Optimizing Helping Babies Breathe implementation in a resource limited setting to improve perinatal outcome

by

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Dedication:

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Abbreviations

AAP	American academy for pediatric
APGAR	Appearance, pulse, grimace, activity and respiration
BA	Birth asyphixia
BAB	Bleeding after birth
BCG	Bacille calmette-guérin
BMV	Bag mask ventilation
CQI	Continuous quality improvement
CUSUM	Cumulative sum
CS	Cesarean section
CI	Confidence interval
COI	Conflict of interest
EBP	Evidence based practice
END	Early neonatal death
ENM	Early neonatal mortality
EmONC	Emergency obstetric and newborn care
ePMR	Early perinatal mortality rate
EM	Estomih Mduma
FBOS	Frequent brief on-site simulation
FHR	Fetal heart rate

Abbreviations

FSB	Fresh stillbirth
GCP	Good clinical practice
HBB	Helping babies breathes
HCW	Health care worker
HDLF	High-dose low-frequency
HE	Hege Ersdal
HGHRC	Haydom global health research centre
HLH	Haydom Lutheran hospital
HMS	Helping mothers survive
LMIC	Low and middle income countries
LDHF	Low-dose high-frequency
MDG	Millenium development goals
MoH	Ministry of health
NIMR	National institute for medical research
PDSA	Plan do study act
PPH	Postpartum hemorrhage
PI	Principal investigator
RCHS	Reproductive and child health service
RCT	Randomized control trial
RR	Relative risks

Abbreviations

SDG	Sustainable development goals
SPC	Statistical process control
SOP	Standard operating procedures
SPSS	Statistical package for social sciences
UFS	Utstain formula for survival
UNICEF	United nations children fund
UNFPA	United nations funds for population activities
VLAD	Variable-life adjusted display
WHO	World health organization
WMA	World medical association

Definitions of key terms:

Birth asphyxia (WHO): Failure to initiate and sustain breathing at birth

Continuous quality improvement: the extent to which continuous health care services are provided to individuals and patient populations to meet improved desired health outcome

Early neonatal mortality: (in this PhD thesis) death occuring immediately after birth (the first 24hours following delivery)

Early perinatal mortality (ePMR): (In this PhD thesis) Fetal and/or neonatal death occurring after the onset of labor (FSB) through the first 24 hours of life

Fresh stillbirth: a baby born dead without signs of skin disintegration (death occurs mostly less than 12hrs prior to birth)

Macerated stillbirth: a baby born dead with skin disintegration (death assumed to occur more than 12hrs prior to birth)

Neonatal period: period from birth to 28 days of life

Perinatal mortality (WHO): Death at 22 completed weeks (154 days) of gestation and ends seven completed days after birth

Stillbirth: is a term used to express a fetus born with no signs of life, where the demise has occurred before the initiation of labor i.e. macerated stillbirth (MSB), or during labor before birth i.e. FSB

Summary:

Background:

Globally, deaths around the time of birth are unacceptably high of which there are about 2.7 million neonatal deaths and 2.6 million stillborn annually. Perinatal mortality accounts for deaths after 28 weeks of gestation to seven days after birth. Perinatal mortality is a public health concern with a huge impact on the health, social and economic well being affecting both family and society. The burden of perinatal mortality is obvious in the low and middle-income countries, and more on the countries south of sub-Sahara Africa. East Africa being among the sub-Sahara countries is also experiencing a high rate of perinatal mortally, with Tanzania taking the lead. Almost half of stillborns are alive at the start of labor offering an opportunity for prevention. Likewise, 44% of the neonatal deaths occur on the first day of life and are predominantly the result of intrapartum events. Events during labor, including birth asphyxia (interruption of placental blood flow) account for one-quarter of the global newborn deaths. These deaths can be substantially reduced by improving quality of care around the time of labor and childbirth. The Helping Babies Breathe (HBB) curriculum, involves training to improve knowledge and skills of midwives and other birth attendants, to provide improved basic care to new-borns including timely breathing support and as a consequence to improve newborn survival as needed. It became apparent the course did not alter outcome following one day training i.e. improve survival. This pointed to the need for more frequent training. Thus the concept of frequent brief onsite simulation (FBOS) HBB training was introduced at Haydom Lutheran Hospital as part of continuous quality improvement (CQI), in an effort to reduce perinatal mortality. This became the central thrust of this thesis as described below.

Aim: The aim of this thesis is to evaluate the process and impact for optimizing implementation of HBB project to improve early perinatal

outcome at Haydom Lutheran Hospital, a rural referral hospital in north-central in Tanzania.

Method: We conducted three studies between February 2011 and January 2017 to evaluate the process and impact of HBB project to improve early perinatal outcome. The study site was labor ward and operating theatre at Haydom Lutheran hospital. The study intervention involved implementation of FBOS training using a low fidelity manikin with the ability to provide bag/mask ventilation and feel a pulse on different simulation scenarios and also having repeated feedback.

Study I was a one-year project from February 2011 through January 2012 that involved FBOS. This was a before-after prospective education intervention study in a cohort of midwives (birth attendants), pregnant women attending to give birth and their newborns. The labor management process and outcomes of birth in the first 24hrs were evaluated. The outcome of pregnancy (n=4814) was compared to a baseline period (n=4894), which was also a one-year period between February 2010 through January 2011. Secondary outcomes included care provider change in behavior i.e. frequency in resuscitation practice, labor management which involved, fetal heart rate monitoring, mode of delivery and resuscitation practice.

Study II was a five years follow-up from February 2011 through January 2016. Perinatal outcome during the study period was compared to the baseline period as in study I (Feb. 2010 through Jan 2011). The study involved continuous observation to trace and document perinatal outcomes over time and evaluate the implementation process. The cohort involved 22,176 newborns and compared the outcome to the baseline (n=4894). Factors included in the analysis involved those with potential co-relationship with perinatal outcomes as interventions, administrative events and facility process.

Study III was also a continuous observation to trace and document perinatal outcomes as in study II. The cohort involved a total of 31122

newborns of which intervention period was for six years from Feb 2011 through Jan 2017 with 26220 newborns and one year of baseline period (Feb 2010 through Jan 2011). Logistic regression modeling was used to construct risk-adjusted variable-life adjusted display (VLAD) and cumulative sum (CUSUM) plots to monitor changes in perinatal survival (primary outcome). Plots of unadjusted changes in perinatal risks were compared to risks adjusted plots.

Results: In Study I, There was a significant reduction in early neonatal mortality rate (eNMR) from 11.1/1000 during baseline to 7.2/1000 (p0.040) after implementation of FBOS HBB training. During the period, the proportion of resuscitation through stimulation increased from 14.5% to 16.3% (p 0.016), and suction increased from 13.0% to 15.8% ($p \leq 0.0005$) while the proportion receiving bag-mask ventilation (BMV) decreased from 7.3% to 5.9% ($p \leq 0.005$) in Cohort 1 versus Cohort 2, respectively.

In study II, the CUSUM plot in most of the period was lower than the baseline level of 2.7% with slight variation on ePMR months indicating reduction after implementation of FBOS HBB training. In the VLAD plot there was a continuous upward trend on cumulative monthly number of lives saved compared to baseline, with few fluctuations indicating that the outcome (perinatal survival) was better than in the baseline. The trend indicated continuous improvement in perinatal outcome during the five years follow-up period. The trend of outcomes had some variations in some point, which could be linked with different interventions and events of which improvement in survival linked refresher HBB training and reduced survival linked trained midwifes leaving the hospital and new recruited who have not attended FBOS HBB training. The VLAD plot showed an overall positive trend, reflecting more than 120 extra lives saved over the 5-year period.

In study III, Persistent and steady increase in perinatal survival was observed following implementation of FBOS HBB training. Six years

follow-up revealed 150 extra lives saved according to VLAD plot. After adjusting for the risk factors VLAD plot indicated that an estimated 250 extra lives were saved which indicate that survival was maintained even when the cohort included high risks cases indicating a further improvement in survival compared to when the risks were not considered.

Conclusion: This PhD project show that optimizing the implementation of FBOS simulation training is associated with improvement on clinical practice and neonatal survival. This is the first published report that documented the important association of FBOS and reduce neonatal mortality. During the CQI, continuous evaluation in the SPC revealed that the improvement in perinatal outcome matched with the activities related to FBOS training. Additionally, the reduction on perinatal mortality was even more evident when adjusting for risks in the cohort. To conclude, optimizing implementation of HBB training has the potential to improve perinatal outcome.

Publications included:

The basis for this thesis is on the below published study articles:

Paper I.

Mduma E, Ersdal H, Svensen E, Hussein K, Bjorn A, Perlman J. **Frequent brief on-site simulation training and reduction in 24-h neonatal mortality-An education intervention study**. Resuscitation 2015; 93: 1-7. doi: 10.1016/j.resuscitation.2015.04.019

Paper II.

Mduma E, Ersdal H, Kvaloy J, Svensen E, Mdoe P, Perlman J, Kidanto H, Soreide E; **Using statistical process control methods to trace small changes in perinatal mortality after a training program in a low-resource setting.** International Journal for Quality in Health Care, Volume 30, Issue 4, 1 May 2018, doi. 10.1093/intqhc/mzy003

Paper III.

Mduma E, Kvaløy J, Søreide E, Svensen E, Mdoe P, Perlman J, Johnson C, Kidanto H, Ersdal H. **Frequent refresher training on new-born resuscitation and potential impact on perinatal outcome over time in a rural Tanzanian hospital - An observational study**. Sep 2019, BMJ open, 2019;0:e030572. doi: 10.1136/bmjopen-2019-030572

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1 Introduction

1.1 The burden of perinatal mortality, globally

Loss of life on the day of birth is still common worldwide with huge inequities in perinatal mortality and morbidity between countries [1,2]. Globally, an estimated 136 million newborns are born every year [3]. The perinatal period is thought to be the most vulnerable period during life [4-6]. Childbirth is regarded as a normal physiological, social and cultural process but it is prone to complications, which may lead to demise of the fetus or the newborn. Perinatal mortality is defined by WHO as fetal and/or newborn death occurring from 22 weeks (154 days) post conception to the end of first week of life [7]. In this thesis we define early perinatal mortality (ePMR) as a fetal and/or neonatal death occurring after the onset of labor (fresh stillbirth (FSB)) through the first 24 hours of life. Stillbirth is a term used to express a fetus born with no signs of life, where the demise has occurred before the initiation of labor i.e. macerated stillbirth (MSB), or during labor before birth i.e. FSB. Stillbirths represent a health burden that has not received enough global attention [4]. Neonatal deaths involve life lost within the first-month period after birth. Neonatal deaths happening within one week after birth, is part of perinatal deaths. About 60-70 percent of neonatal deaths are estimated to occur within the first 24 hours of life [8-11], defined as early neonatal deaths (END) in this thesis.

Globally, an estimated 2.7 million neonatal deaths and 2.6 million macerated and FSB, occur annually [2, 12-14]. These rates of stillbirths and neonatal deaths are unacceptably high, with more than 80% occurring in low and middle-income countries (LMIC) [5, 15-28]. Approximately 50 per cent of these deaths occur in Sub-Saharan Africa, where the demand of health-services overweighs the services available

[29,30]. A meta-analysis by Akombi et al. [30], who reviewed demographic and health surveys on perinatal mortality in Sub-Saharan Africa, found that Tanzania has the highest rate of perinatal mortality in the Eastern African countries. Kidanto et al also reported high perinatal mortality rates in Tanzania [31]. Furthermore, Baqui et al [32] report in a study on neonatal mortality in six LMIC including Tanzania, that 65.5% of neonatal deaths occurred within 24 hours of birth in Tanzania. A sub-group of perinatal mortality involves deaths that occur around the time of birth i.e. ePMR which includes FSB and END. The course leading to both FSB and END are often related to the process of interruption of placental blood flow, referred to asphyxia [17-24]. Many of the asphyxia-related END in resource-limited countries have been misclassified as FSB [33]. This highlights the complexity of the problem particularly as it relates to prevention.

1.1.1 Causes of Perinatal Mortality

Approximately 1.3 million FSB and 1 million newborn deaths occur in relation to birth [16]. Events during labor, including interruption of placental blood flow (birth asphyxia), account for one-quarter of the global newborn deaths [25]. This translates to approximately 44% of the END that occur on the first day of life, [1, 12,34]. Birth Asphyxia (BA) is a process of failed oxygen delivery, leading to hypoxia and often the inability to initiate breathing at birth [35]. The WHO defines BA as failure to initiate and sustain breathing at birth [36]. BA invariably results from impairment of umbilical cord circulation due to compression, early placenta separation or/and strong continuous uterus contractions during labor. At birth, BA presents clinically as: an apneic, flaccid and pale/cyanotic neonate [37].

Other common causes of death immediately after birth include prematurity (< 37 gestational weeks) complications, and infections, [1, 15, 20, 38]. There are also indirect factors that contribute to perinatal mortality, e.g. factors related to the capacity of the health facilities

where births are taking place; the skills of midwives/birth attendants and lack of required medical supplies to intervene during life threatening conditions [30, 31, 39-41].

1.2 Global efforts to reduce perinatal mortality

In 2000, leaders from 189 countries met and signed a millennium declaration agreement. The agreement consisted of eight Millennium Development Goals (MDG) where goal number 4 was focused on a reduction in the under-five years mortality by two-third by the year 2015 [42]. The effort to reduce under-five mortality has been shown to be successful, with the global mortality numbers having declined from 12.6 million in 1990 to 5.6 million in 2016. This represents an average reduction from 35,000 to 15,000 deaths per day [14, 43]. However, this success was not reflected in the neonatal mortality. Thus, neonatal deaths (deaths during the first month) contributed to 41% of the under-five mortality in 2000 and 46% in 2016 [23, 27,28]. Importantly Stillbirths are not included in the MDG 4.

In 2015, global leaders held a meeting at the United Nation's headquarter and agreed on developing and implementing Sustainable Development Goals (SDG): "The 2030 agenda for sustainable development" [28]. The SDG replaced and aim to sustain the success resulted from the MDG, and also in addition set new universal goals. Thus the SDG include 17 goals with 169 targets, building on the MDG. Among the 17 goals, goal number 3 targets ensuring healthy life and promotes well-being for all ages, while goal number 3.2 focuses on reducing neonatal mortality to at least to as low as 12 per 1000 live births. Among all the goals, none mentioned stillbirths and consequently no targets were set. However, in 2014, the "Every Newborn Action Plan", published by WHO [18], targeted to end all preventable newborn deaths and set a target to reduce stillbirths to ≤ 10

per 1000 by the year 2035. These early perinatal deaths can be substantially reduced by improving quality of care around the time of labor and childbirth [44].

Tanzania met the MDG 4 on the reduction of under-five mortality, but Neonatal Mortality Rate (NMR) remained unacceptably high. In 2015, the country's NMR was 25 per 1,000 live births, which represents about 40,000 newborn deaths annually [45,46]. This NMR is double the SDG target 3.2 for 2030, which is ≤12 deaths per 1000 live births. The stillbirth rate was estimated as 20 deaths per 1000 births, which is double the set target of ≤ 10 per 1000 set by WHO (2014) [44]

1.3 Interventions to reduce perinatal mortality

1.3.1. Improving quality of care

Most of the deaths from BA are preventable with low cost interventions. Improving health care delivery and safety is a global priority at all levels, from the Government (Health Ministry) extending to the communities [47]. The successful life serving effort in clinical care greatly depends on the provision of good quality care. The latter is a complex concept, and is often dependent on a combination of several strategies from multiple disciplines. WHO define quality of care as "the extent to which health care services provided to individuals and patient populations improve desired health outcomes". In order to achieve this, health care must be safe, effective, timely, efficient, equitable and "people-centered" [48]. Multiple efforts are required in order to improve outcomes. The effort depends on a well-established clinical knowledge, the capacity of care providers, and an environment that facilitates provision of good care.

1.3.2 Continuous quality improvement (CQI)

CQI is a useful approach to improve health services through identifying gaps/challenges, and follow-up, by implementing and monitoring resolutions [49]. Different methods of CQI have been found to improve practices, resulting in improvement of health services [50,51]. Around 1990's, CQI started to be used widely and is considered valuable in improving the quality of health service delivery [52-55].

The Plan-Do-Study-Act (PDSA) model is among the most fundamental approaches in CQI programs, and is widely used for improving health service [55-59]. Chaney et al [60] found that in CQI, PDSA was the most frequently used approach to improve health service outcomes. In 28 RCTs, 12 used PDSA as method for CQI [61-70]. In one systematic review, training was also outlined as an important component in CQI [59]. Moreover, training lasting a short time period (some hours), coupled with feedback meetings to discuss implementation of improvement services, was found to be significantly beneficial [66,71,72]

Figure 1. Plan-do-study-act cycle. Freely available from Internet [www.plan-do-study-act cycle]

In life-threatening patient situations with impairment of breathing, resuscitation is urgently required to save lives. The International Liaison Committee on Resuscitation (ILCOR) develops consensus on science treatment recommendations for different resuscitation situations to improve quality of care. ILCOR publishes new treatment recommendations every five years [73], and these updates serve as inputs to different resuscitation guidelines around the world, for example guidelines for newborn resuscitation contained in the Helping Babies Breathe curriculum [74, 75].

In 2003, there was a consensus meeting in the historic Utstein Abbey, Norway. During the meeting there was a discussion on the relationship between scientific evidence (e.g. resuscitation guidelines), education and local implementation and patient outcomes. They developed a

hypothetical formula for survival, which outlined a strategy to facilitate better outcomes after resuscitation. The hypothetical formula; the "Utstein Formula for Survival" (UFS) presents three inter-related factors to affect outcome; guideline quality (science), efficient education of patient caregivers (education) and a well-functioning "chain of survival" at a local level (local implementation)" [76, 77].

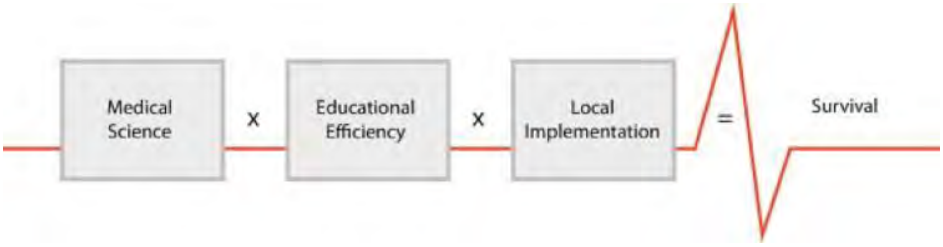


Figure 2: The formula of survival in resuscitation. (Utstein formula for survival) Reprinted from Resuscitation 2013.127 Copyright

The UFS outlines that better survival outcome depend on three interrelated factors [76,77]. The first factor, "science" depends on the current available best evidence knowledge on intervention and translated into a functioning guideline, which is continually updated as new knowledge is available (e.g. through the ILCOR process). The existing science needs to have potential benefits, which includes the evidence that when effectively applied will yield the most beneficial outcome. The second factor, efficient "education" involves a well-developed curriculum for training. An efficient education curriculum when well utilized will equip the care provider with the required knowledge and skills. Lastly, the local "implementation" third factor incorporates the strategies to facilitate effective implementation of the guideline (translation of knowledge and skills to clinical practice). A

combination of the three factors (science, efficient education and local implementation) will influence patient outcomes.

1.3.3 Learning theories, knowledge and adult learning

Learning is an active process to acquire new knowledge, skills and attitude by being taught, through research, and experience. Further, learning is described as a process of putting together different experiences being cognitive, emotion and environment to attain, improve or changes on one's knowledge, skills, behavior and values. Learning has been described in several theories of which the common are three; behaviorism theory of which new or change in behavior are acquired through association of stimuli and response [78]; cognitivism theory that learning happen through internal processing, and constructivism theory which state that learning is built step-by step and frequently change as individually continually interact with surrounding [79]. Development of the theories goes back to the last two centuries by the work of Piaget J. [80] and Pavlov I. [81].

Knowledge is knowing the facts, information, and/or skills, and is defined by the Cambridge English dictionary [82] as the "awareness, understanding or information that has been obtained by experience or study, and that is either in a person's mind or possessed by people generally". The process for gaining knowledge usually takes place over time. Knowledge is often acquired primarily during the first time of learning. On some occasions knowledge is gained secondarily, and this is when the current knowledge replaces the already existing knowledge. Secondary knowledge is most common in adult learning (andragogy).

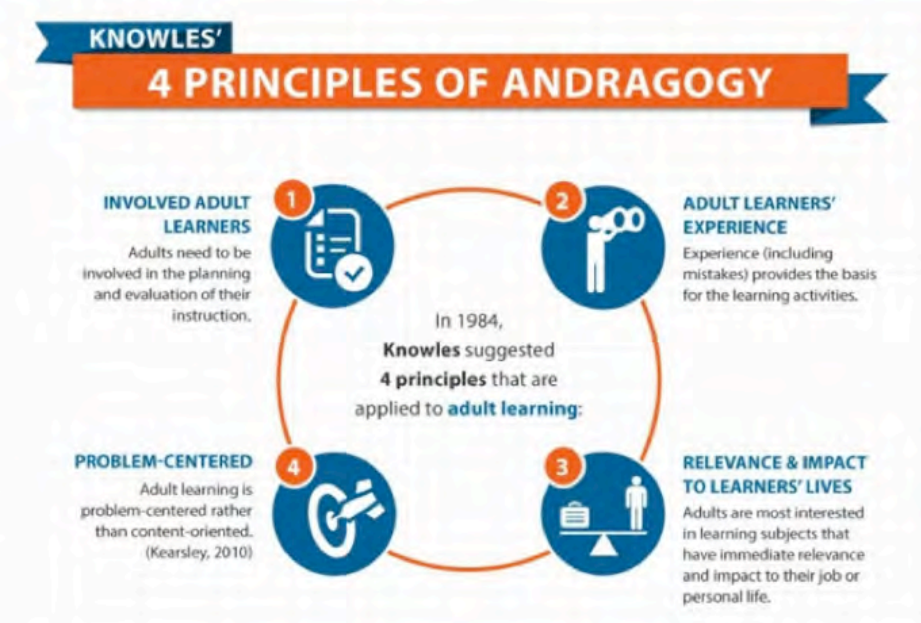


Figure 3A. Andragogy 4 principles of adult learning, freely available from internet [https://elearninginfographics.com/adult-learning-theory-andragogy-infographic/]

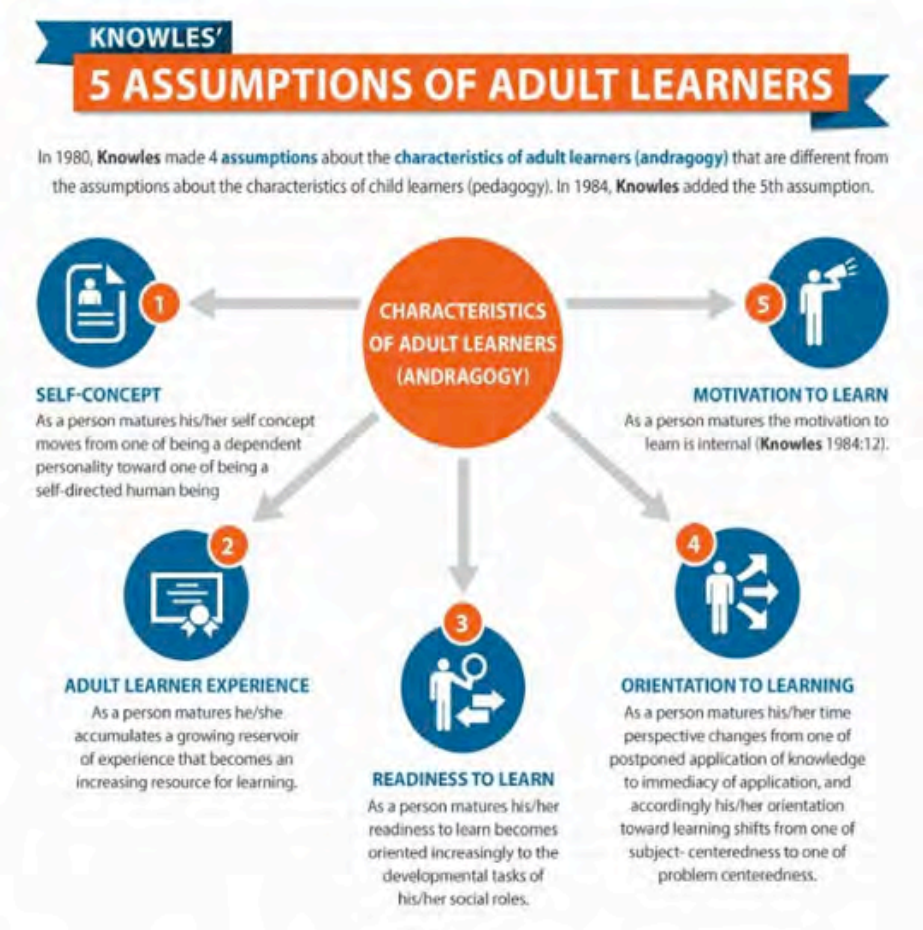


Figure 3B. Andragogy 5 assumptions of learning, freely available from internet [https://elearninginfographics.com/adult-learning-theory-andragogy-infographic/].

The concept of knowledge is also self-centered, often aiming to address issues that a learner is concerned about, thus making the learning motivation centered to the learner. Gaining knowledge takes place through a process, and usually the gain in knowledge increases with time [83]. Knowledge cannot be complete without being ascertained and/or applied. Knowledge is embedded in "ability", and the ability is what is revealed by the truth of the available knowledge and also observed to prove its existence, which is also pointed out by Hacker

[83]. Hacker [83] also point out “Knowledge ‘knowing’ is dynamic and can change due to what has been recently discovered.

Adult learning has been explained as the process of acquiring new knowledge to replace existing knowledge [84]. Adult learning can be challenging when learning aims to replace existing knowledge, and acquires some level of trust. Adult learning (andragogy) is different from the learning of children and youth (pedagogy)[85]. The difference in learning approaches has been explained by Merriam et al [86] and Knowles [87]. Adult learning is mostly goal-oriented or centered on problem solving, and learners actively take responsibility for their own learning processes, e.g. during clinical practice [86,88]. Adult learning is broad and grouped into several theories as behavioral theories [89], self-determination theory [90,91], motivation to learn, context and social factors [92], self-directed learning [93], the value expectancy theory [94], reflective learning [95], and the role of deliberate practice [96]. Learning is strengthened by three stimulus elements which includes: 1) frequency (the number of times the stimulus is presented); 2) continuity (the time between the stimulus and response); and 3) contingency (the continued link between the stimulus and the response) [97,98].

According to Kolb’s scheme [99], an adult learner has a concrete experience, which they reflect upon, followed by abstract conceptualization and active experimentation. Thus the experiential learning model is considered more ideal for training.

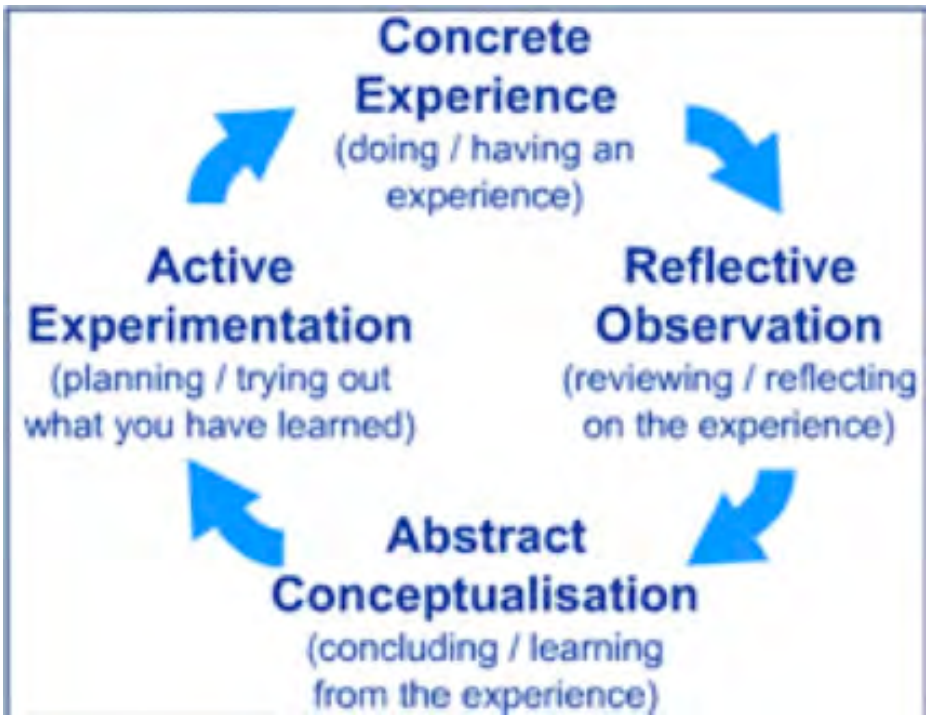


Figure 4: Kolb`s experiential learning cycle, (Modified from Kolb, D.A Experiential learning: experience as the source of learning and development. Ref. McLeod, S. A. (2017, Oct 24). Retrieved from [https://www.simplypsychology.org/learning-kolb.html]

1.3.4 Training of health staff

Health staff training is performed to equip the health staff with required competence to care for the individual. Care provision is accomplished in different dimensions, related to prevention of illness, care of patients with treatable illness, and care of patients with incurable illness. The purpose of training is to make health staff competent in provision of services. To fulfill the goal of establishing competence there are

different approaches used in different settings, both during pre-service and post-training or in-service training [100]. In-service training often contributes in building competence as it commonly focuses on specific clinical need(s). Additionally, during in-service training, the trainees have already been exposed to clinical work and have some level of experience. The knowledge acquired during pre-service training, and the experience during work periods usually builds confidence among health staff related to their competence in care provision. The increased competence, with an enhanced body of knowledge, should stimulate better services. During in-service training, to further improve competence by enhancing or replacing existing knowledge/skills with new discoveries, there is often a resistance from the trainee to change as pointed out by Hacker [83]; "…the greater the emotional investment in beliefs or practices, the greater the disturbance caused by efforts to change them". Different barriers for not changing clinical practice following a training are not well described and understood, and it is important that efforts are made to better understand these barriers and find ways to mitigate them [102].

1.3.5 Simulation training for health staff

Simulation is a way to mimic a real situation to enable a more conducive way of training and/or evaluation of a situation [103]. Initially, simulation was instituted in high risks professions such as aviation. In principal, simulation is used in a situation when it is not possible or convenient to learn or acquire enough skills in the real situation and in settings where real situations doesn't appear frequently enough to get enough practice. There are different reasons that favors simulation training such as ethical, financial and risks to the patient [104-106]

The history of simulation goes back to several centuries, and in the last century (1922) Edward Link in the United States presented his homemade flight simulator [107]. Later simulation advanced to involve

other industrial areas, and later in health care. In the 1950s, Peter Safar from Baltimore was involved in medical simulation in an effort to improve resuscitation performance [108]. In the 1960s, the Norwegian Bjorn Lind and colleagues shared the idea of developing a simulator for cardio-pulmonary resuscitation to Asmund Laerdal who was manufacturing toys. The effort resulted in the development of Resusci-Anne by the Laerdal Company to support training and skill acquisition for cardio-pulmonary resuscitation [108].

Training of health staff was challenged by ineffective and inefficient approaches to equip professionals with required skills, especially in resuscitation [109]. It is documented that lack of required skills after inadequate training is a leading cause for preventable adverse events, including deaths [109,110]. Williams et al [111] demonstrated the potential of simulation to paramedics training and simulation was rated as a valuable learning experience and credited for better academic performance.

Simulation provides an ideal environment for frequent and continuous practicing, for trainees to acquire ability and retain the competence acquired. The goal of health staff simulation training is to attain competence, which may be determined by the level of fidelity and realism [112]. Introduction and innovation of simulation training aimed to improve the practical health training without inconvenience to patients [108]. With time there have been advancement in the simulation field and development of mannequin-based simulators has also advanced [113,114]. Among the added advantage of simulation training is to be able to simulate rare clinical conditions, and allow the trainee to observe, learn and practice. Simulation provides an opportunity to practice frequently as individuals or in a team/group setting, since it does not involve use of patients. During the learning process the trainee can make mistakes and learn from the mistakes to continually improve skills and build competence to improve care in clinical practice [112]. To have successful simulation training, the

simulator must have the ability to replicate the major cognitive operations of the real-world, and support psychological fidelity [115]. Simulation training education has further developed, and has facilitated competence through effective acquisition of knowledge, skills, experience and attitude, to enhance growth of clinical skills [116]. Ongoing simulation training with feedback stimulates deliberate practice and reflection [117]. More information that are related to health simulation evolution has been presented by Grenvik and Schaefer [113].

Simulation training was recently introduced to LMIC. Simulations in such settings commonly require robust and easy to operate technologies, which are relatively less expensive and affordable in the settings [118,119]. The usefulness of simulation to improve care has resulted in an increased use and wider acceptance [120].

Simulation by itself has no ability to facilitate competence. Rather, the success depends on how the trainer and the trainees will properly and adequately use the opportunity to build competence. Additionally, despite advances in simulator the ability to achieve complete realism in simulation is almost impossible [121].

