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Evaluation of the Helping Babies Breathe (HBB) Initiative Scale-Up in Malawi

Results from a Dose-Response Analysis

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September 2014

This report was made possible by the generous support of the American people through the United States Agency for International Development (USAID), under the terms of the Leader with Associates Cooperative Agreement GHS-A-00-08-00002-00 and Cooperative Agreement AID-OAA-A-14-00028. The contents are the responsibility of The Maternal and Child Health Integrated Program (MCHIP) and The Maternal and Child Survival Program (MCSP), and do not necessarily reflect the views of USAID or the United States Government.

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Abbreviations

HBB	Helping Babies Breathe
MCHIP	Maternal and Child Health Integrated Program
MDG	Millennium Development Goals
MNCH	maternal, newborn, and child health
MOH	ministry of health
RHD	Reproductive Health Division
USAID	United States Agency for International Development

Acknowledgments

The primary objective of this study is to evaluate the quality and coverage of the Helping Babies Breathe (HBB) newborn resuscitation intervention scale-up at the facility level in Malawi over time. An evaluation like this one requires contributions and the dedication of many people, and the authors would like to recognize those who made this study possible.

First and foremost, we thank the Malawi Ministry of Health. We would also like to thank the maternity clients who agreed to allow our study teams to observe their care and the care of their newborns, even under emergency circumstances. Without their participation, this study would not have been possible. We also extend our thanks to all the health facility directors and medical personnel in the health facilities assessed for their participation. We understand that they are extremely busy, and we very much appreciate the time they devoted to this evaluation. In addition, we are grateful to the HBB implementation team for their continued support to this evaluation.

The study modified MCHIP quality of care survey tools and the HBB simulation tools developed by the HBB Global Development Alliance (GDA). Service Provision Assessment tools informed the inventory tool and provider interviews.

Executive Summary

Global evidence suggests that improving the quality of obstetric and newborn care can directly reduce maternal and neonatal deaths. **Helping Babies Breathe (HBB)** is an educational program that teaches essential neonatal resuscitation techniques to health workers in resource-limited areas.

The Malawi Ministry of Health (MOH), Reproductive Health Division (RHD), has been working with partners since March 2011 to scale up the HBB approach nationally. Accurate and reliable data are needed on the quality of the Helping Babies Breathe program and the resulting services offered in health facilities in Malawi. With support from the United States Agency for International Development (USAID), and in collaboration with the Malawi MOH, the Maternal and Child Health Integrated Program (MCHIP) and the Support for Service Delivery Integration Program (SSDI) conducted a performance evaluation of the Helping Babies Breathe program in Malawi.

The primary objective of the evaluation was to assess the quality of care and coverage of the HBB newborn resuscitation intervention at the facility level in Malawi. The results of this evaluation will help to inform and guide the ongoing scale-up of this program in Malawi and in other countries. A similar evaluation of the HBB initiative in Bangladesh is currently under way and will complement impact evaluations being conducted by the United States' National Institute of Child Health and Human Development in India and Kenya.

The evaluation consisted of data collection at two points in time: the first round was in September 2012, after the intervention had begun in 13 districts; and the second round was in September 2013, when the intervention had been expanded to all districts in Malawi.

The methodological strength of this evaluation is that it employs direct observation of labor and delivery and management of newborns who are not breathing at birth, complemented by data collected through interviews, facility audits, and qualitative key informant interviews. Seven data collection tools were used to gather data during health facility visits: (1) health worker interviews and knowledge assessments on essential newborn care; (2 and 3) skills assessments of health providers using clinical simulations of newborn resuscitation; (4) a structured clinical observation checklist for labor and delivery (L&D); (5) a structured clinical observation checklist for the management of asphyxiated newborns; (6) in-depth interviews with key stakeholders who either made or influenced policy decisions related to newborn health in Malawi; and (7) a health facility supply and equipment inventory checklist.

The evaluation used a quasi-experimental design for the initial analysis of round 1, whereby 13 districts were classified as "intervention" districts if they were part of the first phase of HBB scale-up in Malawi. The remaining districts were classified as "comparison" districts. However, by the time of the round 2 data collection, all districts in Malawi had been exposed to the HBB intervention. Thus, the final comparative analysis of the round 1 and round 2 data used a dose-response analysis. For this analysis, districts were classified into three dose-response groups based on their level of exposure to the different elements of the HBB intervention—high, medium, and low dose—based on a score created by combining responses for 16 items related to health provider training, practice with the NeoNatalie anatomic model, supervision, and availability of equipment and supplies for newborn care at facility level.

Results

This report presents results from the first and second rounds of data collection.[1] The first round of the study included 81 health facilities and the second round included 90. A total of 190 and 202 facility-based health workers who attend labor and deliveries were interviewed in round 1 and 2 respectively. In both rounds, about 60% of all health providers interviewed were nurse/midwife technicians. The mean number of years that respondents had provided delivery services was 5.9 in round 1 and 6.0 in round 2, with nurse/midwife technicians having an average of 4.3 years and 4.5 years of delivery services in rounds 1 and 2 respectively. There were no significant differences between the high-, medium-, and low-dose districts in the mean number of years of service. More health workers interviewed had received training in subjects related to newborn care in the past two years in round 2 (68.4%) than in round 1 (59.7%). The trained individuals largely came from the nurse/midwife technician group (34.8% and 41.8% in rounds 1 and 2 respectively). There were no differences in health provider training by dose group in either round of the study.

The majority of supervisors checked the records of their supervisees (81.7% and 88.8% in rounds 1 and 2, respectively) and observed their work (78.6% and 87.3% in rounds 1 and 2, respectively). However, only slightly more than one-third (39.7% and 41.5% in rounds 1 and 2 respectively) of supervisees had received any written comments from their supervisors. Most supervisees were able to discuss any problems encountered with their supervisor (86% and 90% overall in rounds 1 and 2, respectively) and were given verbal feedback (82.2% and 88.6% overall in rounds 1 and 2, respectively). More supervisors observed work in the medium-dose group in round 1 compared to the other groups; however, there were no obvious differences in supervision by dose in round 2.

Quality of resuscitation care using clinical simulations with the NeoNatalie model

Among the health workers who participated in a clinical simulation of bag and mask ventilation using the NeoNatalie anatomic model, the mean number of steps that were correctly completed (out of a total possible score of 10) was higher in round 2 (mean of 7.1) compared to round 1 (mean of 6.2).

In both rounds, the steps completed by the fewest respondents were squeezing the bag harder if the newborn's chest did not move and testing the function of the bag and mask. The step completed by the highest proportion of respondents in both rounds was extending the newborn's head. The overall mean score was higher in the high-dose arm than in the medium-dose arm (p=0.041) in round 1. The overall mean score was not significantly different by dose in round 2. However, health workers in the high-dose arm scored higher at testing the function of the bag and mask and squeezing the bag harder.

Respondents were asked to complete two role-play case scenarios with the newborn simulator (NeoNatalie). In the first scenario, the mean number of steps performed correctly was lower in round 1 (mean 10.1; SD 3.3) than round 2 (mean 11.0; SD 2.9) out of 16 possible total correct steps, with a range of two to 16 steps performed correctly in both rounds. In both rounds, most respondents dried the baby thoroughly while few made an emergency plan.

In the second scenario the mean number of steps performed correctly was higher in round 2 (mean 19.5; SD 5.8; range 4–29) than in round 1 (mean 17.4; SD 6.6; range 2–29). Most providers remembered to thoroughly dry the baby, and as with the first scenario, the fewest respondents called for help in both round 1 and 2.

[1] Results from the first round alone were presented earlier in a separate report.

Overall, the proportion of facilities that had the equipment required for newborn care was not different by dose group. One exception was suction bulbs for mucus extraction, which were more common in the high-dose group in round 1 and more common in the medium-dose group in round 2. In both rounds, the proportion of facilities that had the equipment required for delivery services was not different by dose group except for single-use hand-drying towels, which were more common in the medium-dose group.

Observed quality of routine labor and delivery care

All stages of labor were observed in 175 cases in round 1 and 193 cases in 2. The second, third, and immediate postpartum stages of labor were observed in 1,417 cases in round 1 and 1,842 cases in round 2 to assess whether women and newborns were receiving evidence-based interventions such as screening and prevention of pre-eclampsia/eclampsia, postpartum hemorrhage, and newborn asphyxia and hypothermia.

Although most mothers were checked for their client card, fetal presentation, and fetal heart rate and most received a vaginal exam, only about half in each round had their temperature or pulse taken, and only 5.7% in round 1 and 3.6% in round 2 were tested for urine protein. Only 32.6% and 24.4% of mothers were checked for fundal height in rounds 1 and 2, respectively. A higher percentage of providers in the low-dose group asked about at least one danger sign, performed general examination (anemia, edema, etc.), and checked fundal height in round 1. In round 2, a higher percentage of providers in the medium-dose group than in the other dose groups took the woman's temperature and blood pressure and performed a general examination.

More than 85% of mothers in both rounds were greeted respectfully, but less than 20% were encouraged to have someone in attendance at delivery. Less than 30% were asked whether they had any questions for the health provider or provided with drapes. Less than 60% were encouraged to hydrate and eat during labor. The only differences in performance by dose group were that providers in the high-dose arm more often informed the pregnant woman of findings in round 1 and more often explained procedures to the woman in round 2.

As part of active management of the third stage of labor, 91% and 98% of women in round 1 and 2, respectively, were given a uterotonic immediately after birth. More nonbeneficial behaviors were reported in round 1 (5.6%) than in round 2 (2.7%). Very few nonindicated practices were reported in either round. The most frequently reported nonbeneficial and nonindicated behaviors were holding the newborn upside-down, applying fundal pressure, and stretching the perineum.

Data were complete for a total of 1,303 and 1,800 observations of immediate newborn care in rounds 1 and 2, respectively. Close to 70% of newborns had delayed cord clamping after birth as recommended, over 95% were immediately dried, and almost all newborns were either placed skin-to-skin or wrapped in a dry towel in both rounds. In round 1, 42% of women started breastfeeding their newborns within one hour after birth compared to 78% in round 2. Newborns were more likely to be placed skin-to-skin or wrapped in a dry towel and breastfed within the first hour in the medium-dose group in round 1. Delayed cord clamping and cutting the cord with a clean blade were more prevalent in the high-dose group in round 1. In round 2, immediately drying the baby, delayed cord clamping, and initiation of breastfeeding in the first hour were more common in the low-dose group than in the other groups.

Observed quality of management of newborns not breathing at birth

A key component of this evaluation was observing the management of newborns who were not breathing at birth. Out of the 1,747 valid observations in round 1, 88 newborns in the high-dose group, 46 in the medium-dose group, and 59 in the low-dose group were found not to be breathing at birth (a total of 193 newborns). Among the newborns who were found not to be breathing at birth, 84 survived in the high-dose arm (95.5%), 42 survived in the medium-dose arm (91.3%), and 54 survived in the low dose arm (91.5%).

Stimulation was given to 66 newborns in the high-dose arm (75%), 32 newborns in the medium-dose arm (69.6%), and 47 newborns in the low-dose arm (79.7%). After stimulation, 63.6%, 37.5% and 52.2% of the newborns in the high-, medium-, and low-dose groups, respectively, started breathing. Among the babies who were not revived by initial stimulation, 23 of 24 in the high dose group (95.8%), 19 of 20 in the medium-dose group (95%), and 20 of 22 in the low-dose group (90.9%) received a bag-and-mask intervention.

After the bag-and-mask intervention, 21of 23 babies survived in the high-dose group (91.3%), 18 of 19 (94.7%) survived in the medium-dose group, and 18 of 20 (90%) survived in the low-dose group. The differences in proportion between the dose groups were not statistically significant for any outcome.

Out of the 2,093 valid observations in round 2, 91 newborns in the high-dose group, 90 in the medium-dose group, and 99 in the low-dose group were found not to be breathing at birth (a total of 291 newborns). Among the babies found not to be breathing at birth, 88 survived in the high-dose group (96.7%), 87 survived in the medium-dose group (95.6%), and 92 survived in the low-dose group (92.9%).

Stimulation was given to 68 newborns in the high-dose arm (74.7%), 74 in the medium-dose arm (81.1%), and 82 in the low-dose (82.9%). After stimulation, 48.5%, 63.5%, and 52.4% of the newborns in the high-, medium-, and low-dose groups, respectively, started breathing. Among the babies who were not revived after stimulation, 29 of 35 in the high-dose group (82.9%), 25 of 26 in the medium-dose group (96.2%), and 32 of 39 in the low-dose group (82.1%) received a bag-and-mask intervention.

Among babies who received a bag-and-mask intervention, 28 of 29 survived in the high-dose group (91.1%), 22 of 25 survived in the medium-dose group (88%), and 27 of 32 survived in the low-dose group (84.4%). The differences in proportion between the arms were not statistically significant for any outcome.

In summary, there was an overall improvement in health worker training, knowledge, equipment availability, and management of labor and delivery, including newborn care, over the two rounds of data collection in Malawi. However, there were no significant differences between the high-, medium-, and low-dose groups in any of the two rounds. Although health worker performance in round 2 was better than in round 1, a majority of the findings in this report indicate the absence of significant differences by dose group in the two rounds.

Background

A review of progress toward Millennium Development Goal Four (MDG 4) indicates that while under-five mortality has declined worldwide, neonatal mortality has not experienced a similar decline. An estimated 3.6 million neonates die each year globally, 99% of them in developing countries (Lawn et al. 2010; Black et al. 2010). Neonatal deaths represent an increasing proportion of under-five deaths—an estimated 41% globally in 2008 compared to 38% in 2000—due to the stagnation in neonatal mortality rates. Neonatal mortality is largely attributable to three preventable conditions: birth asphyxia, prematurity, and infections. Globally, about one-tenth of the under-five deaths, an estimated 814,000 deaths per year, are caused by birth asphyxia (intrapartum-related deaths) (Bryce et al. 2005). Even in low-resource settings, many of these deaths can be prevented by improving early recognition of newborn asphyxia and access to appropriate and timely resuscitation. A Delphi estimation reported that immediate newborn assessment and stimulation could lead to a 10% drop in intrapartum-related and preterm deaths, and to an additional 30% drop with facility-based resuscitation (Lee et al. 2011).

Birth asphyxia occurs as a consequence of interrupted placental blood flow

In low- and middle-income countries, birth asphyxia is defined as failure to initiate respiration at birth. Despite efforts to improve outcomes, morbidity and mortality rates associated with birth asphyxia have remained unchanged. This reflects several factors, including a lack of essential basic resuscitation equipment and a failure to initiate resuscitation in a timely manner.

Although maternal, newborn, and child health (MNCH) programs are being scaled up in many low-resource settings, limited guidance has been provided to health workers regarding identification and management of newborn asphyxia. Furthermore, health workers may find it difficult to sustain and improve their resuscitation skills because the rarity of asphyxia provides too few cases for adequate training and practice.

Helping Babies Breathe (HBB) is an educational program developed by a group of stakeholders that include:

- American Academy of Pediatrics
- U.S. Agency for International Development
- Saving Newborn Lives/Save the Children
- Eunice Kennedy Shriver National Institute of Child Health and Human Development
- Laerdal Global Health
- Johnson & Johnson
- Latter Day Saint Charities

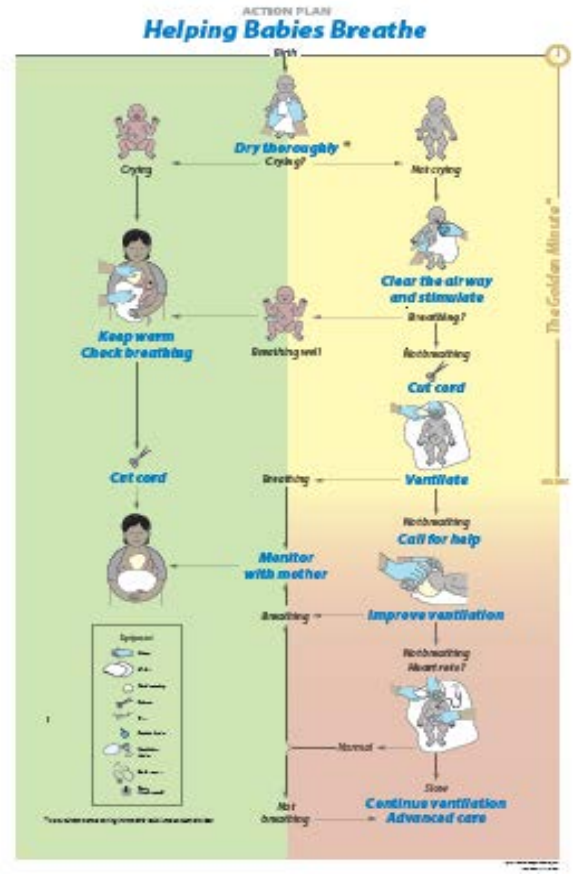
HBB is used to train health workers in essential neonatal resuscitation knowledge, skills, and techniques to manage asphyxiated newborns in resource-limited areas. An important goal of this initiative is to have at least one person skilled in neonatal resuscitation present at the birth of every baby. The HBB curriculum was designed to be used as part of a coordinated educational approach to early neonatal care and can be effectively combined with other curricula. It can be used locally for training birth attendants in diverse venues and locations. HBB focuses on practices that everyone who cares for newborns can learn and use to assist babies who do not breathe on their own at birth.

