with the mother and infant pair during the first week after birth and to refer neonates for care if they appeared unwell, intervention birth attendants were also trained to recognise cardinal symptoms and signs of possible sepsis (see web extra on bmj.com).[14,15] On identifying a neonate with any of these findings, intervention birth attendants administered a single dose of oral amoxicillin (powder from two 250 mg amoxicillin capsules mixed with 8 mL chlorinated water) and then referred the mother and infant pair to the nearest health facility, ideally accompanying them. Amoxicillin was selected because of its known safety record and high therapeutic index, its anticipated activity against common pathogens causing neonatal sepsis, and because it can be stored without refrigeration. We chose the 500 mg dose to maximise therapeutic levels of drug in instances where sepsis might have reduced enteric absorption.

Birthing kits and supplies

Both intervention and control birth attendants were issued with one clean delivery kit per birth. Each kit contained a plastic delivery sheet, a cord cutter, cotton cord ties, one pair of latex gloves, soap, and a candle with matches (for deliveries at night).

In addition, each intervention birth attendant received a resuscitator mask and polypropylene bottle with chlorinated water, plus, for each delivery, two absorbent flannel blankets (one for drying the infant, the other for swaddling), a soft rubber bulb syringe, two 250 mg amoxicillin capsules, a 2 ounce (59 ml) mixing cup and spoon, and a 3 ml oral syringe. Intervention birth attendants received laminated reference cards summarising the neonatal resuscitation protocol and the trigger conditions for antibiotics with facilitated referral (see web extra).

Data collection

A team of 16 data collectors was responsible for ascertaining the final vital status of the infants. The data collectors were recruited from, and in all but one case resided within, the Lufwanyama community. Each data collector was assigned to cover a specific geographical zone in Lufwanyama and was responsible for following the activities of all of the birth attendants who resided in that zone. To accomplish this, each data collector received a mountain bicycle and was required to maintain weekly face to face contact with their assigned birth attendants, to keep an up to date record of the pregnant women each birth attendant was following and their estimated delivery dates, and to determine whether any of these mothers had delivered. To ensure that all births were reported, the data collectors queried the birth attendants if expected delivery dates passed without the birth being reported.

The birth attendants completed a standardised birth record for every delivery, capturing basic information about the mother's antenatal status, interventions provided during delivery, and the infant's vital status on the day of delivery. The birth attendants were instructed to inform their assigned data collector within 48 hours of a delivery. The data collector then retrieved the delivery report from the birth attendant, reviewed and verified the contents of the report with the birth attendant, and carried out up to two follow-up visits (at one and four weeks) with the mother and infant pair. At the first visit, the birth attendant guided the data collector to the mother's home and made introductions. Baseline data collected included maternal household demographic and economic data, data regarding payments made to the birth attendant by the mother, and maternal reproductive history. Additionally, the visits at one and four weeks assessed the vital status of the infant. Data collectors submitted case report forms to the field manager each month, which were entered into the database (CSPro; US Census Bureau, Washington, DC) at the LUNESP offices, using dual data entry. The study was closely monitored by the research team throughout the period of data collection, and the computerised data were cross checked with the paper records at the end of the trial to ensure accuracy.

If a neonate died at any time during the first month after birth (including stillbirths), the data collectors were trained to interview the mother or guardian of the infant, using the World Health Organization's verbal autopsy algorithm[16] to help define the most likely cause of death. A panel of three Boston based neonatologists, who had no contact with the birth attendants or data collectors and were blinded to group allocation, independently reviewed the delivery reports and verbal autopsy findings to ascribe a presumptive cause of death for each case, selecting from among serious infection, birth asphyxia, prematurity, tetanus, congenital

Table 1 | Baseline characteristics of traditional birth attendants. Values are numbers (percentages) unless stated otherwise

Characteristics	Intervention birth attendants (n=60)	Control birth attendants (n=58)*
Mean (SE) age (years)	49.2 (0.79)	49.6 (1.32)
Education:		
Never attended school	3 (5)	17 (29)
Some primary education	47 (78)	36 (62)
Some secondary education	10 (17)	5 (9)
Mean (SE) years of education	6.3 (0.48)	4.3 (0.55)
Mean (SE) No of deliveries during study	33.6 (3.12)	24.6 (1.90)
Marital status:		
Married	42 (70)	47 (81)
Single	1 (2)	1 (2)
Divorced	8 (13)	1 (2)
Widowed	9 (15)	9 (16)
Main occupation:		
Traditional birth attendant	1 (2)	5 (9)
Farmer	59 (98)	53 (90)
Sources of training as birth attendant before LUNESP†:		
Family	7 (12)	3 (5)
Community not family	26 (43)	31 (43)
Lufwanyama District Health Management Team	36 (60)	38 (65)
Other government organisation	20 (33)	11 (20)
Trained by non-governmental organisation programme	20 (33)	14 (24)
Mean (SE) No of years as traditional birth attendant	6.3 (0.81)	7.0 (0.95)

