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Stillbirth and Newborn Mortality in India After Helping Babies Breathe Training

Shivaprasad S. Goudar, Manjunath S. Somannavar, Robert Clark, Jocelyn M. Lockyer, Amit P. Revankar, Herta M. Fidler, Nancy L. Sloan, Susan Niermeyer, William J. Keenan and Nalini Singhal

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WHAT'S KNOWN ON THIS SUBJECT: A few methodologically sound studies demonstrate that birth attendant training in essential newborn care, including neonatal resuscitation, may play a tremendous role in averting a substantial proportion of the 2.6 million stillbirths and 3.1 million neonatal deaths that occur annually.

WHAT THIS STUDY ADDS: This before-and-after study evaluated the effectiveness of the Helping Babies Breathe basic neonatal resuscitation interactive skill-based educational program to improve providers' knowledge and skills and to reduce stillbirth and neonatal mortality in southern India.

abstract

OBJECTIVE: This study evaluated the effectiveness of Helping Babies Breathe (HBB) newborn care and resuscitation training for birth attendants in reducing stillbirth (SB), and predischarge and neonatal mortality (NMR). India contributes to a large proportion of the worlds annual 3.1 million neonatal deaths and 2.6 million SBs.

METHODS: This prospective study included 4187 births at >28 weeks' gestation before and 5411 births after HBB training in Karnataka. A total of 599 birth attendants from rural primary health centers and district and urban hospitals received HBB training developed by the American Academy of Pediatrics, using a train-the-trainer cascade. Pre-post written trainee knowledge, posttraining provider performance and skills, SB, predischarge mortality, and NMR before and after HBB training were assessed by using χ^2 and *t*-tests for categorical and continuous variables, respectively. Backward stepwise logistic regression analysis adjusted for potential confounding.

RESULTS: Provider knowledge and performance systematically improved with HBB training. HBB training reduced resuscitation but increased assisted bag and mask ventilation incidence. SB declined from 3.0% to 2.3% (odds ratio [OR] 0.76, 95% confidence interval [CI] 0.59–0.98) and fresh SB from 1.7% to 0.9% (OR 0.54, 95% CI 0.37–0.78) after HBB training. Predischarge mortality was 0.1% in both periods. NMR was 1.8% before and 1.9% after HBB training (OR 1.09, 95% CI 0.80–1.47, $P = .59$) but unknown status at 28 days was 2% greater after HBB training ($P = .007$).

CONCLUSIONS: HBB training reduced SB without increasing NMR, indicating that resuscitated infants survived the neonatal period. Monitoring and community-based assessment are recommended. *Pediatrics* 2013;131:e344–e352

AUTHORS: Shivaprasad S. Goudar, MD, MHPE,[a,b] Manjunath S. Somannavar, MD,[c] Robert Clark,[d] Jocelyn M. Lockyer, PhD,[e] Amit P. Revankar, MBA,[b] Herta M. Fidler, MSc,[f] Nancy L. Sloan, DrPH,[g] Susan Niermeyer, MD, MPH,[h] William J. Keenan, MD,[i] and Nalini Singhal, MBBS, FRCPC[j]

Departments of [a]Physiology, [b]Women's and Children's Health Research Unit, and [c]Biochemistry, KLE University's Jawaharlal Nehru Medical College, Belgaum, Karnataka, India; [d]Humanitarian Services, Latter-Day Saints Charities, Salt Lake City, Utah; [e]Department of Community Health Sciences, [f]Office of Continuing Medical Education and Professional Development, and [j]Department of Pediatrics, University of Calgary, Calgary, Alberta, Canada; [g]Department of Obstetrics and Gynecology, Christiana Care Health Services, Newark, Delaware; [h]Department of Pediatrics, University of Colorado School of Medicine, Aurora, Colorado; and [i]Department of Pediatrics, Saint Louis University School of Medicine, St. Louis, Missouri

KEY WORDS

Helping Babies Breathe, resuscitation, stillbirth, neonatal mortality, asphyxia neonatorum

ABBREVIATIONS

ANM—auxiliary nurse midwife
B&M—bag and mask
CI—confidence interval
HBB—Helping Babies Breathe
IHE—intrapartum hypoxic event
MDG—Millennium Development Goal
NMR—neonatal mortality rate
OR—odds ratio
OSCE—Objective Structured Clinical Evaluation
PHC—primary health center
SB—stillbirth

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Address correspondence to Shivaprasad S. Goudar, MD, MHPE, Department of Physiology, KLE University's Jawaharlal Nehru Medical College, Belgaum, Karnataka, India 590010. E-mail: sgoudar@jnmc.edu

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India is the largest single-country contributor to the 3.1 million neonatal deaths and 2.6 million stillbirths (SBs) that occur globally every year.[1,2] Intrapartum hypoxic events (IHEs, eg, birth asphyxia), defined as failure to initiate or maintain regular breathing at birth,[3,4] accounts for ∼717 000 intrapartum deaths each year and a morbidity burden of 42 million disability adjusted life years.[5] Prevention and effective response to IHEs can avert many of these losses and are essential to achieving Millennium Development Goal (MDG) 4 (to reduce, by two-thirds, mortality in children <5 years old between 1990 and 2015). With a neonatal mortality rate (NMR) of 34 of 1000 live births[6] and a declining but still high SB rate of 27 of 1000 births, India is not yet on target to achieve its MDG 4, with annual SB and neonatal deaths at over 1 million.[7]

