Newborn Mortality and Fresh Stillbirth Rates in Tanzania After Helping Babies Breathe Training

WHAT’S KNOWN ON THIS SUBJECT: Birth asphyxia, or failure to initiate or sustain spontaneous breathing at birth, contributes to ~27% to 30% of neonatal deaths in resource-limited countries, including Tanzania. Without change, these countries will fail to meet Millennium Development Goal 4 targets by 2015.

WHAT THIS STUDY ADDS: The Helping Babies Breathe program was implemented in 8 hospitals in Tanzania in 2009. It has been associated with a sustained 47% reduction in early neonatal mortality within 24 hours and a 24% reduction in fresh stillbirths after 2 years.

abstract

BACKGROUND: Early neonatal mortality has remained high and unchanged for many years in Tanzania, a resource-limited country. Helping Babies Breathe (HBB), a novel educational program using basic interventions to enhance delivery room stabilization/resuscitation, has been developed to reduce the number of these deaths.

METHODS: Master trainers from the 3 major referral hospitals, 4 associated regional hospitals, and 1 district hospital were trained in the HBB program to serve as trainers for national dissemination. A before (n = 8124) and after (n = 78,500) design was used for implementation. The primary outcomes were a reduction in early neonatal deaths within 24 hours and rates of FSB.

RESULTS: Implementation was associated with a significant reduction in neonatal deaths (relative risk [RR] with training 0.53; 95% confidence interval [CI] 0.43–0.65; P ≤ .0001) and rates of FSB (RR with training 0.76; 95% CI 0.64–0.90; P = .001). The use of stimulation increased from 47% to 88% (RR 1.87; 95% CI 1.82–1.90; P ≤ .0001) and suctioning from 15% to 22% (RR 1.40; 95% CI 1.33–1.46; P ≤ .0001) whereas face mask ventilation decreased from 8.2% to 5.2% (RR 0.65; 95% CI 0.60–0.72; P = .0001).

CONCLUSIONS: HBB implementation was associated with a significant reduction in both early neonatal deaths within 24 hours and rates of FSB. HBB uses a basic intervention approach readily applicable at all deliveries. These findings should serve as a call to action for other resource-limited countries striving to meet Millennium Development Goal 4. Pediatrics 2013;131:e353–e360

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KEY WORDS
Helping Babies Breathe, neonatal mortality, fresh stillbirths, premature infants, birth asphyxia

ABBREVIATIONS
BA—birth asphyxia
BW—birth weight
CI—confidence interval
ENM—early neonatal mortality (within 24 hours)
FMV—face mask ventilation
FSB—fresh stillbirths
GA—gestational age
HBB—Helping Babies Breathe
MDG—Millennium Development Goal
ND—neonatal deaths
RR—relative risk

(Continued on last page)
The most important driving force behind the recent increased attention of neonatal deaths (NDs) is Millennium Development Goal (MDG) 4, which in 2000 called for a two-thirds reduction in mortality risks of children <5 years of age by 2015, which translates to an average annual reduction of 4.4%. In recent years progress has been made toward meeting this goal; however, this has been slowed by limited reduction in ND resulting in an over-representation of the global under-5 deaths.

The first day and especially the first hour is critical to newborn survival with the highest risk of intrapartum-related ND, from 60% to 70%, occurring within 24 hours of birth. The common causes include birth asphyxia (BA), infection, and prematurity. BA, or failure to initiate or sustain spontaneous breathing at birth, contributes to ure to initiate or sustain spontaneous respiration, and prematurity. BA, or fail-ure to initiate or sustain spontaneous breathing at birth, contributes to newborn mortality. Early intervention is critical to newborn survival with the first hour being the most critical. The common causes of death include birth asphyxia (BA), infection, and prematurity. BA, or failure to initiate or sustain spontaneous breathing at birth, contributes to 27% to 30% of NDs, and substantially to neurodevelopmental disabilities in survivors. It is estimated that 1 million infants die each year from BA. In Tanzania, the neonatal mortality rate is 32 in 1000 live infants, that is, 40,000 deaths annually with 13,000 attributed to BA. A comparable number of fresh stillborn (FSB) infants are also delivered annually. Despite efforts over time to intervene, early neonatal mortality (ENM) including BA has remained unchanged over the past 15 years in Tanzania. Several interwoven factors likely contributed to this sobering observation, including the fact that BA was not a national priority, resuscitation training was localized, training was not targeted at the appropriate provider (ie, the midwife), there was often a lack of basic equipment, and a failure to initiate resuscitative steps in a timely manner. These deficiencies were observed in all health facilities including referral hospitals.

