Newborn Care Training of Midwives and Neonatal and Perinatal Mortality Rates in a Developing Country

**WHAT’S KNOWN ON THIS SUBJECT:** The majority of infant deaths occur during the neonatal period. Educational programs available to train neonatal health care workers are effective in improving knowledge and skills, but there are limited data on their effects on neonatal mortality rates.

**WHAT THIS STUDY ADDS:** Training midwives in neonatal care reduces early neonatal mortality rates for infants born in low-risk, first-level facilities.

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**abstract**

**OBJECTIVE:** This study was designed to test the hypothesis that 2 training programs would reduce incrementally 7-day neonatal mortality rates for low-risk institutional deliveries.

**METHODS:** Using a train-the-trainer model, certified research midwives sequentially trained the midwives who performed deliveries in low-risk, first-level, urban, community health clinics in 2 cities in Zambia in the protocol and data collection, in the World Health Organization Essential Newborn Care (ENC) course (universal precautions and cleanliness, routine neonatal care, resuscitation, thermoregulation, breastfeeding, kangaroo care, care of small infants, and common illnesses), and in the American Academy of Pediatrics Neonatal Resuscitation Program (in-depth basic resuscitation). Data were collected during 3 periods, after implementation of each training course.

**RESULTS:** A total of 71,689 neonates were enrolled in the 3 study periods. All-cause, 7-day neonatal mortality rates decreased from 11.5 deaths per 1000 live births to 6.8 deaths per 1000 live births after ENC training (relative risk: 0.59 [95% confidence interval: 0.48–0.77]; P < .001), because of decreases in rates of deaths attributable to birth asphyxia and infection. Perinatal mortality rates but not stillbirth rates decreased. The 7-day neonatal mortality rate was decreased further after Neonatal Resuscitation Program training, after correction for loss to follow-up monitoring.

**CONCLUSIONS:** ENC training for midwives reduced 7-day neonatal mortality rates in low-risk clinics. Additional in-depth basic training in neonatal resuscitation may reduce mortality rates further. *Pediatrics* 2010;126:e1064–e1071

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**KEY WORDS** neonatal mortality, perinatal mortality, developing countries, health systems, effectiveness

**ABBREVIATIONS**

ENC—Essential Newborn Care  
NRP—Neonatal Resuscitation Program  
WHO—World Health Organization

This article does not necessarily represent the decisions, policies, or views of the World Health Organization.

This trial has been registered at www.clinicaltrials.gov (identifier NCT 00097097).

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There are ~3.7 million neonatal deaths and 3 million stillbirths per year throughout the world. Deaths in the first 28 days after birth constitute an increasing proportion of deaths among children <5 years of age, because the decrease in neonatal mortality rates has been slower than the decrease in 0- to 5-year mortality rates. Currently, 38% of deaths among 0- to 5-year-old children occur in the first 28 days after birth, and 75% of neonatal deaths occur within the first 7 days. Therefore, without a major reduction in 7-day neonatal mortality rates, it will be impossible to achieve United Nations Millennium Declaration Development Goal 4, to reduce 0- to 5-year mortality rates by two-thirds between 1990 and 2015. The overwhelming majority (98%) of neonatal deaths occur in developing countries. During the previous decade, neonatal mortality rates decreased in all of the World Health Organization (WHO) regions except Africa, in part because of the persistently high mortality rates in sub-Saharan countries. Reduction in neonatal mortality rates in Zambia has lagged, even in comparison with many sub-Saharan countries. Zambia is one of the countries in which 0- to 5-year mortality rates have increased since 1990.

Throughout the world, birth asphyxia, low birth weight/prematurity, and infections are major causes of death during the first 7 days after birth. Low-cost interventions introduced as an early neonatal/postnatal package, including neonatal resuscitation training, may be effective in reducing rates of deaths attributable to these major causes. The WHO developed the Essential Newborn Care (ENC) course, a course that sets minimal neonatal care standards, to strengthen the capacity of countries to train skilled birth attendants in evidence-based guidelines for newborn care. The ENC course complements Pregnancy, Childbirth, Postpartum and Newborn Care: A Guide for Essential Practice, and together the course and the guide provide evidence-based guidelines for routine care and initial treatment of neonates during the first week after birth. The ENC course has been taught, but its effect on major outcomes has not been tested in a large clinical study. The Neonatal Resuscitation Program (NRP) of the American Academy of Pediatrics is a train-the-trainer, hands-on course to develop expertise in the evidenced-based knowledge and skills of neonatal resuscitation. NRP training decreased rates of asphyxia-related deaths among institutional births in academic medical centers in India, but there have been limited evaluations in first-level facilities. This study was designed to test the hypothesis that training midwives in the ENC course, followed by NRP training, would incrementally reduce all-cause, 7-day (early) neonatal mortality rates for low-risk institutional deliveries in a developing country.