Neonatal resuscitation programs are low-cost interventions and effectively reduce perinatal mortality by up to 30%.[8–12] Basic resuscitation focusing on initial steps and assisted ventilation, without the use of endotracheal intubation or drugs, is sufficient for the vast majority of newborns.[13] To assist developing countries with the immense task of scaling up resuscitation training, Helping Babies Breathe (HBB), a graphically based curriculum designed for resource-limited settings, was produced by the American Academy of Pediatrics and launched in 2010.[14,15] The HBB program targets developing country health care providers with a combination of best practices, simplified protocols, and teaching techniques. HBB promotes multidisciplinary teams of physicians, nurses, and midwives, including auxiliary nurse midwives (ANMs), as master trainers and instructors. The HBB curriculum, first developed and assessed in Kenya and Pakistan, focuses on achieving spontaneous respiration or, when indicated, providing ventilation within the first minute after birth, called The Golden Minute, for infants who do not begin to breathe on their own.[15] Drying, clearing the airway, stimulation, and assisted ventilation with a self-inflating bag and mask (B&M) and air are the key steps of the resuscitation process.

The *Eunice Kennedy Shriver* National Institute of Child Health and Human Development Global Network for Women's and Children's Health Research had previously conducted a trial called "First Breath: Community-Based Training and Intervention in Neonatal Resuscitation" in 7 sites in Asia, Africa, and Latin America in which the Jawaharlal Nehru Medical College site in Belgaum, southern India, contributed to nearly 30% of the sample.[8,16,17] First Breath was a major initiative to train community-based birth attendants in neonatal resuscitation with the aim of reducing early NMR in the developing world; however, the trial results were mixed. Thus, this prospective pre-post study was conducted independently by the same group of local investigators, but in a different geographic area of Belgaum, Karnataka, with the primary objective to evaluate the effectiveness of HBB training on reducing SB and NMR (death within 28 days of birth). Secondary objectives included determining HBB acceptance by facility-based providers and assessment of HBB training on other clinical outcomes and educational outcomes.

METHODS

Using a train-the-trainer model and paired teaching and skills and practice exchange, experienced American Academy of Pediatrics faculty instructors initiated the training cascade by preparing 18 local master trainers (11 physicians, 5 nurses, 2 ANMs). The 2-day HBB master trainer workshop included discussion, practice, and simulation using the HBB Learner's Workbook,[18] the HBB Flipchart,[19] and NeoNatalie simulators.[20] Using a similar format, the master trainers then taught 7 HBB trainers (2 physicians, 4 nurses, 1 ANM) and, in 53 single-day sessions, these 18 master and 7 HBB trainers taught 599 birth attendants from rural communities, primary health centers (PHCs), and hospitals and conducted the learner assessments. Training materials, resuscitation bags and masks, neonatal simulators, stethoscopes, and sterile disposable delivery kits were provided to the 12 PHCs and the hospitals, and infant scales were provided to the PHCs. Multiple HBB training courses were conducted between November 2009 and April 2010 and September and December 2010. The second set of courses permitted a single repetition for providers desiring a refresher course (with an average of 230 ± 32 days between the initial and refresher training) and included trainees who, because of provider turnover, had not previously received HBB training.

All women delivering at >28 weeks' gestation in PHCs, district hospitals, and urban hospitals in Belgaum in the pre (October 15, 2009, to March 14, 2010) and post (March 15, 2010, to September 30, 2010) HBB training periods were eligible to participate with their infants.

Three types of educational (secondary) outcomes were evaluated: (1) trainee knowledge, assessed by a written or verbal 16- item multiple choice questionnaire (each composed of multiple conditions) for which scores of ≥80% indicated a passing mark; (2) B&M skills performance assessed by a 12-item checklist requiring demonstration of all skills to pass; and (3) 2 Objective Structured Clinical Evaluation (OSCE) assessments (OSCE A and B) that appraised trainees' response to 2 standardized case studies of newborns not breathing at birth.[15] OSCE A evaluated thorough drying, recognition that the newborn was not crying, positioning the newborn, and clearing the airway. OSCE B evaluated recognition that the newborn was not breathing, appropriate mask selection and application, clearing the airway, and ventilation with corrective actions. Accurate demonstration of all critical items for each case study and an 80% overall successful completion of OSCE activities was required to pass.

De-identified clinical outcomes data, including resuscitation (defined as stimulation to breathe, clearing of the airway, and/or B&M ventilation), were obtained from birth facilities through discharge, and the area vital events registry through 42 days after birth, and by telephone interview to determine neonatal status at 28 days for those living in areas not covered by the registry.