1.3.6 Implementation of new practices

Implementation is a method to promote and/or ensure the systematic uptake of research (new) findings and other evidence-based knowledge into routine practice [122]. Implementation aims to improve the quality and effectiveness of health services and care [123]. Closing the gap between best evidence practice and existing clinical practice has the potential to improve health outcomes [124,125]. To make new discoveries and knowledge meaningful, must translate into improving health care service. The findings from clinical and health services studies cannot change population health outcomes unless health care

systems, organizations, and professionals adopt them into practice [125,126]. Unfortunately, the process of implementing evidence-based practices is often complex and fraught with challenges [126,127]. There have been gaps between evidence-based practices from research findings and the routine clinical practice of healthcare professionals [128,129]. A wide range of factors can influence the clinical practice of healthcare professionals [130]. Many efforts to implement programs designed to improve the quality and outcomes of human services have not reached their full potential, due to a variety of challenges inherent in the implementation process. Implementation of innovative human service technologies is generally considered to be more complex than implementation of other types of technology, due to the fact that human service technologies are delivered through the actions of individuals and organizations, which exist within complex, multiple social contexts [127,131]. Dewey et al [132] and Glisson et al [133] also use the terms "creature of habit" and "resistance to change" to describe humans in general and physicians. Several inefficiencies in health-care delivery result from overuse of unnecessary services underuse of beneficial interventions, or medical errors [134,135].

Multiple factors may influence individual motivational predispositions to change. However, our understanding of those factors and optimal approaches to change healthcare professional practice is incomplete since it has to go through a complex process. In a systematic review by Greenhalgh et al. [136], it was found that "individuals are not passive receiver of innovation rather (and to a greater or lesser extent in different persons) they seek innovations, experiment with them, evaluate them to find (or fail to find) meaning. Later, individuals develop feeling (positive or negative) about them and challenge them. Resulting effect may result in worries about them, and/or complain about them, 'work around' them and gaining experience with them, often through a dialogue with other users to most" [137].

In effort to close the gap between scientific discoveries and implementation, guidelines are developed to help care providers. Clinical practice guidelines can be defined as “systematically developed statements to assist practitioners’ decisions about appropriate health care for specific clinical circumstances” [138]. However, the use of guidelines during implementation is frequently reported as being uncertain [136,139] where non-adherence may result in misdiagnosis and mismanagement [140]. Poor adherence to guidelines is reported to result to about 30%–40% of patients not receiving appropriate treatment, and 20%–25% receive unnecessary or potentially harmful treatment [139,141,142]. However, there is a belief that well planned implementation can improve adherence to guidelines [143]. To ensure effective implementation and adherence to guidelines, there is a need to scrutinize and plan strategies. Among others, strategies have to consider the environment, level of knowledge and attitude of implementers to be able to adopt changes. To facilitate this process, it is important to involve local stakeholders to overcome barriers and increase the chances for effective guideline implementation. Kotter JP [144] explains that for a successful change to occur three processes are necessary. First, there is a need to have a team of competent trainers who will take the lead in training team members, Second, there needs to be communication amongst team members (shared mental model) and third an effective feedback process (debriefing) is necessary to discuss successes and failures. Lewin [145] also explains the process that potentially results in change described as "Lewin's 3-Stage Model of Change: Unfreezing, Changing & Refreezing."

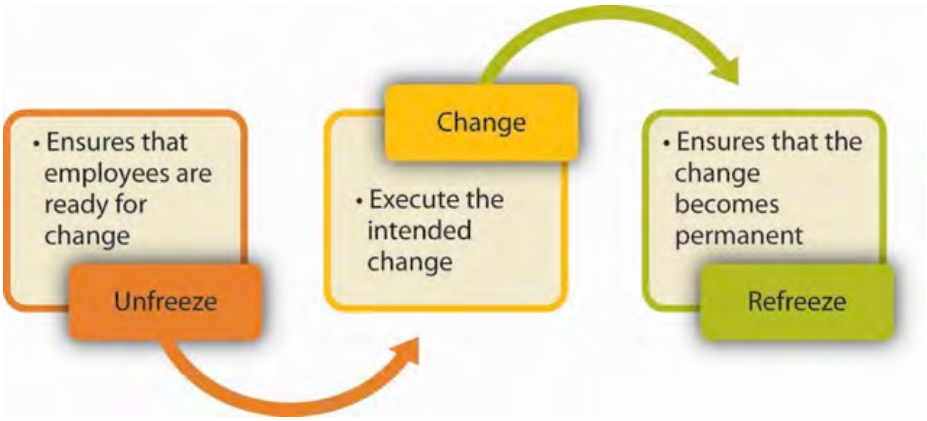


Figure 5: Lewin's three-stages process of change-planning and executing change (Kurt Lewin). [Ref. "Lewin's 3-Stage Model of Change: Unfreezing, Changing & Refreezing." Study.com, 11 September 2012, study.com/academy/lesson/lewins-3-stage-model-of-change-unfreezing-changing-refreezing.html]

1.4 Evaluating effects of educational programs

Educational programs aim at improving performance and patient outcomes through improving the knowledge and skills of providers. To be certain that an educational program meets the expectation, there is a need to have a plan to facilitate evaluation in different levels of implementation. In practice, the common levels included are those related to the training and learning and those related to influencing practice and outcomes. Immediately after training, it is common to assess the level of acceptance and relevance of the course among the participants, and if there is a gain in knowledge and skills at the end of the training compared to before the training. Further evaluation of changes in clinical management, tries to assess if those who attended the training have changed their practice following the training, compared to before the training, sometime termed as behavior change. Finally, if there is a described behavior change, it is valuable to evaluate how this may influence patient outcomes.

There are several models and tools used for evaluation of training. A commonly used framework is the Kirkpatrick model, which has been used to evaluate the effectiveness of education programs for decades. [146]. The evaluation involves four steps (or levels). The first level evaluates the reaction of the participants towards the training, assess acceptability, relevance and if they liked the course. This evaluation is feasible shortly after the course, and helps the instructor to learn if the course has been acceptable to the participant, which can help in planning future courses. Positive evaluations at this "level one" do not guarantee if the learning process has been successful, but it is important to motivate the participant to continue participating. Evaluation on the second level is whether learning has happened, and this can be assessed in different ways, for example conducting a pre- and post-course tests where the result in pre-test can be compared to the post-test evaluation, and to determine whether there is a gain in knowledge and skills. The third level evaluates potential changes in practice, e.g. if health staff change (improve) their performance in an area (clinics, delivery room) where the new skills are intended to improve performance. This evaluation commonly takes time, is more complex, and can be expensive. Level four evaluation, relates to the impact of the learning into the workplace, e.g. if the course in the delivery room results in a favourable outcome i.e. improvement in survival.

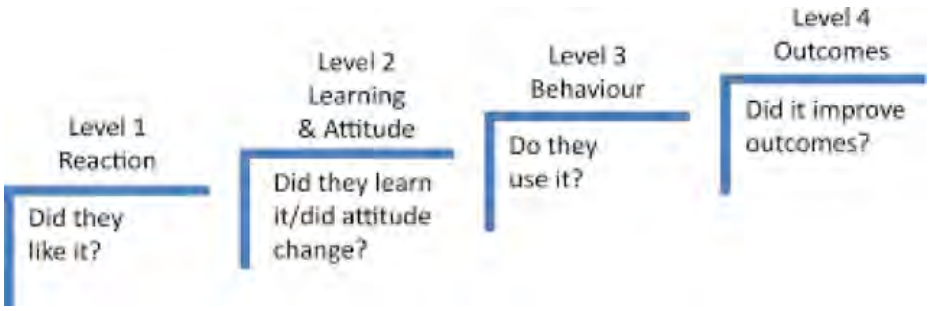


Figure 6: Kirkpatrick four level of evaluation of training. Freely available from internet.

1.5 Statistical Process Control

Statistical process control (SPC) is the use of statistic techniques to monitor a process [147]. A common tool in SPC is the control chart, which was developed by Walter Shewhart in the early 1920s [147]. The chart was mostly used in industries to monitor production. It was olso used during the Second World War by the United States Army to monitor and control the quality of munitions and other important products. [148]. SPC is usually presented in a chart format, where the outcome of the process can be visualized. The charts are made by continuous data plots, showing a trend, which can reveal unusual or undesired outcome deviations, being high or low compared to the expected baseline outcome. In health care, the application and further development of SPC methods spread to several areas to monitor quality of care [149].

1.5.1 Use of Statistical Process Control in health research

A cumulative sum (CUSUM) chart is a particular form of SPC, which is well suited for detecting smaller but persistent changes in a process over

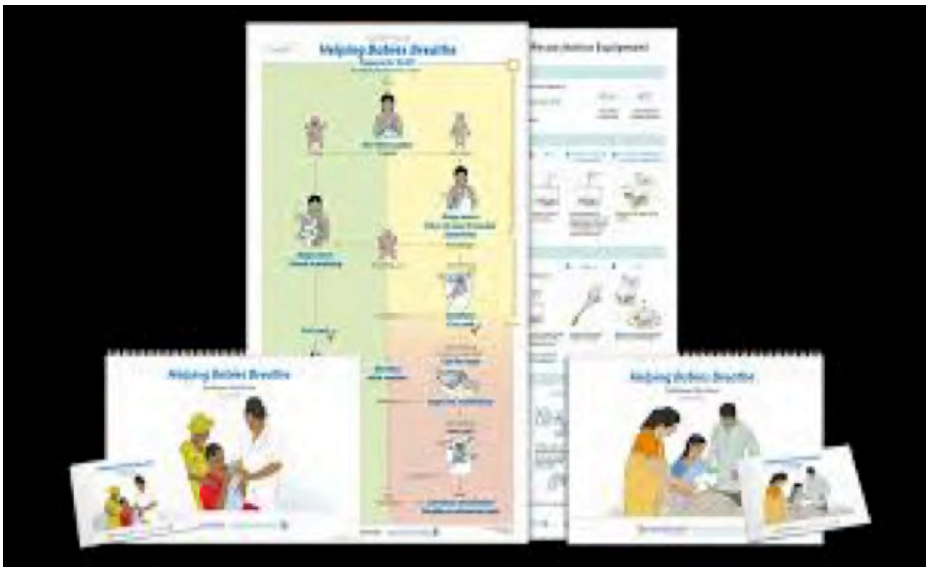
time. CUSUM charts have proven to be a valuable tool for medical and health care applications. CUSUM-based methods have been used to monitor hospital performance, such as disease outbreak, birth defects, and surgical performance [150]. Further, it has been used to monitor healthcare quality associated with rare health conditions [151]. Using CUSUM charting to continuously monitor outcomes in a labor ward would therefore appear logical and constitute a simple quality improvement tool to help detect negative trends, on a monthly basis, and provoke timely responses. In addition to the CUSUM chart, an accompanying plot of cumulative number of lives saved, called variable life-adjusted display (VLAD) [152] is often used. VLAD is shown to complement the CUSUM plots by enhancing interpretation and illustrating the impact of interventions. Further, to have a more valid explanation of varying health conditions in a population, medical processes and patient outcomes, risks-adjustment analyses have an important role [153,154].

1.6 Helping Babies Breathe (HBB) simulation training

Globally, there have been long-standing diverse efforts to improve patient outcomes, of which training of providers has been among the leading ones. However, training efforts has not met the desired patient outcomes in low resource settings [155]. In 1997 the WHO, UNICEF and United Nations Funds for Population Activities (UNFPA) introduced an initiative focused on emergency obstetric and newborn care (EmONC). The initiative aimed to reduce maternal and neonatal mortality related to the time around birth through facilitating the delivery of evidence-based services [156]. This effort resulted in innovative practical, basic, low-cost, low-tech simulation-based trainings. The HBB program was the first to be implemented and followed by Helping babies survive (HBS) and Helping Mothers Survive (HMS) [157].

Helping Babies Breathe (HBB) is an evidence-based simulation education program. The program is developed with the goal of enabling birth attendants to acquire basic knowledge skills and attitudes in resuscitation of newborns, and other basic care. The American Academy of Pediatrics (AAP) developed the program with global partners [158]. The program is intended for use in LMIC where skilled health staff and equipment are limited. The program aims to capacitate birth attendants to provide breathing support when needed and improve survival. Much time during HBB training is allocated to simulate different resuscitation scenarios to enhance the birth attendant's capacity to properly use a bag-mask resuscitator and to provide effective ventilation/breathing support when needed.

The educational material required to facilitate training includes a learner workbook, a facilitator flip chart, an action plan, and a low-cost newborn simulator (NeoNatalie^{TM}). The HBB program was first tested in Tanzania in a pilot program, [159] and thereafter rolled out to 80 countries, with more than 850,000 birth attendants trained [160-162]



Picture 1: HBB training tools (flip chart, learner book etc), American Academy of Pediatric. Freely available from internet [www.HBB training tools]

In most countries, the course has been associated with reduction in early perinatal mortality, i.e. FSB and END [163-167]. The main concern accompanying implementation of HBB globally have been associated with an inability to translate training into clinical competence. Thus in some cases there has been no impact on perinatal mortality as well as a falloff in retention of skills over time [164,165,168-171,173]. A systematic review by Reisman et al. [161], found that in up to 50% of the studies they analyzed, there was a significant decline in skills over time. The precise time when the decline happens is not well established, and is likely multifactorial [150,170,173].

Positive effects of training on mortality have also been reported by Msemo et al and Kc et al. [159, 165]. Kc et al [165] reported trainning a cohort of hospital workers at a tertiary hospital in Nepal using a CQI approach. They found a significant reduction in perinatal deaths before and after implementation, i.e. perinatal mortality decreased from 30.9/1000 to 23.3/1000 births.

HBB has expanded to include the HBS program. The program also includes Essential Care for Small Babies, and Improving Care Babies and helping mothers survive (HMS.) The program is designed to continue improving newborn care and reduce neonatal mortality [162].

1.6.1 Implementation of HBB in Tanzania

1.6.1.1 Tanzania as a country

Tanzania an African country was formed by union of two countries, Tanganyika (termed as mainland) and Zanzibar (islands). In 1964, the countries united to form the " The United Republic of Tanzania". Geographically, Tanzania coverage is 940,000 square kilometers and is the largest country in Eastern Africa. The country lies south of the equator and shares borders with eight countries: Kenya and Uganda (to the North); Rwanda, Burundi, the Democratic Republic of Congo, and Zambia (to the West); Malawi and Mozambique (to the South). On the eastern part the country is bordering the Indian Ocean. Administratively, Tanzania is divided into 30 regions (25 in mainland, and 5 in Zanzibar). Each region is subdivided into several districts. In the year 2012 the population was 44.9 million. High fertility rate and declining mortality levels was the factor associated with high population growth rate. According to the 2012 census, the life expectancy at birth was 62 years. The population has continued to be predominantly rural despite the increase in the proportion of urban residents over-time from 6% in 1967 to 30% in 2012. The population is sparse in most of the areas with high density in few urban areas. The average population density (2012) was 51 per square kilometer. The government set strategies to transform the country and improve economy and better living. Several priories were outlined in the 5 years strategic plan (2011/12-2015/16), to be achieved. Some of the priorities were in the health sector and targeted to ensure that basic health services are available, accessible and with improved quality. The

strategic plan included efforts to reduce maternal mortality from 578 to 193 deaths per 100,000 live births in 2030 and to reduce neonatal mortality from 32 to 19 deaths per 1,000 live births. This information is according to the 2015-16 demographic and health survey report [45], the period that accounts for most of the time in this PhD project.

1.6.1.2 Tanzania health system

Tanzania health system comprises of health facilities at different levels in "hierarchical health system" (figure 7), which align with the political-administrative hierarchy [http://www.mof.go.tz/mofdocs/overarch/Vision2025.pdf]. At the lower tier, at the community level are the facilities that provide primary health care, and focus at preventives and management of minor illnesses. The facilities in this group starting from the lowest level are termed; community health care where a community health worker visits the households, dispensaries which serves a catchment population of about 6,000-10,000 and health centers which are referral points for dispensaries and serves a catchment population of about 50,000. Service providers in the primary facilities are mostly those in the level of certificates and diplomas. The next group levels includes the facilities with more advanced health care and are the referral points from the facilities providing primary health care. The facilities in this group starting from the lower to highest level are; district hospitals, which serves approximately 100,000-200,000 population and the service providers, are in the lever of diploma and first-degree e.g. Medical doctors. Regional referral hospital serves a catchment of approximately 1 Million. Service providers in the regional level are as those in the district hospitals with an additions of medical specialist is some area, mostly pediatrics, obstetric and gynecology, surgery and medicine. Zonal referral hospitals are referral point for the regions hospitals. The staffing for a zonal referral hospital includes a wide

range of medical specialists additional to those in reginal hospitals e.g. ophthalmologists, radiologist, cardiologists, dermatologists and urologists. On top is the National referral hospital, which is a point of referral for all zonal hospitals, and comprise a big group of highly experienced medical specialist and super specialties in multiple areas. There are also other facilities with some specialized levels that may not directly fit well in this hierarchy system.

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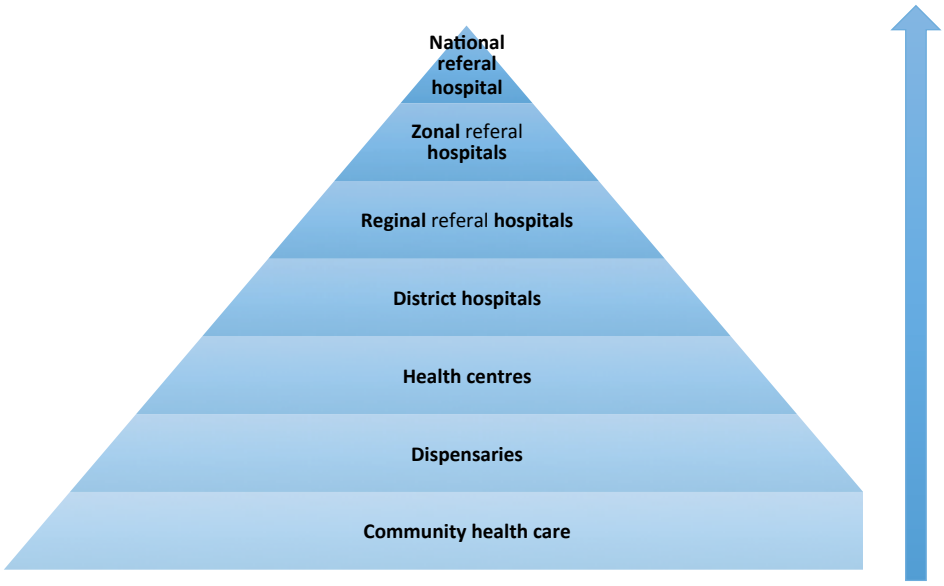


Figure 7. Healthy system hierarchy in Tanzania. The arrow indicates the direction of referrals from the bottom to the top. (figure by Estomih Mduma)

1.6.1.3 HBB project in Tanzania

Globally, HBB was initially piloted in Tanzania, (from 2009) and involved eight hospitals in a before-after study design. Among the eight hospitals, three were at referral hospitals (national and zonal); four were

regional referral hospitals, and one (HLH) in district hospital level. Seven of these hospitals (except HLH) were affiliated with health universities with teaching capacity. Baseline data was collected for two months in each study site. The Ministry of Health (MoH) identified potential national master trainers (40) for rolling out the HBB curriculum. The master trainers were trained for two days and visited all of the eight sites in the country including HLH to train midwives and other birth attendants. The training lasted for one day for each group of trainees [159]. Evaluation of the course impact following one year after implementation showed a 47 % reduction in early neonatal mortality (< 24 hours)($p < 0.0001$) and a 24% in FSB rates ($p < 0.0001$), pre versus post course implementation respectively. [159].

1.6.2 Implementation of HBB in the project site – HLH

HLH comprised of two groups, each attending one day training "High-dose low-frequency" (HDLF). HDLF is the implementation that involved intensive one day (high dose) training with less follow-up training over time. Evaluation seven months post course (HDLF), revealed that skills and performance were maintained and even improved when tested using the NeoNatalie^{TM} simulator. Thus there was a significant increase in a "neonatal resuscitation scenario" from 18% prior HBB training to 74% post training ($p \leq 0.0001$). For a second scenario "proper mask positioning" there was a mean improvement by 41% comparing prior to post training. However, there was no improvement in observed clinical management, and even reduced performance in the delivery rooms (Kirkpatrick level 3). The number of newborns stimulated pre compared to post training, significantly decreased from 17.7% to 14.1% ($p < 0.0001$), respectively, while the number of those suctioned and BMV remained almost the same pre versus post HBB training. The number of midwives/BA who reported to

be confident in resuscitating newborns significantly decreased from 74% to 19% pre versus post training (p = 0.001) [169]. This finding necessitated a review to improve the local implementation process so as to improve clinical practice and hopefully patient outcomes.

Picture 2: Map of Tanzania and surrounding countries and location of study site-Haydom. Picture reprinted from the Internet free source

1.7 Statement of the problem and rationale of this PhD project

BA is a leading cause of early perinatal mortality, which has also been observed in the setting for this thesis [35]. Most newborns initiate spontaneous respirations or require minimal support such as stimulation following delivery. However, about 8- 10 % fail to initiate spontaneous breathing despite stimulation and/or gentle suctioning [174]. For those who fail to initiate spontaneous-breathing, appropriate evaluation, resuscitation skills and timely actions are required to restore respirations and save lives. An effort to reduce neonatal mortality, one of the leading causes of deaths in LMIC, has not been uniformly successive [12,26,34,169,175]. It was recognized that newly born infants who failed to initiate respirations had delayed interventions, which was often associated with mortality and those who survived with hypoxic ischemic brain injury.

In response to this critical need, HBB was developed as a means to equip midwives and birth attendants with the knowledge and skills to care for newborn, in particular those failing to initiate spontaneous breathing. A two days HBB training was conducted by National master trainers at HLH in early 2010, to two groups, (each attending a one day training) [159]. However, during evaluation seven months later, there were no observed changes in clinical practice and perinatal outcome (see above) [169]. We speculate that failure to improve clinical practice at HLH was a result of missing continuous practice after HBB training. This dilemma necessitated fostering a local HBB implementation process.

2 Theory

The overall aim of this PhD work was to implement frequent brief on-site (FBOS) HBB simulation training to optimize HBB implementation and to study potential changes in clinical practice and perinatal outcomes over time in a low-resource setting

2.1 Hypotheses:

1. Optimizing the implementation process of HBB through FBOS training will decrease 24-hour newborn mortality (Study I).

2. CQI efforts including FBOS HBB training will facilitate improvement of midwives' practice and continuously improve perinatal survival over time (Study II).

3. CQI including FBOS HBB training will facilitate improvement of perinatal survival even when with an increase in high-risk deliveries over time (Study III).

2.2 Specific objectives

1. To assess the impact of FBOS HBB training on 24-hour newborn mortality (Study I).

2. To document the implementation process of CQI with FBOS HBB training and changes in early perinatal survival over time, and describe other interventions and activities that may impact perinatal outcome (Study II).

3. To document changes in perinatal survival over time during implementation of CQI efforts including FBOS HBB training while adjusting for maternal and perinatal risk-factors (Study III).

2.3 Study questions

1. Does optimizing the HBB implementation process by introducing FBOS training result in reduction of 24-hour newborn mortality?

2. Does using SPC facilitate tracing and documentation of changes in perinatal survival over time?

3. Does CQI efforts with focus on FBOS HBB training improve perinatal survival even with a higher-risk population over time?

3 Methodology

3.1 Study design and study population

All three studies in this thesis followed a before-after intervention observational study design - a prospective study. Baseline data was used as a control period and interventions following baseline data collection as the comparison period, and the findings were compared to baseline to describe differences between the two periods.

The predominant population attending to the HLH is of low social-economic status, scattered in a wide catchment area [177,178]. Participants in all of the three studies contained in this thesis were laboring women admitted at HLH to give birth and their newborns. Health staffs involved in deliveries at HLH were also participants and midwives accounted for the majority of the providers. Laboring women were admitted directly from home due to their willingness to give birth at HLH while others were referred from other health facilities due to anticipated birth complications.

3.2 Study setting

All the three studies were conducted at HLH, a regional referral hospital level. HLH is located in a small town in a rural remote area called Haydom. Haydom town has a population of about 20,000. Haydom is within Mbulu district, which is among the 4 districts in Manyara region. Manyara region, is one of the 30 regions in Tanzania and is located in northern-central part of the country. HLH serves the population of 4 regions and 7 districts. During the study period, HLH was the only hospital with the capacity of a regional referral hospital level in the region. The surrounding hospitals and other health facilities

were referring complicated cases, which were beyond their capacities, to HLH. HLH served an immediate catchment population of about 500,000 for primary health services and was a referral hospital for a large catchment of about two million people widely located [179]. The population at Haydom was also widely spread, and ground transportation was the only mean of local population to access the hospital. Roads from all directions were rough and most of them in bad condition, worse during the wet rainy season.

3.3 Haydom Lutheran Hospital

3.3.1 General information about the hospital

HLH is a non-governmental, faith-based institution owned by the Lutheran church. In 2011, services offered by HLH catered for outpatients, in-patients and mobile clinics, and the statistics in this paragraph refer to the period of 2011 [180]. Services offered at HLH are divided into 8 divisions, including; reproductive and child health service (RCHS), medical, surgical, outpatient, pharmacy, medical and technical divisional services. Within the surgical department there are three theatres where operative procedures take place including cesarean sections. HLH has 420 beds, which were used for patients admitted for medical services (in-patients). A total of 16744 patients were admitted during the period. Outpatient services offer day-time medical service for 72484 patients, with an average of 200-250 per day. In total, 30,108 pregnant women and 83,610 children under five years of age attended the RCHS. In the labor ward, a total of 5464 (about 15 per day) deliveries took place, of which 600 (11%) were cesarean sections. The hospital offers mobile health services to 29 mobile clinics. Each clinic is visited once in every month. The mobile clinics are within a radius of about 100 kilometers from HLH. Health staff transport to the clinics is by car on poor roads and by a small-charted airplane for those located in a very distant area. External donors support the mobile clinic

services. The mobile services focus on maternal and child health and included antenatal care, vaccination, weight measurement, health check of children under five years, family planning, and health education. Management for minor health conditions are performed. However serious and high-risk cases are referred to HLH or nearby health facilities for expertise services.

HLH staffing comprised of about 700 staff with different expertise (medical and non-medical). Among the medical staff, about 35 were midwives working in the maternity ward [35]. There were three general medical practitioners who worked intermittently in the labor word. In 2013 a specialist in obstetrics and gynecology and more general medical practitioners were recruited.

3.3.2 Labor Ward

The labor ward and different activities changed over time during the study period. Initially, the labor ward consisted of one large delivery room with three beds separated by curtains. Two years later, the labor ward was expanded to have two additional delivery rooms. In 2013, a new extended labor ward was opened with six individual delivery rooms, each with one delivery bed and a small table for newborn resuscitation, located in the corner. Additional space included rooms for; admission procedures, equipment sterilization, storage for linen, and equipment sluice for equipment cleaning. There was a central open space for multiple uses such as a midwives station, a reception for women attending to give birth and for brief small group meetings and trainings. The ward offered comprehensive obstetric care and basic newborn care 24 hours/seven days a week [181]. The midwives worked in three shifts over 24 hours, and doctors were available during daytime. During the nighttime and holidays doctors were available onsite and upon request when there was a difficult labor. About 3-5 midwives worked in each shift, and one midwife was always allocated to the neonatal area (see below). There were also “ward attendants”

with no medical background who helped in cleaning the rooms and assisted midwives during delivery. There were nurse students from the Haydom school of nursing who worked in the ward as part of their clinical training. Haydom school of nursing was located within the hospital compound. All activities related to giving birth were supervised and coordinated by midwives. Their activities included management of labor and birth, caring for the newborns, consulting doctors when necessary, and accompanying parturient women to operating theatre for caesarean sections.

3.3.3 Neonatal and Postnatal Area

There was one neonatal area/unit, where severely sick newborns were admitted. During initiation of the study-period (2009), the neonatal unit consisted of two small rooms. One room was used as a nurse station and storage space, and the other as a ward for neonatal admissions. The admission room had one long bench where several neonates were placed next to each other. In 2016 the unit was expanded and improved to have three rooms, two were used for admitted sick neonates (aseptic and septic), and the remaining room was used as a nurse station and storage space for equipment. The ward-rooms were equipped with emergency medicines, including oxygen. There was a small heater situated in the ward-rooms for warming when required. Staffing included one nurse who was responsible for management and supervision in the unit, one “ward attendant” who helped with cleaning and other non-medical activities. Doctors usually visited the unit once a day (during ward round) during the regular five workdays. The visit was to review the admitted newborns, their progress and instruct on further care/management. Additionally, after the routine ward round, doctor visited the room upon request and this also included during the weekend and public holidays. Occasionally, student nurses also worked in the unit as part of their clinical training.

There is a postnatal area (three rooms) close to the labor ward. This is the area where women after giving birth (mothers) and their newborn with no series illness are observed. Among the three rooms, one room is used for Kangaroo mother care for premature newborns. Mothers are observed for excessive post delivery bleeding, and any signs of infection and/or other illness. Childhood vaccinations are offered to newborns, and at this time point included BCG vaccination for prevention of severe Tuberculosis infection and oral polio drops for prevention of Polio infection. Additionally, health education on newborn care including feeding (lactation) is provided. As routine, after 24 hours of observation health assessment was conducted (mothers and newborns) and those with no illness were given permission to leave the hospital (discharged). Mothers or newborn found with any illness continued with medical care and observations. During discharge, mothers are scheduled to return for newborn growth assessment and vaccination, and also advised to return at any time with any health concern.

3.3.4 Haydom Global Health Research Center

The research center department was established a few months before initiation of this PhD project, in 2009. The center “Haydom Global Health Research Center” (HGHRC) was relatively well-equipped with required facilities for collection and management of data. During the project period several other local and international collaborative research projects took place. The center consists of several sections and subsections to facilitate smoothly and effective management of research projects. The sections (and subsections) catering for several research projects include Data collection (hospital and community), Data management (quality control, data entry, data sharing, data archive), Research administration (human resource, financial management, transport), Laboratory (microbiology, molecular,

biological sample archive), and Pharmacy (study product storage and dispensing).

3.4 Administrative events and research activities at Haydom

3.4.1 Administrative events 2009-2017

Between 2009 and 2017, the clinical staff turnover, including midwives was high with about 45% leaving the hospital to join other health institutions, especially governmental organizations. This dislocation of staff may be because HLH is located in a rural setting and is a non-government hospital. Several of the staff usually felt more secure by working in governmental organizations. Recruitment of new midwives to replace those who left, usually took place during the second half of the year. Most of the newly recruited staff were individuals who had recently qualified (completed nursing and midwifery school) and still with no working experience. Other administrative events in the study period included rotation of staff within HLH. Some of midwives who worked in labor and already with experience in labor management were shifted to work in different clinical sections and their position replaced with less qualified midwives in labor management. Furthermore, in 2013 and 2014, HLH introduced ambulance and delivery fees respectively. Previously, these services had been free of charge. In 2014, the hospital was formally upgraded and granted an offer to become a regional referral hospital, which increased the capacity. The opportunity resulted to further advancement in care i.e. recruitment of a specialist in obstetrics. The upgrading resulted to increased referrals from other health facilities [182,183].

3.4.2 Research activities 2009-2017

In mid 2009, the HBB study project was initiated and involved recruitment and training of research staff. Continuous observations and data collection of every delivery and newborn started in July 2009 for the HBB study. This study aimed to improve perinatal outcome through training birth attendants. In 2011, the National Institute for Medical Research (NIMR) endorsed the project "Towards MDG 4 and 5 "Helping Babies Breathe (HBB)" and "Helping Mothers Survive (HMS) Bleeding After Birth (BAB)" which was then implemented. This project, Towards MDG 4 and 5, aimed to improve perinatal and maternal outcomes, through continuous quality improvement (CQI) programs. These programs included continuous simulation training for midwives on basic delivery skills, management of third stage of labor and Postpartum Hemorrhage (PPH). HBB simulation training was also part of the project. HBB project as part of CQI, implementation approach was changed to FBOS HBB training.

3.4.3 Safer Births Project

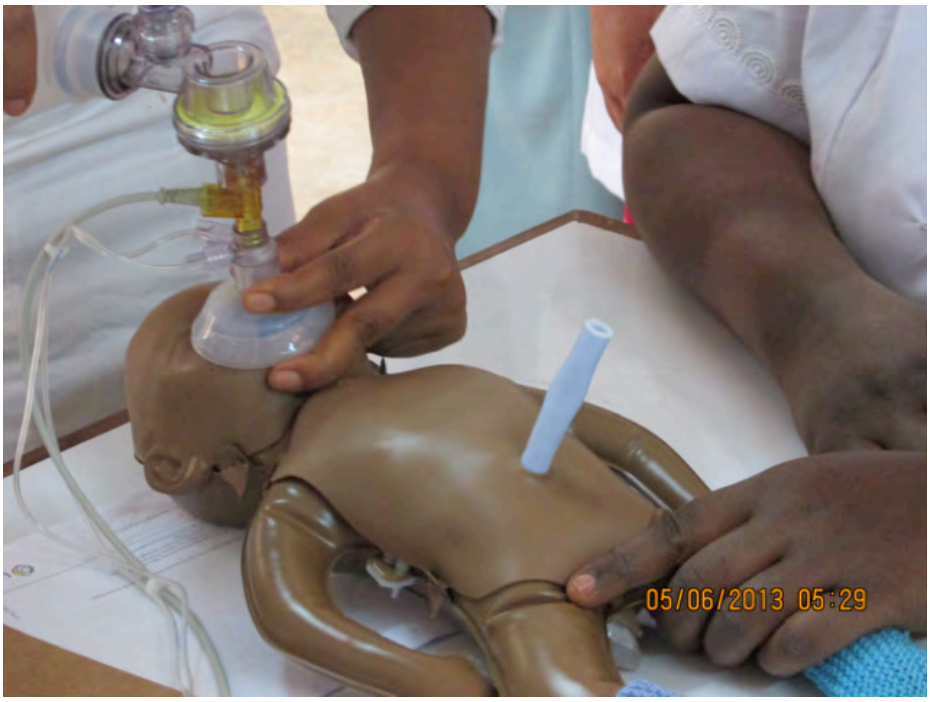
In 2012, the Safer Births project was registered by NIMR as a sub study of the protocol "Toward MDG 4 and 5 HBB and HMS BAB". In 2013, the Safer Births project (http://www.saferbirths.com/) was introduced as a main study. Safer Births is a research and continuous developing project to help in the efforts to reduce perinatal mortality globally. The efforts were through development of better tools and training strategies and guidelines for FHR monitoring and resuscitation. Safer Births project included sub-studies as noted next; 1. Clinical randomized clinical trials (RCT) to compare the effectiveness of different devices for monitoring fetal heart rate (FHR) (2013) and for application of bag mask ventilation (BMV) (2014). 2. FHR clinical RCTs evaluated the effectiveness of FHR monitoring devices; Pinnard fetoscope and Doppler (Free Play,Power-free Education Technology, Pet.og.za) and Pinnard fetoscope with multicrystal Doppler called

Moyo (Laerdal Global Health, Stavanger Norway) [184]. 3. A clinical RCT for BMV compared upright (Laedal Medical, Stavanger Norway) and conventional bag mask for ventilating non-breathing newborns [177]. Newborn resuscitation monitors (Laerdal medical) were installed in every room where delivery took place (including operating theatres) to help in monitoring FHR of newborn and collect electronic data on resuscitation.