LUNESP=Lufwanyama Neonatal Survival Project.
*Baseline demographic data only collected among initial group of 120 randomised birth attendants; two control birth attendants did not complete a baseline assessment questionnaire.
†Birthing attendants may have received basic training from more than one source.

malformation, diarrhoea, stillbirth, other, or unknown; concordance of two reviewers was required.

Statistical analysis

The study was powered to detect a 35% difference between the two birth cohorts in the proportion of liveborn neonates delivered by the birth attendants surviving to day 28 after birth.[17-19] Since the study only assessed outcomes among deliveries carried out by the traditional birth attendants, we did not assess referrals who delivered at health facilities. We calculated the sample size using the formula for proportions in unmatched studies assuming 80% power, a two sided α of 0.05, and a coefficient of variation of 0.25. According to official mortality statistics, the neonatal mortality rate in Zambia is about 30-40 per 1000 live births.[20,21] Assuming 60 clusters per arm with an estimated 28 births per birth attendant, 1680 participants per study arm would provide sufficient power, for a total of 3360 neonates—that is, a decline from 40 per 1000 live births to 26 per 1000 live births, rate ratio 0.35. Given the rural and isolated nature of Lufwanyama and based on discussions with the Lufwanyama District Health Management Team, we made the assumption that the neonatal mortality rate in the district might be lower than reported. Therefore, given potential year to year fluctuations in infant mortality, uncertainties about the baseline neonatal mortality estimates in Lufwanyama, and the magnitude of potential loss to follow-up, we presumptively increased the target sample size to 4000.

For the purposes of sample size estimation, it was assumed that the study groups would be of equal sizes. In practice, we recognised that some imbalance could occur. This was because the randomisation only controlled the distribution of intervention skills among the birth attendants. For evident practical and ethical reasons, randomisation could not influence the number of deliveries each birth attendant would actually carry out over the ensuing years, nor control the process by which Lufwanyama mothers selected birth attendants for their deliveries.

The primary end point was the proportion of liveborn infants who died by day 28 after birth. Additional mortality outcomes included comparisons of proportions of stillbirths, and mortality rates at different time points during the 28 days. To estimate the possible effect of misclassification of failed resuscitations as stillbirths, we compared stillbirth rates between the two groups and calculated overall mortality rates including and excluding stillbirths (defined as babies born after six months of gestation without any movement, spontaneous breathing, or heartbeat during or after the delivery).

Each cluster was defined as all babies delivered by a given birth attendant during the study, and roughly corresponded to the catchment area in which each birth attendant operated, although adjacent catchment areas often overlapped. The need to adjust for clustering rested on the assumption of a "by traditional birth attendant" effect associated with outcomes, such that individual outcomes could not be combined as if they were independent events. For the mortality end points, we carried out a modified intention to treat analysis,

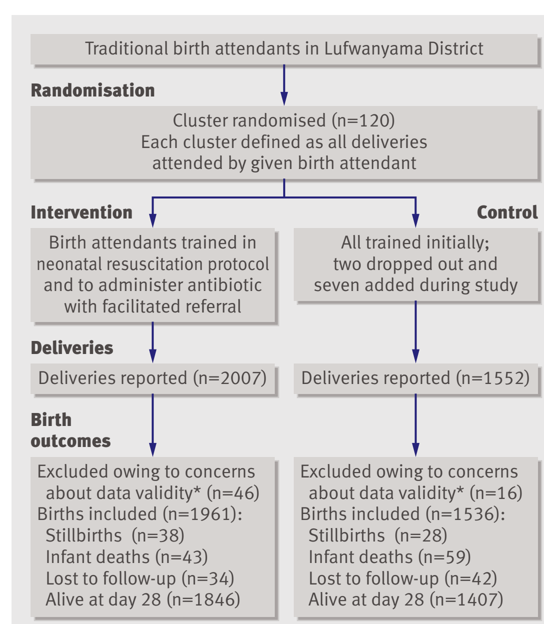

Fig 1 | Study flow diagram. *Data on delivery and follow-up reports from one data collector were excluded owing to falsification

Table 2 | Baseline characteristics of mothers and their newborn infants. Values are numbers (percentages) unless stated otherwise