To accomplish this goal, the HBB approach to newborn resuscitation was developed as a practical and easy-to-use training solution, which includes:

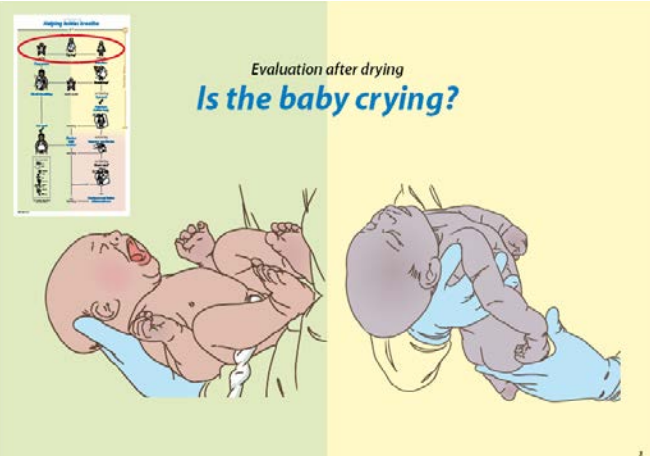
- An evidence-based educational program, based on the International Liaison Committee on Resuscitation (ILCOR) consensus on science conclusions that have undergone a World Health Organization scientific technical review;
- Culturally sensitive, pictorial-based learning materials, including a learner workbook, an action plan wall poster, and a facilitator flip chart;
- Realistic newborn NeoNatalie anatomic simulator (developed by Laerdal Medical, a Norwegian medical device company), which simulates breathing during resuscitation with bag and mask ventilation, imitates an umbilical pulse, and comes with a newborn size bag-mask ventilator and penguin suction bulb that can be cleaned and disinfected by boiling (all equipment has been tested for durability in a variety of climates and teaching conditions and has been made available at cost to MDG countries); and
- An ongoing mentorship program to provide expert assistance, implementation guidance, knowledge exchange, integration and evaluation support, and continuous quality improvement for sustained practice outcomes and decreased infant mortality.

Elements of the HBB tool kit

Action plan

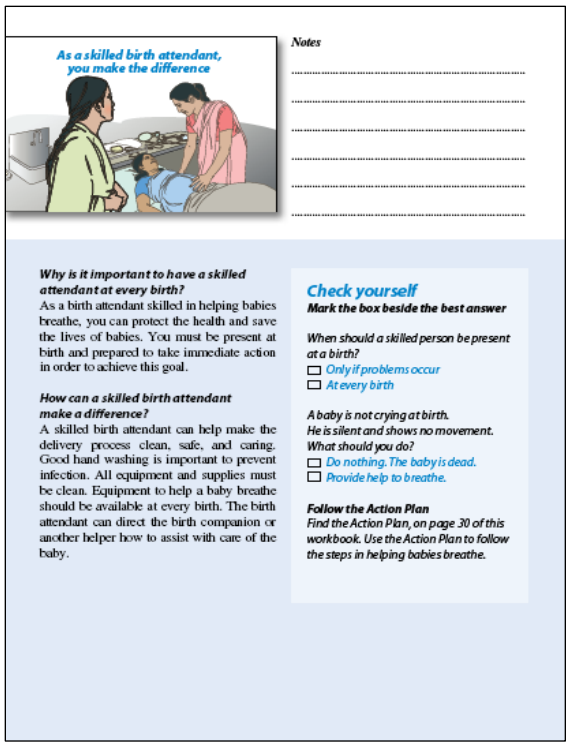


Facilitator flip chart



Exercises with neonatal simulator (low-cost mannequin)

Learner workbook



The HBB toolkit also includes the following:

- Performance evaluation (OSCE)
- Written/verbal evaluation
- Video

Situated in the southeastern part of Africa, Malawi has a population of 14 million people and ranks as one of the poorest countries in the world. The country is administratively divided into three regions (Northern, Central, and Southern), which are further divided into 28 districts. Each district is divided into 250 traditional authorities and 110 administrative wards.

Malawi's health profile is characterized by a high prevalence of communicable diseases. The major burden of disease is due to HIV/AIDS, malaria, tuberculosis, sexually transmitted infections, diarrhea, and acute respiratory infections. The neonatal mortality rate in Malawi is 31 per 1,000 live births Macro (NSOMaO 2011). Major causes of neonatal mortality include neonatal sepsis (29%), prematurity (29%), and asphyxia (23%) (Lawn et al. 2010). Ensuring health workers who attend births have resuscitation skills is a crucial aspect of efforts to prevent asphyxia-related deaths in Malawi.

Study objectives

The **primary objective** of this study was to evaluate the quality and coverage of HBB interventions at the facility level in Malawi. This evaluation included a facility survey and direct observation of labor and delivery. Complementary qualitative research was conducted to elicit additional information and context for the evaluation. The report provides guidance and recommendations for further strengthening HBB implementation and scale-up and improving newborn care in Malawi. It includes key information for policymakers regarding the value of integrating HBB into the strategy for basic emergency obstetric and

neonatal care. Furthermore, it sheds light on the availability and quality of neonatal health services in Malawi, highlighting strengths and areas for improvement.

The evaluation addressed the following questions:

- Are newborn resuscitation service delivery guidelines and supplies available and compliant with the national rollout plan?
- Are the HBB-trained health workers able to apply the newborn resuscitation and essential newborn care skills after 18 and 30 months of training?
- What recommendations can be made for improved availability and quality of neonatal health services in Malawi?

Methodology

Study design and analysis plan

HBB was rolled out in Malawi starting in early 2011. According to the original scale-up plan developed by stakeholders, the rollout was to be financed and led by the Ministry of Health, with support from USAID/MCHIP, Johnson & Johnson/Save the Children International, and other development partners. According to the initial plan, implementation of HBB was to begin in February 2011 in a phased manner in 13 districts (MCHIP), with implementation in the remaining districts during 2012 and 2013.

The first round of data collection and analysis was based on the original scale-up plan, whereby the first 13 districts were classified as intervention districts and the remaining 14 as comparison districts.[2] The first round of data was collected in August and September 2012 and results were presented in July 2013. Health provider knowledge improved more in intervention districts than in comparison districts; however, this improvement was not associated with a corresponding improvement in provider performance.

Need for dose-response analyses

HBB had been scaled up all over Malawi by the time of the second round of data collection in August and September 2013, and there were no comparison districts available to continue with the original analysis plan. Moreover, due to several financial and logistical difficulties (documented in the recent process documentation conducted by Saving Newborn Lives), the Ministry of Health could not lead the scale-up as proposed in the original rollout plan. Therefore, the districts were grouped according to the "dose" of HBB for analysis after the second round of data collection. The purpose of the dose-response analysis was to measure the extent to which districts were exposed to different domains of HBB intervention and assess whether the difference in dose was associated with difference in availability of equipment, supplies, health worker training, knowledge, and performance. Use of dose-response analyses allowed classification of districts according to the actual strength of the HBB intervention, rather than as intervention and comparison groups, which had limited utility as a measure of exposure to HBB intervention. The four domains that constituted the HBB dose in each district were:

- Training and capacity-building
- Practice with newborn simulator, "NeoNatalie"
- Supervision
- Availability of equipment, supplies, and guidelines

Sixteen items (variables) were used to constitute these four domains. Each of the 16 items was scored as a percentage, calculated for each district, for a total possible score of 1600. The scores were ranked from highest to lowest, and the 27 districts were divided into three groups—high, medium, and low dose—based on the score created from the 16 items (Table 1). Overall scores and dose-response districts are presented in Tables 2 and 3 for round 1 and 2, respectively.

[2] Likoma district was excluded from this evaluation.

Table 1: Items in Dose Calculation for Each District

Training and capacity-building	1	Received any training on how to resuscitate a newborn with bag and mask in the past 2 years
	2	Received any training on resuscitation of newborns not breathing at birth in the past 2 years
	3	Received this newborn resuscitation training as part of the HBB initiative
Practice with model	4	Facility has an anatomic model to use to practice resuscitation of newborns that do not breathe (for example, a "NeoNatalie")
	5	Opportunity to practice resuscitating a newborn using a newborn anatomic model/doll after you were trained
	6	Opportunity to practice resuscitating a newborn using a newborn anatomic model/doll in the past 3 months
Supervision	7	Supervised in the past 3 months
	8	Supervisor observed performing newborn resuscitation with a newborn anatomic model/doll (NeoNatalie)
Availability of equipment, supplies, and guidelines	9	Facility performed newborn resuscitation
	10	Facility performed newborn resuscitation in the past 3 months with bag and mask
	11	Bag and mask (infant size) for resuscitation—Size 0
	12	Bag and mask (infant size) for resuscitation—Size 1
	13	Suction bulb for mucus extraction
	14	Towel or blanket to wrap baby
	15	Helping Babies Breathe guidelines for newborns not breathing at birth
	16	Facility has the Helping Babies Breathe action plan posted on the wall in L&D

Table 2: Aggregated Score and Classification of Districts into Dose Groups in Round 1

District	Score	Dose
Blantyre	608.3	low
Chiradzulu	764.3	low
Karonga	599.9	low
Mangochi	708.3	low
Mchinji	633.7	low
Mwanza	685.7	low
Neno	727.5	low
Ntcheu	739	low
Salima	660.8	low
Balaka	799.9	medium
Chikwawa	850.1	medium
Lilongwe	959.7	medium
Machinga	1000	medium
Mulanje	881.7	medium
Mzimba	893.8	medium
Nsanje	931.9	medium
Rumphi	944.2	medium
Zomba	859.3	medium
Chitipa	1091.7	high
Dedza	1235.8	high
Dowa	1026.3	high
Kasungu	1116.7	high
Nkhata Bay	1060	high
Nkhotakota	1111.2	high
Ntchisi	1110.8	high
Phalombe	1180	high
Thyolo	1095.5	high

Table 3: Aggregated Score and Classification of Districts into Dose Groups in Round 2

DISTRICT	SCORE	DOSE
Blantyre	1080	low
Chiradzulu	835.7	low
Kasungu	1105.4	low
Ntcheu	864	low
Nkhotakota	1121.1	low
Karonga	883.3	low
Mangochi	1006.8	low
Balaka	1002.7	low
Mchinji	877.7	low
Mulunje	1142.6	medium
Phalombe	1175	medium
Dedza	1206.7	medium
Lilongwe	1207.1	medium
Nkhata Bay	1189.9	medium
Chikwawa	1150	medium
Nsanje	1203.3	medium
Zomba	1122.6	medium
Dowa	1173.4	medium
Neno	1228.6	high
Thyolo	1272.5	high
Mwanza	1278.6	high
Ntchisi	1322.7	high
Rumphi	1310.1	high
Salima	1295.9	high
Chitipa	1341.6	high
Machinga	1356.9	high
Mzimba	1460.6	high

Data collection tools

The following tools were developed for this evaluation:

- **Health worker interview and knowledge and skill assessment.** Three tools, including both quantitative and qualitative components, were used for health care worker interviews. A short structured interview assessed each provider's knowledge and practice of HBB. The goal was to collect information on the constraints in and facilitators of delivering quality care, and recommendations for ways to improve quality of care. The quantitative instruments included two observational clinical case studies/ simulations, which were the providers completed and which assessed the providers' clinical decision-making pertaining to screening, management, and treatment of newborn birth asphyxia.
- **Direct observation of deliveries.** Two quantitative observation checklists were used for observation of deliveries—specifically, the provider's performance of labor, delivery, newborn, and immediate postpartum care and newborn resuscitation. Provider practice during labor, delivery, and the immediate postpartum period were observed and documented by study staff in the selected facilities. The labor and delivery and newborn resuscitation observation checklists were adapted from the MCHIP maternal and newborn health quality of care facility survey, which has been conducted in multiple countries in sub-Saharan Africa. The newborn resuscitation checklist documented adherence to American Academy of

Pediatrics (AAP)-developed HBB protocols for screening, management, and treatment of birth asphyxia in newborns; age, gravidity, and parity of the mother; qualification of the provider; and level of health facility.

- **Key informant interview.** A key informant interview guide was used with stakeholders at the national, district, and facility levels to determine the status of HBB rollout and the quality of maternal and newborn care. The respondents were asked questions related to strengths, weaknesses, and recommendation for improvement. Respondents were selected so that there would be representation from the following organizations: the national Ministry of Health, the national professional society of obstetrics/gynecology, the national association of midwives, and hospital maternity ward in-charges and district health officers/district nursing officers from zonal MOHs. The study co-investigators selected the key informants based on their influence, knowledge, and work related to the HBB initiative in Malawi.
- **Record review.** This tool captured the number of antenatal care consults, deliveries, births, deaths, and obstetric complications at each facility for the last year from facility records, including maternity registers.
- **Facility inventory.** The facility inventory tool assessed infrastructure conditions and verified the availability of and storage conditions for medications, supplies, and equipment. Through an interview with the head of each health facility or their designee, a listing was generated of all health workers who attend deliveries and/or provide antenatal care.

Sample

A total of 90 (data available for 81) facilities were randomly selected to be representative of the 27 high-, medium-, and low-dose districts in round 1. In round 2, only two out of 90 facilities were replaced due to low patient volume or non-availability of health workers providing labor and delivery services. Two or three health workers working in the maternity and labor ward in each sampled facility were included in the study. A total of 190 and 202 health workers were sampled from the selected facilities in round 1 and 2, respectively. The sample sizes of the high-, medium-, and low-dose arms in round 1 were 55, 70, and 65 health workers, respectively (Table 1). The sample sizes for the high-, medium-, and low-dose arms in round 2 were 66, 68, and 68 health workers, respectively.

Direct observation of patient care was conducted only in facilities in which at least five deliveries were conducted per day on average and that were capable of managing obstetric emergencies. Therefore, data on labor and delivery observations were collected in only 44 facilities in each round.

Table 4: Health Facility Sample, Health Workers Interviewed, and Labor and Delivery Observations

	Round 1				Round 2			
	High	Medium	Low	Total	High	Medium	Low	Total
Health facility	23	28	30	81	30	30	30	90
Health providers	55	70	65	190	66	68	68	202
Women in labor	527	567	476	1,570	635	742	732	2,109
Newborns not breathing at birth	98	70	57	225	96	93	102	291

Table 5: Components of Labor and Delivery (L&D) Observed

	Round 1				Round 2			
	High	Medium	Low	Total	High	Medium	Low	Total
Components of labor and delivery observed	Number of cases	Number of cases	Number of cases	Number of cases	Number of cases	Number of cases	Number of cases	Number of cases
Initial client assessment	66	62	65	193	59	67	67	193
First stage of labor	66	62	65	193	62	75	71	208
Second and third stage of labor	527	567	476	1,570	635	742	732	2,109
Immediate newborn care and postpartum care	527	567	476	1,570	635	742	732	2,109
Total number of L&D observations	527	567	476	1,570	635	742	732	2,109

Data collection procedure

A week of training for 34 data collectors was conducted in August 2012 and August 2013 in Lilongwe, Malawi. The data collectors were previously trained health care workers who had experience in basic emergency obstetric and neonatal care. Most of these data collectors had also been trained previously in the Helping Babies Breathe curriculum. The data collector training included briefings on the background and rationale of the study and a description of and technical instructions for completion of data collection tools. The trainees also had an opportunity to go to the field to practice using actual tools for data collection at health facilities and to observe actual maternity clients. Data collection was monitored on an ongoing basis by a trained team of supervisors and was overseen by a study coordinator. The supervisors checked the data collection plans, observed data collection, and reviewed completed forms during their monitoring visit. The fieldwork occurred between August 20 and September 22, 2012, for round 1 and between September 1 and September 30, 2013, for round 2.