**METHODS**

**Study Design**

This study was conducted as a preintervention/postintervention study with an active baseline design (Fig 1). The active baseline study design requires all training except that related to the interventions to be completed before the initiation of baseline data collection. The active baseline design is an improvement over the before/after controlled study design because both the preintervention and postintervention data are collected prospectively and only after all of the study components, except the specific interventions, have been put in place. The hypotheses were that training and implementation of each course (ENC and NRP) would decrease all-cause, 7-day mortality rates. Secondary hypotheses were that ENC and NRP training also would decrease rates of deaths attributable to birth asphyxia (defined as failure to initiate and to sustain normal breathing at birth, according to WHO criteria), neonatal deaths by discharge (usually by 12 hours after birth or at transfer), postdischarge neonatal deaths, stillbirths, perinatal deaths, and deaths according to birth weight. Perinatal mortality figures included any deaths that occurred in the first 7 days, including stillbirths. Secondary outcomes also included maternal and neonatal demographic features, Apgar scores, and use of resuscitation interventions.

**Study Location and Population**

This study was conducted in 18 low-risk, first-level, urban, community, public-sector, delivery clinics (health centers) in the 2 largest Zambian cities (Lusaka and Ndola) from October 2004 to October 2005 and from December 2005 to November 2006. More than 98% of institutional low-risk deliveries in these 2 cities occur in these clinics. Patients with any identified pregnancy or labor complications are referred prenatally or during early labor to the respective hospital in each city unless transport cannot be accomplished safely. The referral criteria and patterns have been stable since 2002, when training in obstetric care was conducted.

Government officials and leaders in these clinics agreed to facilitate the training of all delivery midwives in the protocol and data collection, the ENC course, and the NRP, as well as allowing them to obtain consent and to collect data. The study was approved by the institutional review boards of the University of Zambia, the University of Alabama at Birmingham, and RTI International.

The study population included all births at the study clinics. A study
screening log was used at each clinic to enter limited demographic data, including immediate outcomes (stillbirths and death before discharge), for all deliveries and was verified for completeness and accuracy by a research nurse with the clinic’s delivery log. Collection of additional maternal, pregnancy, delivery, and neonatal data, including 7-day outcomes, was limited to births with parental consent. A tracking system was used to facilitate the collection of 7-day follow-up data.

**Procedures**

A train-the-trainer model was used to train all \( N = 123 \) practicing midwives (with a 3-year college degree in midwifery) who performed deliveries in the clinics. The train-the-trainer program was developed by using a variety of teaching methods for participant learning, including demonstrations and clinical practice sessions for trainees, with performance evaluations. Experienced researchers (Drs Carlo, and Wright, Ms McClure, Ms Harris, and Monica Collins, RN, MaEd) trained 18 midwives (1 per clinic) to become research nurses, to train the practicing midwives, and to supervise in all aspects of the study. The initial training before patient data collection included research concepts, ethics, and data collection, including differentiation between stillbirth and early neonatal death and Apgar scores during a 5-day course. The 18 research nurses trained all of the practicing midwives at their clinics before initiation of the baseline (pre–ENC training) data collection period.

After pre–ENC training data collection, the research nurses underwent ENC training (5 days) by a WHO officer (Dr Lincetto) and 2 experienced trainers who had been involved in the development of WHO training materials. The elements of the ENC course included universal precautions and cleanliness, routine neonatal care, initiation of breathing and resuscitation (including bag-mask ventilation), prevention of hypothermia, early and exclusive breastfeeding, kangaroo (skin-to-skin) care, care of small infants, counseling on infant care and danger signs, and recognition and initial management of complications. The research nurses trained all of the practicing midwives at their clinics before initiation of post–ENC training data collection.

After completion of the post–ENC training data collection, the research nurses underwent NRP training (5 days) by an experienced instructor (Dr
The elements of the NRP included in the training were in-depth basic resuscitation knowledge and skills, including initial steps of resuscitation, bag-mask ventilation, and chest compressions. The research nurses subsequently trained all midwives in a subset of the largest clinics (7 clinics in Lusaka and 7 clinics in Ndola) in which the NRP intervention was tested. The midwives performed all interventions and assessments, provided advice to the mothers about neonatal care, and collected all predischarge data. The research nurses reviewed the screening logs in comparison with the clinic logs and the data collection forms and collected the data in the 7-day follow-up evaluations.

