Increase in Newborns Ventilated Within the First Minute of Life and Reduced Mortality After Clinical Data-Guided Simulation Training

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Introduction: Birth asphyxia–related deaths is a major global concern. Rapid initiation of ventilation within the "Golden Minute" is important for intact survival but reported to be challenging, especially in low-/middle-income countries. Helping Babies Breathe (HBB) is a simulation-based training program for newborn resuscitation. The aim of this HBB quality improvement (QI) intervention was to decrease time from birth to ventilation and document potential changes in perinatal outcomes.

Method: Prospective observational QI study in a rural Tanzanian hospital, October 1, 2017, to August 31, 2021, first-year baseline, second-year QI/simulation intervention, and 2-year postintervention. Trained research assistants observed wide-ranging information from all births (N = 12,938). The intervention included monthly targeted HBB simulation training addressing documented gaps in clinical care, clinical debriefings, and feedback meetings.

Results: During the QI/simulation intervention, 68.5% nonbreathing newborns were ventilated within 60 seconds after birth compared with 15.8% during baseline and 42.2% and 28.9% during the 2 postintervention years ($P < 0.001$). Time to first ventilation decreased from median 101 (quartiles 72–150) to 55 (45–67) seconds ($P < 0.001$), before increasing to 67 (49–97) and 85 (57–133) seconds after intervention. More nonbreathing newborns were ventilated in the intervention period (12.9%) compared with baseline (8.5%) and the postintervention years (10.6% and 9.4%) ($P < 0.001$). Assumed fresh stillborns decreased significantly from baseline to intervention (3.2%–0.7%) ($P = 0.013$).

Conclusions: This QI study demonstrates an increase in nonbreathing newborns being ventilated within the Golden Minute and a significant reduction in fresh stillborns after introduction of an HBB QI/simulation intervention. Improvements are partially reversed after intervention, highlighting the need for continuous simulation-based training and research into QI efforts essential for sustainable changes.
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Key Words: Clinical performance, Helping Babies Breathe, Second Edition, low-resource setting, newborn mortality, newborn resuscitation, perinatal mortality, patient outcome, simulation-based training.

Each year, 1.5 million fresh stillbirths (FSBs) and early newborn deaths occur because of intrapartum related events.[1,2] Timely and skilled resuscitation of the nonbreathing newborns could prevent the majority of these deaths.[3] Initiating bag-mask ventilation (BMV) within 60 seconds is recommended by newborn resuscitation guidelines,[4] and the risk of death and/or morbidity, in a low-resource setting, increased with 16% for every 30-second delay in start of ventilation after birth.[5] However, it remains a huge challenge to achieve initiation of BMV within the so-called Golden Minute.[6–10] A recent study of nearly 23,000 births from 5 public hospitals in high mortality burden countries found only 1% of nonbreathing newborns receiving ventilation within 60 seconds after birth.[6] A tertiary hospital in Nepal managed to increase the proportion of nonbreathing newborns receiving BMV within the Golden Minute by 83.9% after implementing a quality improvement (QI) intervention, and the researchers address the need for studies on similar interventions from district hospitals.[11]

Helping Babies Breathe (HBB) is a simulation-based training program in basic newborn resuscitation.[12] Helping Babies Breathe is endorsed by the World Health Organization and introduced in more than 80 low-/middle-income countries worldwide.[13] The program was launched in 2009, and several studies have shown reduced early neonatal mortality and FSB

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Data may be available upon reasonable request.

The study was approved by the National Institute for Medical Research, Tanzania (NIMR/HQ/R.8a/Vol.IX/3852) and the Regional Committee for Medical and Health Research Ethics, Western Norway (ref.no. 172126). Informed consent from the mothers was not required by the ethical committees due to the descriptive quality improvement study design.

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after implementation of HBB, First Edition.[8,11,14–16] Still, challenges of sustained changes have been identified, and to further improve implementation and sustainability of the training program, the HBB, Second Edition, was launched in 2016.[9,14,17] Moreover, in 2017, 10 essential action points for better implementation of the Helping Babies and Mothers Survive training program were formulated.[17] These included focus on local champions, local systems for low-dose high-frequency simulation training, facility-level perinatal QI teams, and systems for collecting clinical data to drive local QI. There is a need to study whether a combination of such simulation and implementation strategies lead to changes in clinical practice and patient outcome over time.[14]

Haydom Lutheran Hospital in rural Tanzania has practiced HBB simulation-based training since 2010.[16] However, mean time to start BMV of nonbreathing newborns has been constantly approximately 2 minutes. A previous study investigating the effect of local champions to motivate for simulation-based training demonstrated improved ventilation of nonbreathing newborns and reduced time to start BMV from approximately 2 minutes to 100 seconds.[18] Still, only 14.6% of nonbreathing newborns received BMV within the first minute as recommended. To increase the numbers of nonbreathing newborns receiving BMV within the Golden Minute, a QI/simulation intervention consistent with the HBB, Second Edition started September 1, 2018, named "The Golden Minute Campaign." The goal was to ventilate 70% of nonbreathing newborns within the first minute of life. The study aimed to document potential changes in time from birth to start of ventilation and in perinatal outcomes after implementation of this QI/simulation intervention.

METHODS

This was a prospective 4-year observational QI study including all deliveries at Haydom Lutheran Hospital, from October 1, 2017, through August 31, 2021. All deliveries were observed by research assistants and all live births and FSB were included in the analysis.