The recent development of the Helping Babies Breathe (HBB) program, which includes a simulator for hands-on training and emphasis of the “Golden Minute” following birth to restore spontaneous respirations, has served as an impetus for potentially reducing BA-related mortality in resource-limited countries. Although clearly an exciting first step, history strongly indicated that without direct commitment of the Ministry of Health for making BA a national priority, a reduction in neonatal and BA-related mortality was unlikely to occur. Given the large burden related to ENM and substantial neurologic morbidity in survivors, coupled with a mismatch in resources, and the short time frame before the MDG targets in 2015, the Tanzanian Ministry of Health and Social Welfare launched the HBB training program in September 2009. There were 2 broad objectives: to determine if implementation of the HBB educational and training program (1) would enhance the basic skills of birth attendants including application of face mask ventilation (FMV) and (2) would reduce ENM on day 1 by 50% and reduce by 25% the rates of FSB.

METHODS
Implementation of HBB Training Program
HBB implementation has been facilitated by a Health Ministry Commitment and integration into the Health Care System. Before national rollout, HBB was implemented in 8 hospitals designated as study sites. The program was launched with 2 days training of 40 master trainers selected from these hospitals. Over the subsequent 6 to 9 months, the program was implemented at the 8 hospitals individually as follows: a 1-day training of health care providers was conducted by the principal investigator (G.M.) and other master trainers at each hospital; some of these providers became regional trainers and district instructors with the defined role of subsequently training health care providers in hospitals, health centers, and dispensaries within each district. This represents a cascade model approach to train providers throughout the country. Additionally, these trained providers continue to provide “on-the-job” and refresher training to other service providers in the same facilities. A simulator was placed in the labor and delivery suite where every provider must document application of basic skills including FMV before starting a shift. Because midwives attend most deliveries, a major emphasis has been placed on their training. Additionally, a midwife at each of the 8 sites was appointed to assume primary responsibility of teaching, reinforce the quality of training, and oversee the quality of data entry. Training is based on the HBB course material. Although initially conducted in English, future training will be in both English and Swahili.

Program Evaluation
The 8 hospitals designated study sites included 3 referral hospitals (Muhimbili National Hospital, Bugando Medical Centre, Kilimanjaro Christian Medical Center); 4 regional hospitals (Amani, Burunguni, Sekotoure, and Mawenzi), and 1 district hospital (Haydom Lutheran Hospital). Seven of the hospitals are affiliated with a corresponding institution (Muhimbili University of Health and Allied Sciences, Tumaini University, and Bugando Health Sciences) with a teaching history as well as research activities, including involvement with multicenter studies. Hence, trained staff could successfully conduct computerized data processing and analysis.

Data Monitoring
A computer was placed in or close to every labor ward for data entry and subsequent transmission of data to a central repository in the Health
Ministry in Dar es Salaam. A national data collection form that includes core and desired elements was developed by the Data Oversight Committee. Each hospital collected baseline data for 2 months before implementation, which was used as baseline information. Postimplementation data collection was only initiated after the initial training of providers in each hospital. Data are analyzed by a data analyst (H.K.) and technical consultant (J.M.P.), and evaluated every 6 months by the Data Oversight Committee. Consistency checks of the data were performed intermittently by the principal investigator (G.M.) and every 6 months by the technical consultant at the primary sites, and the data were edited as appropriate. There were no formal stopping rules.

