Simulation-based training and data-guided feedback for neonatal resuscitation in rural Tanzania

by

May Sissel Vadla

Thesis for the degree of
PHILOSOPHIAE DOCTOR
(Ph.D.)

Universitetet i Stavanger

Faculty of Health Sciences
Department of Quality and Health Technology
2023

Universitetet i Stavanger
NO-4036 Stavanger
NORWAY
www.uis.no

ISBN:978-82-8439-178-6
ISSN:1890-1387
Doktorgradsavhandling nr. 711

Acknowledgments

I am very grateful to a number of people who have made this work possible.

First and foremost, my main supervisor Professor Hege Ersdal for your diligent effort in guiding and supporting me through this project. I am deeply impressed by your knowledge, capacity, and the impact of your work for increased newborn survival globally. Regardless of your extraordinary workload, you always found time to answer my questions and reassure me in my concerns. Thank you.

To my co supervisor, Professor Bjørg Oftedal for your valuable contributions in sharing your experience and encouraging me throughout the project. Thank you for your tireless effort in broadening my perspectives, especially regarding theoretical frameworks, and for believing in me from the very start. To my co supervisor Professor Jan Terje Kvaløy, I highly admire your competence in statistics and your pedagogical skills and patience in passing your knowledge forward. I also truly appreciate the warm and friendly atmosphere you create around you.

To the Safer Births research group, I really appreciate to be part of this impressive research collaborative, knowing that my thesis is part of a bigger picture, contributing to the vast amount of knowledge already gained by my great colleagues.

To all my co-authors, Paschal Mdoe, Robert Moshiro, Estomih Mduma, Barikiel Hhando Hhoki, Paskalina Michael, Sabrina Sarangu, Ingunn Anda, Joar Eilivstjønn and Øystein Gomo, for your crucial contributions and support in writing the papers.

I would also like to thank all the members of staff at Laerdal Global Health, Laerdal Medical and the SAFER Foundation for your support

and technical guidance whenever it was needed. As well, I express my gratitude and admiration towards the staff at the Haydom Global Health Research centre. Your dedication and desire to improve maternal and newborn health is truly outstanding. Equally, I admire the impressive effort made by the local champions; Barikiel Hhando Hhoki, Paskalina Michael, Sabrina Sarangu and Noelina Samson Quwanga for increased simulation-based training and your achievements of improved clinical practice.
I am also indebted to all the women who gave birth at Haydom Lutheran Hospital and participated in the studies.

To my previous employers, Oddny Hovtun Bjorland and Magne Fjell, for accepting my requests to pursue this project and for your encouragement.

To my colleague and friend, Dr. Ole Bernt Lenning, for all your support, especially through the pandemic, enabling my progress of this work despite our considerable workload as District Medical Officers in Randaberg.

To my parents, Sigrund and Leif Magne, and my parents in law, Synnøve and Sigbjørn, for all your help, and especially for being such wonderful grandparents for my boys. To all my dear friends, none mentioned, none forgotten, for your encouragement and for providing highly needed distractions.

To my beautiful children, Sondre and Simon, for being just who you are; fun, kind, caring and clever, you are by far my highest priority and the joy of my life. Finally, to my energetic and loving husband, Sveinar, for encouraging me to pursue this project and for taking care of our boys during my travels. Thank you for lifting my spirit during the more frustrating parts of this journey; I could not have done this without you.

Financial support

I am grateful for the financial support received from the University of Stavanger, Global Health and Vaccines Research (GLOBVAC) program at the Research Council of Norway (grant number 228203), Saving Lives at Birth Grand Challenges, and the Laerdal Foundation. The development of NeoNatalie Live received funding from Innovation Norway, the Research Council of Norway (228203) and Skattefunn (ES519418). The study was performed using simulation equipment provided by Laerdal Global Health.

Abbreviations

A&F Audit and feedback

BMV Bag-mask ventilation

END Early neonatal death

FSB Fresh stillbirths

HLH Haydom Lutheran Hospital

HSSP Health Sector Strategic Plan

ILCOR International Liaison Committee on Resuscitation

MOHSW The Ministry of Health and Social Welfare

NRP Neonatal Resuscitation Program

PDSA Plan-do-study-act

QI Quality Improvement

RCT Randomized controlled trial

SBT Simulation-based training

SDG Sustainable Development Goals

WHO World Health Organisation

Definition of terms

Early neonatal mortality: Death of a newborn between zero and seven days after birth.

Fresh stillborn: A "fresh" stillborn foetus lacks skin changes and is presumed to have died intrapartum.

Macerated stillborn: A "macerated" stillborn foetus presents skin and soft-tissue changes suggesting that death occurred well before start of labour.

Neonatal encephalopathy: The American Academy of Pediatrics defines neonatal encephalopathy as "a clinically defined syndrome of disturbed neurologic function in the earliest days of life in an infant born at or beyond 35 weeks of gestation, manifested by a subnormal level of consciousness or seizures, and often accompanied by difficulty with initiating and maintaining respiration and depression of tone and reflexes" (1).

Perinatal mortality: Early neonatal mortality and fresh stillbirths.

Neonatal mortality: Death of a newborn < 28 days after birth.

Under-five mortality: Death of a child < 5 years after birth.

Summary

Background: Globally, 1.4 million newborns die every year due to intra-partum related events and fresh stillbirths, nearly all occurring in low- and middle-income countries. Many of these deaths could be prevented

if the non-breathing newborns received skilled and timely bag-mask ventilation at birth. Neonatal resuscitation guidelines recommend onset of bag-mask ventilation for non-breathing newborns within the first minute of life, the so-called Golden Minute. Guideline adherence for timely ventilation is challenging in clinical practice, and a multi-country study demonstrated that less than one percent of newborns were ventilated within the Golden Minute. The Helping Babies Breathe educational program improves knowledge and simulated skills in neonatal resuscitation. However, two systematic reviews found no overall difference in stimulation, suctioning, or bag-mask ventilation after implementation of the program, demonstrating the challenge of translating improved training-skills into clinical practice. The Helping Babies Breathe 2nd Edition addresses the challenges regarding program implementation and achievement of sustainable results.

Aim: The overall aim of the thesis was to investigate the effects of several quality improvement/simulation-based training interventions, on simulation-based training performance, clinical practice, and perinatal outcome.

Methods: The study design was a prospective, pre/post observational study conducted over a six-year period from 01.09.2015 to 31.08.2021, including two years post-intervention at a rural referral hospital, Haydom Lutheran Hospital, in Tanzania. We conducted three studies throughout the study period. In Study I, initiated September 2016, a novel newborn simulator was implemented for in-situ, individual skill-training, and scenario team-training at labour ward, consistent with the Helping Babies Breathe 2nd Edition program. In Study II, initiated October 2017, local champions were appointed to encourage the midwives for enhanced simulation-based training effort. And finally, in Study III initiated September 2018, the local champions facilitated scenario team-trainings and led a quality improvement project, the Golden Minute Campaign. The campaign included data-guided scenario team training, frequent quality improvement meetings and clinical debriefings, and engaged all healthcare workers at labour ward and participants from the management. The study included a two-year post-intervention period. Data regarding training frequency and performance was collected automatically from the newborn manikin (Study I). All births, resuscitations and newborns were observed by trained research assistants and documented using a comprehensive data collection form containing wide-ranging information (Study II and III). In addition, physiological measures from the resuscitations were collected by a newborn resuscitation monitor for Study II.

Results:

Study I demonstrated increased training frequency, training performance and staff participation after the appointment of local champions to motivate for simulation-training in neonatal resuscitation using the new simulator. The number of individual skill-trainings increased from 688 in 12 months to 8451 in 11 months, the number of monthly trainings per midwife increased from 2.3 to 26 ($p<0.001$) and the staff participation increased from 43% to 74% ($p=0.016$). The training performance,

measured as trainings conducted without errors, increased from 75% to 91% ($p<0.001$).

Study II showed translation of improved simulated ventilation skills to improved clinical performance with decreased time from birth to first ventilation and more continuous ventilations. Median time from birth to first ventilation decreased from 118 to 101 seconds ($p=0.018$), and time-pauses during ventilation decreased from 28% to 16% ($p<0.001$).

Study III demonstrated further reduction in time from birth to first ventilation, more non-breathing newborns ventilated within the Golden Minute and reduction in fresh stillbirths after implementation of the Golden Minute Campaign. During the quality improvement intervention, 69% newborns were ventilated within the Golden Minute compared to 16% during baseline and 42% and 29% post-intervention ($p<0.001$). Time to first ventilation decreased from median 101 (quartiles 72-150) to 55 (45-67) seconds, before increasing to 67 (49-97) and 85 (57-133) seconds post-intervention ($p<0.001$). More non-breathing newborns were ventilated in the intervention period (13%) compared to baseline (8.5%) and the post-intervention years (10.6% and 9.4%) ($p<0.001$). Among the newborns receiving bag-mask ventilation, there was a reduction in fresh stillbirths from baseline to intervention (3.2% to 0.7%) ($p=0.013$).

Conclusion: This thesis demonstrates translation of simulated ventilation skills to enhanced clinical resuscitation performance, and ultimately improved patient outcome. Improvement of the time-critical procedure

of rapid onset of bag-mask ventilation, required data-guided scenario trainings led by qualified facilitators, in combination with a broader quality improvement effort, including provision of feedback from clinical data at quality improvement meetings. The benefits demonstrated for the fresh stillborns, might be due to more non-breathing newborns being correctly classified as severely asphyxiated newborns and additionally receiving rapid and good quality resuscitations by skilled midwives. The local champions seem to have played a crucial role when implementing the quality improvement efforts, especially for simulation-based training. The interventions investigated in this thesis is considered useful for other healthcare facilities, both in high- and low resource setting, for improved quality of care of the non-breathing newborns.

Publications included

The thesis is based on the following papers which will be referred to in the text by their Roman numerals:

Study I

Vadla MS, Mdoe P, Moshiro R, Haug I, Gomo Ø, Kvaløy JT, Oftedal B, and Ersdal H. **Neonatal resuscitation skill-training using a new neonatal simulator, facilitated by local motivators; 2-year prospective observational study of 9000 trainings.** Children. 2022;9(2):134.

Study II

Vadla MS, Moshiro R, Mdoe P, Eilevstjønn J, Kvaløy JT, Hhando B, and Ersdal H. **Newborn resuscitation simulation training and changes in clinical performance and perinatal outcomes: a clinical observational study of 10,481 births.** Advances in Simulation. 2022;7(1):38.

Study III

Vadla MS, Mduma E, Kvaløy JT, Mdoe P, Hhando B, Sarangu S, Michael P, Oftedal B and Ersdal H. **Increase in newborns ventilated within the first minute of life and reduced mortality following clinical data-guided simulation training.** Simulation in Healthcare (in review). 2023.

Content

1 Introduction

The United Nations Sustainable Development Goal (SDG) 3.2 aims to end preventable deaths of newborns and children under five years of age (2). To reach that goal, the countries need cost-effective, high-impact interventions in newborn care (3). Neonatal resuscitation is considered an essential intervention for reducing neonatal mortality (3,4). Research on the impact of interventions to provide healthcare workers with improved skills and knowledge in neonatal resuscitation, is therefore of great significance. This project intended to investigate the effects of several simulation-based training (QI/SBT) interventions using a novel simulator for neonatal resuscitation, in regards of SBT performance, clinical practice, and perinatal outcome.

1.1 The burden of under-five mortality and perinatal mortality

Following The Millennium Development Goals, there was a global reduction of under-five mortality rate by more than half, from 90 to 43 deaths per 1,000 live births between 1990 and 2015 (5). The continued effort through the United Nations SDG 3.2 aims to end preventable deaths of newborns and children under five years of age. All countries are seeking to reduce under-five mortality to at least as low as 25 per 1,000 live births and neonatal mortality to at least 12 per 1,000 live births within 2030 (6). So far, the global mortality rate of children under age five has fallen by 14 percent from 2015 to 2020 (6). Still, the uneven distribution of under-five-mortality remains a challenge. Sub-Saharan Africa and central and southern Asia account for more than 80 percent of the under-five deaths in 2019, while they only account for 52 percent of the global under-five population (7). Further, the decline in neonatal mortality is slow, falling from 18.8/1000 in 2016 to 18.0/1000 in 2021 (8,9). Globally, 2.3 million newborns die every year during their first month of life, and about a third of all neonatal deaths occur on the day of birth (8). Intrapartum-related events, commonly referred to as birth asphyxia, accounts for approximately 24 percent of the neonatal deaths (Figure 1) (10,11).

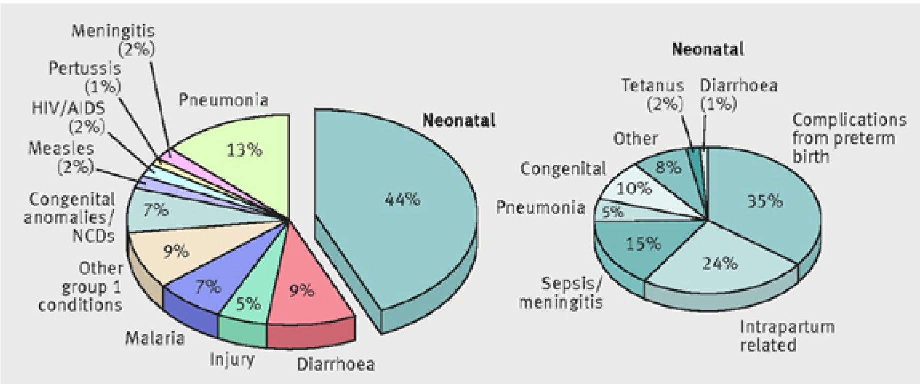


Figure 1 Global causes of newborn and under 5 mortality. NCD=non-communicable disease. Reprinted from Children's health priorities and interventions, by Wilson M Were et al., BMJ 2015, under the terms of the Creative Commons Attribution IGO License (11).

In addition, approximately two million stillbirths occur annualy (12). More than 40 percent of stillbirths take place during labour and are classified as fresh stillbirths (FSB) or intrapartum stillbirths (12). Data on stillbirth rates are unprecise and most likely underestimated, due to underreporting (12,13). There is no specific aim of reducing stillbirths in the SDG. However, the World Health Organisation (WHO) includes stillbirths in the Every Newborn Action Plan with the aim of reducing stillbirths to less than 12 or fewer per 1000 births in every country by 2030 (14).

Altogether, approximately 1.4 million newborns die every year due to intrapartum-related events and fresh stillbirths, and most of these deaths are preventable (3,12,14,15). It should be noted that there is uncertainty regarding the exact numbers of deaths, due to challenges in registration, especially for rural setting, and thus these numbers vary in different sources (10). Distinguishing between a stillbirth and a severely asphyxiated newborn resulting in early neonatal death (END) is evidently clinically challenging, demonstrating the need for tracking changes in mortality rates with measures combining FSB and early neonatal deaths (END), e.g., perinatal mortality (16).

Neonatal disorders are the leading cause of disability adjusted life years (DALY) globally with neonatal encephalopathy being a major contributor (17). In addition to the wide number of deaths caused by intrapartum-related events, there are approximately one million disabled survivors due to neonatal encephalopathy with long-term neuro-developmental injury, including cerebral palsy, global developmental problems, and malnutrition (18). Hypoxic ischaemic encephalopathy is a subgroup of neonatal encephalopathy that develops mainly from hypoxic ischaemia in the newborn (19,20).

1.1.1 Risk factors for intrapartum-related events and FSB

Intrapartum-related events originate from hypoxia and subsequent ischemia often caused by disruption of placental blood flow, infection, or a newborn failing to establish and maintain regular breathing at birth (21). The pathophysiology processes may occur before, during or after birth. Conditions at risk of causing foetal hypoxia are e.g., pre-eclampsia/eclampsia, disruptions of placental circulation (i.e. placental abruption), compressed umbilical cord, prolonged labour, breech presentation and shoulder dystocia (22). Postpartum hypoxia results from the failure of the newborn to initiate breathing after birth (22).

Severely asphyxiated newborns and fresh stillborns seem to share a common hypoxic pathway, and many fresh stillborns are probably misclassified (23,24). A study demonstrated that many of the classified FSB were actually in secondary apnoea with cardiovascular collapse because of severe asphyxia (23).

1.1.2 Interventions to reduce perinatal mortality

To reduce perinatal mortality and reach the targets of the SDG 3.2 and Every Newborn Action Plan, a variety of available, cost-effective interventions are needed, ranging from reproductive health efforts like family planning, to pregnancy care including management of pregnancy complications and further through labour management and finally newborn care (14). A previous analysis of available interventions for reduction of newborn mortality concluded that the highest effect on neonatal deaths is achieved through interventions delivered during labour and birth (3,14). This includes interventions for obstetric complications, followed by care of small and sick newborns, including neonatal resuscitation. Available interventions are thought to reduce the most common causes of neonatal mortality—preterm, intrapartum, and infection-related deaths—by 58%, 79%, and 84%, respectively (3). Every Newborn Action Plan highlights the importance of interventions for mother and newborn addressed as a functional unit delivered in a narrow time window by the same healthcare provider (or team) and in the same place, with referral for management of complications including mother and baby together (14). Specifically relevant for the present thesis, is the evidence of a 30% reduction in term intra-partum-related deaths following neonatal resuscitation training in healthcare facilities (4).

1.2 Neonatal resuscitation

In 1992, the International Liaison Committee on Resuscitation (ILCOR) was established (25). The collaboration consists of numerous member organisations, i.e., the American Heart Association and resuscitation councils from various continents. Within ILCOR, the Neonatal Life Support Task Force focuses on development of consensus on science and treatment recommendations (CosTR), based on systematic and scoping reviews (25). Guidelines for neonatal resuscitation are updated frequently, most recent in 2020 (Appendix 1) (26).

A previous study demonstrated that 93 percent of the live newborns, who initiate spontaneous breathing after birth, do so in less than 30 seconds and 99 percent in less than 60 seconds (27). Further, approximately 3-10 percent of liveborn need respiratory support, and <1 percent require advanced cardiopulmonary resuscitation (27–31). In low-resourced settings, access to advanced treatment of asphyxiated newborns is limited, and tailored resuscitation algorithms, like the Helping Babies Breathe (HBB) program, are needed (32). Importantly, all neonatal resuscitation algorithms, regardless of resource-setting, share the basic resuscitation steps of drying, warming, stimulation, clearing of airways when needed and early onset of BMV. These initial steps should be completed within 60 seconds after birth, the so-called Golden Minute (Appendix 1).

1.2.1 Helping Babies Breathe

The American Academy of Pediatrics (AAP) launched the Neonatal Resuscitation Program (NRP) in 1987, based on the ILCOR guidelines, to ensure a standardised and evidence-based approach to training in the resuscitation of the newborn (33). The program is currently implemented in 130 countries with over 5 million healthcare workers trained (34). Several neonatal programs and guidelines for increased survival have been initiated since the launch of NRP, including HBB that was introduced in 2009 (32). The paper "Neonatal resuscitation in global health settings: an examination of the past to prepare for the future", provides an overview of the different programs from NRP to Helping Babies Breathe 2nd Edition, including the Helping Mothers Survive, Every Newborn Action Plan and Essential Care for Every Baby (32).

HBB is a global curriculum applying SBT as part of the skill-training for basic neonatal resuscitation (35). The first edition of the HBB curriculum was developed by the Global Implementation Task Force, a private-public collaboration consisting of stakeholders brought together by the American Academy of Pediatrics (AAP) (32). The aim was to develop a standardized, simplified neonatal resuscitation curriculum based on the same evidence as the NRP (36). The program was especially designed for low-resource settings and has been introduced in over 80 low/middle-income countries worldwide since the introduction of the program (37). HBB focuses on improving healthcare workers understanding and basic resuscitation skills through SBT, emphasizing training with peers to build teamwork, communication skills, and reflective learning (38). Following the implementation of HBB 1st Edition, challenges of sustained changes was identified, requiring improvements of the educational package and implementation approach in the program (38). In 2016, the HBB 2nd Edition was launched, aiming to achieve more longstanding changes (Figure 2) (39).

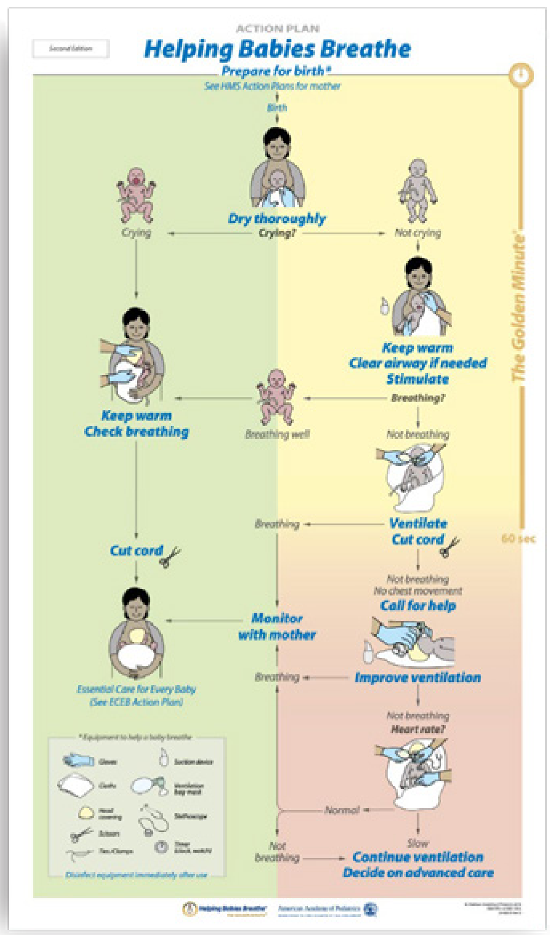


Figure 2 Action Plan for Helping Babies Breathe (HBB) 2nd Edition by American Academy of Pediatrics, Laerdal Global Health. Helping Babies Survive, 2016 Chicago. Reprinted with permission from Laerdal Global Health.

Additionally, in 2017, an Utstein-paper formulated 10 essential action points for implementation of the Helping Babies and Mothers Survive programs (40). These action points included focus on local champions, local systems for low-dose high-frequency training, facility-level perinatal QI teams and systems for collecting clinical data to drive local QI (40).

1.2.2 Helping Babies Breathe at Haydom

In 2010, Haydom Lutheran Hospital (HLH) introduced HBB as one of eight sites in a multicentre study to evaluate implementation and impact of the HBB program (30,41). Initially, the training was a one-day course, but in 2011, frequent brief on-site training was implemented to support the training with the aim of translating the skills from training to clinical practice (42). During this period, five midwives were educated as HBB trainers with responsibility of conducting a one-day HBB course annually. The trainers also provided a weekly brief (3-5 minutes) at the ward, and a monthly 40-minute HBB simulation-training for all midwives. Midwives were encouraged to conduct high-frequent individual skill-training whenever time allowed. SBT at Haydom, previous to and throughout the studies included in this thesis, is shown in Figure 3. During the study period, several QI/SBT interventions using the HBB 2nd Edition were implemented. Study I investigated the impact of implementing a novel simulator, NeoNatalie Live, using local champions to motivate for training in regards of simulation-training outcome. Study II investigated the potential improvements in clinical resuscitation performance and perinatal outcome following this implementation. Finally, Study III investigated the impact of a QI/SBT project, the Golden Minute Campaign, including e.g., data-guided feedback for scenario team trainings and monthly QI meetings, in regards of potential improvements in clinical performance and perinatal outcome. Detailed information regarding all study interventions is provided in chapter 4.4 Interventions.

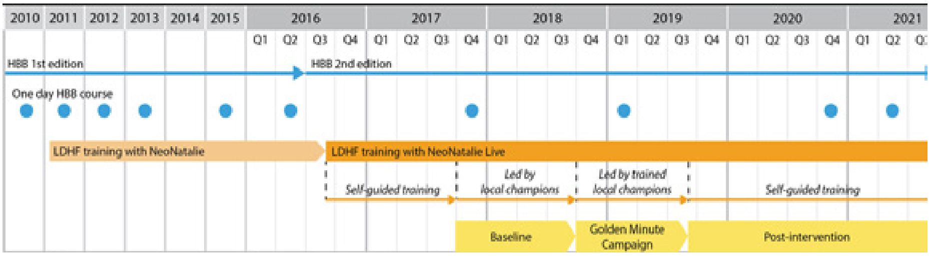


Figure 3. Simulation-based training at Haydom Lutheran Hospital 2010–2021. HBB; Helping Babies Breathe, LDHF; low-dose high frequency training; Local Champions; dedicated midwives in charge of facilitation and motivation for one-site training in HBB 2nd Edition. The Golden Minute Campaign was a QI/SBT project, including data-guided feedback, during the post-intervention period the QI effort were scaled down. The figure is reprinted from Increase in newborns ventilated within the first minute of life and reduced mortality following clinical data-guided simulation training, by Vadla MS et. al, Simulation in Healthcare (in review), 2023, under the terms of the Creative Commons Attribution IGO License (Study III).

1.2.3 Safer Births

The present thesis is part of the Safer Births research project. Safer Births is a research and development project to save lives at birth initiated at HLH in 2013 (43). Throughout the last decade, clinical tools and educational interventions have been implemented and investigated at the hospital, resulting in more than 100 published papers, and improved neonatal survival (43). The clinical tools consist of a novel foetal heart rate monitor, newborn heart rate meter, an upright bag-mask ventilator and a newborn resuscitation simulator and is described in the Safer Births Report (44). Clinical data-driven feedback, where clinicians receive clinical data from their ward, has recently been an important feature of the QI effort in the Safer Births project.

1.2.4 The Golden Minute

Both the ILCOR guideline and the HBB algorithm highlight the importance of rapid initiation of BMV within the first minute of life. Guideline adherence of rapid initiation of BMV has proven to be challenging (45–48). A recent study from three low-income countries demonstrated that only <1 percent of non-breathing newborns received BMV within the Golden Minute (45). The reasons underlying the difficulties of timely BMV is not well documented but is thought to be caused by time constraint and cognitive load, due to multiple tasks required completed within a constricted timeframe (49). In a qualitative study, simulation-facilitators regarded challenges in understanding the clinical relevance of the Golden Minute and struggles of accurately identify non-breathing newborns needing resuscitation as main barriers for timely BMV (48). In addition, they mentioned slow cord clamping, performance of initial resuscitation steps, and care for the mother as factors increasing time to onset of BMV (48). Despite these barriers, a recent a study from Nepal managed to demonstrate an increase newborns ventilated within the Golden Minute from none to 84 percent following a QI intervention at a tertiary hospital, showing the potential of improving this challenging time-critical procedure (50).

1.3 Simulation-based training

Simulation-based training is commonly used to improve skills in neonatal resuscitation and is a key component of the HBB program (51,52). Gaba defines simulation as "a technique to replace or amplify real experiences with guided experiences, often immersive in nature, that evoke or replicate aspects of the real world in a fully interactive manner" (53). Simulation may include role-playing, use of standardized patients, computer patients or electronic patients (manikins/simulators) (51). Simulators features varying levels of fidelity: low fidelity simulators offer a physical body, but require an instructor to provide physiological information, while as high-fidelity simulators are interactive and life-like and can illuminate physiological conditions (51). Issenberg et al. lists several features that are associated with effectiveness in high-fidelity simulators including i.e., provision of feedback, curriculum integration, range of difficulty level, repetitive practice, and individualized learning (54). SBT can be located in-situ or off-cite, e.g., at a simulation-centre, and the advantages for different locations depend on the aim of the training (55). Superiority of in-situ SBT for individual or team learning has not been demonstrated, but in-situ SBT has shown an advantage for organisational learning (56,57). Prof. Brazil introduced the term translational simulation as an alternative for the more narrowed focus of SBT location and modality and described the term as "healthcare simulation focused directly on improving patient care and healthcare systems, through diagnosing safety and performance issues and delivering simulation-based intervention, irrespective of the location, modality or content of the simulation." (55). The simulator used for SBT in this thesis was a low-cost, but high-fidelity manikin, NeoNatalie Live (Laerdal Global Health) providing in-situ SBT at the labour ward in a rural Tanzanian hospital.

SBT can be carried out individually or in a team, depending on the aim of the training. Individual training mainly focuses on improving technical skills, like bag-mask ventilation (BMV) of newborns or surgical suturing, while team training additionally enables learning of non-technical skills, i.e., situation awareness, leadership and decision making, through predefined scenarios (58). For time dependent medical procedures, like rapid onset of BMV or stroke management, scenario team-training has been proven effectful for improved quality of care (59,60). In these clinical settings, it is necessary to offer healthcare workers learning opportunities that includes realistic scenarios capturing the complete timeline of the procedure, involves the entire team and includes debriefing in a safe learning environment (59–62). Feedback loops, where factors relevant to local practice is guiding the scenario team-trainings, as part of QI projects are promising, but the literature on the topic is limited (59,60). Audit and feedback will be discussed in greater detail in the theory section. The SBT interventions in the included studies of this thesis included both individual skill-training and scenario team-training.

In general, barriers to clinical in-service SBT are typically high staff turnover and limited time to focus on training and practice (63). For resource-limited settings, it is essential that developers of SBT interventions carefully consider culture and contextual factors, e.g., available equipment and drug names, when designing and implementing scenarios for SBT, to avoid unrealistic or potentially hazardous scenarios (64). In many settings, feedback and debriefing as part of education are new concepts, and "shame and blame" culture might be barriers for creating the necessary psychological safety for SBT (65). (65). Further, sustainability must be considered carefully, e.g., using low-cost, low-fidelity simulators that require minimal maintenance and training, limiting supplies needed for facilitating the scenario and having collaborators eager to continue the training (64).

1.3.1 Simulation-based training in neonatal resuscitation

SBT in neonatal resuscitation is considered highly effective regardless of assessed outcome, level of learning, study design og specific task trained (66). Simulation-based team training also holds the potential of improving important non-technical skills in neonatal resuscitation (67). A Cochrane review concluded that training healthcare workers in standardized formal neonatal resuscitation training programs resulted in a reduction of early neonatal and 28-day mortality (68). The study highlights the need for further research in educational methods that facilitate acquisition and retention of knowledge and skills and encourage future studies to report outcomes related to long-term health (68).

Patel et al (69) showed a significant reduction in perinatal mortality after implementation of a variety of neonatal resuscitation training (NRT) programmes (all the NRT programmes included SBT for skill-training). Stillbirths were reduced by 12 percent, fresh stillbirths by 26 percent and one-day mortality by 42 percent. The authors highlight the need for further studies to investigate the best combination of setting and type of trainee, in addition to assessing the optimal frequency of training (69).

The literature on HBB show reduced early neonatal mortality and FSB following implementation of HBB 1st Edition (30,42,50,63,70). A recent systematic review of the HBB program, highlights the need for studies related to HBB 2nd Edition and other guidelines for implementing sustained practice and local mentorship (63).

1.4 Quality Improvement in healthcare

There is growing body of supporting evidence demonstrating SBT to be an effective learning method (51,52,71). However, the greater potential might be utilized when embedding SBT in broader QI efforts. Then SBT might contribute to and shape the culture and relationships that strengthen structural or process specific intervention (72). In general, QI efforts in healthcare are implemented to provide delivery of care that is safe, timely, equitable and cost effective (73). Healthcare systems are dynamical, complex social systems, changing over time, consequently challenging the processes of QI (73). Evidence of the impact of QI interventions diverge, and systematic reviews conclude that QI interventions depend on the specific setting for implementation (74–76). The literature on QI from developing countries identifies some success factors for improved patient care and healthcare delivery in low-resourced settings (77). These studies show that successful QI interventions are often multifaceted, concurrently addressing providers, patients and system interventions, and establishing standards and then continuous measurement and feedback to track progress (77,78). As the science of QI has progressed, the focus of utilizing high-quality data to identify gaps in service delivery and inform improvement approaches has increased (79–81). Audit and feedback (A&F) will be discussed in further detail in chapter 3. Theoretical perspectives.

Among several implementation strategies for QI interventions, the use of local champions is widely recommended (80,82–85). Miech et al. define a champion as "an implementation-related role occupied by people who (a) are internal to an organization; (b) generally have an intrinsic interest and commitment to implementing a change; (c) work diligently and relentlessly to drive implementation forward, even if those efforts receive no formal recognition or compensation; (d) are enthusiastic, dynamic, energetic, personable, and persistent; and (e) have strength of conviction" (84). Local champions have been appointed when implementing QI interventions in several clinical areas, including stroke management (86,87), resuscitation (88) and mental health (85) and was used to facilitate the QI/SBT intervention in the present thesis.

Overall, there is a need for more knowledge regarding translation of simulated skills into clinical practice and impact of patient outcome, as well as research of SBT as part of more comprehensive QI efforts.

2 Aims

The overall aim of the thesis was to investigate the effects of several QI/SBT interventions, on SBT performance, clinical practice, and perinatal outcome in neonatal resuscitation. The thesis aimed at providing new knowledge regarding implementation strategies for the HBB 2nd Edition and to achieve successful translation of simulation-based training skills into improved clinical performance.

2.1 The specific aims of the studies

1. To describe changes in staff participation in SBT, training frequency, and simulated ventilation quality, before and after introduction of local champions to facilitate HBB training using a novel simulator for neonatal resuscitation (Study I).

2. To describe changes in clinical resuscitation practice and perinatal outcomes, before and after introduction of a novel newborn simulator and then local champions to facilitate in-situ SBT and scenario team-training for neonatal resuscitation (Study II).

3. To decrease time from birth to start of ventilation and document potential changes in perinatal outcomes after implementation of an HBB QI intervention (Study III).

3 Theoretical perspectives

3.1 Kirkpatrick model-evaluation of simulation-based training

The Kirkpatrick model has been used for evaluation of training effectiveness since 1959 (89) and the model is often used to evaluate SBT interventions (90–93). The Kirkpatrick model comprises four-levels of training evaluation, illustrated in Figure 4 (94). Level 1-reaction, evaluates whether the participant find the training favourable, engaging, and relevant for their jobs. Level 2 - learning, evaluates the learning in terms of improved knowledge and simulated skills, in addition to increased confidence and commitment. Level 3 – behaviour, evaluates the participants behaviour in their clinical work, investigating the translation of simulated skills to clinical performance. Finally, Level 4 – results, evaluates if the targeted results, e.g., improved patient outcomes, occur as a result of the training. The Kirkpatrick model was chosen as a theoretical model in this thesis, due to the aim of evaluating SBT interventions at various outcome levels, learning, clinical performance, and patient outcome. The model is known to be operational, providing clear evaluative steps, and relevant across settings and industries (95), and was thus considered suitable for evaluating the present interventions. The SBT interventions in the thesis will be evaluated according to the Kirkpatrick model, Level 2 (learning), 3 (behaviour) and 4 (results).

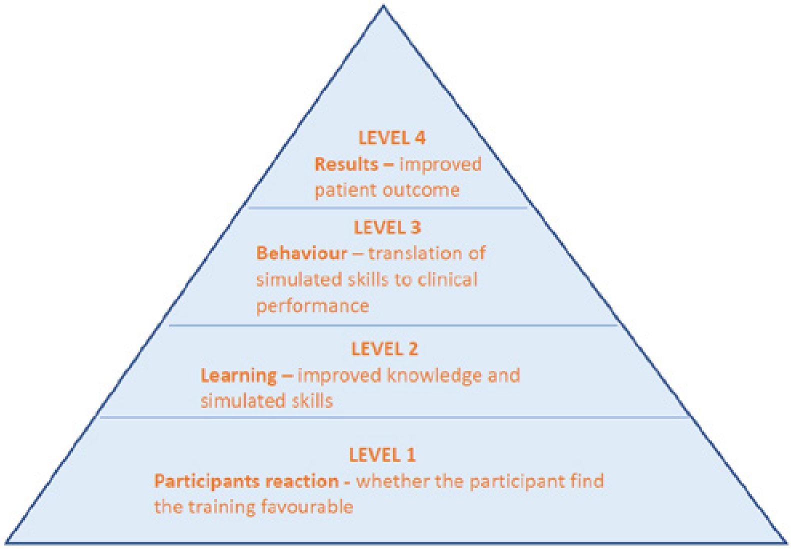


Figure 4 Kirkpatrick model illustrating the four levels of evaluation of training effectiveness.

3.2 Audit & Feedback- a QI tool

In the present thesis, feedback was a substantial part of the interventions, both in individual skill-training (automated performance feedback), scenario-based team-training (clinical data-guided scenario design and debriefing) and during the more comprehensive QI intervention, the Golden Minute Campaign (clinical data for QI meeting discussions). Audit and feedback (A&F) means supporting recipients with a summary of their performance over a specified period of time (96). A&F is considered an important tool in QI and has received enhanced focus as high-quality data is increasingly used to identify gaps in service delivery and inform improvement approaches (79–81). Previous reviews of A&F in healthcare concluded that the approach led to small but potentially important improvements in professional practice, but with wide variations in its impact (96–98). Further, the effectiveness of A&F seemed to depend on baseline performance and how the feedback was provided (97). Five important features of effective A&F were summed up in a Cochrane review: i) the health professionals are not performing well to start out with; ii) the person responsible for the audit and feedback is a supervisor or colleague; iii) feedback is provided more than once; iv) feedback is given both verbally and in writing; v) feedback includes clear targets and an action plan (97).

A recent model, the Clinical Performance Feedback Intervention Theory (CP-FIT), claims to explain reasons for feedback effectiveness variation found in the latest Cochrane review (98,99). This model will be used for a more detailed discussion of the complex feedback component of the QI intervention, the Golden Minute Campaign, in this thesis. The model was preferred because it offers, to our knowledge, the most comprehensive theory to date on terms for optimal audit and feedback and is developed specifically for the complexity of healthcare systems.