Direct observation of patient care was conducted at 44 facilities that had an average of five deliveries per day and were capable of managing obstetric emergencies. At each of these facilities, one data collector spent 10–12 days. In addition to conducting the facility inventory, record review, health worker interview, and knowledge assessment, the data collector observed the care provided during all types of deliveries: normal vaginal delivery, assisted (vacuum or forceps) or cesarean section. At each of the remaining facilities (46 in round 1 and round 2), a team of two data collectors spent one day conducting only the facility inventory, the record review, and the health worker interview/knowledge assessment.

Data analysis

Data were collected on paper-based forms and then entered by trained data entry clerks into a Microsoft Access database that was designed for this evaluation. Data were analyzed using Stata analytical software (Stata SE), version 12. Descriptive statistics, including means and percentage distributions, were calculated.

All three components of the study's primary objectives were assessed: quality, coverage, and outcomes of the Helping Babies Breathe newborn resuscitation intervention at the facility level. Tabulations were run on the collected data. For each topic or subtopic area for which data were collected (i.e., initial client assessment during delivery and labor, and partograph use), tabulations were only conducted for those individuals who had answers for all observational items in that particular section/sub-section of the clinical observation checklist. This allowed us to have a consistent denominator for each section/subsection. The tabulations are reported stratified by group (intervention/non-intervention) or dose (high/medium/low) and also combined (total).

Ethical considerations

The study protocol was approved by the College of Medicine Research Ethics Committee in Malawi and the Institutional Review Board of the Johns Hopkins Bloomberg School of Public Health (JHSPH). Informed consent was obtained from all participating health providers and patients, and permission to visit the health facilities was obtained from facility directors. If a woman was incapacitated, consent was to be obtained from next of kin or guardian. However, this situation did not occur in the course of the study.

Limitations

There are several important limitations that should be noted. Simulation of newborn resuscitation on models to assess health worker skills has limitations; for example, extension of the model's neck may need to be exaggerated to achieve simulated breathing, and a standardized "mother" or "guardian" should be used to test the provider's interpersonal skills during resuscitation. Some providers stopped after the stimulation and suction portion and did not perform bag and mask resuscitation. In addition, in interpreting the results from the simulation, the fact that the model was new for some providers, especially those who had not yet received training in HBB, should be considered. However, providers were given an opportunity to examine the model and familiarize themselves with it before the simulation began.

Results

Health personnel and years of service

As part of the evaluation, health providers were interviewed about their educational background, years providing services, training received, working conditions, and knowledge of maternal and newborn care. A total of 188 and 202 health workers were interviewed in rounds 1 and 2, respectively. More than 59% and 62% of all health providers interviewed classified themselves as nurse/midwife technicians in rounds 1 and 2, respectively (Table 6).

Table 6: Health Providers Interviewed, by Type

	Round 1				Round 2			
	High (n=61)	Medium (n=67)	Low (n=60)	Total (n=188)	High (n=66)	Medium (n=68)	Low (n=68)	Total (n=202)
Medical assistant	8 (13.1%)	8 (11.9%)	9 (15.0%)	25 (13.3%)	13 (19.7%)	10 (14.7%)	13 (19.1%)	36 (17.85)
Clinical officer	1 (1.6%)	1 (1.5%)	-	2 (1.1%)	-	-	3 (4.4%)	3 (1.5%)
Registered midwife	7 (11.5%)	11 (16.4%)	7 (11.7%)	25 (13.3%)	5 (7.6%)	4 (5.9%)	5 (7.4%)	14 (6.9%)
Enrolled nurse/midwife	4 (6.6%)	8 (11.9%)	9 (15.0%)	21 (11.2%)	3 (4.6%)	9 (13.2%)	6 (8.9%)	18 (8.9%)
Nurse/midwife technician	40 (65.6%)	38 (56.7%)	33 (55.0%)	111 (59.0%)	43 (65.2%)	43 (63.2%)	40 (58.8%)	126 (62.45)
Other	1 (1.6%)	1 (1.5%)	2 (3.3%)	4 (2.1%)	2 (3.0%)	2 (2.9%)	1 (1.5%)	5 (2.5%)

The profile of maternity providers included in this study was comparable between dose groups and reflects the anticipated distribution of provider cadres (Tables 7a and 7b). Overall, the mean number of years that the health worker had been providing any type of health service was 5.9 years in round 1 and 6.6 years in round 2 (range 0 to 35 years). Providers in the largest group (nurse/midwife technician) had on average been providing services for 4.3 years in round 1 and 4.5 years in round 2. There were no significant differences in the mean years of service by dose group in either round 1 or round 2.

Health worker training and knowledge

More health workers interviewed received training in subjects related to newborn care in the past two years in round 2 (68.4%) compared to round 1 (59.7%) (Table 8). The trained individuals largely came from the nurse/midwife technician group (34.8 and 41.8% in round 1 and 2 respectively). There were no differences in health provider training by dose group in both round 1 and 2.

Table 7a: Years of Experience in Service Delivery, by Type of Health Worker, Round 1

Cadre	Total years of providing delivery services												
	High			Medium			Low			Total			*p*-value
	n	Mean	Range	n	Mean	Range	n	Mean	Range	N	Mean	Range	
Medical assistant	8	7	0–21	8	5.1	2–19	8	2.4	1–5	24	4.8	0–21	0.459
Clinical officer	1	31	31–31	1	9	9–9	-	-	-	2	20	9–31	0.157
Registered midwife	7	0.9	0–2	11	2.4	0–17	7	1.6	0–5	25	1.7	0–17	0.258
Enrolled nurse/midwife	4	18	0–30	8	20.8	5–42	9	25.4	1–40	21	22.2	0–42	0.237
Nurse/midwife technician	40	3.2	0–24	37	4.3	0–21	33	5.4	0–21	110	4.2	0–24	0.067
Other	1	53	0–53	1	12	12–12	2	16	12–20	4	24.3	12–53	0.287
Total	61	5.6	0–53	66	6.3	0–42	59	7.9	0–40	186	6.6	0–53	0.091

Table 7b: Years of Experience in Service Delivery, by Type of Health Worker, Round 2

Cadre	Total years of providing delivery services												
	High			Medium			Low			Total			*p*-value
	n	Mean	Range	n	Mean	Range	n	Mean	Range	N	Mean	Range	
Medical assistant	12	4.3	0–20	9	7.3	2–20	13	4	1–7	34	5	0–20	0.430
Clinical officer	-	-	-	-	-	-	3	7.3	0–20	3	7.3	0–20	-
Registered midwife	5	1.6	0–4	4	0.5	0–2	5	1.2	0–4	14	1.1	0–4	0.643
Enrolled nurse/midwife	3	24.3	17–31	8	18.8	8–26	6	18.8	0–28	17	19.8	0–31	0.383
Nurse/midwife technician	43	3.7	0–25	43	3.8	0–18	40	6.1	0–30	126	4.5	0–30	0.731
Other	2	14.5	0–29	2	2.5	0–5	1	35	35–35	5	13.8	0–35	0.277
Total	65	5.0	0–31	66	5.9	0–26	68	6.9	0–35	199	5.9	0–35	0.538

Table 8: Proportion of Health Providers Who Received Training in Newborn Care in Past Two Years

Cadre	Round 1									Round 2								
	High (n=60)		Medium (n=63)		Low (n=58)		Total (N=118)		*p*-value	High (n=63)		Medium (n=66)		Low (n=67)		Total (n=196)		*p*-value
	n	%	n	%	n	%	n	%		n	%	n	%	n	%	N	%	
Medical assistant	2	3.3	4	6.4	4	6.9	10	5.5	0.561	9	14.3	5	7.6	6	9.0	20	10.2	0.333
Clinical officer	0	0.0	-	-	-	-	0	0.0	-	-	-	-	-	2	3.0	2	1.0	-
Registered midwife	4	6.7	7	11.1	6	10.3	17	9.4	0.499	5	7.9	4	6.1	5	7.5	14	7.1	-
Enrolled nurse/midwife	4	6.7	4	6.4	6	10.3	14	7.7	0.189	2	3.2	7	10.6	3	4.5	12	6.1	0.535
Nurse/midwife technician	26	43.3	17	27.0	20	34.5	63	34.8	0.205	30	47.6	24	36.4	28	41.8	82	41.8	0.227
Other	1	1.7	1	1.6	2	3.5	4	2.2	-	1	1.6	2	3.0	1	1.5	4	2.0	0.392
Total	37	61.7	33	52.4	38	65.5	108	59.7	0.314	47	74.6	42	63.6	45	67.2	134	68.4	0.394

Knowledge and skills during simulation of bag-and-mask ventilation

Table 9 presents assessment data for health workers who participated in the bag and mask ventilation assessment using the NeoNatalie anatomic model. The mean number of steps that were completed correctly was higher in round 2 (mean 7.1; SD 2.0) than round 1 (mean 6.2; SD 2.4), out of a total possible score of 10.

In both rounds, the steps completed by the lowest proportion of respondents were squeezing the bag harder if the newborn's chest did not move and testing the function of the bag and mask. The step completed by the highest proportion of respondents in both rounds was extending the newborn's head. The overall mean score was higher in the high-dose arm than the medium dose arm (p=0.041) in round 1. The overall mean score was not different by dose in round 2, although health workers in the high-dose arm scored higher on testing the function of the bag and mask and squeezing the bag harder.

The respondents were asked to complete two case scenarios using the NeoNatalie anatomic model. In the first case scenario, the respondent was asked to perform the steps necessary to deliver a term baby without complications in pregnancy (Table 10). The mean number of steps performed correctly was lower in round 1 (mean 10.1; SD 3.3) than round 2 (mean 11.0; SD 2.9), out of 16 steps, with a range of 2 to 16 steps performed correctly in both rounds. In both rounds most respondents dried the baby thoroughly, and the fewest respondents made an emergency plan.

Providers were asked to complete a second case scenario with the NeoNatalie anatomic model in which they were to pretend that they were assisting at the birth of a baby at 34 weeks' gestation. The mean number of steps performed correctly out of 29 steps was higher in round 2 (mean 19.5; SD 5.8; range 4–29) than round 1 (mean 17.4; SD 6.6; range 2–29). In both round 1 and round 2, most providers remembered to thoroughly dry the baby and, as with the first scenario, the fewest respondents called for help. The results of the second case scenario are presented in Table 11. In round 1, health workers in the high-dose arm had higher overall scores than those in the medium- and low-dose arms. In round 2, health workers in the medium-dose group scored higher on recognizing that baby was not crying, calling for help, continuing ventilation, but the overall mean score was not statistically significantly different from the high- or low-dose groups.

Table 9: Clinical Simulation of Bag-and-Mask Ventilation Using NeoNatalie Model

	Round 1					Round 2				
	High (n=53) %	Medium (n=57) %	Low (n=61) %	Total (N=171) %	*p*-value	High (n=64) %	Medium (n=63) %	Low (n=66) %	Total (N=194) %	*p*-value
Checks equipment and selects the correct mask										
Tests function of bag and mask	55.6	34.5	44.3	44.5	0.081	59.4	43.8	37.9	46.9	0.041
Makes sure mask fits the baby's face	68.5	55.2	70.5	64.7	0.17	85.9	79.7	87.9	84.5	0.404
Applies the mask to make a firm seal										
Extends the head	88.9	84.5	93.4	89	0.295	93.8	93.8	92.4	93.3	0.941
Places mask on the chin, then mouth and nose	83.3	82.8	86.9	84.4	0.798	85.9	85.9	86.4	86.1	0.997
Ensures a firm seal to permit chest movement when the bag is squeezed	66.7	63.8	68.9	66.5	0.842	78.1	85.9	77.3	80.4	0.393
Ventilates at 40 breaths per minute	61.1	39.7	55.7	52	0.058	62.5	54.7	65.2	60.8	0.448
Looks for chest movement	75.9	67.2	80.3	74.6	0.251	84.4	87.5	81.8	84.5	0.669
Improves ventilation if the chest does not move										
Reapplies mask and repositions head	63	63.8	52.5	59.5	0.374	81.2	71.9	74.2	75.8	0.436
Clears secretions and opens the mouth	53.7	53.4	45.9	50.9	0.628	59.4	56.2	62.1	59.3	0.793
Squeezes the bag harder	40.7	20.7	26.2	28.9	0.055	42.2	39.1	22.7	34.5	0.043
Mean number steps performed correctly	6.6	5.7	6.2	6.2	0.041[a] & 0.404[b]	7.3	7.0	6.8	7.1	0.379[a] & 0.235[b]
SD	2.5	5.7	2.4	2.4		2.0	1.9	2.1	2.0	
Range	1–10	1–10	1–10	1–10		0–10	1–10	1–10	0–10	

[a]High dose compared to medium dose

[b]High dose compared to low dose

Table 10: Results of Clinical Simulation to Assess Health Worker Knowledge: Initial Stimulation

	Round 1					Round 2				
	High (n=56) %	Medium (n=60) %	Low (n=60) %	Total (n=176) %	*p*-value	High (n=63) %	Medium (n=66) %	Low (n=64) %	Total (n=193) %	*p*-value
Prepares for birth										
Identify a helper	64.3	16.7	36.7	38.6	0	36.5	43.9	29.7	36.8	0.242
Makes an emergency plan	53.6	21.7	28.3	34.1	0.001	30.2	45.5	26.6	34.2	0.054
Prepares area for delivery	83.9	71.7	73.3	76.1	0.248	76.2	87.9	79.7	81.4	0.215
Cleans hands and maintains clean technique throughout	75	31.7	28.3	44.3	0	44.4	51.5	43.8	46.6	0.617
Prepares an area for ventilation	71.4	60	68.3	66.5	0.399	68.3	71.2	64.1	67.9	0.681
Checks equipment	53.6	36.7	50	46.6	0.153	61.9	47.0	45.3	51.3	0.119
Keeps baby warm										
Dries thoroughly	96.4	90	96.7	94.3	0.205	95.2	97.0	95.3	95.9	0.855
Removes wet cloth	83.9	70	80	77.8	0.173	76.2	90.9	81.3	82.9	0.078
Covers baby with dry cloth	78.6	71.7	83.3	77.8	0.302	77.8	84.9	78.1	80.3	0.520
Evaluates crying										
Recognizes baby is not crying	83.9	70	63.3	72.2	0.042	90.5	92.4	90.6	91.2	0.909
Clears airway and stimulates breathing										
Positions head and clears airway	75	68.3	61.7	68.2	0.305	76.2	83.3	76.6	78.8	0.533
Simulates breathing by rubbing the back	58.9	53.3	50	54	0.624	55.6	68.2	57.8	60.6	0.291
Evaluates breathing										
Recognizes baby is breathing well	85.7	78.3	68.3	77.3	0.08	90.5	89.4	95.3	91.7	0.431
Clamps or ties and cuts cord	78.6	73.3	73.3	75	0.756	79.4	69.7	78.1	75.7	0.376
Positions skin-to-skin on mother's chest	80.4	65	70	71.6	0.176	68.2	72.7	75.0	72.0	0.690
Communicates with mother	57.1	33.3	28.3	39.2	0.003	50.8	51.5	51.6	51.3	0.995
Mean number done correctly	11.8	9.1	9.6	10.1	<0.001[a] & <0.001[b]	10.8	11.5	10.7	11.0	0.181[a] & 0.862[b]

	Round 1					Round 2				
	High (n=56) %	Medium (n=60) %	Low (n=60) %	Total (n=176) %	*p*-value	High (n=63) %	Medium (n=66) %	Low (n=64) %	Total (n=193) %	*p*-value
SD	2.9	3.2	3.3	3.3		2.8	3.1	2.9	2.9	
Range of correct responses	6–16	2–16	3–16	2–16		2–16	3–16	2–16	2–16	

[a]High dose compared to medium dose

[b]High dose compared to low dose

Table 11: Results from Clinical Simulation to Assess Health Worker Knowledge: Case Scenario 2