SB and NMRs were the primary outcomes. Other clinical outcomes included the incidence of fresh SB, stimulation, clearing of the airway, B&M ventilation, and provider HBB knowledge and skills. A nonbreathing infant who was not successfully revived was classified as a fresh SB if there were no signs of life or fetal heart rate, and no evidence of maceration. No a priori hypothesis regarding birth outcomes' effect or sample size determinations were posed. The goal was to evaluate ≥6 months of data in each of the pre- and post-HBB periods. Given a Type I error = 0.05, power = 80%, and a 2-tailed test, a harmonic mean sample of 7103 infants was required to test a 25% reduction in SB incidence from 3% and a harmonic mean sample of 11 965 was required to test a 25% reduction in NMR from 1.8% in the pre-HBB period. The attained harmonic mean sample was 4721.[21] SPSS 18.0 (IBM SPSS Statistics, IBM Corporation, Armonk, NY) and Stata version 8 (Stata Corp, College Station, TX) were used for data analysis. The χ^2 and Student's *t*-test were used to test differences in categorical and continuous variables, respectively. McNemar χ^2 and paired *t*-tests were used to assess matched pre-post provider knowledge and skills scores. Backward Wald stepwise logistic regressions using entry $P = .10$ and removal $P = .05$ criteria were conducted to adjust for potential confounding. As only 2 related primary outcomes are assessed, no multiple comparisons adjustment was made.

The study was approved by the institutional review board of Jawaharlal Nehru Medical College, Belgaum, Karnataka, India, and the University of Calgary, Conjoint Health Research Ethics Board. The study was approved by the Ministry of Health, Government of Karnataka, Bangalore, and Indian Council of Medical Research, New Delhi. Individual informed consent was waived, as resuscitation is an emergency procedure and all clinical and birth registry data were de-identified.

RESULTS

Trainees' knowledge scores increased significantly after HBB training (Table 1). Mean knowledge scores increased in initial and refresher (both $P \leq .001$) training courses. Trainees with passing knowledge scores increased 46.1% to 88.6% in the initial and from 69.3% to 90.4% in refresher sessions (both $P \leq .001$). The refresher training participants had slightly higher mean scores for the B&M skills and OSCE case studies than those participating in a single training session (all $P \leq .001$). More trainees had passing scores after the

TABLE 1 Knowledge, B&M Skills Performance, and OSCE Assessments

	Initial Training Session					Refresher Training Session					Initial vs Refresher
	Pre		Post			Pre		Post			
	%	*n*	%	*n*	*P*	%	*n*	%	*n*	*P*	*P*
Percent passed											
Knowledge assessment	46.1	599	88.6	599	<.001	69.3	228	90.4	228	≤.001	—
B&M skills performance	—	—	57.6	599	—	—	—	68.0	228	—	.006
OSCE station A	—	—	89.6	599	—	—	—	98.2	228	—	≤0.001
OSCE station B	—	—	77.3	599	—	—	—	85.5	227	—	.009
	Initial Training Session					**Refresher Training Session**					**Initial vs Refresher**
	mean ± SD	*n*	mean ± SD	*n*	*P*	mean ± SD	*n*	mean ± SD	*n*	*P*	
Mean scores											
Knowledge assessment	17.93 ± 3.24	599	21.23 ± 2.25	599	≤.001	19.45 ± 3.16	228	21.36 ± 2.40	228	≤.001	—
B&M skills performance (maximum score = 12)	—	—	11.14 ± 1.33	599	—	—	—	11.52 ± 0.87	228	—	≤.001
OSCE station A (maximum score = 3)	—	—	2.88 ± 0.35	599	—	—	—	2.98 ± 0.13	225	—	≤.001
OSCE station B (maximum score = 9)	—	—	8.57 ± 1.03	599	—	—	—	8.78 ± 0.67	227	—	≤.001

refresher than initial sessions: B&M (68.0% vs 57.6%, $P \leq .006$), OSCE A (98.2% vs 89.6%, $P \leq .001$), and OSCE B (85.5% vs 77.3%, $P \leq .009$).

A total of 4139 and 5335 women delivering 4187 and 5411 infants were registered in the pre- and post-intervention periods (Fig 1). Subjects' characteristics were generally comparable, although some small differences were statistically significant owing to the large sample (Table 2). Women had slightly lower parity in the post than pre periods ($P = .03$). Most women delivered at a hospital, although slightly more in the post period delivered with a traditional birth attendant at home. Fewer (82.4% vs 88.4%, $P \leq .001$) had ≥3 antenatal care visits and male infants (51% vs 53%, $P = .05$) in the post period. More women in the post period experienced severe preeclampsia/eclampsia ($P = .004$). Mean gestation was 38.2 ± 1.8 and 38.1 ± 1.6 weeks in the pre and post periods, respectively ($P \leq .001$). There was no difference in preterm delivery rates. Gestation was more frequently determined by fundal height in the post than pre period ($P \leq .001$). Although the incidence of multiple gestation was slightly higher ($P = .15$), average birth weight was 21 g higher in the post than pre period ($P = .05$).