3.5 Study interventions

3.5.1 Frequent brief onsite simulation (FBOS) HBB training as part of CQI

The project FBOS HBB training was implemented in February 2011 and aimed at optimizing HBB training through fostering the implementation process. Five local midwives at HLH were trained by a national HBB master trainer to become trainers. The trainer (local midwives) conducted a one-time, one-day HBB training to their peer midwives and other births attendants working in the labor ward. The training involved basic care for newborns, which involved assessment of the newborn. Additionally, stabilization/resuscitation (stimulation and suction of airway), BMV were part of training. The importance of time-critical actions during resuscitation training was emphasized. Additionally, proper positioning of the facemask and proper squeezing of the bag during BMV was emphasized for successive ventilations and effective resuscitation.



Picture 3: Proper mask positioning on a manikin during BMV simulation practice. Photo by Estomih Mduma (2013)

During practicing, care providers were always reminded about the importance of the "Golden Minute" – the baby should either be breathing or ventilated within the first minute post-delivery. Midwives were also reminded to call for help in a situation when someone felt not confident to resuscitate the non-breathing newborn. Posters with HBB action steps were mounted on the walls above the resuscitation tables in the labor rooms and operating theatres. Additionally, poster was also mounted above the HBB practicing table. Posters were intended to ease the steps when resuscitating a non-breathing newborn or during simulation practicing.

Picture 4: HBB poster mounted on the wall above newborn resuscitation table to easy reference. (Photo by Moshiro R. with permission)

The training also included the importance of preparing the delivery and resuscitation kits. Midwives were responsible for preparing the resuscitation table, including the kits before attending a delivery. Availability of a resuscitation kit was important for timely use in case of non-breathing newborn. Resuscitation kits were equipped with; manual sucker (Penguin; Laerdal Global Health, Norway), Newborn Resuscitator (Laerdal Global Health, Norway), and warmth clothes (cap and socks).

After a one-day HBB training, there was a mandatory brief (about 3-5 minutes) follow up practice once every week to midwives and other

birth attendants on duty in the labor ward. Additionally, midwives were also encouraged to practice frequently and the newborn simulator (NeoNatalieTM; Laerdal Global Health, Norway) was located in a central open space in the labor room, which made it easy for the midwives to practice when time allowed.

Midwives practiced individually or in pairs whichever they preferred, and the local trainers were available for support during practicing as needed. Each month the trainer scheduled a 40-minute HBB simulation training for all midwives. Repeatedly, midwives were advised to ask for help from their peers or trainers if in doubt when they were to resuscitate asphyxiated newborns or during simulation training.

Picture 5: Midwives practicing BMV at the central place in the labor ward, Photo by Estomih Mduma (2013). Oral consent obtained to use the picture in publication

Regular feedback during daily reports, and during the weekly and monthly trainings on the efforts to improve newborn survival was regarded as very important. Audits of rare resuscitation outcomes like a newborn thought to be a FSB, but recovering after immediate resuscitation were conducted. This was to further motivate the midwives to perform immediate resuscitation even if they suspected the baby to be a FSB.

3.5.2 Continuous quality improvement efforts

Continuous evaluation of new programs, including new interventions in health care is important to continually improve health outcomes. Among the frameworks commonly used is the Plan-Do-Study-Act (PDSA) model (Figure 1) [142]. At HLH, this framework was applied starting with; "Plan" for HBB training. Master trainers from the ministry of health facilitated a one-day HBB training "Do" to midwives and other birth attendants. Data collection took place to "Study" the effectiveness of HBB implementation. After seven months the providers performance was evaluated. While performance improved one-day HBB training failed to improve newborn survival [169]. Thus, the "Act" step in the PDSA loop was the planning and introduction of the CQI efforts. More local midwives were trained to become HBB trainers and facilitate continuous HBB training, termed FBOS HBB training, commonly referred to as "low-dose high-frequency" (LDHF) training. CQI efforts including FBOS HBB training was implemented "Do", and all midwives underwent mandatory repeated brief training through working hours. Data collection continued "Study" and feedback on the status of perinatal outcome were given regularly. A substantial reduction in ePMR was evident and the PDSA circle continued.

3.5.3 Study timelines

Research assistants started observation in the labor rooms in July 2009, and the period for collecting baseline data was Feb 2010 through Jan 2011 (Figure 8). Duration between initiations of data collection to baseline data collection aimed to familiarize the midwives to being observed and minimizes the Hawthorne effect. Baseline data collection (February 2010 through January 2011) was for all the three studies.

After-intervention evaluations of the three studies started on February 2011. For study I, the after period lasted for one year (February 2011 through January 2012). For study II, the after period was five years (February 2011 through January 2016). Lastly, the after period for study III took place for six years (February 2011 through January 2017).

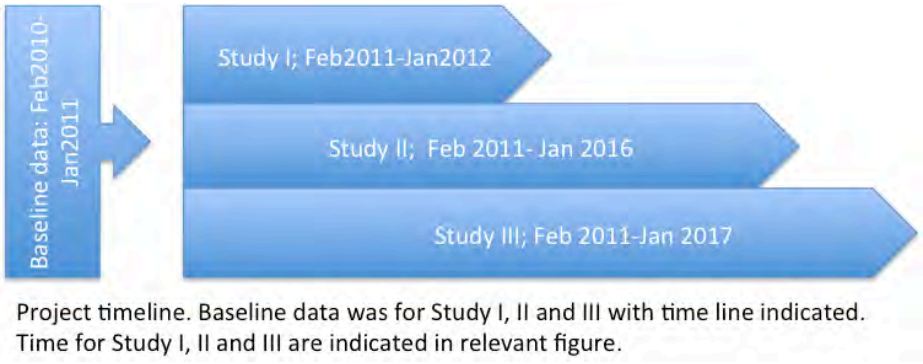


Figure 8; Project data collection time-line for the three studies (figure by Estomih Mduma)

3.6 Training and Data collection

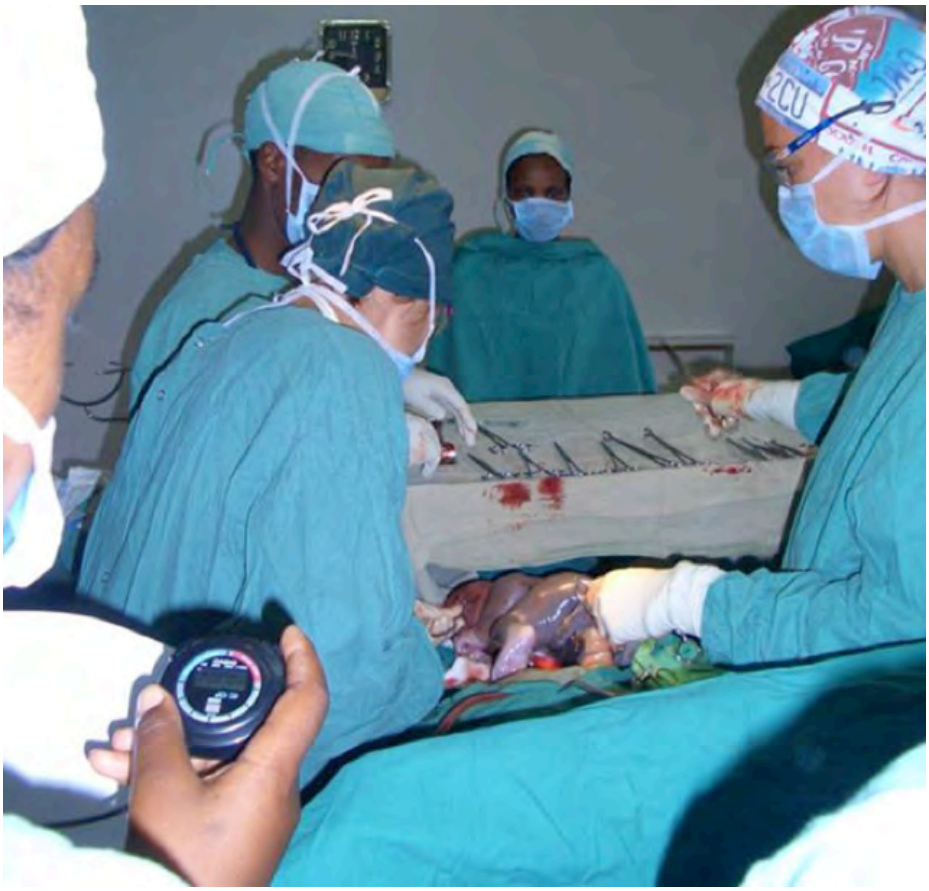
The local Principal investigator (PI) EM, was accountable to oversee all the activities related to the study project, including regulatory issues. The Study coordinator was responsible to coordinate and train on the activities related to data collection, and research team, including research assistants. Research assistants were trained (Picture 6) on the procedure to collect and document data on the data collection form (appendix 1,2). Research assistants did not have medical background, but with capacity to observe, read and document both in local and English language. The purpose to recruit research assistants with no medical background was to ensure that they would not interfere in clinical work and also reduce potential reporting bias. The Standard

operating procedures (SOP) was used during training and research assistants were instructed to follow SOP (appendix 3,4) when collecting data, for consistency purpose. Additionally, research assistants received training in study protocol, good clinical practice (GCP) and research ethics. The research coordinator was also responsible to re-train research assistants regularly and oversee the day-to-day activities related to data collection in the labor ward. There was a routine biannual retraining, and when indicated e.g. when there was a change of data collection form and if there were observed repeated errors in data collection.

Data collection took place in the labor ward and operating theatre. Additionally, data was collected from the postnatal ward and the newborn unit for the 24-hour newborn outcomes. Research assistants who were non-medical personnel and not involved in delivery service provision were responsible for collecting data. Data collection forms (appendix 1,2) were used throughout the study period for data recording guided by SOP (appendix 3,4). Data collection took place 24hours, 7days a week through the study period. Research assistants working in three shifts were available in the delivery room and prospectively observed, timed and recorded each birth's related information. The timeline for data collection started in February 2010, and lasted for a period of seven year i.e. up through January 2017. The first year (Feb 2010 through Jan 2011) was the period for baseline data collection, followed by six years of after intervention data collection. Different events during the labor process, newborn care, newborn characteristics and perinatal outcomes within the first 24 hours after birth were recorded on the "data collection form" (appendix 1,2). The research assistants collected data through various means and included observation of the process (preparedness of delivery and resuscitation kits as required), different actions taken by the birth attendants, timing of events e.g. birth, cord clamping, timing of breathing, and timing of actions during resuscitation, if happen. Collection of other information

was from patient records i.e. antenatal cards (appendix 5) and delivery sheets/partograms (appendix 6). Information about last conducted HBB training was collected from the HBB training log (a log where each midwife recorded after practicing) (appendix 7) to capture frequency of training/practicing. Other events that took place in the labor room, which may have had an impact on newborn outcomes, were also tracked and recorded. Information about other projects during the period (e.g. RCTs for testing different devices for fetal heart rate monitoring and ventilation of non-breathing newborns) were recorded. Administrative events and issues related to labor management were tracked. Such information included; timing of midwives leaving the labor ward/HLH and recruitment of new midwives not trained in HBB to fill the gaps, introduction of fees (delivery and ambulance transport).

Picture 6. Research assistants training on data collection, Photo by Estomih Mduma (2013). Oral consent obtained to use the picture in publication



Picture 7 Research assistant timing events during caesarian section as part of timely data collection. Photo by Ersdal H, with permission to use

3.7 Data management and quality control.

After completing data collection on each birth, research assistants inserted initials at the end of the data collection form. Inserting initials aimed to identify research assistant who was responsible to collect and document the form. Forms completed for data collection were submitted to the data management team, in the section of “data

editing". The data editing team consisted of research assistants who were trained to review entries on the "data collection form". Edit of forms looked for completeness of documentation and missed entries, and any queries were flagged. The forms with missing data and/or information that was thought to not be relevant, were returned to the research assistant (who completed the form) for review. Reviewed forms were then returned back to the editing section. Well-completed forms were submitted to data clerks for data entry. Data clerks were individuals with competence in computer use and able to read numbers and the language used (English). Data clerks were trained on the procedure of data entry to the database, and correction of issues as were instructed by the data-entry supervisor and manager. Data entry involved double entry for each data collection form, by two independent data-clerks. The database was password protected and each data clerk had a password to access. The database was programmed to automatically flag any inconsistency between the two data clerks' entries, which was visible on the supervisor display. Capturing the inconsistences between entries was part of quality control to ensure correct entries in the database. The supervisor printed all the queries and retuned to data clerks for correction using the data collection form (source document). Upon completing, the PI (external) ran a data query to the database to additionally check for missed data or irrelevant data. The external PI, HL (stationed in Stavanger Norway), was responsible for the final quality check of the data. Queries found were retuned back to data manager/supervisor through email, then to data clerks or editing section for review and correction. In the occasion that repeated queries were observed, coordinator and/or supervisor planned a refresher training either to the individual research assistant or to the group, whichever was found relevant to address the challenge.

During working days, at the end of working day, one research assistant presented the report for the past 24 hours, or 72 hours after the weekend. This report intended to have the entire research team

including the study PI to track the ongoing performance and issues, if any. Question(s) raised, success and any issue of concern were discussed for further improvement. Once every month the coordinator planned and conducted monthly meeting where research assistants attended to discuss issues related to data collection with the intention to continually facilitate effective collection of data. In some occasions, the study PI also attended the meeting as a routine or invitation if there was an issue(s) that required PI presence.

3.8 Variables and study outcomes

In Study I: The variables included were; newborn birth weight (in grams), labor complication (yes/no), fetal heart rate (normal 120-140 beats/minute, abnormal <120 or >140 beats/minute, not detected, and not measured), cesarean sections (yes/no), cord clamping (time in seconds from birth to clamping), initiation of breathing (time in seconds from birth to start breathing), resuscitation actions; stimulation, suction and BMV (yes/no), Apgar score 0-10 (at 1 and 5 minutes), admission to the neonatal unit (yes/no), deaths within 24 hours (yes/no), FSB (yes/no), Health Care Worker (HCW) managing second stage of labor, HCW performing resuscitation, HCW with HBB training (one day only training/FBOS training) and 24 hours newborn outcome (normal, admitted in neonatal unit, FSB, MSB, referral to other hospitals or END)

In Study II: Included variables were related to labor processes and administrative events with potential impact on perinatal care and outcomes: introduction of FBOS HBB training, experienced midwives leaving labor ward and their replacement with non-experienced midwives (staff reallocation noted by labor ward supervisor)), clinical RCTs for devices to monitor FHR and for BMV, upgrading of hospital status, introduction of fees (ambulance and delivery). The study outcome was early perinatal outcomes (FSB/END).

In Study III: Included variables were related to maternal and newborn characteristics, labor processes and administrative events: births (number), source of admission (home/referral), pregnancy complications (yes/no), singleton birth/multiple births, newborn birth weight (gm), labor complication (yes/no), fetal heart rate (normal 120-140/abnormal <120 or >140/missing), cesarean sections (yes/no), cord clamping (time from birth to clumping), breathing (seconds from birth-start breathing), resuscitation; stimulation, suction and bag mask ventilation (yes/no), Apgar score 0-10 (at 5 and 10 min), admission to the neonatal unit (yes/no), deaths within 24 h (time), fresh stillbirths (yes/no).

Multiple exposures variables with potential impact on newborn outcome were considered in Study I and III. The exposures included FBOS HBB training, activities intended for CQI, clinical RCTs and Administrative events. FBOS HBB training was the only intervention, which took place through the 6 years follow-up period.

Background variables; included variables (study I and III) measured before the onset of labor. These variables were collected from antenatal card (appendix 5); antenatal care attendance (yes/no), gestational age (care provided assessment which included estimation using last menstrual history, ultrasound measurements), pregnancy complication (yes/no) and maternal infection (yes/no).

Table 1. Table for presentation of variables accounted in the three studies

Variable	Value	Study I	Study II	Study III
Antenatal care attendance	Yes/no	✓		
Pregnancy complications	Yes/no	✓		✓
Maternal infections	Yes/no			✓
Source of admission	Referral from health center/inpatient (home)			✓
Fetal presentation	Cephalic, breach, shoulder dystocia			✓
Fetal heart rate	Normal, abnormal, not detected, not measured	✓		✓
Mode of delivery	SVD, C/S, ABD, Vacuum	✓		✓
Labor complication	eclampsia, bleeding, uterine rupture, cord prolapse	✓		✓
Number births	Singleton/multiple		✓	✓
Newborn Gender	Male/female			
Birth Weight	Gram (g)	✓		✓
Gestational Age	Weeks (wk)	✓		✓
APGAR scores	0-10	✓		
Resuscitation	Yes/no	✓		
Time Cord clump	Minutes (m)	✓		

HBB training	Yes/no	✓	✓	
Staff re-allocation	Transfer out/in labor ward		✓	
RCT studies	FHR study, BMV study		✓	
Fee	Delivery and transport payment		✓	✓
Upgrading hospital status			✓	
Perinatal outcome	Normal/death	✓	✓	✓
Newborn Admission	Yes/No	✓		

Abbreviations SVD = Spontaneous vaginal delivery, C/S = caesarian section, ABD= Assisted breach delivery, RCT = randomized control trial, FHR=fetal heart rate, BMV=bag and mask ventilation, HBB=Helping Babies Breathe

3.9 Statistical methods

Study I: Dataset was analyzed using the Statistical Package for Social Sciences (SPSS) 22. Two-sided test at significance level 0.05 was used. Interim analyses were performed after six months. Chi-square calculations and independent-samples t-tests were utilized to compare pre- versus post-implementation data. Relative risk (RR) and 95% confidence interval (CI) were presented when indicated. Since the number of data points was large, in the two samples compared; the two-sample t-test was used without concern about the normality of the data. All data were presented as mean ± standard deviation unless as otherwise stated.

Study II: Analysis was performed to plot the trend on newborn survival at birth and at 24 hours following delivery as an outcome measure at monthly intervals. VLAD, a plot of the cumulative number of excess survivors compared to the baseline rate was constructed. CUSUM charts were then constructed to determine an alternative value of the

quantity monitored and also made a corresponding CUSUM for monitoring against decreased survival, using a decrease of 0.5 percent points as alternative. The graphs were matched with the HBB educational interventions, changes in labor staffing, other interventions and activities in the labor ward-taking place in the same time period.

Study III: a risk-adjusted VLAD plot was constructed to present the cumulative sum of expected outcome for each birth if the baseline situation had persisted, minus the observed outcome. The VLAD plot was interpreted as the cumulative excess number of survivors over time, compared to the baseline rate taking into account risk factors. A risk adjusted CUSUM was based on the same logistic regression model as the VLAD plot was constructed

3.10 Ethical considerations

Before implementation, the administration team and health staffs at HLH were informed about the HBB and later CQI project and accompanying studies. The local and government authorities, both at the district and regional levels, were informed and supported the project. All devices that were used in the project had approval and on use in other settings as part of care. Study staff involved in data collection were trained and certified in research ethics and good clinical practice (GCP) before being involved in data collection and management.

All women who attended labor ward at HLH to give birth were informed about the project and included in the study. The National Institute of Medical Research (NIMR) did not require consenting since the project was a quality improvement effort to improve routine/resuscitation care in the labor ward.

Data collected did not include identification information for confidentiality purpose (de-identified data). Additionally, completed

data collection forms were secured and locked in research office and only authorized personnel had access for confidentiality purposes. Computers, which were used for data entries were password protected for confidentiality purpose. For publication of the results, the NIMR reviewed all the manuscripts that involved data from the project, before submission to request publications. The review intended to ensure the relevance of the contents, if meeting the scientific and ethical requirements before offering permission for publication.

3.10.1 Ethical clearances

The projects were reviewed and received ethical approvals from the NIMR and the Ministry of Health and Social Welfare in Tanzania with certification References: NIMR/HQ/R.8a/Vol.IX/1247 (appendix 8) and NIMR/HQ/R.8a/Vol.II/667 (appendix 9). Since this was a collaborative project with institutions in Norway, the project was also reviewed by the Regional Committee for Medical and Health Research Ethics, Western Norway and received approval with Ref. 2009/302 (appendix 10) and 2013/110/REK (appendix 11). The study was registered in the clinicalTrials.gov Identifier: NCT01681017; 04 September 2012,

4 Summary of Results

In all the three studies, improved perinatal outcomes following implementation of a CQI program including FBOS HBB training were described

4.1 Study I:

Study I was conducted to investigate potential effects of implementing FBOS HBB training over one year, on newborn resuscitation practice and newborn outcomes. Implementation of FBOS HBB simulation training was associated with a 40% reduction in END compared to baseline.

The numbers of births before versus after implementation were almost the same i.e. 4894 (baseline/Cohort 1) versus 4814 (Cohort 2), respectively (Table 2). Birth weight (grams) and gestational age (weeks) were significantly lower in Cohort 2 compared to Cohort 1, 3155±490 versus 3093±494 ($p=0.0005$) and 36.7±1.7 versus 36.3±1.3 ($p=0.0005$), respectively. The incidence of labor complications and fetal heart rate (FHR) abnormalities in both cohorts were almost the same. However, cesarean sections (CS) (predominantly emergence) were more frequent in Cohort 2, i.e. 13.5% compared to baseline 11.8% ($p=0.012$). The time from birth to cord clamping increased from mean 52.8±41.5 seconds during baseline to 67.2±46.9 seconds after implementation ($p\leq0.0005$). More infants were stabilized and/or resuscitated post versus pre implementation, i.e. 787 (16.3%) versus 717 (14.6%), respectively ($p=0.021$). More specifically, the number of infants stimulated increased from 14.5% to 16.3% ($p=0.016$) and those suctioned increased from 13.0% to 15.8% ($p\leq0.0005$) while those receiving BMV decreased from 7.3% to 5.9% ($p=0.005$) in Cohort 1 versus Cohort 2 respectively. The number of deaths within 24 hours (END) after birth decreased significantly from 54 (11.1/1000) to 34

(7.2/1000) (RR 0.64, 95% CI 0.41-0.98, p=0.040) in Cohort 1 versus Cohort 2. The differences in proportions of FSB were not statistically significant between the two Cohorts [185].

Table 2. Neonatal descriptors, management and outcomes pre- versus post-implementation of FBOS HBB simulation training.

	Pre-Implementation Cohort 1; n=4894	Post-Implementation Cohort 2; n=4814	P-value
Descriptors			
Gestational age, weeks	36.7±1.7	36.3±1.3	≤0.0005**
Birth weight, grams	3155±490	3093±494	≤0.0005**
Birth weight < 2500 grams	317 (6.5)	367 (7.6)	0.023*
Attended antenatal care	4878 (99.7)	4776 (99.2)	0.002*
Pregnancy complications	49 (1.0)	42 (0.9)	0.484*
Abnormal fetal heart rate	97 (2.0)	133 (2.8)	0.07*
Labor complications Emergency CS	666 (13.6) 576 (11.8)	699 (14.5) 648 (13.5)	0.198* 0.012*
Resuscitation			
Total number resuscitated Resuscitated after CS	717 (14.6) 186/576 (32.3)	787 (16.3) 210/648 (32.4)	0.021* 0.96*
Stimulated	712 (14.5)	785 (16.3)	0.016*
Suctioned	634 (13.0)	762 (15.8)	≤0.0005*
BMV	357 (7.3)	283 (5.9)	0.005*

Outcome			
Apgar score 1 minute ≤7	347 (7.1)	439 (9.1)	0.0005*
Apgar score 5 minutes ≤7	53 (1.1)	62 (1.3)	0.350*
Normal at 24 hour	4702 (96.1)	4630 (96.2)	0.066*
Admitted neonatal room			
At 30 minutes	258 (5.3)	229 (4.8)	0.254*
At 24 hour	10 (0.2)	15 (0.3)	0.300*
Deaths, n/1000			
At 30 minutes	5 (1.0/1000)	5 (1.0/1000)	0.984*
At 24 hour	54 (11.1/1000)	34 (7.2/1000)	0.040*
Birth weight < 2500 grams	20/54 (37)	11/34 (32)	0.050*
Fresh stillbirths, n/1000	79 (16.0/1000)	70 (14.5/1000)	0.517*
Macerated stillbirths, n/1000	49 (10.0/1000)	65 (13.5/1000)	0.116*

Values are given as n (%) unless otherwise stated. *Chi-Square, two-tailed, **Independent samples T-test, two-tailed. CS = cesarean section

4.2 Study II

Study II was conducted to trace and document smaller changes in perinatal survival over 5 years following implementation of a CQI program including FBOS HBB training. Further, other interventions and administrative events during the period were described to elucidate potential associations. A cohort of 22,176 consecutive newborns over six years was included, with an average of 400 deliveries per month

with minimum variation between months. There was an observed increased survival during the five-year follow-up period compared to baseline. Most of the time the CUSUM trend was rising, indicating an improvement in survival, but with some variation in perinatal survival from month to month (Figure 9).

The dot-line in Figure 9 indicates the baseline survival rate. The numbers inserted along the dot-line illustrate events and other intervention activities that happened during the study period, which were thought to potentially impact perinatal survival.

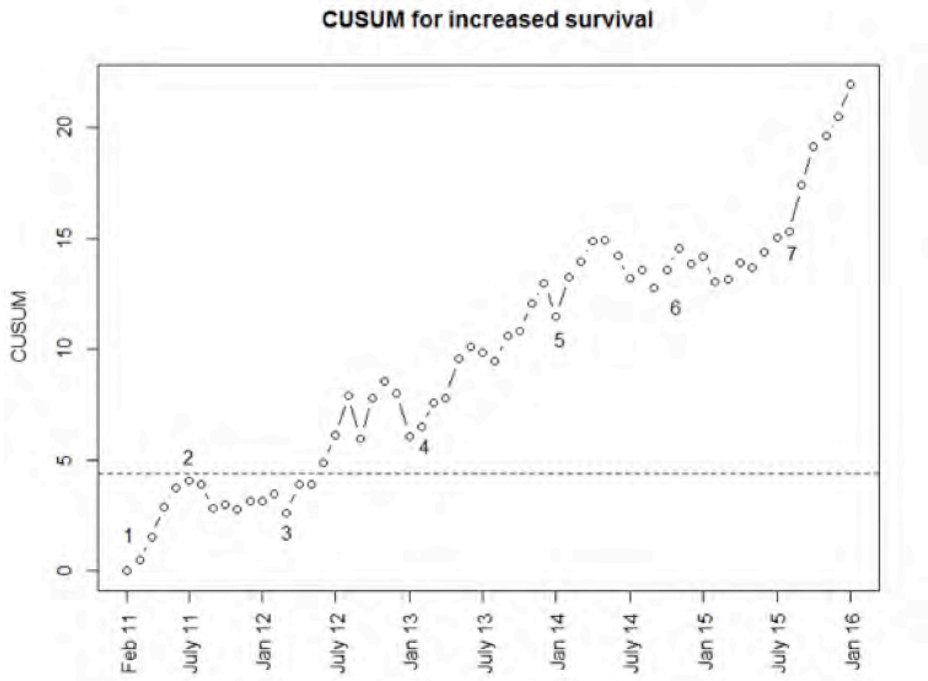


Figure 9. CUSUM plot; Cusum chart illustrating the most important interventions and events during the study period. The upward trend indicates improvement in survival. A horizontal dashed line indicates the signal limit and crossing this line is a signal of survival improvement over the baseline level.

Explanation of the numbers in the chart: (1) Introduction of frequent brief on-site HBB trainings. (2) Every year experienced nurses leave the hospital in July-August and new nurses are recruited in September-November. (3) Continued focus on frequent brief on-site HBB trainings. (4) Initiation of a study comparing two devices for fetal heart rate monitoring and implementation of newborn resuscitation monitors next to the delivery beds. (5) Referral hospital status with employment of junior doctors and a specialist in Obstetrics, and introduction of a patient delivery fee. (6) Initiation of a study comparing two devices for newborn ventilation, and (7) Renewed focus on systematic HBB training engaging the locals (5) HBB trainers [183].

During the implementation period, about 120 extra lives were saved compared to the baseline level.

4.3 Study III

Study III was conducted to investigate whether a persistent increase in perinatal survival, after introduction of the CQI program including FBOS HBB training, could be detected when adjusting for changes in perinatal risk factors. A total number of 31,122 consecutive newborns were observed during the seven-year study period (Table 3). Perinatal characteristics and risk factors not related to clinical management were included in the model as explanatory variables. SPC charts (CUSUM and VLAD), with and without risk adjustment were used to plot the survival trend. There was a significant improvement in perinatal survival overtime in spite of concomitant increase in perinatal risk factors. The estimated numbers of newborns saved during the intervention period when adjusted for changes in perinatal risk factors was 250 compared to with no risk-adjustment which was 150. FBOS HBB training was the only persistent intervention throughout the study period.

Table 3 presents labor and newborn characteristics for every year from 2010 through 2016. The number of births was less (range 3731-4296) over the final three years compared to before (range 4787-4893). The percentage of cases where FHR were not measured was substantially higher in the last three years (average proportion 12.1%) compared to before (3.5%). The percentage of babies with abnormal FHR increased with an average proportion of 4.8% during the last three years compared to before where the average proportion was 2.8%. The proportion of cases with labor complications was higher in the later (last four year) period resulting in the proportion of CS being higher (21-23%) compared to before (11-15%). There was an increase in newborns being resuscitated by stimulation after birth in 2015 and 2016 (>28%) compared to before i.e. 2010-2014 (<16.5%), but the number

receiving BMV for resuscitation was relatively constant over the period. The mean birth weights during the last three years were higher (average 3282 grams) compared to the previous four years (average 3113 grams) [181].