	Round 1					Round 2				
	High (n=49) %	Medium (n=53) %	Low (n=55) %	Total (N=157) %	*p*-value	High (n=60) %	Medium (n=64) %	Low (n=63) %	Total (N=187) %	*p*-value
Prepares for birth										
Identifies a helper	46.9	11.3	25.5	27.4	<0.001	45	37.5	23.8	35.3	0.044
Prepares area for delivery	71.4	73.6	72.7	72.6	0.97	73.3	79.7	73	75.4	0.617
Cleans hands	63.3	fxz	27.3	37.6	<0.001	43.3	43.8	36.5	41.2	0.651
Prepares an area for ventilation	71.4	64.2	60	65	0.47	73.3	68.8	61.9	67.9	0.392
Checks equipment	59.2	30.2	36.4	41.4	0.008	55	50	46	50.3	0.609
Keeps baby warm										
Dries thoroughly	93.9	92.5	92.7	93	0.957	93.3	95.3	95.2	94.7	0.859
Removes wet cloth	77.6	71.7	69.1	72.6	0.617	75	81.2	74.6	77	0.609
Covers baby with dry cloth	79.6	67.9	80	75.8	0.259	73.3	85.9	76.2	78.6	0.196
Evaluates crying										
Recognizes baby is not crying	83.7	77.4	61.8	73.9	0.032	86.7	93.8	98.4	93	0.036
Clears airway and stimulates breathing										
Positions head and clears airway	49	50.9	47.3	49	0.93	61.7	71.9	69.8	67.9	0.44
Clears airway	69.4	66	67.3	67.5	0.936	78.3	90.6	85.7	85	0.156
Simulates breathing by rubbing the back	67.3	54.7	49.1	56.7	0.162	48.3	60.9	54	54.5	0.368
Evaluates breathing										
Recognizes baby is not breathing	85.7	73.6	58.2	72	0.007	76.7	85.9	84.1	82.4	0.361
Ventilates with bag and mask										
Cuts cord	71.4	67.9	69.1	69.4	0.927	66.7	73.4	71.4	70.6	0.699
Moves to area for ventilation	75.5	64.2	74.5	71.3	0.362	75	75	79.4	76.5	0.802
Starts ventilation within the Golden Minute	57.1	47.2	49.1	51	0.568	63.3	67.2	66.7	65.8	0.888
Ventilates at 40 breaths per min	61.2	49.1	49.1	52.9	0.368	68.3	57.8	68.3	64.7	0.363
Looks for chest movement	75.5	64.2	69.1	69.4	0.46	63.3	79.7	73	72.2	0.125

	Round 1					Round 2				
	High (n=49) %	Medium (n=53) %	Low (n=55) %	Total (N=157) %	*p*-value	High (n=60) %	Medium (n=64) %	Low (n=63) %	Total (N=187) %	*p*-value
Evaluate breathing										
Recognizes baby is not breathing	77.6	73.6	61.8	70.7	0.181	75	85.9	69.8	77	0.089
Calls for help	34.7	17	25.5	25.5	0.122	25	46.9	27	33.2	0.016
Continues ventilation	87.8	75.5	67.3	76.4	0.048	71.7	87.5	77.8	79.1	0.09
Improves ventilation										
Head-reposition neck	61.2	50.9	50.9	54.1	0.487	61.7	70.3	71.4	67.9	0.449
Reapplies mask	67.3	56.6	65.5	63.1	0.479	65	79.7	73	72.7	0.185
Mouth-clears secretion, opens mouth slightly	42.9	39.6	40	40.8	0.937	51.7	56.2	57.1	55.1	0.808
Bag-squeezes bag harder	38.8	22.6	27.3	29.3	0.186	45	37.5	28.6	36.9	0.167
Evaluates breathing and heart rate										
Recognizes baby is breathing	81.6	69.8	67.3	72.6	0.223	78.3	89.1	71.4	79.7	0.045
Stops ventilation	79.6	84.9	74.5	79.6	0.41	81.7	93.8	79.4	85	0.051
Monitors baby	59.2	56.6	60	58.6	0.933	45	64.1	44.4	51.3	0.043
Communicates with mother	57.1	45.3	54.5	52.2	0.445	65	51.6	55.6	57.2	0.302
Mean number done correctly	19.5	16.4	16.5	17.4	0.020[a] & 0.023[b]	18.9	20.6	18.9	19.5	0.097[a] & 0.935[b]
SD	6.3	5.4	7.6	6.6		6.4	5.4	5.9	5.9	
Range of correct responses	4–29	5–27	2–28	2–29		4–28	4–29	4–28	4–29	

[a]High dose compared to medium dose

[b]High dose compared to low dose

Availability of Supplies, Equipment, and Guidelines

An inventory was taken of available essential equipment, mediations, and supplies for delivery and newborn care, and results are shown for 76 study facilities that had complete data in round 1 and 87 facilities in round 2 (Tables 12 and 13). In both rounds, the proportion of facilities that had the equipment required for delivery services was not different by dose group, except for single-use hand-drying towels, which were more commonly available in the medium-dose groups. The proportion of facilities that had the equipment required for newborn care was not different by dose group, except for suction bulbs for mucus extraction, which were more commonly found in the high-dose group in round 1 and in the medium-dose group in round 2.

Overall, guidelines were more commonly available in round 2 compared to round 1. There were no significant differences in the availability of guidelines by dose in round 1. In round 2, 84% of the high-dose facilities had a copy of the HBB guidelines compared to 57% of the medium-dose facilities and 37% of the low-dose facilities (p=0.001).

Health providers were asked what actions their supervisors had taken the last time they were supervised. Table 15 shows that the majority of supervisors checked the records of their supervisees (81.7% and 88.8%, respectively, in rounds 1 and 2and observed their work (78.6% and 87.3%, respectively, in rounds 1 and 2). However, only slightly more than one-third of supervisees (39.7% and 41.5%, respectively, in rounds 1 and 2) had received any written comments from their supervisors. Most supervisees were able to discuss any problems encountered with their supervisor (86% and 90%, respectively, in rounds 1 and 2) and were given verbal feedback (82.2% and 88.6%, respectively, in rounds 1 and 2). More supervisors observed work in the medium-dose group in round 1 compared to the other groups; there were no obvious differences in supervision by dose in round 2.

Table 12: Availability of Equipment for Delivery Services

Equipment	Round 1					Round 2				
	High (n=23)	Medium (n=26)	Low (n=27)	Total (N=76)	*p*-value	High (n=29)	Medium (n=29)	Low (n=29)	Total (N=87)	*p*-value
	Observed %	Observed %	Observed %	Observed %		Observed %	Observed %	Observed %	Observed %	
Spotlight for pelvic exam	34.8	42.3	44.4	41.8	0.772	69.0	41.4	44.8	51.7	0.073
Table or bed for delivery	100	100	100	100	-	100	100	100	100	-
Clean or sterile gloves	95.7	100	96.3	97.5	0.580	100	97.0	97.0	97.7	0.599
Sharps container	100	96.2	100	98.7	0.377	96.6	93.1	86.2	92.0	0.337
At least 5+ 2ml or 3ml syringes	91.3	96.2	92.6	92.4	0.773	96.6	93.1	86.2	92	0.337
Already mixed decontaminating solution	82.6	80.8	81.5	79.8	0.986	83.0	90.0	82.8	85.1	0.696
Hand disinfectant	21.7	19.2	14.8	20.2	0.813	20.7	27.6	7.0	18.4	0.117
Waste receptacle with lid & plastic liner	73.9	65.4	51.9	63.3	0.262	51.7	58.6	65.5	58.6	0.566
Soap for hand-washing	73.9	69.2	81.5	73.4	0.582	83.0	90.0	90.0	87.4	0.660
Single-use hand-drying towel	13.0	15.4	3.7	11.4	0.343	<0.001	3.5	20.7	8.1	0.008
Water for hand-washing	100	92.3	100	97.5	0.139	100	97.0	100	98.9	0.364

Table 13: Availability of Equipment for Newborn Care

Equipment	Round 1					Round 2				
	High (n=23)	Medium (n=28)	Low (n=30)	Total (N=81)	*p*-value	High (n=29)	Medium (n=28)	Low (n=28)	Total (N=85)	*p*-value
	Observed %	Observed %	Observed %	Observed %		Observed %	Observed %	Observed %	Observed %	
Bag and mask (infant size) for resuscitation	78.3	67.9	58.6	67.5	0.323	89.7	89.3	71.4	83.5	0.108
Tube and mask	52.4	71.4	66.7	64.6	0.368	41.4	53.6	53.6	49.4	0.567
Incubator	26.1	21.4	6.7	17.3	0.139	24.1	14.3	10.7	16.5	0.366
Other source of heat for premature infant	38.1	25	30	30.4	0.614	20.7	32.1	21.4	24.7	0.536
Infant scale	91.3	92.9	100	95.1	0.281	100	100	100	100	-
Suction bulb for mucus extraction	81.8	67.9	40	61.3	0.006	89.7	96.4	71.4	85.9	0.021
Suction apparatus for use with catheter	81	82.1	83.3	82.3	0.976	86.2	78.6	85.7	83.5	0.688
Resuscitation table for baby	87	67.9	69	73.8	0.233	69	75	60.7	68.2	0.515
Disposable cord ties or clamps	78.3	85.7	93.3	86.4	0.281	100	100	100	100	-
Towel or blanket to wrap baby	26.1	37	10	23.8	0.054	3.4	28.6	21.4	17.6	0.037

Table 14: Availability of Guidelines

	Round 1					Round 2				
	High (n=21)	Medium (n=25)	Low (n=28)	Total (N=74)	*p*-value	High (n=31)	Medium (n=30)	Low (n=28)	Total (N=89)	*p*-value
	Observed %	Observed %	Observed %	Observed %		Observed %	Observed %	Observed %	Observed %	
Guidelines for normal delivery	47.6	28.0	28.6	33.8	0.285	38.7	60.7	40.0	46.1	0.171
Guidelines for emergency obstetric care	81.0	84.0	96.4	82.9	0.201	93.6	92.9	96.7	96.4	0.795
Blank partographs	95.2	88.0	89.3	90.5	0.677	93.6	96.4	90.0	93.3	0.619
Helping Babies Breathe guidelines	52.4	40.0	17.9	35.1	0.036	83.9	57.1	36.7	59.6	0.001

Table 15: Supervisor's Action during Last Supervision Visit, as Reported by Supervisee

	Round 1					Round 2				
	High (n=43)	Medium (n=48)	Low (n=40)	Total (n=133)	p-value	High (n=48)	Medium (n=45)	Low (n=47)	Total (n=140)	*p*-value
	n (%)	n (%)	n (%)	N (%)		n (%)	n (%)	n (%)	N (%)	
Checked records	39 (90.7)	36 (75)	32 (80)	107 (81.7)	0.146	43 (90.0)	39 (86.7)	42 (89.3)	124 (88.6)	0.887
Observed work	37 (86)	40 (83.3)	26 (65)	103 (78.6)	0.04	40 (83.3)	42 (93.3)	40 (85.1)	122 (87.1)	0.311
Gave verbal feedback	41 (95.3)	33 (85.4)	41 (82.5)	115 (87.8)	0.166	44 (91.7)	42 (93.3)	38 (80.9)	124 (88.6)	0.121
Provided written comments	18 (41.9)	16 (33.3)	18 (45)	52 (39.7)	0.505	16 (33.3)	24 (53.3)	18 (38.3)	58 (41.4)	0.128
Provided updates on technical and administrative issues	30 (69.8)	27 (56.2)	23 (57.5)	80 (61.1)	0.359	33 (68.8)	35 (77.8)	30 (63.8)	98 (70.0)	0.336
Discussed problems you encountered	37 (86)	40 (83.3)	36 (90)	113 (86.3)	0.663	42 (87.5)	42 (93.3)	42 (89.4)	126 (90.0)	0.634
Participated in quality of care improvement activities	43 (74.4)	48 (62.5)	40 (70)	90 (68.7)	0.462	33 (68.8)	37 (82.2)	30 (63.8)	100 (71.4)	0.131

Routine Newborn and Maternal Care

Performance of initial client assessment

Complete answers for all questions regarding performance of initial client assessment tasks for mothers in labor were provided for 175 observations of deliveries in round 1 and 193 observations of deliveries in round 2 (Tables 16a and 16b).

Although most mothers were checked for their client card, fetal presentation, fetal heart rate, and were given a vaginal exam, only about half of the mothers in both round 1 and round 2 had their temperature or pulse taken, and as few as 5.7 % in round 1 and 3.6% in round 2 were tested for urine protein. Only 32.6% and 24.4% of mothers were checked for fundal height in rounds 1 and 2, respectively. In round 1 a higher percentage of providers in the low-dose group asked about at least one danger sign, performed a general examination (anemia, edema, etc.), and checked fundal height. In round 2, a higher percentage of providers in the medium-dose group took the woman's temperature and blood pressure and performed a general examination.

Table 16a: Performance of Initial Client Assessment Tasks Observed in Round 1

Tasks	High (n=64)		Medium (n=51)		Low (n=60)		Total (n=175)		*p*-value
	n	%	n	%	n	%	N	%	
Checks client card; asks age, length of pregnancy, and parity	63	98.4	50	98.0	58	96.7	171	97.7	0.791
Asks about at least one danger sign	52	81.2	37	72.6	57	95.0	146	83.4	0.006
Takes temperature	28	43.8	27	52.9	26	43.3	81	46.3	0.526
Takes pulse	30	46.9	27	52.9	30	50.0	87	49.7	0.810
Takes blood pressure	41	64.1	33	64.7	37	61.7	111	63.4	0.938
Asks about/notes urine output	15	23.4	4	7.8	5	8.3	24	13.7	0.018
Tests urine for protein	6	9.4	1	2.0	3	5.0	10	5.7	0.225
Performs general examination (anemia, edema, etc.)	47	73.4	25	49.0	46	76.7	118	67.4	0.004
Checks fundal height	17	26.6	12	23.5	28	46.7	57	32.6	0.015
Checks fetal presentation	62	96.9	49	96.1	58	96.7	169	96.6	0.972
Checks fetal heart rate with fetoscope/ ultrasound	64	100	48	94.1	58	96.7	170	97.1	0.164
Performs vaginal exam	62	96.9	50	98.0	59	98.3	171	97.7	0.848
Asks about at least one complication in previous pregnancies*	35	81.4	29	78.4	36	90.0	100	83.3	0.359

*The denominators were different for this question, as this was the first pregnancy for some women.

Table 16b: Performance of Initial Client Assessment Tasks Observed in Round 2

Tasks	High (n=59)		Medium (n=67)		Low (n=67)		Total (n=193)		*p*-value
	n	%	n	%	n	%	N	%	
Checks client card; asks age, length of pregnancy, and parity	58	98.3	64	95.5	63	94.0	185	95.9	0.479
Asks about at least one danger sign	46	78.0	49	73.1	46	68.7	141	73.1	0.501
Takes temperature	27	45.8	37	55.2	22	32.8	86	44.6	0.033
Takes pulse	37	62.7	41	61.2	24	35.8	102	52.9	0.003
Takes blood pressure	40	67.8	50	74.6	32	47.8	122	63.2	0.004
Asks about/notes urine output	7	11.9	16	23.9	11	16.4	34	17.6	0.200
Test urine for protein	1	1.7	4	6.0	2	3.0	7	3.63	0.414
Performs general examination (anemia, edema, etc.)	21	35.6	49	73.1	42	62.7	112	58.0	<0.001
Checks fundal height	15	25.4	13	19.4	19	28.4	47	24.4	0.470
Checks fetal presentation	53	89.8	62	92.5	65	97.0	180	93.3	0.264
Checks fetal heart rate with fetoscope/ ultrasound	59	100	65	97.0	66	98.5	190	98.5	0.401
Performs vaginal exam	57	96.6	67	100	67	100	191	99.0	0.101
Asks about at least one complication in previous pregnancies*	30	83.3	35	74.5	32	80.0	97 out of 123	78.9	0.604

*The denominators were different for this question, as this was the first pregnancy for some women.

Provider communication and support

Complete answers for communication and respectful, humanistic care before and during labor were provided for 188 and 199 observations in rounds 1 and 2, respectively (Tables 17a and 17b). In both round 1 and round 2, more than 85% of mothers were greeted respectfully, but less than 20% received encouragement to have someone in attendance at delivery. Less than 30% were provided with drapes or asked whether they had any questions for the health provider. Less than 60% were encouraged to hydrate and eat during labor. The only differences in performance by dose group were that providers in the high-dose arm in round 2 more often informed the pregnant woman of findings and in round 2 more often explained procedures to the woman.