3.2.1 Clinical Performance Feedback Intervention Theory (CP-FIT)

CP-FIT was designed due to existing theories lacking comprehensiveness and specificity necessary for feedback interventions in healthcare. The authors synthesised 65 papers evaluating 73 feedback interventions from countries spanning five continents and developed their model from the synthesis which builds on 30 pre-existing theories

(99). The CP FIT model was specifically developed for the healthcare system to explain factors that influence chances of successful use of audit and feedback. The model is illustrated in Figure 5 (99). Three sets of variables: the feedback variables, recipient variables and context variables, all influence the feedback cycle through common mechanisms, as illustrated in Figure 5. The eleven steps of the feedback cycle, e.g., goal setting, data collection and analysis, are sequential actions necessary to improve clinical performance. Initially, there is goal setting for improvement, then data on this specific clinical task is collected, analysed, and presented to the healthcare workers. Further the reception, comprehension, and acceptance of this by the healthcare workers result in a planned behavioural response based on the feedback which ultimately leads to improved clinical performance. In some cases, a further step of verification could occur between perception and acceptance of feedback where recipients question the data underlying their feedback. In addition to improved clinical performance, positive and/or negative unintended consequences may occur as a result of the feedback intervention. To ensure a successful progress of the feedback cycle, it is substantial that all steps are completed and that the feedback intervention includes theory-based, influential variables (feedback, recipient, and context variables).

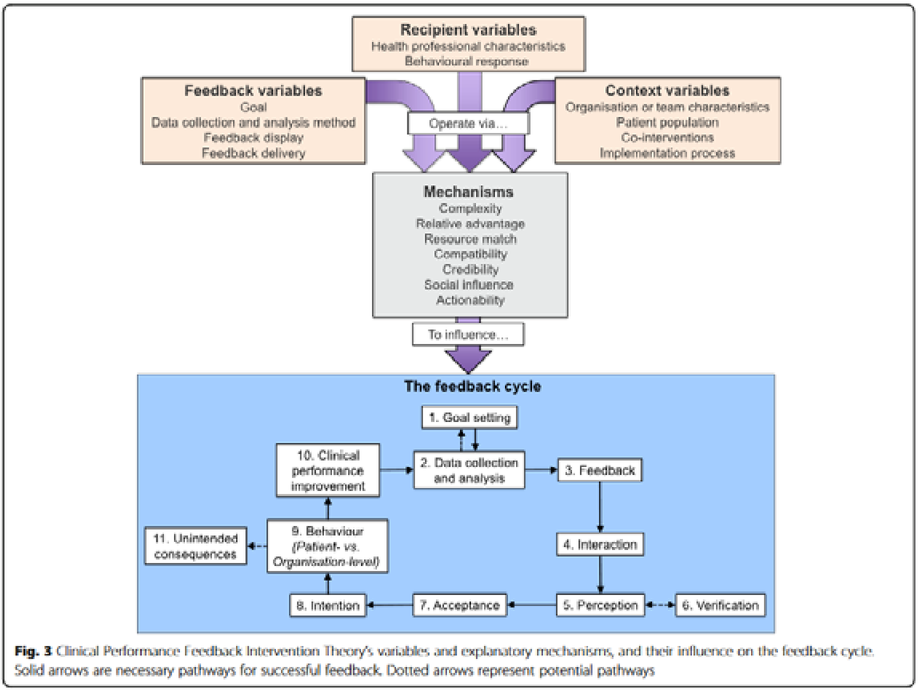


Figure 5 Clinical Performance Feedback Intervention Theory: the variables, explanatory mechanisms, and feedback cycle. Reprinted from Clinical Performance Feedback Intervention Theory (CP-FIT): a new theory for designing, implementing, and evaluating feedback in health care based on a systematic review and meta-synthesis of qualitative research by Brown et al., Implementation Science, 2019, under the terms of the Creative Commons Attribution IGO License (99).

CP-FIT states that "effective feedback works in a cycle of sequential processes; it becomes less effective if any individual process fails, thus halting progress round the cycle. Feedback's success is influenced by several factors operating via a set of common explanatory mechanisms." (99). These explanatory mechanisms, e.g., resource match and complexity, enhance or diminish the effect of the feedback cycle by affecting the different steps in the cycle. CP-FIT summarises these effects in three propositions: "(1) health care professionals and organisations have a finite capacity to engage with feedback, (2) these parties have strong beliefs regarding how patient care should be provided that influence their interactions with feedback, and (3) feedback that directly supports clinical behaviours is most effective" (99).

3.2.2 CP-FIT and the Golden Minute Campaign

The Golden Minute Campaign was designed according to the Plan-Do-Study-Act (PDSA) cycle (73). The PDSA method follow a specified four phase cyclic learning approach to achieve desired changes aimed at improvement. In the 'plan' phase a change aimed at improvement is identified, the 'do' phase apply the change, the 'study' stage examines the effect of the change, and the 'act' phase identifies adaptations and next steps to inform a new cycle (73). The "study" component of the PDSA cycle in this thesis involved a comprehensive feedback intervention, with collection of clinical data and the presentation of feedback regarding clinical performance to the healthcare workers during e.g., monthly QI meetings. The feedback was discussed at the meetings with the aim of agreement on action points for clinical performance improvement. In addition, feedback on individual performance during real-life resuscitations were debriefed immediately and further conversed at ward meeting during the week. Clinical data guided the design of scenarios for team-trainings, hence addressing gaps in clinical performance and facilitating targeted training. This part of the PDSA cycle includes the components of Feedback Cycle process of CP-FIT in the present thesis and will serve as a theoretical perspective to broaden the discussion and evaluation of the QI/SBT intervention (the Golden Minute Campaign). According to Bong, comprehensive theory allows researcher to select variables of interest and analyse their relationship without losing sight of the big picture (100). CP-FIT aims at utilizing feedback from clinical patient data, thus it is not considered suitable for evaluation of the feedback provided by the simulator and during scenario debriefings in Study I and II.

4 Methodology

4.1 Study design

The thesis comprised three quantitative pre/post observational studies shown in Figure 6. All studies were conducted at HLH; Study I was conducted from 1st September 2016 to 31st August 2018, Study II was conducted from 1st September 2015 to 31st August 2018, and Study III was conducted from 1st October 2017 to 31st August 2021.

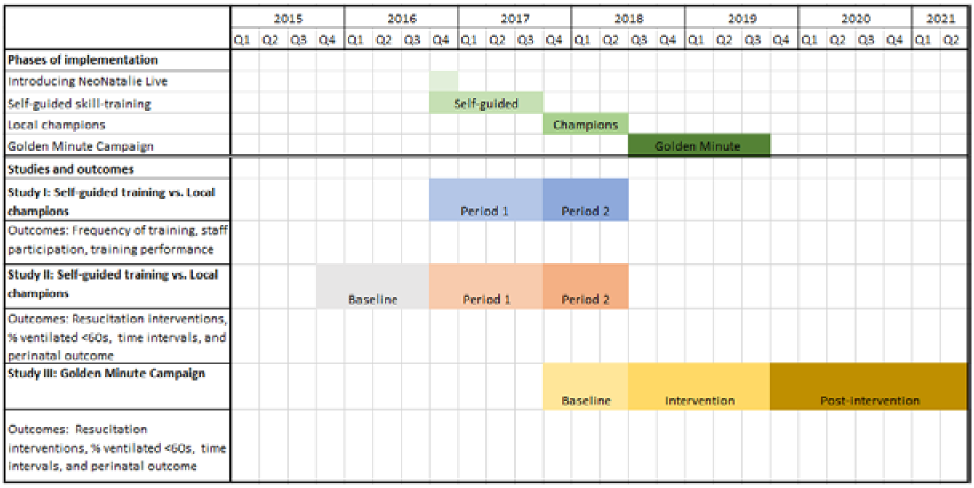


Figure 6. Overview of the studies included in the thesis: Study I and II: Self-guided training vs. Local champions, Study III: Local champions vs the Golden Minute Campaign.

4.2 Participants

The participants of the SBT intervention for Study I and II were midwives working at labour ward and in neonatal care unit (included from January 2018). All midwives at the labour ward, and the neonatal unit from January 2018, were eligible for the study and all gave consent for participation in the study. The ward experiences a high-staff turnover, due to new government employment opportunities every midyear, leading to experienced midwives leaving the hospital and newly educated midwives starting at the end of each year. Thus, the number of participants in Study I and II varied throughout the study period (n= 15-27). Training data were recorded from the simulator, NeoNatalie Live, and all individual skill-training sessions conducted by the midwives were recorded during the study. In Study III, all healthcare workers at labour ward were included in the intervention, the Golden Minute Campaign, however most participants were midwives. For Study II and III, clinical performance and perinatal outcomes were recorded from all births. All labouring women and newborns at HLH were participating in the study from 1st September 2015 to 31st of August 2021.

4.3 Study setting

4.3.1 Tanzania

The United Republic of Tanzania is the largest country in East Africa, capturing an area of about 945,087 square kilometres (101). The union was formed in April 1964 and Tanzania Mainland comprises 27 administrative regions, 133 districts and 162 councils (101). Over the past decade, Tanzania has achieved relatively strong economic growth and declining poverty rates, but the country is still considered a lower middle-income country (102). Some key indicators are presented in Table 1.

Table 1. Key indicators for The United Republic of Tanzania regarding demographics, mortality, and healthcare.

Indicator	
Estimated Population December 2022	63,918,927[a]
Population density	69.14 persons per square kilometre[b]
Population composition	Males 51.7%, Female 48.3%[b]
Population growth per year	3.0%[b]
Births per year	2,145,193[b]
Total fertility rate	4.7 per woman[b]
Life expectancy	66.1 years[b]
Median age	18 years[b]
Poverty rate (the percentage of the population living on less than $5.50 a day)	91.8%[b]
Literacy rate	71.8%[b]
Maternal mortality rate	5.2/1000[b]
Under-five-mortality rate	48.9/1000[c]
Neonatal mortality rate	20.1/1000[c]
Antenatal care 1+ visit - percentage of women (aged 15-49 years) attended at least once during pregnancy by skilled health personnel	98%[c]
Antenatal care 4+ visits - percentage of women (aged 15-49 years) attended at least four times during pregnancy by any provider	62.2%[c]
Skilled birth attendant - percentage of deliveries attended by skilled health personnel	63.5%[c]
Postnatal care for newborns - percentage of newborns who have a postnatal contact with a health provider within 2 days of delivery	42.9%[c]
Government expenditure on health (% GDP)	3.83[d]

[a]Worldometer (103); [b]Tanzania Fertility Rate 1950-2022 (104); [c]United Republic of Tanzania (TZA) - Demographics, Health & Infant Mortality UNICEF DATA (105); [d]Current health expenditure (% of GDP) – Tanzania (106)

The Ministry of Health and Social Welfare (MOHSW) owns the overall responsibility for the health and social welfare services and defines the priorities for the sector services (101). Every fifth year, MOHSW publishes the Health Sector Strategic Plan (HSSP) as their guiding reference document for further planning at all levels of the healthcare system (101,107).

An overview of the healthcare system in Tanzania is shown in Figure 7, as presented in HSSP IV (101). Tanzania has a long history of public-private partnerships, and about 40% of health facilities are owned by private sector, which include faith-based organisations, civil society organizations, and private-for-profit providers (107). Primary healthcare services are the basis of the healthcare system where healthcare workers are engaged at dispensaries and health centres (101). Dispensaries provide preventive and curative outpatient services, while health centres also admit patients and occasionally provide surgical services. Council hospitals offer healthcare to referred patients and provide medical and basic surgical services. Regional Referral Hospitals function as referral hospitals delivering specialist medical care. Zonal and National Hospitals deliver advanced medical care and are educating hospitals for medical, paramedical, and nursing training (101). The educational qualification of midwives in Tanzania is a Bachelor of Science in nursing-midwifery (108).

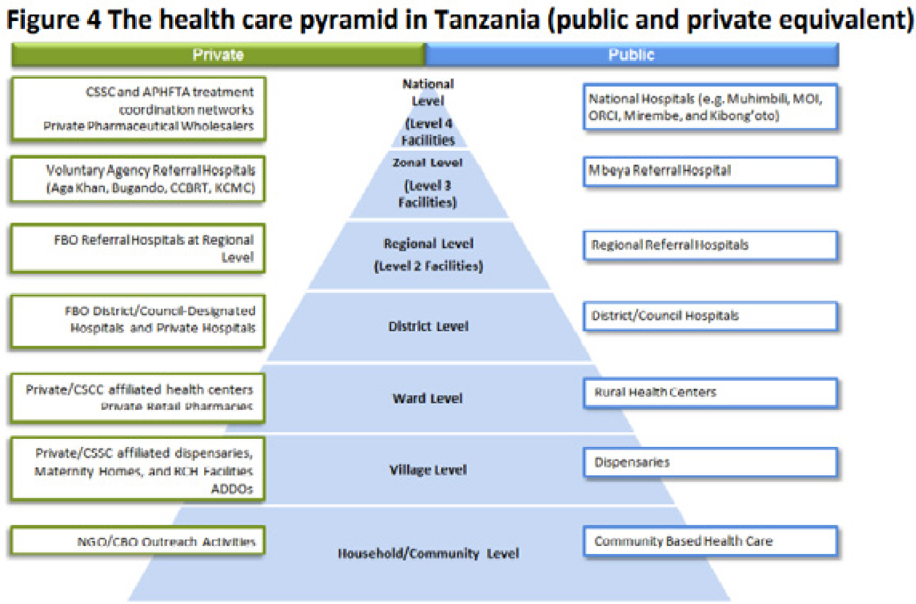


Figure 7. An overview of the healthcare system in Tanzania with a collaboration of public and private healthcare providers at different levels. Figure reprinted from Health Sector Strategic Plan IV (HSSP IV), by United Republic of Tanzania Ministry of Health and Social Welfare (101).

According to the HSSP IV, reproductive health services are not performing as intended in Tanzania and most targets for these services in HSSP III have not been reached (101). Even though there has been increasing numbers of facilities that offer reproductive health services, skilled birth attendance and post-natal care during the HSSP III period, the facilities still face shortages of skilled staff and supplies (101). In many rural areas, the pace of quality improvement and availability of health services lags that of urban areas. Additionally, the healthcare provided for persons with disabilities in Tanzania are inadequate and inequitable, and particularly challenging in rural areas (109).

4.3.2 Haydom Lutheran Hospital

Haydom Lutheran Hospital (HLH) is a referral hospital in the Manyara region of the northern-central part of Tanzania. HLH is a non-governmental hospital owned by the Lutheran church. The Manyara region has four hospitals, where HLH serves a catchment area of about 500 000 people, and a higher reference area covering 2 million people (110). The Haydom Township, where HLH is located, is a rural, low-income setting with 20,000 inhabitants. HLH has a capacity of 450 beds and provides reproductive and child health services, in addition to medical, surgical, outpatient, pharmacy, and medical and technical divisional services. During the study period, 3,000-3,500 births were conducted annually at the hospital. Approximately 50 percent of the births in the catchment area are taking place outside healthcare facilities (111). Prior to 2013, delivery services at HLH were free of charge, but in 2013/2014 the hospital introduced several user fees. In July 2013, HLH introduced a fee of about 1 USD per kilometre distance for ambulance services, and in January 2014 a delivery fee of 12 USD for a vaginal delivery and about 30 USD for a caesarean section, unless it was proved that the family was not able to afford the cost (112). A previous study demonstrated an increase in labour complications and caesarean sections at HLH after the introduction of these fees (112).

4.3.3 Labour ward

The maternity block at HLH includes the labour ward, postnatal ward, and neonatal care unit. Labour ward consists of six one-bed delivery rooms with neonatal resuscitation tables present in every room and one operating theatre for caesarean sections. Midwives are working in three shifts, covering 24/7, and are responsible for all births and most of the neonatal resuscitations. There are three to five midwives present on each shift. Physicians are present during daytime and on-call during night-time, and the ward provides comprehensive obstetric and basic newborn care on a 24/7-basis. One midwife covers the neonatal unit, where severely sick newborns are admitted.

4.4 Interventions

4.4.1 NeoNatalie Live

In September 2016, HLH implemented a novel newborn simulator, NeoNatalie Live (Laerdal Global Health, Stavanger, Norway), at their labour ward for in-situ SBT. Their main focuses were to reduce time to start ventilation, improve time of applied continuous ventilation, and utilization of heart rate as an indicator of ventilation quality. The simulator was easily accessible, and the midwives were instructed to train whenever time allowed during their working shifts according to self-guided practice.

NeoNatalie Live is a novel simulator for neonatal resuscitation, co-designed with clinicians from HLH (Figure 8). The simulator features four different patient cases based on 1,237 live neonatal resuscitations recorded at HLH (113). The manikin is substantially improved compared to the original manikin, NeoNatalie, previously used in the HBB program. The manikin has a realistic appearance, e.g., variable lung compliance and dynamic heart rate that varies with lung aeration (114). The simulator provides training opportunities for individual skill-training as well as scenario-based team training.

Figure 8. The simulator, NeoNatalie Live, located at one of the delivery rooms at labour ward at Haydom Lutheran Hospital. The equipment used for training is the newborn simulator, Ipad, heart rate meter, suction device (penguin) for clearing airways and the upright bag for ventilation. (Photo: private)

Automated feedback, according to the action points of the HBB algorithm, is provided immediately following each session. There are eight possible feedback messages prioritized according to clinical relevance: missing head tilt, insufficient opening ventilations, paused ventilations, mask leak, too high ventilation pressure, and ventilation rate. After receiving the initial feedback, the learner is encouraged to try again and receives new feedback after the second attempt (Figure 9.) Sessions with no errors receives the feedback “Well done”. The Learner Guide used in the studies is available in Appendix 2.

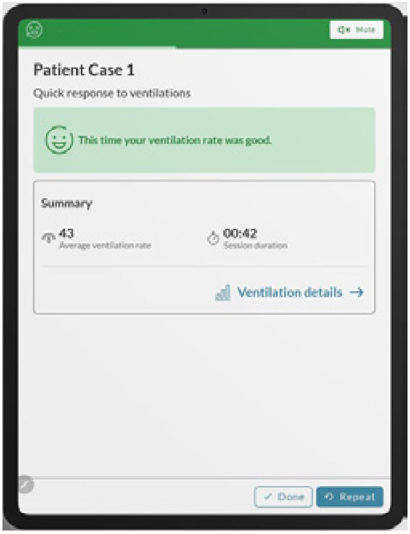


Figure 9. An example of feedback provided after second attempt in a training session with NeoNatalie Live (Photo: Laerdal Global Health).

The simulator can be operated using an Ipad or manually through a display at the head of the manikin. When using the Ipad, various information regarding the training-session is automatically stored in a weblog and can be accessed for QI efforts (Figure 10). Stored information includes time and date, learner ID, and the full recording of the resuscitation. "Valid ventilations" is defined as ventilations with correct head tilt and ventilation peak inflation pressure but does not include ventilation rate and pauses in ventilations.

Figure 10. NeoNatalie Live: The newborn manikin communicates with the Ipad and wide-ranging information from the training session is stored in a Web log (Photo: Laerdal Global Health).

4.4.2 Local champions facilitating SBT

Following one year of self-guided individual skill-training using the novel manikin, the hospital management appointed four midwives as local champions to motivate for enhanced SBT effort at the labour ward. The local champions were junior midwives, carefully selected according to their personality traits: hard-working, inspiring, team builders and easy approachable, and their beneficial influence and accessibility at the ward. These midwives were responsible for encouraging their colleague midwives to train and for technical support to ensure an all-time functioning simulator. In addition to their motivating role, they were also responsible for scenario team-trainings at the ward. Preceding the appointment, the local champions received a Master Trainer Guide for the manikin (Appendix 3) and a Learner Trainer Guide (Appendix 2) for their colleagues. The local champions possessed a beneficial social position, competence in neonatal resuscitation and they were committed for the task, in line with recommendations from previous research

(115,116). They did not receive any remuneration for this specific assignment and did not possess other roles, apart from their clinical tasks, during the study period.

Figure 11. Three out of four appointed local champions responsible for encouraging their colleagues for simulation-based training at labour ward in Haydom: Sabrina Sarangu, Paskalina Michael and Barikiel Hhando Hhoki. (Photo: private)

4.4.3 The Golden Minute Campaign

After two years of high-frequent SBT, with more than 9,000 recorded trainings conducted and improved training- and clinical performance (Study I and Study II), HLH acknowledged the need for a more comprehensive QI strategy to reach their goal of reduced time from birth to first ventilation. The hospital decided on a goal of 70 percent of non-breathing newborns receiving ventilation within the Golden Minute. Prior to the QI project, the local champions received a 4-day adopted EU SimLevel-1 Train-the-Trainer simulation course at SAFER, Norway (117). The local champions were appointed to take the lead in the QI project, with support from the management team. QI activities incorporated in the project are presented in Table 2, and included QI meetings, scenario based SBT and individual SBT, in addition to action plans for necessary changes at the ward. One important aspect of the project was the use of clinical data-driven feedback. Clinical data was collected from all resuscitations and newborns at the hospital and presented to the healthcare workers at QI meetings, providing opportunities for informed changes through action points and scenario trainings. Action points agreed upon during the project included increased awareness of important aspects of neonatal resuscitation, increased preparedness for resuscitation, continuous training of new staff, and recording of resuscitations. It was also agreed that research assistants should inform the healthcare worker at 30 and 50 seconds after birth during a real-life resuscitation.

The scenario team-trainings were conducted in-situ at labour ward. The sessions lasted for 1.5-2 hours and involved three midwives and at least one local champion. Initiating the training, a short briefing with information about the scenario and the learning objectives were provided. Learning objectives were e.g., 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 following 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 (Study III).

Table 2. Overview of the QI activities, responsible and participants for the Golden Minute Campaign.

Activity	Description	Responsible	Participants
Train-the-trainer simulation course to become simulation- "facilitator"	EU-sim 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
Weekly morning report	Presentation of clinical data from the last week resuscitations, including perinatal outcomes.	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 three 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".	Midwife	Staff from labor ward present at shift meeting
Clinical debriefing after resuscitation	7-10 minutes 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.	Midwives and local champion (if available)	Midwives, research assistant, other healthcare workers and physician involved in the resuscitation
Low-Dose High-Frequency individual skill-training	Midwives were encouraged to carry out individual skill-training four times per month, in addition to a monthly scenario team-training.		
Annual one-day-HBB course	One-day HBB course providing knowledge and skill training in newborn resuscitation.	HBB master trainers (midwives at Haydom who have conducted a one-day HBB Master Trainer Course) and local champions	Staff in the labor ward

QI= Quality Improvements, HBB=Helping Babies Breathe. The table is reprinted from Increase in newborns ventilated within the first minute of life and reduced mortality following clinical data-guided simulation training by Vadla MS et. al, Simulation in Healthcare (in review), 2023, under the terms of the Creative Commons Attribution IGO License (Study III).

During the two-year post-intervention period, 01.09.19-31.08.21, the QI efforts were substantially scaled down; weekly reports concerning clinical outcomes continued, but there were no monthly meetings and decreased focus on SBT, both individual skill-training and scenario team-training. In the analyses, we divide the post-intervention period into two one-year periods to study time trends.

4.5 Data collection

For Study I, data were collected from the simulator, NeoNatalie Live, from the training sessions stored in the weblog. The weblog provided detailed information about each individual training session recorded between 1st September 2016 and 31st August 2018, aside from December 2016 when the simulator was out of order.

For Study II, data were collected from a comprehensive data collection form (Appendix 4) and from the Newborn Resuscitation Monitor (Laerdal Global Health, Stavanger, Norway), Figure 12. Trained research assistants, working in three shifts covering day and night at labour ward, observed and recorded information regarding labour and newborn characteristics, events and resuscitation interventions from all births throughout the study period. The research assistants did not have a medical education and have been conducting data collection for several previous studies at HLH, since 2009 (118). In addition, the Newborn Resuscitation Monitor collected data through sensors located between the ventilation bag and the facemask. The sensors synchronously captured and recorded heart rate from ECG, as well as airway pressure, flow, volume, and expired CO2 during BMV (119). Data were collected from all neonatal resuscitations performed by healthcare personnel working in the labor ward, although most resuscitations (66-84%) were delivered by midwives, who were the target of the SBT intervention.

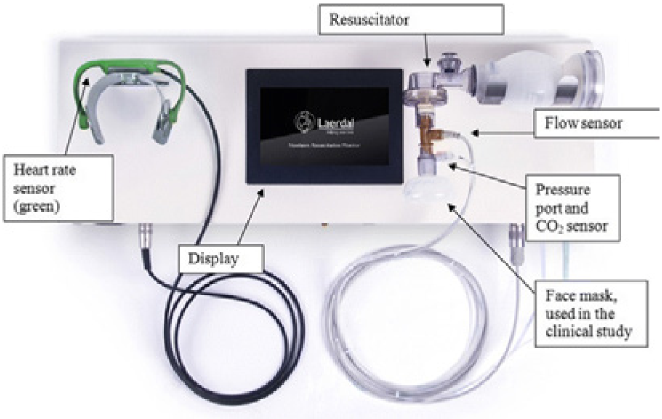


Figure 12. The Newborn Resuscitation Monitor with sensors capturing and recording heart rate, airway pressure, flow, volume, and expired CO2 during bag-mask ventilation. Photo reprinted from Størdal K, Eilevstjønn J, Mduma E, Holte K, Thallinger M, Linde J, et al. Increased perinatal survival and improved ventilation skills over a five-year period: An observational study. PLOS ONE. 2020 Oct 12;15(10):e0240520 under the terms of the Creative Commons Attribution IGO License (119).

For Study III, data were collected from the same data collection form used for Study II (Appendix 4).

4.6 Data management and quality control

According to the instructions for dataflow in the Safer Births project, a designated and trained data management team (Research Quality Controllers) handled data management at HLH. Data from the data collection form where double-entered using Epidata 3.1 by trained data clerks and transferred to SPSS for statistical analysis. The internal principal investigator of Safer Births 2.0 was responsible for supervising the data collection and data management at HLH. All raw data resided at HLH, while de-identified copies were made available to researchers abroad. Data sharing were controlled by the Scientific Steering Committee to maintain full data integrity and privacy.

4.7 Measures/variables

During the studies conducted in the present thesis, measures of demographics, training frequency and performance, resuscitation characteristics, BMV characteristics and newborn outcome were taken. Detailed information regarding outcomes in the three individual studies is presented in Table 3.

Table 3. Participants, interventions, and outcome variables for the three studies comprising the thesis.

Time periods	Study I 01.09.16- 31.08.18	Study II 01.09.15- 31.08.18	Study III 01.10.17- 31.08.21
Participants			
Midwives	+	+	+
All healthcare workers	-	-	+
Mothers and newborns	-	+	+
Intervention	Local champions	Local champions	Golden Minute Campaign
Outcomes			
Training	+	-	-
Training frequency	+	+	+
Staff participation	+	-	-
Patient case	+	-	-
Training performance	+	-	-
Valid ventilations	+	-	-
Ventilation rate	+	-	-
Clinical performance			
Bag-mask ventilation	-	+	+
Stimulation	-	+	+
Suction	-	+	+
Time to ventilation	-	+	+
% ventilated <60 seconds	-	+	+
Midwives performing resuscitation	-	+	+
Heart rate characteristics	-	+	-
BMV characteristics	-	+	-
Newborn outcomes			
APGAR 1 min. and 5 min.	-	+	+
Fresh stillbirths	-	+	+
30 min. perinatal mortality	-	+	+
24 h. neonatal mortality	-	+	+
Admitted neonatal care unit	-	+	+

BMV=bag-mask ventilation

4.8 Statistical analysis

Data analysis was performed by Matlab (MathWorks, Natick, MA) and SPSS (IBM Corp., Armonk, NY). Continuous data were presented by mean±SD or median (quartiles), as appropriate, and categorical data by percentages (numbers), unless otherwise stated. For Study II and III, including multiple study periods, Kruskal Wallis and Mann-Whitney tests were used to test for differences over the periods in continuous variables. In Study III, run charts were used to assess the main outcome measures; 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. For categorical data the same approach was used, but then applying the Chi-squared or Fischer exact test as appropriate. In Study II and III, logistic regression was used to test for differences between the periods in proportions of fatale outcomes adjusted for risk factors. A significance level of 0.05 was used in all hypothesis tests.

4.9 Ethical approval

All studies in the thesis were part of the Safer Births and the Safer Births 2.0 project. Ethical approval was obtained from the National Institute for Medical Research (NIMR), Tanzania

(Ref. NIMR/HQ/R.8a/Vol.IX/2877 and NIMR/HQ/R.8a/Vol.IX/3852) and the Regional Committee for Medical and Health Research Ethics in Western Norway (Ref.no. 2013/110 and 172126). All labouring women at HLH were informed about the Safer Births research, however, informed consent from the women was not required by the ethical committees due to the descriptive QI study design. For Study I, all relevant healthcare workers were informed about the study and oral consent was obtained. The participants received no compensation for participation in the study.

5 Summary of Results

This thesis aimed at investigating the effects of several QI/SBT interventions using a novel simulator for neonatal resuscitation, on SBT performance, clinical practice, and perinatal outcome. The following section summarizes the findings of all three studies, while detailed results from each study are presented in the individual papers included in the thesis.

Table 4. summarizes some important demographic variables for the total study period, 01.09.15-31.08.21, while comprehensive demographics are available in the publications included in the thesis.

Table 4. Some demographic variables for mother and newborns from Haydom Lutheran Hospital for the time period 01.09.15-31.08.21.

	01.09.15-31.08.16	**01.09.16-30.09.17**	**01.10.17-31.08.18**	**01.09.18-31.08.19**	**01.09.19-31.08.20**	**01.09.20-31.08.21**
	Baseline	SBT-Self-guided	SBT-Local Champions	The Golden Minute Campaign	Post-intervention	Post-intervention
Births, n	3,572	4,003	2,906	3,291	3,142	3,332
Referrals, n (%)	3.9 (140)	5.6 (226)	5.9 (171)	6.4 (210)	7.6 (240)	7.6 (253)
Birth weight, g± SD	3,302 ±524	3,358 ±557	3,335 ±551	3,231 ±552	3,173 ±533	3,161 ±542
Preterm, n (%)	2.9 (103)	3.8 (151)	4.1 (118)	4.8 (158)	5.1 (160)	5.4 (181)
Abnormal FHR during labor, n (%)	5.3 (190)	7.3 (291)	8.7 (252)	5.3 (175)	4.0 (126)	2.9 (97)
Multiples, n (%)	4.0 (144)	3.9 (56)	3.4 (98)	4.6 (151)	4.4 (137)	5.1 (169)

SBT= Simulation-based training, FHR = foetal heart rate

5.1 Study I

The aim of Study I was to describe changes in staff participation in SBT, training frequency, and simulated ventilation quality, before and after introduction of local champions to facilitate HBB training. In total, 27 midwives (n=15-27) participated in the SBT interventions implemented during the study period (01.09.16-31.08.18). The number of individual SBT sessions increased from 688 sessions before to 8,451 after introduction of local champions in October 2017, (Table 5). Staff participation increased from 43% to 74% of the midwives ($p=0.016$). The quality of training performance, measured as “Well done” feedback, increased from 75% to 92% ($p<0.001$). Based on these results, we rejected our main null hypothesis of no difference in training frequency before and after appointment of local champions ($p<0.001$).

Table 5. Changes in mandatory learners, training frequency, participation, training performance, and selection of patient cases for simulation-based training using NeoNatalie Live, comparing the period before and after appointment of local champions (120)**.**

	Period 1 Individual SBT 01.09.16-30.09.17	**Period 2** Local champions 01.10.17-31.08.18	**P-value**
Months, n	13	11	
Births, n	4,003	2,906	
Mandatory learners, n	15-18	18-27	
Median per month (quartiles)	17.0 (15.0, 19.3)	27.0 (18.0, 27.0)	<0.001[a]
Skill-trainings, n	688	8,451	
Median per month (quartiles)	39.5 (8.3, 87.0)	713.0 (173.0, 1,455.0)	<0.001[a]
Skill-trainings/midwife /month, n median (quartiles)	2.3 (0.5, 5.0)	26.4 (6.4, 53.9)	<0.001[a]
Midwives training, % median (quartiles)	43 (21, 60)	74 (41, 94)	0.016[a]
Trainings "well done", % median (quartiles)	75 (66, 80)	92 (83, 95)	<0.001[a]
Valid ventilations, % median (quartiles)	98 (87, 100)	100 (88, 100)	<0.001[a]
Ventilation rate, n median (quartiles)	51 (45, 56)	51 (47, 54)	0.754[a]

[a] Mann-Whitney U test, SBT=Simulation-based training

5.2 Study II

The aim of Study II was to describe changes in clinical resuscitation practice and perinatal outcomes, before and after introduction of the novel newborn simulator and then local champions to facilitate in-situ SBT and scenario team-training for neonatal resuscitation. In total, 10,672 births, live and stillbirths, were included in this study. Macerated stillbirths (n=191) were excluded before analysis. There were 12% missing registrations for the variable "cervical dilatation" and <0.1% for the remaining variables. The main findings are presented in Table 6.

Midwives had practiced self-guided skill-training during the last seven days prior to a real neonatal resuscitation in 34% of cases during baseline, 30% in period 2 (self-guided SBT), and 71% in period 3 (local champions) (p<0.001). Most real resuscitations were provided by midwives, increasing from 66% in baseline, to 77% in period 2, and further to 84% in period 3 (p<0.001). Median time from birth to first ventilation decreased between baseline and period 3 from 118 (85-165) to 101 (72-150) seconds (p=0.018), and time-pauses during ventilation decreased from 28% to 16% (p<0.001). Ventilations initiated within the first minute did not change significantly (13%-16%). The proportion of high-risk deliveries increased during the study period, while perinatal mortality remained unchanged. Based on these results, we rejected our main null hypothesis of no change in time from birth to first ventilation before and after implementation of the present interventions (p=0.018).

Table 6. Resuscitation characteristics of newborns (n=10,481) and newborns receiving bag-mask ventilations (n=816).

	Period 1 Baseline 01.09.15-31.08.16	**Period 2** Individual SBT 01.09.16-30.09.17	**Period 3** Local champions 01.10.17-31.08.18	**P-value**
All live births (n=10,481)				
Months, n	12	13	11	
Births, n	3,572	4,003	2,906	
Perinatal mortality at 30 min, % (n)	0.3 (9)	0.3 (13)	0.3 (10)	0.013[a]
Stimulation, % (n)	31.0 (1,109)	27.6 (1,104)	34.4 (1,001)	<0.001[a]
Suction, % (n)	28.2 (1,009)	23.6 (943)	28.0 (815)	<0.001[a]
BMV, % (n)	7.0 (249)	8.0 (319)	8.5 (248)	0.056[a]
Newborns receiving BMV (n=816)				
Midwife providing resuscitation, % (n)	66.3 (165)	77.1 (246)	83.5 (207)	<0.001[a]
Midwife trained with NeoNatalie last 7 days, % (n)	33.8 (54)	29.6 (72)	71.4 (147)	<0.001[a]
Time from birth to start BMV (seconds), median (quartiles)	118 (85-165)	100 (74-160)	101 (72-150)	0.018[b]
BMV initiated ≤60 seconds, %, median (quartiles)	13.3 (33)	13.2 (42)	15.7 (39)	0.633[b]
Total BMV pause[c], %, median (quartiles)	27.9 (15.2, 44.8)	19.1 (8.2, 34.9)	15.7 (4.0, 31.2)	<0.001[b]

[a]Chi-square test. [b]Kruskal-Wallis test. [c]Number of resuscitations recorded from the Newborn Resuscitation Monitor (n= 644). SBT= Simulation-based training, BMV= Bag-mask ventilation

5.3 Study III

The aim of Study III was to decrease time from birth to start of ventilation and document potential changes in perinatal outcomes after implementation of an HBB QI intervention. In total, 12,938 live and stillbirths, were included in this study. Macerated stillbirths (n=260) were excluded before analysis. There were 15% missing registrations for the variable "cervical dilatation", 5% for "last foetal heart rate before delivery" and <0.1% for the remaining variables. The main findings are presented in Table 7.

During the Golden Minute Campaign, 69% of the newborns were ventilated within 60 seconds after birth compared to 16% during baseline and 42% and 29% during the post-intervention years (p<0.001). Median time to first ventilation decreased from 101 (72-150) to 55 (45-67) seconds, before increasing to 67 (49-97) and 85 (57-133) seconds post-intervention (p<0.001). More non-breathing newborns were ventilated in the intervention period (13%) compared to baseline (8.5%) and the post-intervention period (10.6%-9.4%) (p<0.001). Midwives performed an increasing proportion of resuscitations (84%-93%-98%-97%) (p<0.001). For the non-breathing newborns receiving BMV, assumed fresh stillborns decreased significantly from baseline to intervention (3.2%-0.7%) (p=0.013). Comparing the baseline period with the intervention period, a significant reduction in perinatal mortality, 12.6%-7.5%, (p=0.03) was found, but the change did not remain statistically significant after adjustment for source of admission, antenatal problem, premature/term, mode of delivery, and fetal heart rate during labor (p=0.111).

Based on these results, we rejected our main null hypothesis of no change in proportion of non-breathing newborns ventilated within the 60 seconds after birth before and after implementing the Golden Minute Campaign (p<0.001).

Table 7. Resuscitation characteristics (n=12,678) and newborns receiving bag-mask ventilation (n= 1,320).