Table 3 Total number of births, labor characteristics, fetal heart rate distribution, newborn resuscitation and newborn characteristics per year, counted from February 1st through January 31st the next year

Characteristics	Baseline	Implementation of HBB frequent training and the Safer Births CQI project						
Year	**2010**	**2011**	**2012**	**2013**	**2014**	**2015**	**2016**	**Total**
Number of births	4893	4813	4787	4836	4296	3731	3766	31122
Source of admissions Referrals	181 (4.6)	90 (1.9)	73 (1.5)	211 (4.4)	168 (3.9)	111 (3.0)	193 (5.1)	1027 (3.4)
Home	3778 (95.4)	4723 (98.1)	4714 (98.5)	4624 (95.6)	4128 (96.1)	3620 (97.0)	3571 (94.9)	29158 (96.6)
Pregnancy complications Yes	49 (1.0)	42(0.9)	42(0.9)	65 (1.3)	36 (0.8)	33 (0.9)	76 (2.0)	343 (1.1)
Singleton birth	3813 (96.3)	4662 (96.9)	4607 (96.2)	4663 (96.4)	4123 (96.0)	3593 (96.3)	3611 (95.9)	29072 (96.3)
Multiples birth	147 (3.7)	151 (3.1)	178(3.9)	173 (3.5)	173 (4,1)	138 (3.750)	155 (4.1)	1117 (3.7)
FHR Measurements Normal	4647 (95.0)	4540 (94.3)	4477 (93.5)	4078 (84.3)	3438 (80.0)	3039 (81.8)	3108 (82.5)	27327 (87.8)
Abnormal FHR	97 (2.0)	136 (2.8)	183 (3.8)	123 (2.5)	191 (4.4)	158 (4.2)	212 (5.6)	1100 (3.5)
Not detectable	96 (2.0)	92 (1.9)	90 (1.9)	96 (2.0)	74 (1.7)	69 (1.8)	77 (2.0)	594 (1.9)
Not measured	52 (1.1)	45 (0.9)	37 (0.9)	539 (11.1)	593 (13.8)	464 (12.4)	369 (9.8)	2099 (6.7)
Labor complication Yes	710 (14.5)	777 (16.1)	841 (17.6)	1113 (23.0)	1006 (23.4)	892 (23.9)	910 (24.2)	6249 (20.1)
No	4183 (85.5)	4036 (83.9)	3946 (82.4)	3723 (77.0)	3290 (76.6)	2839 (76.1)	2856 (75.8)	24873 (79.9)
Fetal presentation Cephalic	4586 (93.8)	4490 (93)	4470 (93.4)	4537 (93.9)	4073 (94.8)	3566 (95.6)	3696 (95.5)	29318 (94.2)
Breech	167 (3.4)	179 (3.7)	180 (3.8)	202 (4.2)	172 (4.0)	144 (3.9)	138 (3.7)	1182 (3.8)
Shoulder Dystocia	10 (0.2)	12 (0.2)	14 (0.3)	80 (1.7)	51 (1.2)	20 (0.5)	6 (0.2)	193 (0.6)
Transverse	27 (0.6)	14 (0.3)	20 (0.4)	31 (0.4)	27 (0.6)	18 (0.5)	24 (0.6)	170 (0.5)
Others	101 (2.1)	118 (2.5)	103 (2.2)	9 (0.2)*	0(0)*	0(0)*	25 (0.7)*	354 (1.1)
Mode of Delivery Vaginal	3387 (84.6)	4013 (83.4)	3925 (82)	3690 (76.3)	3252 (75.7)	2789 (74.8)	2801 (74.4)	23857 (78.9)
Cesarean section	460 (11.5)	645 (13.4)	729 (15.2)	1025 (21.2)	957 (22.3)	863 (23.1)	886 (23.5)	5565 (18.4)
Assisted breech delivery	119 (3.0)	126 (2.6)	110 (2.3)	95 (2.0)	79 (1.8)	73 (2.0)	68 (1.8)	670 (2.2)

Vacuum	38 (0.9)	28 (0.6)	23 (0.5)	12 (0.2)	7 (0.2)	6 (0.2)	11 (0.3)	125 (0.4)
Newborn resuscitation Stimulation	718 (14.7)	788 (16.4)	725 (15.1)	727 (15.0)	590 (13.7)	1051 (28.2)	1075 (28.5)	5674 (18.2)
Bag-mask ventilation	358 (7.4)	283 (6.0)	262 (5.5)	337 (7.1)	312 (7.3)	247 (6.7)	269 (7.3)	2068 (6.7)
Birth weight grams**	3155(490)	3095(494)	3075(460)	3125(522)	3248(537)	3255(523)	3347(536)	3176 (515)

Data is shown as n (%) unless otherwise stated. HBB = Helping Babies Breathe, CQI = Continuous Quality Improvement, FHR = Fetal Heart Rate. * The data collection form was slightly changed in March 2013 and the variable (others) was not recorded from March 2013 towards the end of 2016. **Mean (± Standard Deviation)

5 General discussion

5.1 General Discussion of result

In this thesis, we find that CQI including FBOS HBB simulation training was associated with improved perinatal survival over the period of six years. When evaluating potential effects of the FBOS HBB training, we documented that basic clinical practice, in particular resuscitating asphyxiated newborns improved. Birth asphyxia is the leading cause of perinatal mortality in this study setting [35]. During the CQI period, in 2013, the Safer Births research and innovation project was initiated. This project included some clinical RCTs to test novel equipment, focusing on improving FHR monitoring and BMV resuscitation [177,184]. These RCTs research projects could have influenced perinatal outcomes during parts of the six-year CQI study period, since fetuses with abnormal FHR are at high risk for negative birth outcomes due to asphyxia. Having a device that could easily detect abnormal FHR increased the chances for timely intervention [184]. Likewise, introducing a better tool to ventilate non-breathing newborns had the potential to reduce mortality due to birth asphyxia [177]. However, the findings from these RCTs did not demonstrate significant differences or improvement in perinatal outcomes. FBOS HBB simulation training, as part of CQI was the only potential intervention to improve clinical skills through the six years follow up period and we associate with improvement in perinatal survival that we observed.

5.1.1 Study I

FBOS HBB simulation training was evaluated for a one-year period following implementation. There was a substantial reduction in 24 hours newborn mortality by 39% compared to baseline [185], almost similar to what was found by Msemo et al. [159]. This powerful

observation is the first time that FBOS (LDHF) was shown to reduce neonatal mortality. LDHF training has also been useful in other settings [201-203]. After implementation of FBOS HBB training, there was a substantial increase in the number of newborns being stimulated and suctioned, with a concomitant decrease in newborns who received BMV. We speculate that the described changes in implementation decrease use of BMV was due to increased competence among the midwives and timely management of newborns requiring some breathing support i.e. stimulation which helped to initiate spontaneous breathing. These finding are akin to those reported by Msemo et al [159]. More frequent practice of early appropriate stimulation and/or suction likely resulted in fewer cases requiring BMV. For the asphyxiated newborn who received BMV, the mortality decreased from 12.6% during baseline to 8.8% during FBOS HBB training. An improvement in BMV technique may have caused this reduction in mortality. Kc et al [190] reported a reduction in perinatal mortality following improvement in BMV practice. During the period with FBOS HBB training we observed an increased number of midwives involved in resuscitation from 72.8% during baseline to 77.5%, while involvement of operating room nurses decreased from 8.5% to 5.3% and involvement of doctors from 7.4% to 4.0%. We associate the increased involvement of midwives in resuscitation to reflect an improved ability and confidence resulting from FBOS HBB training. We speculate that increased competence, knowledge, skills and confidence, gained through FBOS training, are the reasons for the documented changes in clinical practice. Subsequent studies by Gomez et al [191] and Drake et al [192] also found that frequent HBB training reduced perinatal mortality. These findings further support our assumption that FBOS HBB training was the driving force for improved clinical skills and improved 24 hours newborn survival.

5.1.2 Study II

Perinatal survival on monthly intervals through the study period was plotted using statistical process control (SPC) methods. Mukhtar-Vola et al [193] also used SPC in a low-resource setting. SPC has been useful in assessing processes where a trend (outcome) can be matched with different events taking place during the time-period to predict potential relationships [53]. In Study II, our evaluation included introduction and continuation of the CQI FBOS HBB training program, and other relevant interventions and events were noted in the CUSUM chart. Additionally, administrative actions with potential to influence perinatal outcomes were included. For example, midwives who were already experienced in FBOS HBB training were regularly replaced with midwives who had not been part of FBOS HBB training, and the promotion of HLH to become a referral level hospital. The CUSUM and VLAD charts illustrated continuous improvement of perinatal survival through the period with minimal variation at some time-period. Transient reduction in newborn survival matched the dropout periods of midwives skilled through FBOS training. However, the SPC charts revealed improvement in survival again after a few months. We associate this improvement in newborn survival with the new midwives becoming skilled in HBB following their participation in ongoing FBOS HBB training. The concordances between the documented SPC trends and different events with potential to influence perinatal outcome, shows the relevance of SPC in evaluating healthcare services. Additionally, the matching between FBOS HBB training related events (positive and negative) and changes in perinatal survival (in the CUSUM chart, Figure 9) reveals the critical potential of FBOS HBB training in improving perinatal survival. Study II lasted for a long period (5 years), and a continuous improvement in perinatal survival, compared to baseline was observed. We speculate that the CQI FBOS HBB training program was also responsible for sustaining improved

clinical practice, which has been reported to be among the main challenges in HBB training [194,195].

5.1.3. Study III

We observed that after patient-risk adjustment, the SPC models revealed a further improvement in perinatal survival compared to before risk adjustment, in spite of an increased number of high-risk patients overtime. Using methods that account for the level of risks in a cohort, when evaluating an impact over time, has been applied in other settings and found to be valuable [196-198]. Risk factors that were not associated with clinical management were included in the model; i.e. perinatal and maternal characteristics and risk factors like birth weight, pregnancy complication, and abnormal FHR. The increase in patients with higher risk was observed particularly during the last three years of the study. Abnormal FHR and not measured FHR were the most significant risks found, which is similar to what has been previously reported by Ersdal et al from the same clinical setting [199]. We observed that the increase in cases with abnormal and not measured FHR were associated with the introduction of ambulance (2013) and hospital delivery (2014) fees, and thus late hospital arrivals. Our catchment population is of low socio-economic status and introducing the fees could have resulted in more women giving birth at home and only attending HLH late when in complicated labor. Sialubanje et al [200] reported in a study done in Zambia that high cost for hospitalization was a reason for home deliveries. During the study period, we observed a reduction in number of women delivery at HLH from > 4300 during the years 2010-2013 to < 3750 between 2014-2017. There was also an increase in complicated labor cases and the CS rate increased from 15% prior to 2012 to 21% after 2013. The VLAD plot revealed a total of 150 extra-averted perinatal deaths over the period of six years before adjusting for risk factors. After adjusting for the patient risks, the VLAD plot revealed 250 extra lives saved, which is an

addition of 100 lives saved compared to before risk adjustment. The finding was surprising and interesting, illustrating that in spite of increased cases with high risks, improved survival was maintained. If the patient risks had been constant over the study period, perinatal survival might have been even greater than what was actually observed.

We speculate that the reduction in perinatal mortality observed in all three studies was due to improved birth attendant resuscitation practice (behavior) resulting from the CQI FBOS HBB simulation-training program. The observed change in behavior, i.e. improved clinical management, is most likely predominant cause of the beneficial perinatal outcome (increased survival).

5.2 Implementation of CQI efforts including FBOS HBB

Good local implementation of FBOS HBB training was an essential component for saving more newborn lives, especially within the first hour of life, and the first day. The other main components contributing to improved outcomes were the existing knowledge of “best evidence science” and “efficient training” as described in the Utstein formula for Survival [77]. However, implementation, often described as the task to introduce new knowledge into practice, is much more complex. Introduction of new knowledge, if well done, has a potential to meet desired goals/changes. Birken et al [210] in their review described gaps in implementation of evidence-based practices (EBP) where most gaps were related to missing initial uptake and use of EBP, and further, a lack of sustainment of EBP. To have an effective implementation, it is important to consider both the translation of the new knowledge into clinical practice, and also sustainment over time. In study I, we observed the translation of knowledge to clinical practice. In study II and III, we speculate that the sustained change and improved in clinical

practice to midwives over time was a result of retraining and feedback, and contributed to the improved survival during the period of 6 years.

5.2.1 FBOS HBB simulation training at Haydom (HLH)

Local implementation of HBB training involved optimization of training through the CQI program. CQI efforts aimed to facilitate the translation of acquired knowledge and skills during training to routine clinical practice to influence the perinatal outcome. During FBOS HBB training the trainers (local midwives) and their peer midwives "owned" the CQI process. Local ownership is regarded as "key" in implementation of CQI as stated in the PDSA framework "…ownership is key to implementing the improvement successfully" [184]. After implementing FBOS training we observed increased survival (Kirkpatrick level 4) [185]. This was the first time that FBOS HBB simulation training was associated with a reduction in END. The usefulness of FBOS has also subsequently been observed in other settings [201-203]. Prior to start of the CQI FBOS HBB training program, a one-time training conducted by external facilitators did not result in a change in clinical practice, compared to what was observed after initiation of FBOS HBB training. These findings from two different training approaches almost match what Schon [204] argues in his theory of reflective practice; i.e. formal theory through professional training often fails to solve the real life challenges, - the "messy, indeterminate" reality of practice. Schon further "labels professionals' automatic ways of practicing as professional 'zones of mastery'—that is, areas of competence" which is in line with FBOS HBB practicing. We speculate that the improvement in birth outcome observed was made possible by the change and improvement in clinical practice (Kirkpatrick level 3). We speculate that FBOS simulation training and feedback using peer facilitators was a better methodological approach to facilitate implementation. Such efforts have also led to changes in

clinical practice and improved birth outcomes in other settings [205,206].

Local implementation is equally important as the medical evidence and educational efficiency as stated in the Utstein formula for Survival [77]. The three factors, "medical science", "educational efficiency/training" and "local implementation" are briefly described in the below paragraphs.

5.2.2 Medical Science

The American Academy of Pediatrics (AAP) and global partners developed HBB, the key component of our CQI program. HBB is a carriculum to train midwives and improve practice in basic newborn care and resuscitation, in particular those requiring breathing support [158]. The curriculum is based on updated international medical science of newborn resuscitation. Science is usually presented as "the theory", a description of ideology or knowledge, which results from experiments and/or research. The source of theory/knowledge is usually from one or few settings, while its application can be representative to multiple diverse settings, to other implementers and beneficiaries. In this project, the implementers were midwives (and other birth attendants). The beneficiaries were the non-breathing newborn. Theory and its application is also described by Gadamer [101] where the process of learning contribute in filing the gaps between care provider and the recipient (patients).

5.2.3 Training and learning

HBB training is a curriculum to help midwives' and other birth attendants to learn the basic care for newborn, and resuscitation in particular. Learning by itself is a broad term and encompasses a wide

range of experiences in a process to gain new knowledge. Kolb [99] explain learning as a major central process for humans where a holistic approach will result in adaptation in social and physical environments. During the FBOS training, learning was a continuous process and midwives had the opportunity to practice at any time during a work time and they attended weekly and monthly compulsory brief training sessions. Kolb [99] describes learning, which influences decision-making as "… learning is described as a process whereby concepts are derived from and continually modified by experience". Local midwives were trained to become trainers of their peer. This helped the local implementation process, as they were part of the culture and aware of the cultural and environmental challenges, facilitators and other issues in the setting (HLH), which may accompany learning. Knowles [87] proposed several principles for learning. Among them are effective learning environments and that learners have to focus on their needs, which will elicit their internal motivation. This may explain part of the success story at HLH, where FBOS HBB simulation training, and feedback targeted a common need. Furthermore, FBOS HBB training involved self and group practicing, which is in line with another assumption outlined by Knowles [87] i.e. in adult learning independence and self-directing is required. During daily practicing, weekly and monthly trainings, feedback on efforts to save newborn lives were shared. The successes observed further motivated to continue training. One of Knowles [87] principles in andragogy, related to what influences learning, is the "opportunity for learners to evaluate their own learning, which can develop their skills on critical reflection". We attribute all the above perspectives to be part of our CQI including FBOS HBB training, and feedback.

5.2.4 Practice (behavior) Change

Acquired knowledge from HBB training required to be translated into action as 'doing or performing' to attain a desired outcome. From this

we find that not only that knowledge and practice are inseparable but also that practice and knowledge are interdependent. Practice depends on knowing, also mentioned by Gadamer [101] "All practical decisions of human beings depend indeed on their general knowledge". FBOS HBB training aimed to change behavior of the midwives to follow the HBB algorism when caring for asphyxiated newborns. The process of behavior change is usually underestimated and thought to be straightforward. However, behavior change may be complex, as pointed out by Gadamer [101] in application of modern science "the technical wonders of modern medicine … make us forget that the application of this knowledge is a highly demanding and responsible task of the broadest human and social dimensions". Midwives continually practiced "steps to do/follow", which may not have been identical, and therefore leading to some variations, which again may have affected the outcomes as observed in study II, also explained by Hacker [83]. Such variations could have happened even if the sources of knowledge and skills acquisition were similar, as pointed out by Macintyre [207]; "what we need to understand is how the social and intellectual order on which morality finds its place is one that involves the deformation of desire and the invention of new forms of practical reasoning". Individual's variability to change places us into different group personalities like "leaders" and "laggers" [209]. During FBOS training and feedback, among the strengths is the potential for leaders to influence laggers to improve their practice over time [201,202]. Schon [204] in his "theory of reflection" presents two arguments that influence practice as "reflection in action," which occurs immediately and "reflection on action" which occurs later. In "reflection in action" the learner develops the ability to learn continually by creatively applying the current and past experiences. This concurs with the midwives who continued to train and resuscitating asphyxiated newborn. The "reflection on action" involves a process of thinking on the past events and the outcome of action taken to help in decision-making, which also may influence future practice. This could relate to

the weekly and monthly feedback that involved audits of success stories in resuscitation and future plans.

5.2.5 Trust and experience

Midwives were required to trust the HBB algorithm, to apply the guideline in their routine clinical practice. Trust or belief influences one's practice and makes it subjective and complex. Trust can be graded into different levels from mild to strong. We hypothesize that each midwife passed through the different levels of trust so as to better understand and thus trust the HBB algorithm. Trust depends on several attributes such as intellectual and moral, as described by Hacker [83]; that "one may come to believe something from different kinds of reasons and one's belief may derive from different kind of sources". We speculate that the midwives individual attributes influenced HBB implementation, resulting in some variations in performance, as pointed by Macintyre [207]; "From the standpoint of the virtues [...] every life has or lacks a certain kind of directedness toward that agent's end, and individual acts are to be understood either as so directed or as frustrating movement toward that end. [...] As with judgments on individuals...". There may be considerably variability between individuals, and sometimes even within an individual at different time points. Variability at the individual level is usually influenced through repeated performances, which continually build trust and experience. Experience, in a greater extent, is a result of reflections on the history and the individual's continuous work and manipulate with an intention to keep improving. Kolb [99] philosophically explained the formation of purposes as a complex intellectual operation involving observations of the surrounding condition, knowledge of past experiences in the same situation, and judgments of what may result as consequences of an action. Results of such variations may be among the explanations of the variation in the CUSUM trend observed in study II.

5.2.6 Decision-making

Decision-making to initiate, continue and how, what and when to practice, is a process. FBOS HBB training was a process that involved frequent training as an individual or in small groups. During the CQI process, there was regular feedback on outcomes from resuscitation efforts. The feedback, which involved success stories and as well as challenges encountered, were motivating and used to further focus the training. We consider that this type of learning helped to influence decision-making related to several attributes such as individual behavior as observed in Study I [185].

5.2.7 Motivation to continue training and improve clinical practice

We speculate that repeated HBB algorithm skill-training continually built experience and led to behavior changes that may not depend on "memorizing for action". Hacker [83] outlined such memorizing, which is presented by the experience of doing (practice) being polymorphous. Practice was executed both in the simulation setting and in clinical situations with a newborn requiring resuscitation. We speculate that repeated practicing with a manikin in a simulation setting helped to promote skills and build competence on the steps to follow, as mentioned by Hacker [83] "… practical empirical knowledge is built up step by step as is molded by …with experience". However, making mistakes during simulations with the manikin may not have induced a moral reward, thus with less chance to promote confidence and trust. Contrary, in real newborn resuscitation, there is a moral consequence, such as death if not well done, and this consequence is irreversible. If we consider moral reward as a motivation to change practice, then practicing on a manikin may result in less chance to change behavior. However, opportunity for repeated simulation practice can help to master the steps, and help during resuscitation as outlined by Gadamer [101]; "…sphere of practical application of rules, ... that the more one

‘masters’ one’s know-how the more one possesses...”. Furthermore, we speculate that repeated practicing contributed in midwives to achieve a standardized requirement to properly perform resuscitation (competence) and self-efficacy [208]. The improvement may have resulted to some manipulations and, be in a form of an “art” where the implementer of the practice become “an artist” and practice in the best way thought [83]. Such mastery also align with Schon [95] that “through the process of reflecting both ‘in practice’ and ‘on practice’ practitioners continually reshape their approaches and develop “wisdom” or “artistry” in their practice”. This may be the explanation of what was observed in study III, which in spite of increased cases with high risks still improved survival was observed.

5.2.8 Evaluation of local implementation

Evaluation of the impact following implementation of new practices is a common practice and have logic since practices usually aims to achieve specific outcomes. However, sometime both the practices (process) and outcomes are evaluated and compared as the process against the outcome. Evaluating both, gives a broader understanding on the interaction of processes against the outcomes. Process evaluation helps to outline the strengths and gaps e.g. what/where/when/why they happen as pointed by Hacker [83]; “We need an account of how philosophical theorizing about morality [...] does on occasion function so as to disguise and conceal key aspects of social realities, of practice”. Understanding the process against the outcome helps to plan future improvement. In study II and III we evaluated both the process and impact of CQI project, and FBOS training in particular.

5.3 Improved perinatal survival over six years

The FBOS HBB simulation training at HLH aimed to translate the new knowledge acquired from HBB training to clinical practice and also to sustain the improvement over time. Continuous sustainment in improved outcomes over time was attained through CQI, of which continuous practice both in a form of brief simulation training and clinical practice were important. For continuous improvement in HBB resuscitation practice and newborn survival, the process was continually reviewed. The continuous review was coupled with feedback to midwives about the gaps and potential areas for improvement. The above efforts were executed in a continuous repeated process like a circle, adopting the PDSA model [186]. The continuation of CQI including FBOS HBB training was associated with improved perinatal outcome throughout the project period (6 years), including the period when there were observed more cases with high risks. In other settings, HBB training was not successful and there was no accompanying reduction in ePMR mortality [161]. Cancedda et al [155] have reported missing the impact of training for health professionals following educational interventions in LMIC. Efforts in other settings have resulted in improved newborn survival but with no sustainment over time [172]. Tabangin ME, et al [164] report different practices and the impact of retention of skills following HBB training. Such differences in reduction and sustained impact after implementation of EBP has also been reported by Birken et al [210] in their review of several evidence-based practice (EBP) in different settings. Further, several others studies have observed sustained reduction in ePMR over time [160,166]. In 2017, Ersdal et al [211] published a report entitled the “Successful implementation of Helping Babies Survive and Helping Mothers Survive programs - An Utstein formula for newborn and maternal survival” resulting from an Utstein consensus process and meeting. The consensus led to ten key action points for a successive implementation of HBS/HMS programs. The

QCI program including FBOS HBB simulation training conducted at HLH, contributed to seven of the ten key points from this consensus deliberation. The remaining three points were targeting involvement at the national level, and were implemented during the countrywide HBB implementation including at HLH [159]. Implementation and evaluation of the HBB curriculum at HLH contributed to the HBB revision process and development of the second HBB edition [212].

6 Discussion of the Methodology

6.1 General considerations

All the included studies in this thesis followed an observational before-after descriptive design. This methodology affords the potential to evaluate multiple exposures and outcomes [176]. However, observational methodologies start on a low certain evidence level at the beginning of analysis, according to the Grade which refers to a Grading of Recommendations, Evaluation, Assessment, Development and Evaluation system/criteria [https://gdt.gradepro.org/app/handbook/handbook.html]. The evidence level may later be upgraded or downgraded when examined in detail. Later, I will discuss potential areas that could explain the certainty of the observational methodology as applied in this thesis. The three studies looked at the influence of CQI and FBOS HBB simulation training on perinatal outcome (survival). The methodology involved baseline data collection for a period before implementation of CQI, and this posed risks for bias. Additionally, the methodology used posed a risk for confounders, resulting in an uncertainty to confirm exposure-causal effect relationships, as could have been done if a RCT methodology were used. However, to choose a RCT methodology for this CQI project, with the intention to confirm exposure-outcome relationships, would also pause uncertainties. The CQI efforts were intended to improve perinatal outcomes, and using an RCT design could mean denying one group (control group) quality practice, which we consider unethical. Further, the methodology used had multiple advantages that included assessing multiple exposures and outcomes, and was necessary for all the studies in this thesis [213].

The differences in time for data collection between baseline and the QCI intervention, and the long follow up period (study II and III) could

create several biases. We made several efforts to minimize or avoid such biases on different levels (see below).

6.2 Confounding

Confounding is a potential challenge to the validity of a causal-outcome relationship. A confounder is a potential factor in the pathway that could influence the outcome if not considered or adjusted for [214,215]. In the design used in this thesis, there was a potential for different explanations, not related to the CQI, which may have improved outcomes (survival). Such confounders included environment factors e.g. improvement of the labor ward, which could influence the birth outcome. Over time, the skills of care providers improved (experience), while other HCW with experience left HLH, and both these aspects had potential to influence perinatal outcome. Confounders from environmental factors over a protracted time period makes the methodology inferior to RCTs where typically two groups would have been compared in the same environment and time-period [60,63,64]. The long-term intervention/follow up period increased a potential for changes in the level of risks in the cohort, which may influence the outcome. In effort to reduce or eliminate the confounders from changes in risk we applied a risk adjusted regression model (study III), which concurs with a similar approach reported in the studies by Moger et al [197] and Omachi et al [198]. These are among the confounding factors that we considered, but there is a possibility for others that we did not account for, which could have influenced perinatal outcomes. Due to the confounding effects related to the methodology we used, it is difficult to be certain that the optimization of HBB implementation was the cause of the outcome observed. Reliance on such findings could have been stronger if the study was a RCT [214].

6.3 Biases

To achieve more reliable findings from research projects it is important to avoid or minimize biases as much as possible [216]. Clinical studies are accompanied with several challenges that affect scientific merit and affect the validity of the findings. Biases are among factors that negatively influence scientific studies validity. Biases can result at different levels in research such as when designing the protocol, collecting data, planning analysis, performance of analysis, and decision to publish the findings. In this thesis, there were at least six potential types of biases; recall bias, sampling or selection bias, observation bias, measurement bias (error), confirmation bias and publishing bias, and each is explained below.

6.3.1 Recall bias

There was a risk for this type of bias since information about pregnancy, labor and newborn were required, of which some happened sometime prior to collecting information. Recall bias usually results when the respondent is required to provide information about past events [216]. The extent of misreporting usually depends on the time-lapse between when the incidence of interest happened to when the information is collected. Usually, the longer the periods, the less reliable the information is expected. In the studies in this thesis, to prevent such bias, most information was collected from direct-real time observations e.g. birthing and birth outcome information. Information from the past events were collected from documented reports e.g. history of pregnancy from the antenatal clinic cards (appendix 5) and this minimized or avoided this type of bias.

6.3.2. Sampling bias

Sampling bias usually happen when there is an unfair selection of sample not representing the population where the study is done. In this project, the study design involved collection of data from all midwives and other birth attendants, birthing women and newborns (birth outcomes) at HLH. As a result bias related to selection of participants was minimized or avoided. Women were involved in the period during labor and newborns were involved up to 24 hours post-delivery in the ward. This design prevented bias from dropout. However, there were two potential sampling biases. First, experienced midwives who dropped out and the recruitment of non-experienced midwives during the study period. Second, if we consider the entire population (catchment area), then sampling bias existed as this project involved only women giving birth at HLH and excluded those giving birth in other areas in the catchment, e.g. other health facilities and home. In this catchment area about 50% give birth at home and others in other health facilities [178].

6.3.3 Observation bias (Hawthorne effect)

The three studies involved using observers to collect data. The presence of observers could potentially affect the performance of midwives knowing that they were observed and their performance recorded. Such observations are prone to cause a positive influence on performance [217]. To reduce this threat, data collection started several months (about 7 months) before implementation of the project (i.e. start of baseline data collection) to make midwives used to the observers and being observed. Additionally, the observers were present 24/7 throughout the whole study period. Being present throughout the period should bias the pre and post intervention periods in the same way, thus reducing potential differences between the periods. Further,

if a Hawthorne effect was present, it is most likely to affect the baseline period and thus making the baseline better.

6.3.4. Measurement errors (bias)

Self-reported measurements and device inaccuracy are potential causes for measurement errors. Measurement errors have been reported in several health projects [218]. To avoid or reduce self-reported bias, the observations and measurements involved non-professional observers (trained research assistants, called “watch girls” at HLH) who were not part of health care. These “research assistants” were trained to observe events and time-intervals and to record the information on structured data collection form (appendix 1,2) guided by the SOP (appendix 3, 4). Collections of data by observers, who were not part of the clinical team, aimed to avoid or reduce measurement and reporting biases. Earlier studies have shown that CQI based on self-reporting by the involved staff may be flawed [193]. The devices used in collecting data were those originating from the research department (timers/stop watches) and devices to measure fetal heart rate from the research and clinical departments. The HCW validated the clinical devices, while other research tools were validated in the research department. Due to the efforts to validate the devices, we believe there were only minimal errors and these were systematic. Measurement errors may also be due to different measurements in different research groups. There were no different intervention groups, but a baseline and a CQI group, which avoided or reduced this type of bias. Having different groups, as in a blinded RCT design may result in HCWs practicing differently during intervention [216,218].

6.3.5 Confirmation bias

Confirmation bias usually happens when researchers struggle to achieve results that will support their ideas. There was a potential for this type of bias as the goal for CQI was to improve birth outcome. Such bias may result from a design that purposely aims to support what is expected and may also involve the type of analysis to be used. However, there was a genuine intention, and there was no personal benefit from supportive findings. To further justify that any of the findings were important, was the use of the PDSA model, where negative outcomes were welcomed to help planning improvements. For example, the negative findings from the initial one-day HBB training with no improvement in clinical care [169], was used to plan the CQI efforts and FBOS HBB training program.

6.3.6. Publishing bias

Data collection in research aims to answer the research question. There is a tendency that findings that seem to oppose what was expected, is not published - resulting in publication bias. Publishing positive or negative results is equally important as both informs the readers, including scientists about what is found from the study and may avoid other scientists to repeat a similar study. However, other scientists may repeat a "similar" study to either prove or disapprove the previous reported findings or try to find out if the findings were due to methodological related issues. In occasions that studies with positive and negative findings are not reported equally, when metanalyses or systemic reviews are performed, the findings may be biased, as studies with negative findings will be underreported and the results will be skewed towards the positive side. To avoid this challenge, both negative and positive findings are to be included. In this setting, the

negative findings were also published [169] which avoided this type of bias.

6.4 Generalization (external validity), strengths and limitations:

All three studies in the project took place in a single site, resulting in a socio-demographic restriction, and generalization from these findings may be questioned. Due to this limitation, we suggest that similar studies are conducted in different settings to clear this type of bias [219,220]

6.4.1 Strengths

The sample sizes were large, between 9000 (pre/post cohort) in study I, to about 31000 newborns in study III, and the big cohorts are among the strengths of the three studies. The baseline group, without CQI including FBOS HBB simulation training, was compared to the group with CQI in a “similar” cohort (participants) and environment (HLH) [221-223]. Further, the focus of the studies was about learning and changes in clinical practice, and we believe that the findings can be generalized since learning processes are almost the same across different individuals and settings [98]. Additionally, the HBB curriculum as part of QCI (and the main focus in the three studies) is designed to be used worldwide, especially in LMIC. Thus, the findings in this project are relevant in other LMIC settings [212]. Finally, we evaluated the findings on three levels of the Kirkpatrick model (level II, III and IV) and found improved knowledge, translation of clinical skills to clinical practice and improved survival.

6.4.2 Limitations

The studies were conducted in a single rural setting, which limits the findings to be applied in other settings. The focus of the CQI HBB training was to change behavior (resuscitation practice). However, learning as a result of training and changes in behavior are influenced by several other attributes such as culture, social life, setting and education background, as explained before [79]. The design (before-after observation study) for this project limits causal evidence, i.e. that the observed improved survival in perinatal outcome was a result of optimizing HBB implementation [176]. The evidence could be certain if a clinical RCT design was applied, as is the only design that evident a causal effect in intervention studies [213].

6.5 Statistical analyses

All three studies used "Before versus after" analyses to document the impact of CQI, and further to find the association between the FBOS HBB training (as part of QCI) and perinatal outcome [53, 175, 220]. In this design the period "before" implementation was used for baseline (control) and considered as an existing situation. The period "after" was the period after implementation of CQI, FBOS HBB training included. The impact of CQI was evaluated by measuring the changes between the two periods i.e. "before" and "after".

In study I; the samples were grouped on an annual basis to be able to achieve an adequate sample size and also to capture monthly changes (seasonality) which could have different level of risks e.g. during wet rainy season delay of women to visit HLH to give birth was expected as roads were worse. The different in data-points between the two periods was associated with CQI, FBOS HB training in particular, and there was a significant improved newborn survival [159,162, 167, 203].

In study II; for long terms follow up to evaluate the process, we established a monthly baseline value. In each month the differences

between observed outcome (survival) and base line were plotted on SPC charts (CUSUM and VLAD). The time points for events that could potentially influence the perinatal outcome were marked on the trend. The plotted trend helped to visualize the process (changes) during the five years follow up period, and both improved and reduced survival were observed. CUSUM showed an increase in survival connected to renewed focus on training, this may be of a universal interest. Reduced survival was associated with the period when experienced nurses left the hospital (figure 9).

In study III, the SPC charts were used to plot ePMR as done in study II. However, in study III, the aim was to document the changes in perinatal survival over time when considering the level of risks on the exposures. Adjustment of risk was important due to the fact that risks are not constant over time, and due to the long period (6 years) changes in risks were significantly expected [149,196,197]. Univariable logistic regression was applied to identify the exposures with significant risks. Hosmer-Lemeshow test was applied to find the variables that could have influenced the outcome and were included in the regression model. Finally, the SPC model/plots with no risk adjustment and with risk adjustment were compared to document the differences and is when about 100 extra survivals were observed after risk adjustment. We speculate that the continuous improvement in perinatal survival through the study period, even when the risks were increased is the result of continuous improved midwives practice, and mostly in resuscitation from FBOS simulation training. FBOS (LDHF) has been found useful to improve skills in other setting [190,201-203]. In spite of the intervention and other activities, different in time could also have effect and is a potential limitation as was not considered in analysis. This methodology has limitation due to data collection in different time period (“before” and “after”). The unknown factor(s) that could have relationship with the exposure and outcome were likely to confound the

findings of which RCT could be more appropriate to avoid such a limitation.

6.6 Ethical considerations

6.6.1 Introduction

There is an agreement globally that the conduct of research involving human participants must be guided by ethical principles and guidelines to ensure their safety and wellbeing. Research has been of much benefit in improving human leaving, but some have raised several questions on ethical issues. The Nuremberg code includes a set of principles and guidelines for medical research. This code was developed after crimes taken place during the Second World War "Nazi crimes" [187]. Among the set-principles was the "voluntary informed consent". Later, the "Declaration of Helsinki" resulted from the World Medical Association (WMA) conference held in Helsinki Finland in 1964. The declaration has undergone several (six to date) revisions, resulting in the current set standards. Among the standards outlined are; requirements of informed consent, participant safety/confidentiality, care for vulnerable population, review by independent review board, and policy for publication [187]. The summary of basic ethical principles and guidelines for health research was presented in the Belmont report (1974). The report summarized the three basic principles; (1) respect for person, (2) beneficence, and (3) justice [187 -189]. Additionally, the report outlines the boundaries between medical service and medical research. Application of all the three studies on this thesis considered the ethical requirements to safeguard the participants and community at large, and below I discuss the issues in relation to the studies.