Table 17a: Communication and Support Tasks Before and During Labor, Round 1, by Dose Group

	High (n=64)		Medium (n=59)		Low (n=65)		Total (N=188)		*p*-value
	n	%	n	%	n	%	N	%	
Initial assessment									
Respectfully greets pregnant woman	61	92.4	46	78.0	54	85.7	161	85.6	0.071
Encourages the woman to have a support person present throughout labor and birth	7	10.6	2	3.4	11	17.5	20	10.6	0.042
The woman has support person at some point during labor	19	28.8	13	22.4	9	14.8	41	22.2	0.163
Asks woman (and support person, if present) if she has any questions	14	21.2	19	32.2	18	28.6	51	27.1	0.367
Explains procedures to woman (and support person) before proceeding	55	83.3	45	76.3	53	84.1	153	81.4	0.473
Informs the pregnant woman of findings	62	93.9	46	78.0	55	87.3	163	86.7	0.031
Communication and support tasks for first stage of labor									
At least once, explains what will happen in labor to pregnant woman and her support person	40	62.5	34	57.6	49	75.4	123	65.4	0.096
At least once, encourages woman to consume fluids/food throughout labor	34	53.1	30	50.9	37	56.9	101	53.7	0.789
At least once, encourages/assists woman to ambulate and assume different positions during labor	44	67.7	44	74.6	44	74.6	132	70.2	0.670
Drapes woman	12	18.8	15	25.4	19	29.2	46	24.5	0.375

Table 17b: Communication and Support Tasks Before and During Labor, Round 2, by Dose Group

	High (n=61)		Medium (n=69)		Low (n=69)		Total (N=199)		*p*-value
	n	%	N	%	n	%	N	%	
Initial assessment									
Respectfully greets pregnant woman	52	85.2	61	88.4	60	87.0	173	86.9	0.867
Encourages the woman to have a support person present throughout labor and birth	14	23.0	10	14.5	2	11.6	32	16.1	0.193
The woman has a support person at some point during labor	20	32.8	26	37.7	25	36.2	71	35.7	0.839
Asks woman (and support person, if present) if she has any questions	23	37.7	18	26.1	14	20.3	55	27.6	0.081
Explains procedures to woman (support person) before proceeding	58	95.1	54	78.3	53	76.8	165	82.9	0.010
Informs the pregnant woman of findings	55	90.2	64	92.8	60	87.0	179	90.0	0.525

	High (n=61)		Medium (n=69)		Low (n=69)		Total (N=199)		*p*-value
	n	%	N	%	n	%	N	%	
Communication and support tasks for first stage of labor									
At least once, explains what will happen in labor to pregnant woman and her support person	54	87.1	53	74.7	58	77.3	165	79.3	0.182
At least once, encourages woman to consume fluids/food throughout labor	37	59.7	47	62.7	54	76.1	138	66.4	0.096
At least once, encourages/assists woman to ambulate and assume different positions during labor	40	64.5	53	70.7	57	80.3	150	72.1	0.122
Drapes woman	19	30.7	22	29.3	15	21.1	56	26.9	0.392

Prevention of Postpartum Hemorrhage

Complete answers for all items pertaining to active management of the third stage of labor and other activities associated with prevention of postpartum hemorrhage were obtained for 1,417 observations in round 1 and 1,842 observations in round 2 (Tables 18a and 18b). Compliance was high, with approximately 91% and 98% of women receiving an uterotonic in rounds 1 and 2, respectively, and 94% and 97% of women receiving traction to the cord in rounds 1 and 2, respectively. In round 1 a higher percentage of women in the medium-dose group had a health worker apply traction to the cord while applying suprapubic counter traction and had a uterine massage immediately following the delivery of the placenta (p<0.001).

In round 2, 90.8% of women in the high-dose arm had the placenta and membranes assessed, compared to 75% and 81% in the medium- and low-dose arms, respectively (p<0.001).

Table 18a: Observation of Tasks Performed to Prevent Postpartum Hemorrhage, Round 1

Task	High (n=469)		Medium (n=445)		Low (n=503)		Total (n=1,417)		*p*-value
	n	%	n	%	n	%	N	%	
Administers uterotonic	444	96.7	413	92.8	427	84.9	1,284	90.6	<0.001
Applies traction to the cord while applying suprapubic counter traction	430	91.7	422	94.8	490	97.4	1,342	94.7	<0.001
Performs uterine massage immediately following the delivery of the placenta	406	86.6	398	89.4	329	65.4	1,133	80.0	<0.001
Assesses completeness of placenta and membranes	353	75.3	345	77.5	403	80.1	1,101	77.7	0.191
Assesses for perineal and vaginal lacerations	453	96.6	438	98.4	495	98.4	1,386	97.8	0.086

Table 18b: Observation of Tasks Performed to Prevent Postpartum Hemorrhage, Round 2

Task	High (n=535)		Medium (n=690)		Low (n=617)		Total (n=1, 842)		*p*-value
	n	%	n	%	n	%	N	%	
Administers uterotonic	527	98.5	680	98.6	609	98.7	1,816	98.6	0.955
Applies traction to the cord while applying suprapubic counter traction	514	96.1	676	98.0	603	97.7	1,793	97.3	0.094
Performs uterine massage immediately following the delivery of the placenta	489	91.4	619	89.7	558	90.4	1,666	90.5	0.607
Assesses completeness of placenta and membranes	486	90.8	517	74.9	502	81.4	1,505	81.7	<0.001
Assesses for perineal and vaginal lacerations	517	96.6	674	97.7	608	98.5	1,799	97.7	0.102

Partograph use

Complete answers for all items regarding partograph use were obtained for 986 observations in round 1 and 1,180 observations in round 2 (Tables 19a and 19b). More than 90% of the partographs had birth information recorded (time, delivery method, weight) in both rounds, but less than 1% of the partographs were properly/fully completed in round 2, compared to 9.4% in round 1. Only 1.8% had fetal heart rate, frequency/duration of contractions, and maternal pulse plotted every half-hour in round 2, compared to 12.2% in round 1. The high-dose group performed better on most indicators in round 1. In round 2, the high-dose group performed better than the other dose groups on plotting data at least every half-hour during labor and at recording birth information after delivery.

Table 19a: Observed Use of Partographs, Round 1

Task	High (n=359)		Medium (n=275)		Low (n=352)		Total (n=986)		*p*-value
	n	%	n	%	n	%	N	%	
Partograph initiated at appropriate time	288	80.2	236	85.8	275	78.1	799	81.0	0.045
Data plotted at least every half-hour during labor	19	5.3	1	0.4	100	28.4	120	12.2	<0.001
Birth information recorded after delivery	350	97.5	253	92.0	348	98.9	951	96.5	<0.001
Blood pressure recorded at least every four hours	86	24.0	20	7.3	108	30.7	214	21.7	<0.001
Filled in completely (1)	13	3.6	0	0	80	23.7	93	9.4	<0.001

Table 19b: Observed Use of Partographs, Round 2

Task	High (n=320)		Medium (n=414)		Low (n=446)		Total (n=1,180)		*p*-value
	n	%	n	%	n	%	N	%	
Partograph initiated at appropriate time	303	94.7	382	92.3	417	93.5	1,102	93.4	0.423
Data plotted at least every half-hour during labor	12	3.8	7	1.7	2	0.5	21	1.8	0.003
Birth information recorded after delivery	306	95.6	399	96.4	392	87.9	1,097	93.0	<0.001
Blood pressure recorded at least every four hours	22	6.9	45	10.9	47	10.5	114	9.7	0.140
Filled in completely (1)	4	1.3	4	1.0	2	0.5	10	0.85	0.465

Provider performance of infection prevention practices before and after delivery

Complete responses for all items regarding infection prevention behavior before delivery were obtained for 183 observations in round 1 and 202 observations in round 2 (Tables 20a and 20b). In both rounds more than 30% of providers washed their hands before conducting an examination during the first stage of labor, and more than 80% wore sterile gloves for vaginal examination. In round 1 53% wore protective clothing for delivery, compared to 30% in round 2. Round 1 providers in the low-dose group were more likely than providers in the other groups to wash their hands before performing an examination during the first stage of

labor and to wear protective clothing for delivery. In round 2, providers in the low-dose group were more likely to wear sterile gloves for vaginal examinations, and providers in the high dose group were more likely to wear protective clothing for delivery.

Table 20a: Performance of Infection Prevention Practices before Delivery, Round 1

Provider Practice	High (n=64)		Medium (n=59)		Low (n=60)		Total (n=183)		*p*-value
	n	%	n	%	n	%	N	%	
Washes hands before any examination in first stage of labor	15	23.4	23	39.0	31	51.7	69	37.7	0.005
Wears high-level disinfected or sterile gloves for vaginal exam	58	90.6	46	78.0	45	75.0	149	81.4	0.058
Puts on clean protective clothing in preparation for birth	25	39.1	31	52.5	41	68.3	97	53.0	0.005

Table 20b: Performance of Infection Prevention Practices before Delivery, Round 2

Provider Practice	High (n=61)		Medium (n=72)		Low (n=69)		Total (n=202)		*p*-value
	n	%	n	%	n	%	N	%	
Washes hands before any examination in first stage of labor	16	26.2	29	40.3	18	26.1	63	31.2	0.116
Wears high-level disinfected or sterile gloves for vaginal exam	50	82.0	56	77.8	66	95.7	172	85.2	0.008
Puts on clean protective clothing in preparation for birth	26	42.6	11	15.3	24	34.8	61	30.2	0.002

Complete data regarding provider performance of infection prevention behavior after delivery were obtained for 1,411 observations in round 1 and 1,967 observations in round 2 (Tables 21a and 21b). Notably, a much larger percentage of providers washed their hands after delivery than before the delivery. While almost all providers in both rounds disposed of sharps and waste appropriately and decontaminated equipment, only about 28% in round 1 and 60% in round 2 wiped their aprons with chlorhexidine wipes.

Nonbeneficial and nonindicated practices

Among the 1,747 observations in rounds 1 and 2,109 observations in round 2, more nonbeneficial behaviors were reported in round 1 (5.6%) compared to round 2 (2.7%) (Tables 22a and 22b). The most frequently observed nonbeneficial practices were holding the newborn upside down, applying fundal pressure, and stretching the perineum. There were very few reports of health workers conducting nonindicated practices in either round (0.7% in round 1 and 0.3% in round 2. More nonbeneficial practices were reported in the high-dose group in round 1 compared to the other two groups. There were no significant differences in reported nonbeneficial or nonindicated behaviors by dose in round 2.

Table 21a: Performance of Infection Prevention Practices after Delivery, Round 1, by Dose Group

Provider Practice	High (n=471)		Medium (n=431)		Low (n=509)		Total (n=1,411)		*p*-value
	n	%	n	%	n	%	N	%	
Disposes of all sharps in puncture-proof container immediately after use	470	99.8	428	99.3	479	94.1	1377	97.6	<0.001
Disposes of all contaminated waste in leakproof containers	427	90.7	376	86.2	488	95.9	1291	91.5	<0.001
Decontaminates all reusable instruments in 0.5% chlorine solution	411	87.3	396	91.9	472	92.7	1279	90.6	<0.008
Removes apron and wipes with 0.5% chlorine solution	106	22.5	62	14.4	237	46.6	405	28.7	<0.001
Washes hands thoroughly with soap and water	360	76.4	320	74.3	423	83.1	1103	78.2	<0.002

Table 21b: Performance of Infection Prevention Practices after Delivery, Round 2, by Dose Group

Practice	High (n=604)		Medium (n=695)		Low (n=668)		Total (n=1967)		*p*-value
	N	%	N	%	N	%	N	%	
Disposes of all sharps in puncture-proof container immediately after use	599	99.2	689	99.1	656	98.2	1944	98.8	0.179
Disposes of all contaminated waste in leak proof containers	590	97.7	598	86.0	574	85.9	1762	89.6	<0.001
Decontaminates all reusable instruments in 0.5% chlorine solution	559	92.6	483	69.5	626	93.7	1668	84.8	<0.001
Removes apron and wipes with 0.5% chlorine solution	398	65.9	413	59.4	369	55.2	1180	60.0	0.001
Washes hands thoroughly with soap and water	565	93.5	611	87.9	599	89.7	1775	90.2	0.002

Table 22a: Performance of Nonbeneficial and Nonindicated Practices, Round 1, by Dose Group

Negative practices	High		Medium		Low		Total		*p*-value
	n	%	n	%	n	%	N	%	
	n=577		*n= 551*		*n=619*		*N=1747*		
Nonbeneficial practices									
Use of enema	0	0	1	0.2	0	0	1	0.1	0.338
Pubic shaving	0	0	0	0	0	0	0	0	-
Applying fundal pressure	5	0.9	26	4.7	2	0.3	33	1.9	<0.001
Lavage of the uterus after delivery	2	0.4	0	0	1	0.2	3	0.2	0.371
Slapping newborn	1	0.2	1	0.2	2	0.3	4	0.2	0.830
Holding newborn upside down	25	4.3	5	0.9	5	0.8	35	2.0	<0.001
Milking the newborn's chest	8	1.4	2	0.4	4	0.7	14	0.8	0.135
Stretching of the perineum	7	1.2	3	0.5	9	1.5	19	1.1	0.306
Had at least one non-beneficial practice	46	8.0	37	6.7	21	3.4	104	5.6	0.002
Nonindicated practices									
Manual exploration of the uterus after delivery	2	0.4	0	0	1	0.2	3	0.2	0.371
Use of episiotomy	1	0.2	0	0	4	0.7	5	0.3	0.098
Aspiration of newborn mouth and nose at birth	0	0	1	0.2	0	0	1	0.1	0.338
Restricting food and fluids in labor	1	0.2	1	0.2	2	0.3	4	0.2	0.830
At least one non-indicated practice	4	0.7	2	0.4	7	1.1	13	0.7	0.308

Table 22b: Performance of Nonbeneficial and Nonindicated Practices, Round 2, by Dose Group

Negative practices	High		Medium		Low		Total		*p*-value
	n	%	n	%	n	%	N	%	
	n=635		*n= 742*		*n=732*		*N=2,109*		
Nonbeneficial									
Use of enema	-	-	-	-	-	-	-	-	-
Pubic shaving	-	-	-	-	-	-	-	-	-
Applying fundal pressure	1	0.2	11	1.5	7	1.0	19	0.9	0.034

Negative practices	High		Medium		Low		Total		*p*-value
	n	%	n	%	n	%	N	%	
	n=635		*n= 742*		*n=732*		*N=2,109*		
Lavage of the uterus after delivery	-	-	-	-	1	0.1	1	0.1	0.390
Slapping newborn	-	-	5	0.5	4	0.6	8	0.4	0.177
Holding newborn upside down	4	0.6	9	1.2	8	1.1	21	1.0	0.525
Milking the newborn's chest	3	0.5	2	0.3	6	0.8	11	0.5	0.334
Stretching of the perineum	3	0.5	5	0.7	5	0.7	13	0.6	0.857
Had at least one nonbeneficial practice	11	1.7	26	3.5	20	2.7	57	2.7	0.129
Nonindicated practices									
Manual exploration of the uterus after delivery	-	-	1	0.1	2	0.3	3	0.1	0.408
Use of episiotomy	-	-	-	-	2	0.3	2	0.1	0.152
Aspiration of newborn mouth and nose at birth	-	-	-	-	1	0.1	1	0.1	0.390
Restricting food and fluids in labor	-	-	1	0.1	-	-	1	0.1	0.398
At least one nonindicated practice	-	-	2	0.3	5	0.7	7	0.3	0.085

Immediate newborn care tasks

Complete data were obtained for 1,303 observations of immediate newborn care in round 1 and 1,800 observations in round 2 (Tables 23a and 23b). Close to 70% of newborns had delayed cord clamping after birth, as recommended, more than 95% were immediately dried, and almost all newborns were either placed skin-to-skin or wrapped in a dry towel in both round 1 and round 2. In round 1, 42% of women started breastfeeding their newborns within one hour after birth, compared to 78% in round 2. Newborns in the medium-dose group in round 1 were more likely to be placed skin-to-skin or wrapped in a dry towel and breastfed within the first hour. Delayed cord clamping and cutting the cord with a clean blade were more prevalent in the high-dose group in round 1. In round 2, immediately drying the baby, delayed cord clamping, and initiation of breastfeeding in the first hour were more common in the low-dose group than the other groups.