**Data Management and Statistical Analyses**

On the basis of the 7-day neonatal mortality data for the active baseline data collection period, enrollment of at least 20,000 and 25,000 births in the post–ENC training and post–NRP training periods, respectively, was required to detect a >40% relative risk reduction for all-cause, 7-day neonatal death with >80% power and a 5% level of significance, with the use of a 2-tailed test. A data safety and monitoring board reviewed the data during the planned 2 interim evaluations at 33% and 67% of enrollment during the post–NRP training period (O’Brien-Fleming boundary method). There were no formal stopping rules.

All data were entered centrally in Lusaka. Data edits, including interf orm and intraform consistency checks, were performed at data entry, with additional edits performed by the data center. Stillbirth was defined as no signs of life at birth for infants thought to be ≥28 weeks, and rates were calculated by using all births as the denominator. Seven-day neonatal deaths were defined as deaths after birth up to day 7 after birth, and rates were calculated by using all live births as the denominator. Perinatal deaths were defined as the sum of stillbirths and 7-day neonatal deaths, and rates were calculated by using all births as the denominator.

Appropriate χ² tests and tests of proportions were performed to compare the maternal and neonatal characteristics of subjects with known 7-day outcomes and subjects missing 7-day outcome data. Relative risks and confidence intervals were calculated by using a Cochran-Mantel-Haenszel test. Generalized estimating equations for Poisson regression models accounting for cluster effects were used to test the differences between the pre–ENC training and post–ENC training data and between the post–ENC training and post–NRP training data. Because all follow-up data were censored after 7 days, survival analysis using hazard ratios to compare the relative likelihood of death by 7 days according to phase was performed. A “difference-in-difference” analysis tested whether there were time-trend effects between 2 consecutive phases within each period (pre–ENC training, post–ENC training, and post–NRP training periods), to determine whether the effects were attributable to the interventions rather than changes over time.

Because of the missing 7-day follow-up outcome data, posthoc generalized estimating equations for Poisson regression models were used for all patients with known (nonmissing) 7-day follow-up data from the pre–ENC training, post–ENC training, and post–NRP training periods, to impute 7-day outcomes. Maternal and neonatal demographic data were used to develop the model. The known (nonmissing) follow-up data were used to determine cutoff points for imputation. These cutoff points were the actual 7-day mortality rates reported for the pre–ENC training, post–ENC training, and post–NRP training periods. If the model predicted a probability of death greater than the cutoff value (the average 7-day neonatal mortality rate), then the outcome of death was assigned for infants with missing 7-day mortality data. If the model predicted a probability of death lower than the cutoff value, then the neonate was considered to have survived until day 7.

We used tests of proportions to compare 7-day neonatal mortality rates by using the complete data set. The data were analyzed by using SAS 9.1 (SAS Institute, Cary, NC). All analyses, including subgroup analyses, were prespecified except for the analysis to impute missing follow-up outcome data.

**RESULTS**

A total of 71,689 neonates were enrolled in the 3 study periods (Fig 1). All maternal and neonatal demographic characteristics were comparable in the 3 periods. The majority of women were African (99.9%), were married (98%), had <8 years of formal education (55%), were multigravida (63%), and had ≥1 prenatal visit (98%). There were small but significant reductions in the rates of 1-minute Apgar scores of 0 to 3 and 4 to 6 after the ENC training period (P = .04) (Table 1). Use of resuscitation interventions decreased in the post–ENC training period because of decreases in the use of oxygen and medications, but bag-mask ventilation became part of 99% of all advanced resuscitations.

After ENC training, the all-cause, 7-day neonatal mortality rate decreased from 11.5 deaths per 1000 live births to 6.8 deaths per 1000 live births (P < .001) (Table 2) because of a decrease in the postdischarge mortality rate (P < .001). The perinatal mortality rate decreased from 18.3 deaths per 1000 births to 12.9 deaths per 1000 births.
The decrease in the 7-day mortality rate after ENC training was attributable to decreases in the rates of deaths attributable to birth asphyxia (from 3.4 to 1.9 deaths per 1000 live births; $P = .02$), infections (from 2.2 to 0.8 deaths per 1000 live births; $P = .02$), and unknown/other causes (from 2.1 to 1.0 deaths per 1000 live births; $P = .02$; data not shown). There were no significant decreases in the rates of deaths attributable to low birth weight/prematurity (from 2.8 to 2.1 deaths per 1000 live births; $P = .28$) or malformations (from 0.2 to 0.1 deaths per 1000 live births; $P = .57$). The increase in the mortality rate in the post–NRP training period was attributable to unknown/other causes of death (from 1.0 to 2.5 deaths per 1000 live births; $P < .001$). The rate of transport of infants to a NICU decreased slightly after ENC training (from 6.8 to 6.1 deaths per 1000 live births; $P = .05$) but increased slightly after NRP training (to 7.4 deaths per 1000 live births; $P = .05$). For the difference-in-differences analysis, the cutoff values shown in Fig 2 were used to divide the data into 2 consecutive phases within the periods. There were no significant differences between the phases in 7-day neonatal mortality, stillbirth, or perinatal mortality rates.