Resuscitation, defined as clearing the airway, specific stimulation to breathe, and/or bag-and-mask ventilation, was implemented for 28.9% in the pre but only 11.9% in the post period ($P \leq .001$, Table 3). In the pre-intervention period, 26.7% of newborns had their airways cleared by suction compared with 10% in the post period ($P \leq .001$); 15.8% of infants in the pre and 9.1% in the post period received stimulation ($P \leq .001$). Few (pre: 0.7%; post: 0.3%) infants received other resuscitation efforts ($P = .008$). Of those resuscitated, 33.1% received B&M ventilation after HBB training compared with 10.3% before training ($P \leq .001$). Physicians performed B&M ventilation in most cases; however, nurses provided ventilation in 7.5% in the post period compared with 2.3% in the pre period. Although 22.3% of resuscitated infants received Golden Minute B&M ventilation in the post period only, 7.8% did so in the pre period ($P \leq .001$). Slightly more newborns in the post than pre group were held skin-to-skin ($P = .03$), but the proportion breastfed within the first 30 minutes of life was similar ($P = .10$).

The incidence of SB was 3.0% in the pre and 2.3% in post training period (odds ratio [OR] 0.76, 95% confidence interval [CI] 0.59–0.98, $P = .035$; Table 4). The fresh SB rate was 1.72% in the pre and 0.92% in the post training period (OR 0.54, 95% CI 0.37–0.78, $P \leq .001$). Of the 6.6% and 8.7% ($P \leq .001$) liveborn infants identified as not breathing at birth in the pre and post periods, 66.0% and 74.3%, respectively, were breathing at 1 minute ($P = .06$), 92.5% and 94.4% at 5 minutes ($P = .41$), and 98.1% and 97.5% at 10 minutes ($P \leq .65$) after birth. The proportion with Apgar scores below 5 was similar in both periods. All newborns were followed through discharge. Predischarge death was 0.1% in both periods ($P = .75$); all 3 cases before training were attributed to prematurity/low birth weight and all 3 cases after training were attributed to birth asphyxia.

NMR was 1.8% in the pre and 1.9% in the post periods (OR 1.09, 95% CI 0.80–1.47, $P = .59$). Most pre- and post-training neonatal deaths were attributed to prematurity/low birth weight (48% and 43%, respectively), IHEs (31% and 28%, respectively), and other causes (12% and 10%, respectively); however, 13.6% of neonatal deaths were attributed to infection in the post compared with 6.6% in the pre period ($P \leq .001$). The incidence of an unknown vital status at 28 days of life was 13.9% in the pre- and 15.9% in the post-training periods ($P = .007$).

The lack of difference in NMR persisted in adjusted analysis (data available on request). The effects of HBB training on SB and fresh SB reduction were increased to 38% (Table 5), and 54% (Table 6), respectively, in logistic regression analyses. Gestational age and having ≥3 ANC visits were inversely associated with SB, fresh SB, and pregnancy and labor complications. Cesarean delivery and birth weight ≤2000 g were positively associated with SB and fresh SB. Multiple gestation was directly associated with the incidence of fresh SB.

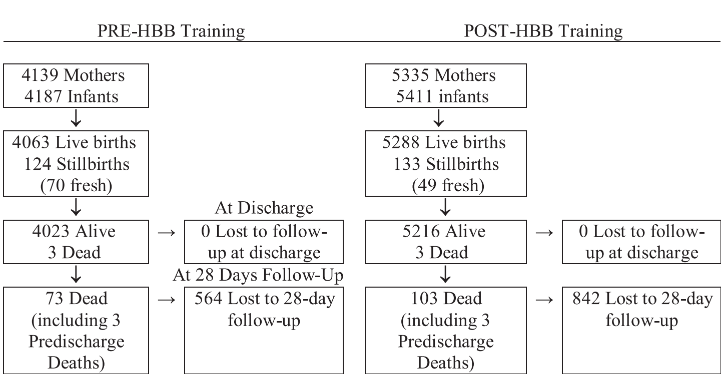

FIGURE 1
Consolidated Standards of Reporting Trials (CONSORT) diagram.

DISCUSSION

Findings from methodologically sound published studies of similar training in basic neonatal resuscitation on SB and NMR vary. Although there was site heterogeneity, the First Breath trial[8]

TABLE 2 Women's and Newborns' Characteristics

	Pre (n = 4187)		Post (n = 5411)		P
	% or mean ± SD	n	% or mean ± SD	n	
Parity	1.28 ± 0.99	4187	1.24 ± 0.98	5411	.03
Place of birth					≤.001
Clinic/Health center	8.1	339	6.8	370	
Hospital	90.5	3789	92.1	4986	
Mother's/Family's home	0.5	23	0.1	7	
Subcenter	0.7	29	0.5	26	
TBA home		0	0.2	9	
Other/In transport	0.2		0.2		
Antenatal care ≥3 visits	88.4	3703	82.4	4459	≤.001
Multiple gestation	2.3	98	2.8	152	.15
Pregnancy complication	6.9	288	6.9	376	.89
Labor complication	18.5	774	19.0	1027	.54
Type of labor complication					
Obstructed/prolonged labor	6.0	250	6.1	332	.74
Major ante or post partum hemorrhage	0.5	19	0.4	19	.43
Transverse/oblique lie/breech presentation	1.3	55	1.6	84	.33
Severe preeclampsia/Eclampsia	0.9	37	1.5	83	.004
Fetal distress/cord prolapse	2.1	89	2.6	142	.11
Other	7.9	332	8.2	444	.62
Mode of delivery					.06
Cesarean delivery	23.2	972	22.9	1239	
Instrument assisted	2.1	90	2.9	158	
Vaginal	74.6	3125	74.2	4014	
Newborn gender male	53.3	2231	51.2	2772	.05
Gestational age completed, wk (mean ± SD)	38.2 ± 1.8	4187	38.1 ± 1.6	5411	≤.001
<33	2.8	118	2.3	127	.15
<35	4.6	194	4.1	224	.24
<37	16.0	669	16.1	871	.87
Gestational age determined by					≤.001
Clinical exam of infant	0.5	20	0.8	42	
Fundal height	4.2	175	11.6	625	
Last Menstrual Period (LMP)	84.4	3535	78.2	4234	
Ultrasound examination	10.9	457	9.4	510	
Birth weight, g[a]	2701 ± 530	4186	2722 ± 532	5410	.05
≤1500	4.0	167	3.8	203	.55
≤2000	9.9	414	10.1	549	.67
≤2500	33.5	1403	33.6	1818	.92