Table 23a: Performance of Newborn Care Tasks for Babies Breathing at Birth, Round 1, by Dose Group

Provider Task	High (n=339)		Medium (n=409)		Low (n=495)		Total (n=1303)		*p*-value
	n	%	n	%	n	%	N	%	
Immediately dries baby with towel	383	96.0	393	96.1	473	95.6	1,249	95.9	0.911
Discards wet towel	316	79.2	321	78.5	408	82.4	1,045	80.2	0.279
Places newborn skin-to-skin with mother	234	58.7	301	73.6	339	68.5	874	67.1	<0.001
Places skin-to-skin or wrapped with towel	393	98.5	406	99.3	493	99.6	1,292	99.2	0.194
Ties/clamps cord when pulsations stop, or within 2–3 minutes after birth (but not immediately after birth)	292	73.2	260	63.6	343	69.3	895	68.7	0.012
Cuts cord with clean blade	388	97.2	358	87.5	474	95.8	1,220	93.6	<0.001
Initiate breast feeding within the first hour	141	35.3	279	56.4	132	32.3	552	42.4	<0.001

Table 23b: Performance of Newborn Care Tasks for Babies Breathing at Birth, Round 2, by Dose Group

Provider Task	High (n=550)		Medium (n=637)		Low (n=613)		Total (n=1,800)		*p*-value
	n	%	n	%	n	%	N	%	
Immediately dries baby with towel	541	98.4	598	93.9	610	99.5	1,749	97.2	<0.001
Discards wet towel	521	94.7	548	86.0	546	89.1	1,615	89.7	<0.001
Places newborn skin-to-skin with mother	382	69.5	457	71.7	447	72.9	1,286	71.4	0.417
Placed skin-to-skin or wrapped with towel	543	100.0	633	99.4	611	99.7	1,775	99.0	0.003

Provider Task	High (n=550)		Medium (n=637)		Low (n=613)		Total (n=1,800)		*p*-value
	n	%	n	%	n	%	N	%	
Ties/clamps cord when pulsations stop, or within 2–3 minutes after birth (but not immediately after birth)	371	67.5	412	64.7	488	79.6	1,271	70.6	<0.001
Cuts cord with clean blade	437	79.5	532	83.5	436	71.1	1,405	78.1	<0.001
Initiate breast feeding within the first hour	388	70.6	479	75.2	543	88.6	1,410	78.3	<0.001

Newborn asphyxia management

Observation of neonatal asphyxia management in round 1

Among the 1,747 babies that had valid answers pertaining to whether they were breathing at birth and the management of birth asphyxia, 88, 46, and 59 newborns in the high-, medium-, and low-dose intervention groups were found not to be breathing at birth (a total of 193 newborns).

Among the babies that were not breathing at birth, 84 (95.5%) newborns survived in the high-dose arm, 42 (91.3%) survived in the medium-dose arm, and 54 (91.5%) survived in the low-dose arm (Figures 1, 2, and 3). Sixty-six newborns in the high-dose group (75%), 32 in the medium-dose group (69.6%), and 47 in the low-dose group (79.7%) received stimulation. Among the newborns receiving stimulation, 63.6%, 37.5%, and 52.2% in the high-, medium-, and low-dose groups, respectively, started breathing after stimulation.

Bag and mask were administered to 23 of 24 non-breathing babies who were not revived after initial stimulation (95.8%) in the high-dose group, 19 out of 20 non-breathing babies (95%) in the medium-dose group, and 20 out of 22 non-breathing babies (90.9%) in the low-dose group. After the bag-and-mask intervention, 21 of 23 babies (91.3%) in the high-dose group, 18 of 19 (94.7%) in the medium-dose group, and 18 of 20 (90%) in the low-dose group survived. The differences in proportion between the groups were not statistically significant for any outcome.

Observation of newborn asphyxia management in round 2

Out of the 2,093 babies that had valid answers pertaining to whether they were breathing at birth and the management of birth asphyxia, 91, 90, and 99 newborns in the high-, medium-, and low-dose intervention groups, respectively, were found not to be breathing at birth (a total of 280 newborns).

Among the newborns that were not breathing at birth, 88 (96.7%) in the high-dose arm survived, 87 (95.6%) in the medium-dose arm survived, and 92 (92.9%) in the low-dose arm survived (Figures 5, 6, and 7). Sixty-eight newborns in the high-dose group (74.7%), 74 in the medium-dose group (81.1%), and 82 in the low-dose group (82.9%) received stimulation. Among the newborns receiving stimulation, 48.5%, 63.5%, and 52.4% of the newborns in the high-, medium-, and low-dose group, respectively, started breathing after stimulation.

Bag and mask were administered to 29 out of 35 non-breathing babies who were not revived after initial stimulation (82.9%) in the high-dose group, 25 out of 26 non-breathing babies (96.2%) in the medium-dose group. and 32 out of 39 non-breathing babies (82.1%) in the low-dose group.

After the bag-and-mask intervention, 28 of 29 babies (91.1%) in the high-dose group, 22 of 25 babies (88%) in the medium-dose group, and 27 of 32 babies (84.4%) survived. The differences in proportion between the dose groups were not statistically significant.

Figure 1: Management of Asphyxiated Newborns in High-Dose Intervention Facilities in Round 1

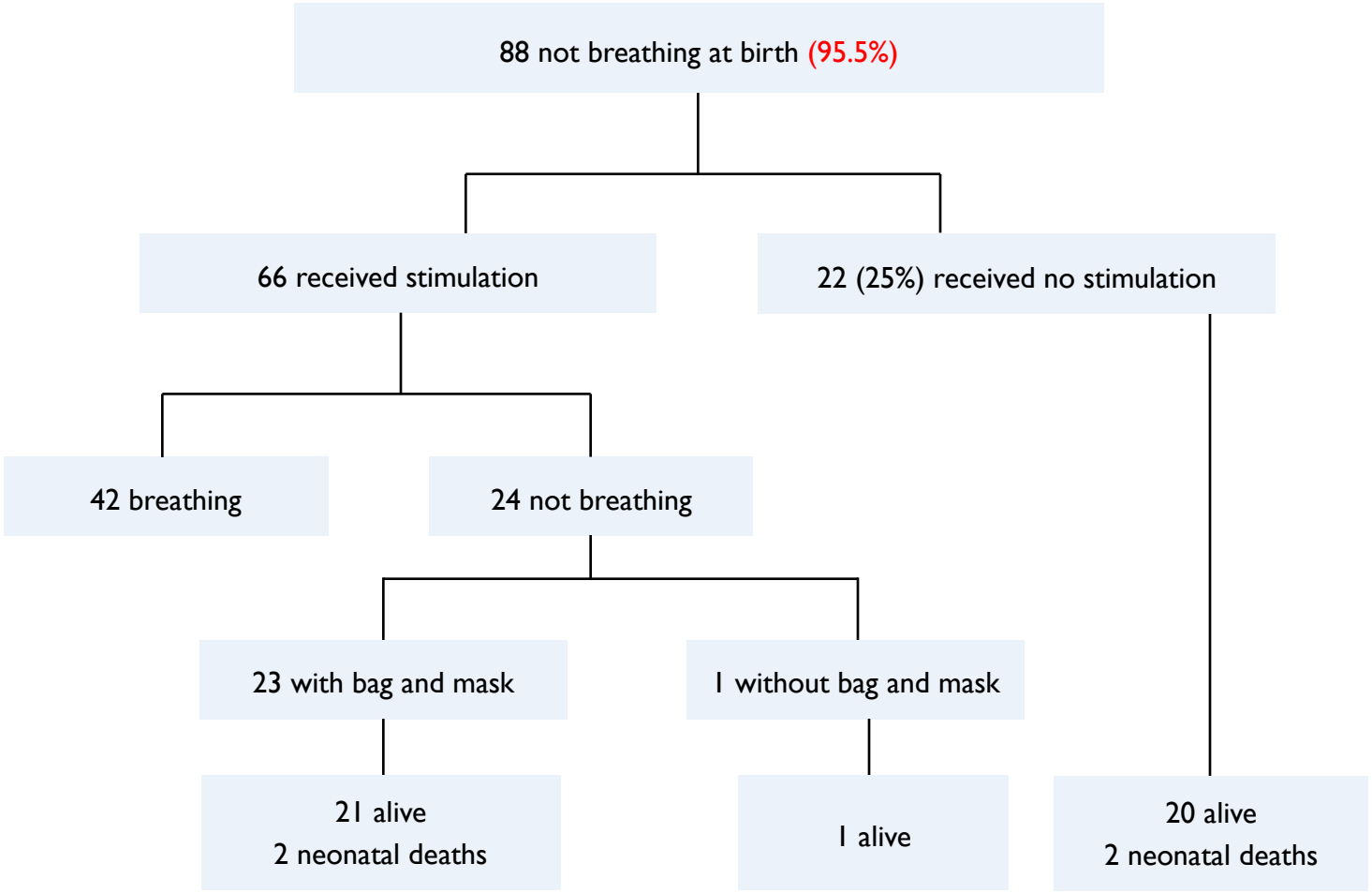


Figure 2: Management of Asphyxiated Newborns in Medium-Dose Intervention Facilities in Round 1

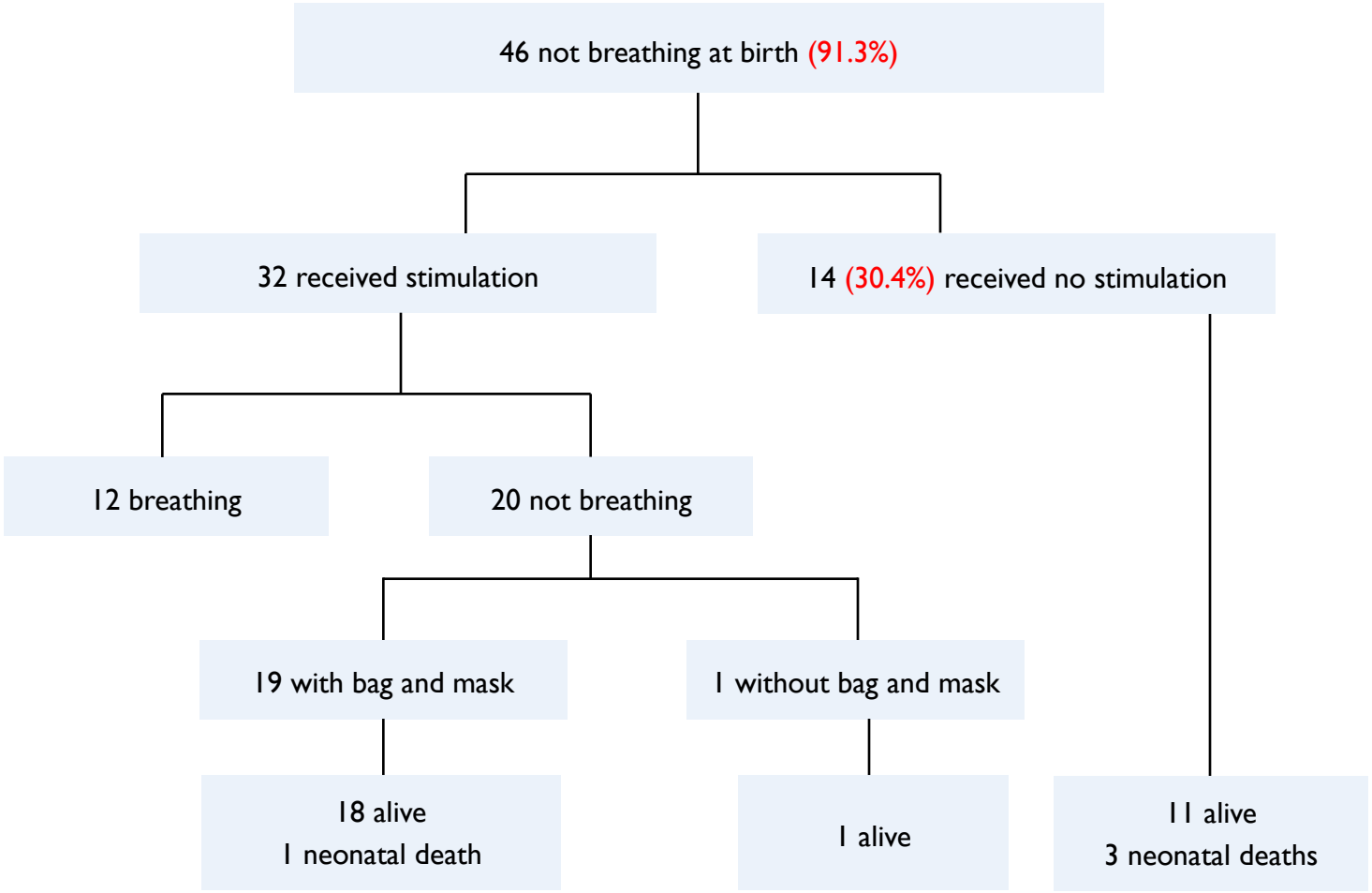


Figure 3: Management of Asphyxiated Newborns in Low-Dose Intervention Facilities in Round 1