Study Setting

Haydom Lutheran Hospital is a rural referral hospital in Northern Tanzania that serves a population of approximately 2 million people and had 3000 to 3500 deliveries, on average, annually during the study period. Deliveries and newborn resuscitations are mainly conducted by 18 to 22 midwives working 2 to 3 on every shift, with physicians on-call. In addition, student nurses conduct some deliveries and resuscitations. The hospital experiences a high turnover of midwives due to new government employment opportunities every midyear, leading to experienced midwives leaving and newly educated midwives starting at the end of each year.

Since introduction of HBB in 2010, regular simulation-based skill training has been conducted.[19] Since September 2016, the NeoNatalie Live simulator (Laerdal Global Health) with variable lung compliance, realistic tactile appearance, and automated feedback[20] has been available in the labor ward for individual self-guided skill training. NeoNatalie Live enables healthcare workers to practice essential technical skills such as proper head tilt, adequate ventilation pressure and frequency, continuous ventilation, and reduction of mask leaks.[18]

In October 2017, "local champions" were appointed to encourage midwives to continue frequent simulation training. The champions were junior midwives, carefully selected by the management according to their personality traits and engagement in the ward. They did not receive any formal simulation facilitator training at that time. Nevertheless, in the baseline period of this study, October 1, 2017, to August 31, 2018, 8451 individual skill trainings and 307 scenario team trainings were conducted.[21] Figure 1 presents an overview of simulation-based training at the hospital, before and throughout this study period.

Intervention

The Golden Minute Campaign started September 1, 2018, and remained through August 31, 2019. Before launching the campaign, the local champions received a 4-day adopted EU Sim Level 1 Train-the-Trainer simulation course[22] and were appointed simulation facilitators. We thought that this would improve the quality of the team scenario simulation trainings and enable the trained simulation facilitators/local champions to continuously adjust training focus (learning objectives) to address learning needs as documented in clinical performance data. Several QI efforts were introduced to support this linking between clinical data and training, create awareness and consensus among staff, and establish a sustainable system for QI. The Golden Minute QI/simulation interventions are summarized in Table 1.

During the intervention period, the local champions arranged monthly team scenario simulation training targeting gaps in real-life resuscitations with a special focus on reducing time from birth to start BMV. Nontechnical skills, including decision making, communication, teamwork, and leadership, were also addressed. The team trainings were conducted in situ at labor ward. The sessions continued for 1.5 to 2 hours and involved 3 participants and 1 local champion. Initiating the training, a short briefing with information about the scenario and the learning objectives were provided. Learning objectives

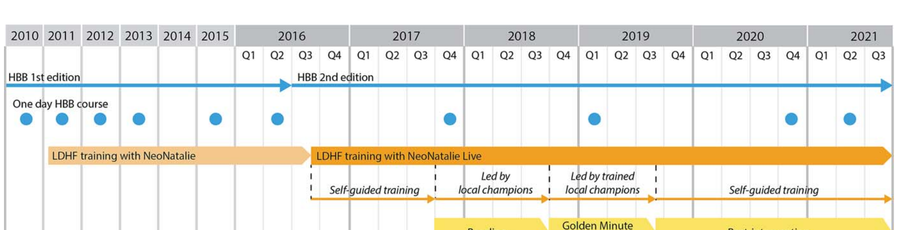

FIGURE 1. Simulation-based training at Haydom Lutheran Hospital 2010–2021. LDHF, low-dose high-frequency training; Local Champions, dedicated midwives in charge of facilitation and motivation for one-site training in HBB, Second Edition. (Modified from source: Vadla et al.[18] Reprinted according to Creative Commons Attribution 4.0 International License).

TABLE 1. The Golden Minute Campaign; Activities, Responsible Part, and Participants

Activity	Description	Responsible	Participants
Train-the-trainer simulation course to become simulation "facilitator"	EUsim level 1 course enabling the local champions to start running simulation-based scenario training, emphasizing feedback relevant for learning in a safe and constructive atmosphere.	SAFER-Stavanger	Local champions
QI monthly meetings	Clinical data were presented by one of the local champions. Implementation of action points agreed upon in previous QI meetings was evaluated, and further potential improvements were discussed until consensus on new action points was reached. Action points included increased awareness and knowledge of important aspects of newborn resuscitation; increased preparedness for resuscitation, training of new staff, recording of resuscitations, research assistants informing the healthcare worker at 30 and 50 seconds after birth during a resuscitation, among others.	Hospital management and local champions	All healthcare workers from labor ward, research assistants, nursing matron, and hospital management
Follow-up of action points established during QI monthly meeting	Progress of the QI intervention goal and agreed action points were displayed at a progress board in labor ward and shared in a WhatsApp group. Local champions were responsible for designing relevant scenarios for simulation-based team training to address gaps in knowledge/skills discussed at the QI monthly meeting.	Local champions	Midwives and staff labor ward
Monthly scenario team simulation training	Monthly scenario team trainings targeting gaps from the real-life resuscitations at the ward, identified by clinical data and the other ongoing QI activities.	Local champions	Midwives at labor ward
Low-dose high-frequency individual skill training	Midwives were encouraged to carry out individual skill training four times per month covering different patient cases, in addition to the monthly scenario team training.	Local champions, midwives at labor ward	Midwives at labor ward
Weekly morning report	Clinical data from the resuscitations were presented at one of the morning reports at the ward each week.	One of the local champions	Midwives and physicians from the night shift and the day shift, and the nursing matron
Daily clinical debriefing at shift meeting	Daily debriefings and reports of the most recent resuscitations at the shift meeting by application of 3 phases of debriefing; description, analysis, and application under the assistance of a local champion if present. Report concluding with a "take home message", such as "Bag-mask ventilation equipment not present."	Midwives	Staff from labor ward present at shift meeting Midwives, research assistant, other healthcare workers, and physician involved in the resuscitation
Clinical debriefing after resuscitation	7–10 min debriefing after a neonatal resuscitation, involving the group of midwives, the research assistant observing the resuscitation and physician if present during the resuscitation. The debriefing included reflections on what went well, what could be improved, and what was learnt. A take home message was created and presented at the shift meeting.	Midwives and local champion (if available)	
Annual 1-d HBB course	One-day HBB course providing knowledge and skill training in newborn resuscitation.	HBB master trainers (midwives at Haydom who have conducted a 1-day HBB Master Trainer Course) and local champions	Staff in the labor ward