Definitions
BA was defined as a 5-minute Apgar score <7 coupled with the need for FMV. FMV was added to the long accepted definition of BA to provide objective evidence for the lack of the inability to initiate spontaneous respirations. Gestational age (GA) was based on self-report of the last menstrual period and distance from symphysis pubis to the fundus as is the standard practice in Tanzania. Prematurity was defined as a GA <37 weeks and included infants of gestational age ≥28 weeks. Birth weight (BW) cutoff for live births was 750 g. FSB was defined as an Apgar score of 0 at both 1 and 5 minutes with intact skin and suspected death during labor/delivery and BW >1000 g.

Study Goals
The primary goals were to reduce the rate of ENM in the first 24 hours after birth by 50% and the rate of FSB by 25%. Prespecified secondary goals were to reduce death in the first 24 hours attributable to BA, the rate of early perinatal mortality (ENM and FSB) in the first 24 hours, and rates of mortality stratified according to BW and GA.

Statistical Analysis
A power analysis based on previous national data8 assumed an ENM rate of 14 in 1000 live births, indicated that ~2500 infants before and after implementation would be needed to show a 50% reduction in ENM (a reduction in absolute risk of 7 deaths per 1000 live births) with 80% power; and with the use of a 2-tailed test at a significance level of 5%.

Analysis has been performed by using SPSS 15 and 17, descriptive statistics, χ2 analysis, t tests, and relative risk calculations. All data are presented as mean ± SD unless as otherwise stated.

Ethical Considerations
HBB implementation received ethical clearance from the National Institute of Medical Research of Tanzania.

RESULTS
HBB was launched in September 2009, and the data presented extend through March 2012. Data are available on 8124 births before and 78 500 births after implementation. There were 155 FSB (19.0 per 1000 births) before and 1131 FSB (14.4 per 1000 births) after implementation (Fig 1).

There were in addition 145 macerated stillbirths before and 1415 after implementation.

ENM Within 24 Hours
There were 107 deaths out of 7969 deliveries before and 552 deaths out of 77 369 deliveries after implementation. This represents a significant reduction in ENM from 13.4 to 7.1 per 1000 live-born deliveries (relative risk [RR] 0.53; 95% confidence interval [CI] 0.43–0.65; P < .0001; Figs 1 and 2). The reduction in ENM was significant for both normal and low birth weight as well as term and preterm infants (Tables 1 and 2). Regarding BW, the reduction for infants ≥2500 g before and after implementation was 60 of 7200 (8.3/1000) versus 336 of 69 946 (4.8/1000; RR 0.57; 95% CI 0.43–0.75; P < .0001), and for infants <2500 g 47 of 769 (61/1000) versus 216 of 7423 (29/1000; RR 0.48; 95% CI 0.35–0.64; P < .0001; Table 2). There were no differences in BW before versus after implementation between infants alive, those who died, and FSB (Table 1). However, both before and after implementation, infants who died and FSB were of significantly lesser BW versus those born alive (Table 1).

FIGURE 1
Impact of HBB Program on ENM and FSB.
Regarding GA, comparing before and after implementation, the reduction for infants $\geq 37$ weeks was 38 of 3073 (12.3/1000; RR 0.45; 95% CI 0.32–0.63; $P = .0001$) and for infants <37 weeks was 69 of 4896 (14.0/1000) versus 282 of 30 712 (9.1/1000) (RR 0.65; 95% CI 0.50–0.84; $P = .001$). Decreasing GA was associated with increased ENM. Specifically, preimplementation, infants of GA $\geq 34$ versus $\geq 37$ weeks were 12.2-fold and after implementation 12.6-fold more likely to die. Infants before versus after implementation born alive were of lesser GA (ie, 36.1 ± 1.5 vs 37.5 ± 1.7; $P = .001$). There were no differences for those who died or FSB (Table 1). Infants who died and FSB were of lesser GA versus those alive both before and after implementation (Table 1).