Characteristics	Intervention group (n=1920)	Control group (n=1517)
Maternal characteristics		
Mean (SE) age (years)	25.3 (0.15)	25.3 (0.17)
Education (highest level attained):		
No formal education	325 (16.9)	281 (18.5)
Some primary	1323 (68.9)	1051 (69.3)
Some secondary	267 (13.9)	179 (11.8)
Some higher	5 (0.3)	6 (0.4)
Marital status:		
Married	1709 (89.0)	1367 (90.1)
Widowed	17 (0.9)	9 (0.6)
Separated or divorced	48 (2.5)	41 (2.7)
Never married	146 (7.6)	100 (6.6)
Mean (SE) No of people living in household	5.2 (0.05)	5.3 (0.06)
Mean (SE) No of antenatal clinic visits attended	3.3 (0.03)	3.2 (0.04)
Antenatal care received:		
Intermittent presumptive treatment of malaria*	1482 (88.7)	1326 (87.4)
Deworming drugs	1252 (65.2)	971 (64.0)
Folic acid supplementation	1632 (85.0)	1271 (83.8)
Iron supplementation	1759 (91.6)	1393 (91.8)
Tetanus toxoid	1382 (72.0)	1098 (72.4)
Infant characteristics†		
Female	50.1	48.2
Mean (SE) gestational age (weeks)	38.1 (0.31)	37.7 (0.31)
Exclusively breast feeding	96.8	97.1

*Treated with sulfadoxine-pyrimethamine.
†Total of 1961 infants in intervention group and 1536 in control group.

where participants who were lost during follow-up were treated as missing rather than as deaths. We also carried out a sensitivity analysis for our primary end point in which participants who were lost to follow-up were analysed under the assumption that they represented unrecorded deaths.

The Wilcoxon rank sum test was used to contrast the mean number of babies delivered by intervention or control birth attendants. We calculated cluster adjusted rate ratios and 95% confidence intervals using binomial regression in a generalised estimating equation to regress the risk of death as a function of assigned treatment group. We adjusted for clustering of babies within a birth attendant by specifying an exchangeable correlation matrix.[22] Models presented labelled as cluster adjusted did not adjust for other covariates. We adjusted models labelled as cluster adjusted and covariate adjusted for both clustering at birth attendant level and for imbalances in baseline covariates, including years of education, birth attendants' marital status, and whether the birth attendant reported that being a birth attendant was her primary job. These covariates were selected for inclusion in the model after the baseline characteristics of the birth attendants had been inspected for imbalances.

Ethical oversight and safety monitoring

The birth attendants and mothers provided written informed consent, using forms in English and the local languages Bemba and Lamba. A data safety monitoring board provided a single mid-point evaluation; the nominal significance value to adjust for the mid-point analysis, based on the O'Brien-Fleming stopping rules, was 0.0489 (nominal z score 1.97) (EAST software; Cytel, Cambridge, MA).

RESULTS

The study was carried out between June 2006 and November 2008, ending when the funding had elapsed. Figure 1 shows the study profile. Seven control birth attendants were added during the study, establishing 60 intervention and 67 control clusters for analysis. These seven control birth attendants were added during the final six months of the study as part of an exploratory substudy within the Lufwanyama Neonatal Survival Project on the feasibility of using traditional birth attendants in the prevention of mother to child transmission of HIV.

Table 1 summarises the baseline characteristics of the birth attendants. The groups were well balanced except that control birth attendants had lower schooling rates than the intervention birth attendants and more intervention than control birth attendants were divorced. The characteristics of infants and their mothers were similar between the groups (table 2), and were also similar to the birth attendants. Most of the mothers received routine antenatal care (provided at the government supported health centres as an activity unrelated to the present study), as suggested by rates of sulfadoxine-pyrimethamine and folic acid use during pregnancy. On average, mothers lived closer to their birth attendants than to the nearest health facility: only 32% of mothers lived within an hour's walk of the nearest health centre (maximum 11 hours), whereas 85% of mothers lived within an hour's walk of their birth attendant (maximum five hours). Two maternal deaths were reported, one per study arm: one was reported as "cause unknown" (control group) and one resulted from postpartum haemorrhage (intervention group).

Some of the reports from one data collector were found to have been falsified. Consequently, all of the data on deliveries from that data collector (including reports for intervention and control birth attendants) were excluded from the final analysis (fig 1). Overall, 3497 of 3559 (98.3%) babies delivered in the study contributed valid data for the analysis. Of these, 1961 (56.1%) were delivered by intervention birth attendants and 1536 (43.2%) by control birth attendants. Before final vital status had been determined at 28 days, 76 infants (2.1%) were lost to follow-up: 34 of 2007 (1.7%) intervention deliveries and 42 of 1552 (2.7%) control deliveries.