	Period 1 Baseline FST 01.10.17-31.08.18	**Period 2** Golden Minute Campaign 01.09.18-31.08.19	**Period 3** Post intervention 01.09.19-31.08.20	**Period 4** Post intervention 01.09.20-31.08.21	**P-value**
All live births (n=12,678)					
Births, n	2,913	3,291	3,142	3,332	
Perinatal mortality at 30 min, % (n)	0.3 (10)	0.5 (17)	0.4 (11)	0.3 (11)	0.579[a]
Stimulation, % (n)	34.5 (1,104)	40.4 (1,328)	37.2 (1,169)	26.2 (873)	<0.001[a]
Suction	28.1 (818)	31.4 (1,033)	31.4 (988)	23.6 (785)	<0.001[a]
BMV, % (n)	8.5 (248)	12.9 (426)	10.6 (333)	9.4 (313)	<0.001[a]
Newborns receiving BMV (n=1,320)					
Midwife providing resuscitation, % (n)	83.5 (207)	92.7 (395)	98.2 (324)	97.1 (304)	<0.001[a]
HCW trained with NeoNatalie last 7 days, % (n)	64.7 (161)	44.6 (189)	6.7 (22)	5.8 (18)	<0.001[a]
Time from birth to start BMV (seconds), median (quartiles)	101 (72-150)	55 (45-67)	67 (49-97)	85 (57-133)	<0.001[b]
BMV initiated ≤60 seconds, % (n)	15.8 (39)	68.5 (292)	42.2 (137)	28.9 (88)	<0.001[a]
Fresh stillbirth, % (n)	3.2 (8)	0.7 (3)	1.8 (6)	2.9 (9)	0.074[a]
FSB/30min/24h-mortality,[c] % (n)	12.6 (31)	7.5 (32)	8.4 (28)	9.3 (29)	0.164[a]

[a]Chi-square test. [b]Kruskal-Wallis test. [c]Fresh Stillbirths, 30 min perinatal deaths and 24 h neonatal deaths. FST= Frequent simulation training, BMV= Bag-mask ventilation, HCW= Healthcare worker, FSB= Fresh stillbirths

6 General discussion of the results

This thesis demonstrates enhanced training performance (Study I), changes in clinical practice (Study II and Study III) and improved patient outcome (Study III) after implementation of different QI/SBT efforts in neonatal resuscitation, led by local champions. The results are also evaluated in accordance with the Kirkpatrick model on learning/simulation (Level 2), behaviour/clinical performance (Level 3) and results/patient outcome (Level 4). The results demonstrate improvements in accordance with the Kirkpatricks Model Level 2, 3 and 4. Overall, it seems that more wide-ranging QI efforts were required to improve the most challenging time-critical clinical procedures, like rapid onset of BMV. The impressive increase in non-breathing newborns ventilated within the Golden Minute, was first achieved after a comprehensive QI/SBT project, the Golden Minute Campaign, which included clinical data-driven feedback and data-guided SBT. Increased use of stimulation and BMV was demonstrated after SBT led by local champions (Study II), and further enhanced following the implementation of the Golden Minute Campaign (Study III). Patient outcome remained stable, despite a more vulnerable population during Study II. However, improvement of perinatal mortality was achieved for fresh stillbirths after the Golden Minute Campaign (Study III), possibly due to earlier start of ventilation that likely improved outcome of the most severely asphyxiated newborns, assumed to be fresh stillborns.

6.1 Outcomes- simulation-based training, clinical performance, and perinatal mortality

6.1.1 SBT outcomes- frequency, participation, and performance

Previous studies have shown the need for refresher training to retain knowledge and skills after SBT in neonatal resuscitation (41,63,110,121,122). This thesis demonstrates the advantage of using local champions to lead SBT to achieve refresher training and engage most midwives in training (Study I). The results did not show increased use of the novel simulator compared to the original simulator prior to the appointment of local champions (Study II). The proportion of midwives trained using the original NeoNatalie did not change after the implementation of the novel simulator, Neo Natalie Live (Table 5). However, after the appointment of local champions, there was a substantial increase in training frequency and the midwives conducted nearly daily SBT, 26 trainings/month/midwife (Study I). During the Golden Minute Campaign, SBT frequency declined slightly when the hospital shifted the focus to a more comprehensive QI effort. Still, 45 percent of the healthcare workers had trained the last 7 days prior to a real resuscitation (Study III). This number decreased to only 6.7 percent after the end of the campaign. The study demonstrates the challenge of maintaining SBT over time, even at a hospital which has emphasized SBT for a decade. It is likely that a minimum of QI efforts is necessary to accomplish longstanding change, even when implementing high-fidelity, user-friendly simulators. Training frequency was measured solemnly for midwives during Study II, but due to the QI/SBT intervention in Study III including a broader part of the healthcare staff these were also included in the analyses of training frequency for this study.

Some of the major challenges for in-service SBT, are high staff-turnover and limited time for training (63). HLH experienced both obstacles, and the need for QI interventions targeting these aspects were crucial for success. During the study periods including local champions, either to encourage colleagues for SBT (Study I/II) or leading the Golden Minute Campaign (Study III), the ward experienced a high staff participation in the QI/SBT activities. Proportion of midwives participating in SBT increased after appointment of local champions from 43 to 75 percent (Study I), consequently, this enabled most providers opportunities for training. This seems to have improved guideline adherence as demonstrated by less monthly variation in time to ventilation and newborns ventilated within the first 60 seconds of life during the campaign compared to the post-intervention period when QI efforts were scaled down (Study III).

The midwives experienced an increase in training performance from 75 percent training sessions conducted without errors during self-guided SBT, to 92 percent following the profound rise in SBT frequency (Study I). There is scarce evidence regarding recommended SBT frequency (63,123). A single study indicates a frequency of 8 trainings per 3 months to achieve effective simulated performance (124). It is of great importance to gain more knowledge regarding optimal SBT frequency, so that the valuable resources in healthcare can be utilized wisely. Trainings of short duration, with an easily accessible simulator featuring automated feedback, enables refresher training in settings with limited time and shortage of healthcare workers (110). The improvements of the novel simulator, especially the automated feedback, might have motivated the midwives for training in this study. A previous study showed that skill acquisition in cardiac compression training with automated feedback was not inferior when compared to a human instructor, and the majority of the participants found the automated simulator feedback more useful than the instructor feedback (125). A qualitative study could potentially have provided important insight regarding possible motivating factors for SBT using the novel simulator compared to the original version in this thesis.

6.1.2 Clinical performance outcome

Clinical performance improved following increased SBT frequency and even more so after the QI efforts conducted during the Golden Minute Campaign. One crucial, time-critical recommendation in the neonatal resuscitation guideline, is initiation of BMV within 60 seconds after birth. Even after conducting nearly 8,500 SBT sessions, and achieving reduction in time from birth to ventilation, only 16 percent of the non-breathing newborns at HLH received BMV within the Golden Minute (Study II). Aiming at increasing this proportion to 70 percent, HLH launched the Golden Minute Campaign and managed to increase this number to 69 percent (Study III). Several studies have reported difficulties in achieving guideline adherence at this crucial point (41,45–47,70). The Golden Minute Campaign was a multifaceted QI intervention (Table 2), combining SBT, clinical debriefing and feedback of local clinical data discussed in QI meetings and guiding scenario team-trainings. The study was not designed to evaluate the separate QI efforts in the Golden Minute Campaign, but monthly data-guided scenario team-trainings, focusing on complete timelines from birth to start ventilation, might have been important in changing the clinical practice of timely BMV. Frequent HBB trainings prior to the Golden Minute Campaign were typically individual skill-trainings, starting with the newborn simulator on the resuscitation table, focusing on ventilation techniques. During the campaign, neonatal resuscitation scenarios were carefully adjusted to address identified quality gaps in clinical care and included the complete timeline from birth through BMV. After a near decade with no improvement in time from birth to start BMV, the midwives managed to halve this time in real situations and virtually reach their goal of 70 percent newborns ventilated within the Golden Minute. This is consistent with findings from studies of scenario team-training in comparable time-critical procedures in emergency medicine (59,60).

The QI efforts were substantially scaled down during the post-intervention period, with consequently deterioration of the improvements in timely BMV. The monthly meetings were not continued post-intervention, and it seems this QI effort was vital for achieving sustainable changes in clinical performance. The monthly meeting provided an arena for clinical staff, research assistants, and the management to meet and discuss the challenges of timely BMV. Support from leaders, and discussions of potential improvements in a psychologically safe learning environment, might have been necessary to maintain the improvements in clinical performance. The lack of qualitative data in the thesis, restricts the possibilities to explore this further, however other studies supports these assumptions (76,96,99,126,127).

Non-breathing newborns receiving BMV increased steadily throughout the study period until the end of the Golden Minute Campaign when the trend was reversed. Still, more newborns received BMV post-intervention compared to the period prior to implementation of NeoNatalie Live. Globally, 3-8 percent of newborns receive respiratory support, beyond drying and stimulation, during the first minutes of life (27–30). The BMV frequency at Haydom, after the QI interventions, was high, 13 percent, though comparable to similar resource settings (50,128). The reasons for the increase might be due to a more vulnerable newborn population during Study II, combined with possible increased confidence of midwives following high-frequent SBT. Again, the more comprehensive approach during the Golden Minute Campaign seems to have impacted clinical behaviour more than merely focus on SBT, with a rise from 8.5 to 13 percent newborns receiving BMV. During the Golden Minute Campaign (Study III), the newborns had lower birthweights, but the proportion of preterms was stable, and we observed an increase in normal foetal heart rate during labor, compared to the previous years. This might indicate other explanations for the increase in BMV during this study period than a vulnerable patient population and could possibly be due to increased focus and confidence in BMV among healthcare workers. In general, the proportion of non-breathing newborns who would benefit from BMV is probably unknown and varies across settings, depending on maternal and newborn vulnerability and obstetric and newborn care (129). Therefore, it is challenging to evaluate if the observed frequency of BMV in this thesis is appropriate and to compare it with other settings. All newborns in this thesis being ventilated were observed by the trained research assistants as “not breathing” before initiation of BMV, thus limiting the possibility of the increased BMV frequency being due to altered indication for BMV after intervention.

To provide sufficient oxygenation of the non-breathing newborn, continuous ventilations are recommended (130). NeoNatalie Live provides feedback on this action point in the HBB algorithm, and the thesis demonstrates reduction in ventilation pauses after high-frequent SBT (Study II). It is likely that frequent training with focus on continuous ventilations have improved this skill.

The simulator is proven comparable to real-life resuscitations, thus providing realistic training opportunities for correct BMV, including skills like reduced mask leak and tidal volume (114). However, the thesis shows a reduction in expired tidal volume and minute volume, and a trend of increased mask leak despite high-frequent BMV skill training (Study II) (129). During this study period, the newborn population was more vulnerable, with more preterms and more foetuses with abnormal heart rate during labour, making it more challenging to provide sufficient minute volume during BMV. The decreased static lung compliance also indicates more vulnerable newborns with stiffer lungs in this study population. To establish functional residual capacity in stiff lungs may be difficult, and possibly explains the trend towards more mask leak in the first minute of BMV (131).

Neonatal resuscitation guidelines no longer recommend suction of airways that are not blocked by secretion (130,132). In this thesis, use of suction increased in all study periods, apart from the period of self-guided SBT. The simulator does not provide feedback regarding this step in the resuscitation algorithm; therefore, reduction of unnecessary suctioning was not anticipated after the SBT intervention. During the Golden Minute Campaign, focus was directed at timely BMV, thus the increase in use of suction in real resuscitations might not have been addressed. It is known that there is a risk of singular focus during QI interventions, where aspects of healthcare not included in the intervention is neglected, thus imposing a risk of worsened patient care (99). Several studies report reduction in unnecessary suctioning following implementation of HBB training (47,50,133). A review of the harms and benefits regarding suctioning of clear amniotic fluid at birth concluded that there were no benefits of this practice, however the risk of adverse outcome was more uncertain (132). If possible, QI efforts in neonatal resuscitation, should have a broad focus to improve guideline adherence in a wider sense.

In general, the thesis demonstrates a successful translation of knowledge and skills from SBT to clinical pratice. Previous individual studies differ regarding accomplishments of this crucial translation, and a systematic review of implementation of HBB training concluded that impact on provider practices varied largely (29,30,41,63,134). The thesis confirms previous research regarding the need for refresher training, but also highlights the potential of data-guided scenario-team trainings and SBT as part of more comprehensive QI efforts to achieve improvements of time-critical clinical procedures. This is consistent with the concept “translational simulation” by prof. Brazil, where healthcare simulation is focused directly on improving patient care, offering a functional alignment with QI efforts in healthcare institutions, while covering educational interventions targeting practice behaviour and/or patient outcomes (55).

6.1.3 Perinatal outcome

Perinatal outcome was assessed over a six-year period in this thesis, following varying QI/SBT interventions aiming at improving clinical performance and ultimately perinatal outcome (Study II and III). For all births, perinatal mortality remained stable throughout the study period 3-5/1000. Regarding the study population, there were trends of increasing proportion of mothers admitted from health centres and preterm newborns during the study period. Abnormal FHR during labor increased during Study II but decreased to baseline level and below during Study III. There are several causes of perinatal mortality, apart from birth asphyxia, and multiple factors affecting this outcome. Thus, the vulnerability of the patient population varied throughout the present studies, introducing potential confounding factors, challenging the interpretation of the results regarding perinatal mortality.

Interestingly, FSB in the group of newborns receiving BMV decreased from 3.2 percent to 0.7 percent during the Golden Minute Campaign (Study III). A reduction in FSB would be anticipated, due to the increased number of non-breathing newborns ventilated within 60 seconds after birth. The reasoning for rapid onset of bag-mask ventilation of non-breathing newborns is the known pathophysiological mechanisms for birth asphyxia (135,136). A newborn with primary apnoea responds well to initial resuscitation steps, such as stimulation, and will initiate spontaneous respiration in the majority of the cases (27). When the newborn enters secondary apnoea, it requires artificial ventilation to gain spontaneous respiration (27,136). A previous study found the risk for death or prolonged admission increasing by 16 percent for every 30 seconds delay in initiating BMV (27). Perinatal death, following intrapartum hypoxia, and FSB is probably part of the same circulatory end-process (23). Distinguishing FSB from severely asphyxiated newborns is known to be clinically difficult (13,23). Neonatal resuscitation training has been demonstrated to reduce this misclassification by increasing the likelihood of healthcare workers to initiate BMV of non-breathing newborns assumed to be fresh stillborn (24,29,30,50). The reduction in FSB shown in the present study, indicates the potential of timely BMV for improved outcome for this patient group. Due to the challenges of misclassification, a previous paper recommends combining FSB and live birth/neonatal death outcome for the least biased description of a trial outcome (16). In Study III, there was significant reduction from baseline to intervention for a combined measure of FSB and 30 min perinatal/24 h neonatal deaths from 12.6 to 7.5 percent (p-value=0.03). However, the result did not remain significant after adjusting for relevant confounders.

6.2 Potential success factors – Local champions and Audit & Feedback

6.2.1 Local champions

This thesis highlights the advantage of using local champions when implementing QI efforts in neonatal resuscitation. Their motivating roles seemed to increase SBT frequency and staff participation (Study I and II), and they most likely affected the success of the multifaceted QI/SBT-intervention, the Golden Minute Campaign (Study III). The benefits of using local champions when implementing various innovations in healthcare is well-known (82–84,137,138). Strategies for selection of local champions varies and clear evidence of the most effectful strategy is lacking (82,115). A combination of champion commitment, including allocated time and dedication, champions previous experience with the innovation and role, and self-efficacy influence champion performance and ultimately the campions` impact (116). Post-intervention, we observed a slight decline of the improvements in clinical practice of timely BMV (Study III). During this period, the QI interventions were scaled down and less focus were directed at SBT among the staff and the local champions. The local champions did not receive any financial remuneration for their task, and one can speculate whether it is necessary to provide more time and resources to this crucial role to achieve sustained quality improvements over time.

6.2.2 Audit & Feedback- Clinical Performance-Fit model

The present thesis demonstrates improvements in clinical performance and perinatal outcome, following a QI/SBT intervention, including audit and feedback interventions. A&F is considered an essential tool in QI and has received increased focus as high-quality data is increasingly used to identify quality gaps in healthcare and guide improvement approaches (79–81). A Cochrane review indicates that feedback could be more effective when baseline performance is low, the source is a supervisor/colleague, feedback is provided more than once, is delivered in both verbal and written formats, and includes both explicit targets and an action plan (97). The Golden Minute Campaign met all these recommendations regarding feedback features, and this will be further outlined in the following section when discussing the A&F components of the intervention related to CP-FIT.

CP-FIT, described in chapter 3.2.1, will serve as the theoretical framework for the following discussion of the feedback component of the QI/SBT intervention. Variables concerning the feedback (goal setting, data collection and analysis, feedback display and delivery), recipients (behavioural response) and context (organisation/team characteristics, co-Interventions, and implementation process) presented in CP-FIT (Figure 5), will be discussed in relation to the design of the Golden Minute Campaign (99).

Overall, the A&F component of the Golden Minute Campaign was conducted according to most of the recommendations of CP-FIT comprising a successful feedback cycle. This strengthens the assumption that this QI/SBT intervention affected the documented improvements of clinical performance in neonatal resuscitation and patient outcome.

Regarding the feedback variables, goal setting was prominent in the Golden Minute Campaign and was nearly reached during the study period. The goal of timelier BMV was important due to its evidence-based effect on perinatal mortality; it represented good clinical practice and addressed a perceived quality problem at the ward in line with the recommendations of CP-FIT. Further, the data collection for A&F was performed by research assistants and the analysis conducted by the research department. CP-FIT states that data should not be collected by participants, due to increased resource demands and complexity of the intervention. However, data collection performed by research assistants 24/7 is undeniably resource demanding, and a limitation in the generalisation of this QI intervention compared to automatically collected feedback. The positive effects of this method are the accuracy and the relevance of the data, that might improve the recipients trust in the clinical feedback. The inability for participants to exclude patients deemed unsuitable from the data collection is in general known to lower the acceptance of the intervention. In the present study this is less relevant, because all the non-breathing newborns included in the clinical data feedback would benefit from timelier BMV.

CP-FIT advocates for few numbers of feedback metrics to decrease complexity of the intervention. In the Golden Minute Campaign, feedback was displayed at the monthly meeting as only one metric: time to BMV. However, several metrics were provided on the weekly meetings, including information of patient outcome of non-breathing newborns during the last week. Feedback on performance level and trends are recommended in both the Cochrane review and the CP-FIT model (97,99). Proportion of newborns receiving BMV was tracked throughout the QI intervention period, and thus both level and trend of performance was provided, but not at an individual level. Feedback was also given immediately after resuscitation to the individual healthcare worker, in addition to the weekly and monthly QI meetings, which is close in time to the performance, as advised by the CP-FIT model. Feedback on individual performance is thought to increase feedback specificity and enhance the participants chances of changing behaviour. The present intervention provided feedback both at the individual and group level, facilitating increased teamwork and social influence.

Feedback was delivered actively, both verbally, during QI meetings, and in writing through a What`s App group and at the notification board in the ward. The delivery of feedback in the intervention was in line with the CP-FIT model recommendations.

The recipient variable evaluated in QI/SBT intervention, behavioural response, was directed at the individual patient level and the organisational level. The healthcare workers were able to communicate structural challenges at the ward directly to their leaders, thus facilitating organisational changes as to further enhance individual clinical performance. It also guided scenario team-training related to gaps in clinical performance. Scenario trainings provided opportunities for teamwork as a response to the clinical feedback provided at the QI meeting. The intra-organisational network, through the What's App group, the scenario trainings, and the leadership support, through their participation at the monthly meetings, might have contributed to the success of the intervention.

Regarding context variables, the positive effect of local champions leading QI interventions is well-documented and consistent with CP-FIT and the Cochrane review (82,83,85). The local champions in the present study, led the simulation-training as well as the QI/SBT intervention and their role has been discussed previously (6.2.1). High staff turnover is a challenge at the labour ward at HLH, and in general thought to be a challenge for feedback interventions. To meet this challenge, new staff was trained in HBB, and the high frequency of meeting ensured enrolment of new staff into the QI project. This might have limited the negative impact of high staff turnover and contributed to the reduced variance in clinical performance. An organisational challenge of the Golden Minute Campaign was the complex clinical task the midwives are facing when conducting labours and resuscitations at their ward. This task extended beyond the feedback intervention of timely BMV and thus decreased the resource match to engage with and respond to the changes required by the feedback intervention, as highlighted in the model. Further, The Golden Minute Campaign included several co-interventions: problem solving, action planning and peer discussions to act on the clinical feedback to improve clinical performance, as recommended by CP-FIT and the Cochrane review (97,99). The CP-FIT model also highlights external change agents to positively influence all feedback intervention processes by providing an additional resource to increase resource match. Adding external agents might have further increased the effect of the present feedback intervention. Regarding the implementation process and resources, the feedback intervention was developed for the local context and tailored to ongoing routines, e.g., research assistants already observing all births. Thus, extra costs related to data collection were minimal, only requiring extra expenses for the specific analysis and feedback display for the Golden Minute Campaign. The monthly meetings, however, did require human resources outside working hours, representing a challenge of maintenance of the intervention.

Discussion of the healthcare workers characteristics, and some of the features of the discussed variables e.g., the recipients' perception of whether the function of the feedback intervention was to punish or support them, would have required studies targeting healthcare workers beliefs and perspectives of the intervention and is therefore un-known in this quantitative thesis.

The assessment of the Golden Minute Campaign in regards of the CP-FIT recommendations, shows consistency with the model and strengthens the assumption that the Golden Minute Campaign was associated with the demonstrated improvements of clinical resuscitation performance and perinatal outcome at HLH.

7 Discussion of the Methodology

7.1 General consideration

All the included studies in the present thesis are quantitative, prospective observational pre/post studies. The studies investigated labour characteristics, resuscitation performance and perinatal outcomes over several years, before and after the implementation of QI/SBT interventions. This thesis investigated potential associations between the exposure, QI/SBT, and several outcomes: SBT frequency/performance, clinical performance, and perinatal mortality. The chosen design enables investigations of complex interventions implemented in a clinical environment. The strengths and limitations of the study design will be discussed in the following section.

For some research questions, like assessing the efficacy of medical treatments, randomized controlled trials (RCT) are favourable due to the advantages of controlling confounders and biases (139). However, RCT`s are not well suited for investigating more multifaceted interventions in complex healthcare systems and in these studies observational pre/post design possess some benefits (139,140). Moreover, observational studies are relatively less expensive and easy to undertake and can be performed when RCT`s would be considered unethical or impracticable to conduct (139). Among observational studies, cohort studies provide a higher level of evidence of causality than e.g., case-control studies because temporality is preserved (139). According to the Hill`s criteria for causation, the time of exposure must occur prior to the outcome in order to claim causality, and the temporality is highly agreed upon among epidemiologists as necessary for causation (141). Observational pre/post design also have the advantage of opportunities for investigating multiple exposures and outcomes as done in the present studies (139,142).

If the design should follow a conventional RCT design, a control group receiving no intervention, or a different intervention, would be needed (143). In this thesis, the aim of improving quality of care for newborns through a QI project, would deny the control group of newborns quality practice, which would be considered unethical. In addition, the hospital was a rural referral hospital with only one labour ward including approximately 20 midwives. This restricted the opportunities for a control group of midwives receiving no intervention or a different intervention than the intervention group. Keeping track of which arm each birth should be assigned to would be difficult since in real-life clinical practice, several midwives participate in many of the labours. It would be possible to choose a multicentred design and compare a labour ward without interventions with the labour ward at HLH. However, there would be challenges of standardising the groups because of the many varying factors between hospitals and labor wards in regards of resources, previous QI/SBT efforts etc., thus requiring randomization of several labour wards at different hospitals for comparison.

7.2 Confounding

Confounding refers to the mixing of effects when investigating potential causation between an exposure and an outcome, leading to erroneous results (144). To be considered a confounder, a variable need to be associated with the exposure and influence the outcome. In addition, the variable should not be an intermediate variable in the causal pathway between exposure and outcome (144).

Several potential confounders needed to be considered when investigating the outcomes in the present thesis. The staff turnover, where experienced midwives left the hospital and newly educated midwives started, could have affected the clinical performance and the perinatal outcome. Still, the QI/SBT intervention focused on enrolment of new staff in training and the results show limited variation in clinical performance through the Golden Minute Campaign (Study III). There were no other training interventions for neonatal resuscitation during the study period that could have affected the increase in training performance. The outcomes measured for training performance and clinical performance were very specific and unlikely affected by other factors then the study intervention. Other interventions targeting perinatal care could have affected the patient outcome, but to our knowledge, no such interventions were implemented during the study period. Risk adjustments for potential confounders were carried out when analysing changes in perinatal mortality. This reduced the risk of erroneous conclusions but did not eliminate the risk confounders. It is possible that confounders existed that we were not aware of, which might have influenced the outcomes.

7.3 Biases

Bias is defined as "a systematic error introduced into sampling or testing by selecting or encouraging one outcome or answer over others" (145). Biases can cause under-estimation or over-estimation of the true effect and can vary in magnitude (146). Bias is a threat to the validity of a study and includes different subgroups e.g., selection bias, recall bias, observational bias and publication bias (147).

In the first two studies, Study I and Study II, all midwives at labour ward were included in the studies. Even so, it was not mandatory to conduct SBT, and there is a risk of selection bias in the participation in training for these two studies. If, supposedly, only the midwives most interested or skilled in neonatal resuscitation participated, this could influence the results. During the intervention period of these studies, 75% of the midwives at the ward participated in SBT monthly, thus indicating that most midwives participated and diminishing the risk of selection bias.

In the third study, all healthcare workers at labour ward were eligible for participating in the Golden Minute Campaign. The QI activities were not mandatory, and we cannot know with certainty that all healthcare workers participated at the QI meetings or the scenario team-trainings. However, the training and the meetings were organized to facilitate participation and we have reason to believe that most healthcare workers participated. The outcomes measured were clinical performance of all healthcare workers at the ward, regardless of participation at the QI activities, and perinatal outcomes from all live births and stillbirths. The proportion of missing data were <0.1% for most variables. Thus, there is no reason to suspect selection bias of the observed births taking place at the hospital. Still, only 50% of labouring women give birth at HLH, introducing a risk of selection bias for the overall patient population in the catchment area (111).

The data collection form (Study II/III) contains some questions for the mother concerning information about past events e.g., antenatal care, antenatal problems, and level of education. Apart from these questions in the data collection form, all data gathered for the analyses are objective data collected by the simulator, trained research assistants and the Newborn Resuscitation Monitor. Collecting information retrospectively, poses the risk of recall bias or responder bias, due to differences in the accuracy of the memories recalled by study participants regarding events or experiences from the past (148,149). This recall bias can be unintentionally, caused by poor memory, or intentionally, due to participants reluctance to provide the required information or intentional providing incorrect information (150). Most of the questions posed to the mothers in this study relates to recent events from the last nine months, and mainly asks for objective information like number of pregnancies, children, or mothers age, reducing the risk of recall bias. The information collected in this thesis is not particularly sensitive and not assumed at risk for intentional recall bias. Importantly, it is unlikely that the information provided by the population of mothers before the implementation of the interventions, are less accurate than the information from the mothers provided during or after the intervention. Therefore, the information collected in this thesis is not assumed at risk for intentional recall bias.

Hawthorne effect is described as a change in behaviour of the study participants in experimental or observational studies (151). This was relevant for this thesis (Study II/III) as the healthcare workers were observed and measured in their clinical performance in neonatal resuscitation. The Hawthorne effect could influence the healthcare workers performance in a positive manner, generating better clinical outcomes. However, HLH has been conducting clinical research, including observation of all births, since 2010. Thus, the healthcare workers were accustomed to being observed for many years prior to the data collection in the present thesis, reducing the risk of Hawthorne effect considerably.

In research there is a risk of the response or measured value differing from the real value. Measurement error or misclassification may result from disregard by the researcher or from poor quality of measuring or survey instruments (152). With continuous variables there is a risk of measurement errors resulting from e.g., not calibrated measuring equipment and for categorical variables there is a risk of misclassification (152). There are several survey instruments in the present study e.g., FHR detectors (Moyo/Pinard stethoscope), blood pressure monitors and the Newborn Resuscitation Monitor. HLH has reliable routines for maintenance of the technical equipment with support from Laerdal Medical and all devices were validated by either clinicians or the research department. To our knowledge there is no reason to suspect measurement errors caused by poor quality of survey instruments in the present thesis. To avoid measurement errors from self-reported surveys, the collection of data using the data observation form (Appendix 4) was undertaken by trained research assistants. These research assistants were not healthcare workers and did not have any other role at the hospital apart from this task.

Regarding misclassification, there are concerns regarding the accuracy of APGAR scoring of newborns (153). In this study we have several variables for evaluation of perinatal outcome besides APGAR score, e.g., FHR, admission to Neonatal Care Unit and mortality, overall increasing the chances of correct assessment of the newborn. Classification of FSB can be challenging, due to difficulties in clinically distinguish a true FSB from severely asphyxiated newborns (136). This may lead to more newborns classified as FSB, when they should be classified as live born. Throughout the study period, midwives at HLH were equipped with either the Newborn Resuscitation Monitor or the NeoBeat (154) to measure heart rate of the newborns, though the use of these devices for classification of stillbirth during the study period is uncertain. If used thoroughly, this would reduce the risk of misclassification. Due to the challenges of misclassification of stillbirth, we also included an outcome combining FSB and early neonatal mortality. Overall, we do not consider measurement errors or misclassification a major threat to internal validity in the present thesis.

Publication bias refers to the fact that researchers and trial sponsors may be unwilling to publish unfavourable results, thus, positive results are more likely to be submitted for publication than negative results (149). In the present thesis all findings, positive and negative, were included in the results and published.

7.4 Strengths, limitations, and generalizability

One important strength of all the studies included in the thesis is the high number of observations. For Study I, a major strength is the high number of trainings, over 9 000 sessions, analysed based on the automated and continuous measures of simulated ventilation quality recorded from each training session. For both Study II and Study III, the large population size is considered a great strength, as well as the rigorous data management system and comprehensive data collection form presenting detailed information on resuscitation practice and patient outcome. For Study II these data were combined with physiological data during the first minutes of life providing unique information. Study III provided information from a two-year follow-up period, enabling the gain of knowledge on the sustainability of the improvements post-intervention.

The main limitation of all the included studies is the non-randomized, single-center design. This restricts the possibilities of claiming causation between the intervention and the demonstrated improvements of outcomes. A limitation of Study I is the new evaluation method of ventilation quality using data from the simulator in contrast to the frequently used OSCE score, making this indicator less comparable to previous studies. For study III the multi-faceted QI/SBT intervention constrains the opportunities of analysing the separate QI activities and their individual effect on the outcomes. Additionally, qualitative data regarding midwives' and local champions' perceptions and experiences of the SBT would have contributed to illuminating the results in this thesis.

In terms of generalizability, HBB and the NeoNatalie Live simulator is a low-cost program and hence possible to implement in other resource-limited settings (155). High-income settings might require additional training on more advanced interventions for neonatal resuscitation, but the implementation strategy of using local champions (Study I/II/III) and the data-guided QI activities (Study III) is considered generalisable (129). HLH has emphasized individual SBT for a decade, therefore the management and staff are used to such learning methods, and this might have impacted their effective adoption of the SBT intervention. Labor wards with less experience with SBT practice might achieve other results or may need more time to achieve similar results (129).

7.5 Ethical issues

All the studies in the thesis were approved by the National Institute for Medical Research (NIMR) and Ministry of Health in Tanzania (NIMR/HQ/R.8a/Vol.IX/3852) and by the Regional Committee for

Medical and Health Research Ethics, Western Norway (Ref. 2013/110/REK and 172126). All relevant health care workers were informed about the different quality assessment studies and oral consent was obtained. Patients were also informed about ongoing studies; however, consent for these descriptive studies was not considered necessary by the ethical committees due to the descriptive QI study design.

The World Medical Association (WMA) Declaration of Helsinki provides ethical principles for medical research involving human subject (156). The document has been regularly amended since the first version in 1964 and is currently under revision (156). All the studies in the thesis were conducted according to the ethical principles of this declaration.

Declaration of Helsinki states that all vulnerable groups and individuals participating in research should receive specifically considered protection (156). The International Ethical Guidelines for Biomedical Research Involving Human Subjects states that “vulnerable persons are those who are relatively (or absolutely) incapable of protecting their own interests” (157). The study population in this project was highly vulnerable. This project aimed to investigate the impact of a QI/SBT intervention in neonatal resuscitation, thus it was necessary to include vulnerable subjects to obtain the most relevant and solid results. The intervention had no previously known potential of imposing harm on the newborns or the mothers; on the contrary, increased training in neonatal resuscitation was expected to improve care. The guidelines highlight the importance of research projects to make developed products reasonably available for the low-resource country that hosts the project (157). NeoNatalie Live was developed in close cooperation with healthcare workers at HLH and is offered to a not-for profit price for low-resource countries, to meet this ethical standard (158). The guidelines, consistent with guidelines from the Norwegian National Committee for Medical and Health Research Ethics (159), also states that projects should assist in building local research capacity, which has been a fundamental principle for the Safer Births study since the initiation of the project (43).

7.6 The role of sponsors and funding agencies

The studies in the thesis were funded by the University of Stavanger, the Global Health and Vaccines Research (GLOBVAC) program at the Research Council of Norway, Saving Lives at Birth Grand Challenges, and the Laerdal Foundation. The development of NeoNatalie Live received funding from Innovation Norway, the Research Council of Norway and Skattefunn. The study was performed using simulation equipment provided by Laerdal Global Health. The funders had no role in the design of the study; in the collection, analyses, or interpretation of data; in the writing of the manuscript, or in the decision to publish the results.

8 Conclusion

The overall aim of the thesis was to investigate the effects of different QI/SBT interventions using a novel simulator for neonatal resuscitation, on SBT performance, clinical performance, and perinatal outcome. The thesis demonstrates improvements of outcomes corresponding with Kirkpatrick level 2 (learning), 3 (behaviour) and 4 (results). Most importantly, median time from birth to ventilation decreased by 46 seconds, and the proportion of non-breathing newborns ventilated within the Golden Minute increased from 16 to 69 percent. Subsequently, FSB in the group of newborns receiving BMV, decreased from 3.2 to 0.7 percent. It seems that a comprehensive QI approach, i.e., the Golden Minute Campaign, was necessary to achieve improvement in the complex, time-critical clinical procedure, of timely BMV. Providing feedback of clinical data for discussions at QI meetings and to guide scenario team-trainings appears to be effective in changing clinical performance. Local champions increased training frequency and staff participation dramatically, with over 9,000 trainings conducted, and they most likely played a crucial role in leading the Golden Minute Campaign. The gained knowledge from this thesis could be utilized by other healthcare facilities when implementing SBT for improved neonatal resuscitation.

8.1 Future perspectives

8.1.1 Implication for practice

The QI/SBT interventions in the present thesis, have been demonstrated to have a positive impact on skills, clinical resuscitation performance and perinatal survival. Especially the use of local champions when implementing QI/SBT interventions, and the use of clinical data-guided feedback, both for SBT scenario team-trainings and QI meetings, should be considered when planning QI efforts for improved neonatal resuscitation in different settings. These interventions can be implemented as part of the work towards reaching SDG 3.2 and hopefully more lives can be saved.

8.1.2 Future studies

There is a need for studies applying a mixed-method design to explore the beliefs and the underlying reasons for the observed changes in clinical performance following similar QI/SBT interventions. There is also a need for knowledge regarding the optimal training frequency to achieve sustained improvements in neonatal resuscitation and regarding the success factors and barriers to optimize the use of local champions. QI interventions in healthcare are often, intentionally, multifaceted, however studies exploring the effect of separate QI activities could be valuable to gain more knowledge on the best QI approach for improved care of non-breathing newborns. When feasible, randomized, multi-centred studies of similar QI/SBT interventions would enable stronger evidence for potential causation. Finally, follow-up studies of the resuscitated newborns should be conducted to gain insight regarding the long-term consequences for the patients.

9 References

1. Neonatal Encephalopathy and Neurologic Outcome, Second Edition. Pediatrics. 2014 May 1;133(5):e1482–8.

2. THE 17 GOALS | Sustainable Development [Internet]. [cited 2022 Nov 23]. Available from: https://sdgs.un.org/goals

3. Bhutta ZA, Das JK, Bahl R, Lawn JE, Salam RA, Paul VK, et al. Can available interventions end preventable deaths in mothers, newborn babies, and stillbirths, and at what cost? The Lancet. 2014 Jul 26;384(9940):347–70.

4. Lee AC, Cousens S, Wall SN, Niermeyer S, Darmstadt GL, Carlo WA, et al. Neonatal resuscitation and immediate newborn assessment and stimulation for the prevention of neonatal deaths: a systematic review, meta-analysis and Delphi estimation of mortality effect. BMC Public Health. 2011 Apr 13;11(Suppl 3):S12.

5. MDG 2015 Summary web_english.pdf [Internet]. [cited 2021 Mar 12]. Available from: https://www.un.org/millenniumgoals/2015_MDG_Report/pdf/MDG%202015%20Summary%20web_english.pdf

6. Martin. Health [Internet]. United Nations Sustainable Development. [cited 2022 Nov 9]. Available from: https://www.un.org/sustainabledevelopment/health/

7. Children: improving survival and well-being [Internet]. [cited 2022 Nov 9]. Available from: https://www.who.int/news-room/fact-sheets/detail/children-reducing-mortality

8. UN-IGME-Child-Mortality-Report-2022.pdf [Internet]. [cited 2023 Feb 1]. Available from: https://childmortality.org/wp-content/uploads/2023/01/UN-IGME-Child-Mortality-Report-2022.pdf

9. Data Warehouse [Internet]. UNICEF DATA. [cited 2022 Nov 9]. Available from: https://data.unicef.org/resources/data_explorer/unicef_f/

10. Perin J, Mulick A, Yeung D, Villavicencio F, Lopez G, Strong KL, et al. Global, regional, and national causes of under-5 mortality in 2000–19: an updated systematic analysis with implications for the Sustainable Development Goals. Lancet Child Adolesc Health. 2022 Feb;6(2):106–15.

11. Were WM, Daelmans B, Bhutta Z, Duke T, Bahl R, Boschi-Pinto C, et al. Children's health priorities and interventions. BMJ. 2015 Sep 14;351:h4300.

12. UN-IGME-the-global-burden-of-stillbirths-2020.pdf [Internet]. [cited 2022 Dec 15]. Available from: https://www.unicef.org/media/84851/file/UN-IGME-the-global-burden-of-stillbirths-2020.pdf

13. Peven K, Day LT, Ruysen H, Tahsina T, KC A, Shabani J, et al. Stillbirths including intrapartum timing: EN-BIRTH multi-country validation study. BMC Pregnancy Childbirth. 2021 Mar 26;21(Suppl 1):226.

14. Every Newborn Action Plan [Internet]. [cited 2022 Nov 9]. Available from: https://www.who.int/initiatives/every-newborn-action-plan

15. Lawn JE, Blencowe H, Waiswa P, Amouzou A, Mathers C, Hogan D, et al. Stillbirths: rates, risk factors, and acceleration towards 2030. The Lancet. 2016;387(10018):587–603.