**FSB**

There was a significant decrease in FSB before versus after implementation from 155 of 8124 births (19.0 per 1000) to 14.4/1000 ($P = .0001$).
to 1131 of 78,500 (14.5 per 1000; RR 0.76; 95% CI 0.64–0.90; P = 0.001).

Early Perinatal Mortality

Early perinatal mortality decreased significantly before versus after implementation from 262 of 8124 (32.2 per 1000) to 1683 of 78,500 (21.6 per 1000; RR 0.76; 95% CI 0.60–0.90; P = 0.001). The number of infants with a 5-minute Apgar score <7 increased before versus after implementation from 123 of 7969 (1.54%) to 1496 of 76,817 (1.93%; RR 1.33; 95% CI 1.20–1.47; P = 0.0001). Referred versus inborn infants were more likely to die both before (P = 0.02) and after implementation (P < 0.0001; Table 1). Infants who died were more likely to be delivered via cesarean delivery both before (P ≤ 0.0001) and after implementation (P = 0.01; Table 1).

Impact of Implementation on the Use of Stimulation, Suctioning, and FMV

Providers trained in HBB who attended a delivery increased from 10% ± 5% to 80% ± 13% (P = 0.0001). There was no difference in the overall percentage of providers trained and the percentage who attended deliveries of infants who died (P = 0.26). The use of stimulation increased before versus after implementation from 3756 of 7969 (47%) to 67,769 of 76,817 (88%; RR 1.87; 95% CI 1.82–1.90; P ≤ 0.0001), as well as use of suctioning from 1227 of 7969 (15%) to 16,628 of 76,817 (22%; RR 1.40; 95% CI 1.33–1.49; P ≤ 0.0001). In contrast, the use of FMV before versus after implementation decreased from 636 of 7969 (8.2%) to 3998 of 76,817 (5.2%; RR 0.65; 95% CI 0.60–0.72; P < 0.0001). More specifically, the use of stimulation increased significantly after implementation for infants alive and FSB but not those who died (Table 3). The use of suction also increased significantly for all groups. The use of FMV decreased significantly in those alive infants but was not different in those who died and FSB (Table 3).

DISCUSSION

This large study conducted in Tanzania shows that training in and targeted implementation of the HBB Program was associated with a significant reduction in the primary outcomes of ENM in the first 24 hours, rates of FSB, and rate of early perinatal mortality. The significant reduction in ENM was observed in both term and preterm infants, and the positive impact extended to include those of lesser BW and GA with the highest inherent burden of death.

This is the first study to document the effectiveness of the HBB educational curriculum, as well as to demonstrate a significant reduction in both ENM and the rates of FSB. This positive effect was achieved without supplemental oxygen in most cases, endotracheal intubation, or chest compressions. Several previous observational studies involving birth attendants using a before-after strategy in facilities and communities in developing countries have shown a reduction in neonatal mortality,12–14 and there are studies that

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**Table 2** ENM Based on Different BW Categories Before and After Implementation

<table>
<thead>
<tr>
<th>Birth wt (g)</th>
<th>Before</th>
<th>After</th>
<th>RR 95% CI</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>≥2500</td>
<td>60/7200 (8.3/1000)</td>
<td>336/69,946 (4.8/1000)</td>
<td>0.57 (0.04–0.75)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>2000–2498</td>
<td>11/560 (19.6/1000)</td>
<td>68/5284 (12.6/1000)</td>
<td>0.65 (0.35–1.22)</td>
<td>0.19</td>
</tr>
<tr>
<td>1000–1998</td>
<td>36/209 (172/1000)</td>
<td>146/2129 (68.5/1000)</td>
<td>0.40 (0.26–0.56)</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

Comparing ENM in infants with BW <2500 versus ≥2500 g, there was a significant difference before implementation, 47/769 versus 60/7200 (RR 0.15; 95% CI 0.09–0.20, P < 0.001), and after implementation, 216/7423 versus 336/69,946 (RR 0.16; 95% CI 0.14–0.18; P < 0.001).