LMP, ; TBA, traditional birth attendant.
[a] n Pre = 4186, n Post = 5410.

and other studies found that similar interventions reduce the incidence of newborns classified as SBs, consistent with this study.[13,22] Unlike this study, some have found similar training significantly reduces early (through 7 days of life) NMR[7,8,23–26] and NMR.[23,26] A meta-analysis[27] of 3 pre-post studies[17,23,28] found a significant 30% IHE case fatality reduction and a significant 38% reduction in early NMR.[17,23,25] The single-site cluster trial[17] found resuscitation training reduced SB but not early NMR incidence because most births were attended by physicians, yet neonatal resuscitation training was mostly given to lower-level providers.[29] Our results are similar, yet most of our deliveries and resuscitations were conducted by physicians in hospitals.[17] The sample (post hoc) has 68.5% power to detect the observed SB rates given a 1-tailed test, without sufficient power to detect a difference in NMR. The baseline NMR (1.8%), high compared with developed countries, was sufficiently low to make further reduction relatively difficult. NMR is substantially higher in home births, other areas of India, and many African and Asian countries where the HBB training might offer its greatest benefit and reduce NMR. In such settings, HBB may substantially avert IHE consequences, including neonatal death, essential to achieving MDG 4 and merits investigation. Resuscitation training improved recognition that some nonbreathing infants are not SB and promoted intervention for infants with apnea at birth, and reduced predischarge asphyxia deaths without increasing NMR. Elevated NMR might be expected if HBB training and resuscitation efforts improve immediate survival of precarious newborns, but death might be deferred only among some of these infants; although unlikely,[30] it is unknown whether survivors might experience suboptimal long-term outcomes or pose societal burden. Efforts to improve neonatal care beyond discharge, particularly for the prevention and treatment of infection, may be necessary to sustain or improve neonatal outcome.

Although our study found no NMR difference, more newborns had unknown vital status at 28 days in the post than pre training periods (OR 1.18, 95% CI 1.05–1.32). Thus, our conclusions about NMR are uncertain and require further pre-post assessment or cluster randomized controlled trials. It is difficult to determine whether there was biased survival, as among those lost to 28-day follow-up, more newborns received stimulation and suction airway clearance in the pre (15.4% and 24.3%) than post (10.2% and 12.0%) HBB period, respectively, yet fewer received B&M ventilation resuscitation (4.6% pre versus 4.9% post). Most study participants and those lost to follow-up (98%) delivered in the District Hospital and KLES Hospital in Belgaum. The Ministry of Health introduced a cash-incentive scheme, supporting emergency transportation to augment institutional delivery, during the post HBB period. This dramatically increased the

TABLE 3 Newborn Care

	Pre (n = 4187)		Post (n = 5411)		P
	% or mean ± SD	n	% or mean ± SD	n	
Clearing the airway	26.7	1117	10.0	543	≤.001
Resuscitated (eg, stimulation, clearing of airway and/or B&M ventilation)	28.9	1212	11.9	645	≤.001
Stimulation	15.8	662	9.1	490	≤.001
B&M ventilation	3.1	128	4.0	219	.01
Other revival efforts	0.7	30	0.3	18	.008
Proportion of resuscitation by B&M ventilation[a]	10.3	124	33.1	210	≤.001
B&M resuscitation ventilation done by[a]					.04
Physician	96.1	123	92.5	198	
Midwife	0.8	1	0	0	
Nurse	2.3	3	7.5	16	
TBA	0.8	1	0	0	
Not reported			2.3	5	
Golden Minute B&M resuscitation[a]	7.8	95	22.3	144	≤.001
Skin-to-skin contact[b]	65.3	2655	67.5	3569	.03
Breastfed within 30 min of birth[c]	74.8	3039	76.3	4034	.10

TBA, traditional birth attendant.

[a] Denominator is cases resuscitated: n Pre = 1212, n Post = 645.

[b] Denominator is livebirths: n Pre = 4063, n Post = 5288.