6.6.2 Vulnerable population

Vulnerable population involves a group of people who require extra protection to ensure their rights and safety in research from potential risks due to their involvement for several reasons [187]. Among the groups and reasons include those with cognitive incompetence and minors who are not able to make legal decisions on participation/consenting, pregnant women, those economically disadvantaged, and very sick individuals. Our CQI project involved pregnant women, who visited HLH to give birth and their newborns. Most women visiting HLH were from low social-economic status, which make them vulnerable for exploitation for research interest. The National Institute for Medical Research (NIMR), an independent ethical committee reviewed and approved the CQI project and other projects during the period. Among others, the review was to ensure the rights and safety of this vulnerable population for their involvement in research. The project involved training midwives in basic care around the time of birth, which is in line with better protection, also affecting the newborn. The principle investigator was obliged to protect the right of the research participant, which included training of the team and overseeing the research team on ethical practice.

6.6.3 Informed consent and participant safety

In the application of respect for a person (autonomy), informed consent and voluntariness are basic requirements [187]. In this CQI project, no consent was obtained and all women attending to give birth at HLH were included in the project, which pause an ethical dilemma. This uncertainty was addressed through the proposal being reviewed by the national health and research ethics committees in both nations related to the project i.e. Tanzania and Norway. After review, the committees found that the project was a quality improvement and aimed to improve

midwives and other birth attendant's clinical skills. The committees also came into consensus that denying a woman to better care from further skilled attendants was to prevent their rights to the best available care, which was unethical. For other sub-studies, which were part of the Safer Births project and happened during the CQI period, informed consent were required. Those studies involved testing of different medical devises (RCTs) [177,184]. In the RCT almost 50% did not consent to participate indicating that their right to voluntary participation was respected [184]. This further gives an impression that there was also no coercion to influence participation in this population where the level of illiteracy and ignorance is substantial high and low economy.

6.6.4 Beneficence

Wellbeing of the participants is important in research participation. The investigators are obliged to ensure the wellbeing of research participants. There are rules to ensure that benefit is maximized, to minimize risks as much as possible, and at least no harm should result by participating [187]. The CQI and FBOS HBB training aimed to equip midwives with the required skills to improve birth outcome. Newborn survival in the area where the project took place was unacceptably low. Efforts to promote survival were in line with the principle of beneficence. During the project period, there was observable improvement in birth outcomes over time, making the project beneficial to women attending to give birth and the community they belonged to. During the period, the Safer Births project involved testing new devices [177,184], which also aimed to improve birth outcomes and ease midwives' working environment. The research assistants, who were responsible for data collection, helped with some non-professional works like cleaning, when there was no birthing

woman (no data collection). Thereby, they reduced the burden of work to the midwives and hence benefitted this group of participants.

6.6.5 Justice

Justice is about fairness when involving participants or selecting settings for a research project. For a project to be fair, those who take the burden to participate have to be among the potential groups or settings to receive potential benefits. This project took place where the burden of perinatal deaths was high especially for asphyxiated newborns [35]. Having this project at HLH was fair since women and society were part of those to benefit if the project resulted to improvement on perinatal survival.

6.6.6 Safety and confidentiality

Protecting participants and their information are among the requirements in ethical conduct of biomedical and social research [189]. Improvement of midwives' and other birth attendants' skills through CQI including HBB training were positively affecting maternal and newborns safety. There were several efforts set in place to ensure confidentiality or to minimize the chances of breaking confidentiality, i.e. the project team involved in data collection was trained and certified in research ethics and good clinical practice (GCP) before being involved in data collection and management. Data collected did not include identification information (de-identified data) of the participants and only used unique numbers. Completed data collection forms were secured and locked in cabinets within the research office, and only authorized personnel had access. Computers, which were used for data entries were password protected and only those involved in data entries had access. In spite that data collected did not include identifying information, still there was a possibility to trace back and identify participants by using date and time of birth, which paused an ethical dilemma. However, due to the above multiple protection

strategies, we assume that the risk to track-back and break confidentiality were avoided, and if existed then were very minimal.

6.6.7 Funding

Funding is among the important parts of research projects, as this is required to help facilitate project activities. However, in some occasions funding pause ethical dilemmas since funders may be prone to conflict of interest (COI). This HBB and Safer Births projects had multiple funders, including the Norwegian Research Council, Global health and vaccination research (GLOBVAC), the Laerdal foundation, Norway, and Saving lives at Birth Grand challenge. This PhD thesis was funded by the Stavanger University Hospital. The Laerdal foundation; a non-for-profit organization is connected with the Laerdal Company that manufactured some of the equipment's used in this CQI project, hence with potential COI. The activities related to data collection, management and publication of the findings were independent from the Laerdal Company, which removes this potential conflict. The rest of the funders did not have any connections with the project, besides funding.

7 Conclusion

This PhD project documents the potential of optimizing the implementation of CQI programs, in particular FBOS HBB simulation training to improve clinical practice and specifically increased survival. The improvement in clinical practice was associated with improved early perinatal survival in all the three studies.

The findings demonstrate a change in clinical practice, where more asphyxiated newborns were stimulated and suctioned after implementation of CQI FBOS HBB training compared to the baseline period. The number of asphyxiated newborns who received BMV was reduced, likely because of the increase in newborns being stimulated. Further, we speculate that for severely asphyxiated newborns, BMV was more timely and effectively applied, reversing the asphyxia process. During the CQI period, several administrative events and other research activities, that potentially could have influenced early perinatal outcome, took place. However, FBOS HBB simulation training was the only intervention that continued throughout the period and found to be significantly associated with increased early perinatal survival. Further, a risk adjusted SPC model demonstrated increased early perinatal survival even when there were more high-risk patient cases that could negatively have impact survival. The findings indicate that CQI, FBOS simulation HBB training contributed to the observed improved early perinatal survival. Finally, this thesis provides important knowledge about the local implementation process of new health service interventions, and the critical importance of continuous monitoring and evaluation of both processes and outcomes to make a change.

8 Future studies

During the CQI period we observed significant improvement in perinatal survival and associating factors that may potentially influence the findings. There were potential issues that could be associated with positive or negative outcomes in survival, which necessitate further studies to provide more insight. The following future studies are proposed:

1. Multi-sites studies to evaluate effects of CQI, FBOS simulation training and practice in particular to reduce early perinatal mortality.
2. Document potential reasons for not assessing FHR during labor.
3. Document potential reasons for women to delay admission to health facilities (labor ward) to give birth.
4. Evaluate the cost-benefit of delivery and ambulance fees for women who are to attend and give birth in health facilities.
5. Document pre-disposing factors and timing for referral of women from primary health facilities to referral hospital.

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Appendices

Appendix 1. Data collection form (Version 1)

MOTHERS HOSPITAL ID	☐☐☐☐☐☐☐☐☐☐
NEWBORN ID	☐☐☐☐☐☐☐☐☐☐
**If Multiplies (twins and more)	☐ Newborn number (write 8 if single birth)
Date of birth	☐☐ DAY ☐☐ MONTH ☐☐ YEAR
Time of birth	☐☐ HOURS ☐☐ MINUTES
Antenatal care attendance	☐1 YES ☐2 NO
Pregnancy complication	☐1 YES ☐2 NO
**Source of admission	☐Referred from health centre ☐2 Inpatient

LABOUR INFORMATION	
Equipment checked	☐1 YES ☐2 NO
Delivery kit present	☐1 YES ☐2 NO
Resuscitation kit present	☐1 YES ☐2 NO
Maternal Infection	☐1 no ☐2 uterine ☐3 malaria ☐4 HIV ☐5 others
Sepsis	☐1 YES ☐2 NO
Fetal heart rate	☐1 Normal (120-160) ☐2 Abnormal ☐3 Not detectable ☐9 Not measured
**Mode of delivery	☐1 SVD ☐2 C/S ☐3 ABD ☐4 Vaccum

Presentation	☐1 Cephalic ☐2 Breech ☐3 Shoulder dystocia ☐4 Transverse ☐5 Others
HCW attending the delivery	☐1 Midwife ☐2 Ward attendant ☐5 Doctor ☐3 Student ☐4 Clinical officer ☐6 None

LABOUR COMPLICATION	☐1 YES; Fill in this section ☐2 NO; go to next section
Prolonged labour	☐1 YES ☐2 NO
Obstructed labour	☐1 YES ☐2 NO
Vacuum	☐1 YES ☐2 NO
Cesarean Section	☐1 YES ☐2 NO ☐3 Elective_____
Pre-eclampsia	☐1 YES ☐2 NO
Eclampsia	☐1 YES ☐2 NO
Uterine rupture	☐1 YES ☐2 NO
Cord prolaps	☐1 YES ☐2 NO
Bleeding (i.e. placenta previa)	☐1 YES ☐2 NO

NEONATAL INFORMATION	
Birth weight	☐☐☐☐ GRAM
Gestational age	☐☐ WEEKS
Sex of newborn	☐1 MALE ☐2 FEMALE
Time intervals	

birth – breathing birth - cord clump	☐☐☐☐ SEC (skip if resuscitation is needed) ☐☐☐ SEC
Apgar score (range 0-10)	☐☐ 1 MIN ☐☐ 5 MIN

RESUSCITATION ATTEMPTED	☐1 YES; Fill in this section ☐2 NO; go to next section
stimulation	☐1 YES ☐2 NO
suction	☐1 YES ☐2 NO
bag valve ventilation	☐1 YES ☐2 NO
**heart rate evaluated	☐1 YES ☐2 NO
**heart rate present	☐1 YES ☐2 NO
Time intervals birth - breathing or ventilation ventilation - breathing or death	 ☐☐☐☐ SEC ☐1 Breathing ☐2 Ventilation ☐☐☐☐☐☐SEC ☐1 Breathing ☐2 Death
**Who provided resuscitation	☐1 Midwife ☐2 Operating Nurse ☐3 Clinical Officer ☐4 Doctor ☐5 Other; _____ ☐6 AMO
Last training in newborn resuscitation Was that a HBB course?	☐☐ MONTH ☐☐ YEAR ☐ 1 YES ☐ 2 NO

**PERINATAL OUTCOME within 30 min	☐1 NORMAL ☐2 Admitted 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 /or at discharge ____ hours postpartum	☐1 NORMAL ☐2 Still in Room 20 ☐3 Death
POST PARTUM MATERNAL COMPLICATION	☐1 YES; Fill in separate form ☐2 NO; End of form
Observers initials	

Appendix 2. Data collection form (version 2)

Study Station	☐ HLH
Mother Hospital ID	☐☐☐☐☐☐☐☐☐☐
Newborn ID	☐☐☐☐☐☐☐☐☐☐
*If Multiplies (twins and more)	☐ Newborn number (write 8 if single birth)
Date of birth	☐☐ DAY ☐☐ MONTH ☐☐ YEAR
Time of birth	☐☐ HOURS ☐☐ MINUTES
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	
*Gestational age	☐1 Term ☐2 Pre-term ☐☐ WEEKS
*Foetal Heart Rate (FHR) on admission	☐1 Normal (120-160 BPM)

	☐2 Abnormal (< 120 > 160 BPM) ☐3 Not detectable ☐9 Not measured
*Cervical dilatation (on admission)	☐☐ CM ☐9 Not measured
*Presentation	☐1 Cephalic ☐2 Breech ☐ 3 Others_____
*CONSENT	☐1 YES ☐2 NO ☐3 NA *(If NO or NA skip to Labour information)*
SCREENING (all with * mark) Eligible if:	Singleton (Y) Gestation age (term) Cephalic presentation (Y) FHR (120-160 BPM) Cervical dilatation (≤7cm) Placenta abruption/praevia (N) Ruptured uterus (N) Consent (Y)
ELIGIBLE for FHR study?	☐1 YES ☐2 NO *(If NO skip to Labour information)*
RANDOMISATION	☐1 Pinard fetoscope ☐2 Handheld Doppler ☐3 Laerdal FHR monitor; number of monitor ☐☐

LABOUR/DELIVERY INFORMATION	
Maternal fever	☐1 YES ☐2 NO
Maternal Infection (more than 1 is possible)	☐1 NO ☐2 uterine ☐3 malaria ☐4 HIV ☐5 Others; mention _____
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
If abnormal; what rate Confirm with handheld doppler	☐☐☐ BPM *(if with Doppler skip next question)* ☐☐☐ BPM
Duration of labour	
1st. stage 2nd. stage 3rd. stage	☐☐:☐☐ hrs:min ☐☐:☐☐ hrs:min ☐☐:☐☐ hrs:min
Last FHR measurement before delivery	☐☐☐ BPM Time ☐☐:☐☐ ☐ Not measured
Mode of delivery *(If 1,3,4 or 5 skip to HCW attending delivery)*	☐1 SVD ☐2 CS ☐3 ABD ☐4 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 Malpresentation ☐ 5 Others; mention_____
HCW attending the delivery	☐ 1 Midwife ☐ 2 Ward attendant ☐ 5 Doctor ☐3 Student ☐ 4 Clinical officer ☐ 6 None

LABOUR COMPLICATION	
Obstructed labour	☐1 YES ☐2 NO
*Uterine Rupture	☐1 YES ☐2 NO
Pre-eclampsia	☐1 YES ☐2 NO
Eclampsia	☐1 YES ☐2 NO
Cord prolapse	☐1 YES ☐2 NO
*Bleeding (i.e. placenta previa)	☐1 YES ☐2 NO
Shoulder dystocia	☐1 YES ☐2 NO

NEONATAL INFORMATION	
Birth weight	☐☐☐☐ GRAM
Sex of newborn	☐1 MALE ☐2 FEMALE ☐ 3 Ambiguous
Time intervals (for HLH)	
birth – breathing	☐☐☐☐ SEC *(skip if resuscitation is needed)*
birth - cord clump	☐☐☐ SEC
birth - use of heart rate buckle	☐☐☐ 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)	☐1 YES ☐2 NO ☐3 NA If Yes; name of monitor _____ If No; mention reason _____

Stimulation Suction Bag mask ventilation	☐1 YES ☐2 NO ☐1 YES; by use of Penguin ☐3 YES; not Penguin ☐2 NO ☐1 YES ☐2 NO
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 HBB full course attended?	☐☐ MONTH ☐☐ YEAR ☐ 2 NA
Ever practiced with NeoNatalie in past 7 days?	☐1 YES ☐2 NO

PERINATAL OUTCOME within 30 min	☐1 NORMAL ☐2 Admitted neonatal unit (room 20) ☐3 Death (END)

	☐4 Stillbirth (fresh) ☐5 Stillbirth (macerated) *(If 3,4, or 5 skip neonatal outcome)*
Neonatal outcome at 24 hours postpartum /or at discharge _____ hours postpartum	☐1 NORMAL ☐2 still in neonatal unit ☐6 Seizures ☐3 Death
Neonatal outcome of admitted baby at _____ days (max 7 days)	☐1 NORMAL ☐2 still in neonatal unit ☐6 Seizures ☐3 Death
Observer's initials	

Appendix 3. SOP for completing data collection form (version 1)

Purpose: The purpose for this SOP is to describe the requirement and procedure to follow in collecting and filling the HBB form in maternity Ward at Haydom Lutheran Hospital (HLH) for standardization and adherence to HBB study protocol.

Scope: This SOP applies to all HBB study team involved in collecting the information, filling the forms, doing QC and data entry.

Responsibilities: The Investigators (PI and Co-PIs), study supervisor and other staff are obliged to read, understand and follow this SOP during developing and revision of the SOP to be used in the HBB study Protocol.

Procedure:

1. Involved study staff will have to Identify all the procedure that will be involved in the "Towards MDG4&5" study. RA will be responsible to fill the form
2. Whenever possible, the research staff who will be involved in following the SOP should be involved in the SOP development process
3. The SOP effective date and date of revision should be modified wherever there is change and be started by mentioning the revision date
4. All those who should be involved in using/following the SOPs for the study procedure conduct should be stated on the scope and sometime including their roles e.g. study

Variables and description of collecting and recording the information:

MOTHERS HOSPITAL ID	Mother ID should be hospital ID and the last 2 digit be last 2 digit of exciting year e.g. 12 (for year 2012). Boxes with no entry filed with 000. e.g. mother ID 2556, year 2012 will be: "0000255612"
NEWBORN ID	This is new born unique number, and will be filled during data entry
**If Multiplies (twins and more)	Newborn number(s) if twins write "1" for 1st twin and "2" for 2nd twin etc. If single birth write "8"
Date of birth	Record 2 digit on date, 2 on month and 2 last digit for year. E.g. "02 11 12" (for 2 November 2012)
Time of birth	Record hours on 24 round time, and 2 digits for minutes(s). e.g. "14.08" (for 2pm and 8 minutes)
Antenatal care attendance	Collect this information from mother of Antenatal card, and record "YES" if attended antenatal care and "NO" if was not enrolled and attending antenatal
Pregnancy complication	Information from patient hospital record or caregiver e.g. midwife, doctor etc. Record "1 YES" if there was complication and "2 NO" if there was no complication
**Source of admission	If patient was referred from other health facility mark "X" on Referred from health centre box, and if not e.g. from home mark "X" on 2 Inpatient box

LABOUR INFORMATION	
Equipment checked Delivery kit present Resuscitation kit present	Observe If caregiver checked delivery kit equipment before starting conducting delivery mark "X on 1 YES" box, if didn't check mark "X on 2 NO" box. Observe If care gives checked Resuscitation kit before starting conducting delivery mar "X on 1 YES" box, if didn't not check mark "X on 2 NO" box.
Maternal Infection Sepsis	Collect information from patient file or caregiver if patient have infection and mark "X" on appropriate box YES/NO. Collect information from patient or care give if patient have sepsis and mark "X" on appropriate box YES/NO
Fetal heart rate	Collect information from patient file or caregiver about fetal heart rate and mark "X" on appropriate box. Possible answers are "1 Normal (120-160)", "2 Abnormal" "3 Not detectable" and "9 Not measured"
Presentation	Collect information from patient file or caregiver, and mark "X" on appropriate box possible answers are "1 Cephalic", "2 Breech", "3 Shoulder dystocia", "4 Transverse" or "5 Others"
HCW attending the delivery	Observe or collect from caregiver and mark "X" on appropriate box. Possible answers are "1 Midwife", "2 Ward attendants", "5 Doctor". "3 Student", "4 Clinical officer" or "6 None"

LABOUR COMPLICATION	Observe or collect from caregiver and mark "X" on appropriate box. Possible answers are "1 YES" if had complication and proceed to Fill in this section, or "2 NO" there was no complication and skip to next section
Prolonged labour	Collect from caregiver and mark "X" on appropriate box. Possible answers are "1 YES" if was prolonged and "2 NO" Collect from caregiver and mark "X" on appropriate box. Possible answers are"1 YES" if was obstructed labour meaning the newborn was not able to pass through the

Obstructed labour	birth canal for any reason e.g. CPD, malposition etc, or "2 NO" if was not obstructed.
Vacuum Cesarean Section	Observe and mark "X" on appropriate box. Possible answers are "1 YES" if vaccum was done. Observe and mark "X" on appropriate box. Possible answers are "1" YES if CS was done or "2 NO" if CS was not done, or "3 Elective" if CS was done following pre-plan before starting labour and have to mention the reason on space provided "_____"
Pre-eclampsia Eclampsia	From caregiver (on few occasion Observe) and mark "X" on appropriate box. Possible answers are "1 YES" if patient was reported to have pre-eclampsia defined as BP > ___, and albumin in urine ____ and "2 NO" if not. From caregiver (observation on some occasion) and mark "X" on appropriate box. Possible answers are "1 Yes" if patient has both signs of Pre-eclampsia and Fits, and "2NO" if not.
Uterine rupture	Collect from caregiver and mark "X" on appropriate box. Possible answers are "1 YES" if reported to have rupture of uterus, or "2 NO" if uterus was intact
Cord prolaps	Observe or collect from caregiver and mark "X" on appropriate box. Possible answers are "1 YES" if cord was preceding/ahead of the fetus before deliver or "2 NO" if the cord followed after delivery.
Bleeding (i.e. placenta previa)	Observe and collect from caregiver and mark "X" on appropriate box. This involves bleeding that occurred before delivery. Possible answers are "1 YES" if bleeding was estimated to be ≥ 500mls or "2 NO" if bleeding was estimated to be <500mls

NEONATAL INFORMATION	
Birth weight	Weigh the newborn or collect from caregiver and write the weight in GRAM in the boxes provided and fill all. If Macerated stillbirth, don't respond
Gestational age	Observe from ANT card or collect from caregiver and

	write the WEEKS in the boxes provided.
Sex of newborn	Observe and mark "X" on appropriate box. Possible answers are "1 MALE" or "2 FEMALE"
Time intervals birth – breathing birth - cord clump	 Observe and measure with STOP WATCH time from when the newborn was out of the birth canal to when started breathing/crying Possible answers write time in SECONDS in 4 boxes provide or SKIP if resuscitation is needed Observe and measure using STOP WATCH time from when the newborn was out of the birth canal to when the cord was clumped, record time in SECONDS in provided boxes. If clumped before delivery (e.g. In cord prolapsed fill 00)
Apgar score (range 0-10)	Collect from Patient file or Caregiver and record score in "1 MIN" and Score at "5 MIN"

RESUSCITATION ATTEMPTED stimulation suction bag valve ventilation	Observe if resuscitation was attempted, possible answer is "1 YES" if was attempted or "2 NO" if was not attempted and have to SKIP to next section If stimulation was done by rubbing the newborn and possible answers are "1 YES" if was done, or "2 NO" if no rubbing was attempted If stimulation was done by sucking the newborn and possible answers are "1 YES" if was done, or "2 NO" if no sanction was attempted Observe if bag valve was used to ventilate the newborn. Possible answer "1 YES" if was done, and "2 NO" if was not done.
Time intervals birth - breathing or ventilation	 Time from Birth to start breathing in seconds using stop watch and mark "X" on appropriate box. Possible "1 breathing" or "2 ventilation". If the response is "1" fill seconds on box and skip the following question to who provided. If the answer is "2" record seconds of time from

ventilation - breathing or death	birth to start ventilation. Record time using stop watch in seconds, possible answer after recording seconds "1 breathing" or "2 Death".
**Who provided resuscitation	Observe or ask and record who provided resuscitation to the new born and mark "X" on appropriate box. Possible answer is "1 Midwife" "2 Operating Nurse", "3 Clinical Officer", "4 Doctor" "5 Other" or "6 AMO", if response is "5" mention designation of who provided resuscitation
Last training in newborn resuscitation Was that a HBB course?	Last time that resuscitation provider attended training on resuscitating newborn, record date in format DDMMYY. Ask and record if that training in newborn resuscitation was HBB training. Possible answer is "YES" or "2 NO"

**PERINATAL OUTCOME within 30 min	Observation and confirming from caregiver, The outcome of birth within the first 30 minutes post delivery and mark with "X" on appropriate box. Possible answer is "1 NORMAL, "2 Admitted (room 20)" , "3 Death", "4 Stillbirth (fresh)" or "5 Stillbirth (macerated)" If response is "3", "4", or "5" skip neonatal outcome)
**Neonatal outcome at 24 hours postpartum /or at discharge ____ hours postpartum	Observe **and** find more from caregiver, and mark appropriate box with "X". Possible response "1 NORMAL, "2 Seizures", "3 Death" or "6 Difficulties in breathing"

Appendix 4. SOP for data collection form (version 2)

ON ADMISSION	
MOTHERS HOSPITAL ID	Mother ID should be hospital ID and the last 2 digit be last 2 digit of exciting year e.g. 12 (for year 2012). Boxes with no entry filed with 000. e.g. mother ID 2556, year 2012 will be: "0000255612"
NEWBORN ID	This is new born unique number, and will be filled during data entry
**If Multiplies (twins and more)	Newborn number(s) if twins write "1" for 1st twin and "2" for 2nd twin etc. If single birth write "8"
Date of birth	Record 2 digits on date, 2 on month and 2 last digits for year. E.g. "02 11 12" (for 2 November 2012)
Time of birth	Record hours on 24 round time, and 2 digits for minutes. e.g. "14.08" (for 2pm and 8 minutes)
Antenatal care attendance	Collect this information from mother Antenatal card, and record "1 YES" if attended antenatal care at least once or "2 NO" if did not attend.
Antenatal problem	Information from patient hospital record or caregiver e.g. midwife, doctor etc. Record "1 YES" if there was complication and "2 NO" if there was no complication
Source of admission	If patient was referred from other health facility mark "1 X" on Referred from health centre box and specify which place on the open line, or if not e.g. from home mark "2 X" on home and specify approximately how many hours since start of labor.
**Gestational age	Ask the caregiver if the baby is term or pre-term and mark in the box "1 term" or "2 preterm". Note the GA in weeks given by the caregiver or from the ANT card.
**Fetal heart rate (on admission)	Collect information from patient file or caregiver about fetal heart rate and mark "X" on appropriate box. Possible answers are "1 Normal fetal heart rate (120-160bpm)", "2 Abnormal" fetal heart rate less than 120bpm or higher than 160bpm (<120 or >160bpm , "3 Not detectable" and "9 Not measured"
**Cervical dilatation (on admission)	Collect information from patient file or caregiver and record the dilatation in centimeters or if not measured mark "9"

**Presentation	Mark "X" on appropriate box possible answer is "1" for Cephalic or "2" for Breech OR if different from above mark on "3" others and mention
**Consent	Collect from HCW if consent was obtain and mark "1 X" on YES if patient agreed to participate or "2 X" on NO If refused, or "3 X" on NA if not applicable. If NO or NA, skip the following two questions to Labour Information question
Screening (**mark is for eligibility criteria)	Review if: **Singleton (Y), **Gestation (Term = ≥37weeks), **Cephalic presentation (Y), FHR(normal=120-160), **Cervical dilatation (≥7cm), **Placenta abruption/praevia (N), **Ruptured uterus (N) and **Consent (Y), then eligible to join
Eligible for FHR study	Review all the above eligibility and respond "1 YES" if meet all the above to join the study or "2 NO" if miss any or combined of the above; if "2 NO" skip the next question to labour/delivery information
Randomization	Eligible women will be randomly allocated to one of the two methods under study by means of serially numbered sealed opaque envelopes containing the allocation. Mark "1 X" if on Pinnard group or "2 X" if on Doppler group or "3 X" if on Laerdal FHR monitor. For "3" Laerdal group put the number of the FHR monitor in use to monitor the fetal heart rate in the boxes provided
Labour Information	
Fever	Ask the HCW or collect from the form and possible answer is "1 YES" if mother has fever or "2 NO" if has No fever
Maternal Infection	Collect information from patient file or caregiver if patient have infection and mark **"X"** on appropriate box. Possible answer(s) are "X 1" No, or "X 2" Uterine infection and/or "X 3" Malaria and/or "X 4" HIV and/or "X 5" Others, and if "X 5" mention what other infection **Note;** Uterine infection should be suspected in case of prolonged rupture of membranes with foul smelling amniotic fluid discharge. If others, mention. More than one option is possible

Equipment checked Delivery kit present Resuscitation Kit (equipment) present	Observe If caregiver checked equipment (delivery and resuscitation "kit") before starting conducting delivery. Possible answer is " X 1" YES if were checked or "X 2" if were not checked. Observe If Delivery Kit is present. Possible answer is "X 1" if present or "X 2" if not present. Observe if Resuscitation Kit/equipments (Bag-mask, suction, dry towel) is Present or not. Possible answer is "X 1" if present or "X 2" if not present
Bag-mask present	Observe if Bag-Mask is present. Possible answer "X 1" if present or "X 2" if not present.
LABOUR/DELIVERY	
Fetal Heart Rate	Collect information from patient file or caregiver about fetal heart rate and mark **"X"** on appropriate box. Possible answers are "**1** Normal (120-160BPM)", "**2** Abnormal" if abnormal FHR is detected, record at first noted and record time "**3** Not detectable" and "**9** Not measured"
If abnormal what rate Confirm with the Doppler	Mention the rate in beats per minute e.g. 170BPM. If Measured by Doppler skip the next question In the Pinard group women whose fetus has an abnormal or undetected FHR will have the abnormality verified by Doppler. Repeat measurement with the Doppler if in the Pinard group
Duration of labour 1st stage 2nd stage 3rd stage	Record the duration of first, second and third stage of labour. **1st stage** is from onset of active labour (4cm) to 10cm dilatation, **2nd stage** is 10cm to delivery of the baby and **3rd stage** is from delivery of the baby to complete delivery of the placenta and membranes. ***If CS only fill part of 1st stage of labour and if is Elective CS skip this part.***
Last FHR before delivery	Copy the last FHR measured before delivery of the baby, record the rate and time measured. If no assessment was done, tick the "not measured" box

Mode of delivery	Observe or collect from caregiver and mark **"X"** on appropriate box. Possible answers are "1 SVD", "2 C/S", "3 ABD" or "4 Vaccum" or "5 Others; if "5" mention other method used". If not CS skip the following 2 questions.
Category CS Indication for CS	Observe or ask HCW and mark **"X"** on appropriate box. Possible answers are "1" emergency CS was done, or "2" elective CS was done. Elective mean CS was planned and done before the start of labour. Observe or ask care giver Tick the correct indication for the CS: "1" Obstructed labour, "2" Fetal distress, "3" Previous CS, "4" Malpresentation, or "5" Others and write the reason. .
HCW attending the delivery	Observe or collect from caregiver and mark **"X"** on appropriate box. Possible answers are "1 Midwife", "2 Ward attendants", "5 Doctor". "3 Student", "4 Clinical officer" or "6 None"

LABOUR COMPLICATION	Observe or collect from caregiver and mark **"X"** on appropriate box.
Obstructed labour	Collect from caregiver and mark **"X"** on appropriate box. Possible answers are"1 YES" if was obstructed labour meaning the newborn was not able to pass through the birth canal for any reason e.g. malposition etc, or "2 NO" if was not obstructed. Despite adequate uterine contraction no progress of labour. (in terms of descent and dilatation)
**Uterine rupture	Collect from caregiver and mark "X" on appropriate box. Possible answers are "1 YES" if reported to have rupture of uterus, or "2 NO" if uterus was intact. **Note:** The preoperative diagnosis need to be confirmed by the operative diagnosis.
Pre-eclampsia	From caregiver or patient file and mark **"X"** on appropriate box. Possible answers are "1 YES" if patient was reported to have pre-eclampsia defined as BP ≥ 140/90mmHg, and albumin in urine ≥+1 and "2 NO" if

	not.
Eclampsia	Ask caregiver (observation on some occasion) and mark **"X"** on appropriate box. Possible answers are "1 Yes" if patient has both signs of Pre-eclampsia and Fits, and "2" NO if not.
Cord prolapse	Observe or collect from caregiver and mark **"X"** on appropriate box. Possible answers are "1 YES" if cord was preceding/ahead of the fetus before deliver or "2 NO" if the cord followed after delivery.
**Bleeding (i.e. placenta praevia)	Observe and collect from caregiver and mark **"X"** on appropriate box. This involves bleeding that occurred before delivery. Possible answers are "1 YES" if bleeding was estimated to be ≥ 500mls or "2 NO" if bleeding was estimated to be <500mls
Shoulder dystocia	Collect from HCW, if there was shoulder dystocia, possible answer is "1 YES" or "2 NO".