Intervention birth attendants delivered an average of 32.7 babies (interquartile range 16-44 babies, maximum 112) compared with 22.9 babies (interquartile range 13-32 babies, maximum 63) per control birth attendant (P=0.03). This difference expanded over the course of the trial. During the first three months of the study, intervention birth attendants delivered

Table 3 | Mortality among infants delivered by intervention or control traditional birth attendants

End point	Deaths per 1000 infants delivered			
	Intervention group (60 clusters)	Control group (67 clusters)	Total	Cluster adjusted rate ratios (95% CI)
Stillbirths only*	19.4 (38/1961)	18.2 (28/1536)	18.9 (66/3497)	1.07 (0.64 to 1.77)
All cause mortality				
Excluding stillbirths:				
Day 28†	22.8 (43/1889)	40.2 (59/1466)	30.4 (102/3355)	0.55 (0.33 to 0.90)
Week 1†	18.2 (35/1923)	30.5 (46/1508)	23.6 (81/3431)	0.56 (0.31 to 1.01)
Weeks 2-4‡	4.3 (8/1854)	9.2 (13/1420)	6.4 (21/3274)	0.47 (0.20 to 1.11)
Including stillbirths:				
Day 28§	42.0 (81/1927)	58.2 (87/1494)	49.1 (168/3421)	0.72 (0.51 to 1.00)

*Denominator is all births.
†Denominator is all live births.
‡Denominator is all live births, minus week 1 deaths, excluding loss to follow-up during weeks 1-4.
§Denominator is all births, excluding loss to follow-up during weeks 1-4.

13% more babies than control birth attendants; during the last three months they delivered 62% more babies than control birth attendants.

Effect of interventions on neonatal mortality

A total of 168 infant deaths were reported; 66 (39%) were stillbirths (table 3). Stillbirth rates were similar between the groups. Of the 102 deaths among liveborn infants, 43 (42%) occurred in infants delivered by intervention birth attendants and 59 (58%) by control birth attendants.

The proportion of liveborn infants who died by day 28 was 45% lower among those delivered by intervention birth attendants (rate ratio 0.55, 95% confidence interval 0.33 to 0.90), for an absolute risk reduction of 17.9 deaths per 1000 live births (95% confidence interval 4.1 to 31.8). Adjusting this result for imbalances in baseline characteristics of birth attendants had minimal effect on this result (covariate adjusted and cluster adjusted rate ratio 0.52, 0.28 to 0.95). In the sensitivity analysis, reanalysing the primary end point by treating the neonates who were lost to follow-up as "dead" rather than "missing" also had minimal impact on the primary end point (rate ratio 0.58, 95% confidence interval 0.41 to 0.84).

Of the 102 neonatal deaths, 81 (79%) occurred during the first week of life, and were less common among infants delivered by intervention than control birth attendants (0.56, 0.32 to 1.01). Neonatal mortality was also lower during weeks 2-4, but the difference did not reach statistical significance (0.47, 0.20 to 1.11).

Given the higher mortality rates observed during the first week, the distribution of deaths over time were further examined between the groups. The distribution of deaths was heavily skewed towards the first few days of life (fig 2). The largest reductions in mortality among liveborn infants occurred on the day of delivery, where mortality was 7.8 deaths per 1000 liveborn infants delivered by intervention birth attendants and 19.9 deaths per 1000 liveborn infants delivered by control birth attendants (0.40, 0.19 to 0.83).

Table 4 summarises the causes of death from analysis of the verbal autopsy reports. Most deaths were ascribed to serious infections or birth asphyxia. Deaths attributed to serious infection occurred at similar rates in the two groups (0.82, 0.41 to 1.63). Deaths attributed to birth asphyxia were, however, 63% lower among infants delivered by intervention birth attendants (0.37, 0.17 to 0.81), and 81% lower during the first two days after birth (0.19, 0.07 to 0.52).

Utilisation of interventions

Intervention birth attendants reported using the early steps in the neonatal resuscitation protocol algorithm (drying the infant and swaddling in a fresh dry blanket, clearing airways) in nearly all cases (table 5). The drying and swaddling technique was inappropriate in about 10% of control deliveries compared with about 1% of intervention deliveries, which fell to 0% of intervention deliveries after excluding stillbirths. Intervention birth attendants cleared airways in nearly all cases, consistent with their training in the neonatal resuscitation protocol,[5] whereas among infants delivered by control birth attendants, clearing of the airways was either not done or done by wiping with a cloth. Assisted breathing was required in only a few deliveries and when carried out by the intervention birth attendants was nearly always with the pocket resuscitator, whereas the control birth attendants used mouth to mouth resuscitation.