were, for example, equipment preparations before entering second stage of labor, adherence to the HBB action plan, closed-loop communication between the team members, and assessment and decision making concerning the need for BMV within 60 seconds after birth. The participants' performance of the learning objectives was evaluated by the local champion and discussed in the debriefing after the training. The debriefing was carried out according to principles of psychological safety and focused on successes and areas of improvement recognized through the training. All midwives had to participate regularly in the team simulations, and they were encouraged to carry out individual skill training 4 times per month. The NeoNatalie Live simulator was available for all healthcare workers defined as nurses and physicians including nurse students. However, the QI/simulation intervention was focusing on midwives because they are responsible for newborn resuscitations in this setting.

Moreover, during the QI/simulation intervention, all newborn resuscitations were debriefed immediately and at the daily shift meeting. Clinical data from real resuscitations were summarized and presented at one morning report each week. Clinical data were also presented at monthly meetings including both clinical staff, research assistants, and hospital management. At these meetings questions and challenges were examined, implementation of previous action points was evaluated, and further potential improvements were discussed until consensus on new action points was reached. The action points from the monthly meetings were displayed on a progress board in the labor ward. Action points included increased awareness and knowledge of important aspects of newborn resuscitation, increased preparedness for resuscitation, training of new staff, and documentation of resuscitations. In addition, it was decided that research assistants should inform the healthcare worker at 30 and 50 seconds after birth during real-life resuscitations.

In the 2-year postintervention period, September 1, 2019, August 31, 2021, weekly reports concerning clinical outcomes continued; however, there were no monthly meetings and decreased focus on simulations, both individual skill training and scenario team training. In the analyses, we divide the postintervention period into two 1-year periods, to study time trends.

Data Collection and Management

Trained research assistants, a total of 16 assistants, worked in pairs in the labor ward to observe and record information (labor and newborn characteristics, events, and resuscitation interventions) about all births, day and night. Data were registered on a data collection form, specifically designed to suit several newborn resuscitation and QI studies at Haydom and in the Liveborn app.[23] The Liveborn app was used to record data from resuscitations, such as time from birth to first ventilation. Trained data clerks double-entered data using Epidata 3.1.

Outcomes

The primary outcomes were time from birth to first ventilation attempt and proportion of nonbreathing newborns ventilated within the Golden Minute, proportion of newborns receiving stimulation, suction and/or BMV immediately after birth, and healthcare workers' frequency of BMV training. Secondary outcomes included FSB, 24-hour newborn deaths and admissions to neonatal care unit.

A nonbreathing newborn was defined as a newborn who did not start spontaneous breathing after birth or started insufficient breathing, that is, not "breathing well" according to international guidelines.[12]

Statistical Methods

Analysis was performed using SPSS version 26 (IBM Corp, Armonk, NY). Continuous data were summarized by mean and standard deviation (SD) or median and quartiles, according to the distribution of the data, and categorical data by percentages and numbers. The Kruskal-Wallis test was used to test for differences over the periods in continuous variables, as well as the χ^2 or Fisher exact tests for categorical data. To test for differences between the periods in proportions of fatale outcomes, adjusted for risk factors, logistic regression was used. P values less than 0.05 were considered statically significant for all hypothesis tests. In addition to the interferential statistical approach, we used run charts for descriptive purposes to display the development over time for the primary outcome measures; nonbreathing newborns ventilated within the Golden Minute and time from birth to start ventilation over the study period with the median line for each study period.

Ethical Considerations

The study was approved by the National Institute for Medical Research, Tanzania (NIMR/HQ/R.8a/Vol.IX/3852) and the Regional Committee for Medical and Health Research Ethics, Western Norway (ref.no. 172126). Informed consent from the mothers was not required by the ethical committees because of the prospective, observational QI study design.

RESULTS

During the study period, 12,938 births were recorded; 260 macerated stillbirths (baby born dead with skin disintegration, assumingly died >12 hours before birth) were excluded, while 12,678 births, including 143 FSB, were included for further analysis. There were 15% missing registrations for the variable "cervical dilatation," 5% for "last fetal heart rate before delivery" and less than 0.1% for the remaining variables.

More parturient women were admitted as referrals from health centers in the postintervention period compared with baseline (Table 2). The proportion of newborns with a normal fetal heart rate during labor increased (Table 2), whereas average birth weight decreased despite a stable number of preterm newborns throughout the study (Table 3). Newborns with low APGAR 1 minute (APGAR ≤7) increased from baseline to intervention period.