16. Goldenberg RL, McClure EM, Jobe AH, Kamath-Rayne BD, Gravette MG, Rubens CE. Stillbirths and neonatal mortality as outcomes. Int J Gynaecol Obstet. 2013 Dec;123(3):252–3.

17. GBD Compare [Internet]. Institute for Health Metrics and Evaluation. [cited 2022 Nov 9]. Available from: http://vizhub.healthdata.org/gbd-compare

18. Tann CJ, Webb EL, Lassman R, Ssekyewa J, Sewegaba M, Musoke M, et al. Early Childhood Outcomes After Neonatal Encephalopathy in Uganda: A Cohort Study. EClinicalMedicine. 2018 Dec;6:26–35.

19. Quirke FA, Healy P, Bhraonáin EN, Daly M, Biesty L, Hurley T, et al. COHESION: core outcomes in neonatal encephalopathy (protocol). Trials. 2021 Feb 8;22(1):125.

20. Molloy EJ, Bearer C. Neonatal encephalopathy versus Hypoxic-Ischemic Encephalopathy. Pediatr Res. 2018 Nov;84(5):574–574.

21. Dempsey T, Nguyen HL, Nguyen HT, Bui XA, Pham PTT, Nguyen TK, et al. Incidence of Intrapartum-Related Events at the Largest Obstetric Hospital in Hanoi, Vietnam: A Retrospective Study. Children (Basel). 2022 Feb 28;9(3):321.

22. Wall SN, Lee AC, Niermeyer S, English M, Keenan WJ, Carlo W, et al. Neonatal resuscitation in low-resource settings: What, who, and how to overcome challenges to scale up? Int J Gynaecol Obstet. 2009 Oct;107(Suppl 1):S47–64.

23. Ersdal HL, Eilevstjønn J, Linde JE, Yeconia A, Mduma ER, Kidanto H, et al. Fresh stillborn and severely asphyxiated neonates share a common hypoxic–ischemic pathway. International Journal of Gynecology & Obstetrics. 2018;141(2):171–80.

24. Patterson J, Berkelhamer S, Ishoso D, Iyer P, Lowman C, Bauserman M, et al. Effect of resuscitation training and implementation of continuous electronic heart rate monitoring on identification of stillbirth. Resuscitation. 2022 Feb;171:57–63.

25. International Liaison Committee on Resuscitation [Internet]. [cited 2022 Nov 7]. Available from: https://www.ilcor.org/

26. Wyckoff MH, Wyllie J, Aziz K, de Almeida MF, Fabres JW, Fawke J, et al. Neonatal Life Support 2020 International Consensus on Cardiopulmonary Resuscitation and Emergency Cardiovascular Care Science With Treatment Recommendations. Resuscitation. 2020 Nov 1;156:A156–87.

27. Ersdal HL, Mduma E, Svensen E, Perlman JM. Early initiation of basic resuscitation interventions including face mask ventilation may reduce birth asphyxia related mortality in low-income countries: a prospective descriptive observational study. Resuscitation. 2012 Jul;83(7):869–73.

28. Bjorland PA, Øymar K, Ersdal HL, Rettedal SI. Incidence of newborn resuscitative interventions at birth and short-term outcomes: a regional population-based study. BMJ Paediatr Open. 2019 Dec 29;3(1):e000592.

29. Goudar SS, Somannavar MS, Clark R, Lockyer JM, Revankar AP, Fidler HM, et al. Stillbirth and Newborn Mortality in India After Helping Babies Breathe Training. Pediatrics. 2013 Feb 1;131(2):e344–52.

30. Msemo G, Massawe A, Mmbando D, Rusibamayila N, Manji K, Kidanto HL, et al. Newborn Mortality and Fresh Stillbirth Rates in Tanzania After Helping Babies Breathe Training. Pediatrics. 2013 Feb 1;131(2):e353–60.

31. Perlman JM, Wyllie J, Kattwinkel J, Atkins DL, Chameides L, Goldsmith JP, et al. Part 11: Neonatal Resuscitation. Circulation. 2010 Oct 19;122(16_suppl_2):S516–38.

32. Kamath-Rayne BD, Berkelhamer SK, Kc A, Ersdal HL, Niermeyer S. Neonatal resuscitation in global health settings: an

examination of the past to prepare for the future. Pediatr Res. 2017 Aug;82(2):194–200.

33. Halamek LP. Educational Perspectives. NeoReviews. 2008 Apr 1;9(4):e142–9.

34. Neonatal Resuscitation Program [Internet]. [cited 2022 Nov 7]. Available from: https://www.aap.org/en/learning/neonatal-resuscitation-program/

35. Helping Babies Breathe [Internet]. AAP.org. [cited 2021 Feb 25]. Available from: http://www.aap.org/en-us/advocacy-and-policy/aap-health-initiatives/helping-babies-survive/Pages/Helping-Babies-Breathe.aspx

36. Arnold J. The Neonatal Resuscitation Program Comes of Age. The Journal of Pediatrics. 2011 Sep 1;159(3):357-358.e1.

37. WHO launches the second edition of Essential Newborn Care Course (interim version) for field testing [Internet]. [cited 2022 Sep 30]. Available from: https://www.who.int/news/item/11-04-2022-who-launches-the-second-edition-of-essential-newborn-care-course-(interim-version)-for-field-testing

38. Kamath-Rayne B, Thukral A, Visick M, Schoen E, Amick E, Deorari A, et al. Helping Babies Breathe, Second Edition: A Model for Strengthening Educational Programs to Increase Global Newborn Survival. Global Health: Science and Practice. 2018 Oct 3;6:538–51.

39. Helping Babies Breathe 2nd Edition Summary of Changes [Internet]. [cited 2021 Feb 25]. Available from: https://www.aap.org/en-us/advocacy-and-policy/aap-health-initiatives/helping-babies-survive/Pages/Helping-Babies-Breathe-2nd-Edition-Summmary-of-Changes.aspx

40. Ersdal HL, Singhal N, Msemo G, KC A, Data S, Moyo NT, et al. Successful implementation of Helping Babies Survive and Helping Mothers Survive programs—An Utstein formula for newborn and maternal survival. PLoS One [Internet]. 2017 Jun 7 [cited 2021 Feb 25];12(6). Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5462342/

41. Ersdal HL, Vossius C, Bayo E, Mduma E, Perlman J, Lippert A, et al. A one-day 'Helping Babies Breathe' course improves simulated performance but not clinical management of neonates. Resuscitation. 2013 Oct;84(10):1422–7.

42. Mduma E, Ersdal H, Svensen E, Kidanto H, Auestad B, Perlman J. Frequent brief on-site simulation training and reduction in 24-h neonatal mortality--an educational intervention study. Resuscitation. 2015 Aug;93:1–7.

43. safer-births-report-screens-07.08.29.pdf [Internet]. [cited 2022 Oct 5]. Available from: https://laerdalglobalhealth.com/cdn-4a257a/globalassets/lgh/partnerships--programs/safer-births/safer-births-report-screens-07.08.29.pdf

44. Innovations – Safer Births [Internet]. [cited 2022 Oct 5]. Available from: https://saferbirths.com/innovations/

45. KC A, Peven K, Ameen S, Msemo G, Basnet O, Ruysen H, et al. Neonatal resuscitation: EN-BIRTH multi-country validation study. BMC Pregnancy Childbirth. 2021 Mar 26;21(Suppl 1):235.

46. Branche T, Perez M, Saugstad OD. The first golden minute — Is it relevant? Resuscitation. 2020 Nov;156:284–5.

47. Chaulagain DR, Malqvist M, Brunell O, Wrammert J, Basnet O, KC A. Performance of health workers on neonatal resuscitation care following scaled-up quality improvement interventions in public hospitals of Nepal - a prospective observational study. BMC Health Serv

Res [Internet]. 2021 Apr 19 [cited 2021 Apr 28];21. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8054430/

48. Vail B, Morgan MC, Spindler H, Christmas A, Cohen SR, Walker DM. The power of practice: simulation training improving the quality of neonatal resuscitation skills in Bihar, India. BMC Pediatr. 2018 Sep 3;18:291.

49. Boithias C, Jule L, Le Foulgoc S, Jourdain G, Benhamou D. Allowing more time to ILCOR Step A of neonatal resuscitation leads to better residents' task completion in simulated scenarios. A problem of time pressure? BMC Pediatr. 2020 Jul 3;20:331.

50. Kc A, Wrammert J, Clark RB, Ewald U, Vitrakoti R, Chaudhary P, et al. Reducing Perinatal Mortality in Nepal Using Helping Babies Breathe. Pediatrics [Internet]. 2016 Jun 1 [cited 2021 Feb 25];137(6). Available from: https://pediatrics.aappublications.org/content/137/6/e20150117

51. Ojha R, Liu A, Rai D, Nanan R. Review of Simulation in Pediatrics: The Evolution of a Revolution. Front Pediatr [Internet]. 2015 [cited 2021 Feb 25];3. Available from: https://www.frontiersin.org/articles/10.3389/fped.2015.00106/full

52. Yousef N, Moreau R, Soghier L. Simulation in neonatal care: towards a change in traditional training? Eur J Pediatr. 2022 Jan 12;1–8.

53. Gaba DM. The Future Vision of Simulation in Healthcare. Simulation in Healthcare. 2007 Summer;2(2):126–35.

54. Issenberg SB, McGaghie WC, Petrusa ER, Lee Gordon D, Scalese RJ. Features and uses of high-fidelity medical simulations that lead to effective learning: a BEME systematic review. Med Teach. 2005 Jan;27(1):10–28.

55. Brazil V. Translational simulation: not 'where?' but 'why?' A functional view of in situ simulation. Advances in Simulation. 2017 Oct 19;2(1):20.

56. Sørensen JL, Østergaard D, LeBlanc V, Ottesen B, Konge L, Dieckmann P, et al. Design of simulation-based medical education and advantages and disadvantages of in situ simulation versus off-site simulation. BMC Med Educ. 2017 Jan 21;17(1):20.

57. Sørensen JL, Vleuten C van der, Rosthøj S, Østergaard D, LeBlanc V, Johansen M, et al. Simulation-based multiprofessional obstetric anaesthesia training conducted in situ versus off-site leads to similar individual and team outcomes: a randomised educational trial. BMJ Open. 2015 Oct 1;5(10):e008344.

58. Lateef F. Simulation-based learning: Just like the real thing. J Emerg Trauma Shock. 2010;3(4):348–52.

59. Ajmi SC, Advani R, Fjetland L, Kurz KD, Lindner T, Qvindesland SA, et al. Reducing door-to-needle times in stroke thrombolysis to 13 min through protocol revision and simulation training: a quality improvement project in a Norwegian stroke centre. BMJ Qual Saf. 2019 Nov;28(11):939–48.

60. Theilen U, Fraser L, Jones P, Leonard P, Simpson D. Regular in-situ simulation training of paediatric Medical Emergency Team leads to sustained improvements in hospital response to deteriorating patients, improved outcomes in intensive care and financial savings. Resuscitation. 2017 Jun 1;115:61–7.

61. Kurz MW, Ospel JM, Advani R, Sandset EC, Aamodt AH, Tennøe B, et al. Simulation Methods in Acute Stroke Treatment. Stroke. 2020 Jul;51(7):1978–82.

62. Madireddy S, Rufa EP. Maintaining Confidentiality and Psychological Safety in Medical Simulation. In: StatPearls [Internet].

Treasure Island (FL): StatPearls Publishing; 2022 [cited 2022 Nov 16]. Available from: http://www.ncbi.nlm.nih.gov/books/NBK559259/

63. Morris SM, Fratt EM, Rodriguez J, Ruman A, Wibecan L, Nelson BD. Implementation of the Helping Babies Breathe Training Program: A Systematic Review. Pediatrics [Internet]. 2020 Sep 1 [cited 2021 Feb 25];146(3). Available from: https://pediatrics.aappublications.org/content/146/3/e20193938

64. Pitt MB, Eppich WJ, Shane ML, Butteris SM. Using Simulation in Global Health: Considerations for Design and Implementation. Simulation in Healthcare. 2017 Jun;12(3):177–81.

65. Rule ARL, Tabangin M, Cheruiyot D, Mueri P, Kamath-Rayne BD. The Call and the Challenge of Pediatric Resuscitation and Simulation Research in Low-Resource Settings. Simulation in Healthcare. 2017 Dec;12(6):402–6.

66. Mundell WC, Kennedy CC, Szostek JH, Cook DA. Simulation technology for resuscitation training: a systematic review and meta-analysis. Resuscitation. 2013 Sep;84(9):1174–83.

67. Lindhard MS, Thim S, Laursen HS, Schram AW, Paltved C, Henriksen TB. Simulation-Based Neonatal Resuscitation Team Training: A Systematic Review. Pediatrics. 2021 Apr;147(4):e2020042010.

68. Dempsey E, Pammi M, Ryan AC, Barrington KJ. Standardised formal resuscitation training programmes for reducing mortality and morbidity in newborn infants. Cochrane Database of Systematic Reviews [Internet]. 2015 [cited 2021 Feb 25];(9). Available from: https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD009106.pub2/full

69. Patel A, Khatib MN, Kurhe K, Bhargava S, Bang A. Impact of neonatal resuscitation trainings on neonatal and perinatal mortality: a

systematic review and meta-analysis. BMJ Paediatrics Open. 2017 Nov 1;1(1):e000183.

70. Dol J, Campbell-Yeo M, Murphy GT, Aston M, McMillan D, Richardson B. The impact of the Helping Babies Survive program on neonatal outcomes and health provider skills: a systematic review. JBI Database System Rev Implement Rep. 2018 Mar;16(3):701–37.

71. Goldshtein D, Krensky C, Doshi S, Perelman VS. In situ simulation and its effects on patient outcomes: a systematic review. BMJ Simul Technol Enhanc Learn. 2019 Dec 24;6(1):3–9.

72. Brazil V, Purdy EI, Bajaj K. Connecting simulation and quality improvement: how can healthcare simulation really improve patient care? BMJ Qual Saf. 2019 Nov;28(11):862–5.

73. Taylor MJ, McNicholas C, Nicolay C, Darzi A, Bell D, Reed JE. Systematic review of the application of the plan–do–study–act method to improve quality in healthcare. BMJ Qual Saf. 2014 Apr;23(4):290–8.

74. Schouten LMT, Hulscher MEJL, van Everdingen JJE, Huijsman R, Grol RPTM. Evidence for the impact of quality improvement collaboratives: systematic review. BMJ. 2008 Jun 28;336(7659):1491–4.

75. Nicolay CR, Purkayastha S, Greenhalgh A, Benn J, Chaturvedi S, Phillips N, et al. Systematic review of the application of quality improvement methodologies from the manufacturing industry to surgical healthcare. British Journal of Surgery. 2012 Jan 30;99(3):324–35.

76. Kaplan HC, Brady PW, Dritz MC, Hooper DK, Linam WM, Froehle CM, et al. The Influence of Context on Quality Improvement Success in Health Care: A Systematic Review of the Literature. Milbank Q. 2010 Dec;88(4):500–59.

77. Leatherman S, Ferris TG, Berwick D, Omaswa F, Crisp N. The role of quality improvement in strengthening health systems in developing countries. International Journal for Quality in Health Care. 2010 Aug 1;22(4):237–43.

78. Smits HL, Leatherman S, Berwick DM. Quality improvement in the developing world. International Journal for Quality in Health Care. 2002 Dec 1;14(6):439–40.

79. Wagenaar BH, Hirschhorn LR, Henley C, Gremu A, Sindano N, Chilengi R, et al. Data-driven quality improvement in low-and middle-income country health systems: lessons from seven years of implementation experience across Mozambique, Rwanda, and Zambia. BMC Health Services Research. 2017 Dec 21;17(3):830.

80. Powell BJ, Waltz TJ, Chinman MJ, Damschroder LJ, Smith JL, Matthieu MM, et al. A refined compilation of implementation strategies: results from the Expert Recommendations for Implementing Change (ERIC) project. Implement Sci. 2015 Feb 12;10:21.

81. Perry CK, Damschroder LJ, Hemler JR, Woodson TT, Ono SS, Cohen DJ. Specifying and comparing implementation strategies across seven large implementation interventions: a practical application of theory. Implement Sci. 2019 Mar 21;14:32.

82. Flodgren G, Parmelli E, Doumit G, Gattellari M, O'Brien MA, Grimshaw J, et al. Local opinion leaders: effects on professional practice and health care outcomes. Cochrane Database Syst Rev. 2011 Aug 10;(8):CD000125.

83. Soo S, Berta W, Baker GR. Role of champions in the implementation of patient safety practice change. Healthc Q. 2009;12 Spec No Patient:123–8.

84. Miech EJ, Rattray NA, Flanagan ME, Damschroder L, Schmid AA, Damush TM. Inside help: An integrative review of champions in

healthcare-related implementation. SAGE Open Med. 2018 May 17;6:2050312118773261.

85. Wood K, Giannopoulos V, Louie E, Baillie A, Uribe G, Lee KS, et al. The role of clinical champions in facilitating the use of evidence-based practice in drug and alcohol and mental health settings: A systematic review. Implementation Research and Practice. 2020 Jan 1;1:2633489520959072.

86. Dale S, Levi C, Ward J, Grimshaw JM, Jammali-Blasi A, D'Este C, et al. Barriers and Enablers to Implementing Clinical Treatment Protocols for Fever, Hyperglycaemia, and Swallowing Dysfunction in the Quality in Acute Stroke Care (QASC) Project—A Mixed Methods Study. Worldviews on Evidence-Based Nursing. 2015;12(1):41–50.

87. Flanagan ME, Plue L, Miller KK, Schmid AA, Myers L, Graham G, et al. A qualitative study of clinical champions in context: Clinical champions across three levels of acute care. SAGE Open Med. 2018 Aug 1;6:2050312118792426.

88. O'Halloran A, Shepard LN, Nadkarni VM. Building a Culture of Champions: The Importance of Leadership in Resuscitation. J Am Heart Assoc. 2021 Feb 15;10(5):e020390.

89. Kirkpatric D. Techniques for Evaluation Training Programs. Journal of the American Society of Training Directors. 1959;

90. Ando K, Ando A, Tanaka A, Koba S, Sagara H. Educational Effects of Simulation and Non-Simulation Training in Airway Management according to Levels of the Kirkpatrick Model: A Systematic Review and Network Meta-Analysis. J Clin Med. 2022 Sep 23;11(19):5614.

91. van Tetering AAC, Segers MHM, Ntuyo P, Namagambe I, van der Hout-van der Jagt MB, Byamugisha JK, et al. Evaluating the Instructional Design and Effect on Knowledge, Teamwork, and Skills of

Technology-Enhanced Simulation-Based Training in Obstetrics in Uganda: Stepped-Wedge Cluster Randomized Trial. JMIR Med Educ. 2021 Feb 5;7(1):e17277.

92. Chia NH, Cheung VKL, Lam MLY, Cheung IWK, Wong TKY, So SS, et al. Harnessing power of simulation training effectiveness with Kirkpatrick model in emergency surgical airway procedures. Heliyon. 2022 Oct 6;8(10):e10886.

93. Blackmore A, Kasfiki EV, Purva M. Simulation-based education to improve communication skills: a systematic review and identification of current best practice. BMJ Simul Technol Enhanc Learn. 2018 Oct 4;4(4):159–64.

94. The Kirkpatrick Model [Internet]. Kirkpatrick Partners, LLC. [cited 2022 Nov 18]. Available from: https://kirkpatrickpartners.com/the-kirkpatrick-model/

95. Bhatia M, Stewart AE, Wallace A, Kumar A, Malhotra A. Evaluation of an In-Situ Neonatal Resuscitation Simulation Program Using the New World Kirkpatrick Model. Clinical Simulation in Nursing. 2021 Jan 1;50:27–37.

96. Ivers NM, Sales A, Colquhoun H, Michie S, Foy R, Francis JJ, et al. No more ‘business as usual’ with audit and feedback interventions: towards an agenda for a reinvigorated intervention. Implement Sci. 2014 Jan 17;9:14.

97. Ivers N, Jamtvedt G, Flottorp S, Young JM, Odgaard-Jensen J, French SD, et al. Audit and feedback: effects on professional practice and healthcare outcomes. Cochrane Database of Systematic Reviews [Internet]. 2012 [cited 2022 Sep 5];(6). Available from: http://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD000259.pub3/full

98. Ivers NM, Grimshaw JM, Jamtvedt G, Flottorp S, O'Brien MA, French SD, et al. Growing Literature, Stagnant Science? Systematic Review, Meta-Regression and Cumulative Analysis of Audit and Feedback Interventions in Health Care. J Gen Intern Med. 2014 Nov;29(11):1534–41.

99. Brown B, Gude WT, Blakeman T, van der Veer SN, Ivers N, Francis JJ, et al. Clinical Performance Feedback Intervention Theory (CP-FIT): a new theory for designing, implementing, and evaluating feedback in health care based on a systematic review and meta-synthesis of qualitative research. Implementation Sci. 2019 Dec;14(1):40.

100. Bong M. Problems in Academic Motivation Research and Advantages and Disadvantages of Their Solutions. Contemporary Educational Psychology. 1996 Apr 1;21(2):149–65.

101. Tanzania-Health-Sector-Strategic-Plan-IV-2015-2020-1-4.pdf [Internet]. [cited 2022 Nov 11]. Available from: https://www.prb.org/wp-content/uploads/2020/06/Tanzania-Health-Sector-Strategic-Plan-IV-2015-2020-1-4.pdf

102. Overview [Internet]. World Bank. [cited 2022 Nov 11]. Available from: https://www.worldbank.org/en/country/tanzania/overview

103. Tanzania Population (2022) - Worldometer [Internet]. [cited 2022 Dec 20]. Available from: https://www.worldometers.info/world-population/tanzania-population/

104. Tanzania Fertility Rate 1950-2022 [Internet]. [cited 2022 Nov 11]. Available from: https://www.macrotrends.net/countries/TZA/tanzania/fertility-rate

105. United Republic of Tanzania (TZA) - Demographics, Health & Infant Mortality [Internet]. UNICEF DATA. [cited 2021 Apr 28]. Available from: https://data.unicef.org/country/tza/

106. Current health expenditure (% of GDP) - Tanzania | Data [Internet]. [cited 2022 Nov 11]. Available from: https://data.worldbank.org/indicator/SH.XPD.CHEX.GD.ZS?locations=TZ

107. TZA 2009 Health Sector Strategic Plan III.pdf [Internet]. [cited 2022 Nov 11]. Available from: https://extranet.who.int/nutrition/gina/sites/default/filesstore/TZA%202009%20Health%20Sector%20Strategic%20Plan%20III.pdf

108. School and program approval guideline and process [Internet]. TNMC. [cited 2023 Jan 3]. Available from: http://www.tnmc.go.tz/education-and-examinations/school-and-program-approval-guideline-and-process

109. Swai EA, Msuya SE, Moshi H, Lindkvist M, Sörlin A, Sahlén KG. Children and adolescents with physical disabilities: describing characteristics and disability-related needs in the Kilimanjaro region, north-eastern Tanzania – a cross-sectional survey. BMJ Open. 2023 Jan 1;13(1):e064849.

110. Mduma E, Kvaløy JT, Soreide E, Svensen E, Mdoe P, Perlman J, et al. Frequent refresher training on newborn resuscitation and potential impact on perinatal outcome over time in a rural Tanzanian hospital: an observational study. BMJ Open [Internet]. 2019 Sep 27 [cited 2021 Feb 22];9(9). Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6773328/

111. Mduma ER, Gratz J, Patil C, Matson K, Dakay M, Liu S, et al. The etiology, risk factors, and interactions of enteric infections and malnutrition and the consequences for child health and development study (MAL-ED): description of the Tanzanian site. Clin Infect Dis. 2014 Nov 1;59 Suppl 4:S325-30.

112. Vossius C, Mduma E, Moshiro R, Mdoe P, Kvaløy JT, Kidanto H, et al. The impact of introducing ambulance and delivery fees in a rural hospital in Tanzania. BMC Health Services Research. 2021 Jan 28;21(1):99.

113. NeoNatalie Live – Safer Births [Internet]. [cited 2021 Feb 25]. Available from: http://www.saferbirths.com/portfolio_page/newborn-ventilation-trainer/

114. Haynes J, Bjorland P, Gomo Ø, Ushakova A, Rettedal S, Perlman J, et al. Novel Neonatal Simulator Provides High-Fidelity Ventilation Training Comparable to Real-Life Newborn Ventilation. Children (Basel). 2021 Oct 19;8(10):940.

115. Valente TW, Pumpuang P. Identifying Opinion Leaders to Promote Behavior Change. Health Educ Behav. 2007 Dec 1;34(6):881–96.

116. Shea CM. A conceptual model to guide research on the activities and effects of innovation champions. Implement Res Pract. 2021 Jan 1;2:10.1177/2633489521990443.

117. Courses [Internet]. EuSim. [cited 2022 Sep 1]. Available from: https://eusim.org/courses/

118. Mduma ER. Optimizing Helping Babies Breathe implementation in a resource limited setting to improve perinatal outcome [Internet]. University of Stavanger; 2021 [cited 2022 Oct 6]. Available from: https://ebooks.uis.no/index.php/USPS/catalog/book/95

119. Størdal K, Eilevstjønn J, Mduma E, Holte K, Thallinger M, Linde J, et al. Increased perinatal survival and improved ventilation skills over a five-year period: An observational study. PLOS ONE. 2020 Oct 12;15(10):e0240520.

120. Vadla MS, Mdoe P, Moshiro R, Haug IA, Gomo Ø, Kvaløy JT, et al. Neonatal Resuscitation Skill-Training Using a New Neonatal Simulator, Facilitated by Local Motivators: Two-Year Prospective Observational Study of 9000 Trainings. Children. 2022 Feb;9(2):134.

121. Arlington L, Kairuki AK, Isangula KG, Meda RA, Thomas E, Temu A, et al. Implementation of "Helping Babies Breathe": A 3-Year Experience in Tanzania. Pediatrics [Internet]. 2017 May 1 [cited 2021 Feb 25];139(5). Available from: https://pediatrics.aappublications.org/content/139/5/e20162132

122. KC A, Wrammert J, Nelin V, Clark RB, Ewald U, Peterson S, et al. Evaluation of Helping Babies Breathe Quality Improvement Cycle (HBB-QIC) on retention of neonatal resuscitation skills six months after training in Nepal. BMC Pediatr [Internet]. 2017 Apr 11 [cited 2021 Feb 25];17. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5387236/

123. Wyllie J, Perlman JM, Kattwinkel J, Wyckoff MH, Aziz K, Guinsburg R, et al. Part 7: Neonatal resuscitation: 2015 International Consensus on Cardiopulmonary Resuscitation and Emergency Cardiovascular Care Science with Treatment Recommendations. Resuscitation. 2015 Oct 1;95:e169–201.

124. Gurung R, Gurung A, Sunny AK, Basnet O, Shrestha SK, Gomo ØH, et al. Effect of skill drills on neonatal ventilation performance in a simulated setting- observation study in Nepal. BMC Pediatr. 2019 Oct 28;19(1):387.

125. Wilson C, Furness E, Proctor L, Sweetman G, Hird K. A randomised trial of the effectiveness of instructor versus automated manikin feedback for training junior doctors in life support skills. Perspect Med Educ. 2021 Mar 1;10(2):95–100.

126. Wardhani V, Utarini A, van Dijk JP, Post D, Groothoff JW. Determinants of quality management systems implementation in hospitals. Health Policy. 2009 Mar;89(3):239–51.

127. Hill JE, Stephani AM, Sapple P, Clegg AJ. The effectiveness of continuous quality improvement for developing professional practice and improving health care outcomes: a systematic review. Implementation Sci. 2020 Dec;15(1):1–14.

128. Mayer M, Xhinti N, Dyavuza V, Bobotyana L, Perlman J, Velaphi S. Assessing Implementation of Helping Babies Breathe Program Through Observing Immediate Care of Neonates at Time of Delivery. Front Pediatr. 2022 Apr 25;10:864431.

129. Vadla MS, Moshiro R, Mdoe P, Eilevstjønn J, Kvaløy JT, Hhoki BH, et al. Newborn resuscitation simulation training and changes in clinical performance and perinatal outcomes: a clinical observational study of 10,481 births. Adv Simul. 2022 Nov 5;7(1):38.

130. Wyckoff MH, Aziz K, Escobedo MB, Kapadia VS, Kattwinkel J, Perlman JM, et al. Part 13: Neonatal Resuscitation: 2015 American Heart Association Guidelines Update for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care (Reprint). Pediatrics [Internet]. 2015 Oct 1 [cited 2021 Feb 25]; Available from: https://pediatrics.aappublications.org/content/early/2015/10/13/peds.2015-3373G

131. Ersdal HL, Eilevstjonn J, Perlman J, Gomo Ø, Moshiro R, Mdoe P, et al. Establishment of functional residual capacity at birth: Observational study of 821 neonatal resuscitations. Resuscitation. 2020 Aug 1;153:71–8.

132. Fawke J, Wyllie J, Udaeta E, Rüdiger M, Ersdal H, Wright MD, et al. Suctioning of clear amniotic fluid at birth: A systematic review. Resuscitation Plus. 2022 Aug 17;12.

133. Arabi AME, Ibrahim SA, Manar AR, Abdalla MS, Ahmed SE, Dempsey EP, et al. Perinatal outcomes following Helping Babies Breathe training and regular peer–peer skills practice among village midwives in Sudan. Arch Dis Child. 2018 Jan;103(1):24–7.

134. Budhathoki SS, Gurung R, Ewald U, Thapa J, Kc A. Does the Helping Babies Breathe Programme impact on neonatal resuscitation care practices? Results from systematic review and meta-analysis. Acta Paediatrica. 2019;108(5):806–13.

135. Dawes GS, Jacobson HN, Mott JC, Shelley HJ, Stafford A. The treatment of asphyxiated, mature foetal lambs and rhesus monkeys with intravenous glucose and sodium carbonate. J Physiol. 1963 Nov;169(1):167–84.

136. Moshiro R, Mdoe P, Perlman JM. A Global View of Neonatal Asphyxia and Resuscitation. Front Pediatr. 2019 Nov 26;7:489.

137. Hall AM, Flodgren GM, Richmond HL, Welsh S, Thompson JY, Furlong BM, et al. Champions for improved adherence to guidelines in long-term care homes: a systematic review. Implement Sci Commun. 2021 Aug 3;2(1):85.

138. Santos WJ, Graham ID, Lalonde M, Demery Varin M, Squires JE. The effectiveness of champions in implementing innovations in health care: a systematic review. Implement Sci Commun. 2022 Jul 22;3:80.

139. Gilmartin-Thomas JF, Liew D, Hopper I. Observational studies and their utility for practice. Aust Prescr. 2018 Jun;41(3):82–5.

140. Barratt H, Campbell M, Moore L, Zwarenstein M, Bower P. Randomised controlled trials of complex interventions and large-scale transformation of services [Internet]. Challenges, solutions and future directions in the evaluation of service innovations in health care and

public health. NIHR Journals Library; 2016 [cited 2023 Feb 26]. Available from: http://www.ncbi.nlm.nih.gov/books/NBK361251/

141. Fedak KM, Bernal A, Capshaw ZA, Gross S. Applying the Bradford Hill criteria in the 21st century: how data integration has changed causal inference in molecular epidemiology. Emerg Themes Epidemiol. 2015 Sep 30;12:14.

142. Thiese MS. Observational and interventional study design types; an overview. Biochem Med (Zagreb). 2014 Jun 15;24(2):199–210.

143. Deaton A, Cartwright N. Understanding and misunderstanding randomized controlled trials. Soc Sci Med. 2018 Aug;210:2–21.

144. Stralen KJ van, Dekker FW, Zoccali C, Jager KJ. Confounding. NEC. 2010;116(2):c143–7.

145. Definition of BIAS [Internet]. [cited 2022 Nov 21]. Available from: https://www.merriam-webster.com/dictionary/bias

146. Cochrane Handbook for Systematic Reviews of Interventions [Internet]. [cited 2022 Nov 21]. Available from: https://web-s-ebscohost-com.ezproxy.uis.no/ehost/ebookviewer/ebook/bmxlYmtfXzIyNTk4NTVfX0FO0?sid=f4afb283-dfde-419f-871a-91ee5514352b@redis&vid=0&format=EB&rid=1

147. Published: 10/29/2015 AS. Bias [Internet]. Forskningsetikk. [cited 2022 Nov 21]. Available from: https://www.forskningsetikk.no/en/resources/the-research-ethics-library/independence/bias/

148. Vetter TR, Mascha EJ. Bias, Confounding, and Interaction: Lions and Tigers, and Bears, Oh My! Anesthesia & Analgesia. 2017 Sep;125(3):1042–8.

149. Pannucci CJ, Wilkins EG. Identifying and Avoiding Bias in Research. Plast Reconstr Surg. 2010 Aug;126(2):619–25.

150. Hassan E. Recall Bias can be a Threat to Retrospective and Prospective Research Designs. The Internet Journal of Epidemiology [Internet]. 2005 Dec 31 [cited 2022 Nov 22];3(2). Available from: https://ispub.com/IJE/3/2/13060

151. Sedgwick P, Greenwood N. Understanding the Hawthorne effect. BMJ. 2015 Sep 4;351:h4672.

152. Hammer GP, du Prel JB, Blettner M. Avoiding Bias in Observational Studies. Dtsch Arztebl Int. 2009 Oct;106(41):664–8.

153. Ersdal HL, Mduma E, Svensen E, Perlman J. Birth Asphyxia: A Major Cause of Early Neonatal Mortality in a Tanzanian Rural Hospital. Pediatrics. 2012 May 1;129(5):e1238–43.

154. NeoBeat | Laerdal Medical [Internet]. [cited 2022 Nov 23]. Available from: https://edit.laerdal.com/products/tech/simulation-technology/neobeat/

155. Vossius C, Lotto E, Lyanga S, Mduma E, Msemo G, Perlman J, et al. Cost-Effectiveness of the "Helping Babies Breathe" Program in a Missionary Hospital in Rural Tanzania. PLoS One [Internet]. 2014 Jul 9 [cited 2021 Jun 11];9(7). Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4090230/

156. WMA - The World Medical Association-WMA Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects [Internet]. [cited 2023 Feb 23]. Available from: https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/

157. Council for International Organizations of Medical Sciences (CIOMS). International Ethical Guidelines for Health-related Research

involving Humans [Internet]. Council for International Organizations of Medical Sciences (CIOMS); 2016 [cited 2022 Nov 23]. Available from: https://cioms.ch/publications/product/international-ethical-guidelines-for-health-related-research-involving-humans/

158. Q&A - NeoNatalie Live [Internet]. Laerdal Global Health. [cited 2022 Nov 29]. Available from: https://laerdalglobalhealth.com/Resources/qa-neonatalie-live/

159. medical-and-health-research-in-low-and-middle-income-countries-en.pdf [Internet]. [cited 2023 Feb 23]. Available from: https://www.forskningsetikk.no/globalassets/dokumenter/4-publikasjoner-som-pdf/medical-and-health-research-in-low-and-middle-income-countries-en.pdf

Appendix 1

The Neonatal Resuscitation Algorithm

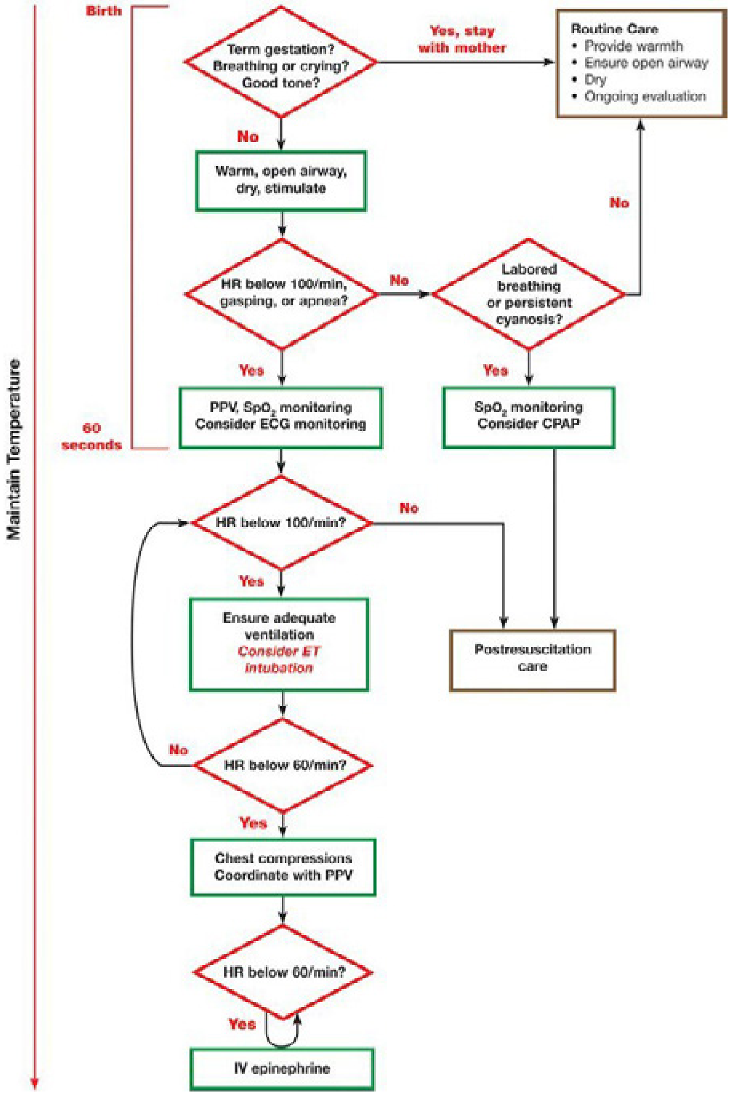


Figure reprinted from Resuscitation. 2020 Nov 1;156:A156–87, Wyckoff MH, Wyllie J, Aziz K, de Almeida MF, Fabres JW, Fawke J, et al. 2020 International Consensus on Cardiopulmonary Resuscitation and Emergency Cardiovascular Care Science With Treatment Recommendations, Copyright (2020) with permission from Elsevier.