The frequency of postnatal visits by birth attendants did not differ between the two arms: both carried out a median of two visits during the first postnatal week. Infants were referred to a health centre 215 times by intervention birth attendants and 85 times by control birth attendants (rate ratio of being referred by intervention compared with control birth attendant 1.97, 95% confidence interval 1.6 to 2.5). Intervention birth attendants administered amoxicillin on 202 occasions, 101 (50%) during the first week of life and 64 (31.7%) within the first two days of life.

Intervention birth attendants were less likely than control birth attendants to attend a delivery without payment (40% *v* 49%, rate ratio 0.82, 95% confidence interval 0.68 to 0.99) and more likely to be paid in cash (55% *v* 43%, 1.27, 1.18 to 1.36). On average, mothers paid intervention birth attendants more than they paid control birth attendants, although the differences were

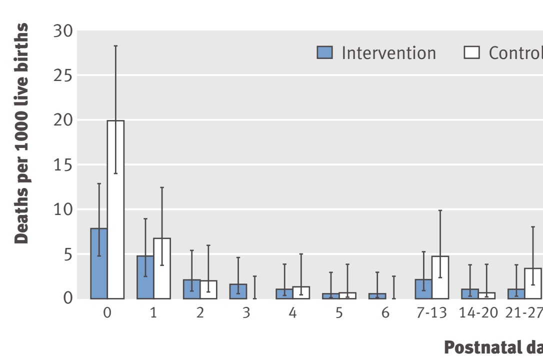

Fig 2 | Neonatal mortality rates during first month of life among liveborn infants delivered by intervention or control traditional birth attendants, Zambia

Table 4 | Primary causes of deaths from analysis of verbal autopsy reports

Cause of death	Infants delivered by intervention birth attendant (n=1899)		Infants delivered by control birth attendant (n=1466)	
	Days 0-1	Days 2-27	Days 0-1	Days 2-27
Serious infection	4	12	6	11
Birth asphyxia	5	5	21	0
Prematurity	12	0	8	2
Tetanus	0	1	0	0
Congenital defects	1	0	2	0
Diarrhoea	0	0	0	4
Other or unknown	2	0	3	1
Total	24	18	40	18

small: 6371 Kwacha (£0.83; €0.98; $1.32) *v* 4953 ZMK per delivery (difference 1418 ZMK, 95% confidence interval 277 to 2559).

DISCUSSION

Zambian infants delivered by traditional birth attendants who had been trained to manage several perinatal conditions were nearly half as likely to die during their first month of life than infants delivered by control traditional birth attendants who received no such training. This equated to one death averted for every 56 deliveries attended by an intervention birth attendant (number needed to treat), or an absolute reduction of about 18 deaths per 1000 live births. Putting this in context, in 2007 the countrywide neonatal mortality rate in Zambia was 34 per 1000 live births.[21] We observed no difference in the proportion of stillborn infants between the two groups—an important internal control, since the study interventions should have had no effect on stillbirth rates.

Although our primary end point was all cause mortality by day 28, and reflected the combined effects of the neonatal resuscitation protocol and use of antibiotics with facilitated referral, training in the resuscitation protocol seems to have been the most effective component of the study interventions. Despite a steep increase in referrals to health centres by intervention birth attendants, and the predominance of amoxicillin use during the first week after delivery, when most of the deaths occurred, the verbal autopsy data did not suggest a significant reduction in deaths from serious infections. By contrast, deaths attributed to asphyxia were about 70% less common among infants delivered by intervention birth attendants. Given recent estimates that around 800 000 infants die each year worldwide as a result of birth asphyxia, these findings have broad public health relevance.[2 11]

Although the effectiveness of the intervention using antibiotics with facilitated referral was less apparent than for the neonatal resuscitation protocol, the higher frequency of referrals to health centres by the intervention birth attendants was an important secondary benefit of the intervention. This is important when traditional birth attendants are viewed as the final stage in an extended healthcare system. In Lufwanyama, traditional birth attendants are an important link between a highly dispersed rural community and the rural health centres, and this link seemed to be strengthened by the intervention to train the birth attendants. This reinforces the need to improve the capacity of rural health centres to care effectively for children with serious infections. In the present study, the intervention using single dose amoxicillin with facilitated referral was not expected to be curative, but rather was hoped to help bridge the transition to a higher level of care—hence the importance of coupling provision of antibiotics with facilitated referral. Unfortunately, the Lufwanyama health centres often could not offer more definitive care, and this might partially explain why the antibiotics with facilitated referral did not show a greater benefit.