Throughout the study period, 4474 newborns (35%) were stimulated to start breathing and 1320 of these (10.4%) were also ventilated. Both stimulation (34.5%–40.4%), suction (28.1%–31.4%), and BMV (8.5%–12.9%) increased from baseline to the intervention period (Table 3). Stimulation (40.4%–37.2%–26.2%) and BMV (12.9%–10.6%–9.4%) decreased from the intervention period to postintervention (Table 3).

The percentage of nonbreathing newborns ventilated within 1 minute and time from birth to first ventilation are presented in Figures 2 and 3. There was an increase in nonbreathing newborns receiving ventilation within the Golden Minute from 15.8% at baseline to 68.5% ($P < 0.001$) during intervention, and a decrease (68.5%–42.2%–28.9%, $P < 0.001$), from intervention to postintervention periods (Table 4). Time from birth to first ventilation decreased from median 101 (quartiles 72–150) seconds in baseline to 55 (45–67) seconds in the intervention period, and then increased to 67 (49–97) seconds, and further to 85 (57–133) seconds during the postintervention periods (Table 4).

Most resuscitations were provided by midwives, increasing throughout the study period (83.5%–92.7%–98.2%–97.1%, $P < 0.001$) (Table 4). Healthcare workers who had trained using NeoNatalie Live in the last 7 days before conducting a real resuscitation decreased throughout the study (64.7%–44.6%–6.7%–5.5%) (Table 4).

For the subgroup of nonbreathing newborns receiving BMV, proportions of fatale outcomes (24-hour newborn deaths and FSB) over the study period were as follows: 12.6%–7.5%–8.4%–9.3% ($P = 0.164$). Comparing the baseline period with the intervention period, a significant reduction in perinatal mortality (FSB and 24-hour newborn deaths, 12.6%–7.5%, $P = 0.03$) was found. However, the results were no longer statistically significant ($P = 0.111$) after adjustment for source of admission, antenatal problem, premature/term, mode of delivery, and fetal heart rate during labor. Fresh stillbirths decreased significantly from 3.2% to 0.7% ($P = 0.013$) in the intervention period. The decrease in FSB remained significant after adjustment for the same variables as above ($P = 0.034$).

There were no statistically significant changes in perinatal mortality for all births (FSBs and 24-hour newborn deaths), in unadjusted ($P = 0.468$) or adjusted analyses (same variables as above, $P = 0.182$).

TABLE 2. Labor and Maternal Characteristics of Live Births and Fresh Stillbirths (N = 12,678)*

	Period 1, Baseline FST	Period 2, Golden Minute Campaign	Period 3, Postintervention	Period 4, Postintervention	*P*
	01.10.17–31.08.18	01.09.18–31.08.19	01.09.19–31.08.20	01.09.20–31.08.21	
Months, n	11	12	12	12	
Births, n	2913	3291	3142	3332	
Admission from health center	5.9 (171)	6.4 (210)	7.6 (240)	7.6 (253)	0.010†
Mother no formal education	6.3 (184)	8.1 (267)	6.8 (214)	6.0 (199)	0.004†
Maternal age	26.4 ± 6.8	26.3 ± 6.7	26.5 ± 6.9	26.4 ± 6.6	0.889‡
No antenatal care	1.0 (28)	1.1 (35)	1.5 (46)	1.7 (56)	0.038†
Antenatal problem	2.4 (69)	1.7 (57)	2.0 (62)	2.4 (81)	0.163†
Cervical dilatation on admission, cm	5.9 ± 2.6	5.9 ± 2.6	5.8 ± 2.6	6.3 ± 2.3	<0.001‡
10-cm cervical dilatation on admission	8.5 (214)	8.8 (247)	8.0 (210)	8.8 (242)	0.675†
Fetal heart rate on admission					0.051†
Normal (120–160 bpm)	93.2 (2714)	94.0 (3093)	93.3 (2930)	92.4 (3079)	
Abnormal (<120 or >160)	1.3 (38)	1.3 (44)	0.9 (28)	1.0 (33)	
Not detectable	0.7 (20)	0.6 (20)	0.7 (23)	0.7 (23)	
Not measured	4.8 (141)	4.0 (133)	5.1 (160)	5.9 (197)	
Fetal heart rate during labor					<0.001†
Normal (120–160 bpm)	85.5 (2491)	89.9 (2959)	90.1 (2830)	90.6 (3018)	
Abnormal (<120 or >160)	8.7 (252)	5.3 (175)	4.0 (126)	2.9 (97)	
Not detectable	0.7 (20)	0.7 (22)	0.9 (29)	0.7 (24)	
Not measured	5.1 (150)	4.1 (134)	5.0 (157)	5.8 (193)	
Final fetal heart rate before delivery	132.6 ± 18.1	133.4 ± 16.7	131.8 ± 18.2	132.1 ± 18.1	<0.001‡
Mode of delivery					0.043†
Spontaneous vaginal delivery	75.0 (2184)	72.0 (2371)	74.2 (2330)	73.0 (2434)	
Cesarian delivery	23.8 (692)	25.8 (850)	24.2 (759)	25.7 (857)	
Assisted breech delivery	1.1 (31)	1.9 (62)	1.4 (45)	1.2 (39)	
Vacuum extraction	0.2 (5)	0.2 (7)	0.3 (8)	0.1 (2)	
Others	0.0 (1)	0.0 (1)	0.0 (0)	0.0 (0)	
Singleton/multiple					0.013†
Singleton	96.6 (2814)	95.4 (3140)	95.6 (3005)	94.9 (3163)	
Multiple	3.4 (99)	4.6 (151)	4.4 (137)	5.1 (169)	
Labor complications§	2.7 (80)	2.4 (79)	2.2 (69)	2.5 (82)	0.582†
Uterine rupture	0.1 (3)	0.1 (3)	0.2 (5)	0.1 (4)	0.872†
Pre-eclampsia	0.6 (17)	0.2 (6)	0.3 (10)	0.6 (21)	0.015†
Eclampsia	0.5 (14)	0.4 (12)	0.4 (14)	0.2 (6)	0.188†
Cord prolapse	0.5 (16)	0.9 (28)	0.7 (21)	0.8 (28)	0.443†
Prepartum bleeding	1.0 (29)	0.8 (26)	0.5 (17)	0.6 (20)	0.148†
Shoulder dystocia	0.1 (3)	0.2 (5)	0.1 (2)	0.2 (5)	0.719‖