Ventilation Skill Training

How to use manikin and screen

1

Place the manikin on the resuscitation table and put on the green heart rate sensor

2

Activate the screen

Select your name from the list and the level you want to train

Read the introduction and start ventilations

3

Start ventilation

Look for chest rise and observe heart rate on the heart rate monitor

Adjust ventilation technique if needed

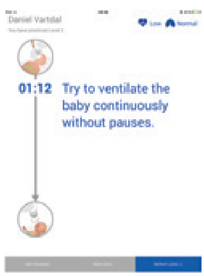
The screen shows how long time you have been ventilating

Ventilate until the manikin starts crying

4

Recieve feedback on ventilation time and how to improve your ventilations

A good advice is to repeat the same level at least one more time

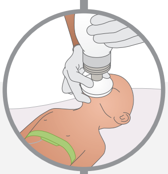


Newborn Resuscitation

How to ventilate newborn babies

Start ventilations within 1 minute after birth

Follow the HBB action plan



Ventilate until baby is breathing

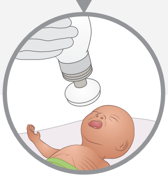
Give 40-60 ventilations per minute
- Open airways
- Good mask seal

Look for chest rise
- Chest rise indicates that the baby gets air into the lungs
- Adjust ventilation technique if you don't see chest rise

Some babies need higher pressure initially for the lungs to open
Give a few ventilations with increased pressure

Observe heart rate
- **Low heart rate** indicates that the baby has had too little oxygen
- **Decreasing heart rate** indicates that the baby does not get enough air into the lungs
- **Increasing heart rate** indicates that the baby gets air into the lungs

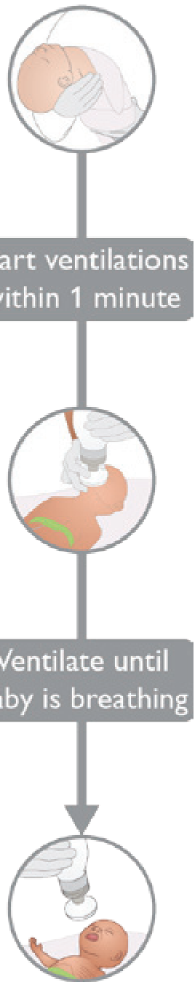
Keep focus on ventilations
- The baby may need ventilations for a while to start breathing
- Avoid any unnecessary pauses



Appendix 3 Master Trainer Guide (reprinted with permission from Laerdal Global Health

Newborn Ventilation Trainer

Master Trainer Guide



Laerdal
helping save lives

To Master Trainers at Haydom Lutheran Hospital,

Congratulations with the Newborn Ventilation Trainer, *a result of the close collaboration between midwives, doctors, researchers and product developers in Tanzania and Norway in the Safer Births project.*

Focus in the newborn ventilation training is quick initiation of ventilations, continuous ventilation and effective ventilations.

We hope master trainers and midwives enjoy the product and that everybody becomes more proficent with repeated training.

Good luck!

Ingunn Anda Haug and Øystein Gomo

Content

Overview

Screen
The screen is used to register training, select training level and give feedback. The screen is fixed to the trolley.

Manikin
Manikin for ventilation training. To be used with bag/mask and heart rate sensor.

Trolley
Trolley for storage of training equipment. Power cable and manikin charge cable are attached to the trolley.

Hat, blanket and cord
Hat, blanket and cord for scenario training.

Learners Guide
Simple introduction to midwives about how to perform Ventilation Skill Training.

Discussion cards
Discussion points related to newborn resuscitation. The cards can be used in group discussions guided by Master Trainers or other skilled staff.

Master Trainer Guide (this folder)
Information to Master Trainers about how to prepare the equipment and perform ventilation training

Where and when to train

The Newborn Ventilation Trainer should be used in the delivery rooms together with the Laerdal Newborn Resuscitation Monitor.

Learners should be encouraged to practice often. After each training the learners will receive feedback from the screen on how to improve. A good advice is to repeat the same training level at least one more time.

Registration of training

The screen is used to guide and to register all training sessions. Learners will have to be registered by Master Trainers in the learner list before first training.

Training results are sent to a training log. The training log can be viewed from a pc or the screen (password needed):

https://researchsandboxapp.azurewebsites.net/

Master Trainers can use this log to follow up the training activities and invite midwives to regular training.

How to train

The Newborn Ventilation Trainer can be used in two different ways:
- Ventilation Skill Training (individual training - without Master Trainer)
- Ventilation Scenario Training (team training - led by Master Trainer)

Ventilation Skill Training

Focus in Ventilation Skill Training is to practice doing **good and continuous ventilations.**

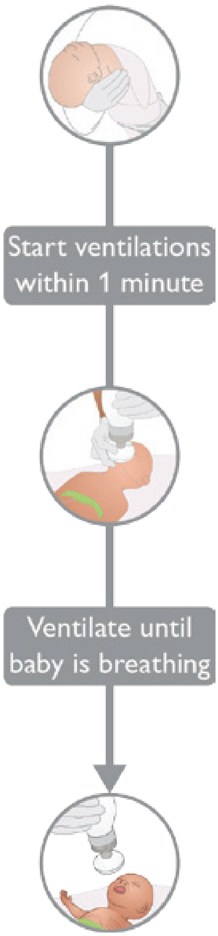
Skill training is for individual learners and can be performed without a master trainer.

Ventilation Scenario Training

Ventilation Scenario Training means to practice the whole sequence from the baby is born until it is breathing. Focus areas are **The Golden Minute** and **good and continuous ventilations**.

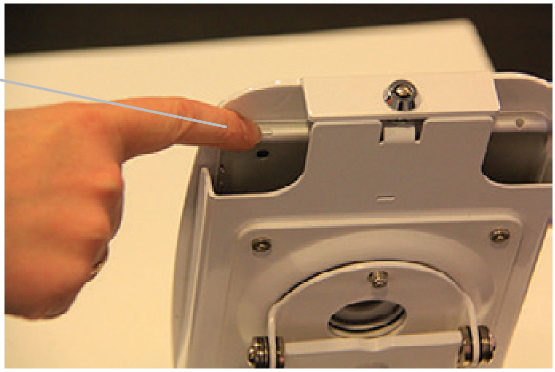
In Scenario Training several learners can practice together. A good advice is to work together as you would during real resuscitations.

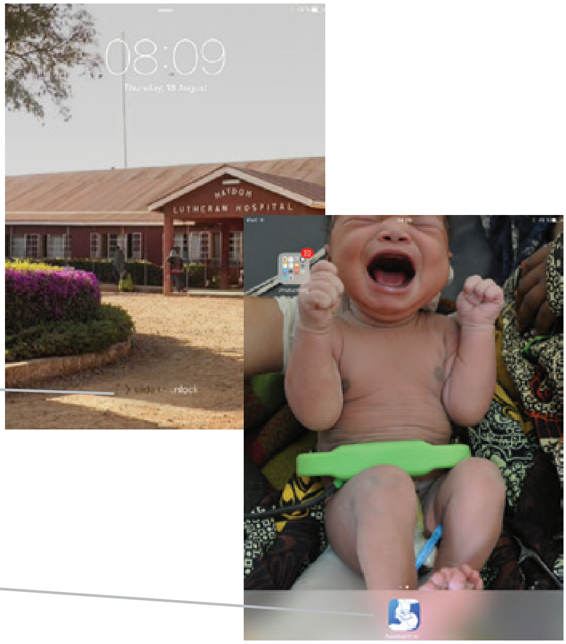
Scenario Training is led by a master trainer.



Screen

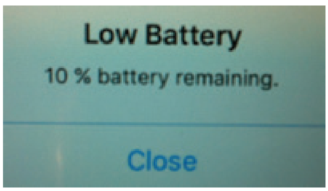
Press and hold button on upper right corner to turn the screen on





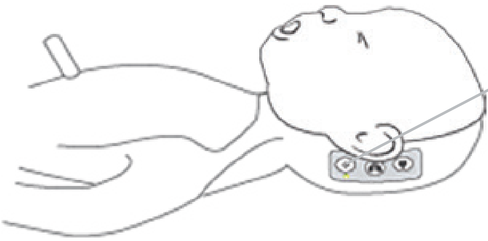
Swipe finger to unlock the screen

Touch  to start Newborn Ventilation Training



To charge the screen, plug the power cable to the wall outlet.

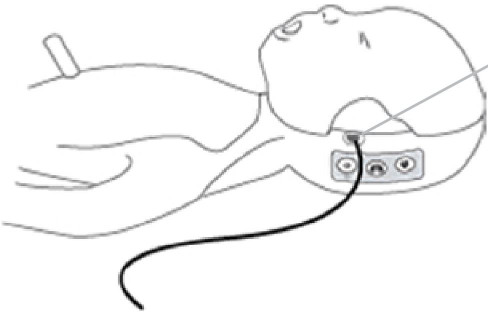
Manikin



Press and hold (power button) to turn on the manikin.

If no light appears, the manikin must be charged.

The manikin will turn off automatically when it has not been used for a while.



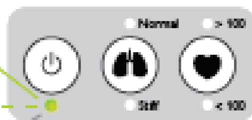
To charge the manikin, plug in the black manikin charge cable under the ear.

Plug the white power cable attached to the trolley to the wall outlet.

Steady light = fully charged and power on

Blinking light = charging

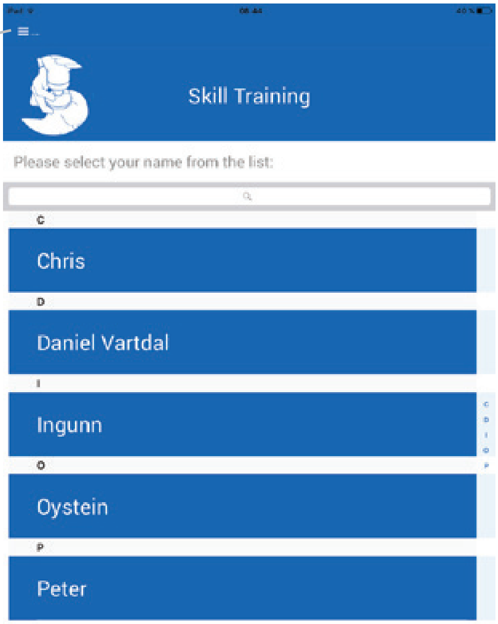
No light = power off or charging needed



Registration of Learners

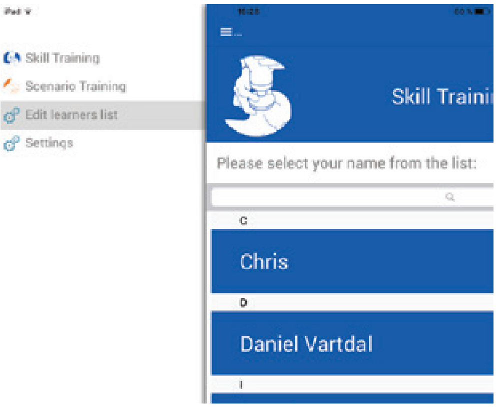
The Ventilation Skill Training startup screen shows a list of registered learners. Learners will have to be registered by a master trainer before their first training.

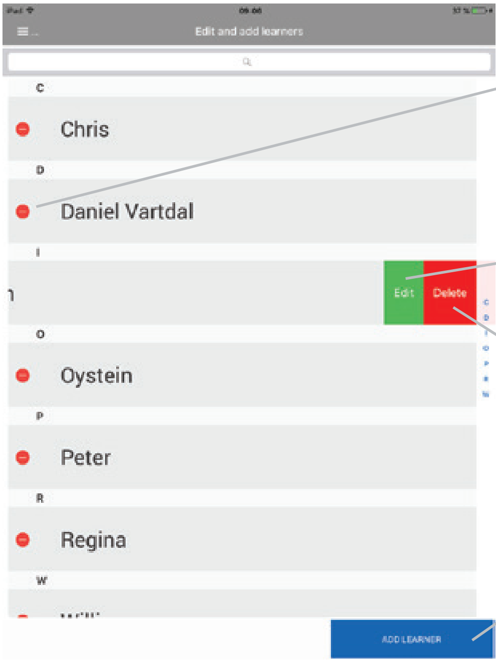
Touch the menu icon in the upper left corner



Select "Edit learner list"

You can now add, remove or correct names in the learner list



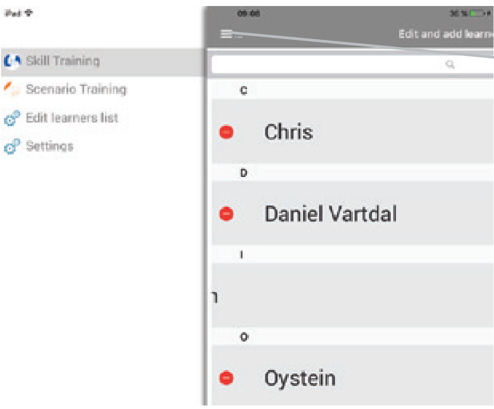


Touch in front of the name you want to edit

Select "Edit" to correct spelling

Select "Delete" to remove the name from the list

Select "Add learner" to include a new learner in the list



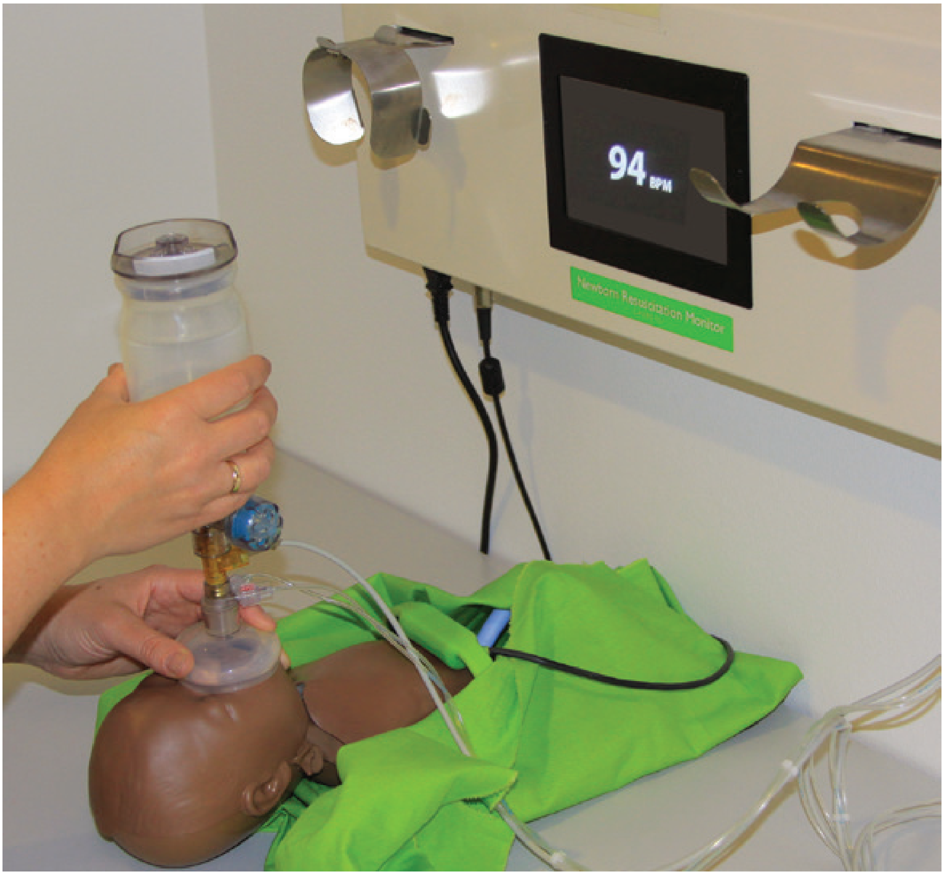
To go back to the startup screen, touch the menu icon in the upper left corner and select "Skill Training" or "Scenario Training"

Ventilations

The manikin represents a newborn baby who is not breathing.
The learners' task is to **ventilate continuously until the baby is breathing.**

To get air into the lungs, you have to

- **open the airways** by tilting the head backwards
- make sure you have a **good mask seal**



Manikins' response to ventilations

- You will see **chest rise** when the manikin gets air into the lungs
- The **heart rate** will increase with good ventilations and decrease with lack of good ventilations. When the green heart rate sensor is placed on the manikin, the heart rate will be displayed on the monitor on the wall.

  Low heart rate means that the baby has been without oxygen for a while. This may require longer ventilation time. The heart rate will increase with good ventilations.

- The manikin will start **crying** after sufficient time of good ventilations. The crying indicates that the baby is breathing.

Simulation of different patient conditions

Babies who are not breathing may have normal or low heart rate and it may be easy or difficult to get air into the lungs. To simulate this, the manikin has **4 different starting conditions** (Training levels).

Training Levels and Learning Objectives

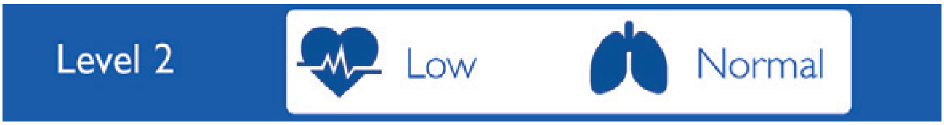
The Newborn Ventilation Trainer has four different training levels. The main learning objective for all levels is to **ventilate continuously until the baby is breatning.**

- Ventilation technique
  - 40-60 ventilations per minute
  - Head tilt and mask seal needed to get air into the lungs
  - Chest rise indicates that the air enters the lungs

- Relationship between heart rate and ventilations
  - Heart rate will increase with good and continuous ventilations
  - Heart rate will decrease with lack of good and continuous ventilations

Training level 1 to 4 have different heart and lung settings, and represents different patient conditions:

Level 1 represents a baby with initial good heart rate and lungs that are easy to ventilate. Learners should start with this level for **basic ventilation training.**



Level 2 represents a baby with initial low heart rate. The learners will see that the **heart rate increases with good and continuous ventilations.**

Level 3 represents a baby with initial stiff lungs. The learners have to **give some ventilations with higher pressure to open the lungs**.

Level 4 represents a baby with both initial low hear rate and stiff lungs. The learners have to **give some ventilations with higher pressure to open the lungs**. When the lungs are open, the learners will see that the **heart rate increases with good and continuous ventilations**.

This will be one of the 4 levels above. The learner will not get any information about the patient condition before start.

How to do Ventilation Skill Training

1

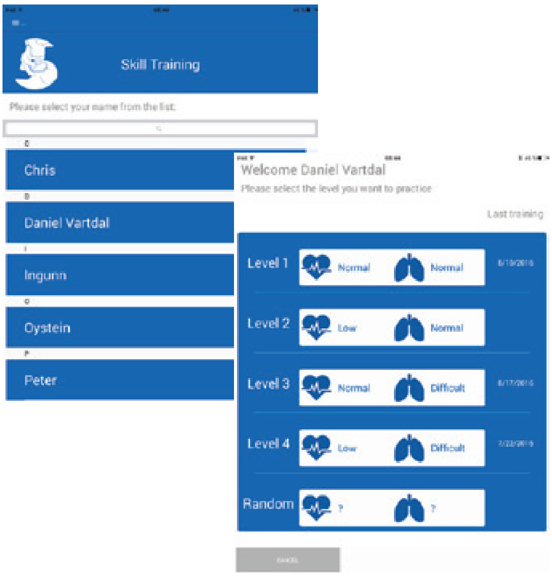
Place the manikin on the resuscitation table and put on the green heart rate sensor

2

Activate the screen

Select your name from the list and the level you want to train

Read the introduction and start ventilations



3

Start ventilation

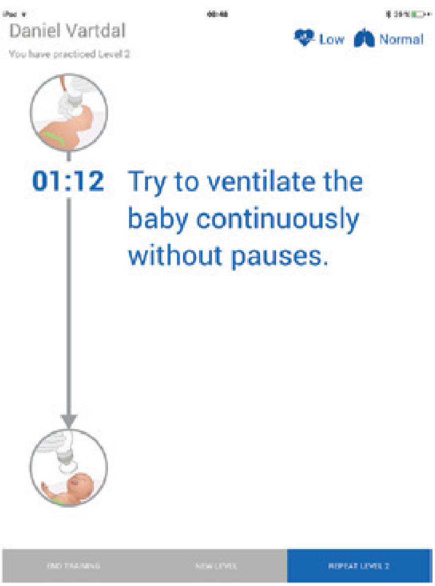
Look for chest rise and observe heart rate on the heart rate monitor

Adjust ventilation technique if needed

The screen shows how long time you have been ventilating

Ventilate until the manikin starts crying

4

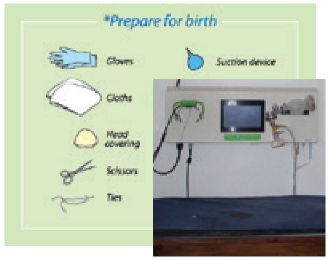


Recieve feedback on ventilation time and how to improve your ventilations

A good advice is to repeat the same level at least one more time

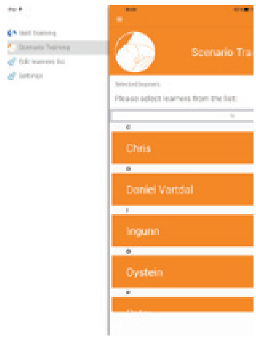
How to do Ventilation Scenario Training

1 - Preparations



Prepare manikin and resuscitation table
- Attach cord to manikin
- Place manikin in delivery bed
- Make sure needed equipment is available on resuscitation table

Prepare screen
- Select Scenario Training from the menu
- Select participants from the learner list
- Select training level

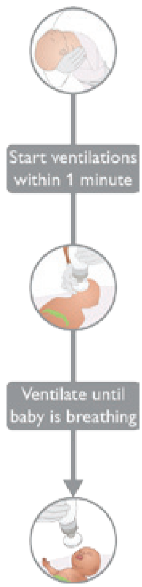


2 - Introduction

Brief participants on how to do scenario training
- We want to do this simulation as realistic as possible - work together as we do with real babies
- Time aspect is important - do all tasks as we would with real babies

Introduce scenario to participants
- Baby is not breathing after delivery
- Follow HBB action plan
- Start ventilations within 1 minute
- Ventilate until baby is breathing
- Observe heart rate during ventilation

Discuss roles and resopnsibilities with participants
- Who will keep track of time?
- Who will be responsible for ventilating the baby?



3 - Scenario

- Press "Baby is born" to start scenario
- Observe participants and log tasks on the screen

4 - Discussion

The discussion is an important part of the scenario training. Encourage participants to talk and share their experiences.

- What happened?
- What worked well?
- How did we work together?
- What can be improved?

A good advice is to repeat the scenario at least one more time after the discussion.

Master Trainer Guide **Rev 01**

Laerdal

helping save lives

Appendix 4 Safer Births Data Collection Form

Form Safer Births_1 – v11July_2018

ONE FORM FOR EACH DELIVERY TO BE FILLED IN AT HLH

Study Station	☐2 HLH
Mother Hospital ID (HLH)	☐☐☐☐☐☐☐☐☐☐
New-born ID (HLH)	☐☐☐☐☐☐☐☐☐☐
If Multiplies (twins and more)	☐New-born number (write 8 if single birth)
Mother's age (in complete years)	☐☐Years
Gravida	☐☐
Marital status	☐1Married ☐2Single ☐3Cohabiting☐4Not specified
Maternal education	☐1No formal education ☐2Primary ☐3 Secondary☐4 College and above
Number of children	☐☐Born alive ☐☐Born dead
Antenatal care attendance	☐1 YES ☐ 2 NO
Antenatal problem	☐1 YES ☐ 2 NO
Source of admission	☐1 Referral: ____________________________ ☐2 Home ☐3 Maternity home (waiting area) ☐☐:☐☐ Hours since start of labour
DURING ADMISSION	Date: ☐☐☐☐☐☐ (ddmmyy) Time ☐☐:☐☐
Number of Fetus	☐ number of foetuses
Gestational age	☐1 Term ☐2 Pre-term ☐☐ WEEKS
Fetal Heart Rate (FHR) on admission	☐1 Normal (120-160 BPM) ☐2 Abnormal; Confirmed ☐1 YES ☐2 NO ☐3 Not detectable ☐9 Not measured
Cervical dilatation (on admission)	☐☐ CM ☐9 Not measured
Presentation	☐1Cephalic ☐2 Breech ☐3 Others (specify)____________
Device used to monitor FHR during labour	☐1 Pinard Intermittent ☐2 Doppler intermittent ☐3 Moyo strap on; ☐5 Moyo intermittent number of Moyo (device) ☐☐☐ ☐4 NA
RANDOMISATION	☐1 Upright ☐2 Standard ☐4Upright with PEEP ☐3 NA

LABOUR/DELIVERY INFORMATION	
Maternal fever	☐1 YES ☐2 NO
Maternal Infection (more than 1 is possible) 1. Lower Reproductive tract 2. UTI 3. malaria 4. PMTCT 1 5. Others; mention ______________	 ☐ 1 YES ☐ 2 NO ☐ 1 YES ☐ 2 NO ☐ 1 YES ☐ 2 NO ☐ 1 YES ☐ 2 NO ☐ 1 YES ☐ 2 NO
Equipment checked	☐1 YES ☐2 NO
Delivery kit present	☐1 YES ☐2 NO
Resuscitation kit present	☐1 YES ☐2 NO
Bag mask present	☐1YES ☐2 NO
Fetal heart rate (Every 30 minutes in 1. Stage and every 15 minutes in 2. Stage)	☐1 Normal (120-160 BPM) ☐2 Abnormal: Time ☐☐:☐☐ ☐3 Not detectable ☐9 Not measured
Device mostly used for taking FHR	☐1Pinard ☐2 Doppler ☐3 None ☐4 Moyo
If abnormal; what rate **Confirmed with Moyo**	☐☐☐ BPM *(if with Moyo skip next question)* ☐1 YES ☐2 NO ☐☐☐BPM Time ☐☐:☐☐
Those in Pinard with abnormal FHR, was Moyo strap on? **Time of strap on Moyo (following abnormal FHR)**	☐1 Yes ☐2 No (If No Skip next question) Time ☐☐:☐☐
If abnormal FHR, What was done? (more than 1 is possible) 1. Stop oxytocin 2. change mother's position 3. IV fluid given 4. Oxygen given 5. Others (Specify)...............................	 ☐ 1 YES ☐ 2 NO ☐ 1 YES ☐ 2 NO ☐ 1 YES ☐ 2 NO ☐ 1 YES ☐ 2 NO ☐ 1 YES ☐ 2 NO
Duration of labour	
1st. Stage 2nd. stage	☐☐:☐☐ hrs: min ☐☐:☐☐ hrs: min

3rd. Stage	☐☐:☐☐ hrs: min
Last FHR measurement/reading before delivery	☐☐☐BPM; Time ☐☐:☐☐ ☐ Not measured (skip to the next question) Confirmed Moyo ☐1 YES ☐2 NO Compared with Maternal HR ☐1 YES ☐2 NO
Amniotic Fluid colour	☐1 Clear ☐2 Slight Meconium ☐3 Thick Meconium ☐ 4 Blood stained
Labour complications • Obstructed labor • Uterine rupture • Pre-Eclampsia • Eclampsia • Cord Prolapse • Bleeding/Placenta Praevia • Shoulder dystocia	 ☐ 1 YES ☐ 2 NO ☐ 1 YES ☐ 2 NO ☐ 1 YES ☐ 2 NO ☐ 1 YES ☐ 2 NO ☐ 1 YES ☐ 2 NO ☐ 1 YES ☐ 2 NO ☐ 1 YES ☐ 2 NO
Date of delivery	☐☐DAY ☐☐ MONTH ☐☐ YEAR
Time of delivery	☐☐ ☐☐ HOURS
Mode of delivery (If 1,3,4 or 5 skip to HCW attending delivery**)**	☐1 VD (SVD) ☐2 CS ☐3 VD (ABD) ☐4 VD (Vacuum) ☐5 Others; mention ____________________
Category of CS	☐1 Emergency CS ☐2 Elective CS
If CS; what indication	☐ 1 Obstructed labour ☐ 2 Fetal distress ☐ 3 Previous CS ☐ 4 Mal-presentation ☐ 5 Prolonged labor ☐ 6 Others; mention_________
HCW attending the delivery	☐1 Midwife ☐2 Ward attendant ☐5 Doctor ☐3 Student ☐4 Clinical officer ☐6 None

NEONATAL INFORMATION	
Birth weight	☐☐☐☐GRAM
Sex of new-born	☐1 MALE ☐2 FEMALE ☐3 Ambiguous
Time intervals (for HLH) birth – breathing birth - cord clump birth- use of heart rate buckle	 ☐☐☐☐SEC *(skip if resuscitation is needed)* ☐☐☐ SEC ☐☐☐ SEC (*skip if not used)* Name of NRM monitor ______________________
Apgar score (range 0-10)	☐☐ 1 MIN ☐☐ 5 MIN

RESUSCITATION ATTEMPTED	☐1 YES; Fill in this section☐2 NO; *go to next section*
Use of Newborn Resuscitation Monitor (NRM) Stimulation Suction Bag mask ventilation Device used for bag mask ventilation	☐1 YES ☐2 NO ☐3 NA If Yes; name of monitor ______________________ If No; mention reason ________________________ ☐1 YES ☐2 NO ☐1 YES; by use of Penguin ☐3 YES; not Penguin ☐2 NO ☐1 YES ☐2 NO ☐1 Upright bag ☐2 Standard bag ☐3 Upright with PEEP bag
Time intervals birth - breathing or ventilation ventilation - breathing or death	 ☐☐☐☐SEC ☐1 Breathing ☐2 Ventilation ☐☐☐☐☐☐SEC ☐1 Breathing ☐2 Death ☐3 Mechanical ventilation
Did the attending HCW/midwife call for help to resuscitate? Who provided resuscitation	☐ 1 YES ☐ 2 NO ☐1 Midwife ☐2 Operating Nurse ☐3 Clinical Officer ☐4 Doctor ☐5 Other; __________________ ☐6 AMO
Last Resuscitation training attended?	☐☐MONTH ☐☐ YEAR ☐ 2 Never Attended ☐ 3. Not Sure
Ever practiced with NeoNatalie in past 7 days?	☐1 YES ☐2 NO

NEONATAL OUTCOME within 30 min	☐1 NORMAL ☐2 Admitted neonatal unit (room 20) ☐3 Death ☐4 Stillbirth (fresh) ☐5 Stillbirth (macerated) *(If 3,4, or 5 skip neonatal outcome)*
Neonatal outcome at 24 hours postpartum /at discharge __________ hours postpartum	☐1 NORMAL ☐2 Still in neonatal unit ☐3 Death ☐6 Seizures
Neonatal outcome of admitted baby at ________ days (max 7 days)	☐1 NORMAL ☐2 Still in neonatal unit ☐3 Death ☐6 Seizures

Maternal outcome - **Complications**	
• PPH	☐ 1 YES ☐ 2 NO
• Perinea tear (3rd degree and above)	☐ 1 YES ☐ 2 NO
• Cervical tear	☐ 1 YES ☐ 2 NO
• Retained placenta	☐ 1 YES ☐ 2 NO
• Others specify ---------------------	☐ 1 YES ☐ 2 NO
Status at 24hours	☐1Alive ☐ 2 Near miss (If mother has succumbed complications and then has not died) ☐3 Dead
Consent; To be obtained by midwife or research nurse.	**Pinard intermittent/ Moyo strap on** ☐1 YES ☐2 NO ☐3 NA (fill "NA") **Upright with PEEP/upright no PEEP** ☐1 YES ☐ 2 NO ☐3 NA

Observer's initials ___________________________

children

Article

Neonatal Resuscitation Skill-Training Using a New Neonatal Simulator, Facilitated by Local Motivators: Two-Year Prospective Observational Study of 9000 Trainings

May Sissel Vadla [1,*], Paschal Mdoe [2], Robert Moshiro [3], Ingunn Anda Haug [4], Øystein Gomo [4], Jan Terje Kvaløy [5,6], Bjørg Oftedal [1] and Hege Ersdal [1,7]

1 Faculty of Health Sciences, University of Stavanger, 4021 Stavanger, Norway; bjorg.oftedal@uis.no (B.O.); hege.ersdal@safer.net (H.E.)
2 Haydom Lutheran Hospital, Haydom P.O. Box 9000, Mbulu, Tanzania; pfmdoe@gmail.com
3 Muhimbili National Hospital, Dar es Salaam P.O. Box 65000, Tanzania; moshiror@gmail.com
4 Laerdal Medical, 4002 Stavanger, Norway; ingunn.haug@laerdal.com (I.A.H.); oystein.gomo@laerdal.com (Ø.G.)
5 Department of Mathematics and Physics, University of Stavanger, 4036 Stavanger, Norway; jan.t.kvaloy@uis.no
6 Department of Research, Stavanger University Hospital, 4011 Stavanger, Norway
7 Department of Anaesthesia, Stavanger University Hospital, 4011 Stavanger, Norway
* Correspondence: may.s.vadla@uis.no; Tel.:+47-98492399

Citation: Vadla, M.S.; Mdoe, P.; Moshiro, R.; Haug, I.A.; Gomo, Ø.; Kvaløy, J.T.; Oftedal, B.; Ersdal, H. Neonatal Resuscitation Skill-Training Using a New Neonatal Simulator, Facilitated by Local Motivators: Two-Year Prospective Observational Study of 9000 Trainings. *Children* **2022**, *9*, 134. https://doi.org/10.3390/children9020134

Academic Editor: Daniele Trevisanuto

Received: 21 November 2021
Accepted: 14 January 2022
Published: 20 January 2022

Abstract: Globally, intrapartum-related complications account for approximately 2 million perinatal deaths annually. Adequate skills in neonatal resuscitation are required to reduce perinatal mortality. NeoNatalie Live is a newborn simulator providing immediate feedback, originally designed to accomplish Helping Babies Breathe training in low-resource settings. The objectives of this study were to describe changes in staff participation, skill-training frequency, and simulated ventilation quality before and after the introduction of "local motivators" in a rural Tanzanian hospital with 4000–5000 deliveries annually. Midwives (n = 15–27) were encouraged to perform in situ low-dose high-frequency simulation skill-training using NeoNatalie Live from September 2016 through to August 2018. Frequency and quality of trainings were automatically recorded in the simulator. The number of skill-trainings increased from 688 (12 months) to 8451 (11 months) after the introduction of local motivators in October 2017. Staff participation increased from 43% to 74% of the midwives. The quality of training performance, measured as "well done" feedback, increased from 75% to 91%. We conclude that training frequency, participation, and performance increased after introduction of dedicated motivators. In addition, the immediate constructive feedback features of the simulator may have influenced motivation and training quality performance.

Keywords: neonatal resuscitation; simulation-based training; self-regulatory; Helping Babies Breathe second edition; feedback; implementation; motivators; training performance; ventilation quality; skill-training

1. Introduction

Despite a global reduction in under-five child mortality over the past several decades, around 5.9 million children under five years die annually, with 2.7 million of these deaths occurring during the neonatal period [1]. Early neonatal mortality, i.e., deaths within the first seven days of life, constitutes 73% of neonatal deaths [2]. Intrapartum-related events, previously known as "birth asphyxia", accounts for around 0.7 million of these cases, and approximately 1.3 million fresh stillbirths [3,4]. Many of these fresh stillbirths may be misclassified [3]. Therefore, in order to reduce perinatal mortality (i.e., fresh stillbirths and early neonatal deaths) it is crucial that health care providers possess adequate skills in neonatal resuscitation [5].

Simulation-based training in neonatal resuscitation is reported to be highly effective regardless of outcome variables, level of learner, and specific tasks being trained [6]. Another meta-analysis presents several features that are associated with increased effectiveness of high-fidelity simulators, such as provision of feedback, curriculum integration, range of difficulty level, repetitive practice, and individualized learning [7]. Barriers to simulation-based skill-training are typically high staff turnover and limited time to focus on training and practice [8]. However, it is also evident that a decline in knowledge and skills over time can be prevented by low-dose high-frequency refresher trainings, on-the-job practice, or similar interventions [8].

Helping Babies Breathe (HBB) is a simulation-based program for birth attendants in low-resource settings with the aim of improving skills in neonatal resuscitation. A low-cost NeoNatalie Newborn Simulator was developed (Laerdal Medical, Stavanger, Norway) to facilitate HBB skill-trainings [9]. The HBB First Edition was introduced in 2010 and is currently implemented in more than 80 low-income countries [10,11]. Several systematic reviews show convincing results regarding training performance, clinical practice, and reduced perinatal mortality following implementation of HBB [8,12–14]. However, midwives in rural Tanzania (i.e., Haydom Lutheran Hospital) have revealed that anxiety and fear of ventilating a non-breathing baby often led to poor resuscitation performance [15]. These midwives did not experience training with the original simulator, NeoNatalie, as sufficient to be optimally prepared for actual resuscitations, due to a lack of “sense of urgency” and missing responses from the simulator during training.

In 2016, the Second Edition of HBB was launched with an increased focus on quality improvement efforts and implementation strategies, including establishment of local facilitators to improve skills retention [10,11]. At the same time, a new, improved simulator, NeoNatalie Live (Laerdal Medical), was developed, featuring different patient cases, integrating HBB action points and scenario training, and automated responses from the simulator, including immediate feedback to the learners [16].

One recent multi-center observational study from Nepal has evaluated changes in practice following introduction of HBB Second Edition training and reported earlier initiation of neonatal ventilation after birth [17]. However, there are no studies evaluating the potential impact of the more advanced simulator, NeoNatalie Live, on training frequency and quality. Additionally, in previous studies, introduction of traditional HBB master trainers or instructors have been the case, but in line with the increased focus on quality improvement efforts in the Second Edition of HBB, we introduced a new role, “local HBB motivators”, to enhance the implementation process.

Implementation of the HBB Second Edition and NeoNatalie Live started in September 2016 at Haydom Lutheran Hospital. The objectives of the present study were to describe changes in staff participation in simulation skill-trainings, training frequency, and simulated ventilation quality over time, before and after the introduction of local motivators to facilitate HBB training from October 2017.

2. Materials and Methods

This is a prospective observational study at Haydom Lutheran Hospital in rural Tanzania from 1 September 2016 to 31 August 2018.