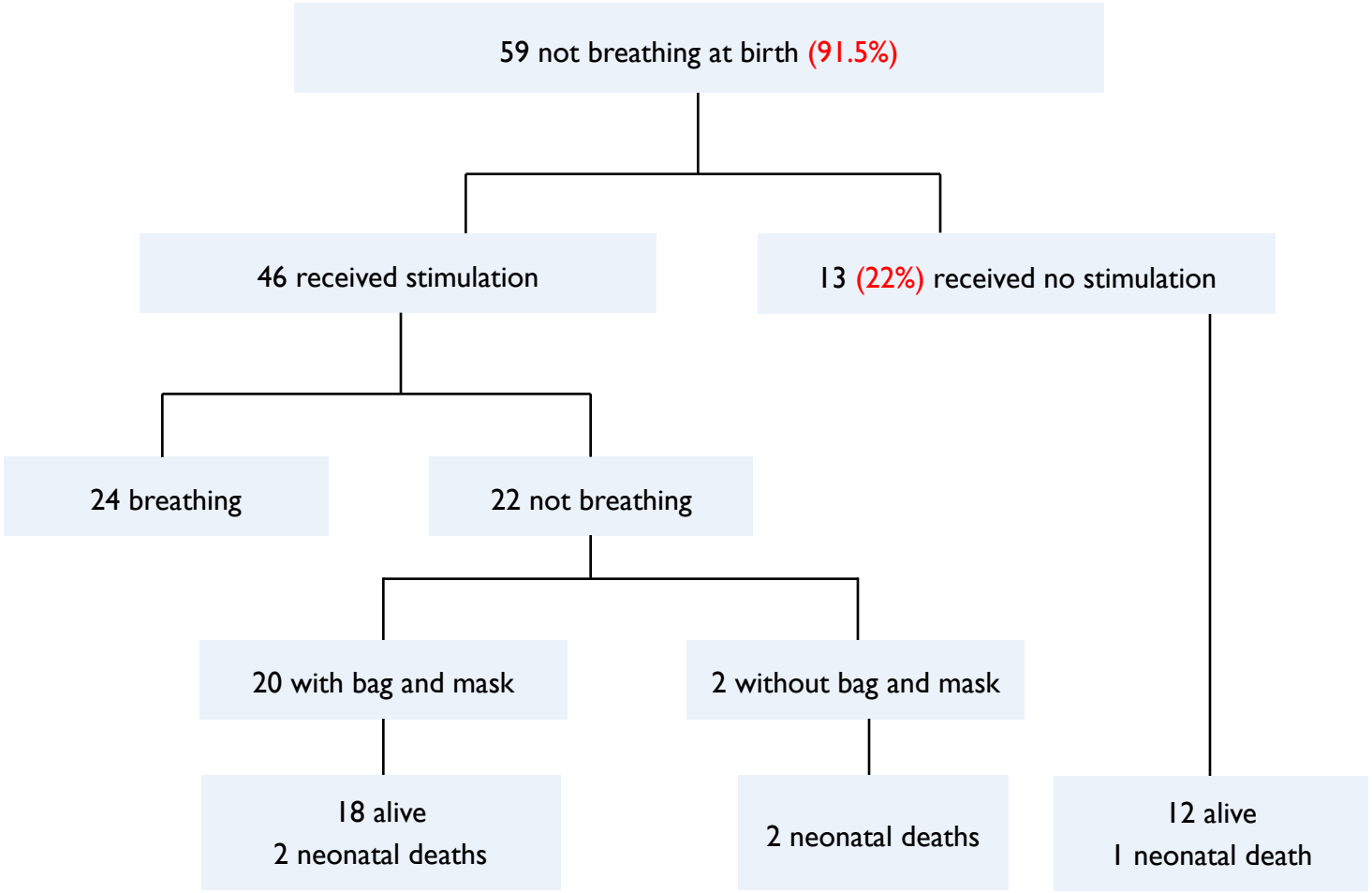


Figure 4: Overall Management of Asphyxiated Newborns in Round 1

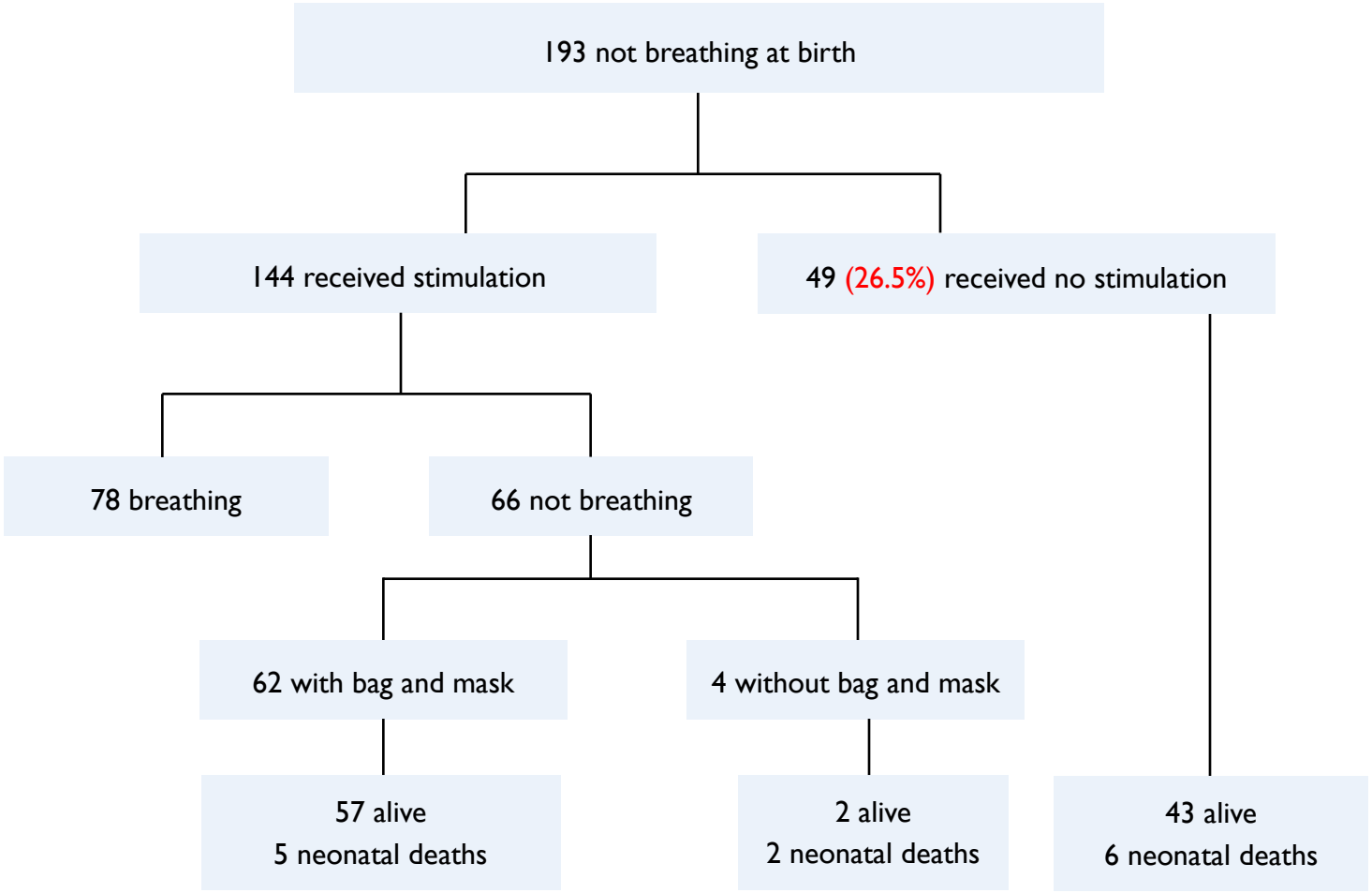


Figure 5: Management of Asphyxiated Newborns in High-Dose Intervention Facilities in Round 2

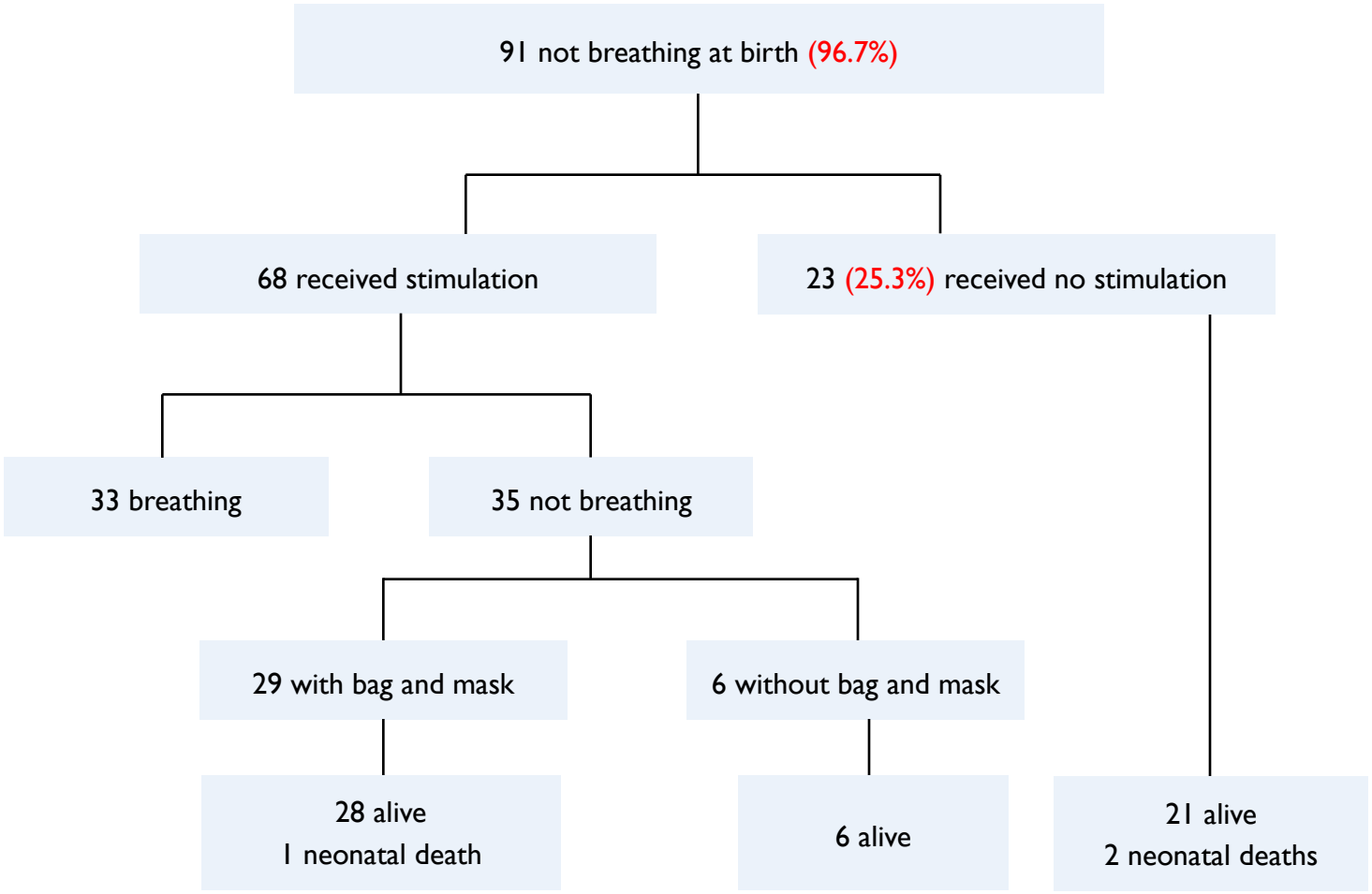


Figure 6: Management of Asphyxiated Newborns in Medium-Dose Intervention Facilities in Round 2

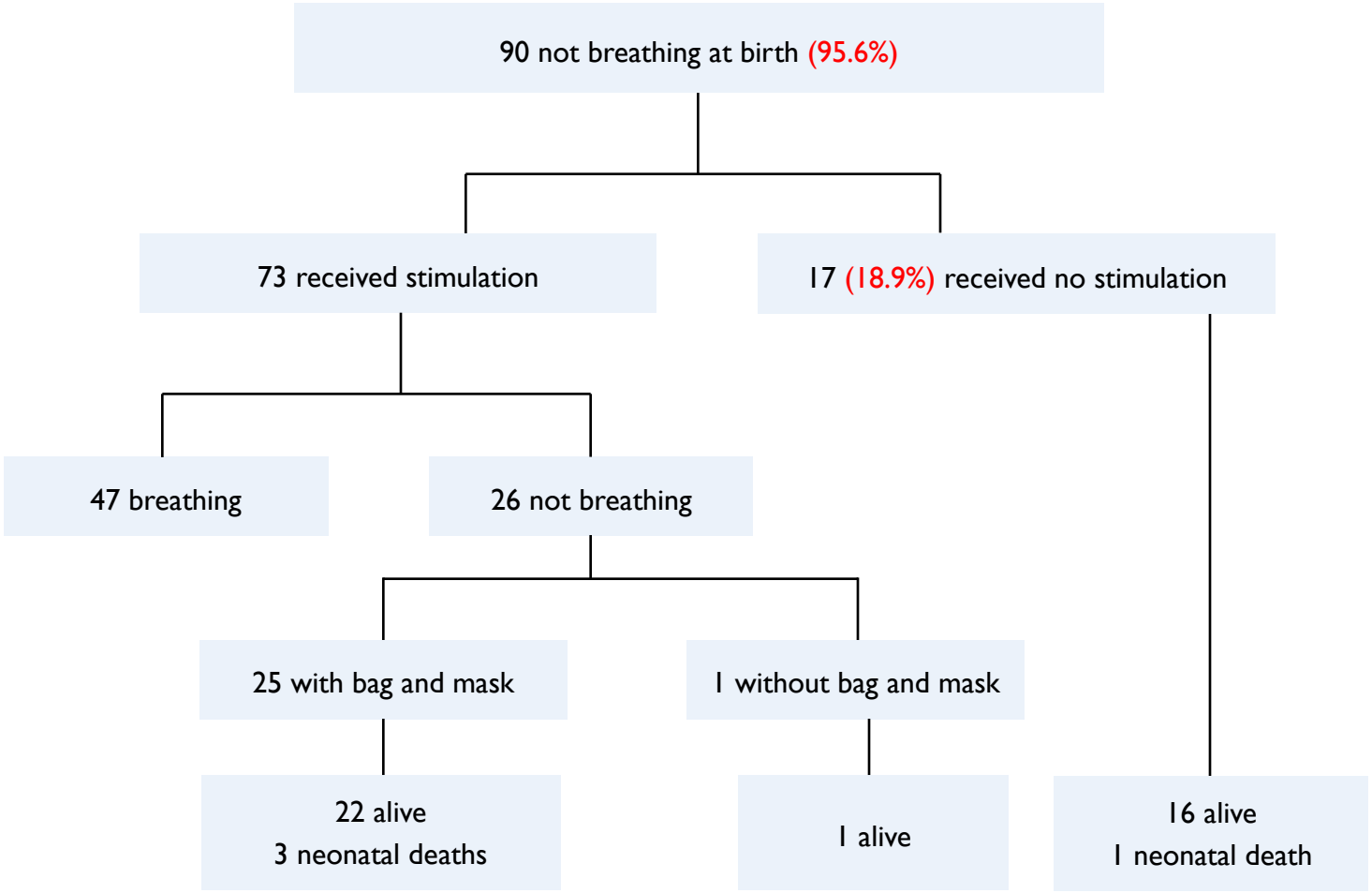


Figure 7: Management of Asphyxiated Newborns in Low-Dose Intervention Facilities in Round 2

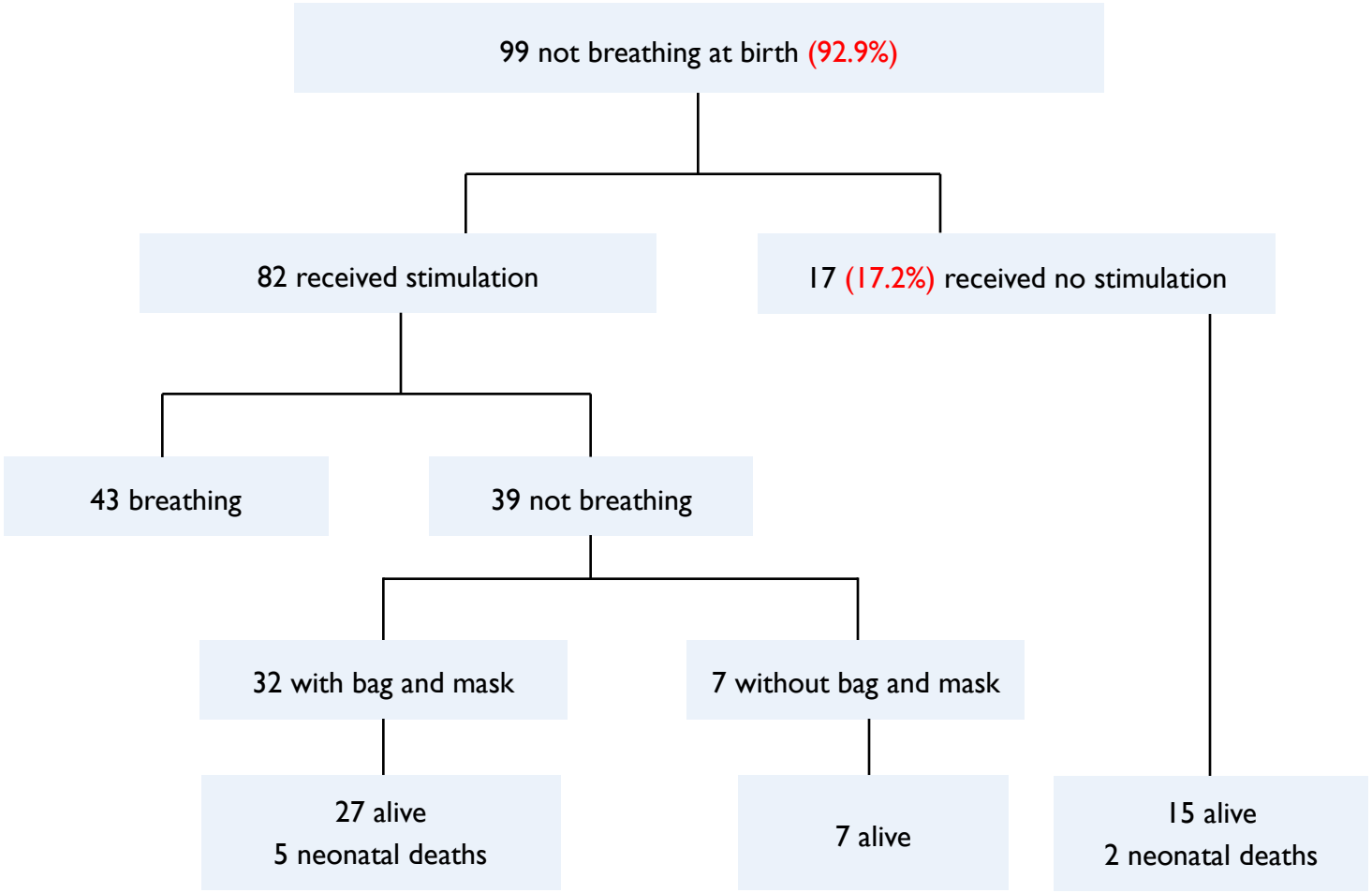
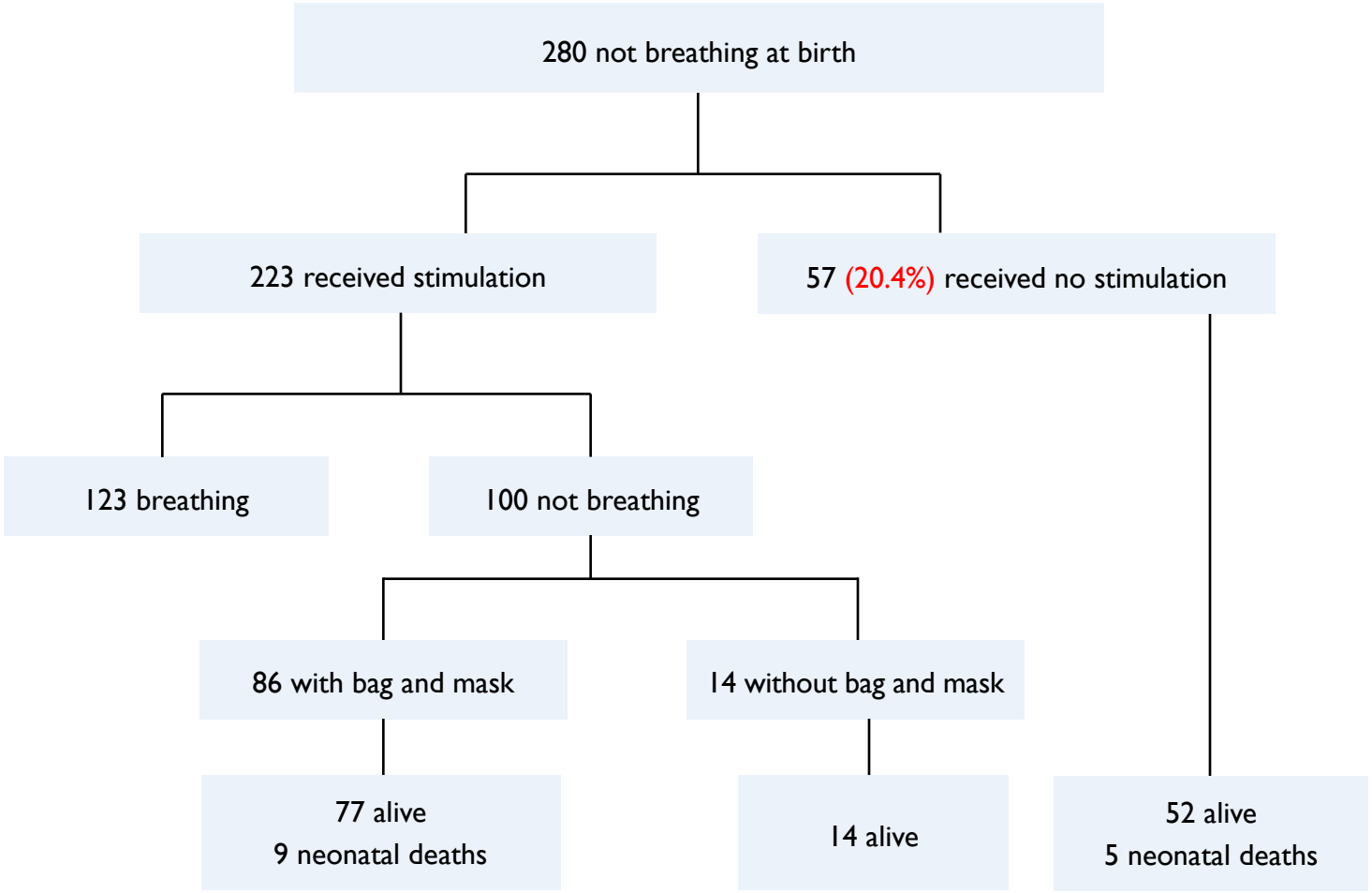