*Values are given as mean ± SD or percentage (number).
†χ^2 test.
‡Kruskal-Wallis test.
§One or several labor complications.
‖Fisher exact test.
FST, frequent skill training.

To our knowledge, there were no other changes in contextual factors during the study period that interacted with the intervention.

DISCUSSION

After implementation of a QI/simulation intervention (ie, the Golden Minute Campaign) at a rural hospital in Tanzania, the proportion of nonbreathing newborns ventilated within the Golden Minute increased from 15.8% to 68.5% and median time from birth to first ventilation decreased by 46 seconds. During the postintervention period, with less organized simulations, time to start ventilation increased and less nonbreathing newborns were ventilated within the Golden Minute. The use of BMV, stimulation, and suction increased from baseline to the intervention period and showed an opposite trend after intervention. Among those being ventilated, FSB rate decreased from 3.2% in baseline to 0.7% during the Golden Minute Campaign.

Haydom has practiced simulation-based skill training in newborn resuscitation for a decade through implementation of the HBB program. A previous study of nearly 8500 trainings demonstrated a decrease in ventilation pauses and reduced time from birth to start ventilation.[18] Still, time to start ventilation remained approximately 2 minutes. Frequent HBB trainings before the Golden Minute Campaign were typically individual skill trainings, starting with the newborn simulator on the resuscitation table, focusing on ventilation techniques. In addition, several scenario team trainings were registered, but these were not guided by clinical learning objectives and the quality of the simulations is uncertain. Therefore, in 2018, the hospital management addressed the gap between HBB resuscitation guidelines and observed clinical performance, agreed on a goal for improvement, and launched the comprehensive

TABLE 3. Resuscitation Characteristics, Newborn Characteristics, and Perinatal Outcomes of All Births (N = 12,678)*

	Period 1, Baseline FST	Period 2, Golden Minute Campaign	Period 3, Postintervention	Period 4, Postintervention	*P*
	01.10.17–31.08.18	01.09.18–31.08.19	01.09.19–31.08.20	01.09.20–31.08.21	
Births, n	2913	3291	3142	3332	
Newborn characteristics					
Gestational age, wk	38.6 ± 2.0	38.6 ± 2.1	38.5 ± 2.1	38.5 ± 1.9	<0.001†
Preterm	4.1 (120)	4.8 (158)	5.1 (160)	5.4 (181)	0.105‡
Birth weight, g	3334.4 ± 552.1	3230.7 ± 552.1	3172.8 ± 532.9	3161.0 ± 541.5	<0.001†
Birth weight categories, g					<0.001‡
<1500	1.1 (31)	0.9 (30)	0.9 (27)	1.1 (37)	
1500–2499	4.4 (127)	6.0 (197)	7.3 (228)	7.7 (256)	
2500–3499	52.7 (1534)	59.8 (1967)	63.2 (1983)	63.2 (2104)	
3500–4499	40.2 (1169)	32.3 (1062)	28.2 (885)	27.6 (919)	
≥4500	1.7 (50)	0.9 (31)	0.5 (16)	0.5 (15)	
Resuscitation characteristics					
Resuscitation kit present	93.6 (2728)	97.1 (3194)	98.4 (3092)	99.2 (3307)	<0.001‡
Bag-mask resuscitator present	97.8 (2849)	98.7 (3246)	99.1 (3114)	99.4 (3311)	<0.001‡
Stimulation	34.5 (1104)	40.4 (1328)	37.2 (1169)	26.2 (873)	<0.001‡
Suction	28.1 (818)	31.4 (1033)	31.4 (988)	23.6 (785)	<0.001‡
Bag/mask ventilation	8.5 (248)	12.9 (426)	10.6 (333)	9.4 (313)	<0.001‡
APGAR 1 min	8.5 ± 1.4	8.3 ± 1.5	8.3 ± 1.5	8.4 ± 1.5	<0.001†
APGAR 5 min	9.7 ± 1.4	9.6 ± 1.5	9.6 ± 1.5	9.6 ± 1.5	<0.001†
Low APGAR 1 min (APGAR ≤7)	9.8 (284)	13.3 (439)	12.5 (395)	11.9 (396)	<0.001‡
Low APGAR 5 min (APGAR ≤7)	4.2 (123)	6.1 (200)	5.6 (177)	5.6 (187)	0.010‡
Perinatal outcome at 30 min					<0.001‡
Normal	91.6 (2667)	87.7 (2886)	84.5 (2654)	83.0 (2766)	
Admitted neonatal unit	6.9 (202)	10.9 (358)	13.9 (438)	15.5 (515)	
Death	0.3 (10)	0.5 (17)	0.4 (11)	0.3 (11)	
Fresh stillbirth	1.2 (34)	0.9 (30)	1.2 (39)	1.2 (40)	
Neonatal outcome at 24 H§					<0.001‡
Normal	93.5 (2720)	89.6 (2904)	87.8 (2715)	87 (2856)	
Still in neonatal care unit	4.1 (118)	9.8 (318)	11.6 (358)	12.5 (411)	
Death	1.0 (28)	0.6 (18)	0.6 (18)	0.4 (14)	
Fresh stillbirth/30-min/24-H mortality‖	2.5 (72)	2.0 (65)	2.2 (68)	2.0 (65)	0.466‡
Early neonatal mortality¶	1.3 (38)	1.1 (35)	0.9 (29)	0.8 (25)	0.178‡