2.1. Study Setting

Haydom is a first referral hospital in rural Tanzania with 4000–5000 deliveries each year. The catchment area is approximately 2 million people. The hospital provides comprehensive emergency obstetric and basic emergency newborn care on a 24/7 basis [18]. Midwives largely conduct deliveries and neonatal resuscitation when indicated [19]. The labor ward holds six delivery beds and one operating theatre for caesarean sections.

HBB First Edition was introduced at Haydom in 2010. In 2013, the Safer Births project began, aiming to further improve HBB training and perinatal care [20]. In September 2016, the HBB Second Edition and NeoNatalie Live was introduced. All midwives were mandated to practice bag-mask ventilation on a weekly basis in addition to an annual one-day HBB course. An overview of simulation-based training at Haydom, prior to and throughout this study period, is presented in Figure 1.

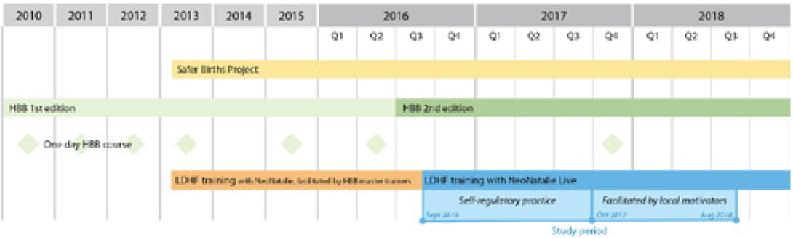


Figure 1. Simulation-based training at Haydom Lutheran Hospital 2010–2018. HBB; Helping Babies Breathe, LDHF; low-dose high frequency training. "Local motivators" were dedicated midwives tasked to facilitate and motivate for on-site LDHF training, following the HBB Second Edition.

2.2. NeoNatalie Live—Newborn Resuscitation Simulator

NeoNatalie Live is a substantially improved newborn resuscitation simulator, compared to the original NeoNatalie [16]. The manikin has a variable lung compliance, enables realistic bag-mask ventilation training, and has a dynamic heart rate that varies with lung aeration [21]. In total, four different patient cases, based on 1237 live resuscitations recorded at Haydom, can be trained [19]. The first patient case simulates a newborn with normal heart rate and normal lung compliance, while patient case four, the most complicated case, simulates low heart rate and stiffer lungs, representing water-filled or low compliant lungs. The simulator is operated by a tablet app where the learner registers and selects patient case (Figure 2). The training sessions last from 30 s to two minutes, depending on patient case and resuscitation/ventilation quality. After sufficient time with good quality ventilations, the mannequin starts crying, and the app provides automated feedback. The feedback suggests how to improve ventilation quality and encourages a new training attempt. The presented feedback is prioritized after the following list based on HBB; missing head tilt, insufficient opening ventilations, paused ventilations, mask leak, too high ventilation pressure, and ventilation rate. In sessions with several errors, only the most critical feedback is given. If the training scenario is repeated and the error is corrected, positive feedback is provided, followed by a new improvement advise. The feedback "well done" is provided when the learner conducts the training without any mistakes. The training session, including time and date, learner, and the full recording of the resuscitation is automatically up-loaded to and stored in a web log (Figure 2). "Valid ventilations" is defined as ventilations with correct head tilt and ventilation peak inflation pressure. This parameter does not include ventilation rate and pauses in ventilations. The percentage of "valid ventilations" is automatically calculated and presented in the web log.

Figure 2. NeoNatalie Live including the manikin, operating/feedback tablet device (app), and web log. Photo by Laerdal Medical.

Both individual skill-training and scenario team training can be undertaken using the simulator. Only skill-trainings are included in this study.

2.3. Implementation of NeoNatalie Live and HBB Second Edition

Haydom implemented HBB Second Edition and NeoNatalie Live in their labor ward, September 2016, to enhance ongoing simulation training (Figure 1). Their main focuses were to reduce time to start ventilation and improve time of applied continuous ventilation and utilization of heart rate as an indicator of ventilation quality. During the first phase of the implementation, 1 September 2016–30 September 2017, the mannequin was used exclusively for individual skill-training according to self-regulatory practice.

Initiating the second implementation phase, 1 October 2017–31 August 2018, the hospital management appointed four dedicated midwives to facilitate and motivate for training. These midwives, named "local motivators", were responsible for encouraging midwives to train and for technical support to ensure an all-time functioning simulator. The local motivators were junior midwives, carefully selected according to their engagement in the ward. They were tasked to arrange scenario team-training and encourage the midwives to conduct self-regulated skill-training whenever time allowed. Initially, the motivators informed the midwives about potential benefits of simulation-based training in terms of increased confidence and improved skills in neonatal resuscitation. Thereafter, they reminded the midwives about training and answered questions on a daily basis. In addition, the group of midwives were divided in two teams, with two local motivators responsible for following up the training in each team. To increase motivation and training frequency, they arranged five informal competitions during the study period where participants on the winning team received a bottle of Coke.

Regular skill-trainings were strongly recommended, but there were no specific rewards or negative consequences following the actual training participation or frequency for each midwife. The hospital management received monthly training-reports from the NeoNatalie Live data weblog, presenting training frequency and performance for the ward and the individual participants. All midwives registered on the NeoNatalie Live app using their true name, even though this was not mandatory.

2.4. Study Participants

The study was conducted in a low-resourced clinical setting with a high turnover of midwives due to new government employment opportunities every midyear, leading to experienced midwives leaving the hospital and newly educated midwives starting at the end of each year. In total, 20 midwives participated from the beginning of the study, one midwife was enrolled in the study from 1 October 2017, and an additional nine midwives from 1 January 2018. During the study period, three midwives dropped out of the study from 1 January 2017, and two midwives were absent for a period of three months, 1 January 2017–31 March 2017. Consequently, the number of participants varied throughout the study period (September–December 2016; $n = 20$, January–April 2017; $n = 15$, May–September 2017; $n = 17$, October–December 2017; $n = 18$ and January–August 2018; $n = 27$). All midwives at the labor ward, and the neonatal unit from January 2018, were eligible for the study. All gave consent for participation in the study. This was not an obligation to participate in training. The participants were labeled "mandatory learners" in the period they were eligible (employed).

2.5. Data Collection

Data from all skill-training sessions were stored in the web log, providing detailed information about each training session registered between 1 September 2016–31 August 2018, except for December 2016, when the mannequin was out of order. The outcomes were participation of midwives, frequency of training, chosen patient case, percentage of trainings with feedback "well done", valid ventilations, and ventilation rate.

2.6. Statistics

Data were analyzed using SPSS version 26. Data were summarized by medians and quartiles. Non-parametric tests were used to compare the variables before and after appointment of motivators. A significance level of 0.05 was used in all hypothesis tests. Figures were produced in Excel.

3. Results

3.1. Participation and Frequency of Trainings Per Midwife

In total, 30 midwives participated in this study. The number of trainings per included midwife through the study period and the time-period where they were classified as "mandatory learner", varied among the midwives (Figure 3). For example, midwife number 3 completed 817 trainings and was employed at the labor ward for eight months during the study period.

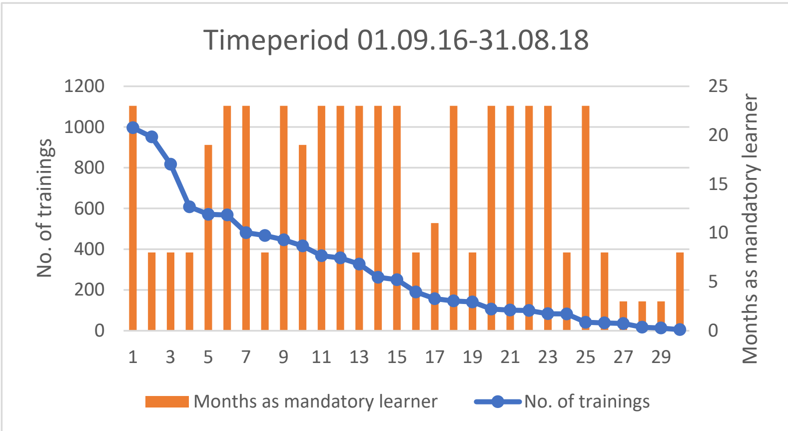


Figure 3. Descriptive data of training frequency for each midwife and duration of time classified as mandatory learner. The X-axis shows the individual midwives participating in the study, numbered from 1–30. The left Y-axis shows the number of trainings per midwife during their period as mandatory learner, illustrated by the blue frequency line. The midwifes are sorted according to this frequency.

The right Y-axis shows the number of months each midwife participated in the study, categorized as a mandatory learner, illustrated by the orange columns.

3.2. Training-Frequency, Participation and Ventilation Quality

Figure 4 describes the number of skill-trainings, median number of skill-trainings per midwife, percentage of midwives training, and percentages of training sessions receiving the feedback "well done" from September 2016 through August 2018. Local motivators were appointed in October 2017, illustrated by the red vertical line.

The total number of skill-trainings increased from 688 during the 12 months with an operative mannequin before October 2017 to 8451 during the 11 months after the introduction of motivators in October 2017. There was a steep incline in number of skill-trainings from November 2017, with a marked decline in April 2018. The percentage of midwives conducting self-regulated trainings increased to almost 100% after introduction of local motivators, remained above 80% until April 2018, and decreased to 20% in July 2018. After November 2017, more than 90% of trainings were classified as "well-done". All indicators appear to increase in August 2018 following a dip in July 2018.

Figure 4. Timelines for number of skill-trainings, median number of skill-trainings per midwife, percentage of midwives participating in training and percentage of sessions receiving feedback "well done".

Table 1 compares changes in number of mandatory learners (i.e., employed midwives), frequency of skill-trainings, participation of midwives (i.e., midwives undergoing training), performance of the trainings, and how often each patient case were selected, before and after appointment of motivators.

The median number of mandatory learners and skill-trainings per month were substantially higher after October 2017 and appointment of local motivators. The number of monthly trainings per midwife increased from median 2.3 to 26.4 and the percentage of mandatory learners (midwives) undertaking training increased from median 43% to 74%. Training performance improved from median 75% to 91% classified as "well done", and the percentage of valid ventilations increased from 98% to 100%. The results show no significant differences in ventilation rate and selection of patient cases between the two time periods.

Table 1. Changes in mandatory learners, training frequency, participation, training performance and selection of patient cases for simulation-based skill-training using NeoNatalie Live, comparing the period before and after appointment of local motivators.

	Before (1 September 2016–30 September 2017)	**After (1 October 2017–31 August 2018)**	***p*-Value**
Mandatory learners, *n*	15–18	18–27	
Median per month (quartiles)	17.0 (15.0, 19.3)	27.0 (18.0, 27.0)	<0.001 †
Skill-trainings, *n*	688	8451	<0.001 †
Median per month (quartiles)	39.5 (8.3, 87.0)	713 (173, 1455)	
Skill-trainings/midwife/month, *n*			
Median (quartiles)	2.3 (0.5, 5.0)	26.4 (6.4, 53.9)	<0.001 †
Midwives training, %			
Median (quartiles)	43 (21, 60)	74 (41, 94)	0.016 †
Training performance			
Trainings "well done", %			
Median (quartiles)	75 (66, 80)	92 (83, 95)	<0.001 †
Valid ventilations, %			
Median (quartiles)	98 (87, 100)	100 (88, 100)	<0.001 †
Ventilation rate, *n*			
Median (quartiles)	51 (45, 56)	51 (47, 54)	0.754 †
Selected patient cases, *n* (%)			
Patient case 1	194 (28.2)	2154 (25.5)	
Patient case 2	134 (19.5)	1924 (22.8)	
Patient case 3	147 (21.4)	1881 (22.3)	0.131 ‡
Patient case 4	142 (20.7)	1760 (20.8)	
Random patient case	71 (10.3)	732 (8.7)	

† Mann–Whitney U test, ‡ Chi-squared test.

4. Discussion

This study indicates that it is possible to establish and maintain a culture of frequent in situ trainings in a hospital with limited resources, high turnover of midwives, and a low midwife-to-delivery ratio. The majority of midwives conducted self-regulated brief skill-trainings, using the NeoNatalie Live simulator, almost every day after appointment of local motivators. The number of simulation-based skill-trainings increased profoundly, and the percentage of newborn resuscitation simulations classified as "well-done" improved to and stabilized above 90%.

No other relevant interventions or changes regarding neonatal resuscitation training was implemented at the hospital during the study period.

4.1. Local Motivators and Training Frequency

The role of the local motivators in our study differs from more traditional master trainers or simulation facilitators who usually instruct in skill-training or facilitate team-simulations and debriefings. Our local motivators mainly motivated for training and provided technical maintenance of the mannequin. The latter is important in order to facilitate ongoing training [22], and preceding October 2017, the simulator was out of order for one month due to technical issues. This new "motivator" role has not been studied before in relation to newborn resuscitation training, as far as the authors are aware.

Since 2011, Haydom has simulated low-dose high-frequency simulation-based HBB training to enhance newborn resuscitation care and specifically reduce challenges related to high staff turnover [18]. This study complements previous studies from Haydom demonstrating that high training frequency and participation (i.e., large proportion of midwives) are possible, even in a setting with low midwife-to-delivery ratio, high staff turnover, and limited resources [18,19]. These findings are contrary to previous literature stating all these aspects as barriers to training [8]. The present study indicates that the dedicated motivators managed to further increase training participation and frequency. Interestingly, the number of trainings and midwives conducting trainings declined markedly in the period with high turnover (April–July). The drop can also be a consequence of more focus towards scenario-based simulation training in the ward, conducted without the mannequin and thus not recorded in the data collection. All these circumstances may partly explain the decreased number of individual skill training between April–July 2018.

Other possible drivers for increased training, may be the strong management support and their acknowledgement of the motivators [22]. In addition, the midwives knew that the management could follow their participation and training frequency. Furthermore, it is likely that the long-lasting focus on HBB simulation-based training, placement of the simulator readily in the labor ward, and the short duration of the different patient cases (only a few minutes) contributed to the high training frequency, consistent with previous studies [23]. The improvement of resuscitation and ventilation skills following low-dose high frequency training is in line with other studies [18,19].

4.2. Features of the Simulator, NeoNatalie Live

Even though training frequency increased significantly after the introduction of motivators, still, 686 trainings were conducted during the first 12 months of the study. We speculate that the immediate constructive feedback from the simulator might have contributed to this high training frequency, consistent with other studies [7,24,25]. The automated feedback is related to the HBB action points, followed by recommendations on how to improve. However, it lacks some of the more comprehensive reflection elements that can be gained through facilitator-lead debriefing. A previous study showed that skill acquisition in cardiac compression training with automated feedback was not inferior when compared to a human instructor, and the majority of the participants found the automated mannequin feedback more useful than the instructor feedback [26]. The authors highlight that automated feedback in self-regulatory, individual skill-training, enables opportunities for learning with a potentially reduced need for human instructors. A review found anxiety related to being observed by peers during training perceived as a stressor in simulation training among nursery students, and automated feedback may facilitate a safer learning environment [27]. In addition to feedback, the realistic appearance of the mannequin and the different patient cases, may have contributed to enhanced motivation for training through increased relevance [7,21,28].

4.3. Optimal Level of Training Frequency

One important aspect regarding simulation-based training in neonatal resuscitation is the amount of training needed to improve and maintain skills and to translate acquired skills into clinical practice. A previous study indicates that an average skill drill of eight in three months leads to effective simulated ventilation, but more research is needed to find the optimal level of training frequency [29]. This is important for optimizing cost-benefit aspects of frequent on-site simulation-based training where time and resources are scarce, and training must fit in with clinical tasks.

4.4. Strengths and Limitations

The strengths of this study are the long observation period of two years, the high number of trainings analyzed, and the automated and continuous measures of ventilation quality registered from every training session.

This study is not a randomized controlled trial and cannot claim causality. Still, it seems likely that the increase in training frequency and participation among the midwives can be explained by the presence of dedicated motivators at the ward and the features of the simulator. Another limitation of the study is the new evaluation method of ventilation quality using data from the simulator in contrast to the frequently used OSCE score, making this indicator less comparable to previous studies.

4.5. Future Studies

Skill-trainings with NeoNatalie Live aim to enhance the ability to follow the resuscitative HBB steps and mastery of bag-mask ventilations, which is fundamental to improve overall quality of newborn resuscitations [5]. Scenario team-trainings might be necessary to enhance clinical management, by increasing situation-awareness and decision-making regarding when to initiate resuscitation, and a rapid onset of ventilation when indicated. Further research should focus on using NeoNatalie Live for scenario-team training and investigate if the combination of individual skill-trainings and scenario-team trainings lead to improved clinical management of neonatal resuscitations and perinatal outcome.

5. Conclusions

Appointing dedicated motivators when implementing HBB Second Edition and NeoNatalie Live most likely increased training frequency, staff participation, and ventilation quality.

Further research is needed regarding the underlying reasons for the increase in training, and whether this high training frequency had an impact on clinical management and perinatal outcome.

Author Contributions: Conceptualization, M.S.V., I.A.H., B.O. and H.E.; Data curation, M.S.V., P.M., R.M., I.A.H., Ø.G. and H.E.; Formal analysis, M.S.V., J.T.K. and H.E.; Funding acquisition, P.M., R.M. and H.E.; Investigation, M.S.V., P.M., R.M., I.A.H. and H.E.; Methodology, M.S.V., P.M., R.M., J.T.K. and H.E.; Project administration, M.S.V., P.M., R.M., I.A.H. and H.E.; Resources, P.M., R.M., I.A.H. and Ø.G.; Software, I.A.H. and Ø.G.; Supervision, J.T.K., B.O. and H.E.; Validation, M.S.V., P.M., R.M., I.A.H., J.T.K., B.O. and H.E.; Visualization, M.S.V.; Writing—original draft, M.S.V.; Writing—review & editing, M.S.V., P.M., R.M., I.A.H., Ø.G., J.T.K., B.O. and H.E. All authors have read and agreed to the published version of the manuscript.

Funding: This research was funded by the University of Stavanger, the Global Health and Vaccines Research (GLOBVAC) program at the Research Council of Norway (grant number 228203); and the Laerdal Foundation. The development of NeoNatalie Live received funding from Innovation Norway, the Research Council of Norway (228203) and Skattefunn (ES519418). The study was performed using simulation equipment provided by Laerdal Medical. The funders had no role in the design of the study; in the collection, analyses, or interpretation of data; in the writing of the manuscript, or in the decision to publish the results.

Institutional Review Board Statement: The study was conducted according to the guidelines of the Declaration of Helsinki, and approved by the National Institute for Medical Research in Tanzania (Ref. NIMR/HQ/R.8a./Vol.IX/2877) and by the Regional Committee for Medical and Health Research Ethics, Western Norway (Ref. 2013/110/REK).

Informed Consent Statement: All relevant healthcare providers were informed about the study and oral consent was obtained. The participants received no compensation for participation in the study.

Data Availability Statement: The data presented in this study are available on reasonable request to the corresponding author. However, we are not allowed to make these openly available due to regulations from the National Institute of Medical Research in Tanzania.

Acknowledgments: We thank the midwives working in the labour ward at Haydom Lutheran Hospital, especially the local motivators; Barikiel Hhando Hhoki, Paschalina Michael Bura, Sabrina Sebastian Saragu and Noelina Samson Quwanga, and the Hospital Management team.

Conflicts of Interest: Øystein Gomo and Ingunn Haug are employees for Laerdal Medical. The specific roles of these authors are articulated in the 'author contributions' section. All other authors have no conflicts of interest to declare.

References

1. Liu, L.; Oza, S.; Hogan, D.; Chu, Y.; Perin, J.; Zhu, J.; Lawn, J.E.; Cousens, S.; Mathers, C.; Black, R.E. Global, regional, and national causes of under-5 mortality in 2000–15: An updated systematic analysis with implications for the Sustainable Development Goals. *Lancet* **2016**, *388*, 3027–3035. [CrossRef]
2. Lehtonen, L.; Gimeno, A.; Llorca, A.P.; Vento, M. Early neonatal death: A challenge worldwide. *Semin. Fetal Neonatal Med.* **2017**, *22*, 153–160. [CrossRef]
3. Ersdal, H.L.; Eilevstjønn, J.; Linde, J.E.; Yeconia, A.; Mduma, E.R.; Kidanto, H.; Perlman, J. Fresh stillborn and severely asphyxiated neonates share a common hypoxic–ischemic pathway. *Int. J. Gynecol. Obstet.* **2018**, *141*, 171–180. [CrossRef] [PubMed]
4. Wang, H.; Liddell, C.A.; Coates, M.M.; Mooney, M.D.; Levitz, C.E.; Schumacher, A.E.; Apfel, H.; Iannarone, M.; Phillips, B.; Lofgren, K.T.; et al. Global, regional, and national levels of neonatal, infant, and under-5 mortality during 1990–2013: A systematic analysis for the Global Burden of Disease Study 2013. *Lancet* **2014**, *384*, 957–979. [CrossRef]
5. Dempsey, E.; Pammi, M.; Ryan, A.C.; Barrington, K.J. Standardised formal resuscitation training programmes for reducing mortality and morbidity in newborn infants. *Cochrane Database Syst. Rev.* **2015**. Available online: https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD009106.pub2/full (accessed on 1 November 2021). [CrossRef] [PubMed]
6. Mundell, W.C.; Kennedy, C.C.; Szostek, J.H.; Cook, D.E. Simulation technology for resuscitation training: A systematic review and meta-analysis—ScienceDirect. *Resuscitation* **2012**, *84*, 1174–1183. [CrossRef]
7. Issenberg, S.B.; McGaghie, W.C.; Petrusa, E.R.; Lee Gordon, D.; Scalese, R.J. Features and uses of high-fidelity medical simulations that lead to effective learning: A BEME systematic review. *Med. Teach.* **2005**, *27*, 10–28. [CrossRef]
8. Morris, S.M.; Fratt, E.M.; Rodriguez, J.; Ruman, A.; Wibecan, L.; Nelson, B.D. Implementation of the Helping Babies Breathe Training Program: A Systematic Review. *Pediatrics* **2020**, *146*, e20193938. Available online: https://pediatrics.aappublications.org/content/146/3/e20193938 (accessed on 1 November 2021). [CrossRef]
9. NeoNatalie [Internet]. Laerdal Medical. Available online: https://laerdal.com/no/products/simulation-training/obstetrics-paediatrics/neonatalie/ (accessed on 1 November 2021).
10. Helping Babies Breathe [Internet]. AAP.org. Available online: http://www.aap.org/en-us/advocacy-and-policy/aap-health-initiatives/helping-babies-survive/Pages/Helping-Babies-Breathe.aspx (accessed on 1 November 2021).
11. Kamath-Rayne, B.D.; Thukral, A.; Visick, M.K.; Schoen, E.; Amick, E.; Deorari, A.; Cain, C.J.; Keenan, W.J.; Singhal, N.; Little, G.A.; et al. Helping Babies Breathe, Second Edition: A Model for Strengthening Educational Programs to Increase Global Newborn Survival. *Glob. Health Sci. Pract.* **2018**, *6*, 538–551. [CrossRef]
12. Bang, A.; Patel, A.; Bellad, R.; Gisore, P.; Goudar, S.S.; Esamai, F.; Liechty, E.A.; Meleth, S.; Goco, N.; Niermeyer, S.; et al. Helping Babies Breathe (HBB) training: What happens to knowledge and skills over time? *BMC Pregnancy Childbirth* **2016**, *16*, 364. Available online: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5120476/ (accessed on 1 November 2021). [CrossRef] [PubMed]
13. Versantvoort, J.M.D.; Kleinhout, M.Y.; Ockhuijsen, H.D.L.; Bloemenkamp, K.; Hoogen, A.V.D. Helping Babies Breathe and its effects on intrapartum-related stillbirths and neonatal mortality in low-resource settings: A systematic review. *Arch. Dis. Child.* **2020**, *105*, 127–133. [CrossRef] [PubMed]
14. Dol, J.; Campbell-Yeo, M.; Murphy, G.T.; Aston, M.; McMillan, D.; Richardson, B. The impact of the Helping Babies Survive program on neonatal outcomes and health provider skills: A systematic review. *JBI Database Syst. Rev. Implement Rep.* **2018**, *16*, 701–737. [CrossRef] [PubMed]
15. Moshiro, R.; Ersdal, H.; Mdoe, P.; Kidanto, H.; Mbekenga, C. Factors affecting effective ventilation during newborn resuscitation: A qualitative study among midwives in rural Tanzania. *Glob. Health Action* **2018**, *11*, 1423862. [CrossRef]
16. NeoNatalie Live–Safer Births [Internet]. 2021. Available online: http://www.saferbirths.com/portfolio_page/newborn-ventilation-trainer/ (accessed on 1 November 2021).
17. Chaulagain, D.R.; Malqvist, M.; Brunell, O.; Wrammert, J.; Basnet, O.; Ashish, K.C. Performance of health workers on neonatal resuscitation care following scaled-up quality improvement interventions in public hospitals of Nepal—A prospective observational study. *BMC Health Serv. Res.* **2021**, *21*, 362. Available online: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8054430/ (accessed on 1 November 2021). [CrossRef]
18. Mduma, E.; Ersdal, H.; Svensen, E.; Kidanto, H.; Auestad, B.; Perlman, J. Frequent brief on-site simulation training and reduction in 24-h neonatal mortality–an educational intervention study. *Resuscitation* **2015**, *93*, 1–7. [CrossRef]
19. Mduma, E.; Kvaløy, J.T.; Soreide, E.; Svensen, E.; Mdoe, P.; Perlman, J.; Johnson, C.; Kidanto, H.L.; Ersdal, H.L. Frequent refresher training on newborn resuscitation and potential impact on perinatal outcome over time in a rural Tanzanian hospital: An observational study. *BMJ Open* **2019**, *9*, e030572. Available online: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6773328/ (accessed on 1 November 2021). [CrossRef]
20. Størdal, K.; Eilevstjønn, J.; Mduma, E.; Holte, K.; Thallinger, M.; Linde, J.; Mdoe, P.; Kidanto, H.; Ersdal, H.L. Increased perinatal survival and improved ventilation skills over a five-year period: An observational study. *PLoS ONE* **2020**, *15*, e0240520. [CrossRef]
21. Haynes, J.; Bjorland, P.; Gomo, Ø.; Ushakova, A.; Rettedal, S.; Perlman, J.; Ersdal, H. Novel Neonatal Simulator Provides High-Fidelity Ventilation Training Comparable to Real-Life Newborn Ventilation. *Children* **2021**, *8*, 940. [CrossRef]
22. Al-Ghareeb, A.Z.; Cooper, S.J. Barriers and enablers to the use of high-fidelity patient simulation manikins in nurse education: An integrative review. *Nurse Educ. Today* **2016**, *36*, 281–286. [CrossRef]

23. Bergh, A.-M.; Baloyi, S.; Pattinson, R.C. What is the impact of multi-professional emergency obstetric and neonatal care training? *Best Pract. Res. Clin. Obstet. Gynaecol.* **2015**, *29*, 1028–1043. [CrossRef] [PubMed]
24. McGaghie, W.C.; Issenberg, S.B.; Petrusa, E.R.; Scalese, R.J. A critical review of simulation-based medical education research: 2003–2009. *Med. Educ.* **2010**, *44*, 50–63. [CrossRef] [PubMed]
25. Hatala, R.; Cook, D.A.; Zendejas, B.; Hamstra, S.J.; Brydges, R. Feedback for simulation-based procedural skills training: A meta-analysis and critical narrative synthesis. *Adv. Health Sci. Educ.* **2014**, *19*, 251–272. [CrossRef]
26. Wilson, C.; Furness, E.; Proctor, L.; Sweetman, G.; Hird, K. A randomised trial of the effectiveness of instructor versus automated manikin feedback for training junior doctors in life support skills. *Perspect. Med. Educ.* **2021**, *10*, 95–100. [CrossRef]
27. Handeland, J.A.; Prinz, A.; Ekra, E.M.R.; Fossum, M. The role of manikins in nursing students' learning: A systematic review and thematic metasynthesis. *Nurse Educ. Today* **2021**, *98*, 104661. [CrossRef]
28. Sherwood, R.J.; Francis, G. The effect of mannequin fidelity on the achievement of learning outcomes for nursing, midwifery and allied healthcare practitioners: Systematic review and meta-analysis. *Nurse Educ. Today* **2018**, *69*, 81–94. [CrossRef] [PubMed]
29. Gurung, R.; Gurung, A.; Sunny, A.K.; Basnet, O.; Shrestha, S.K.; Gomo, Ø.H.; Myklebust, H.; Girnary, S.; Ashish, K.C. Effect of skill drills on neonatal ventilation performance in a simulated setting- observation study in Nepal. *BMC Pediatr.* **2019**, *19*, 387. [CrossRef] [PubMed]

Vadla *et al. Advances in Simulation* (2022) 7:38
https://doi.org/10.1186/s41077-022-00234-z

Advances in Simulation

RESEARCH

Open Access

Newborn resuscitation simulation training and changes in clinical performance and perinatal outcomes: a clinical observational study of 10,481 births

May Sissel Vadla[1*], Robert Moshiro[2], Paschal Mdoe[3], Joar Eilevstjønn[4], Jan Terje Kvaløy[5,6], Barikiel Hhando Hhoki[3] and Hege Ersdal[1,7]

Abstract

Background: Annually, 1.5 million intrapartum-related deaths occur; fresh stillbirths and early newborn deaths. Most of these deaths are preventable with skilled ventilation starting within the first minute of life. Helping Babies Breathe is an educational program shown to improve simulated skills in newborn resuscitation. However, translation into clinical practice remains a challenge. The aim was to describe changes in clinical resuscitation and perinatal outcomes (i.e., fresh stillbirths and 24-h newborn deaths) after introducing a novel simulator (phase 1) and then local champions (phase 2) to facilitate ongoing Helping Babies Breathe skill and scenario simulation training.

Methods: This is a 3-year prospective before/after (2 phases) clinical observational study in Tanzania. Research assistants observed all deliveries from September 2015 through August 2018 and recorded labor/newborn information and perinatal outcomes. A novel simulator with automatic feedback to stimulate self-guided skill training was introduced in September 2016. Local champions were introduced in October 2017 to motivate midwives for weekly training, also team simulations.

Results: The study included 10,481 births. Midwives had practiced self-guided skill training during the last week prior to a real newborn resuscitation in 34% of cases during baseline, 30% in phase 1, and 71% in phase 2. Most real resuscitations were provided by midwives, increasing from 66% in the baseline, to 77% in phase 1, and further to 83% in phase 2. The median time from birth to first ventilation decreased between baseline and phase 2 from 118 (85–165) to 101 (72–150) s, and time pauses during ventilation decreased from 28 to 16%. Ventilations initiated within the first minute did not change significantly (13–16%). The proportion of high-risk deliveries increased during the study period, while perinatal mortality remained unchanged.

Conclusions: This study reports a gradual improvement in real newborn resuscitation skills after introducing a novel simulator and then local champions. The frequency of trainings increased first after the introduction of motivating champions. Time from birth to first ventilation decreased; still, merely 16% of newborns received ventilation within the first minute as recommended. This is a remaining challenge that may require more targeted team-scenario training and quality improvement efforts to improve.

*Correspondence: may.s.vadla@uis.no

[1] Faculty of Health Sciences, University of Stavanger, 4021 Stavanger, Norway
Full list of author information is available at the end of the article

Keywords: Helping Babies Breathe 2nd Edition, Implementation, In situ simulation-based training, Local champions, Perinatal mortality

Background

Annually, 1.5 million fresh stillbirths (FSB) and early newborn deaths occur due to intrapartum-related events [1, 2]. The majority of these deaths, including misclassified FSB, could be prevented if non-breathing newborns received skilled resuscitation at birth [3]. Helping Babies Breathe (HBB) is a simulation-based educational program, implemented in more than 80 low-resourced countries, with the aim of increasing skills among birth attendants in newborn resuscitation [4]. The program is shown to be cost-effective, able to enhance knowledge and skills, and able to reduce perinatal mortality [5]. HBB 2nd Edition was launched in 2016, emphasizing educational advice, program implementation, and strategies for quality improvement [6]. Simultaneously, a new and improved simulator, NeoNatalie Live (Laerdal Global Health, Stavanger, Norway), was developed and has shown to provide realistic training comparable to real-life resuscitations [7, 8].

Previous studies have found low-dose high-frequency training strategies effective for knowledge and skills retention [5, 9, 10]. However, individual studies show varied results regarding the translation of improved training skills to clinical practice [5, 11–14]. Two systematic reviews show no overall difference in drying, stimulation, suctioning, or bag-mask ventilation (BMV) after HBB implementation [15, 16]. The number of newborns receiving BMV within 60 s increased significantly in one study following a quality improvement cycle for HBB implementation at a tertiary hospital in Nepal [17]. A study from a high-resourced setting, testing the NeoSim simulation-based training (SBT), demonstrated reduced mortality, and decreased need for suction, BMV, intubation, chest compressions, and adrenaline during newborn resuscitation [18].

In real-life newborn resuscitations, a most crucial step is to start ventilation within the "golden minute" after birth [19, 20]. Preparedness, including available resuscitation equipment, is a key factor for successful resuscitations [19, 21]. Mastery of BMV skills, both during training and in real-life resuscitations, are challenging [22, 23]. Well-known barriers to training include staff turnover and limited time [5, 24, 25]. The rationale for the present study was the need for more research on how to implement and sustain frequent training and improve the translation of training skills into clinical practice.

HBB 2nd Edition, along with the new simulator, NeoNatalie Live, was implemented at Haydom Lutheran Hospital, in Tanzania in September 2016 [26]. The implementation consisted of two phases: first, an intervention period of mainly self-guided individual skill training (13 months) and second, individual skill training and scenario team training facilitated by local champions (11 months). During the first intervention period, 688 skill trainings and 40 team trainings were conducted, whereas 8451 skill trainings and 307 team trainings were conducted during the second intervention period, with a significant increase in staff participation and training performance after the appointment of local champions [26].

The aim of the present study was to describe changes in clinical resuscitation performance and perinatal outcomes, before and after the introduction of the novel simulator (in September 2016) and then local champions (in October 2017) to facilitate ongoing in situ HBB skills and scenario SBT among midwives.

Methods and material

This is a prospective observational study from September 1, 2015, through August 31, 2018, at Haydom Lutheran Hospital in rural Tanzania. All deliveries were observed by research assistants, and all live births and FSB were included in the analysis. The study was approved by the National Institute for Medical Research, Tanzania (NIMR/HQ/R.8a/Vol.IX/2877) and the Regional Committee for Medical and Health Research Ethics, Western Norway (Ref.no. 2013/110). Informed consent from the mothers was not required by the ethical committees due to the descriptive quality improvement study design.

Study setting and participants

Haydom is a rural referral hospital in Northern Tanzania that serves a catchment area of approximately 2 million people and has 3500–4000 deliveries annually. Deliveries and newborn resuscitations are mainly conducted by 18–22 midwives, with physicians on-call. The hospital has emphasized SBT since the introduction of HBB 1st Edition in 2010 and further through the Safer Births project as described by Mduma et al. [12]. An overview of SBT at Haydom, prior to and throughout this study period, is presented in Fig. 1. Simulations were conducted by midwives working in the maternity ward. The number of midwives varied throughout the study period due to a high staff turnover (n=15–27). Other healthcare workers, i.e., physicians and students, were allowed to use the simulator, but were not part of the SBT intervention.

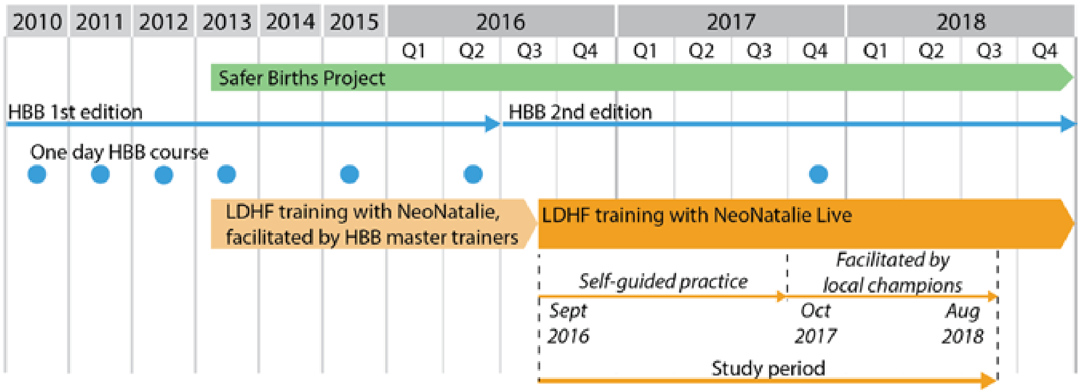


Fig. 1 SBT at Haydom Lutheran Hospital 2010–2018. Simulation-based training at Haydom Lutheran Hospital 2010–2018. HBB, Helping Babies Breathe; LDHF, low-dose high-frequency training; local champions, dedicated midwives in charge of facilitation and motivation for one-site training in HBB 2nd Edition. Figure by Ingunn Anda Haug (Laerdal Medical) [26]

Interventions

NeoNatalie Live—newborn resuscitation simulator

NeoNatalie Live is a substantially improved newborn resuscitation simulator, compared to the original NeoNatalie (Laerdal Global Health, Stavanger, Norway) and provides both individual skill training and scenario team training. The learner guides for the simulator are available in the supplementary information (Additional files 1 and 2). The simulator features variable lung compliance, realistic BMV training, and four different patient cases [8]. The simulator provides automated feedback based on HBB guidelines. The presented feedback is prioritized after the following lists: missing head tilt, insufficient opening ventilations, paused ventilations, mask leak, too high-ventilation pressure, and ventilation rate.

Implementation of NeoNatalie Live and local champions

Preceding implementation, we observed a 1-year baseline period (period 1) with low-dose high-frequency HBB training using the original NeoNatalie simulator. During the first intervention phase (period 2), September 1, 2016–September 30, 2017, Haydom continued HBB training using the 2nd Edition and introduced NeoNatalie Live in their labor ward (Fig. 1). The improved simulator was mainly used for individual skill training according to self-guided practice, and 688 skill-trainings were conducted in this period 2 [26]. In addition, 40 scenario team trainings were performed in the same period.