NEONATAL INFORMATION	
Birth weight	Weigh the newborn or collect from caregiver and write the weight in **GRAM** in the boxes provided and fill all.
Sex of newborn	Observe or ask care giver and mark **"X"** on appropriate box. Possible answers are "1 MALE" or "2 FEMALE" or "3 Ambiguous" meaning not certain about the sex.
Time intervals (HLH) birth – breathing birth - cord clump	Observe and measure with STOP WATCH time from when the newborn was out of the birth canal to when started breathing/crying Possible answers write time in **SECONDS** in 4 boxes provide or **SKIP** if resuscitation is needed Observe and measure using STOP WATCH time from when the newborn was out of the birth canal to when the cord was clamped, record time in SECONDS in provided boxes. If clamped before delivery (e.g. In cord prolapsed fill **00**) If heart rate buckle was used record time from birth to use of buckle, including the name of monitor, ***if was not used skip this question***.

birth - use of heart rate buckle	
Birth- use of heart rate buckle	Observe and measure with STOP WATCH the time (in seconds) from when the newborn was out of the birth canal to the heart rate buckle was applied on the newborn.. If heart rate buckle was not used tick "NA = not applicable" (eg. no resuscitation attempted, not part of a study, not present, not working etc).
Apgar score (range 0-10)	Collect from Patient file or Caregiver and record score in "1 MIN" and Score at "5 MIN"

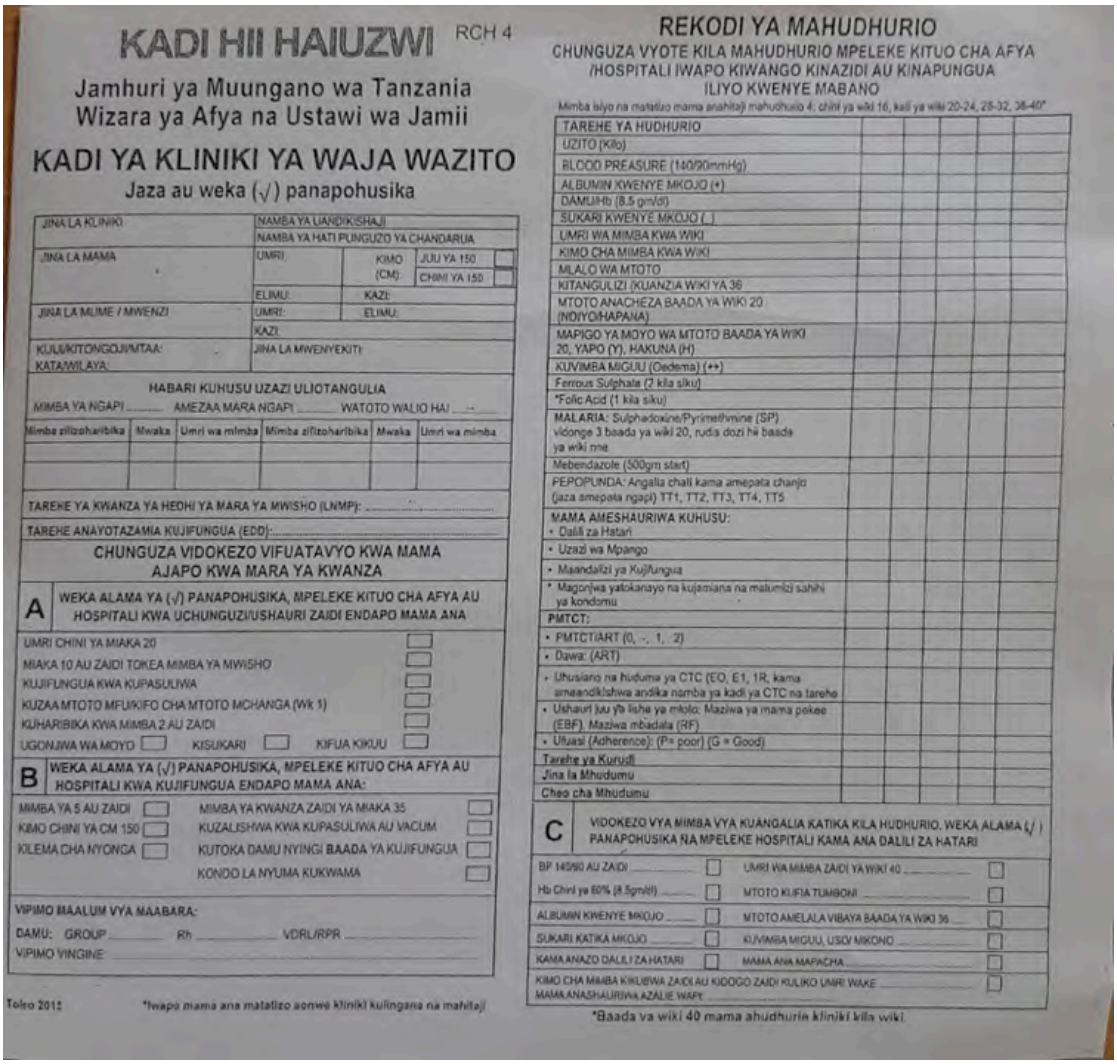
RESUSCITATION ATTEMPTED	Observe if resuscitation was attempted, possible answer is "1 YES" if was attempted or "2 NO" if was not attempted and have to **SKIP** to next section
Use of Newborn Resuscitation Monitor (NRM)	If the NRM was used in resuscitation tick "1 YES" and note which monitor (name). If NRM was not used tick "2 NO" and explain why on space provided e.g. NRM not working or not available
Stimulation	If stimulation was done by rubbing (more than drying i.e. rubbing vigorously on the back) the newborn and possible answers are "1 YES" if was done, or "2 NO" if no rubbing was attempted
Suction	If the newborn was sucked (as effort of resuscitation) by a penguin suction tick "1", if no suction was attempted tick "2", or if suction was performed with other device than a penguin suction tick "3".
bag mask ventilation	Observe if bag mask ventilation was used to ventilate the newborn. Possible answer "1 YES" if was done, and "2 NO" if was not done.

Time intervals (for HLH) birth - breathing or ventilation ventilation - breathing or death	 Time from Birth to start breathing in seconds <u>using stop watch</u> and mark **"X"** on appropriate box. Possible "1 breathing" or "2 ventilation". If the response is "1" fill seconds on box and **SKIP** the following question to who provided resuscitation. If the answer is "2" <u>record</u> seconds of time from birth to start ventilation. <u>Record time</u> using stop watch in seconds, from start of ventilation to stop of ventilation. Note the outcome of the baby when stop of ventilation; possible answer after recording seconds "1 breathing" or "2 Death".
Who provided resuscitation Did the Midwife/Birth attendant call for help to resuscitate?	<u>Observe or ask</u> and record who provided resuscitation to the new born and mark "X" on appropriate box. Possible answer is "1 Midwife" or "2 Operating Nurse", or "3 Clinical Officer", or "4 Doctor" or "5 Other" or "6 AMO", if response is "5" mention designation of who provided resuscitation Observe if the midwife (or other HCW) who delivered the mother asked for someone/another nurse to come and help to resuscitate the baby.
Last HBB full course attended	Last time that resuscitation provider attended full course on resuscitating newborn (usually one day training), record month and year MMYY. Or "NA" if did not attend a full course of HBB.
Ever practiced with NeoNatalie in past 7 days?	Ask if the resuscitation provider have ever practiced (using the bag-mask) with the manikin NeoNatalie in the **<u>past one week</u>**, Possible answer are "1 YES" if practiced one time or more or "2 NO" if did not practice

PERINATAL OUTCOME within 30 min	<u>Observation **and** confirming</u> from caregiver, The outcome of within the first 30 minutes post delivery and mark with "X" on priate box. Possible answer is "1 NORMAL, "2 Admitted (Room "3 Death (END)" Early Neonatal Death - born alive i.e. with PGAR score and died within the 1st 30 min of life), "4 Stillbirth)" born dead with Apgar score of "0" with tight skin or "5 irth (macerated)" born dead with macerated skin, indicating death

	ime before delivery. **If response is "3", "4", or "5" skip to observers initials**
Neonatal outcome at 24 hours postpartum /or at discharge ____hours postpartum	Observe **and** find more from caregiver, and mark appropriate box with "X". Possible response "1 NORMAL, "2 Still in neonatal unit"", "3 Death" or "6 Sizures ". **If 3 Death, skip to observers initials.**
Observer's initials	Initials of RA/research staff who filled the form.

Appendix 5. Antenatal card



KADI HII HAIUZWI RCH 4

Jamhuri ya Muungano wa Tanzania
Wizara ya Afya na Ustawi wa Jamii

KADI YA KLINIKI YA WAJA WAZITO

Jaza au weka (√) panapohusika

JINA LA KLINIKI	NAMBA YA UANDIKISHAJI		
	NAMBA YA HATI PUNGUZO YA CHANDARUA		
JINA LA MAMA	UMRI	KIMO (CM):	JUU YA 150 ☐ / CHINI YA 150 ☐
	ELIMU:	KAZI:	
JINA LA MUME / MWENZI	UMRI:	ELIMU:	
	KAZI:		
KIJIJI/KITONGOJI/MTAA: KATA/WILAYA:	JINA LA MWENYEKITI:		

HABARI KUHUSU UZAZI ULIOTANGULIA

MIMBA YA NGAPI ..... AMEZAA MARA NGAPI ..... WATOTO WALIO HAI ...

Mimba zilizoharibika	Mwaka	Umri wa mimba	Mimba zilizoharibika	Mwaka	Umri wa mimba

TAREHE YA KWANZA YA HEDHI YA MARA YA MWISHO (LNMP): .....

TAREHE ANAYOTAZAMIA KUJIFUNGUA (EDD): .....

CHUNGUZA VIDOKEZO VIFUATAVYO KWA MAMA AJAPO KWA MARA YA KWANZA

A WEKA ALAMA YA (√) PANAPOHUSIKA, MPELEKE KITUO CHA AFYA AU HOSPITALI KWA UCHUNGUZI/USHAURI ZAIDI ENDAPO MAMA ANA

- UMRI CHINI YA MIAKA 20 ☐
- MIAKA 10 AU ZAIDI TOKEA MIMBA YA MWISHO ☐
- KUJIFUNGUA KWA KUPASULIWA ☐
- KUZAA MTOTO MFU/KIFO CHA MTOTO MCHANGA (Wk 1) ☐
- KUHARIBIKA KWA MIMBA 2 AU ZAIDI ☐
- UGONJWA WA MOYO ☐ KISUKARI ☐ KIFUA KIKUU ☐

B WEKA ALAMA YA (√) PANAPOHUSIKA, MPELEKE KITUO CHA AFYA AU HOSPITALI KWA KUJIFUNGUA ENDAPO MAMA ANA:

- MIMBA YA 5 AU ZAIDI ☐
- KIMO CHINI YA CM 150 ☐
- KILEMA CHA NYONGA ☐
- MIMBA YA KWANZA ZAIDI YA MIAKA 35 ☐
- KUZALISHWA KWA KUPASULIWA AU VACUM ☐
- KUTOKA DAMU NYINGI BAADA YA KUJIFUNGUA ☐
- KONDO LA NYUMA KUKWAMA ☐

VIPIMO MAALUM VYA MAABARA:

DAMU: GROUP ..... Rh ..... VDRL/RPR .....

VIPIMO VINGINE .....

Toleo 2012 *Iwapo mama ana matatizo aonwe kliniki kulingana na mahitaji

REKODI YA MAHUDHURIO

CHUNGUZA VYOTE KILA MAHUDHURIO MPELEKE KITUO CHA AFYA /HOSPITALI IWAPO KIWANGO KINAZIDI AU KINAPUNGUA ILIYO KWENYE MABANO

Mimba isiyo na matatizo mama anahitaji mahudhurio 4: chini ya wiki 16, kati ya wiki 20-24, 28-32, 36-40*

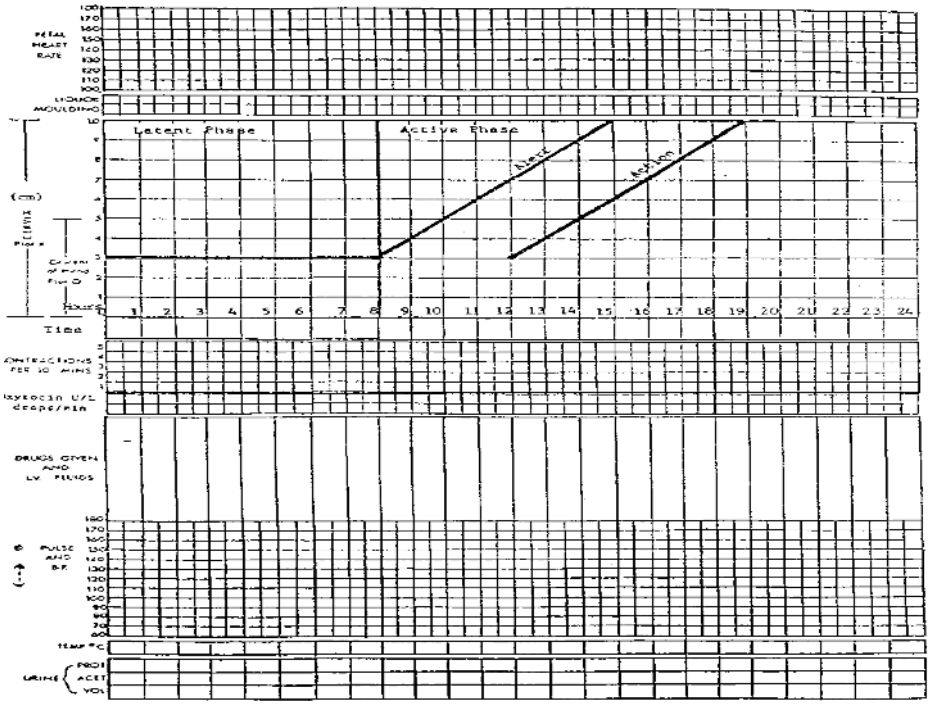
TAREHE YA HUDHURIO					
UZITO (Kilo)					
BLOOD PREASURE (140/90mmHg)					
ALBUMIN KWENYE MKOJO (+)					
DAMU/Hb (8.5 gm/dl)					
SUKARI KWENYE MKOJO ( )					
UMRI WA MIMBA KWA WIKI					
KIMO CHA MIMBA KWA WIKI					
MLALO WA MTOTO					
KITANGULIZI (KUANZIA WIKI YA 36					
MTOTO ANACHEZA BAADA YA WIKI 20 (NDIYO/HAPANA)					
MAPIGO YA MOYO WA MTOTO BAADA YA WIKI 20, YAPO (Y), HAKUNA (H)					
KUVIMBA MIGUU (Oedema) (++)					
Ferrous Sulphate (2 kila siku)					
*Folic Acid (1 kila siku)					
MALARIA: Sulphadoxine/Pyrimethmine (SP) vidonge 3 baada ya wiki 20, rudia dozi hii baada ya wiki nne					
Mebendazole (500gm start)					
PEPOPUNDA: Angalia chali kama amepata chanjo (jaza amepata ngapi) TT1, TT2, TT3, TT4, TT5					
MAMA AMESHAURIWA KUHUSU:					
• Dalili za Hatari					
• Uzazi wa Mpango					
• Maandalizi ya Kujifungua					
* Magonjwa yatokanayo na kujamiana na matumizi sahihi ya kondomu					
PMTCT:					
• PMTCTIART (0, -, 1, 2)					
• Dawa: (ART)					
• Uhusiano na huduma ya CTC (EO, E1, 1R, kama umeandikishwa andika namba ya kadi ya CTC na tarehe					
• Ushauri juu y/a lishe ya mtoto: Maziwa ya mama pekee (EBF), Maziwa mbadala (RF)					
• Ufuasi (Adherence): (P= poor) (G = Good)					
Tarehe ya Kurudi					
Jina la Mhudumu					
Cheo cha Mhudumu					

C VIDOKEZO VYA MIMBA VYA KUANGALIA KATIKA KILA HUDHURIO. WEKA ALAMA (√) PANAPOHUSIKA NA MPELEKE HOSPITALI KAMA ANA DALILI ZA HATARI

- BP 140/90 AU ZAIDI ..... ☐
- Hb Chini ya 60% (8.5gm/dl) ..... ☐
- ALBUMIN KWENYE MKOJO ..... ☐
- SUKARI KATIKA MKOJO ..... ☐
- KAMA ANAZO DALILI ZA HATARI ☐
- KIMO CHA MIMBA KIKUBWA ZAIDI AU KIDOGO ZAIDI KULIKO UMRI WAKE MAMA ANASHAURIWA AZALIE WAPI ..... ☐
- UMRI WA MIMBA ZAIDI YA WIKI 40 ..... ☐
- MTOTO KUFIA TUMBONI ..... ☐
- MTOTO AMELALA VIBAYA BAADA YA WIKI 36 ..... ☐
- KUVIMBA MIGUU, USO/ MIKONO ..... ☐
- MAMA ANA MAPACHA ..... ☐

*Baada ya wiki 40 mama ahudhurie kliniki kila wiki.

Appendix 6. Delivery sheet, partograph



Appendix 7. HBB staff training and practicing log

Year _____ Month_____ Week_____										
	Trainee initials	Mon	Tue	Wed	Thu	Fri	Sat	Sun	Remarks	Trainer signature
1										
2										
3										
4										
5										
6										

Appendix 8. Towards MDG 4 and 5 study National certificate

THE UNITED REPUBLIC OF
TANZANIA

National Institute for Medical Research
P.O. Box 9653
Dar es Salaam
Tel: 255 22 2121400/390
Fax: 255 22 2121380/2121360
E-mail: headquarters@nimr.or.tz

Ministry of Health and Social Welfare
P.O. Box 9083
Dar es Salaam
Tel: 255 22 2120262-7
Fax: 255 22 2110986

NIMR/HQ/R.8a/Vol. IX/1247

06th December 2011

Dr Hege Langli Ersdal
SAFER, Seehusens gate 1, Stavanger, Norway
C/O Estomih Mduma
Haydom Lutheran Hospital,
Private Bag, Mbulu Manyara

CLEARANCE CERTIFICATE FOR CONDUCTING MEDICAL RESEARCH IN TANZANIA

This is to certify that the research entitled: Towards MDG 4&5; Implementing "Helping Babies Breathe" and "Helping Mothers Survive" to improve perinatal and maternal outcome at Haydom Lutheran Hospital, Haydom, in Tanzania (Ersdal H L *et al*), whose Local Investigator is Estomih Mduma, Haydom Lutheran Hospital, Haydom, has been granted ethics clearance to be conducted in Tanzania.

The Principal Investigator of the study must ensure that the following conditions are fulfilled:

1. Progress report is submitted to the Ministry of Health and the National Institute for Medical Research, Regional and District Medical Officers after every six months.
2. Permission to publish the results is obtained from National Institute for Medical Research.
3. Copies of final publications are made available to the Ministry of Health & Social Welfare and the National Institute for Medical Research.
4. Any researcher, who contravenes or fails to comply with these conditions, shall be guilty of an offence and shall be liable on conviction to a fine. NIMR Act No. 23 of 1979, PART III Section 10(2).
5. Approval is for one year: 06th December 2011 to 05th December 2012.

Name: Dr Mwelecele N Malecela

Signature

CHAIRPERSON
MEDICAL RESEARCH
COORDINATING COMMITTEE

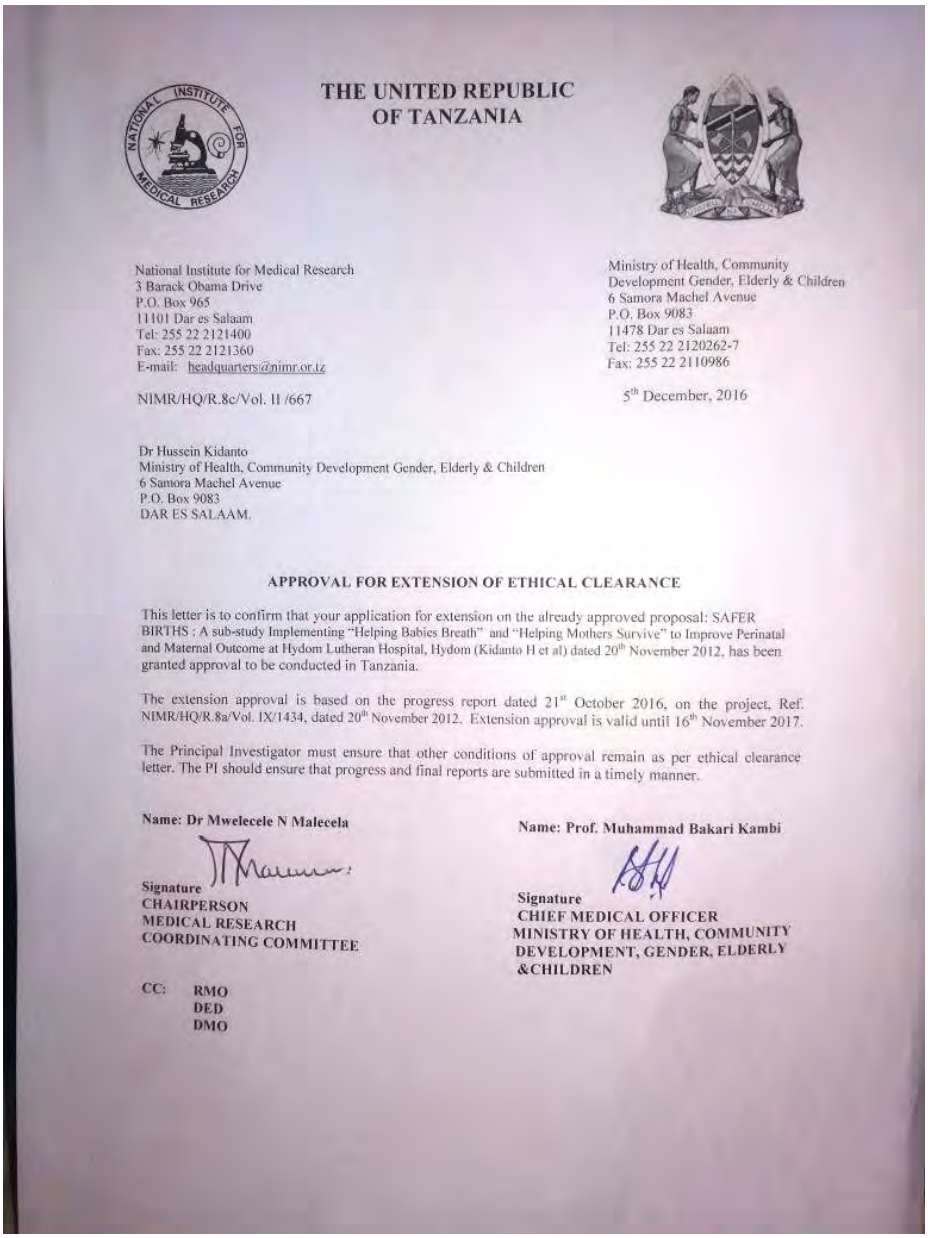
Name: Dr Deo M Mtasiwa

Signature

CHIEF MEDICAL OFFICER
MINISTRY OF HEALTH, SOCIAL WELFARE

CC: RMO
DMO

Appendix 9. Safer births study National certificate



THE UNITED REPUBLIC OF TANZANIA

National Institute for Medical Research
3 Barack Obama Drive
P.O. Box 965
11101 Dar es Salaam
Tel: 255 22 2121400
Fax: 255 22 2121360
E-mail: headquarters@nimr.or.tz

Ministry of Health, Community
Development Gender, Elderly & Children
6 Samora Machel Avenue
P.O. Box 9083
11478 Dar es Salaam
Tel: 255 22 2120262-7
Fax: 255 22 2110986

NIMR/HQ/R.8c/Vol. II /667

5th December, 2016

Dr Hussein Kidanto
Ministry of Health, Community Development Gender, Elderly & Children
6 Samora Machel Avenue
P.O. Box 9083
DAR ES SALAAM.

APPROVAL FOR EXTENSION OF ETHICAL CLEARANCE

This letter is to confirm that your application for extension on the already approved proposal: SAFER BIRTHS : A sub-study Implementing "Helping Babies Breath" and "Helping Mothers Survive" to Improve Perinatal and Maternal Outcome at Hydom Lutheran Hospital, Hydom (Kidanto H et al) dated 20th November 2012, has been granted approval to be conducted in Tanzania.

The extension approval is based on the progress report dated 21st October 2016, on the project, Ref. NIMR/HQ/R.8a/Vol. IX/1434, dated 20th November 2012. Extension approval is valid until 16th November 2017.

The Principal Investigator must ensure that other conditions of approval remain as per ethical clearance letter. The PI should ensure that progress and final reports are submitted in a timely manner.

Name: Dr Mwelecele N Malecela

Signature
CHAIRPERSON
MEDICAL RESEARCH
COORDINATING COMMITTEE

Name: Prof. Muhammad Bakari Kambi

Signature
CHIEF MEDICAL OFFICER
MINISTRY OF HEALTH, COMMUNITY DEVELOPMENT, GENDER, ELDERLY &CHILDREN

CC: RMO
DED
DMO

Appendix 10. Western Norway (REK Vest) HBB Ethical certificate

UNIVERSITY OF BERGEN

Regional Committee for Medical and Health Research Ethics, Western Norway (REK West)

Hege Langli Ersdal

Stavanger universitetssykehus

4022 Stavanger

Your ref	Our ref	Date
	2009/302	12.06.2009

Regional Committee for Medical and Health Research Ethics, Western Norway (REK West) consider the project "The Helping Babies Breath Program - evaluation of the educational material, the dissemination cascade model, and the effects of simulation training on management strategies and skill retention among health care workers in Tanzania" to be an educational program among certified health care workers and a evaluation of the program.

Formal approval from Norwegian ethical committee is thus not required.

We recommend that appropriate Tanzanian authorities approve the project.

Sincerely yours,

Jon Lekven

Chairman, REK Vest

Camilla Gjerstad

Committee secretary

Appendix 11. Western Norway (REK Vest) Safer Ethical certificate

REK
REGIONALE KOMITEER FOR MEDISINSK OG HELSEFAGLIG FORSKNINGSETIKK

Region:	Officer:	Telephone:	Our date:	Our reference:
REK vest	Anne Berit Kolmannskog	55978496	05.03.2013	2013/110/REK vest
			Your date:	Your reference:
			22.01.2013	

Hege Langli Ersdal

Research Department
Stavanger University Hospital

2013/110 Safer Birth

Body responsible for the research: Stavanger University Hospital
Project Manager: Hege Langli Ersdal

With reference to your application dated 2013-01-22. The Regional Committee for Medical and Health Research Ethics, Western Norway (REK Vest) reviewed the application in the meeting, 2013-02-14, pursuant to The Health Research Act § 10.

Description of the project
Haydom Lutheran Hospital is one of eight sites in the Tanzanian "Helping Babies Breathe" evaluation program to reduce perinatal mortality initiated by Laerdal Global Health AS. Observational data shows that infants with abnormal fetal heart rate record and who require face mask ventilation are more likely to die, particularly when interventions are delayed or prolonged.

The objectives of the project "Safer Birth" are to compare different devices for intermittent fetal heart rate assessment related to perinatal outcome, define the normal cardio-respiratory adaption at birth, determine ventilation properties beneficial for neonatal outcome, factors contributing to the need for prolonged face mask ventilation support, and to compare different devices for newborn face mask ventilation related to neonatal outcome.

The planned research project is sponsored by Laerdal Foundation for Acute Medicine and Laerdal Global Health AS and will consist of four parts conducted at Haydom Lutheran Hospital in the time period 2013 – 2016.
1. A descriptive and analytic observational cohort study using an automatic fetal heart rate monitor and a resuscitation monitor to capture and store biomedical signal data during labor and extention through neonatal cardio-respiratory adaption and resuscitation.
2. Training interventions to narrow knowledge and skills gaps identified.
3. Randomized controlled trials comparing different equipment for fetal heart rate assessment during labor and different methods of face mask ventilation applications.
4. Quantitative and qualitative evaluation of feasibility, acceptability, and user-friendliness of the different equipment in use.

Besøksadresse: Haukeland Universitetssykehus, Sentralblokken, 2. etg, Rom 4617
Telefon: 55975000
E-post: rek-vest@uib.no
Web: http://helseforskning.etikkom.no/
All post og e-post som inngår i saksbehandlingen, bes adressert til REK vest og ikke til enkelte personer
Kindly address all mail and e-mails to the Regional Ethics Committee, REK vest, not to individual staff

PUBLICATIONS

Reprint of publications

Resuscitation 93 (2015) 1–7

Contents lists available at ScienceDirect

Resuscitation

journal homepage: www.elsevier.com/locate/resuscitation

Simulation and education

Frequent brief on-site simulation training and reduction in 24-h neonatal mortality—An educational intervention study☆

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[b] Department of Research, Stavanger University Hospital, Stavanger, Norway
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ARTICLE INFO

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Helping Babies Breathe
Resuscitation
Implementation
Frequent brief on-site simulation training

ABSTRACT

Aim of the study: "Helping Babies Breathe" (HBB) is a simulation-based educational program developed to help reduce perinatal mortality worldwide. A one-day HBB training course did not improve clinical management of neonates. The objective was to assess the impact of frequent brief (3–5 min weekly) on-site HBB simulation training on newborn resuscitation practices in the delivery room and the potential impact on 24-h neonatal mortality.

Methods: Before/after educational intervention study in a rural referral hospital in Northern Tanzania. Baseline data was collected from 01.02.2010 to 31.01.2011 and post-intervention data from 01.02.2011 to 31.01.2012. All deliveries were observed by research assistants who recorded information about labor, newborn delivery room management, perinatal characteristics, and neonatal outcomes. A newborn simulator was placed in the labor ward and frequent brief HBB simulation training was implemented on-site; 3-min of weekly paired practice, assisted by local-trainers. Local-trainers also facilitated 40-min monthly re-trainings. Outcome measures were; delivery room management of newborns and 24-h neonatal outcomes (normal, admitted to a neonatal area, death, or stillbirths).

Results: There were 4894 deliveries pre and 4814 post-implementation of frequent brief simulation training. The number of stimulated neonates increased from 712(14.5%) to 785(16.3%) ($p = 0.016$), those suctioned increased from 634(13.0%) to 762(15.8%) ($p \leq 0.0005$). Neonates receiving bag mask ventilation decreased from 357(7.3%) to 283(5.9%) ($p = 0.005$). Mortality at 24-h decreased from 11.1/1000 to 7.2/1000 ($p = 0.040$).

Conclusion: On-site, brief and frequent HBB simulation training appears to facilitate transfer of new knowledge and skills into clinical practice and to be accompanied by a decrease in neonatal mortality.

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1. Introduction

Globally, around 2.9 million newborn infants die each year with as much as 36–70 per cent of these deaths occurring within the first day of life [1–5]. Moreover, neonatal mortality accounts for a steadily increasing proportion of under-five child mortality [1,3,5,6]. Therefore, to meet Millennium Developmental Goal 4 of reducing under-five child mortality by two thirds by 2015, a major focus on optimizing basic newborn care is needed [4,7].

Simulation-based education is increasingly used worldwide as a method of learning- and performance-assessment. Several studies have demonstrated sustained improvement in management of simulated medical emergencies after simulation training [8–11], but very few studies have evaluated whether the acquired skills are translated into clinical practice with improvement in patient outcomes [12,13]. Due to the gaps in knowledge between performance in classroom assessment as compared to clinical practice,

☆ A Spanish translated version of the summary of this article appears as Appendix in the final online version at http://dx.doi.org/10.1016/j.resuscitation.2015.04.019.

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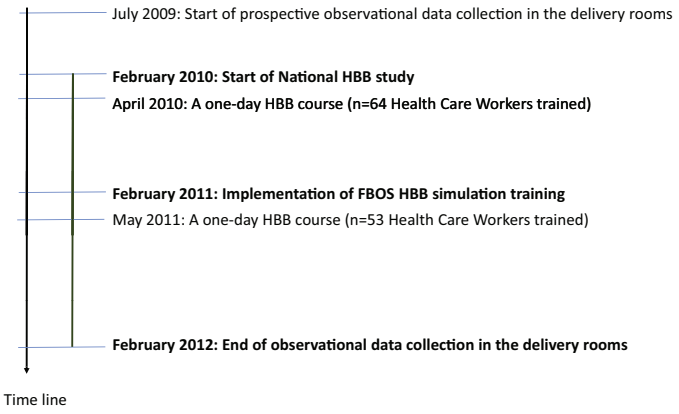

Fig. 1. Timeline of data collection.

evaluation of educational programs during local implementation, designed to facilitate skills translation to clinical practice may in part narrow these gaps.

The simulation-based "Helping Babies Breathe" (HBB) program was developed by the American Academy of Pediatrics with global partners to train providers in basic neonatal care and resuscitation aimed at reducing perinatal mortality worldwide [14]. Currently, HBB is being implemented in more than 60 low-resourced countries [14]. Tanzania was the first country to initiate a National implementation of HBB in 2009, and Haydom Lutheran Hospital (HLH), a rural referral hospital, was one of eight HBB study sites selected to evaluate the effects and impact of local implementation strategies on reducing neonatal mortality (Fig. 1) [15]. At HLH, an observational study started in the delivery rooms in July 2009. Simultaneously, care providers were assessed simulating newborn resuscitation pre and post a one-day HBB course (Fig. 1), and the pass-rate increased from 18 to 74% ($p \leq 0.0001$) [16]. However, basic neonatal resuscitation management, i.e. suctioning, stimulation and application of bag mask ventilation (BMV), coupled with neonatal outcomes as observed in the delivery rooms during the corresponding time-period did not change [16]. No re-trainings were performed in this period.

As a consequence of these observations, frequent and brief on-site (FBOS) HBB simulation-training was initiated, as an effort to enhance clinical translation of simulation training into routine practice. The aim of the study was to assess if FBOS HBB simulation-training would impact clinical practice and reduce 24-h neonatal mortality.

2. Methods

2.1. Setting

HLH serves a catchment of about 2 million people. The hospital provides comprehensive emergency obstetric, and basic emergency newborn care 24 h a day in accordance with WHO guidelines [17]. During the study period, deliveries and newborn resuscitations were predominantly conducted by midwives working in three shifts. During evening- and nightshifts one doctor was on call for the entire hospital. Anesthetic, operating, and student nurses, and ward attendants with no formal medical education were occasionally involved in delivery/newborn care due to shortage of midwives. There were eight delivery beds and approximately 13 (±2.5) deliveries every day throughout the study period. There was one neonatal room for extra care e.g. continued resuscitation, oxygen therapy, intravenous fluids, and antibiotics.

2.2. Intervention

FBOS HBB simulation-training using HBB materials was initiated in February 2011 (Fig. 1). Five local midwives were trained by a national HBB master-trainer to become local HBB trainers. A simulator (NeoNatalie) was placed in a readily accessible location in the labor ward for frequent practices. HBB action posters were mounted on the walls close to the simulators and in labor rooms above each resuscitation table. The local-trainers conducted a full day HBB simulation training [14] for all care providers working in the labor ward (midwives, nurse students, operating nurses, and doctors) in early May 2011 (Fig. 1). During the implementation period, repeated monthly training sessions of approximately 40 min duration were conducted, and included the maternity staff and nursing students, focusing on the HBB action plan with particular emphasis placed on appropriate and timely resuscitation. Available staff and all newly recruited midwives were mandated, by the Tanzanian Ministry of Health and Social Welfare, to participate in this training. Every Thursday morning after the morning report, one of the local trainers conducted a short HBB training session. All labor staff on duty had to practice with the simulator for approximately 3 min and were encouraged to practice frequently whenever time permitted. The time and frequency of training was decided in consensus with the local midwives and based on the success of brief and frequent HBB simulation training at another Tanzanian HBB research site (unpublished observations). The practical sessions were focused on the immediate basic stabilization care (drying, stimulation, suction, warmth, and cord clamping) and resuscitative intervention (BMV); following the HBB action plan. The local-trainers continuously assisted those in need during the routine trainings and practice, and tried to link the scenarios with real-time recent resuscitations of asphyxiated (depressed) babies. This simulation training was the only intervention introduced at the matermity ward during the study period.