*Values are given as mean ± SD or percentage (number).
†Kruskal-Wallis test.
‡χ^2 test.
§Fresh stillbirth is reported for perinatal outcome at 30 minutes.
‖Fresh stillbirths, 30-minute perinatal deaths and 24-hour neonatal deaths.
¶Early neonatal mortality (30-minute perinatal deaths and 24-hour neonatal deaths).
FST, frequent skill training.

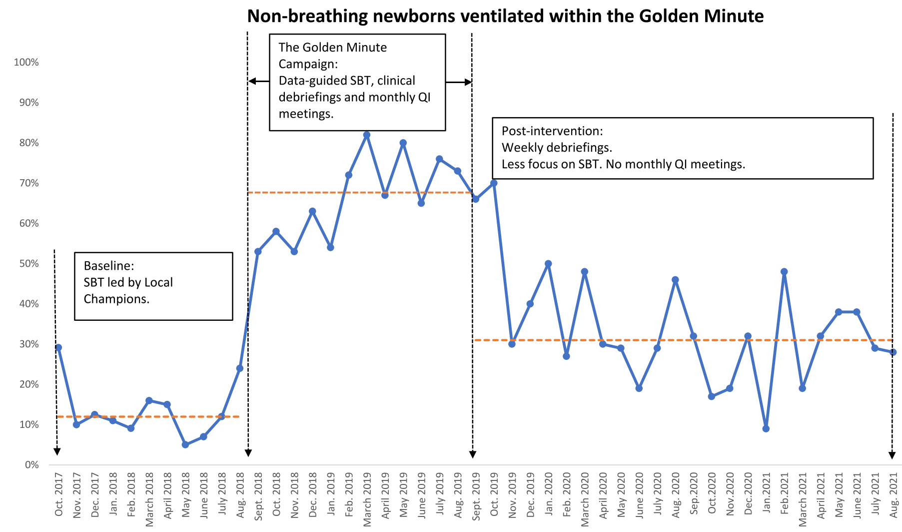

FIGURE 2. Run chart showing the monthly proportion of nonbreathing newborns ventilated within the Golden Minute over time. The median proportion in each period is displayed by the dashed lines.

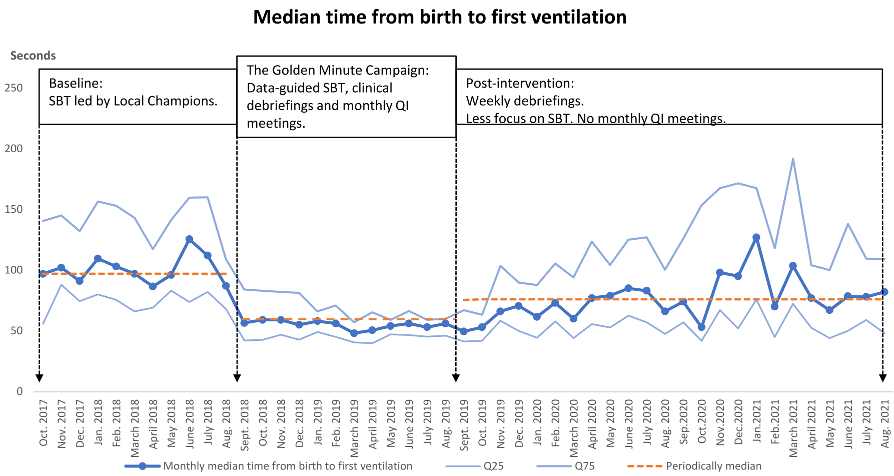

FIGURE 3. Run chart showing the monthly median time from birth to start ventilation for nonbreathing newborns over time. The median for the entire period in each period is displayed by the dashed lines.