Initiating the second intervention phase (period 3), October 1, 2017–August 31, 2018, the hospital management appointed four dedicated midwives, "local champions," to facilitate and motivate for training. The local champions were junior midwives, carefully selected according to their personality traits and their beneficial influence in the ward. They were responsible for encouraging midwives to train and for technical support to ensure an all-time functioning simulator. They were tasked to arrange scenario team training and motivate the midwives to conduct self-guided skill training whenever time allowed. The local champions received a Master Trainer Guide and a Learner Guide for the simulator (Additional files 1 and 2) preceding the appointment. They did not receive any remuneration for this specific assignment or possess other roles apart from their clinical tasks. In period 3, a total of 8451 skill trainings and 307 scenario team trainings were conducted [26].

Data collection and management

Trained research assistants, working in 3 shifts, 24 h a day, observed and recorded information (labor and newborn characteristics, events, and resuscitation interventions) on a data collection form. Trained data clerks double-entered data using Epidata 3.1. Biomedical signal data during resuscitations from September 1, 2015, until June 26, 2018, were obtained using the Newborn Resuscitation Monitor (Laerdal Global Health, Stavanger, Norway). The monitor had sensors to synchronously capture and record heart rate from ECG, as well as airway pressure, flow, volume, and expired CO_2 during BMV using a self-inflating bag [27]. All sensors were located between the resuscitator bag and the facemask.

Outcomes

The main outcomes were the proportion of newborns receiving stimulation, suction, and/or BMV immediately after birth and time from birth to first ventilation.

In addition, the total duration of BMV, pauses during BMV (pauses >3 s), ventilation frequency, tidal volumes, and mask leak was observed. We also investigated initial newborn heart rate, increase in newborn heart rate during BMV, and frequency of BMV training. Secondary outcomes included FSB, a 24-h neonatal mortality, and admissions to the Neonatal Care Unit.

Statistical methods

Data analysis was performed by Matlab R2021a (MathWorks, Natick, MA) and SPSS version 26 (IBM Corp., Armonk, NY). Continuous data were presented by mean±SD or median (quartiles) and categorical data by percentages (numbers), unless otherwise stated. To test for differences over the periods in continuous variables, Kruskal-Wallis test was used. If a significant difference over the periods was found, this was further examined by pairwise comparisons between the periods, using the Mann-Whitney test and a Bonferroni adjustment for multiple testing. For categorical data, the same approach was used, but then applying the chi-squared or Fischer's exact test was appropriate. Logistic regression was used to test for differences between the periods in proportions of fatal outcomes adjusted for risk factors. A significance level of 0.05 was used in all hypothesis tests.

Results

During the study period, 10,672 births were recorded. The 191 macerated stillbirths (i.e., suspected dead before onset of labor) were excluded, while 10,481 births, including 135 FSB, were included for further analysis. Throughout the study period, 816 newborns received BMV and 644 of these resuscitations were recorded using the Newborn Resuscitation Monitor. Resuscitations were mainly performed by midwives, and some were provided by physicians or students. There were 12% missing registrations for the variable "cervical dilatation" and <0.1% for the remaining variables.

Patient vulnerability and perinatal outcome

The proportion of high-risk deliveries increased during the study period. From baseline to each intervention period, a higher number of admissions came from health centers (referrals) and the frequency of abnormal fetal heart rate on admission and during labor increased (Table 1). The proportion of premature newborns increased significantly, from 2.9 to 4.1%, corresponding to an increase in newborns with low birth weight <1500 g (Table 2).

In unadjusted analyses, perinatal mortality (i.e., 24-h newborn deaths and FSB) increased slightly during the study period (*p* value 0.038). After adjustment for the source of admission, premature/term, birth weight, mode of delivery, and the last fetal heart rate before delivery, there was no significant change in risk for perinatal deaths (*p* value 0.898).

Changes in resuscitation performance and training frequency

The proportion of births with a bag/mask resuscitator present before the delivery increased from 91.0 to 98.1% (Table 2). The observed proportion of newborns receiving BMV increased over the periods, from 7.0 to 8.5%, although not statistically significant (*p* value 0.056) (Table 2). We observed a significant decrease in both suction and stimulation in period 2 compared to period 1, but an increase in stimulation between periods 2 and 3 (Table 2). The median time from birth to the start of ventilation decreased from 118 to 101 s (*p* value 0.007) over the whole study period (Table 3). Resuscitations were performed by midwives in 66.3% of the cases in period 1 vs 77.1% in period 2 and 83.5% in period 3 (Table 3). The proportion of midwives who had trained, using NeoNatalie Live, during the last 7 days prior to the resuscitation, increased from 33.8% in period 1 to 71.4% in period 3 (Table 3).

There was a significant decrease in time to start BMV, but no significant change in newborns being ventilated within the golden first minute from birth or the time of applied BMV, throughout the study period. The proportion of pauses during ventilation decreased from 27.9 to 15.7%, and ventilation frequency increased slightly from 45 to 48 ventilations per/min (Table 4). There was no statistically significant change in mask leak, but expired tidal volume decreased from 7.6 to 6.3 ml/kg (Table 4). Static newborn lung compliance decreased during the whole study period (Table 4).

Discussion

Following a period of frequent in situ SBT in newborn resuscitation, preparedness for resuscitation and the number of newborns receiving BMV increased. Time to first ventilation and pauses during ventilation decreased significantly. The vulnerability among admitted women and their newborns seemed to increase during the study period. In line with the intention, we found a significant increase in self-reported training using NeoNatalie Live over the last 7 days before conducting a real resuscitation, from 33.8 to 71.4% throughout the study period, and midwives performed real resuscitations more frequently during the intervention periods.

The use of stimulation during real resuscitation decreased from period 1 to period 2 but increased from period 1 to period 3. Stimulation is an initial intervention in newborn resuscitation and marks the initiation of resuscitation, thus reflecting the number of newborns receiving resuscitation.

Table 1 Labor and maternal characteristics of live births and fresh stillbirths (n=10,481). Values are given as mean± SD or percentage (number)

	Period 1 Baseline 01.09.15–31.08.16	Period 2 Individual skill training 01.09.16–30.09.17	Period 3 Local champions 01.10.17–31.08.18	*P* value	Period 1 vs 2	Period 1 vs 3	Period 2 vs 3
Months (*n*)	12	13	11				
Births (*n*)	3572	4003	2 906				
Admission from the health center	3.9 (140)	5.6 (226)	5.9 (171)	<0.001[a]	<0.001[a]	<0.001[a]	0.675[a]
Mother had no formal education[b]	9.3 (196)	8.2 (328)	6.3 (184)	<0.001[a]	0.140[a]	<0.001[a]	<0.004[a]
Maternal age[b]	26.2 ±6.9	26.1 ±6.7	26.1 ±6.8	0.835[c]			
No antenatal care	0.9 (33)	0.9 (35)	1.0 (28)	0.928[a]			
Antenatal problem	1.5 (52)	2.0 (79)	2.3 (67)	0.039[a]	0.084[a]	0.011[a]	0.343[a]
Cervical dilatation on admission (cm)	5.7 ±2.5	5.6 ±2.6	5.8 ±2.6	0.009[c]	0.897[d]	0.009[d]	0.005[d]
10-cm cervical dilation on admission	6.7 (212)	7.4 (262)	8.5 (212)	0.044[a]	0.263[a]	0.013[a]	0.135[a]
Hours in labor before admission (h:min)	5:08 ±2:29	4:28 ±2:32	4:44 ±2:15	<0.001[c]	<0.001[d]	<0.001[d]	0.004[d]
Fetal heart rate on admission				0.001[a]	0.001[a]	0.006[a]	0.744[a]
Normal (120–160 bpm)	91.7 (3274)	93.1 (3724)	93.2 (2709)				
Abnormal (<120 or >160)	1.0 (37)	1.2 (49)	1.3 (38)				
Not detectable	0.5 (19)	0.9 (37)	0.7 (20)				
Not measured	6.7 (241)	4.8 (192)	4.8 (139)				
Fetal heart rate during labor				<0.001[a]	<0.001[a]	<0.001[a]	0.022[e]
Normal (120–160 bpm)	82.6 (2952)	85.5 (3423)	85.5 (2486)				
Abnormal (<120 or >160)	5.3 (190)	7.3 (291)	8.7 (252)				
Not detectable	0.5 (19)	1.0 (40)	0.7 (20)				
Not measured	11.5 (411)	6.2 (248)	5.1 (148)				
Final fetal heart rate before delivery	134.0 ±14.0	132.9 ±17.3	132.5 ±17.3	0.075[c]			
Mode of delivery				0.020[a]	0.181[a]	0.222[a]	0.010[a]
Spontaneous vaginal delivery	75.3 (2690)	75.8 (3035)	75.0 (2179)				
Cesarian delivery	23.8 (851)	23.0 (922)	23.7 (690)				
Assisted breech delivery	0.6 (22)	0.5 (22)	1.1 (31)				
Vacuum extraction	0.3 (9)	0.6 (23)	0.2 (5)				
Others	0.0 (0)	0.0 (1)	0.0 (1)				
Singleton/multiple				0.353[a]			
Singleton	96.0 (3428)	96.1 (3847)	96.6 (2808)				
Multiple	4.0 (144)	3.9 (56)	3.4 (98)				
Labor complications[f]	2.4 (85)	2.3 (94)	2.7 (78)	0.634[a]			
Uterine rupture	0.2 (6)	0.1 (5)	0.1 (3)	0.763[a]			
Pre-eclampsia	0.5 (17)	0.6 (25)	0.6 (16)	0.686[a]			
Eclampsia	0.3 (9)	0.2 (7)	0.5 (14)	0.056[a]			
Cord prolapse	0.8 (25)	0.7 (29)	0.6 (16)	0.653[a]			
Prepartum bleeding	0.7 (23)	0.8 (31)	1.0 (28)	0.348[a]			
Shoulder dystocia	0.2 (7)	0.0 (1)	0.1 (3)	0.062[g]			

[a] Chi-squared test

[b] Data collection initiated 01.02.2016

[c] Kruskal-Wallis test

[d] Mann-Whitney test

[e] Not significant after Bonferroni correction

[f] One or several labor complications

[g] Fischer's exact test

Table 2 Newborn characteristics, resuscitation characteristics, and outcome of live births and fresh stillbirths (*n*= 10,481). Values are given as mean± SD or percentage (number)

	Period 1 Baseline 01.09.15–31.08.16	Period 2 Individual skill training 01.09.16–30.09.17	Period 3 Local champions 01.10.17–31.08.18	*P* value	Period 1 vs 2	Period 1 vs 3	Period 2 vs 3
Births (*n*)	3572	4003	2906				
Newborn characteristics							
Gestational age (week)	38.8 ±1.9	38.7 ±1.9	38.6 ±2.0	0.003[a]	0.620[b]	0.001[b]	0.005[b]
Preterm	2.9 (103)	3.8 (151)	4.1 (118)	0.024[c]	0.032[cd]	0.009[c]	0.540[c]
Birth weight (gram)	3302.4 ±523.6	3357.7 ±556.6	3335.3 ±550.9	<0.001[a]	<0.001[b]	0.002[b]	0.115[b]
Birth weight categories (gram)				<0.001[c]	<0.001[c]	0.002[c]	0.038[cd]
<1500	0.5 (18)	0.8 (32)	1.0 (30)				
1500–2499	5.0 (178)	4.9 (195)	4.3 (126)				
2500–3499	56.2 (2008)	50.2 (2011)	52.7 (1531)				
3500–4499	37.2 (1328)	42.2 (1690)	40.2 (1167)				
≥4500	1.1 (40)	1.9 (75)	1.8 (52)				
Resuscitation characteristics							
Resuscitation kit present	92.7 (3313)	93.5 (3742)	93.6 (2721)	0.276[c]			
Bag/mask resuscitator present	91.0 (3252)	98.1 (3923)	97.8 (2842)	<0.001[c]	<0.001[c]	<0.001[c]	0.456[c]
Stimulation	31.0 (1109)	27.6 (1104)	34.4 (1001)	<0.001[c]	0.001[c]	<0.004[c]	<0.001[c]
Suction	28.2 (1009)	23.6 (943)	28.0 (815)	<0.001[c]	<0.001[c]	0.857[c]	<0.001[c]
Bag/mask ventilation	7.0 (249)	8.0 (319)	8.5 (248)	0.056[c]			
APGAR 1 min	8.6 ±1.2	8.5 ±1.5	8.5 ±1.4	0.537[a]			
APGAR 5 min	9.8 ±1.2	9.7 ±1.5	9.7 ±1.4	<0.001[a]	0.006[b]	<0.001[b]	0.049[bd]
Low APGAR 1 min (APGAR ≤7)	4.0 (143)	5.0 (200)	5.7 (167)	0.005[a]	0.038[ad]	0.001[a]	0.170[a]
Low APGAR 5 min (APGAR ≤7)	2.3 (81)	3.9 (157)	4.2 (123)	<0.001[c]	<0.001[c]	<0.001[c]	0.518[c]
Perinatal outcome at 30 min				0.013[c]	0.008[c]	0.013[c]	0.563[c]
Normal	93.6 (3345)	91.6 (3666)	91.6 (2662)				
Admitted neonatal unit	5.0 (179)	6.5 (262)	6.9 (200)				
Death	0.3 (9)	0.3 (13)	0.3 (10)				
Fresh stillbirth	1.1 (39)	1.5 (62)	1.2 (34)				
Neonatal outcome at 24 h				0.003[c]	0.002[c]	0.012[c]	0.261[c]
Normal	95.1 (3396)	93.0 (3723)	93.5 (2715)				
Still in the neonatal care unit	3.2 (114)	4.4 (178)	4.0 (116)				
Death	0.6 (23)	1.0 (40)	1.3 (38)				

Fresh stillbirth is reported for perinatal outcome at 30 min

[a] Kruskal-Wallis test

[b] Mann-Whitney test

[c] Chi-square test

[d] Not significant after Bonferroni correction

Table 3 Resuscitation characteristics of newborns receiving bag/mask ventilation (n=816). Values are given as median (quartiles) or percentage (number)

	Period 1 Baseline 01.09.15–31.08.16	Period 2 Individual skill training 01.09.16–30.09.17	Period 3 Local champions 01.10.17–31.08.18	*P* value	Period 1 vs 2	Period 1 vs 3	Period 2 vs 3
Newborns receiving BMV (*n*)	249	319	248				
Midwife providing resuscitation	66.3 (165)	77.1 (246)	83.5 (207)	<0.001[a]	0.004[a]	<0.001[a]	0.061[a]
Midwife trained with NeoNatalie last 7 days	33.8 (54)	29.6 (72)	71.4 (147)	<0.001[a]	0.383[a]	<0.001[a]	<0.001[a]
Time from birth to the start of BMV (seconds)	118 (85–165)	100 (74–160)	101 (72–150)	0.018[b]	0.028[cd]	0.007[c]	0.532[c]
BMV initiated within 60 s	13.3 (33)	13.2 (42)	15.7 (39)	0.633[a]			
Perinatal outcome at 30 min				0.213[a]			
Normal	58.2 (145)	51.7 (165)	52 (129)				
Admitted neonatal unit	33.3 (83)	42.3 (135)	42.3 (105)				
Death	3.2 (8)	3.4 (11)	2.4 (6)				
Fresh stillbirth	5.2 (13)	2.5 (8)	3.2 (8)				
Neonatal outcome at 24 h				0.398[a]			
Normal	66.7 (166)	62.4 (199)	62.6 (154)				
Still in the neonatal care unit	21.7 (54)	25.7 (82)	24.8 (61)				
Death	6.4 (16)	9.4 (30)	9.3 (23)				

BMV bag/mask ventilation

[a] Chi-square test

[b] Kruskal-Wallis test

[c] Mann-Whitney test

[d] Not significant after Bonferroni correction

The increased use of stimulation may reflect the more vulnerable population of newborns or increased training. We documented a decrease in the use of the suction from period 1 to period 2; still, there were no changes from period 1 to period 3. Two systematic reviews found no change in the frequency of either stimulation or suction after HBB training [15, 16]. Newborn resuscitation guidelines no longer recommend suction unless the airway is obstructed by secretions, and several studies show decreased use of unnecessary suctioning after HBB training [17, 19, 28].

As much as 8.5% of the newborns received BMV in period 3, compared to 7.0% during period 1. Several individual studies report more frequent BMV following the implementation of HBB [17, 28, 29]. However, two systematic reviews found no change in the frequency of BMV after HBB training [15, 16]. The not significant tendency towards more newborns receiving BMV in our study is likely due to a more vulnerable population with an increased number of newborns requiring BMV. Daily simulation-based training during the second intervention period might also have contributed to enhanced confidence and thus increased use of BMV. The aim of HBB training is to provide timely and skilled BMV when needed. The actual proportion of non-breathing newborns who would benefit from BMV is probably unknown and varies across settings, depending on maternal and newborn vulnerability and obstetric and newborn care. Thus, it may be difficult to evaluate if the observed frequency of BMV is appropriate and to compare it with other settings. Importantly, all newborns being ventilated were observed by the trained research assistants as "not breathing" until the start of BMV.

Rapid initiation of BMV among non-breathing newborns is critical for intact survival, and guidelines recommend the start of ventilation within 1 min after birth [19, 20]. Time from birth to first ventilation decreased from 118 to 101 s during our study period. Still, merely 15.7% of the newborns receiving BMV were ventilated within the first minute of life, confirming previous literature [28, 30]. Chaulagain et al. found a monthly cumulative median time to first ventilation of 153 s and a proportion of 11.1% of the newborns ventilated within the first minute, showing that even after a targeted quality improvement package in newborn resuscitation, rapid initiation of BMV remains a great challenge [28]. In our study, the increase in births with bag/mask resuscitators present prior to delivery, demonstrating an increased preparedness for resuscitation, in addition to increased skills might have impacted the time to start ventilation [31, 32].

Table 4 Bag/mask ventilation characteristics recorded from the newborn resuscitation monitor (*n*=644). Values are given as median (quartiles) or percentage (number)

	Period 1 Baseline	Period 2 Individual skill training	Period 3 Local champions	*P* value	Period 1 vs 2	Period 1 vs 3	Period 2 vs 3
	01.09.15–31.08.16	01.09.16–30.09.17	01.10.17–26.06.18				
	220	268	156				
Heart rate characteristics							
First HR (bpm)	98 (61–152)	95 (62–149)	88 (60–140)	0.699[a]			
First HR under 100 bpm (%)	50.9 (112)	50.7 (136)	55.1 (86)	0.644[a]			
HR after last ventilation (bpm)	153 (130, 171)	157 (134, 169)	160 (137, 170)	0.621[a]			
HR 60 s after last ventilation (bpm)	160 (138, 176)	163 (145, 176)	160 (140, 175)	0.550[a]			
BMV characteristics							
Total BMV duration (seconds)	135 (66, 349)	127 (64, 266)	152 (82, 347)	0.234[a]			
Total BMV pause (%)	27.9 (15.2, 44.8)	19.1 (8.2, 34.9)	15.7 (4.0, 31.2)	<0.001[a]	<0.001[b]	<0.001[b]	0.077[b]
Tidal volume expired, (ml/kg)	7.6 (4.8, 11.8)	6.0 (2.9, 9.8)	6.3 (3.5, 10.4)	<0.001[a]	<0.001[b]	0.025[bc]	0.137[b]
Mask leak (%)	38.0 (15.8, 57.0)	42.0 (18.5, 61.8)	38.8 (16.0, 60.0)	0.495[a]			
Ventilation frequency, (1/min)	45.0 (36.0, 55.0)	48.0 (42.0, 54.0)	48.0 (42.2, 54.0)	0.006[a]	0.009[b]	0.005[b]	0.542[b]
Peak inspiratory pressure (mbar)	36.0 (30.0, 39.0)	39.0 (36.0, 40.0)	38.0 (37.0, 40.0)	<0.001[a]	<0.001[b]	<0.001[b]	0.498[b]
Minute volume (ml)	369 (225, 556)	287 (181, 459)	324 (198, 449)	0.005[a]	0.001[b]	0.049[bc]	0.335[b]
Number of ventilations	61 (34, 159)	72 (38, 147)	85 (44, 208)	0.017[a]	0.348[b]	0.006[b]	0.029[bc]
Static lung compliance, (ml/mbar)	0.93 (0.60, 1.40)	0.64 (0.38, 1.01)	0.67 (0.40, 1.02)	<0.001[a]	<0.001[b]	<0.001[b]	0.630[b]
First minute of ventilation							
Total BMV pause during first minute (%)	31.1 (12.3, 56.6)	23.6 (8.3, 42.1)	15.1 (5.5, 38.7)	<0.001[a]	0.003[b]	<0.001[b]	0.020[bc]
Tidal volume expired (ml/kg)	7.0 (3.5, 10.6)	4.2 (1.4, 8.1)	4.3 (1.9, 8.7)	<0.001[a]	<0.001[b]	<0.001[b]	0.443[b]
Mask leak (%)	42.2 (21.0, 68.2)	52.8 (24.2, 74.5)	52.5 (26.0, 72.0)	0.068[a]			
Ventilation frequency, (1/min)	46.0 (37.0, 58.0)	48.0 (42.0, 55.5)	49.0 (43.0, 55.0)	0.058[a]			
Peak inspiratory pressure (mbar)	37.0 (32.0, 40.0)	39.0 (37.0, 41.0)	38.8 (37.0, 41.5)	<0.001[a]	<0.001[b]	<0.001[b]	0.742[b]
Minute volume (ml)	317 (183, 494)	241 (113, 385)	247 (153, 387)	<0.001[a]	<0.001[b]	0.002[b]	0.500[b]
Number of ventilations	30 (20, 40)	36 (27, 44)	39 (29, 44)	<0.001[a]	<0.001[b]	<0.001[b]	0.190[b]
Static lung compliance (ml/mbar)	0.93 (0.61, 1.41)	0.65 (0.39, 1.04)	0.71 (0.41, 1.06)	<0.001[a]	<0.001[b]	<0.001[b]	0.396[b]

HR heart rate, *BMV* bag/mask ventilation, *Bpm* beat per minute

[a] Kruskal-Wallis test

[b] Mann-Whitney test

[c] Not significant after Bonferroni correction

Over the study period, midwives at Haydom conducted a large amount of both individual skill training [26] and organized scenario team trainings. It is not possible to analyze how these different training modalities separately may have influenced the documented changes in clinical care. However, we believe that scenario team-trainings may typically influence team work, decision making, and clinical treatment timelines more than individual skill training would do [33, 34]. Therefore, we speculate that more targeted team-scenario trainings in combination with specific continuous quality improvement efforts are necessary to ensure that most non-breathing newborns receive BMV within the first minute.

Regarding ventilation performance, healthcare workers managed to ventilate with less pauses after increased use of self-guided skill training in period 2. The simulator provides feedback regarding this specific action point in the HBB algorithm, making it reasonable that training contributed to enhancing this clinical skill. The observed reduction in expired tidal volume and minute volume during the study period are most likely due to a more vulnerable newborn population. This is supported by the findings of decreased static lung compliance indicating stiffer lungs and thus increased difficulties in providing a sufficient minute volume during BMV, despite the increased number of ventilations and peak inspiratory pressure. Low lung compliance likely represents unmature preterm lungs and/or liquid-filled lungs of severely asphyxiated newborns. To establish functional residual capacity in such lungs may be difficult and likely explains the almost significant trend towards more mask leaks in the first minute of BMV [35].

Regarding mortality, overall 30-min newborn mortality seems to be stable around 3/1000 and the FSB rate changes from 1.1 to 1.5 % throughout the study period, despite an increased population vulnerability (Table 2). The 30-min perinatal outcome is typically associated with intrapartum-related events and complications, causing FSB or severely asphyxiated newborns [36]. The 24-h newborn mortality mainly reflects intrapartum-related deaths, but may also include some deaths secondary to other causes, e.g., prematurity and severe infections [37]. SBT interventions combining obstetric and newborn care might be needed for reducing perinatal mortality [33, 38]. The increase in more vulnerable women being admitted over time is difficult to explain based on our data alone. However, a recent paper from the same setting describes how this poor catchment population reacts to changing conditions like introducing patient fees for ambulance service and hospital delivery [39].

Among several strengths of this study is the large population size. In addition, the rigorous data management system, comprehensive data collection form presenting detailed information on resuscitation practice, combined with physiological data during the first minutes of life provides unique information. One limitation is the non-randomized design and thus the inability to claim causality. In addition, lack of qualitative data restricts the interpretation of reasons behind the successes and potential barriers. A mixed method design could have added important knowledge for further improvement of training approaches and eventually clinical performance.

HBB and the new NeoNatalie Live simulator is a low-cost program and thus possible to scale up in other resource-limited settings [40]. However, Haydom has emphasized individual simulation-based HBB skill training for a decade, thus the management and staff are used to such learning methods. This background likely explains their eagerness to use the new simulator, and furthermore, the huge training load response when the local champions started their work. These responses happened despite the high turnover in clinical staff. Settings with less SBT practice may need more time to achieve similar results. High-income settings might require additional training on more advanced interventions for newborn resuscitation, but the implementation strategy of using local champions is considered generalizable.

Conclusion

Even when caring for a more vulnerable maternal and newborn population, midwives at Haydom managed to improve their clinical skills in newborn resuscitation after an impressive increase in individual training frequency and scenario team trainings using a novel newborn simulator, stimulated by local champions. The low number of newborns receiving BMV within the first minute is a remaining critical challenge, and we think more additional quality improvement efforts are necessary to achieve guideline adherence. Further research should focus on qualitative and/or mixed-methods studies exploring underlying reasons for the described changes and the challenge of timely BMV.

Abbreviations

BMV: Bag-mask ventilation; FSB: Fresh stillbirths; HBB: Helping Babies Breathe; SBT: Simulation-based skill training.

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s41077-022-00234-z.

Additional file 1. Master Trainer Guide. Information folder for master trainers (local champions) about how to prepare the equipment and perform ventilation training.

Additional file 2. Learner Guide. A simple introduction folder for midwives about how to perform ventilation skill training.

Acknowledgements

The authors acknowledge the midwives working in the maternity ward at Haydom Lutheran Hospital, especially the local champions; Barikiel Hhando Hhoki, Sabrina Sebastian Saragu, Paschalina Michael Bura, and Noelina Samson Quwanga and the Hospital Management team. We thank the reviewers for their constructive comments which lead to a substantially improved paper.

Authors' contributions

MSV participated in the conception and design of the study, analysis, and interpretation of the data; drafted the initial manuscript; revised all drafts of the manuscript; approved the final manuscript as submitted; and is responsible for the overall content as the guarantor. JTK participated in the analysis and interpretation of the data, revised drafts of the manuscript, and approved the final manuscript as submitted. RM participated in the acquisition, revised the drafts of the manuscript, and approved the final manuscript as submitted. PM participated in the acquisition, revised the drafts of the manuscript, and approved the final manuscript as submitted. JE participated in the analysis and interpretation of the data, revised the drafts of the manuscript, and approved the final manuscript as submitted. BHH participated in the acquisition, revised the drafts of the manuscript, and approved the final manuscript as submitted. HE participated in the conception and design of the study, acquisition, analysis, and interpretation of the data; revised the drafts of the manuscript; and approved the final manuscript as submitted. The authors read and approved the final manuscript.

Authors' information
Not applicable.

Funding
This research was funded by the University of Stavanger, the Global Health and Vaccines Research (GLOBVAC) program at the Research Council of Norway (grant number 228203); Saving Lives at Birth Grand Challenges, and the Laerdal Foundation. The development of NeoNatalie Live received funding from Innovation Norway, the Research Council of Norway (228203), and Skattefunn (ES519418). The study was performed using simulation equipment provided by Laerdal Global Health. The funders had no role in the design of the study; in the collection, analyses, or interpretation of the data; in the writing of the manuscript; or in the decision to publish the results.

Availability of data and materials
The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate
The study was approved by the National Institute for Medical Research, Tanzania (NIMR/HQ/R.8a/Vol.IX/2877) and the Regional Committee for Medical and Health Research Ethics, Western Norway (Ref.no. 2013/110). Informed consent from the mothers was not required by the ethical committees due to the descriptive quality improvement study design.

Consent for publication
Not applicable.

Competing interests
JE is an employee of Laerdal Medical. The other authors declare that they have no competing interests.

Author details
[1]Faculty of Health Sciences, University of Stavanger, 4021 Stavanger, Norway. [2]Muhimbili National Hospital, P.O Box 65000, Dar es Salaam, Tanzania. [3]Haydom Lutheran Hospital, Box 9000, Haydom, Mbulu, Tanzania. [4]Laerdal Medical, 4002 Stavanger, Norway. [5]Department of Mathematics and Physics, University of Stavanger, 4036 Stavanger, Norway. [6]Department of Research, Stavanger University Hospital, 4011 Stavanger, Norway. [7]Department of Anaesthesia, Stavanger University Hospital, 4011 Stavanger, Norway.

Received: 19 August 2022 Accepted: 23 October 2022
Published online: 05 November 2022

References

1. Indicator Metadata Registry Details. [cited 2022 Oct 13]. Available from: https://www.who.int/data/gho/indicator-metadata-registry/imr-details/2444
2. Liu L, Oza S, Hogan D, Chu Y, Perin J, Zhu J, et al. Global, regional, and national causes of under-5 mortality in 2000–15: an updated systematic analysis with implications for the Sustainable Development Goals. Lancet. 2016;388(10063):3027–35.
3. Bhutta ZA, Das JK, Bahl R, Lawn JE, Salam RA, Paul VK, et al. Can available interventions end preventable deaths in mothers, newborn babies, and stillbirths, and at what cost? Lancet. 2014;384(9940):347–70.
4. Helping Babies Breathe. AAP.org. [cited 2021 Feb 25]. Available from: http://www.aap.org/en-us/advocacy-and-policy/aap-health-initiatives/helping-babies-survive/Pages/Helping-Babies-Breathe.aspx
5. Morris SM, Fratt EM, Rodriguez J, Ruman A, Wibecan L, Nelson BD. Implementation of the helping babies breathe training program: a systematic review. Pediatrics. 2020;146(3) [cited 2021 Feb 25]. Available from: https://pediatrics.aappublications.org/content/146/3/e20193938.
6. Helping Babies Breathe 2nd Edition Summary of Changes. [cited 2021 Feb 25]. Available from: https://www.aap.org/en-us/advocacy-and-policy/aap-health-initiatives/helping-babies-survive/Pages/Helping-Babies-Breathe-2nd-Edition-Summmary-of-Changes.aspx
7. NeoNatalie [Internet]. Laerdal Medical. [cited 2021 Feb 25]. Available from: https://laerdal.com/no/products/simulation-training/obstetrics-paediatrics/neonatalie/
8. Haynes J, Bjorland P, Gomo Ø, Ushakova A, Rettedal S, Perlman J, et al. Novel neonatal simulator provides high-fidelity ventilation training comparable to real-life newborn ventilation. Children (Basel). 2021;8(10):940.
9. Kc A, Wrammert J, Nelin V, Clark RB, Ewald U, Peterson S, et al. Evaluation of Helping Babies Breathe Quality Improvement Cycle (HBB-QIC) on retention of neonatal resuscitation skills six months after training in Nepal. BMC Pediatr. 2017;17 [cited 2021 Feb 25]. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5387236/.
10. Arlington L, Kairuki AK, Isangula KG, Meda RA, Thomas E, Temu A, et al. Implementation of "Helping Babies Breathe": a 3-year experience in Tanzania. Pediatrics. 2017;139(5) [cited 2021 Feb 25]. Available from: https://pediatrics.aappublications.org/content/139/5/e20162132.
11. Ersdal HL, Vossius C, Bayo E, Mduma E, Perlman J, Lippert A, et al. A one-day 'Helping Babies Breathe' course improves simulated performance but not clinical management of neonates. Resuscitation. 2013;84(10):1422–7.
12. Mduma E, Ersdal H, Svensen E, Kidanto H, Auestad B, Perlman J. Frequent brief on-site simulation training and reduction in 24-h neonatal mortality--an educational intervention study. Resuscitation. 2015;93:1–7.
13. Msemo G, Massawe A, Mmbando D, Rusibamayila N, Manji K, Kidanto HL, et al. Newborn mortality and fresh stillbirth rates in Tanzania after Helping Babies Breathe training. Pediatrics. 2013;131(2):e353–60.
14. Goudar SS, Somannavar MS, Clark R, Lockyer JM, Revankar AP, Fidler HM, et al. Stillbirth and newborn mortality in India after Helping Babies Breathe training. Pediatrics. 2013;131(2):e344–52.
15. Budhathoki SS, Gurung R, Ewald U, Thapa J, Kc A. Does the Helping Babies Breathe Programme impact on neonatal resuscitation care practices? Results from systematic review and meta-analysis. Acta Paediatr. 2019;108(5):806–13.
16. Dol J, Campbell-Yeo M, Murphy GT, Aston M, McMillan D, Richardson B. The impact of the Helping Babies Survive program on neonatal outcomes and health provider skills: a systematic review. JBI Database System Rev Implement Rep. 2018;16(3):701–37.
17. Kc A, Wrammert J, Clark RB, Ewald U, Vitrakoti R, Chaudhary P, et al. Reducing perinatal mortality in Nepal using Helping Babies Breathe. Pediatrics. 2016;137(6) [cited 2021 Feb 25]. Available from: https://pediatrics.aappublications.org/content/137/6/e20150117.
18. Bhatia M, Stewart AE, Wallace A, Kumar A, Malhotra A. Evaluation of an in-situ neonatal resuscitation simulation program using the New World Kirkpatrick Model. Clin Simul Nurs. 2021 Jan;1(50):27–37.
19. Wyckoff MH, Aziz K, Escobedo MB, Kapadia VS, Kattwinkel J, Perlman JM, et al. Part 13: neonatal resuscitation: 2015 American Heart Association Guidelines Update for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care (Reprint). Pediatrics. 2015; [cited 2021 Feb 25]. Available from: https://pediatrics.aappublications.org/content/early/2015/10/13/peds.2015-3373G.
20. Ersdal HL, Mduma E, Svensen E, Perlman JM. Early initiation of basic resuscitation interventions including face mask ventilation may reduce birth asphyxia related mortality in low-income countries: a prospective descriptive observational study. Resuscitation. 2012;83(7):869–73.
21. Moshiro R, Ersdal H, Mdoe P, Kidanto H, Mbekenga C. Factors affecting effective ventilation during newborn resuscitation: a qualitative study among midwives in rural Tanzania. Glob Health Action. 2018;11:1423862.
22. Schmölzer GM, Dawson JA, Kamlin COF, O'Donnell CPF, Morley CJ, Davis PG. Airway obstruction and gas leak during mask ventilation of preterm infants in the delivery room. Arch Dis Child Fetal Neonatal Ed. 2011;96(4):F254–7.

23. Schmölzer GM, Roehr CC. Use of respiratory function monitors during simulated neonatal resuscitation. Klin Padiatr. 2011;223(5):261–6.
24. Ersdal HL. Large-scale implementation of Helping Babies Breathe – what is required? Paediatr Int Child Health. 2018;38(1):1–4.
25. Isangula KG, Kassick ME, Kairuki AK, Meda RA, Thomas E, Temu A, et al. Provider experiences with the large-scale 'Helping Babies Breathe' training programme in Tanzania. Paediatr Int Child Health. 2018;38(1):46–52.
26. Vadla MS, Mdoe P, Moshiro R, Haug IA, Gomo Ø, Kvaløy JT, et al. Neonatal resuscitation skill-training using a new neonatal simulator, facilitated by local motivators: two-year prospective observational study of 9000 trainings. Children. 2022;9(2):134.
27. Linde JE, Eilevstjønn J, Øymar K, Ersdal HL. Feasibility of a prototype newborn resuscitation monitor to study transition at birth, measuring heart rate and ventilator parameters, an animal experimental study. BMC Res Notes. 2017;10:235.
28. Chaulagain DR, Malqvist M, Brunell O, Wrammert J, Basnet O, Kc A. Performance of health workers on neonatal resuscitation care following scaled-up quality improvement interventions in public hospitals of Nepal - a prospective observational study. BMC Health Serv Res. 2021;21 [cited 2021 Apr 28]. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8054430/.
29. Arabi AME, Ibrahim SA, Manar AR, Abdalla MS, Ahmed SE, Dempsey EP, et al. Perinatal outcomes following Helping Babies Breathe training and regular peer–peer skills practice among village midwives in Sudan. Arch Dis Child. 2018;103(1):24–7.
30. Kc A, Peven K, Ameen S, Msemo G, Basnet O, Ruysen H, et al. Neonatal resuscitation: EN-BIRTH multi-country validation study. BMC Pregnancy Childbirth. 2021;21(Suppl 1):235.
31. Nelissen E, Ersdal H, Mduma E, Evjen-Olsen B, Broerse J, van Roosmalen J, et al. Helping Mothers Survive Bleeding After Birth: retention of knowledge, skills, and confidence nine months after obstetric simulation-based training. BMC Pregnancy Childbirth. 2015;15(1):190.
32. Ersdal HL, Singhal N, Msemo G, Kc A, Data S, Moyo NT, et al. Successful implementation of Helping Babies Survive and Helping Mothers Survive programs—an Utstein formula for newborn and maternal survival. PLoS One. 2017;12(6) [cited 2021 Feb 25]. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5462342/.
33. Fransen AF, Ven J van de, Banga FR, Mol BWJ, Oei SG. Multi-professional simulation-based team training in obstetric emergencies for improving patient outcomes and trainees' performance. Cochrane Database Syst Rev 2020 ;(12). [cited 2022 Sep 28]. Available from: https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD011545.pub2/full
34. Lindhard MS, Thim S, Laursen HS, Schram AW, Paltved C, Henriksen TB. Simulation-based neonatal resuscitation team training: a systematic review. Pediatrics. 2021;147(4):e2020042010.
35. Ersdal HL, Eilevstjonn J, Perlman J, Gomo Ø, Moshiro R, Mdoe P, et al. Establishment of functional residual capacity at birth: observational study of 821 neonatal resuscitations. Resuscitation. 2020;153:71–8.
36. Ersdal HL, Eilevstjønn J, Linde JE, Yeconia A, Mduma ER, Kidanto H, et al. Fresh stillborn and severely asphyxiated neonates share a common hypoxic–ischemic pathway. Int J Gynecol Obstet. 2018;141(2):171–80.
37. Moshiro R, Perlman JM, Paschale KH, Kvaløy JT, Ersdal HL. Potential causes of early death among admitted newborns in a rural Tanzanian hospital. PLoS One. 2019;14(10):e0222935.
38. Zhong B, Sarkar M, Menon N, Devi S, Budanoor JK, Beerappa N, et al. Obstetric neonatal emergency simulation workshops in remote and regional South India: a qualitative evaluation. Adv Simul (Lond). 2021;6(1):36.
39. Vossius C, Mduma E, Moshiro R, Mdoe P, Kvaløy JT, Kidanto H, et al. The impact of introducing ambulance and delivery fees in a rural hospital in Tanzania. BMC Health Serv Res. 2021;21(1):99.
40. Vossius C, Lotto E, Lyanga S, Mduma E, Msemo G, Perlman J, et al. Cost-Effectiveness of the "Helping Babies Breathe" program in a missionary hospital in rural Tanzania. PLoS One. 2014;9(7) [cited 2021 Jun 11]. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4090230/.