TABLE 4 Birth Outcomes

	Pre (n = 4187)		Post (n = 5411)		P
	% or mean ± SD	n	% or mean ± SD	n	
SB	3.0	124	2.3	123	.035
Fresh SB	1.7	70	0.9	49	≤.001
Macerated	1.3	54	1.4	74	.95
Infant not breathing at birth	6.6	278	8.7	472	≤.001
Liveborn infants not breathing at birth[a]	3.9	159	6.7	354	≤.001
Liveborn infants not breathing at birth who were breathing at[b]					
1 min	66.0	105	74.3	266	.06
5 min	92.5	147	94.4	334	.41
10 min	98.1	156	97.5	345	.65
Unknown	1.9	3	2.5	9	.65
Apgar Scores in livebirths[c]					
1 min	8.67±1.56	4063	8.55±1.44	5288	≤.001
1 min <5	2.2	90	1.8	95	.15
5 min	9.44±1.07	4063	9.36±1.07	5288	≤.001
5 min <5	0.6	23	0.3	18	.10
10 min	9.73±0.81	4063	9.65±0.72	5288	≤.001
10 min <5	0.4	16	0.2	125	.14
Predischarge neonatal death[c]	0.1	3	0.1	3	.75
Predischarge cause of death[d]					
Birth asphyxia (IHEs)			0.1	3	
Preterm/Low birth weight	0.1	3			
Neonatal death (through 28 d)[a]	1.8	73	1.9	103	.59
Neonatal status unknown at 28 d	13.9	564	15.9	842	.007
Neonatal cause of death[e]					.48
Birth asphyxia (IHEs)	30.1	22	28.2	29	
Preterm/Low birth weight	47.9	35	42.7	44	
Infection	6.6	5	13.6	14	
Congenital malformation	2.7	2	5.8	6	
Other	12.3	9	9.7	10	

[a] Denominator is livebirths: n Pre = 4063, n Post = 5288.

[b] Denominator is livebirths not breathing at birth: n Pre = 159, n Post = 354.

[c] Denominator is livebirths cases requiring resuscitation: n Pre = 1200, n Post = 635.

[d] Denominator is predischarge deaths: n Pre = 3, n Post = 3.

[e] Denominator is neonatal deaths: n Pre = 73, n Post = 103.

use of the study facilities by women from neighboring districts from another state, among whom postdischarge loss to follow-up was high because they are not included in the Belgaum registry and could not be reached by telephone.

HBB emphasizes thorough drying, not only to improve thermal stability but also to provide cutaneous stimulation, thus reducing the need for subsequent stimulation to breathe, airway clearance, and positive-pressure ventilation. Thorough drying and its associated stimulation of nonmacerated, nonbreathing infants may induce breathing and explain the decline in fresh SBs and why providers found that fewer infants required resuscitation in the post period. This study did not record thorough drying; however, the universal emphasis on thorough drying by birth attendants may account for the apparent large "decrease" in the proportion of infants receiving resuscitation, including additional stimulation and clearing of the airway after HBB training. It is critical that future studies report thorough drying. When brief rubbing of the back with drying failed to result in spontaneous breathing, B&M ventilation was promptly offered rather than further delaying B&M ventilation. Thus, the incidence of Golden Minute B&M ventilation was substantially higher in the post than pre HBB training period, although it was relatively low even in the post HBB training period, indicating some training modification to improve timeliness of interventions is required.

Refresher training improved skills, but there was little post-training monitoring and supervision, and no evaluation of long-term knowledge and skills retention. Trainees' higher knowledge scores at the beginning of the refresher than at the beginning of the initial training indicates some degree

TABLE 5 SBs: Adjusted[a] Backward Wald Logistic Regression (n = 9601)

SBs	Log OR	95% CI		*P*
		Lower	Upper	
Post HBB training	0.62	0.47	0.83	.001
Resuscitated	10.84	6.34	18.53	.000
≥3 ANC visits	0.34	0.25	0.46	.000
Any pregnancy complication	1.67	1.10	2.54	.016
Any labor complication	6.76	4.73	9.66	.000
Cesarean delivery (reference dummy)				.000
Instrumental delivery	0.20	0.12	0.31	.000
Vaginal delivery	0.46	0.17	1.25	.126
Gestation, wk	0.82	0.77	0.87	.000
Birth weight ≤2000 g	8.01	5.59	11.47	.000
Constant	3.46			.348

ANC, antenatal care.

[a] Variable(s) entered on step 1: Post HBB training, resuscitation required, place of birth (categorically coded), ≥3 ANC visits, multiple gestation, any pregnancy complication, any labor complication, mode of delivery (categorically coded), gestational age (weeks), infant's gender, birth weight <2000 g. All dichotomous variables are coded (0 = No, 1 = Yes). Table variables are those retained on last step given Probability for inclusion in model (PIN)=0.05, Probability for exclusion from model (POUT) =0.10.

TABLE 6 Fresh SB: Adjusted[a] Backward Wald Logistic Regression (n = 9601)

Fresh SBs	Log OR	95% CI		*P*
		Lower	Upper	
Post HBB training	0.46	0.31	0.68	.000
Resuscitated	5.03	2.76	9.16	.000
≥3 ANC visits	0.45	0.29	0.69	.000
Multiple gestation	2.53	1.36	4.69	.003
Any pregnancy complication	2.00	1.22	3.28	.006
Any labor complication	6.23	3.97	9.76	.000
Cesarean delivery (reference dummy)				.000
Instrumental delivery	0.33	0.19	0.56	.000
Vaginal delivery	.65	0.19	2.20	.492
Gestation, wk	0.86	0.79	0.94	.001
Birth weight ≤2000 g	4.40	2.60	7.46	.000
Constant	0.83			.915

ANC, antenatal care.