Strengths and limitations of the study

Key strengths of the study were its cluster randomised design, which distributed the intervention skills within the context of an existing healthcare system; the intensity and frequency of the intervention training, which gave us confidence that the intervention skills were actually being acquired and retained; and our data collection system using data collectors embedded within the communities and in regular contact with the birth attendants. Because the data collectors also tracked the pregnant women followed by each birth attendant, we were confident that all births were accounted for. Additionally, the study had low rates of loss to follow-up (about 2%). Even assuming that all of these losses represented unrecorded deaths, our sensitivity analysis showed that our study conclusions would not have changed.

Several study limitations merit discussion. Firstly, we were unable to observe directly any of the deliveries, forcing us to rely on the birth attendants' delivery records for details of how the neonatal resuscitation protocol was being implemented. However, the study operated across a physically vast area (nearly 10 000 km^2), with the birth attendants carrying out deliveries at mothers' homes. Hence this was an unavoidable consequence of the study design and acceptable in the context of a field effectiveness trial. Moreover, this limitation had no bearing on the primary end point, which rested on information gathered by the data collectors.

Secondly, the relative contribution of the neonatal resuscitation protocol compared with antibiotics with facilitated referral to the overall reduction in mortality was inferred from indirect evidence, including reports from the birth attendants that the resuscitation protocol steps were used in nearly all deliveries, the timing of the deaths, and the verbal autopsy findings. A more definitive assessment of the impact of each component would require a larger study, powered to assess each component independently. Similarly, the study was designed to measure the overall effect of the interventions on mortality. It was not possible, for example, to disaggregate the components of the neonatal resuscitation protocol to assess the effectiveness of each step in the algorithm separately. Although we have shown that the intervention birth attendants reported

Table 5 | Utilisation of steps in neonatal resuscitation protocol by traditional birth attendants. Values are percentages (numbers)

Protocol step	Intervention birth attendants (n=1961)	Control birth attendants (n=1536)	Total (n=3497)
Drying baby:			
Baby wrapped in cloth without drying	1.1* (22)	2.3 (36)	1.7 (58)
Baby dried then wrapped in same blanket	0.1 (2)	9.0 (138)	4.0 (140)
Baby dried then wrapped in separate blanket	98.4 (1930)	88.0 (1351)	93.8 (3281)
Clearing mouth:			
Not cleared	1.7 (34)	32.0 (492)	15.0 (526)
Cleared with a cloth	1.2 (23)	65.3 (1003)	29.3 (1026)
Cleared with suction bulb	96.5 (1893)	1.0 (15)	54.6 (1908)
Clearing nose:			
Not cleared	1.8 (36)	36.1 (555)	16.9 (591)
Cleared with a cloth	1.2 (23)	60.9 (936)	27.4 (959)
Cleared with suction bulb	96.5 (1892)	0.7 (10)	54.4 (1902)
Stimulation of newborn:			
None	81.2 (1592)	76.2 (1171)	79.0 (2763)
Slapping back or buttocks	1.2 (24)	12.4 (191)	6.1 (215)
Rubbing back or tapping feet	15.0 (294)	9.2 (141)	12.4 (435)
Assisted breathing:			
None	90.8 (1780)	89.3 (1372)	90.1 (3152)
Mouth to mouth	0.3 (6)	7.7 (119)	3.6 (125)
Pocket resuscitator	6.1 (119)	0.2 (3)	3.5 (122)

*Totals are all deliveries, including stillbirths. When stillbirths were excluded from this total, the proportion of infants who were swaddled without drying dropped to 0% in the intervention arm.

correctly using the steps of the resuscitation protocol, particularly the early steps of drying, warming, suctioning, and stimulating, at higher rates than the control birth attendants, we have not attempted to draw inferences about which of these steps was chiefly responsible for the overall effect. In fact, our assumption is that the effectiveness of the neonatal resuscitation protocol derives from the complete package of interventions, rather than from specific components.

Thirdly, the planned total of 4000 deliveries was not reached because the study funding expired. However, the lower than feared loss to follow-up rate left us with a final sample size that actually exceeded the 3360 we predicted to be sufficient for statistical power, so the impact of this was minimal.