Because of the improved follow-up rates during the post–ENC training and post–NRP training periods, posthoc analyses were performed by using the generalized estimated equation model to impute missing death data. With this analysis, 7-day mortality rates decreased from 36.2 to 25.1 deaths per 1000 live births after ENC training ($P < .001$) and decreased further after NRP training (to 15.9 deaths per 1000 live births; $P = .003$). Supplemental Table 4 and Supplemental Table 5 compare maternal and infant characteristics according to follow-up status.
DISCUSSION

This large, controlled, multicenter study conducted in clinics caring for women with low-risk pregnancies in Zambia demonstrated that ENC training could reduce 7-day neonatal mortality rates. The reductions in rates of deaths attributable to asphyxia and infections may be the result of improvements in general care, resuscitation techniques, management of birth asphyxia, infection prevention, thermal protection, and breastfeeding, as recommended in the ENC course. Training in the initial steps of resuscitation includes simulation, which may reduce the need for the inappropriate use of more-advanced resuscitation techniques such as medications and oxygen without ventilation, as observed in this study. The beneficial effects on 7-day neonatal mortality rates were most prominent for male infants and infants whose mothers had only primary education or less. The results may indicate that this vulnerable population may benefit preferentially from the intervention.

The strengths of this study are the population-based design, the large sample size, the rigorous training of trainers by master instructors, the exclusive use of local trainers to train the midwives, the accurate clinic registries, and the completeness of data collection before discharge. An important limitation of the study is the before/after design, which was used in large part because of ethical concerns regarding restricting the basic education. However, concerns regarding this design are reduced through the use of an active baseline design. This design reduces bias and is suitable for this 3-period, nonconcurrent, controlled study. ENC training was the only intervention after pre–ENC training data collection. A cluster-randomized, controlled trial of an educational intervention would have required a much larger number of clusters, particularly with the markedly decreased 7-day neonatal mortality rate after ENC training. Another problem is the change in follow-up rates throughout the study. This might bias the mortality results, because the event rate was low and the subjects lost to follow-up monitoring might be at either higher or lower risk of death. On the basis of the generalized estimated equation model used to impute missing deaths, the effect of ENC training might be even larger than demonstrated. Further-

### Table 3: Major Outcomes for Infants in Post–ENC Training and Post–NRP Training Periods

<table>
<thead>
<tr>
<th></th>
<th>After ENC Training</th>
<th>After NRP Training</th>
<th>P</th>
<th>Relative Risk (95% Confidence Interval)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Rate, Cases per 1000</td>
<td>Rate, Cases per 1000</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stillbirths</td>
<td>95/20638 4.6</td>
<td>144/31027 4.6</td>
<td>.97</td>
<td>1.01 (0.70–1.45)</td>
</tr>
<tr>
<td>Deaths by discharge</td>
<td>50/20543 2.4</td>
<td>102/30883 3.3</td>
<td>.02</td>
<td>1.36 (1.04–1.76)</td>
</tr>
<tr>
<td>Deaths after discharge</td>
<td>56/16635 3.4</td>
<td>180/29726 6.3</td>
<td>.004</td>
<td>1.86 (1.22–2.84)</td>
</tr>
<tr>
<td>All-cause, 7-d deaths</td>
<td>106/16685 6.4</td>
<td>280/29828 9.7</td>
<td>.01</td>
<td>1.52 (1.10–2.09)</td>
</tr>
<tr>
<td>Maternal education</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>=7 y</td>
<td>55/8887 6.1</td>
<td>180/16338 11.0</td>
<td>.01</td>
<td>1.80 (1.14–2.85)</td>
</tr>
<tr>
<td>≥8 y</td>
<td>50/7465 6.7</td>
<td>108/13425 8.0</td>
<td>.17</td>
<td>1.20 (0.93–1.56)</td>
</tr>
<tr>
<td>Gravida</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Primigravida</td>
<td>43/4688 9.2</td>
<td>100/7943 12.6</td>
<td>.08</td>
<td>1.37 (0.96–1.97)</td>
</tr>
<tr>
<td>Multigravida</td>
<td>63/1195 5.3</td>
<td>188/21879 8.6</td>
<td>.01</td>
<td>1.63 (1.14–2.34)</td>
</tr>
<tr>
<td>Multiple gestation</td>
<td>10/195 5.1</td>
<td>25/402 6.2</td>
<td>.7</td>
<td>1.21 (0.54–2.72)</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>61/8583 7.1</td>
<td>171/15248 11.2</td>
<td>.002</td>
<td>1.58 (1.18–2.11)</td>
</tr>
<tr>
<td>Female</td>
<td>43/8096 5.3</td>
<td>117/14566 8.0</td>
<td>.32</td>
<td>1.51 (0.88–2.57)</td>
</tr>
<tr>
<td>Birth weight</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≤1500 g</td>
<td>23/69 333.3</td>
<td>30/96 312.5</td>
<td>.84</td>
<td>0.94 (0.50–1.77)</td>
</tr>
<tr>
<td>1501–2000 g</td>
<td>20/288 69.4</td>
<td>45/532 81.5</td>
<td>.41</td>
<td>1.17 (0.80–1.72)</td>
</tr>
<tr>
<td>2001–2500 g</td>
<td>11/1406 7.8</td>
<td>58/2920 20.6</td>
<td>.03</td>
<td>2.63 (1.12–6.19)</td>
</tr>
<tr>
<td>&gt;2500 g</td>
<td>52/1419 3.5</td>
<td>155/2635 5.9</td>
<td>.03</td>
<td>1.89 (1.04–2.74)</td>
</tr>
<tr>
<td>Perinatal deaths</td>
<td>201/16780 12.0</td>
<td>432/29828 14.4</td>
<td>.25</td>
<td>1.20 (0.88–1.55)</td>
</tr>
</tbody>
</table>