Publisher's Note

Springer Nature remains neutral with regard to jurisdictional claims in published maps and institutional affiliations.

(Submitted, in review: Simulation in Healthcare)

Increase in newborns ventilated within the first minute of life and reduced mortality following clinical data-guided simulation training

May Sissel Vadla M.D. [1*]; Estomih Raphael Mduma M.P.H., Ph.D.[2]; Jan Terje Kvaløy Ph.D., Prof. [3,4]; Paschal Mdoe M.D., Ph.D.[2] ; Barikiel Hhando Hhoki CNM[2]; Sabrina Sarangu CNM[2]; Paskalina Michael CNM[2]; Bjørg Oftedal RN, Ph.D., Prof.[1]; and Hege Ersdal M.D, Ph.D., Prof. [1,5]

[1] Faculty of Health Sciences, University of Stavanger, 4021 Stavanger; may.s.vadla@uis.no, bjorg.oftedal@uis.no, hege.ersdal@safer.net

[2] Haydom Lutheran Hospital, Box 9000, Haydom, Mbulu, Tanzania; estomduma@gmail.com, pfmdoe@gmail.com, sybarikiel@gmail.com, sabrina.moyo@uib.no, paskalinamichael11@gmail.com

[3] Department of Mathematics and Physics, University of Stavanger, 4036 Stavanger; jan.t.kvaloy@uis.no

[4] Department of Research, Stavanger University Hospital, 4011 Stavanger

[5] Department of Anesthesia, Stavanger University Hospital, 4011 Stavanger; hege.ersdal@safer.net

*Corresponding author: May Sissel Vadla, Faculty of Health Sciences, University of Stavanger, 4021 Stavanger; may.s.vadla@uis.no, phone number: +47 9849 2399

Abstract

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, 01.10.2017-31.08.2021; 1st year baseline, 2nd year QI/simulation intervention, and two years post-intervention. 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% newborns were ventilated within 60 seconds after birth compared to 15.8% during baseline and 42.2% and 28.9% during the two post-intervention 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 post-intervention. More non-breathing newborns were ventilated in the intervention period (12.9%) compared to baseline (8.5%) and the post-intervention years (10.6% and9.4%) (p<0.001). Assumed fresh stillborns decreased significantly from baseline to intervention (3.2% to 0.7%) (p=0.013).

Conclusions:

This study demonstrates a 4.5-fold increase in 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 post-intervention, highlighting the need for continuous simulation-based training and research into QI efforts essential for sustainable changes.

Keywords

Clinical performance, Helping Babies Breathe 2nd Edition, low-resource setting, newborn mortality, newborn resuscitation, perinatal mortality, patient outcome, simulation-based training

Introduction

Each year, 1.5 million fresh stillbirths (FSB) and early newborn deaths occur due to intrapartum related events(1,2). Timely and skilled resuscitation of the non-breathing 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 five public hospitals in high mortality burden countries found only 1% of non-breathing newborns receiving ventilation within 60 seconds after birth(6). A tertiary hospital in Nepal managed to increase the proportion of 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). HBB is endorsed by WHO and introduced in >80 low/middle-income countries worldwide(13). The program was launched in 2009, and several studies have shown reduced early neonatal mortality and FSB following implementation of HBB 1st Edition(8,11,14–16). Still, challenges of sustained changes have been identified, and in order to further improve implementation and sustainability of the training program, the HBB 2nd 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 non-breathing newborns has been constantly around two minutes. To increase the numbers of newborns receiving BMV within the Golden Minute, a QI/simulation intervention consistent with the HBB 2nd Edition started September 1st, 2018, named "The Golden Minute Campaign". The goal was to ventilate 70% of non-breathing newborns within the first minute of life. The aim of this study was 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 is a prospective 4-year observational QI study including all deliveries at Haydom Lutheran Hospital, from October 1st, 2017, through August 31st, 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 3000–3500 deliveries annually during the study period. Deliveries, including newborn resuscitations, are mainly conducted by 18–22 midwives working two-three on every shift, with physicians on-call. 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(18). Since September 2016, the NeoNatalie Live simulator (Laerdal Global Health) with variable lung compliance, realistic tactile appearance, and automated feedback (19), has been available in the labour 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(20).

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 01.10.17-31.08.18, almost 8 500 individual skill-trainings and around 300 scenario team-trainings were conducted (21). In this baseline period, ventilation of non-breathing newborns improved and time to start BMV decreased from around two minutes to 100 seconds (20). Still, only 14.6% of newborns received BMV within the first minute as recommended. Figure 1 presents an overview of simulation-based training at the hospital, prior to and throughout this study period.

Simulation-based training at Haydom Lutheran Hospital 2010–2021

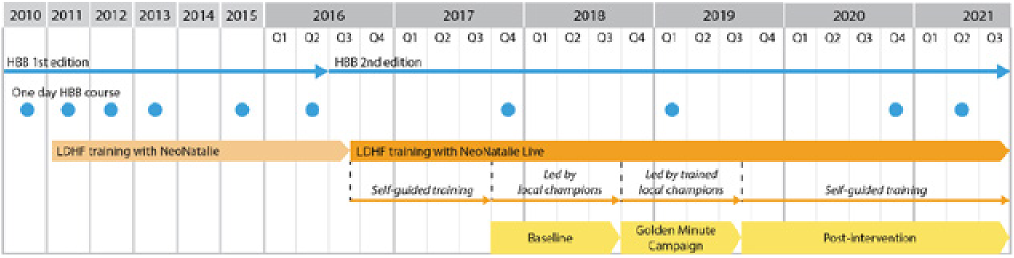


Figure 1 Simulation-based training at Haydom Lutheran Hospital 2010–2021. HBB; Helping Babies Breathe, LDHF; low-dose high frequency training; Local Champions; dedicated midwives in charge of facilitation and motivation for one-site training in HBB 2nd Edition. Figure by Ingunn Anda Haug (Laerdal Medical).

Intervention

The Golden Minute Campaign started September 1st 2018 and remained through August 31st 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 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. Non-technical 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 1.5-2 hours and involved three participants and one local champion. Initiation the training, a short briefing with information about the scenario and the learning objectives were provided. Learning objectives were e.g., 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 following 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 in addition, they were encouraged to carry out individual skill-training four times per month. The NeoNatalie

Live simulator was available for all other healthcare workers, but the QI/simulation intervention was focusing on midwives since 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 recording 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.

Table 1 The Golden Minute Campaign; activities, responsible part, and participants.

Activity	Description	Responsible	Participants
Train-the-trainer simulation course to become simulation- "facilitator"	EU-sim 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 health care 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 three 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
Clinical debriefing after resuscitation	7-10 minutes 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)	Midwives, research assistant, other healthcare workers and physician involved in the resuscitation
Annual one-day-HBB course	One-day HBB course providing knowledge and skill training in newborn resuscitation.	HBB master trainers (midwives at Haydom who have conducted a one-day	Staff in the labor ward

		HBB Master Trainer Course) and local champions

QI= Quality Improvement, HBB=Helping Babies Breathe

In the 2-year post-intervention period, 01.09.19-31.08.21, 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 post-intervention period into two one-year periods, to study time trends.

Data collection and management

Trained research assistants, divided into three shifts over 24 hours covering the labor ward, observed and recorded information (labor and newborn characteristics, events and resuscitation interventions) on a data collection form 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 main outcomes were time from birth to first ventilation; proportion of 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.

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, as appropriate, and categorical data by percentages and numbers. The Kruskal Wallis test was used to test for differences over the periods in continuous variables; and the Chi-squared or Fishers exact tests, as appropriate, for categorical data. To test for differences between the periods in proportions of fatale outcomes, adjusted for risk factors, logistic regression was used. In all hypothesis tests a significance level of 0.05 was used. We used run charts to assess the main outcome measures; 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 due to the descriptive 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 prior to 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 <0.1% for the remaining variables.

More parturient women were admitted as referrals from health centers in the post-intervention period compared to 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).

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** Post intervention	**Period 4** Post intervention	**P-value**
	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)	2 913	3 291	3 142	3 332	
Admission from health center	5.9 (171)	6.4 (210)	7.6 (240)	7.6 (253)	0.010[b]
Mother no formal education	6.3 (184)	8.1 (267)	6.8 (214)	6.0 (199)	0.004[b]
Maternal age	26.4 ±6.8	26.3 ±6.7	26.5 ±6.9	26.4 ±6.6	0.889[c]
No antenatal care	1.0 (28)	1.1 (35)	1.5 (46)	1.7 (56)	0.038[b]
Antenatal problem	2.4 (69)	1.7 (57)	2.0 (62)	2.4 (81)	0.163[b]
Cervical dilatation on admission (cm)	5.9 ±2.6	5.9 ±2.6	5.8 ±2.6	6.3 ±2.3	<0.001[c]
10 cm cervical dilatation on admission	8.5 (214)	8.8 (247)	8.0 (210)	8.8 (242)	0.675[b]
Fetal heart rate on admission					0.051[b]
Normal (120-160 bpm)	93.2 (2 714)	94.0 (3 093)	93.3 (2 930)	92.4 (3 079)	
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[b]
Normal (120-160 bpm)	85.5 (2 491)	89.9 (2 959)	90.1 (2 830)	90.6 (3 018)	
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[c]
Mode of delivery					0.043[b]
Spontaneous vaginal delivery	75.0 (2 184)	72.0 (2 371)	74.2 (2 330)	73.0 (2 434)	
Caesarian 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[b]
Singleton	96.6 (2 814)	95.4 (3 140)	95.6 (3 005)	94.9 (3 163)	
Multiple	3.4 (99)	4.6 (151)	4.4 (137)	5.1 (169)	
Labor complications[d]	2.7 (80)	2.4 (79)	2.2 (69)	2.5 (82)	0.582[b]

Uterine rupture	0.1 (3)	0.1 (3)	0.2 (5)	0.1 (4)	0.872[b]
Pre-eclampsia	0.6 (17)	0.2 (6)	0.3 (10)	0.6 (21)	0.015[b]
Eclampsia	0.5 (14)	0.4 (12)	0.4 (14)	0.2 (6)	0.188[b]
Cord prolapse	0.5 (16)	0.9 (28)	0.7 (21)	0.8 (28)	0.443[b]
Prepartum bleeding	1.0 (29)	0.8 (26)	0.5 (17)	0.6 (20)	0.148[b]
Shoulder dystocia	0.1 (3)	0.2 (5)	0.1 (2)	0.2 (5)	0.719[e]

[a] Values are given as mean± SD or percentage (number).
[b] Chi-squared test.
[c] Kruskal-Wallis test.
[d] One or several labor complications.
[e] Fischer`s exact test.
FST= Frequent Skill Training

Throughout the study period, 4,474 (35%) newborns were stimulated to start breathing and 1,320 (10.4%) of these 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 post-intervention (Table 3).

Table 3. Resuscitation characteristics, newborn characteristics and perinatal outcomes (n=12 678)

	Period 1 Baseline FST	**Period 2** Golden Minute campaign	**Period 3** Post intervention	**Period 4** Post intervention	**P-value**
	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)	2 913	3 291	3 142	3 332	
Newborn characteristics					
Gestational age (week)	38.6 ±2.0	38.6 ±2.1	38.5 ±2.1	38.5 ±1.9	<0.001[b]
Preterm	4.1 (120)	4.8 (158)	5.1 (160)	5.4 (181)	0.105[c]
Birth weight (gram)	3 334.4 ±552.1	3 230.7 ±552.1	3 172.8 ±532.9	3 161.0 ±541.5	<0.001[b]
Birth weight categories (gram)					<0.001[c]
<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 (1 534)	59.8 (1 967)	63.2 (1 983)	63.2 (2 104)	
3500-4499	40.2 (1 169)	32.3 (1 062)	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 (2 728)	97.1 (3 194)	98.4 (3 092)	99.2 (3 307)	<0.001[c]
Bag mask resuscitator present	97.8 (2 849)	98.7 (3 246)	99.1 (3 114)	99.4 (3 311)	<0.001[c]
Stimulation	34.5 (1104)	40.4 (1 328)	37.2 (1 169)	26.2 (873)	<0.001[c]
Suction	28.1 (818)	31.4 (1 033)	31.4 (988)	23.6 (785)	<0.001[c]
Bag/mask ventilation	8.5 (248)	12.9 (426)	10.6 (333)	9.4 (313)	<0.001[c]
APGAR 1 min	8.5 ±1.4	8.3 ±1.5	8.3 ±1.5	8.4 ±1.5	<0.001[b]
APGAR 5 min	9.7 ±1.4	9.6 ±1.5	9.6 ±1.5	9.6 ± 1.5	<0.001[b]
Low APGAR 1 min (APGAR ≤7)	9.8 (284)	13.3 (439)	12.5 (395)	11.9 (396)	<0.001[c]
Low APGAR 5 min (APGAR ≤7)	4.2 (123)	6.1 (200)	5.6 (177)	5.6 (187)	0.010[c]
Perinatal outcome at 30 min					<0.001[c]
Normal	91.6 (2 667)	87.7 (2 886)	84.5 (2 654)	83.0 (2 766)	
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[d]					<0.001[c]

Normal	93.5 (2 720)	89.6 (2 904)	87.8 (2 715)	87 (2 856)	
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/30min/24h-mortality[e]	2.5 (72)	2.0 (65)	2.2 (68)	2.0 (65)	0.466[c]
Early Neonatal Mortality[f]	1.3 (38)	1.1 (35)	0.9 (29)	0.8 (25)	0.178[c]

[a] Values are given as mean± SD or percentage (number).
[b] Kruskal-Wallis test.
[c] Chi-square test.
[d] Fresh Stillbirth is reported for perinatal outcome at 30 min.
[e] Fresh Stillbirths, 30 min perinatal deaths and 24 h neonatal deaths.
[f] Early neonatal mortality (30 min perinatal deaths and 24 h neonatal deaths).
FST= Frequent skill training

Run chart of newborns ventilated within the golden minute

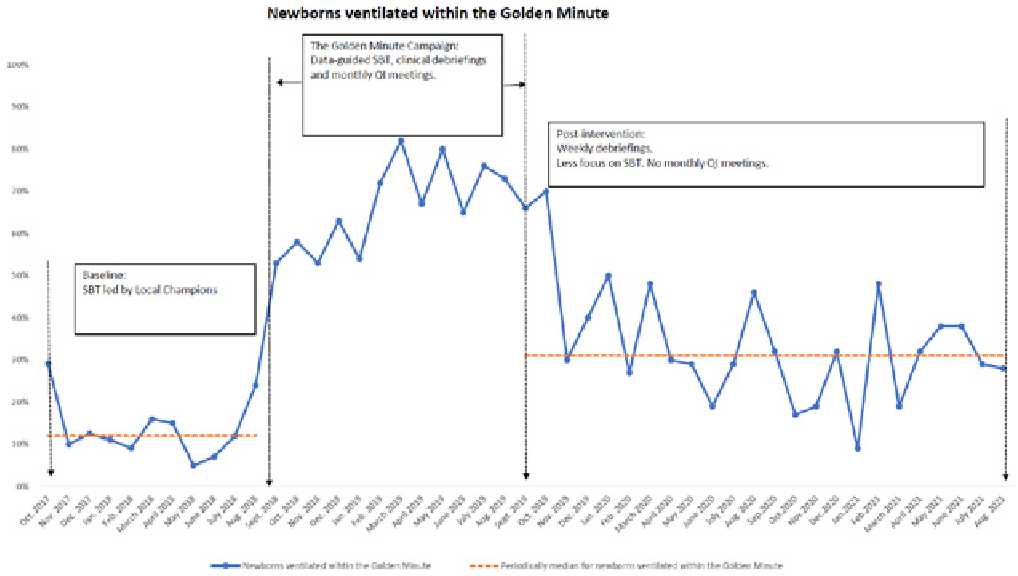


Figure 2: Newborns ventilated within the golden minute and median time from birth to ventilation

Run chart of median time from birth to start ventilation

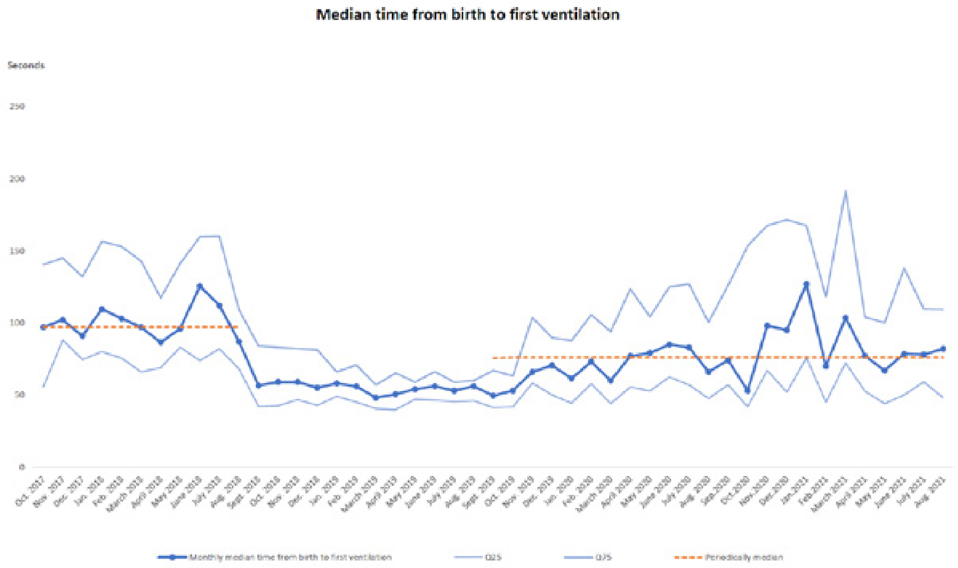


Figure 3: Run chart of median time from birth to start ventilation

The percentage of newborns ventilated within one minute and time from birth to first ventilation are presented in Figures 2 and 3. There is an increase in 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 post-intervention 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 post-intervention 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).

Table 4. Resuscitation characteristics of newborns receiving bag/mask ventilation (n= 1 320)

	Period 1 Baseline FST	**Period 2** Golden Minute campaign	**Period 3** Post intervention	**Period 4** Post intervention	**P-value**
	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[b]
Healthcare Worker trained with NeoNatalie last 7 days	64.7 (161)	44.6 (189)	6.7 (22)	5.8 (18)	<0.001[b]
Time from birth to start BMV (seconds)	101 (72-150)	55 (45-67)	67 (49-97)	85 (57-133)	<0.001[c]
BMV initiated within 60 seconds	15.8 (39)	68.5 (292)	42.2 (137)	28.9 (88)	<0.001[b]
Perinatal outcome at 30 min					<0.001[b]
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[b]
Neonatal outcome at 24h					<0.001[b]
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/30min/24h-mortality[d]	12.6 (31)	7.5 (32)	8.4 (28)	9.3 (29)	0.164[b]
ENM (30 min + 24 h-mortality)	9.3 (23)	6.9 (29)	6.7 (22)	6.6 (20)	0.564[b]

[a] Values are given as median (quartiles) or percentage (number).
[b] Chi-square test.
[c] Kruskal-Wallis test.
[d] Fresh Stillbirths, 30 min perinatal deaths and 24 h neonatal deaths.
FST= Frequent skill training
BMV = Bag mask ventilation
ENM=Early Neonatal Mortality

For the subgroup of newborns receiving BMV, proportions of fatale outcomes (24-hour newborn deaths and FSB) over the study period were, 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. After adjustment for source of admission, antenatal problem, premature/term, mode of delivery, and fetal heart rate during labor, the change was no longer statistically significant (p=0.111). FSB decreased significantly from 3.2%-0.7% (p=0.013) in the intervention period and remained significant after adjustment for the same variables as above (p=0.034).

There were no statistically significant changes in overall perinatal mortality (FSB and 24-hour newborn deaths), in unadjusted (p=0.468) or adjusted analyses (same variables as above; p=0.182).

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

Discussion

Following implementation of a QI/simulation intervention (i.e. the Golden Minute Campaign) at a rural hospital in Tanzania, the proportion of non-breathing newborns ventilated within the Golden Minute increased from 15.8 to 68.5 percent and median time from birth to first ventilation decreased by 46 seconds. During the post-intervention period, with less organized simulations, time to start ventilation increased and less 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 post-intervention. Among those being ventilated, FSB rate decreased from 3.2 percent in baseline to 0.7 percent 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 8 500 trainings, demonstrated a decrease in ventilation pauses and reduced time from birth to start ventilation(20). Still, time to start ventilation remained around two minutes. Frequent HBB trainings prior to 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 are 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 QI/simulation campaign to reach this goal. The large increase in newborns receiving ventilation within the Golden Minute during the QI/simulation campaign, demonstrates that it is possible to achieve guideline adherence even for such a challenging and time-critical procedure as newborn resuscitation in a resource limited setting, consistent with findings from Nepal(11). Given the study design, it is difficult to weight 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, was 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). The newborn resuscitation scenarios were carefully adjusted to address identified challenges in clinical care, and we believe 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 healthcare(27–30).

Furthermore, Figure 3 shows significantly less variation in time to start ventilation during the campaign compared to both baseline and post-intervention 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 Eu- Sim Level 1 course, prior to the Golden Minute Campaign, enabling them to provide high-quality training focusing on goal-oriented simulations in a safe learning environment. The dedicated and trained simulation facilitators/local champions were most likely a crucial factor for the present success in timely BMV. The importance of local champions when implementing changes in healthcare is well documented(31,32). 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 questions 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(10). However, the clinical importance of rapid onset of ventilation in a low-resecured setting has previously been demonstrated by Ersdal et al, documenting an increased risk of death or prolonged admission by 16% for every 30-second delay in initiating BMV(5). Interestingly, the present study reports a significant decline in classified FSB and a trend towards lower perinatal mortality concurrent with faster time to start BMV. Furthermore, we demonstrate that it is possible to start ventilation within 60 seconds for the majority of non-breathing newborns.

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

The QI efforts in our study took advantage of an already established research infrastructure 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.

The number of newborns being ventilated at Haydom is higher than what is expected in high-resourced settings(35,36). Even at baseline, a proportion of 8.5 percent is considered high, and the proportion increases to almost 13 percent during the Golden Minute Campaign. This is likely due to enhanced awareness and confidence among the healthcare workers(37), and directly linked to earlier onset of ventilation of non-breathing newborns. During baseline, median time to start BMV was around two minutes, compared to less than a minute during QI intervention. We cannot claim that no newborns were ventilated unnecessary, but the trained research assistants have many years of experience looking carefully for signs of spontaneous breathing. 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, and obstetric and newborn care, vary across settings, and the true proportion of non-breathing 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 to similar resource settings (11).

Two systematic reviews found no change in the use of stimulation and BMV following HBB implementation(8,35). However, several individual studies report increased frequency of BMV, and a reduction in unnecessary suctioning of non-breathing newborns(7,11,38). Suctioning of clear amniotic fluid in newborn resuscitation is no longer recommended in the 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 post-intervention period 98.2 percent of resuscitations were performed by midwives. This might reflect increased selfconfidence 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 post-intervention periods, only 5.8 to 6.7 percent of the healthcare workers providing BMV, had trained using NeoNatalie Live during the last 7 days before conducting a real resuscitation. Prior to the Golden Minute Campaign, in the baseline period, midwives had conducted nearly 8 500 individual skill-trainings encouraged by local champions(21). 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 towards 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 post-intervention, was not anticipated and might demonstrate the importance of local champions on a continuous basis to ensure frequent trainings(14,18,40). 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 percent in baseline to 0.7 percent during the Golden Minute Campaign. At the same time, there was a trend towards lower perinatal mortality, which was not statistically significant after adjustment. Importantly, perinatal outcome was a secondary outcome, and the study may lack statistical power to show a true difference for the given time period. Due to the increased number of non-breathing 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 for improved outcome for this patient group.

The main strengths of this study are the large population size and follow-up through the post-intervention 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, non-randomized, single-center design. All the simulation/QI interventions described are considered generalizable for 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 such learning methods, and this might have impacted their effective adoption of the simulation intervention. Settings with less experience in simulation practice might have achieved other results.

Conclusion

An HBB simulation-based QI intervention increased the proportion of non-breathing newborns ventilated within the Golden Minute by 4.5-fold, to 68.5 percent. Median time from birth to first ventilation decreased from 101 seconds to 55 seconds. Patient outcome improved, showing a reduction in FSB from 3.2 to 0.7 percent among those being ventilated, demonstrating the importance of timely BMV, especially for severely asphyxiated newborns. This study documents that it is possible to achieve adherence to newborn resuscitation guidelines during clinical care in low-resourced 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 can add valuable information in this regard and explore underlying reasons for the demonstrated changes.

Acknowledgments

The authors acknowledge the midwives working in labour ward at Haydom Lutheran Hospital and the Hospital Management team. We also acknowledge Ingunn Haug Anda, Laerdal Medical, for the illustration in Figure 1 and her valuable advice during the QI intervention.

Funding

This study was funded by the University of Stavanger, the Global Health and Vaccines Research (GLOBVAC) program at the Research Council of Norway (grant number 228203); Saving Lives at Birth Grand Challenges, and the Laerdal Foundation. The development of NeoNatalie Live received funding from Innovation Norway, the Research Council of Norway (228203) and Skattefunn (ES519418). The study was performed using simulation equipment provided by Laerdal Global Health. The funders had no role in the design of the study; in the collection, analyses, or interpretation of data; in the writing of the manuscript, or in the decision to publish the results.

Competing interests

No potential competing interest was reported by the authors.

Author contributions

Conceptualisation: MSV, HE, BH, SS, PMi, PMd and EM. Resources: PMd, BH, SS, PMi and PMd. Data curation: EM, HE and MSV. Data analysis: MSV, HE and JTK. Data interpretation: MSV, HE, JTK, EM and BH. Writing–original draft: MSV. Writing–review and editing: MSV, HE, JTK, EM, BH and BO. Guarantor: MSV. All authors approved the final manuscript.

Data availability statement

Data may be available upon reasonable request.

Ethics statements

Patient consent for publication: Not applicable.

Ethics approval

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 QI study design.

References

1. UN-IGME-child-mortality-report-2019.pdf [Internet]. [cited 2022 Aug 9]. Available from: https://www.unicef.org/media/60561/file/UN-IGME-child-mortality-report-2019.pdf

2. Indicator Metadata Registry Details [Internet]. [cited 2022 Oct 13]. Available from: https://www.who.int/data/gho/indicator-metadata-registry/imr-details/2444

3. Bhutta ZA, Das JK, Bahl R, Lawn JE, Salam RA, Paul VK, et al. Can available interventions end preventable deaths in mothers, newborn babies, and stillbirths, and at what cost? The Lancet. 2014 Jul 26;384(9940):347–70.

4. Neonatal Life Support: 2020 International Consensus on Cardiopulmonary Resuscitation and Emergency Cardiovascular Care Science With Treatment Recommendations [Internet]. [cited 2022 Aug 10]. Available from: https://www.ahajournals.org/doi/epub/10.1161/CIR.0000000000000895

5. Ersdal HL, Mduma E, Svensen E, Perlman JM. Early initiation of basic resuscitation interventions including face mask ventilation may reduce birth asphyxia related mortality in low-income countries: a prospective descriptive observational study. Resuscitation. 2012 Jul;83(7):869–73.

6. KC A, Peven K, Ameen S, Msemo G, Basnet O, Ruysen H, et al. Neonatal resuscitation: EN-BIRTH multi-country validation study. BMC Pregnancy Childbirth. 2021 Mar 26;21(Suppl 1):235.

7. Chaulagain DR, Malqvist M, Brunell O, Wrammert J, Basnet O, KC A. Performance of health workers on neonatal resuscitation care following scaled-up quality improvement interventions in public hospitals of Nepal - a prospective observational study. BMC Health Serv Res [Internet]. 2021 Apr 19 [cited 2021 Apr 28];21. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8054430/

8. Dol J, Campbell-Yeo M, Murphy GT, Aston M, McMillan D, Richardson B. The impact of the Helping Babies Survive program on neonatal outcomes and health provider skills: a systematic review. JBI Database System Rev Implement Rep. 2018 Mar;16(3):701–37.

9. Ersdal HL, Vossius C, Bayo E, Mduma E, Perlman J, Lippert A, et al. A one-day 'Helping Babies Breathe' course improves simulated performance but not clinical management of neonates. Resuscitation. 2013 Oct;84(10):1422–7.

10. Branche T, Perez M, Saugstad OD. The first golden minute — Is it relevant? Resuscitation. 2020 Nov;156:284–5.

11. Kc A, Wrammert J, Clark RB, Ewald U, Vitrakoti R, Chaudhary P, et al. Reducing Perinatal Mortality in Nepal Using Helping Babies Breathe. Pediatrics [Internet]. 2016 Jun 1 [cited 2021 Feb 25];137(6). Available from: https://pediatrics.aappublications.org/content/137/6/e20150117

12. Helping Babies Breathe [Internet]. AAP.org. [cited 2021 Feb 25]. Available from: http://www.aap.org/en-us/advocacy-and-policy/aap-health-initiatives/helping-babies-survive/Pages/Helping-Babies-Breathe.aspx

13. WHO launches the second edition of Essential Newborn Care Course (interim version) for field testing [Internet]. [cited 2022 Sep 30]. Available from: https://www.who.int/news/item/11-04-2022-who-launches-the-second-edition-of-essential-newborn-care-course-(interim-version)-for-field-testing

14. Morris SM, Fratt EM, Rodriguez J, Ruman A, Wibecan L, Nelson BD. Implementation of the Helping Babies Breathe Training Program: A Systematic Review. Pediatrics [Internet]. 2020 Sep 1 [cited 2021 Feb 25];146(3). Available from: https://pediatrics.aappublications.org/content/146/3/e20193938

15. Msemo G, Massawe A, Mmbando D, Rusibamayila N, Manji K, Kidanto HL, et al. Newborn Mortality and Fresh Stillbirth Rates in Tanzania After Helping Babies Breathe Training. Pediatrics. 2013 Feb 1;131(2):e353–60.

16. Mduma E, Kvaløy JT, Soreide E, Svensen E, Mdoe P, Perlman J, et al. Frequent refresher training on newborn resuscitation and potential impact on perinatal outcome over time in a rural Tanzanian hospital: an observational study. BMJ Open [Internet]. 2019 Sep 27 [cited 2021 Feb 22];9(9). Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6773328/

17. Kamath-Rayne B, Thukral A, Visick M, Schoen E, Amick E, Deorari A, et al. Helping Babies Breathe, Second Edition: A Model for Strengthening Educational Programs to Increase Global Newborn Survival. Global Health: Science and Practice. 2018 Oct 3;6:538–51.

18. Mduma E, Ersdal H, Svensen E, Kidanto H, Auestad B, Perlman J. Frequent brief on-site simulation training and reduction in 24-h neonatal mortality--an educational intervention study. Resuscitation. 2015 Aug;93:1–7.

19. Haynes J, Bjorland P, Gomo Ø, Ushakova A, Rettedal S, Perlman J, et al. Novel Neonatal Simulator Provides High-Fidelity Ventilation Training Comparable to Real-Life Newborn Ventilation. Children (Basel). 2021 Oct 19;8(10):940.

20. Vadla MS, Moshiro R, Mdoe P, Eilevstjønn J, Kvaløy JT, Hhoki BH, et al. Newborn resuscitation simulation training and changes in clinical performance and perinatal outcomes: a clinical observational study of 10,481 births. Adv Simul. 2022 Nov 5;7(1):38.

21. Vadla MS, Mdoe P, Moshiro R, Haug IA, Gomo Ø, Kvaløy JT, et al. Neonatal Resuscitation Skill-Training Using a New Neonatal Simulator, Facilitated by Local Motivators: Two-Year Prospective Observational Study of 9000 Trainings. Children. 2022 Feb;9(2):134.

22. Courses [Internet]. EuSim. [cited 2022 Sep 1]. Available from: https://eusim.org/courses/

23. Author AS. Liveborn by LGH [Internet]. AppAdvice. [cited 2022 Aug 4]. Available from: https://appadvice.com/app/liveborn/1358257827

24. Ajmi SC, Advani R, Fjetland L, Kurz KD, Lindner T, Qvindesland SA, et al. Reducing door-to-needle times in stroke thrombolysis to 13 min through protocol revision and simulation training: a quality improvement project in a Norwegian stroke centre. BMJ Qual Saf. 2019 Nov;28(11):939–48.

25. Tahtali D, Bohmann F, Kurka N, Rostek P, Todorova-Rudolph A, Buchkremer M, et al. Implementation of stroke teams and simulation training shortened process times in a regional stroke network—A network-wide prospective trial. PLoS One. 2017 Dec 5;12(12):e0188231.

26. Theilen U, Fraser L, Jones P, Leonard P, Simpson D. Regular in-situ simulation training of paediatric Medical Emergency Team leads to sustained improvements in hospital response to deteriorating patients, improved outcomes in intensive care and financial savings. Resuscitation. 2017 Jun 1;115:61–7.

27. Hill JE, Stephani AM, Sapple P, Clegg AJ. The effectiveness of continuous quality improvement for developing professional practice and improving health care outcomes: a systematic review. Implementation Sci. 2020 Dec;15(1):1–14.

28. Ivers NM, Grimshaw JM, Jamtvedt G, Flottorp S, O'Brien MA, French SD, et al. Growing Literature, Stagnant Science? Systematic Review, Meta-Regression and Cumulative Analysis of Audit and Feedback Interventions in Health Care. J Gen Intern Med. 2014 Nov;29(11):1534–41.

29. Brown B, Gude WT, Blakeman T, van der Veer SN, Ivers N, Francis JJ, et al. Clinical Performance Feedback Intervention Theory (CP-FIT): a new theory for designing, implementing, and evaluating feedback in health care based on a systematic review and meta-synthesis of qualitative research. Implementation Sci. 2019 Dec;14(1):40.

30. Braddock CH, Szaflarski N, Forsey L, Abel L, Hernandez-Boussard T, Morton J. The TRANSFORM Patient Safety Project: A Microsystem Approach to Improving Outcomes on Inpatient Units. J Gen Intern Med. 2015 Apr;30(4):425–33.

31. Hall AM, Flodgren GM, Richmond HL, Welsh S, Thompson JY, Furlong BM, et al. Champions for improved adherence to guidelines in long-term care homes: a systematic review. Implement Sci Commun. 2021 Aug 3;2(1):85.

32. Soo S, Berta W, Baker GR. Role of champions in the implementation of patient safety practice change. Healthc Q. 2009;12 Spec No Patient:123–8.

33. Kaplan HC, Brady PW, Dritz MC, Hooper DK, Linam WM, Froehle CM, et al. The Influence of Context on Quality Improvement Success in Health Care: A Systematic Review of the Literature. Milbank Q. 2010 Dec;88(4):500–59.

34. Wardhani V, Utarini A, van Dijk JP, Post D, Groothoff JW. Determinants of quality management systems implementation in hospitals. Health Policy. 2009 Mar;89(3):239–51.

35. Budhathoki SS, Gurung R, Ewald U, Thapa J, Kc A. Does the Helping Babies Breathe Programme impact on neonatal resuscitation care practices? Results from systematic review and meta-analysis. Acta Paediatrica. 2019;108(5):806–13.

36. Bjorland PA, Øymar K, Ersdal HL, Rettedal SI. Incidence of newborn resuscitative interventions at birth and short-term outcomes: a regional population-based study. BMJ Paediatr Open. 2019 Dec 29;3(1):e000592.

37. Nelissen E, Ersdal H, Mduma E, Evjen-Olsen B, Broerse J, van Roosmalen J, et al. Helping Mothers Survive Bleeding After Birth: retention of knowledge, skills, and confidence nine months after obstetric simulation-based training. BMC Pregnancy Childbirth. 2015 Aug 25;15(1):190.

38. Arabi AME, Ibrahim SA, Manar AR, Abdalla MS, Ahmed SE, Dempsey EP, et al. Perinatal outcomes following Helping Babies Breathe training and regular peer–peer skills practice among village midwives in Sudan. Arch Dis Child. 2018 Jan;103(1):24–7.

39. Fawke J, Wyllie J, Udaeta E, Rüdiger M, Ersdal H, Wright MD, et al. Suctioning of clear amniotic fluid at birth: A systematic review. Resuscitation Plus. 2022 Aug 17;12.

40. KC A, Wrammert J, Nelin V, Clark RB, Ewald U, Peterson S, et al. Evaluation of Helping Babies Breathe Quality Improvement Cycle (HBB-QIC) on retention of neonatal resuscitation skills six months after training in Nepal. BMC Pediatr [Internet]. 2017 Apr 11 [cited 2021 Feb 25];17. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5387236/

41. Dawes GS, Jacobson HN, Mott JC, Shelley HJ, Stafford A. The treatment of asphyxiated, mature foetal lambs and rhesus monkeys with intravenous glucose and sodium carbonate. J Physiol. 1963 Nov;169(1):167–84.

42. Moshiro R, Mdoe P, Perlman JM. A Global View of Neonatal Asphyxia and Resuscitation. Front Pediatr. 2019 Nov 26;7:489.