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**Table 3** Use of Stimulation, Suction, and FMV Before and After Implementation in Alive Infants, Infants Who Died, and Stillbirths

<table>
<thead>
<tr>
<th>Stimulationa</th>
<th>Before Implementation</th>
<th>After Implementation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alive (n = 7862)</td>
<td>Died (n = 107)</td>
<td>Stillbirths (n = 155)</td>
</tr>
<tr>
<td>3657 (47%)</td>
<td>99 (93%)</td>
<td>28 (18%)</td>
</tr>
<tr>
<td>Suctionb</td>
<td>1133 (14%)</td>
<td>94 (88%)</td>
</tr>
<tr>
<td>FMVc</td>
<td>540 (6.8%)</td>
<td>93 (87%)</td>
</tr>
</tbody>
</table>

a Stimulation alive (RR 1.18; 95% CI 1.05–1.32; P = 0.001); died (RR 1.05; 95% CI 0.90–1.11; P = 0.37); stillbirths (RR 1.80; 95% CI 1.27–2.54; P = 0.008).
b Suction alive (RR 1.40; 95% CI 1.33–1.47; P ≤ 0.0001); died (RR 1.10; 95% CI 1.08–1.16; P = 0.03); stillbirths (RR 1.49; 95% CI 1.01–2.11; P = 0.045).
c FMV alive (RR 0.65; 95% CI 0.60–0.72; P ≤ 0.0001); died (RR 1.07; 95% CI 0.99–1.15; P = 0.07); stillbirths (RR 1.29; 95% CI 0.89–1.87; P = 0.16).
have shown a reduction in the rates of FSB.\textsuperscript{15,16} Although a before and after study design limits a conclusion of causality, it is likely that the reductions in ENM and rates of FSB are in part due to specific training elements contained in the HBB program. The first relates to the emphasis on the immediate application of basic steps such as drying, stimulation, and suctioning (if needed) of any newborn. This should rapidly induce spontaneous respirations in those not breathing in >90% of cases, if applied within the “Golden Minute.”\textsuperscript{17} The second relates to the ability to teach providers the basic steps outlined previously, as well as the correct application of a resuscitator for FMV, using a neonatal simulator for both initial and refresher training. Consistent with the goals, a majority of providers who attended a delivery after implementation had received training in HBB. The training was associated with a significant increase both in the number of infants stimulated at birth as well as those who were suctioned. Conversely, there was a significant decrease in the use of FMV. These composite findings are consistent with experimental observations, suggesting that most nonbreathing infants are in primary apnea with a heart rate and will initiate spontaneous respirations in response to drying and stimulation only if implemented in a timely manner (Fig 3).\textsuperscript{17–19} This is the most plausible explanation for the significant reduction in both ENM and rates of FSB. Although counterintuitive, the most likely explanation for the latter finding is that before HBB training, live-born infants without obvious signs of life were likely misidentified as FSB, as has been suggested in previous reports.\textsuperscript{20}

BA as defined in this report, indicating a nonbreathing infant requiring FMV, was the primary cause of death both before and after implementation. Moreover, death related to BA increased significantly after implementation, as noted in more than 80% of cases. It is likely that these infants were in state of prolonged secondary apnea as a result of complications during labor and unresponsive to FMV. Strategies targeted at enhanced monitoring of the fetus during labor may have a potential impact on this group of infants. Interestingly, the proportion of survivors with the diagnosis of BA increased significantly after implementation. We attribute this unanticipated finding to represent another measure of the effectiveness of HBB training, reflecting appropriate FMV in nonbreathing infants with eventual recovery of spontaneous respirations.