Fourthly, given the nature of the interventions in the context of an effectiveness trial, blinding the birth attendants' group allocation was clearly impossible. Since the birth attendants interacted in their communities, it is possible that some exchange of knowledge may have occurred from intervention to control birth attendants. Although we have no evidence that this actually occurred, we believe the effect of this would have been minimal for two reasons. Firstly, the intervention requires that a birth attendant not just be trained in the skills, but also have the equipment (masks, suction bulbs, receiving blankets, and amoxicillin tablets) for using those skills. Without these, a control birth attendant would not have been effective. Secondly, the effect of cross contamination of skills would render the control birth attendants more like the intervention ones. This would make it more difficult to measure a difference in birth outcomes between the two groups, and bias our results to the null. Therefore, the direction of this hypothetical bias would actually strengthen our conclusions by rendering them more conservative.

Lastly, our data collection system was limited to assessing births and outcomes for infants delivered by study birth attendants, but could not assess the impact of the interventions on overall community wide neonatal mortality. Nor could we determine whether some deliveries that might otherwise have occurred at health centres were instead being carried out by the study birth attendants. However, our objective was not to advocate for an alternative to health centre based obstetric care, nor to play down the importance of emergency obstetric care as a key intervention for reducing maternal mortality in low resource settings,[23 24] rather, our goal was strictly limited to determining whether trained traditional birth attendants can save infants' lives.

One important consideration is that showing the effectiveness of enhanced training for birth attendants would have been far more difficult if Lufwanyama did not already have an active programme for traditional birth attendants. Before the study, the birth attendants had all completed Lufwanyama District Health Management Team approved training in standardised basic obstetric care and clean delivery, viewed themselves as part of an extended healthcare system, and reported their activities centrally, allowing their activities to be tracked. Thus, the study provides an example of what can be accomplished when building on an existing standard of care.

Comparisons with other studies

Our findings seem to contrast with the recently reported results from the First Breath study, in which teaching the neonatal resuscitation protocol as part of an expanded programme in essential newborn care had little impact on neonatal mortality rates.[25] However, the present study differed from First Breath in several important aspects. In First Breath the doctors, midwives, or nurses attended around 40% of deliveries, and a third of deliveries occurred in clinics or hospitals. By contrast, 100% of the deliveries in the present study were carried out by traditional birth attendants and all deliveries occurred in remote villages at mothers' homes. In that study only the intervention birth attendants had the equipment and training for the neonatal resuscitation protocol and antibiotics with facilitated referral, whereas in First Breath the intervention and control attendants initially all received the same equipment and training, which included resuscitation; at a later stage in the trial, cluster randomisation was used to allocate birth attendants to receive additional training in a neonatal resuscitation protocol. This may account for the somewhat counterintuitive finding in First Breath that bag-mask assisted breathing was used at similar rates by the intervention and control birth attendants (4.2% *v* 3.6%). This suggests that a much larger gap separated the

WHAT IS ALREADY KNOWN ON THIS TOPIC

In developed countries, the neonatal resuscitation protocol has significantly reduced perinatal mortality

WHAT THIS STUDY ADDS

The neonatal resuscitation protocol was highly effective in the developing world

Training and equipping Zambian traditional birth attendants to carry out an adapted version of the neonatal resuscitation protocol reduced neonatal mortality by day 28 of life by nearly half

Traditional birth attendants can be trained to refer infants who appear unwell to health centres for further care, and to administer a dose of oral amoxicillin to the infant before referral

skill levels of the control and intervention arms in the present study than in First Breath. The difference in neonatal mortality rates in the control arm (21.4 per 1000 live births in First Breath *v* 40.2 per 1000 live births in the present study) emphasises the dissimilarity between the populations studied. In summary, the two studies dealt with fundamentally different questions, in different populations, using different methods.

Two other recent studies are of relevance. Both were community based cluster randomised effectiveness studies, where the primary outcome was neonatal survival. In both, women's groups, not traditional birth attendants, provided the interventions. The first, carried out in Nepal, included a comprehensive neonatal resuscitation intervention similar to that used in the present study, and observed a significant 30% reduction in neonatal mortality.[26] The second study, carried out in Bangladesh, assessed a large number of antenatal, perinatal, and postnatal interventions, of which one was bag-mask ventilation.[27] The study found no significant benefit on mortality. However, the resuscitation intervention was limited to positive pressure ventilation without the other steps in the protocol (drying, warming, suctioning, positioning, and stimulation). Combined, these two studies support the hypothesis that effective neonatal resuscitation cannot simply be limited to positive pressure ventilation but must include the full continuum of early neonatal resuscitation interventions.