[a] Variable(s) entered on step 1: Post HBB training, resuscitation required, place of birth (categorically coded), ≥3 ANC visits, multiple gestation, any pregnancy complication, any labor complication, mode of delivery, gestational age (weeks), infant's gender, birth weight <1500 g. All dichotomous variables are coded (0 = No, 1 = Yes). Table variables are those retained on last step given Probability for inclusion in model (PIN)=0.05, Probability for exclusion from model (POUT)=0.10.

of knowledge retention. Trainees' higher knowledge scores at the end of the initial training compared with the beginning of the refresher training indicates some decline in knowledge retention in those participating in the refresher courses. ANMs accounted for 22% of the refresher but only 15% of initial training participants (P = .014); nearly 19% of initial course participants were physicians compared with almost 7% in the refresher sessions. The core B&M skills test required correct implementation of all 12 components, so although average scores were high, 42% in the initial and 32% in the refresher courses did not pass. After the initial and refresher training, 23% and 15% did not pass OSCE B, respectively, prompting modification of the program and evaluation tools to improve training.[31] The lack of baseline assessment does not permit the study to describe the baseline status, retention, or improvement in B&M or OSCE skills associated with HBB training. Baseline assessment of skills may not be meaningful in providers who have never used them, but should be considered for providers with previous experience in future studies. Those receiving refresher training had slightly higher B&M scores and pass rates (11.3 ± 1.1 and 61%, respectively) during their initial training than those without refresher training, demonstrating skills retention and limited improvement (refresher score 11.5 ± 0.9 and 69% passed). Undergraduate medical students' neonatal resuscitation training improved their immediate knowledge from 25% to 98%; however, knowledge receded to 65% 8 weeks later.[29] Video refresher training improved both knowledge and skills to ≥90% 3 months later. Mastery and retention of HBB skills requires adequate practice.[15] Erosion of knowledge has been a major problem in other life-support courses.[32,33]

CONCLUSIONS

HBB training significantly reduced the incidence of resuscitation, SBs, and fresh SBs, without increasing NMR, which might be expected when improving the immediate survival of newborns with difficulty breathing at birth. Refresher training and monitoring practice are advised to ensure knowledge and skills retention and timely performance. Further evaluation of the impact of HBB training in community-based settings is recommended.