The significant reduction in ENM within 24 hours was initially apparent after 1 year of implementation and has been sustained through 2 years (Fig 2). Although HBB has had a significant impact in reducing ENM including in the premature and low birth weight population, to achieve an even greater effect, additional strategies (eg, targeting temperature regulation) will likely be necessary to avoid later deaths.\textsuperscript{21} A major strength of this study has been the dedicated commitment of the Ministry of Health and Social Welfare to support the training of providers in basic delivery room stabilization/resuscitation and ensuring the availability of appropriate equipment, without which the sustained significant reduction in ENM and rates of FSB would have been less likely, particularly in a developing country like Tanzania where resources are limited. In addition, the focus of training on the midwife, the provider delivering the majority of facility infants in Tanzania, was critical. The midwife invariably has the dual task of managing the mother during delivery, as well as stabilizing and/or resuscitating a depressed newly born. HBB training emphasizes moving the treatment focus away from the mother, as has been the norm in the

FIGURE 3
Schema depicting the potential outcomes in a nonbreathing infant at birth. Infants in primary apnea will generally respond to drying and stimulation only. If intervention is delayed, there will be progression to secondary apnea, and with no intervention, there will be progression to an “apparent FSB.” Infants in secondary apnea in most cases respond to drying, stimulation, and application of FMV with the onset of spontaneous breathing. A small minority will respond more slowly and initiate spontaneous respirations but will progress to a state of hypoxic-ischemic encephalopathy. Another group will show initial signs of life but progress to early death.
past, to the baby during the immediate critical few minutes after birth. This focus on midwife training parallels other reports in which involvement of women (ie, traditional birth attendants and mothers) also using basic interventions has been associated with a reduction in ENM and FSB rates.\textsuperscript{22,23} Potential limitations to this report include the before and after design, which restricts the ability to isolate the effect of the HBB program alone from potential other changes at the health facilities during the time period. Importantly, there have been no other obstetric or neonatal interventions introduced during the implementation period. An additional concern relates to the 2-month baseline time period and whether the data are representative and valid. Importantly, neonatal mortality in the study hospitals had been high and comparable to the baseline data and had remained unchanged for many years.\textsuperscript{8}

Although the observations regarding GA are interesting, given the limitations related to determination, they should be viewed cautiously. We consider our stepwise approach to national implementation extremely important for 2 reasons: first, it was necessary to demonstrate that the program worked in the major institutions; second, we wished to delineate gaps and pitfalls before a full national rollout. As a consequence, there is now a large core of master and regional trainers who have begun to disseminate the program.

CONCLUSIONS

This study in Tanzania has demonstrated a sustained significant reduction in ENM within 24 hours and rates of FSB. The HBB approach is simple, emphasizing immediate drying and stimulation, an intervention that can be readily implemented at any delivery, in health care facilities, or the community. These observations should serve as a potent call to action for other resource-limited countries striving to meet MDG 4 before 2015.

REFERENCES

(Continued from first page)

Dr Msemo is the principal investigator and is responsible for the implementation of the Helping Babies Breathe program. She was involved in experimental design of the implementation program. She does frequent visits to the research sites. She was involved in writing the manuscript and overseeing the data collection. Dr Massawe was involved in experimental design and was a member of the oversight committee of the program. Dr Mmbando was involved in experimental design, was a member of the oversight committee of the program, and was involved in writing the manuscript. Dr Rusibamayila was involved in experimental design, was a member of the oversight committee of the program, and was involved in writing the manuscript. Dr Manji was involved in experimental design, was a member of the oversight committee of the program, and was involved in writing the manuscript. Dr Kidanto was involved in the data analysis. Dr Mwizamuholya was involved in experimental design and was a member of the oversight committee of the program. Ms Ringia was involved in implementation of the program at one of the research sites as well as overseeing data collection at that site. Dr Ersdal was involved in implementation of the program at one of the research sites as well as overseeing data collection at that site. Dr Perlman was involved in the experimental design, reviewed data entry at the research sites, provided technical support to Dr Kidanto, was a member of the oversight committee of the program, and helped write the manuscript. He conceived the idea for the focus of the article, contributed to design of the analyses and interpretation of the results, took the lead in drafting the initial and subsequent versions of the manuscript, ensured that all authors approved of the final version of the manuscript submitted; took the lead in acquisition and analysis of the data, contributed to interpretation of the analysis results, contributed to revisions of the manuscript including drafting content on the methods used, and approved the final version of the manuscript submitted.

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