QI/simulation campaign to reach this goal. The large increase in nonbreathing newborns receiving ventilation within the Golden Minute during the QI/simulation campaign demonstrated that it is possible to achieve guideline adherence even for such a challenging and time-critical procedure. This is consistent with findings from Nepal, from a similar resource-limited setting.[11] Given the study design, it is difficult to weigh the importance of simulation training relative to the other QI interventions, but we speculate that the monthly data-guided scenario team trainings, led by skilled simulation facilitators, focusing on timelines from birth to start ventilation, were fundamental in changing this practice. After a near decade with no improvement in time from birth to start BMV, the midwives managed to halve this time in real situations. This is consistent with findings from studies of scenario team training in comparable time-critical procedures in emergency medicine.[24–26] In the present study, the newborn resuscitation scenarios were carefully adjusted to address identified challenges in clinical care. We believe that a combination of all the different QI efforts was necessary to finally achieve the reduction in time to start ventilation, concurring with previous findings and recommendations on QI efforts in health care.[27–30]

Furthermore, Figure 3 shows significantly less variation in time to start ventilation during the campaign compared with both baseline and postintervention periods. This demonstrates the facilitators' ability to include all healthcare workers, despite a high staff turnover, and enabling most providers to achieve guideline adherence. The local champions received formal facilitator training, through the EuSim Level 1 course, before the Golden Minute Campaign, enabling them to provide high-quality training focusing on goal-oriented simulations in a safe learning environment. The importance of local champions when implementing changes in healthcare is well documented.[31,32] The dedicated and trained simulation facilitators/local champions

TABLE 4. Resuscitation Characteristics of Nonbreathing Newborns Receiving Bag/Mask Ventilation (n = 1320)*

	Period 1, Baseline FST	Period 2, Golden Minute Campaign	Period 3, Postintervention	Period 4, Postintervention	*P*
	01.10.17–31.08.18	01.09.18–31.08.19	01.09.19–31.08.20	01.09.20–31.08.21	
Newborns receiving BMV, n	248	426	333	313	
Midwife providing resuscitation	83.5 (207)	92.7 (395)	98.2 (324)	97.1 (304)	<0.001†
Healthcare worker trained with NeoNatalie last 7 d	64.7 (161)	44.6 (189)	6.7 (22)	5.8 (18)	<0.001†
Time from birth to start BMV, s	101 (72–150)	55 (45–67)	67 (49–97)	85 (57–133)	<0.001‡
BMV initiated within 60 s	15.8 (39)	68.5 (292)	42.2 (137)	28.9 (88)	<0.001†
Perinatal outcome at 30 min					<0.001†
Normal	52.0 (129)	50.0 (213)	34.5 (115)	28.1 (85)	
Admitted neonatal unit	42.3 (105)	46.2 (197)	61.0 (203)	66.5 (208)	
Death	2.4 (6)	3.1 (13)	2.7 (9)	3.5 (11)	
Fresh stillbirth	3.2 (8)	0.7 (3)	1.8 (6)	2.9 (9)	0.074†
Neonatal outcome at 24 H					<0.001†
Normal	66.4 (154)	55.7 (228)	45.6 (145)	41.3 (121)	
Still in neonatal care unit	26.3 (61)	40.3 (165)	50.3 (160)	55.6 (163)	
Death	7.3 (17)	3.9 (16)	4.1 (13)	3.1 (9)	
Fresh stillbirth/30-min/24-H mortality§	12.6 (31)	7.5 (32)	8.4 (28)	9.3 (29)	0.164†
ENM (30-min + 24-H mortality)	9.3 (23)	6.9 (29)	6.7 (22)	6.6 (20)	0.564†

*Values are given as median (quartiles) or percentage (number).
†χ^2 test.
‡Kruskal-Wallis test.
§Fresh stillbirths, 30-minute perinatal deaths and 24-hour neonatal deaths.
BMV, bag-mask ventilation; ENM, early neonatal mortality; FST, frequent skill training.

were most likely a crucial factor for the present success in timely BMV. Importantly, the QI/simulation intervention in the present study was multifaceted including systematic clinical debriefing, own data feedback loops, and regular scenario simulation training targeting identified gaps in clinical care. The QI efforts were assisted by the local champions and strongly supported by the hospital management. Previous studies highlight the importance of engaged leadership for successful QI processes.[33,34]

Several publications have highlighted the challenge of improving timely BMV across a variety of settings.[6,7,9,10] Moreover, Branche et al[10] questioned the achievability and thus relevance of the Golden Minute due to these known challenges in completing all the initial resuscitation steps within 60 seconds, regardless of access to resources. However, the clinical importance of rapid onset of ventilation in a low-resource setting has previously been demonstrated by Ersdal et al,[5] documenting an increased risk of death or prolonged admission by 16% for every 30-second delay in initiating BMV. Interestingly, the present study reports a significant decline in classified FSB and a trend toward lower perinatal mortality concurrent with faster time to start BMV. Furthermore, we demonstrated that it is possible to start ventilation within 60 seconds for most nonbreathing newborns.

One of the strengths of the present study is the 2-year follow-up after the campaign was completed. During the postintervention period, there were no monthly QI meeting and less focus on frequent simulation-based training, but the weekly reports on clinical data were continued. The documented significant improvements from baseline to the HBB QI/simulation intervention period sustained 2 years after implementation. However, from intervention to postintervention, there was a decline in nonbreathing newborns ventilated within the Golden Minute and increased median times from birth to ventilation. This demonstrates the need for continued focus on QI/simulation in newborn resuscitation. More research is needed regarding which QI efforts are required to maintain the desired changes in clinical practice over time.[14]

The QI efforts in our study took advantage of an already established infrastructure for collection of clinical data and local competence and capacity in simulation. Extra costs related to data collection were minimal, only requiring some extra expenses for the tailored feedback analyses as part of the Golden Minute Campaign. The monthly meetings, however, did require human resources outside working hours, representing a challenge for sustainability of QI efforts.