Only data from centers common to these 2 periods are included. Rates and P values report proportion test results. Relative risks and confidence intervals are Cochran-Mantel-Haenszel statistics.

### Figure 2

All-cause, early (7-day) neonatal mortality rates (deaths per 1000 live births), stillbirth rates (stillbirths per 1000 births), and perinatal mortality rates (deaths per 1000 births) before and after ENC training and after NRP training. After ENC training, the all-cause, early (7-day) neonatal mortality rate decreased significantly (* P < .001) for post–ENC training period (both phases) versus pre–ENC training period (both phases), which resulted in a decrease in the perinatal mortality rate († P = .002). Additional training in neonatal resuscitation did not reduce mortality rates further. The all-cause, early (7-day) neonatal mortality rate increased after NRP training (‡ P = .002). Separation of the data from each period into first and second halves of the chronologically enrolled patient groups indicated that the effects on mortality rates were not attributable to changes over time.
more, NRP training also might have resulted in a decrease in the 7-day neonatal mortality rate, on the basis of this analysis. It is unlikely that additional resuscitation training could have increased 7-day neonatal mortality rates.

Several studies evaluated the effect of the ENC course. This course has been used extensively for >8 years in health care facilities in Europe and briefly in Brazil, but its impact on patient outcomes has not been tested. The only clinical studies on the effect of ENC training reported increased use of many of the practices taught. Mortality rates and other major outcomes were not assessed because the studies were too small to detect an effect. The ENC course improved the knowledge and skills of midwives in Zambia. The current study provides the strongest evidence to date of the effectiveness of the training of institution-based midwives in the ENC course in the developing world, although the intervention was not assigned randomly. A recently reported, large, multicountry, community-based study showed that training of birth attendants with the ENC course used in the current study reduced stillbirth rates for all births and reduced perinatal mortality rates for deliveries conducted by birth attendants. Evaluations of other neonatal care packages have been reported. Reductions in neonatal or perinatal mortality rates were reported in randomized trials of training of community-health workers and traditional birth attendants; however, a review of studies that tested neonatal care packages concluded that effectiveness trials are required to test these packages at scale in developing countries, such as was performed in this study.

Data from well-designed studies on the effects of resuscitation training on neonatal mortality rates in developing countries are scant. Implementation of resuscitation training reduced neonatal mortality rates and rates of deaths attributable to birth asphyxia in facility-based studies with historic controls. The current study should not be used to refute the effectiveness of resuscitation training with respect to perinatal outcomes, because basic resuscitation training was part of the ENC training and statistical correction for loss to follow-up monitoring suggested that NRP training reduced 7-day neonatal mortality rates.

This study demonstrates that ENC training in low-risk clinics reduces 7-day neonatal mortality rates, and it adds to the data on the effectiveness of ENC training for community births. Further research is needed to confirm the effectiveness and to assess the sustainability of training in ENC in other institutional settings. Neonatal care educational packages seem to be an effective way to improve neonatal outcomes in the developing world.

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