Questions for further research

Several questions pertaining to the present study remain unanswered. Firstly, what should be the optimal schedule for retraining traditional birth attendants? The goal of the study was to conclusively show the effectiveness of the interventions, not to compare the efficiency of different training schedules or curriculums. By following a rigorous training and retraining schedule, and requiring that each birth attendant undergo a skills assessment at the end of each training session, we were confident that the birth attendants would perform as intended during actual deliveries. It is possible that less frequent retraining or a less intense curriculum could still be effective. That said, a recent study carried out with a group of Zambian birth attendants, unrelated to the present study, reported a significant loss of neonatal resuscitation protocol skills within as few as six months of a primary training.[28]

Secondly, is there still a role for traditional birth attendants in the management of neonatal sepsis? Neonatal mortality seemed to be lower in the intervention group during postnatal weeks 2-4, when the neonatal resuscitation protocol would presumably have had minimal impact on survival. This difference was not statistically different, although the much lower death rate during this period left this portion of the analysis underpowered. Recent reports from South Asia in which community health workers and traditional birth attendants significantly reduced neonatal sepsis using injectable gentamicin and oral cotrimoxazole, suggest that a strategy of community based management of neonatal sepsis using traditional birth attendants could also be effective.[17 29]

Lastly, it would be interesting to understand what drove the imbalance in the proportion of deliveries carried out by intervention and control birth attendants, and to understand better the process by which mothers chose their birth attendant. We hypothesise that this imbalance reflected a relative preference for mothers to select intervention birth attendants when they had a choice. The higher compensations paid by mothers to intervention than to control birth attendants lends support to this explanation. Regardless, it is unlikely that this imbalance would have biased our findings. Although mothers were more likely to choose an intervention birth attendant over a control one, the outcome of any given delivery was unpredictable. A bias would have been created only if there was advance knowledge of the outcome of a future delivery at the time that a mother selected her birth attendant during the antenatal period.

Conclusion and policy implications

In the context of a highly dispersed, rural African community with limited access to healthcare, traditional birth attendants were able to master a set of skills that allowed them to significantly reduce neonatal mortality. This was accomplished in a population of women birth attendants with low rates of formal education and under austere conditions, making this example highly generalisable. We believe that this approach has good potential to be applied in other resource constrained settings.

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Contributors: CJG was the principal investigator, conceived the project, identified the site, was closely involved in the design of the protocol and data collection tools, provided much of the study monitoring, played a lead role in the analysis, and wrote the manuscript. GP-M was the Zambian principal investigator, led the field team, provided primary oversight during the study, contributed to the protocol design and data cleaning, and was instrumental in the analysis and reporting of the study. NGG was chiefly responsible for designing the neonatal resuscitation protocol curriculum and participated in training of the birth attendants throughout the study, participated in protocol development and development of data tools, contributed to the sepsis protocol and trainings, data analysis, cleaning, and manuscript preparation. JK was the field manager during the study. He supervised the 16 data collectors, provided logistical support, was involved in the data collection and cleaning process, supervised the final cleaning and locking of the dataset, and participated in the analysis of the study. CM was the chief trainer of

the neonatal resuscitation protocol/antibiotics with facilitated referral of the birth attendants, and also provided technical support to the field team during the study. WBMacL was the study statistician and was involved in all aspects of the design, data management and analysis, and writing of the manuscript. NW was the field data manager, participated in the protocol design, supervised the data entry and cleaning process, and set up the database in the field. ABK was the Boston based project manager for LUNESP, participated in the data cleaning process, provided in-field technical assistance throughout the study, and was actively involved in the analysis and writing of the manuscript. MM provided technical assistance during the neonatal resuscitation protocol training, was closely involved in the design of the prevention of maternal to child transmission of HIV component to LUNESP (data to be presented separately), and actively participated in the analysis and writing of this manuscript. AM provided technical support to the field team from the BU field office in Lusaka, was instrumental in the data cleaning process, and also provided thoughtful input on the manuscript. MPF worked closely with WBM on the statistical analysis of LUNESP and was closely involved in the writing of the manuscript. LS was chiefly responsible for the design of the cost effectiveness and cost analysis portions of LUNESP (to be presented separately), and was active in the overall protocol design, analysis, and writing of the manuscript. PS supervised the BU field office in Lusaka, provided important technical support to the Lufwanyama field team, was actively involved in the data cleaning, and provided thoughtful input to the manuscript. JLS secured the funding for the project and contributed to the design, monitoring, and reporting of the study. DHH was actively involved at every stage of LUNESP, from protocol design to study implementation, data cleaning, analysis, and writing of the manuscript. CJG and WBMacL are guarantors.

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Data sharing: The full protocol can be provided on request from the corresponding author at cgill@bu.edu.

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