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REFERENCES

1. Liu L, Johnson HL, Cousens S, et al; Child Health Epidemiology Reference Group of WHO and UNICEF. Global, regional, and national causes of child mortality: an updated systematic analysis for 2010 with time trends since 2000. *Lancet*. 2012;379(9832):2151–2161
2. Lawn JE, Blencowe H, Pattinson R, et al; Lancet's Stillbirths Series steering committee. Stillbirths: Where? When? Why? How to make the data count? *Lancet*. 2011;377(9775):1448–1463
3. Lawn JE, Lee AC, Kinney M, et al. Two million intrapartum-related stillbirths and neonatal deaths: where, why, and what can be done? *Int J Gynaecol Obstet*. 2009;107(suppl 1):S5–S18, S19
4. WHO. Basic newborn resuscitation: a practical guide. Geneva: World Health Organization; 1997. Available at: www.who.int/reproductivehealth/ publications/maternal_perinatal_health/MSM_98_1/en/index.html. Accessed December 2, 2010
5. WHO. The global burden of disease: 2004 update. Geneva: World Health Organization; 2008. Available at: www.who.int/healthinfo/global_burden_disease/2004_report_update/en/index.html. Accessed March 3, 2011
6. Rajaratnam JK, Marcus JR, Flaxman AD, et al. Neonatal, postneonatal, childhood, and under-5 mortality for 187 countries, 1970-2010: a systematic analysis of progress towards Millennium Development Goal 4. *Lancet*. 2010;375(9730):1988–2008
7. Cousens S, Blencowe H, Stanton C, et al. National, regional, and worldwide estimates of stillbirth rates in 2009 with trends since 1995: a systematic analysis. *Lancet*. 2011;377(9774):1319–1330
8. Carlo WA, Goudar SS, Jehan I, et al; First Breath Study Group. Newborn-care training and perinatal mortality in developing countries. *N Engl J Med*. 2010;362(7):614–623
9. Yakoob MY, Ali MA, Ali MU, et al. The effect of providing skilled birth attendance and emergency obstetric care in preventing stillbirths. *BMC Public Health*. 2011;11(suppl 3):S7
10. Goldenberg RL, McClure EM, Bhutta ZA, et al; Lancet's Stillbirths Series steering committee. Stillbirths: the vision for 2020. *Lancet*. 2011;377(9779):1798–1805
11. Singhal N, Bhutta ZA. Newborn resuscitation in resource-limited settings. *Semin Fetal Neonat Med*. 2008;13(6):432–439
12. Darmstadt GL, Bhutta ZA, Cousens S, Adam T, Walker N, de Bernis L; Lancet Neonatal Survival Steering Team. Evidence-based, cost-effective interventions: how many newborn babies can we save? *Lancet*. 2005;365(9463):977–988
13. Wall SN, Lee ACC, Niermeyer S, et al. Neonatal resuscitation in low-resource settings: what, who, and how to overcome challenges to scale up? *Int J Gynaecol Obstet*. 2009;107(suppl 1):S47–S62, S63–S64
14. American Academy of Pediatrics. Helping Babies Breath. The golden minute. Available at: www.helpingbabiesbreathe.org/. Accessed March 3, 2011
15. Singhal N, Lockyer J, Fidler H, et al. Helping Babies Breathe: global neonatal resuscitation program development and formative educational evaluation. *Resuscitation*. 2012;83(1):90–96
16. Goudar SS, Dhaded SM, McClure EM, et al; study investigators. ENC training reduces perinatal mortality in Karnataka, India. *J Matern Fetal Neonatal Med*. 2012;25(6):568–574
17. Carlo WA, McClure EM, Chomba E, et al. Newborn care training of midwives and neonatal and perinatal mortality rates in a developing country. *Pediatrics*. 2010;126(5). Available at: www.pediatrics.org/cgi/content/full/216/5/e1064
18. Niermeyer S, Keenan WJ, Little GA, Singhal N. *Helping Babies Breathe Learner Workbook*. 1st ed. Elk Grove Village, IL: American Academy of Pediatrics; 2010
19. Niermeyer S, Keenan WJ, Little GA, Singhal N. *Helping Babies Breathe Facilitator Flip Chart*. Elk Grove Village, IL: American Academy of Pediatrics; 2010
20. Laerdal. NeoNatalie: realistic and affordable training and therapy. Available at: www.laerdal.com/binaries/AEVJNCXO/NeoNatalie-Brochure-310510.pdf. Accessed March 3, 2011
21. Cohen J. Statistical Power Analysis for the Behavioral Sciences. 2nd ed. Hillside, NJ: Lawrence Erlbaum Associates Inc; 1988:179–214
22. Jeffery HE, Kocova M, Tozija F, et al. The impact of evidence-based education on a perinatal capacity-building initiative in Macedonia. *Med Educ*. 2004;38(4):435–447
23. Zhu XY, Fang HQ, Zeng SP, Li YM, Lin HL, Shi SZ. The impact of the neonatal resuscitation program guidelines (NRPG) on the neonatal mortality in a hospital in Zhuhai, China. *Singapore Med J*. 1997;38(11):485–487
24. Chomba E, McClure EM, Wright LL, Carlo WA, Chakraborty H, Harris H. Effect of WHO newborn care training on neonatal mortality by education. *Ambul Pediatr*. 2008;8(5):300–304
25. Vakrilova L, Elleau C, Slŭncheva B. French-Bulgarian program "Resuscitation of the newborn in a delivery room"—results and perspectives [in Bulgarian]. *Akush Ginekol (Sofiia)*. 2005;44(3):35–40
26. Gill CJ, Phiri-Mazala G, Guerina NG, et al. Effect of training traditional birth attendants on neonatal mortality (Lufwanyama Neonatal Survival Project): randomised controlled study. *BMJ*. 2011;342:d346
27. Lee ACC, Cousens S, Wall SN, et al. Neonatal resuscitation and immediate newborn assessment and stimulation for the prevention of neonatal deaths: a systematic review, metaanalysis and Delphi estimation of mortality effect. BMC Public Health. 2011;11(suppl 3):S12. Available at: www.biomedcentral.com/1471-2458/11/S3/S12. Accessed March 3, 2011
28. Deorari AK, Paul VK, Singh M, Vidyasagar D; Medical Colleges Network. Impact of education and training on neonatal resuscitation practices in 14 teaching hospitals in India. *Ann Trop Paediatr*. 2001;21(1):29–33
29. Carlo WA, Wright LL, Hartwell T. Authors' Reply to Comment. *N Engl J Med*. 2010;362(25):2427–2428
30. Carlo WA, Goudar SS, Pasha O, et al. Neurodevelopmental outcomes in infants requiring resuscitation in developing countries. Neurodevelopment-Home-based Intervention Trial Committee. J Pediatr. 2012;160(5):781–785.e1
31. Oermann MH, Kardong-Edgren SE, Odom-Maryon T. Effects of monthly practice on

nursing students' CPR psychomotor skill performance. *Resuscitation*. 2011;82(4):447–453

32. Soar J, Mancini ME, Bhanji F, et al; Education, Implementation, and Teams Chapter Collaborators. Part 12: Education, implementation, and teams: 2010 International Consensus on Cardiopulmonary Resuscitation and Emergency Cardiovascular Care Science with Treatment Recommendations. *Resuscitation*. 2010;81(suppl 1):e288–e330
33. Bhanji F, Mancini ME, Sinz E, et al. Part 16: education, implementation, and teams: 2010 American Heart Association Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care. *Circulation*. 2010;122(18 suppl 3):S920–S933

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Stillbirth and Newborn Mortality in India After Helping Babies Breathe Training

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