2.3. Data collection

Fourteen research assistants were trained to collect data, and 100% of deliveries were observed and recorded. The research assistants recorded data on structured "data collection forms", including providers' preparedness; labour information; neonatal management, characteristics, and outcome; and information about the birth attendants (Appendix A). Three research assistants worked in each shift, with three shifts over 24 h. All data were double entered into Epidata after comprehensive quality control. This paper includes pre-implementation observations from 01.02.2010 to 31.01.2011 and post-implementation from 01.02.2011 to 31.01.2012 (Fig. 1). There is no duplication of data from prior publications [16].

2.4. Statistical methods

With a baseline neonatal death rate at HLH of 1.11%, and aiming to reduce this by 50%, 4245 cases were required in each cohort to achieve a power of 80% using a two-sided test at significance level 0.05. Interim analyses were performed every six months. Data was analyzed using the Statistical Package for Social Sciences (SPSS) 22. Chi-square calculations and independent-samples *t*-tests were utilized to compare pre- versus post-implementation data. Relative risk (RR) and 95% confidence interval (CI) are presented when indicated. Since the number of data points was large, in the two samples compared; the two-sample *t*-test was used without concern about the normality of the data. All data are presented as mean ± standard deviation unless as otherwise stated.

Table 1
Neonatal descriptors, management and outcomes among all infants pre- versus post-implementation of FBOS training.

	Pre-Implementation Cohort 1; $n = 4894$	Post-Implementation Cohort 2; $n = 4814$	p-Value
Descriptors			
Gestational age (weeks)	36.7 ± 1.7	36.3 ± 1.3	≤0.0005**
Birth weight (g)	3155 ± 490	3093 ± 494	≤0.0005**
Birth weight < 2500 g	317 (6.5)	367 (7.6)	0.023*
Attended antenatal care	4878 (99.7)	4776 (99.2)	0.002*
Pregnancy complications	49 (1.0)	42 (0.9)	0.484*
Abnormal fetal heart rate	97 (2.0)	133 (2.8)	0.07*
Labor complication	666 (13.6)	699 (14.5)	0.198*
Cesarean section	576 (11.8)	648 (13.5)	0.012*
Time to cord clamping	52.8 ± 41.5	67.2 ± 46.9	≤0.0005**
Stabilized/resuscitated			
Total No. stabilized/resuscitated	717 (14.6)	787 (16.3)	0.021*
Stabilized/resuscitated after CS	186/576 (32.3)	210/648 (32.4)	0.96*
Stimulated	712 (14.5)	785 (16.3)	0.016*
Suctioned	634 (13.0)	762 (15.8)	≤0.0005*
BMV	357 (7.3)	283 (5.9)	0.005*
Outcome			
Apgar score 1 min ≤ 7	347 (7.1)	439 (9.1)	0.0005*
Apgar score 5 min ≤ 7	53 (1.1)	62 (1.3)	0.350*
Normal at 24 h	4702 (96.1)	4630 (96.2)	0.066*
Admitted neonatal room			
At 30 min	258 (5.3)	229 (4.8)	0.254*
At 24 h	10 (0.2)	15 (0.3)	0.300*
Deaths			
At 30 min	5 (1.0/1000)	5 (1.0/1000)	0.984*
At 24 h	54 (11.1/1000)	34 (7.2/1000)	0.040*
Birth weight < 2500 g	20/54 (37)	11/34 (32)	0.81*
Fresh stillbirths	79 (16.0/1000)	70 (14.5/1000)	0.517*
Macerated stillbirths	49 (10.0/1000)	65 (13.5/1000)	0.116*

Data are presented as mean ± standard deviation and values are given as n (%) unless as otherwise stated. Stabilization includes stimulation and/or suction, Resuscitation includes stabilization and BMV; CS = cesarean section, BMV = bag mask ventilation.

* Chi-Square, two-tailed.

** Independent samples t-test, two-tailed.

2.5. Ethical considerations

Ethical clearance was granted by the National Institute for Medical Research in Tanzania (Ref. NIMR/HQ/R.8a/Vol .IX/1247) and the Regional Committee for Medical and Health Research Ethics, Western Norway (Ref. 2009/302).

3. Results

3.1. Neonatal characteristics, management, and outcomes

3.1.1. Overall population

Table 1 presents neonatal characteristics, provider management, and outcome of all infants born pre-implementation (Cohort 1) compared to post-implementation of FBOS training (Cohort 2). The numbers of deliveries during the two periods were almost similar i.e., 4894 versus 4814, respectively. Birth weight (BW) and gestational age (GA) were significantly lower in Cohort 2. The incidence of labor complications was similar, however fetal heart rate abnormalities and cesarean sections (CS) (predominantly emergent) were significantly more frequent in Cohort 2. The mean time to cord clamping increased from 53 ± 42 to 67 ± 47 s pre versus post implementation, respectively ($p \leq 0.0005$). More infants were stabilized and/or resuscitated post versus pre implementation, i.e. 787 (16.3%) versus 717 (14.6%), respectively ($p = 0.021$). More specifically, the number of infants stimulated increased from 14.5% to 16.3% ($p = 0.016$), those suctioned increased from 13.0% to 15.8% ($p \leq 0.0005$) while those receiving BMV decreased from 7.3% to 5.9% ($p = 0.005$) in Cohort 1 versus Cohort 2, respectively. The number of infants with an Apgar score at 1 min ≤ 7 increased significantly whereas the number with an Apgar score at 5 min ≤ 7 remained unchanged after implementation (Table 1). The number of infants admitted to the neonatal room at 30 min and at 24 h after delivery was comparable between the two Cohorts. The number of deaths within 24 h decreased significantly from 54 (11.1/1000) to 34 (7.2/1000) (RR 0.64, 95% CI 0.41–0.98, $p = 0.040$) in Cohort 1 versus Cohort 2. The proportion of fresh stillbirths did not differ between the two Cohorts.

3.1.2. Infants who established spontaneous breathing

Table 2 presents neonatal characteristics, management and outcome among infants who initiated spontaneous respirations. The mean time to establish spontaneous respirations was significantly shorter in Cohort 1 versus Cohort 2, i.e. 9.8 ± 14.7 versus 11.1 ± 18.3 s ($p \leq 0.0005$), respectively. The mean time to cord clamping significantly increased from 55 to 68 s comparing Cohort 1 versus Cohort 2 ($p \leq 0.0005$). There was no difference in the number of deaths between the two Cohorts.

3.1.3. Infants stimulated, suctioned and/or who received BMV

Table 3 presents neonatal characteristics, management and outcome among infants who were stimulated, suctioned and/or who received BMV. BW, fetal heart rate abnormalities, the frequencies of labor complication and CS were comparable between the two Cohorts. The time to cord clamping was delayed in Cohort 2 versus Cohort 1, i.e. 63 ± 49 versus 42 ± 41 s ($p \leq 0.0005$), respectively. Stimulation was almost universal in both periods, while suctioning increased from 88.4% to 96.8% ($p \leq 0.0005$) and the proportion receiving BMV decreased from 49.8% to 35.9% ($p \leq 0.0005$) during Cohort 1 versus Cohort 2, respectively. There were no differences in the time to initiate and the duration of BMV between the two Cohorts (Table 3). The number of infants with an Apgar score at one and 5 min ≤ 7 and the number of infants who remained admitted in the neonatal room at 24-h after resuscitative actions were comparable between the two Cohorts. The number of deaths within 24-h decreased from 47 (6.6%) to 26 (3.3%) after implementation of FBOS

Table 2
Neonatal descriptors, management and outcomes among infants who started spontaneous respirations and received only routine care pre- versus post-implementation of FBOS training.

	Pre-implementation Cohort 1; $n = 4177$	Post-implementation Cohort 2; $n = 4027$	p-Value
Gestational age (weeks)	36.7 ± 1.6	36.3 ± 1.2	≤0.0005**
Birth weight (g)	3162 ± 472	3097 ± 481	≤0.0005**
Time to start SR (s)	9.76 ± 14.74	11.12 ± 18.23	≤0.0005**
Time to cord clamp (s)	55 ± 41	68 ± 46	≤0.0005**
Outcome			
Apgar score 1 min ≤ 7	34 (0.8)	73 (1.8)	≤0.0005*
Apgar score 5 min ≤ 7	1 (0.02)	3 (0.1)	0.287′
Normal at 24 h	4054 (97.1)	3886 (96.5)	0.734*
Admitted at 24 h	3 (0.1)	5 (0.1)	0.441′
Dead at 24 h	7 (0.2)	8 (0.2)	0.734′

Data are presented as mean ± standard deviation and values are given as n (%) unless as otherwise stated.
* Chi-square, two-tailed.
** Independent samples t-test, two-tailed.
′ Fisher's exact test, two-tailed.

training ($p = 0.003$), with a RR of 0.50 (95% CI 0.31–0.80, $p = 0.004$). Infants classified as fresh stillbirths decreased from 15 (2.1%) to 7 (0.9%) in Cohort 1 versus Cohort 2, respectively ($p = 0.043$). Among infants receiving resuscitation in Cohort 1 versus Cohort 2, 47/717 (6.6%) versus 26/787 (3.3%) died, respectively ($p = 0.003$) (Table 3).

3.1.4. Provider management in the delivery room

Table 4 presents differences in management and outcome of infants who received stabilization and/or resuscitation related to whether the attending health care worker (HCW) was trained in a full one-day HBB course or not, pre- versus post-implementation of FBOS HBB training (including the entire labor staff). Pre-implementation, in Cohort 1, 485/714 (67.6%) resuscitations were performed by a HCW who had undergone a one-day HBB training only. These HCWs versus HCWs ($n = 229$) who had not participated in the one-day HBB course, were more likely to have a resuscitation kit ready before delivery (92% vs 50%; $p \leq 0.0005$), have stimulated (100% vs 98.3%; $p = 0.004$), and suctioned (91.8% vs 81.6%; $p \leq 0.0005$) infants, and were less likely to have applied BMV (47.0% vs 55.5%; $p = 0.035$), respectively. HCWs trained in the one-day course versus HCWs not trained performed cord clamping later i.e. 45 ± 41 versus 39 ± 41 seconds ($p \leq 0.0005$), respectively. The 24-h mortality was comparable, 6.2% versus 7.4% ($p = 0.53$), respectively.

Post-implementation of FBOS HBB training, in Cohort 2, 707/780 (89.8%) resuscitations were managed by a HCW who had completed at least one full (one-day) HBB training and FBOS. The HCWs who had not participated in a full HBB course ($n = 74$ resuscitations) and only received FBOS training had the resuscitation kit more frequently prepared versus those who had attended a one-day HBB course and FBOS i.e., 97.3% versus 89.8% ($p = 0.039$), respectively. The number of infants stimulated, suctioned, receiving BMV as well as the time to cord clamping were comparable between the two groups (Table 4). However, mortality after BMV was lower when resuscitation was performed by a HCW with a one-day HBB training plus FBOS versus a HCW with only FBOS training, i.e. 20/253 (7.9%) compared to 5/27 (18.5%) ($p = 0.061$), respectively.

3.1.5. Potential confounding factors

Comparing the pre- versus post-implementation period, 64.1% vs 68.7% of deliveries were attended by a midwife ($p \leq 0.0005$) (Table 5). Following implementation of FBOS HBB training, more midwives attended deliveries in the theater and conducted resuscitations if necessary. Comparing pre- versus post implementation, the number of resuscitations performed by midwives increased from 72.8% to 77.5% ($p = 0.035$), the number of operating room nurses decreased from 8.5% to 5.3% ($p = 0.012$), as did the number of doctors i.e. 7.4% to 4.0% ($p = 0.004$), respectively (Table 5). However, the number and cadres of care providers present in the labour ward were similar in both cohorts, and the nurse students were working under the supervision of the midwives.

Table 3
Neonatal descriptors, management and outcomes among infants who received stabilization/resuscitation pre- versus post-implementation of FBOS training.

	Pre-Implementation Cohort 1; $n = 717$	Post-Implementation Cohort 2; $n = 787$	p-Value
Gestational age (weeks)	36.5 ± 1.8	36.3 ± 1.5	0.001**
Birth weight (g)	3110 ± 578	3076 ± 556	0.263**
Time to cord clamp (s)	42 ± 41	63 ± 49	≤0.0005**
Stimulation	712 (99.3)	785 (99.7)	0.207*
Suction	634 (88.4)	762 (96.8)	≤0.0005*
BMV	357 (49.8)	283 (35.9)	≤0.0005*
Deaths after BMV	45/357 (12.6)	25/283 (8.8)	0.117
Time to start BMV (s)	89 ± 72	97 ± 76	0.134**
Duration of BMV (s)	432 ± 835	457 ± 1054	0.734**
Outcome			
Apgar score 1 min ≤ 7	313 (43.6)	366 (46.5)	0.344
Apgar score 5 min ≤ 7	52 (7.2)	59 (7.5)	0.88
Normal at 24 h	648 (90.4)	744 (94.5)	0.003*
Admitted at 24 h	7 (1.0)	10 (1.3)	0.659*
Dead at 24 h	47 (6.6)	26 (3.3)	0.003*
Fresh stillbirths	15 (2.1)	7 (0.9)	0.043*

Data are presented as mean ± standard deviation and values are given as n (%) unless as otherwise stated.
CS = cesarean section, BMV = bag mask ventilation.
* Chi-Square, two-tailed.
** Independent samples t-test, two-tailed.

Table 4
Neonatal descriptors, management, and outcomes among infants who received stabilization/resuscitation related to whether the attending Health Care Worker (HCW) was trained in a one-day HBB course or not, pre- versus post-implementation of FBOS training of all HCW in the labor ward.

	Pre-implementation no ongoing FBOS training in labor ward Cohort 1; $n=714$′		p-Value	Post-implementation Ongoing FBOS training, including all labor staff Cohort 2; $n=780$″		p-Value
	Resuscitating HCW not trained in one-day HBB	Resuscitating HCW trained in one-day HBB		Resuscitating HCW not trained in one-day HBB	Resuscitating HCW trained in one-day HBB	
	229	485		74	706	
Resuscitation kit ready	115 (50.1)	446 (92.0)	≤0.005*	72 (97.3)	635 (89.8)	0.039*
Gestational age (weeks)	36.6 ± 1.8	36.5 ± 1.8	0.562**	36.2 ± 0.5	36.3 ± 1.5	0.195**
Birth weight (g)	3084 ± 573	3122 ± 579	0.415**	3072 ± 384	3080 ± 571	0.866**
Time to cord clamp (s)	38.6 ± 41.0	44.5 ± 40.7	0.072**	65.0 ± 49.6	62.5 ± 48.6	0.678**
Stimulation	225 (98.3)	485 (100)	0.004*	74 (100%)	707(100%)	1.00*
Suction	187 (81.6)	445 (91.8)	≤0.005*	73 (98.6)	685 (96.8)	0.422*
BMV	127 (55.5)	228 (47.0)	0.035*	27 (36.5)	253 (35.8)	0.912*
Deaths after BMV	17/127 (13.4)	28/228 (12.3)	0.760*	5/27 (18.5)	20/253 (7.9)	0.061*
Time to start BMV (s)	93.7 ± 74.4	95.4 ± 71.2	0.774**	98.9 ± 61.5	94.1 ± 73.0	0.585**
Duration of BMV (s)	451 ± 825	421 ± 842	0.744**	661 ± 912	436 ± 1071	0.296**
Outcome						
Normal at 24 h	205 (90.0)	440 (90.9)		69 (93.2)	668 (94.6)	
Admitted at 24 h	2 (0.9)	5 (1.0)		0	10 (1.4)	
Dead at 24 h	17 (7.4)	30 (6.2)	0.534*	5 (6.8)	21 (3.0)	0.095*
Fresh stillbirths	5 (2.2)	10 (2.1)		0	7 (1.0)	

Data are presented as mean ± standard deviation and values are given as n (%) unless as otherwise stated. HCW = health care worker, BMV = bag mask ventilation.
′ Three cases missing information about "one-day training or not", outcome of these infants were normal.
″ Seven cases missing information about "one-day training or not", outcome of these infants were normal.
* Chi-Square, two-tailed.
** Independent samples t-test, two-tailed.

Table 5
Type of HCW managing 2nd stage of labor and resuscitations pre- versus post-implementation of FBOS training.

	Pre-implementation Cohort 1; $n=4894$	Post-implementation Cohort 2; $n=4814$	p-Value
HCW managing 2nd stage			
Midwife	3138 (64.1)	3310 (68.7)	≤0.0005*
Nurse student	933 (19.1)	652 (13.5)	≤0.0005*
Doctor/AMO	773 (15.8)	819 (17.0)	0.10*
Ward attendant	48 (1.0)	23 (0.5)	0.004*
Missing information	2	12	
HCW performing resuscitation	$n=717$	$n=787$	
Midwife	520 (72.8)	604 (77.5)	0.035*
Operating nurse	61 (8.5)	41 (5.3)	0.012*
Doctor/AMO	53 (7.4)	31 (4.0)	0.004*
Others (e.g. student nurse)	79 (11.1)	103 (13.2)	0.203*
Missing information	4	8	

Data are presented as mean ± standard deviation and values are given as n (%) unless as otherwise stated.
AMO = assisting medical officer. HCW = health care worker.
* Chi-Square, two-tailed.

4. Discussion

This observational study describes for the first time a change in clinical management of newborn infants accompanied by a substantial reduction (40%) in neonatal mortality during a one-year study period following implementation of FBOS HBB simulation training. More infants were immediately stimulated and suctioned with fewer receiving BMV, resulting in a significant reduction in deaths. The "resuscitation kit" was more frequently prepared before delivery, and midwives took more often responsibility in conducting resuscitations.

We attribute the reduction in 24-h neonatal deaths to reflect the significant increase in early initiation of the basic steps including stimulation and suction with induction of breathing and a corresponding reduction in the need for BMV; a finding consistent with that contained in the report on the national pilot study of HBB in Tanzania [15]. The pathophysiologic basis for these findings relates to experimental and observational studies suggesting that most newly born babies are in "primary apnea" (heart rate >60 beats per minute and adequate blood pressure) and will respond to immediate stabilization with relief of the asphyxial process and initiation of breathing [18,19]. However, without immediate interventions the asphyxial process continues with progressive bradycardia and hypotension before "secondary apnea" develops necessitating BMV. A smaller proportion of newborns maybe in secondary apnea at birth and depending on the severity of intrapartum-related hypoxia, these babies will exhibit a variable response to immediate stabilization and BMV depending on the quality of BMV.

HBB is a practical simulation-based course, whereby providers are engaged to synthesize and apply knowledge and tasks according to a specific scenario, thereby combining theoretical, cognitive, technical, and behavioral skills in a dynamic situation. A one-day HBB simulation training significantly improved overall resuscitation performance of providers when retested with simulated scenarios seven months later (Kirkpatrick Level 2) [16]. However, this improvement was not translated into clinical practice with improved neonatal outcomes (Kirkpatrick Level 3) [16]. It was only

after implementing systematic FBOS HBB simulation training, that a subsequent change in overall routine clinical practice and decline in mortality (Kirkpatrick level 4) was observed. More specifically, it was in the group with a combination of a one-day HBB training and FBOS training where the most compelling findings were noted, with a reduction of death after BMV as well as a reduction in 24-h mortality (Table 4). It is recognized that correct application of a face mask to initiate ventilation can be difficult with both mask leak and obstruction [20,21]. We speculate that the FBFOS training facilitated appropriate application of the face mask and allowed the providers to achieve competency and confidence. Thus, these findings highlight the critical importance of frequent low-dose simulation strategies as an important method for translating acquired skills into clinical practice. However, the findings do not provide insight into how long or how frequent repeat simulations should occur, consistent with observations from Draycott et al. [12,13], These investigators offered no clear guidance or evidence on how mandatory obstetric emergency training improved neonatal outcomes [12,13]. Similar conclusions were inferred in a recent systematic review of neonatal simulation training programs [22].

In Cohort 1, approximately 68% of infants were resuscitated by a provider who had attended the one-day HBB course, whereas in Cohort 2 following initiation of FBOS training, approximately 90% were resuscitated by a provider who had undergone a one-day HBB training, (Fig. 1). Concurrently, there was a significant reduction in the number of infants being resuscitated by doctors and operating nurses. Indeed, this was one of the desired outcomes of the FBOS training i.e. the midwives taking more responsibility of conducting resuscitations. Moreover, the data indicate a balance between the two periods when comparing a composite of trained HCWs managing the second stage of labor, performing resuscitation and the relationship to subsequent neonatal outcome. We speculate that this increased proportion of trained providers coupled with frequent re-training, including new personnel, helped establish and maintain a clinical practice behavior of excellence in the labor ward. Finally, evaluation of management in the delivery room was on a collective level and included new staff as they were employed, excluding staff that left. We consider this to be extremely important in order to obtain an accurate picture of the overall performance in the ward.

An important question is whether a delay in cord clamping noted in Cohort 2, which is consistent with the HBB action plan, might have had an impact on a reduction in the 24-h mortality. Indeed, we recently demonstrated that the risk of death/admission decreased by 20% for every 10-s delay in cord clamping after spontaneous respirations [23]. In this report the majority of deaths occurred in infants who received BMV, a different population.,

There are several limitations to our study. First, this is an observational before-after intervention study, therefore confounding factors may have influenced our findings, and causal relationships cannot be drawn. Although there were significant differences in GA and BW post-implementation these were small and are unlikely to be of biologic significance. Second, HLH represents one low-resource setting. However, we consider that the individual professional process of learning, need for repetitions, evolvement of self-confidence, and collective awareness/agreement of a new procedure may not differ much between settings, making our findings important for others. Third, Apgar scoring and assessment of GA were imprecise in this remote setting. Fourth, we anticipated that the providers might be influenced by a Hawthorne effect during the first months of observations, but the observations started six months prior to this study and likely minimized this potential effect. Fifth, since self-initiated simulation training in the labor ward was not recorded, there is uncertainty surrounding the consistency of this strategy, and thus the potential impact on reducing mortality remains unclear.

5. Conclusion

Implementation of FBOS HBB simulation training may be associated with improved clinical behavior and performance and with a corresponding reduction in 24-h neonatal mortality. These observations suggest the importance of frequent and brief training in facilitating the transfer of new knowledge and skills into clinical practice.

Integrity of the data and the accuracy of the data analysis

Mduma E and Ersdal HL who are principal investigators in this study had full access to all the data in this study and take responsibility for the integrity of the data and the accuracy of the data analysis.

Conflict of interest statement

All authors have indicated that they have no financial relationships relevant to this article to disclose. Dr Ersdal has received research grants and Haydom Lutheran Hospital project funds from the Laerdal Foundation for Acute Medicine. However, study design, data collection, data analysis, data interpretation, writing of the report and/or the decision to submit the article for publication was independent from the financial source.

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The study sponsor, is not involved in the study design, data collection, analysis and interpretation of data; in the writing of the manuscript; and in the decision to submit the manuscript for publication.

Appendix A.

Information recorded on the data collection form.

Antenatal information	Antenatal care	Yes or no
	Pregnancy complications	Yes or no
	Maternal infections	Non, uterine, malaria, HIV, sepsis, or other
Labor information	Fetal presentation	Cephalic, breech, shoulder dystocia, transverse, or other
	Fetal heart rate	Normal: 120 to 160 BPM, abnormal: <120 or >160 BPM, non detected, or not measured
	Mode of delivery	Spontaneous vaginal delivery, caesarean section, assisted breech delivery, and vacuum extraction
	Labor complication	Prolonged labor, obstructed labor, preeclampsia, eclampsia, uterine rupture, haemorrhage, and cord prolapse
Neonatal information	Transitional newborn adaption	Time intervals (s) from birth to initiation of spontaneous respirations and cord clamping
	Gender	Male or female

Appendix A (*Continued*)

	Birth Weight	Grams
	Gestational Age	Weeks: normal in this study is 36 weeks and above as was counted as 9 months amenorrhea times 4 weeks.
	Apgar scores	One and 5 min
	Interventions in the Delivering Room	Stimulation, suction ± BMV with a self-inflating bag, and time interval (sec) to initiation of BMV
	Specific Observations	Newborn heart rate present or not, time interval (s) from initiation of BMV to the onset of spontaneous breathing or death
Perinatal outcome at 24 h postpartum	Normal	Survival > 24 h without any detected difficulties
	Admitted	Designated neonatal area
	Death	
	Stillbirth	Macerated = antepartum or fresh = intrapartum

BPM = beat per minute, BMV = bag mask ventilation.

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Using statistical process control methods to trace small changes in perinatal mortality after a training program in a low-resource setting

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Abstract

Objective: To trace and document smaller changes in perinatal survival over time.

Design: Prospective observational study, with retrospective analysis.

Setting: Labor ward and operating theater at Haydom Lutheran Hospital in rural north-central Tanzania.

Participants: All women giving birth and birth attendants.

Intervention: Helping Babies Breathe (HBB) simulation training on newborn care and resuscitation and some other efforts to improve perinatal outcome.

Main outcome measure: Perinatal survival, including fresh stillbirths and early (24-h) newborn survival.

Result: The variable life-adjusted plot and cumulative sum chart revealed a steady improvement in survival over time, after the baseline period. There were some variations throughout the study period, and some of these could be linked to different interventions and events.

Conclusion: To our knowledge, this is the first time statistical process control methods have been used to document changes in perinatal mortality over time in a rural Sub-Saharan hospital, showing a steady increase in survival. These methods can be utilized to continuously monitor and describe changes in patient outcomes.

Key words: statistical process control (SPC), cumulative sum (CUSUM), variable life-adjusted display (VLAD), perinatal mortality rate, Helping Babies Breathe (HBB)

Introduction

Despite the reduction of under 5-year child mortality rates by almost 50% during the last decades, reducing early perinatal mortality (ePMR) (i.e. fresh stillbirths and neonatal deaths within 24 h after birth) remains a major global challenge [1–5]. A major cause of ePMR in low-resource settings is birth asphyxia, which is due in part to a lack of adequate obstetric care and suboptimal newborn resuscitation skills [6–8]. One approach to reversing this situation is to train and empower birth attendants by enhancing resuscitation skills. This became possible following the introduction of a basic simulationbased training program called Helping Babies Breathe (HBB) [9]. Tanzania was the first country to initiate a national implementation of HBB in 2010, and Haydom Lutheran Hospital (HLH) was included in the initial study [10]. Data from HLH revealed that a full day HBB course (in April 2010) improved attendant's skills in simulation performance but was not accompanied by an improvement in clinical management 7 months after the HBB course [11]. These findings led to implementation of systematic brief and frequent training sessions (February 2011), which eventually had a positive significant impact on early 24-h neonatal mortality rate (eNMR) one year later [12]. Furthermore, the applicability and impact of HBB has been studied in several low-resource settings with varying success rates [10–14]. Importantly, tracing the effect and sustainability of educational interventions like HBB using traditional epidemiological methods is invariably slow, as it mostly requires long term e.g. annual survival numbers, or even longer time cohorts, for comparison. Hence, it would be extremely valuable to have statistical methods that facilitate more continuous monitoring of ePMR to timely detect negative trends with appropriate corrective actions. Methods for continuous monitoring, called statistical process control (SPC), originated in the manufacturing industry to monitor the

quality of mass-produced products. The application and further development of such methods has spread to many other areas, including monitoring of quality in medicine and healthcare [15–18].
A cumulative sum (CUSUM) chart is a particular form of SPC, which is well suited for detecting smaller but persistent changes in a process over time, and has been used in various clinical settings [19–22]. Further, it has been used to monitor healthcare quality in an obstetric unit in a high-resource setting, since maternal and perinatal deaths, are exceedingly rare [23]. Using CUSUM charting to continuously monitor outcomes in a labor ward would constitute a simple quality improvement tool to help to early detect negative trends, for instant on a monthly basis, and immediately intervene. Additional to a CUSUM chart, an accompanying plot of cumulative number of lives saved, often called variable life-adjusted display (VLAD), has been shown to be useful as a complement to a CUSUM plot by enhancing interpretation and illustrating the impact of interventions [24].
The aim of this study was to retrospectively apply CUSUM and VLAD plots on a validated labor database, to monitor changes in ePMR (i.e. deaths [fresh stillbirths] occurring during labor or within 24 h post-delivery) over a 5-year period, and to determine whether noted patterns (either increases or decreases) in survival can be used prospectively to monitor impact and sustainability of interventions like the HBB program (addressing eNMR) as well as facilitate the early detection of negative trends.

Methods
The study was conducted in the labor ward at HLH, which is a referral hospital located in a remote rural area in northern central Tanzania, serving a population predominantly of low social-economic status [25]. HLH provides comprehensive obstetric and basic neonatal care 24 h a day to a catchment of ~2 million people.

HBB interventions, changes in labor ward staff and other events
HBB consists of practical training on basic newborn care and resuscitation (stimulation, clear airway/suction and bag mask ventilation) using a low-cost newborn simulator [9].
Baseline data collection for the national HBB study was initiated at HLH in February 2010. HBB training had never happened previously, and no other newborn resuscitation training programs were conducted during the reference period. The first full day HBB course was conducted in mid April 2010 facilitated by HBB master trainers from the Tanzanian Ministry of Health. Due to no improvements in perinatal outcome, a program encouraging frequent on-site HBB trainings among the midwifes was implemented in February 2011. Five local midwifes were trained to become HBB trainers with the responsibility to facilitate ongoing brief HBB trainings in the labor ward [12]. Thus, the baseline period for this study was February 2010 through January 2011, and the follow-up period was from February 2011 through January 2016.
Every year during the study period, in July through August, there was a rotation of staff, with several providers (including midwifes) leaving the hospital after the government had advertised employment opportunities. Later, between October and December of each year, HLH recruited new midwifes, who recently completed their midwifery training at Haydom School of Nursing, to fill the gaps of those who left.
In February 2013, a randomized controlled study (RCT) was implemented, comparing the frequency of abnormal fetal heart rate detections during labor, using the FreePlay hand-held Doppler and the Pinard fetoscope. The goal of this study was to enhance fetal
monitoring as it relates to the detection of abnormal fetal heart rate. HLH was granted the status of a referral hospital in 2014, and was consequently able to employ junior doctors and specialist in obstetrics. The hospital continued to serve the same catchment area, with no changes in patient population. However, during the same period a patient delivery fee was introduced, making it difficult for several women to afford delivering in the hospital, unless the pregnancy was complicated when the fee was waived. In October 2014, an RCT comparing the Standard Newborn Resuscitator (Laerdal Medical) with a new Upright Resuscitator (Laerdal Global Health) for ventilation of non-breathing newborns, was initiated. The above-mentioned RCTs were introduced with brief training sessions to make all midwives familiar with the new equipment. All the mentioned interventions, events, and facility processes are indicated on the CUSUM chart explained later, illustrating a potential co-relationship to perinatal survival over the 5-year period.

Data collection and management
Since August 2009 trained research assistants (n = 14) have observed every delivery and recorded information about antenatal care, labor events, birth outcomes and birth attendants' performance on a 24/7 basis using a structured data collection form, and comprehensive data quality control systems [26].

Data analysis

A cohort of 22 176 newborns delivered from February 2011 through January 2016 was included in this study. The number of deliveries showed minimal variation from month to month with ~400 deliveries per month. Retrospective analysis was performed to plot the trend in ePMR at monthly intervals. In order to have a fixed baseline value for comparison, it was decided to use an ePMR of 27/1000 deliveries, which represented the rate found during the baseline period, i.e. February 2010 through January 2011 [12].

As a first step, to understand the raw data in this report, a plot showing the monthly ePMR rate over time, was constructed (Fig. 1). As a second step, to further illustrate the changes over time, a VLAD plot was constructed [24]. This is a plot of the cumulative number of excess survivors compared to the baseline rate. Specifically, for each month the difference between the expected number of deaths according to the baseline rate and the actual observed number of deaths was calculated; these monthly differences were then added and presented as a VLAD plot (Fig. 2), which can be interpreted as the cumulative number of lives saved compared to the baseline level.

Finally, as a formal monitoring procedure with signal limits to detect smaller persistent changes in outcome, CUSUM charts for, respectively, increased survival (Fig. 3) and mortality (Fig. 4), were constructed. To construct a CUSUM chart we need to determine a change in the quantity monitored which the CUSUM should quickly detect [16]. In determining increased survival in our setting, a decrease in ePMR of 0.5% points, i.e. from the baseline level of 2.7% to 2.2% was chosen. The CUSUM chart is a plot of the cumulative sum of the differences between a rate half way between these two values (i.e. 2.45%) and the observed monthly rate. In our study, an observed monthly ePMR below 2.45% implies a rise (indicating increased survival) in the CUSUM chart. To quickly detect changes of interest, the CUSUM is constructed such that it is reset to 0 if the cumulative sum becomes negative, i.e. the CUSUM never go below 0. The CUSUM signals a persistent change if it crosses a signal limit. The signal limit was chosen such that with baseline data there will on average be a false signal once per 100 months (8 years), and the calculation of the limit was done using a method implemented in the R-package spcadjust [27]. The corresponding plot for detecting increased mortality was constructed similarly.

Ethical consideration

The HBB study with the related quality improvement program was approved by the National Institute for Medical Research (NIMR) Ref. NIMR/HQ/R.8a/Vol.IX/1247 in Tanzania and the Regional Committee for Medical and Health Research Ethics, Western Norway Ref. 2009/302.

Results

The ePMR rate varied from month to month, but for most of the period it was lower than the baseline level of 2.7% (Fig. 1). The VLAD plot showed an overall positive trend, with some intermittent variation, and demonstrated an upward trend indicating better outcome compared to the baseline (Fig. 2). This plot reflects more than 120 extra lives saved over the 5-year period. The CUSUM chart for survival revealed a steady upward trend, and signaled a sustained improvement in survival by 17 months as indicated by crossing of the signal limit (Fig. 3). Most of the variations in the CUSUM plot coincided with the introduction and continuation of different interventions, events and/or facility processes such as staff turnover or requirement of patient fees for hospital delivery, as illustrated in Fig. 3. The CUSUM chart for increased mortality stayed well below the signal limit (Fig. 4). This indicates that during the study period there were no time intervals with significant increase in mortality. The few dips observed in the VLAD plot are considered to be within the range of natural variation.