Figure 8: Overall Management of Asphyxiated Newborns in Round 2



Results Summary

Consistent with the national distribution of health workers providing maternal and newborn health services in Malawi, about 60% of all health providers interviewed in both round 1 and round 2 were nurse/midwife technicians. More round 2 health workers (68.4%) than round 1 health workers (59.7%) received training in subjects related to newborn care in the past two years. Efforts by the MOH and the Nurses and Midwives Council of Malawi resulted in the inclusion of HBB training in nurse/midwife colleges between 2012 and 2013. Many of the trained health workers are nurse/midwife technicians (34.8% and 41.8% in rounds 1 and 2, respectively). There were no differences in health provider training by dose group in either round 1 or round 2.

The majority of supervisors checked the records of their supervisees (81.7% and 88.8% in rounds 1 and 2, respectively) and observed their supervisees' work (78.6% and 87.3% in rounds 1 and 2, respectively). However, only slightly more than one- third of supervisees (39.7% and 41.5% in rounds 1 and 2, respectively) had received any written comments from their supervisors. Most supervisees were able to discuss problems with their supervisor (86% and 90% in rounds 1 and 2, respectively) and were given verbal feedback (82.2% and 88.6% in rounds 1 and 2, respectively). In round 1 more supervisors in the medium-dose group than the other groups observed their supervisees' work. There were no obvious differences in supervision by dose group in round 2.

In clinical simulations, the mean number of steps (out of 10 possible) that were correctly completed was higher in round 2 (mean 7.1; SD 2.0) compared to round 1 (mean 6.2; SD 2.4). The overall mean score was higher in the high-dose arm than the medium-dose arm (p=0.041) in round 1. The overall mean score was not different by dose group in round 2; however, health workers in the high-dose arm scored higher on testing the function of the bag and mask and squeezing the bag harder.

The providers were asked to complete two role-play case scenarios using the NeoNatalie model (newborn simulator). The mean number of steps performed correctly was lower in round 1 than in round 2 in both scenarios. Health workers in the high-dose arm had higher overall scores compared to the medium- and low-dose arms in round 1. In round 2, while the health workers in the medium-dose group scored higher on recognizing when a baby was not crying, calling for help, continuing ventilation, the overall mean score was not statistically significantly different from the high- or low-dose groups.

The proportion of facilities that had HBB guidelines and the equipment required for newborn care increased over time. This is likely related to provision of newborn supplies and equipment as part of the national rollout of HBB. The distribution was not different by dose group, except for suction bulbs for mucus extraction, which were more common in the high-dose group in round 1 and more common in the medium-dose group in round 2.

Health workers in the high-dose group performed better on some aspects of infection prevention (disposing of all contaminated waste, wiping their aprons, and washing their hands), partograph use (plotting data at least every half-hour during labor and recording birth information after delivery), prevention of postpartum hemorrhage (assessing placenta and membranes), and communication and support (explaining procedures to the woman).

Observations of communication and respectful, humanistic care before and during labor indicated low quality in this aspect of care in general. In both round 1 and round 2 more than 85% of mothers were greeted

respectfully, but less than 20% received encouragement to have a support person in attendance at delivery. In both rounds, less than 30% of women were asked whether they had any questions for the health provider and less than 30% were provided with drapes. Less than 60% were encouraged to hydrate and eat during labor. The only differences in performance by dose group were that providers in the high-dose arm more often informed the pregnant woman of findings in round 1 and more often explained procedures to the woman in round 2.

Very few nonbeneficial and nonindicated practices were reported, with the most frequent being holding the newborn upside down, applying fundal pressure, and stretching the perineum. Again, there were no significant differences in reported nonbeneficial or nonindicated behaviors by dose group in either round, although more nonbeneficial practices were reported in round 1 than round 2.

Contrary to expectations, the key elements of immediate newborn care—immediately drying the baby, delayed cord clamping, and initiation of breastfeeding in the first hour—were more observed more frequently in the low-dose group than in the other groups in round 2. Similarly, in round 1, newborns were more likely to be placed skin-to-skin or wrapped in a dry towel and breastfed within the first hour in the medium-dose group compared to the high-dose group.

Out of the 1,747 babies in round 1 for whom valid answers were obtained pertaining to whether they were breathing at birth and the management of birth asphyxia, 88, 46, and 59 the high-, medium-, and low-dose intervention groups, respectively, were found not to be breathing at birth (a total of 193 newborns).

Among the newborns who were not breathing at birth in round 1, 84 (95.5%) in the high-dose arm, 42 (91.3%) in the medium-dose arm, and 54 (91.5%) in the low-dose arm survived (Figures 1, 2, and 3). Sixty-six (75%) in the high-dose arm, 32 (69.6%) in the medium-dose in the medium-dose arm, and 47 (79.7%) in the low-dose received stimulation. After stimulation, 63.6%, 37.5%, and 52.2% of the newborns in the high-, medium-, and low-dose group, respectively, started breathing after stimulation.

Among those who were not breathing after initial stimulation, 23 of 24 babies (95.8%) in the high-dose group, 19 of 20 (95%) in the medium-dose group, and 20 of 22 (90.9%) in the low-dose group received bag-and-mask.

After the bag-and-mask intervention, 21 of 23 (91.3%) babies in the high-dose group, 18 of 19 (94.7%) babies in the medium-dose group, and 18 of 20 (90%) babies in the low-dose group survived. The differences in proportion between the groups were not statistically significant for any outcome.

Out of the 2,093 babies in round 2 for whom valid answers were obtained pertaining to whether they were breathing at birth and the management of birth asphyxia, 91, 90, and 99 newborns in the high-, medium-, and low-dose intervention groups were found not to be breathing at birth (a total of 280 newborns).

Among the newborns who were not breathing at birth in round 2, 88 (96.7%) in the high-dose arm, 87 (95.6%) in the medium-dose arm, and 92 (92.9%) in the low-dose arm survived (Figures 5, 6, and 7). Sixty-eight in the high-dose group (74.7%), 74 in the medium-dose group (81.1%), and 82 in the low-dose group (82.9%) received stimulation. After stimulation, 48.5%, 63.5%, and 52.4% of the newborns in the high,- medium-, and low-dose groups, respectively, started breathing.

Among those who were not breathing after stimulation, 29 of 35 (82.9%) babies in the high-dose group, 25 of 26 (96.2%) in the medium-dose group, and 32 of 39 (82.1%) in the low-dose group received a bag-and-mask intervention.

After the bag-and-mask intervention, 28 of the 29 babies in the high-dose arm (91.1%), 22 of the 25 babies in the medium-dose arm (88%), and 27 of the 32 babies in the low-dose arm (84.4%) survived. The differences in proportion between the groups were not statistically significant for any outcome.

Discussion

Overall improvement in health worker training and knowledge, equipment availability, and management of labor and delivery, including newborn care, occurred over the two rounds of data collection in Malawi. However, there were no significant differences between the high-, medium-, and low-dose groups in the two rounds. Although health worker performance in round 2 was better than round 1, a majority of findings in this report indicate the absence of significant differences by dose group between the two rounds. These results were consistent irrespective of how districts were grouped. We conducted sensitivity analyses by regrouping the districts and analyzing the data in the following two ways, in addition to comparing the dose-response groups:

1. "Intention to treat" analyses were conducted in which the 13 districts identified as intervention districts during round 1 were grouped as intervention districts for round 2 as well, with the remaining 14 districts grouped comparison districts.
2. "Process documentation" analyses were conducted in which the districts were classified into two groups based on the timing of their HBB training and availability of training and implementation equipment. One group included districts that received training and implementation equipment immediately after training (IAT) or received training equipment IAT but implementation equipment one to 24 months after training. The other group included districts that received training equipment IAT but never received implementation equipment or received both training and implementation equipment one to 12 months after initial HBB training.

The data presented in this report were collected for the first and second round of evaluation of the nationwide scale-up of the HBB initiative in Malawi. The overall findings of second round are similar to the first round, with significant differences found between comparison groups in some aspects of health worker knowledge and skills, but no difference in actual performance while managing newborns who were not breathing at birth. There are a few possible explanations for these findings:

- The scale-up was implemented in a phased manner, but as identified in the HBB process documentation report, a majority of the facilities had a relative short duration of exposure to the HBB initiative due to delays in training and equipment availability. The nationwide scope and short duration of exposure presented logistical and managerial challenges to ensuring an adequate supply of the required equipment, guidelines, and appropriately trained staff in the facilities, which in turn might be reflected in the lower scores even in the high-dose group.
- More specifically, the short duration of implementation and limited supervision are likely to be associated with limited opportunities for health providers to practice the newly acquired skills and assimilate the new knowledge and skills into actual performance.
- The lack of significant differences between different dose groups might also be attributable to the transfer of HBB-trained health workers between high-, medium-, and low-dose facilities. This "contamination" might be associated with the similar distribution of HBB skills among the three dose groups.

Several studies have reported on the effectiveness of training health workers in newborn resuscitation in reducing neonatal mortality attributable to birth asphyxia (Deorari et al. 2001; Carlo 2010; Vakrilova, Elleau, and Sluncheva 2005; Msemo et al. 2013). However, these studies also highlighted the need for implementation research as they were not nested within national health systems in developing countries (Lawn et al. 2011). While other studies use facility records instead of direct observations to evaluate HBB, we used direct observation to measure health workers performance in managing newborns who were not

breathing at birth. Findings from this study provide evidence on the performance of national-level delivery systems in achieving adequate intervention coverage and quality of a potentially efficacious intervention to reduce the number of newborn deaths due to birth asphyxia.

Recommendations and Next Steps

The findings from this evaluation suggest some recommendations for the Ministry of Health and donors to improve newborn care in Malawi. Due to the lack of major differences by dose group, the following recommendations and proposed steps apply to all districts and have been organized according to different domains of HBB intervention.

Training

- Partners should continue incorporating HBB into pre-service training at the remaining health worker training institutions in Malawi and expand the training to all skilled birth assistants (instead of focusing only on nurses and midwives) to ensure complete coverage. All cadres providing services to women in labor (medical assistants, clinical officers, doctors, nurse-midwives) should be included in the HBB training and mentoring programs to ensure maximum coverage and prevent missed opportunities in HBB.
- During training, facilitators should emphasize to the trainees and District Health Management Team members the importance of transferring their skills to other providers at their health facilities who might not receive formal HBB training. This will help to ensure that all providers in the facilities implement HBB.

Follow-up of providers after training

- Following the HBB trainings, district-level plans should be developed to assess provider skills and provide onsite coaching and mentoring at six weeks, three months, and six months to promote retention of skills. The plans should be structured to include coaching and mentoring sessions for providers who did not attend training.
- More emphasis needs to be placed on routine care of the newborn. During onsite coaching and mentoring, emphasis should be placed on providers internalizing the importance of discarding the wet towel, placing the baby in skin-to-skin contact with the mother, covering the baby with a dry towel, and initiating breastfeeding within one hour of birth. These are low-cost, high-impact interventions that contribute to reducing neonatal mortality. During resuscitation, emphasis should be placed on stimulation of the newborn, which seemed to be a major challenge in all facilities across the dose groups.
- District nursing officers and district health officers should be involved in introducing the training program to the districts, and agreements should be made regarding the rotation of the trained providers and handling of new health care workers. The districts should be helped to develop and implement schedules for weekly practice sessions for new providers coming to the maternity department.
- The district health officer, district nursing officer, and Safe Motherhood coordinator should include HBB in their routine supervision and coaching visits.
- The Reproductive Health Division (RHD) of the MOH and partners should work toward ensuring that each facility has a NeoNatalie for practice sessions to promote the acquisition and maintenance of skills.
- Mentors from the RHD and partners should structure integrated quarterly follow-up and supportive visits to the districts to support the district-based mentors and service providers. The follow-up should include assessing provider skills using the NeoNatalie or actual observation of and coaching on deliveries and assessing documentation, reporting, and utilization of data for decision making at district level.

Availability of guidelines and equipment

- The MOH through RHD and partners should advocate for procurement and distribution of HBB equipment and supplies through Central Medical Stores Trust to ensure that HBB equipment is always available.
- The RHD and partners should work together to make available HBB guidelines and guidelines for normal delivery in all facilities with maternity services. This will give providers reference materials to use when they are providing care.

Supervision

- It is important to have close supervision and mentorship at the district and facility levels, not only from the national headquarters.
- Offer mentoring and capacity strengthening of the facility in-charges and supervisors on how to conduct supervision, as opposed to routine ward count and rounds. This training could be reinforced through a job aid/tool for supervisors. Supervisors' HBB knowledge and skills also need to be improved to ensure that the supervisors are adequately knowledgeable about HBB and know the areas to look out for during supervision.

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