The number of nonbreathing newborns being ventilated at Haydom is comparable with other low-resource settings.[35] However, it is higher than what is expected in high-resource settings.[36] Even the baseline proportion of 8.5% is considered high, further increasing to almost 13% during the Golden Minute Campaign. This is likely due to enhanced awareness and confidence among the healthcare workers after simulation-based training[37] and directly linked to earlier onset of ventilation of nonbreathing newborns. During baseline, median time to start BMV was approximately 2 minutes, compared with less than a minute during QI intervention. We cannot claim that unnecessary ventilation never occurred, but both the trained research assistants (observers) and the healthcare workers at Haydom have many years of experience looking carefully for signs of spontaneous breathing. Their ability to correctly classify nonbreathing newborns has been assessed in real-life resuscitations from video recordings. None of the ventilated newborns were reported to have adequate breathing efforts before start of ventilation. Furthermore, the rate of (assumed) FSB was all-time low at Haydom during the QI intervention, indicating that the reported BMV frequency might reflect the actual need in this poor setting. Maternal and newborn vulnerability, as well as obstetric and newborn care, varies across settings, and the true proportion of nonbreathing newborns who would benefit from BMV is probably unknown, thus making it difficult to compare BMV frequencies between settings. The BMV frequency at Haydom is comparable with similar resource settings.[11]

Two systematic reviews found no change in the use of stimulation and BMV after HBB implementation.[8,35] However, several individual studies report increased frequency of BMV and a reduction in unnecessary suctioning of nonbreathing newborns.[7,11,38] Suctioning of clear amniotic fluid in newborn resuscitation is no longer recommended in the newborn resuscitation guidelines, and it seems that this change was not sufficiently addressed through the QI intervention in our study, which mainly focused on timely BMV.[4,39]

Interestingly, the proportion of resuscitations provided by midwives increased throughout the study period, and in the first postintervention period, 98.2% of resuscitations were performed by midwives. This might reflect increased self-confidence due to the QI/simulation intervention engaging all midwives in the ward, improving their clinical performance in newborn resuscitation.[37] Individual skill training declined during the study, and in the postintervention periods, only 5.8% to 6.7% of the healthcare workers providing BMV had trained using NeoNatalie Live during the last 7 days before conducting a real resuscitation. The Golden Minute Campaign shifted the focus from individual skill training to a more comprehensive simulation approach addressing the scenario and team-based challenge of reducing time from birth to first ventilation. Thus, a shift toward more scenario team simulations and less individual skill training during the QI/simulation intervention was expected and in line with defined learning goals. However, the great reduction in training (both individual skill training and scenario simulation training) from intervention to postintervention was not anticipated and might demonstrate the importance of local champions on a continuous basis to ensure frequent trainings.[14,19,40] A recent review highlights the challenge of making sustainable changes in real-life newborn resuscitations, partly due to lack of evidence on the optimal frequency and structure of efforts to prevent skill loss, which may vary across different clinical settings.[14]

Perinatal mortality (24-hour newborn deaths and FSB) did not show any significant change for all livebirths. However, observed proportions of fatale outcomes decreased for the subgroup of newborns receiving BMV, and FSB rate decreased from 3.2% in baseline to 0.7% during the Golden Minute Campaign. At the same time, there was a trend toward lower perinatal mortality, which was not statistically significant after adjustment. Because of the increased number of nonbreathing newborns ventilated within the Golden Minute, a reduction in perinatal mortality would be anticipated. The rationale for rapid onset of ventilation is the known pathophysiological mechanisms of birth asphyxia.[41,42] Newborns with a "mild" degree of hypoxia/asphyxia may respond to initial resuscitation steps, such as stimulation, and eventually start spontaneous breathing—even after the Golden Minute.[5] However, newborns with a more "severe" hypoxia/asphyxia will not respond to stimulation alone and require ventilation to make the transition and initiation of own breathing.[5,42] It may be difficult to quickly evaluate actual newborn status at birth and whether the newborn requires ventilation or not to finally start breathing.[42] It is also difficult to clinically distinguish a true FSB from severely asphyxiated newborns who are still alive and in need of urgent ventilation.[42] The reduction in FSB shown in the present study indicates the potential of timely BMV, enabled by data-guided simulation-based training, for improved outcome for this patient group.

The main strengths of this study are the large population size and follow-up through the postintervention period. Furthermore, the rigorous data management system and the comprehensive data collection, including detailed information on labor courses, resuscitation practice, and newborn outcome, are quite unique. The main limitations are the multifaceted, nonrandomized, single-center design. Perinatal outcome was a secondary outcome, and the study may lack statistical power to show a true difference for the given period. All the simulation/QI interventions described are considered assignable to other settings. However, the unique data collection system, using trained research assistants observing all births with stopwatches, is resource demanding and likely not an option for most places. Haydom has practiced individual simulation training for a decade; therefore, the hospital management and staff were used to this learning methodology, and this might have impacted their effective adoption of the simulation intervention. Implementing this simulation/QI interventions in a setting with less experience in simulation practice might have provided different results.

CONCLUSIONS

An HBB simulation-based QI intervention increased the proportion of nonbreathing newborns ventilated within the Golden Minute and decreased median time from birth to first ventilation. Patient outcome improved, showing a reduction in FSB among those being ventilated, demonstrating the importance of timely BMV, especially for severely asphyxiated newborns. This QI intervention documents that it is possible to achieve adherence to newborn resuscitation guidelines during clinical care in low-resource settings. Further research should focus on the optimal level of training frequency and structure of QI efforts to maintain a culture of frequent training and prevent skill loss over time. Mixed-methods design and/or qualitative studies are known to provide valuable information in this regard and could explore underlying reasons for the demonstrated changes.

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