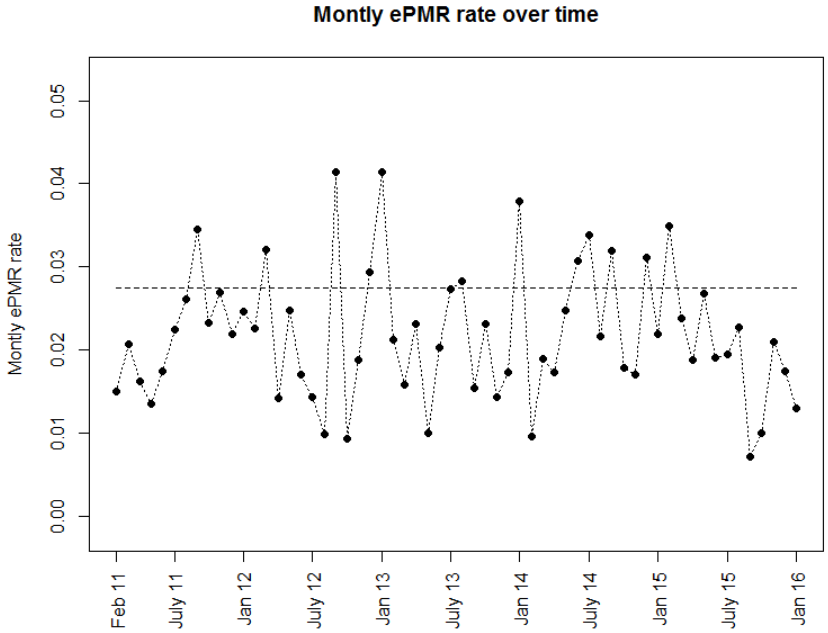

Figure 1 Monthly ePMR from February 2011 to February 2016; The horizontal dashed line at 0.027 indicates the baseline ePMR. The dots represent months and 48 dots (months) were below baseline, indicating improved survival, and 12 dots (months) were above baseline, indicating reduced survival.

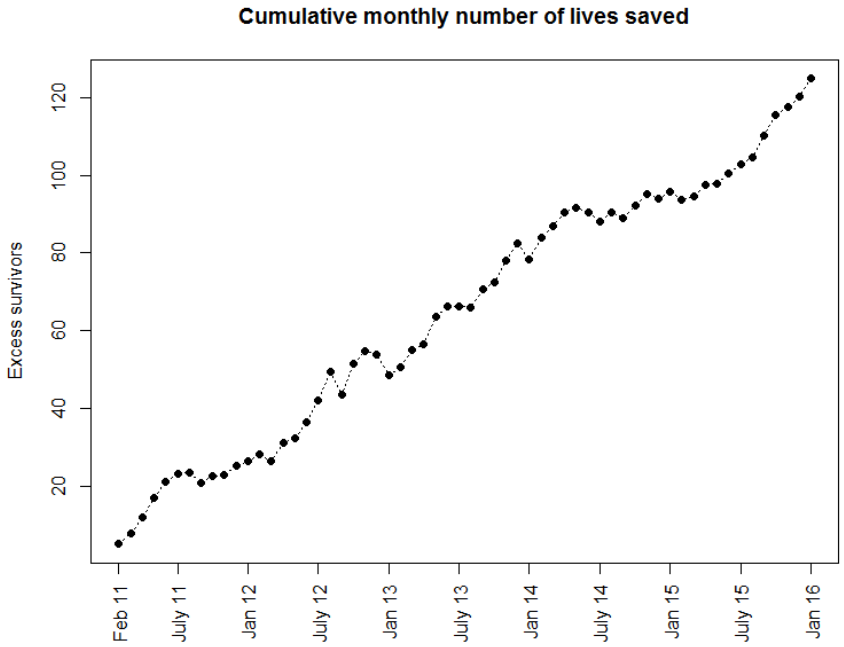

Figure 2 VLAD plot presenting the cumulative monthly number of lives saved compared to baseline. The upward trend indicates that the outcome (perinatal survival) is better than baseline, a horizontal trend indicates that outcome is equal to baseline, and a decreasing trend indicates that outcome is worse than baseline.

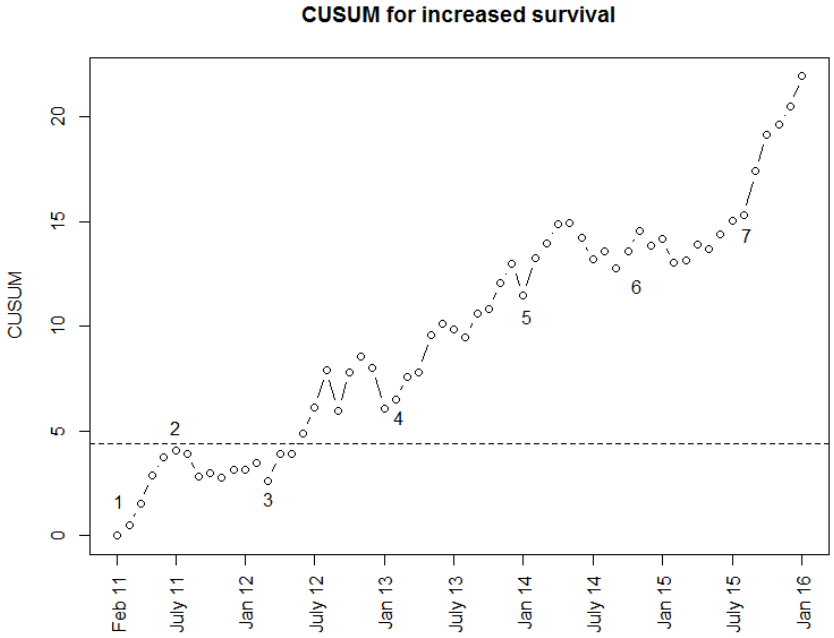

Figure 3 CUSUM chart including illustration of the most important interventions and events that occurred during the five-year study period; The upward trend indicates improved survival. A horizontal dashed line indicates the signal limit and crossing this line is a signal of improvement over the baseline level.

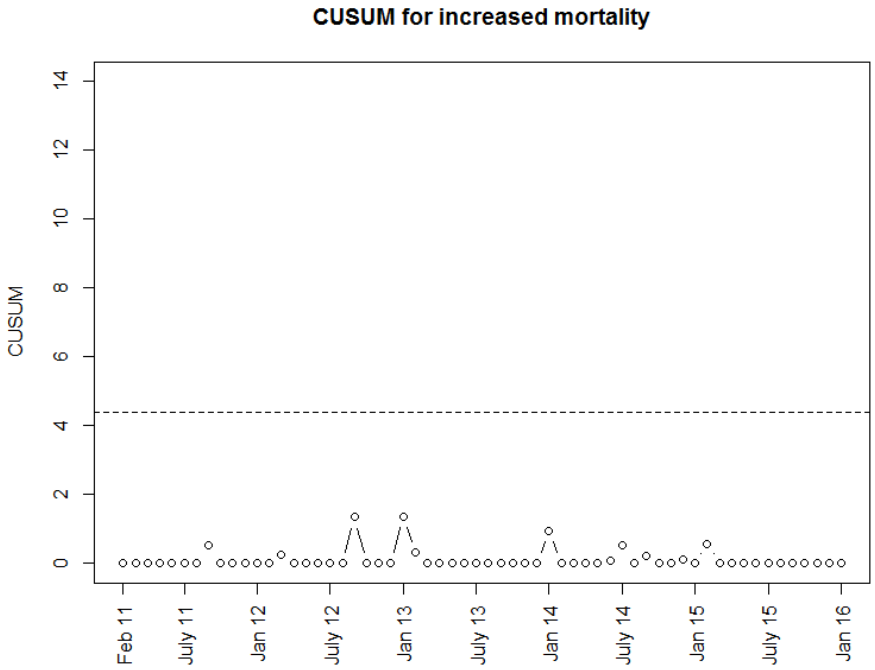

Figure 4. CUSUM for monitoring against increased mortality (decreased survival) from baseline. Each dot represents a month. The dots above 0 on the y-axis indicate reduced survival (increased ePMR).

NB: each dot present a month in all the figures.

Discussion

The primary finding in this report indicates that improvement in ePMR after an educational intervention that includes frequent brief simulation training sessions [12], coincided with a steady increasing CUSUM as well as VLAD plot, which signaled a systematic improvement in survival after several months. Further, the CUSUM and VLAD plots also showed a few small and transient decreases in survival indicating variation in ePMR, that coincided with trained staff leaving the study site, and being replaced with the new staff not trained in HBB. With time, the new personnel enhanced their resuscitation skills due to the ongoing frequent brief training program, and this coincided with reversal of these transient negative trends (Fig. 2). Importantly, these negative trends were not indicative of systematic worsening, since the CUSUM chart monitoring for increased mortality (Fig. 4) never crossed the signal limit. These negative trends may thus be due to natural fluctuations, or other events such as staffing and training factors, that may have either a positive or negative, direct or indirect impact on ePMR.

While the CUSUM plot provides a formal signal limit to detect a systematic change in outcome, the actual numbers within the CUSUM chart may be more difficult to comprehend. Thus, it is very useful to couple a CUSUM with a VLAD plot, which indicates how many lives may be saved to better convey the clinical impact. It has been shown repeatedly, that educational interventions may have no or limited short-term effects on clinical outcome. A sustained positive impact on clinical behavior and patient survival has been difficult to demonstrate [28, 29]. Using statistical control process methods, we demonstrated an improvement in ePMR over time, although with some monthly variations. To what extent these variations in monthly ePMR can be minimized with more ongoing focus on training of the staff is the subject of ongoing studies.

Limitations and strengths

We used CUSUM and VLAD to evaluate the health outcome (ePMR) of interest. To what extent the noted changes reflect the repeated HBB training of the labor ward staff or may be due to other factors can be debated. However, the noted increase in survival concordant with training, suggests that such a relationship was present. Additionally, this was not a randomized control study and involved a single-center, and as such any generalization from our findings may be limited.

Conclusion

This is the first time that the statistical process control methods CUSUM and VLAD have been used to monitor changes in ePMR over time in a low-resource rural setting. The detected changes coin-cided with different interventions, events and system processes which indicate the potential of SPC to expediously capture the impact (both negative and positive) of interventions and policies over time. Additional studies are required to validate these observations.

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BMJ Open

Frequent refresher training on newborn resuscitation and potential impact on perinatal outcome over time in a rural Tanzanian hospital: an observational study

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ABSTRACT

Objectives Globally, perinatal mortality remains high, especially in sub-Saharan countries, mainly because of inadequate obstetric and newborn care. Helping Babies Breathe (HBB) resuscitation training as part of a continuous quality improvement (CQI) programme may improve outcomes. The aim of this study was to describe observed changes in perinatal survival during a 6-year period, while adjusting for relevant perinatal risk factors.

Setting Delivery rooms and operating theatre in a rural referral hospital in northern-central Tanzania providing comprehensive obstetric and basic newborn care 24 hours a day. The hospital serves approximately 2 million people comprising low social-economic status.

Participants All newborns (n=31 122) born in the hospital from February 2010 through January 2017; 4893 were born in the 1-year baseline period (February 2010 through January 2011), 26 229 in the following CQI period.

Interventions The HBB CQI project, including frequent HBB training, was implemented from February 2011. This is a quality assessment analysis of prospectively collected observational data including patient, process and outcome measures of every delivery. Logistic regression modelling was used to construct risk-adjusted variable life adjusted display (VLAD) and cumulative sum (CUSUM) plots to monitor changes in perinatal survival (primary outcome).

Results During the 6-year CQI period, the unadjusted number of extra lives saved according to the VLAD plot was 150 despite more women admitted with pregnancy and labour complications and more caesarean deliveries. After adjusting for these risk factors, the risk-adjusted VLAD plot indicated that an estimated 250 extra lives were saved. The risk-adjusted CUSUM plot confirmed a persistent and steady increase in perinatal survival.

Conclusions The risk-adjusted statistical process control methods indicate significant improvement in perinatal survival after initiation of the HBB CQI project with continuous focus on newborn resuscitation training during the period, despite a concomitant increase in high-risk deliveries. Risk-adjusted VLAD and CUSUM are useful methods to quantify, illustrate and demonstrate persistent changes in outcome over time.

Strengths and limitations of this study

- The prospective and detailed data collection by observers, not taking part in the care of mothers and babies, is a major strength of this study. Previous studies have shown that quality improvement studies based on self-reporting by involved staff may be flawed.
- The long duration of the study, 7 years, made it possible to follow several annual seasonal changes, adding strength to the study.
- The high number of newborns observed in the cohort with complete data set makes the findings from this study more convincing.
- The study had an observational design and was conducted in one setting, both limiting generalisation of the findings.
- There were several randomised controlled studies conducted during the study period, evaluating medical devices for fetal heart rate monitoring and newborn ventilation. These studies could have influenced our findings, however, none of them showed any significant impact on perinatal survival.

INTRODUCTION

Globally, there have been considerable efforts to reduce the under-5 years child mortality, mostly occurring in low-resource countries. These joint efforts have resulted in an approximately 56% reduction in the under-5 years mortality between 1990 and 2016, from 12.7 million to 5.6 million deaths.[1–4] However, despite numerous efforts, newborn mortality has not decreased in a similar way, and currently contributes to approximately 46% of the under-5 years mortality, which reflects an increase of about 41% from 2000.[5] This translates into approximately 7000 newborns dying every day, with the highest burden in sub-Saharan Africa.[5 6] Additionally,

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an estimated 2.6 million fresh stillbirths, that is, intrapartum-related deaths, were reported in 2016[7 8] making the burden of early perinatal mortality (ePMR), that is, fresh stillbirths and 24 hours' newborn deaths, a huge challenge. Importantly, most of these deaths are secondary to potentially preventable causes of birth asphyxia, with disruption of placental blood flow, as the most prominent contributing factor.[6–10]

In 2009, Tanzania was selected to pilot test a new simulation-based training curriculum for newborn resuscitation called Helping Babies Breathe (HBB),[11] to reduce ePMR. Haydom Lutheran Hospital (HLH), a rural referral hospital in northern-central Tanzania, was selected as one of eight study sites, with data collection starting in February 2010.[11] Over the subsequent years, efforts to identify factors contributing to perinatal mortality and strategies to reduce perinatal deaths, especially from birth asphyxia, have been implemented at HLH[10–15] and in similar low-resource settings.[16 17] In February 2011, a continuous quality improvement (CQI) programme was initiated with enforced focus on HBB newborn resuscitation refresher training.[12] Building on the CQI programme focusing on frequent HBB training, the 'Safer Births' project was initiated in 2013, including development and testing of new training and treatment equipment for fetal heart rate monitoring during labour and newborn resuscitation.[15] In 2016, a newborn ventilation trainer system (Laerdal Global Health) for onsite refresher training was introduced. This system was designed to be easily incorporated with the HBB training, comprising automatic training feedback, with the goal to further stimulate frequent HBB scenario training involving all relevant staff.

Using statistical process control (SPC) methods, we recently reported an improved perinatal survival rate from 2011 to 2016 with an estimated 120 extra lives saved in this period at HLH.[15] We also described the different exposures and/or interventions occurring over the time period, which could have had an impact on perinatal outcome. Most trends of improved survival in the applied cumulative sum (CUSUM) plot matched with enforced focus on newborn resuscitation training.[15] SPC methods like CUSUM and variable life adjusted display (VLAD) are well suited for detecting and quantifying small persistent changes in perinatal outcome over time.[18 19]

The aim of this study was to assess whether a persistent increase in perinatal survival over 6 years following introduction of an HBB CQI programme could be detected when adjusting for changes in perinatal risk factors. A limitation with the previous work was that possible changes in patient risk factors for ePMR within the cohort over time were not adjusted for.

METHODS

Setting

This is a retrospective analysis of data from a prospective observational study conducted at HLH, a rural referral hospital located in northern-central Tanzania from February 2010 through January 2017. The baseline ePMR was 2.7% (n=133 deaths). The catchment area for HLH is approximately 2 million people comprising predominantly low social economic status.[20] HLH provides comprehensive obstetric and basic newborn care 24 hours a day, 7 days a week. The labour ward has six delivery rooms with one delivery bed each, and one operating theatre where caesarean sections (CS) take place. Data were collected from all delivery rooms and the operating theatre.

Newborn resuscitation training interventions during the study period

Figure 1 presents different interventions and events during the study period.

One-year baseline period: February 2010 through January 2011

Data collection for the National HBB study started in February 2010. HBB consisted of practical training on basic newborn care and resuscitation.[10–12 15] One full-day HBB training was conducted in April 2010, facilitated by master trainers from the Tanzanian Ministry of Health. However, not all relevant staff were trained and no CQI efforts were introduced after the training. Evaluation 7 months after this 1-day HBB training revealed no

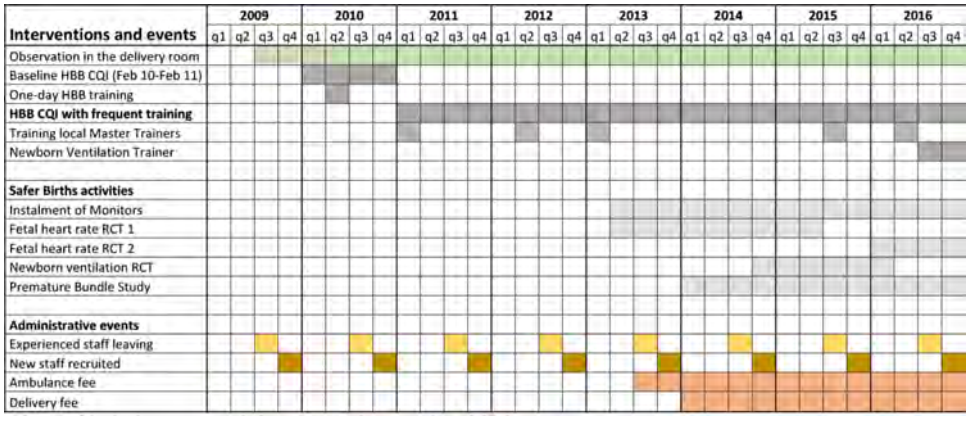

Figure 1 Overview of different interventions and events during the study period. CQI, continuous quality improvement; HBB, Helping Babies Breathe; RCT, randomised controlled trial.

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changes in clinical management,[21] leading to initiation of the HBB CQI programme in 2011.

Introduction of the HBB CQI programme in 2011 and Safer Births in 2013

Due to lack of improvement in clinical management in the delivery room,[21] a programme encouraging frequent brief onsite simulation HBB trainings among the midwives was implemented in February 2011 (HBB CQI). Five local midwives were trained to become HBB trainers, with the responsibility to facilitate ongoing frequent HBB trainings in the labour ward.[12] Short (5–10 min) mandatory HBB simulation-based training sessions were conducted on a weekly basis over the following 6 years.

In early 2013, the Safer Births project was initiated, which included instalment of newborn resuscitation monitors (Laerdal Global Health, Stavanger, Norway). The newborn heart rate was displayed on the monitor as a continuous feedback to the provider. In 2016, a newborn ventilation trainer system (Laerdal Global Health) for low-dose high-frequency onsite practice was introduced. The training involved the use of a novel newborn manikin (NeoNatalie Advanced Prototype, Laerdal Global Health) which could be adjusted to simulate four different common resuscitation scenarios. These were based on real data from more than 1000 live resuscitations observed and recorded by the newborn resuscitation monitor at HLH. The training system was easily operated using a tablet providing an immediate feedback to the provider after a training session, with specific tips to improve. The training system facilitated both individual skills and scenario team training.

Other research and administrative exposures during the study period

Research on fetal heart rate monitoring during labour

As part of Safer Births, two randomised controlled studies comparing different devices for fetal heart rate monitoring, involving low-risk deliveries, were conducted at HLH.[22 23] The first study, from March 2013 to August 2015, compared a wind-up handheld Doppler (FreePlay) and the Pinard fetoscope (commonly used in this setting).[22] The second study, from February 2016 to January 2017, compared a new strap-on continuous fetal heart rate monitor named Moyo (Laerdal Global Health) and the Pinard fetoscope for intermittent monitoring.[23] Moyo is a robust low-cost device developed for low-resource settings, reported to improve midwifery care.[24] No significant changes in ePMR outcomes were reported in the two randomised controlled studies at HLH.[22 23]

Research on newborn care and resuscitation

Between October 2014 and June 2016, a randomised controlled study comparing the standard newborn resuscitator (Laerdal Medical) with a new upright resuscitator (Laerdal Global Health) for ventilation of non-breathing newborns was conducted at HLH.[25] This study included additional training on bag mask ventilation skills. No significant changes in ePMR were reported during the study period.[25]

In 2014–2017, HLH took part in a premature multicentre study led by the Ministry of Health, including premature newborns less than 34 weeks' gestation.[26] A bundle-of-care approach (ie, antenatal corticosteroids, maternal and newborn antibiotics, immediate HBB intervention and avoidance of hypothermia) was introduced, but no significant change in newborn mortality was reported at HLH.[26]

Administrative exposures

During the reference study period (2011–2017), a high turnover of midwives was noted, particularly in relation to new government employment opportunities every midyear (experienced HLH staff leaving to be employed in other government-owned health facilities) and towards the end of each year (HLH recruited new midwives who had completed midwifery training at Haydom School of Nursing to fill the gaps).

An ambulance fee was introduced in July 2013 and a delivery fee in January 2014.

Data collection and management

Trained research assistants have observed every delivery in the labour ward, working 2–3 in each shift covering 24 hours a day, 7 days a week, using a structured data collection form. The observations started in July 2009, 6 months before the National HBB study.[11] In this period the staff became familiar to the observers (minimising the Hawthorne effect) and the research assistants were intensively trained in live observations and accurate data collection and reporting. Data collection for this study took place from February 2010 through January 2017. Information collected included pregnancy complication, labour process and outcome, newborn information and birth attendant information. Additionally, to facilitate electronic physiological data collection, newborn resuscitation monitors (Laerdal Global Health), connected to a dry electrode ECG sensor for rapid heart rate detection and a self-inflating bag mask for newborn ventilation, were installed in every delivery room, including the operating theatre where CS took place from March 2013. Data were collected prospectively during this study period, and there was a data quality control system to ensure the validity.

Patient and public involvement

This study was undertaken in a rural setting, comprising a poor population with a high illiteracy rate and little infrastructure. In such settings, involvement of patients and public is particularly difficult and demanding. However, several individual projects during the study period, like the randomised studies, actively involved the patients. Furthermore, our results are continuously shared through community meetings and community leaders' meetings. The published paper will be located in the hospital library where the community has access.

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Ethical consideration

This study was approved by the National Institute for Medical Research (NIMR) and the Ministry of Health in Tanzania (the HBB CQI programme Ref NIMR/HQ/R.8a/Vol IX/1247 and the Safer Births project Ref NIMR/HQ/R8a/Vol IX/1434), and by the Regional Committee for Medical and Health Research Ethics, Western Norway (Ref 2009/302 and Ref number 2013/110/REK). All relevant healthcare providers were informed about the different HBB CQI and Safer Births quality assessment studies and gave oral consent. Patients were also informed about ongoing studies. Oral consents were obtained for participation in the randomised controlled studies. For the quality assessment studies, patient consents were not obtained as approved by the ethical committees.

Data analysis

Basic count data are presented as numbers and percentages and continuous data as means and SDs. The aim of this study was to monitor and document changes in perinatal survival over time while adjusting for relevant risk factors within the cohort. Therefore, perinatal characteristics and risk factors not related to clinical management were included as explanatory variables in a logistic regression modelling. These risk factors were: birth weight, gestational age, fetal heart rate status, pregnancy complication, fetal presentation of the newborn, multiple birth, source of admission, maternal infection, delivery mode, pre-eclampsia, uterine rupture, cord prolapse and bleeding before labour. First, univariable logistic regression models with each of the listed potential risk factors for perinatal mortality as explanatory variable and perinatal survival as response were fitted. Those risk factors with a p value <0.2 in the univariable model were included in the multivariable modelling. Then a stepwise model selection procedure was run, and finally, removed variables were reintroduced one by one and kept if found significant. Goodness of fit was verified by the Hosmer-Lemeshow test. The regression model was fitted based on the data in the baseline period.

For the data after the baseline period, we constructed a risk-adjusted VLAD plot,[27] presenting the CUSUM of expected outcome for each newborn if the baseline situation had persisted, minus the observed outcome. The expected outcome is the probability of death according to the logistic regression model. The observed outcome is numbered 0 for survival and 1 for death. The VLAD plot can then be interpreted as the cumulative excess number of survivors over time, compared with the baseline rate taking into account risk factors. For comparison we also made a VLAD plot without the risk adjustment.

Moreover, as a formal statistical monitoring procedure with a signal limit to detect persistent changes, a risk-adjusted CUSUM based on the same logistic regression model as the VLAD plot was constructed.[28–30] The CUSUM was constructed to quickly detect an improvement of 0.5 percentage points in the ePMR from the baseline level.

The signal limit of this CUSUM was calculated such that with no change in the true survival probability there would on average be one false alarm every 100 months (ie, if there is no change in the true survival probability the CUSUM would remain close to zero and only go above the signal limit on average once per 100 months). The calculations of the CUSUM were done using methods implemented in the R package spcadjust.[31] For comparison we also made a CUSUM plot without the risk adjustment. Since the aim of this study was to document the impact of improved management on early perinatal (ie, fresh stillbirths and 24 hours' newborn deaths) survival, macerated stillbirths were not included in the regression model and the SPC analyses.

RESULTS

A total number of 31 122 newborns were observed during the time period of February 2010 through January 2017. The number of newborns included in the VLAD and CUSUM analyses (excluding macerated stillbirths and one case with missing outcome data) was 30 718. Of these, 4844 newborns were from the 1-year baseline period (February 2010 through January 2011). Table 1 presents the number of newborns, as well as labour and newborn characteristic distributions across the 7 years' period. The yearly numbers of delivered newborns from 2010 through 2013 were higher (range 4787–4893) compared with the later period from 2014 through 2016 (range 3731–4296). The percentage of babies with abnormal fetal heart rate measurements averaged 2.8% from 2010 to 2013, then increased to an average of 4.8% in the following last 3 years (2014–2016). The percentage of fetal heart rate cases that were not measured was also substantially higher in the last 3 years (2014–2016) (average 12.1%) from an average of 3.5% for years 2010–2013 (table 1). The proportion of babies delivered vaginally was higher in the first 3 years, and the proportion of cases with labour complications was higher in the later period resulting in the proportion of CS being higher in the last 4 years (21%–23%) compared with before, that is, 2010–2012 (11%–15%). There was an increase in newborns being stimulated after birth in 2015 and 2016 (>28%) compared with before, that is, 2010–2014 (<16.5%), but the number receiving bag mask ventilation was relatively constant over the years. The mean birth weights over the last 3 years were higher (average 3282 g) compared with the previous 4 years (average 3113 g).

The VLAD plot without risk adjustment shown in figure 2A indicates that the number of excess survivors was about 150 in the 6-year period following implementation of the HBB CQI training programme (2011–2017) as compared with the baseline ePMR (2010–2011). This amounts to a reduction in the ePMR from 2.7% in the baseline period to 2.2% in the following 6-year period. There are fluctuations in the curve indicating reduced survival during some of the periods, for example, in August 2011, August 2012, between November 2012 and

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Table 1 Total number of births, labour characteristics, fetal heart rate distribution, newborn resuscitation and newborn characteristics per year, counted from 1 February to 31 January the next year over the study period

Characteristics	Baseline	Implementation of HBB CQI frequent training and the Safer Births project						
Year	2010	2011	2012	2013	2014	2015	2016	Total
Births, n	4893	4813	4787	4836	4296	3731	3766	31 122
Source of admissions								
Referrals	181 (4.6)	90 (1.9)	73 (1.5)	211 (4.4)	168 (3.9)	111 (3.0)	193 (5.1)	1027 (3.4)
Home	3778 (95.4)	4723 (98.1)	4714 (98.5)	4624 (95.6)	4128 (96.1)	3620 (97.0)	3571 (94.9)	29 158 (96.6)
Pregnancy complications								
Yes	49 (1.0)	42 (0.9)	42 (0.9)	65 (1.3)	36 (0.8)	33 (0.9)	76 (2.0)	343 (1.1)
Singleton birth	3813 (96.3)	4662 (96.9)	4607 (96.2)	4663 (96.4)	4123 (96.0)	3593 (96.3)	3611 (95.9)	29 072 (96.3)
Multiple birth	147 (3.7)	151 (3.1)	178 (3.9)	173 (3.5)	173 (4,1)	138 (3.750)	155 (4.1)	1117 (3.7)
FHR measurements								
Normal	4647 (95.0)	4540 (94.3)	4477 (93.5)	4078 (84.3)	3438 (80.0)	3039 (81.8)	3108 (82.5)	27 327 (87.8)
Abnormal FHR	97 (2.0)	136 (2.8)	183 (3.8)	123 (2.5)	191 (4.4)	158 (4.2)	212 (5.6)	1100 (3.5)
Not detectable	96 (2.0)	92 (1.9)	90 (1.9)	96 (2.0)	74 (1.7)	69 (1.8)	77 (2.0)	594 (1.9)
Not measured	52 (1.1)	45 (0.9)	37 (0.9)	539 (11.1)	593 (13.8)	464 (12.4)	369 (9.8)	2099 (6.7)
Labour complication								
Yes	710 (14.5)	777 (16.1)	841 (17.6)	1113 (23.0)	1006 (23.4)	892 (23.9)	910 (24.2)	6249 (20.1)
No	4183 (85.5)	4036 (83.9)	3946 (82.4)	3723 (77.0)	3290 (76.6)	2839 (76.1)	2856 (75.8)	24 873 (79.9)
Fetal presentation								
Cephalic	4586 (93.8)	4490 (93)	4470 (93.4)	4537 (93.9)	4073 (94.8)	3566 (95.6)	3696 (95.5)	29 318 (94.2)
Breech	167 (3.4)	179 (3.7)	180 (3.8)	202 (4.2)	172 (4.0)	144 (3.9)	138 (3.7)	1182 (3.8)
Shoulder dystocia	10 (0.2)	12 (0.2)	14 (0.3)	80 (1.7)	51 (1.2)	20 (0.5)	6 (0.2)	193 (0.6)
Transverse	27 (0.6)	14 (0.3)	20 (0.4)	31 (0.4)	27 (0.6)	18 (0.5)	24 (0.6)	170 (0.5)
Others	101 (2.1)	118 (2.5)	103 (2.2)	9 (0.2)*	0 (0)*	0 (0)*	25 (0.7)*	354 (1.1)
Mode of delivery								
Vaginal	3387 (84.6)	4013 (83.4)	3925 (82)	3690 (76.3)	3252 (75.7)	2789 (74.8)	2801 (74.4)	23 857 (78.9)
Caesarean section	460 (11.5)	645 (13.4)	729 (15.2)	1025 (21.2)	957 (22.3)	863 (23.1)	886 (23.5)	5565 (18.4)
Assisted breech delivery	119 (3.0)	126 (2.6)	110 (2.3)	95 (2.0)	79 (1.8)	73 (2.0)	68 (1.8)	670 (2.2)
Vacuum	38 (0.9)	28 (0.6)	23 (0.5)	12 (0.2)	7 (0.2)	6 (0.2)	11 (0.3)	125 (0.4)
Newborn resuscitation								
Stimulation	718 (14.7)	788 (16.4)	725 (15.1)	727 (15.0)	590 (13.7)	1051 (28.2)	1075 (28.5)	5674 (18.2)
Bag mask ventilation	358 (7.4)	283 (6.0)	262 (5.5)	337 (7.1)	312 (7.3)	247 (6.7)	269 (7.3)	2068 (6.7)

Continued

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Table 1 Continued

Characteristics	Baseline	Implementation of HBB CQI frequent training and the Safer Births project					
Birth weight (gt)	3155 (490)	3095 (494)	3075 (460)	3125 (522)	3248 (537)	3255 (523)	3347 (536)	3176 (515)

Data are shown as n (%) unless otherwise stated.
*The data collection form was slightly changed in March 2013 and the variable (others) was not recorded from March 2013 towards the end of 2016.
†Mean (±SD)
CQI, continuous quality improvement; FHR, fetal heart rate; HBB, Helping Babies Breathe.

January 2013, in December 2014, and between September and December 2016 (figure 2A).

The significant risk factors included in the logistic regression model for risk adjustment were birth weight (kg), pregnancy complication (yes or no), fetal heart rate (categorised as normal (ie, 120–160 beats per minute), abnormal (<120 or >160 beats per minute), not detectable, or not measured) and fetal presentation during birth (categorised as cephalic, breech, shoulder dystocia, transverse, or others) (table 2). The risk-adjusted VLAD plot, that is, the calculated number of extra lives saved after adjustment for risk factors, shows a smoother curve, progressively rising, indicating an estimated 250 extra lives saved after risk adjustment (figure 2B). This means that with adjustments for increasing risk factors in the cohort, a calculated 250 extra lives have been saved during the 6-year period, as compared with the baseline period, likely because of improved newborn resuscitation practice.

The unadjusted CUSUM plot signals a persistent improvement after a few months (figure 3A), which confirms that the improvement seen in the VLAD plot is not due to chance. The risk-adjusted CUSUM plot for increased survival crosses the signal limit line earlier and raises more steeply compared with the unadjusted plot (figure 3B).

The risk adjustment had a substantial impact on both the VLAD and the CUSUM plots (figures 2B and 3B), compared with the unadjusted plots (figures 2A and 3A). When adjusting for perinatal risk factors, both plots presented a smoother continuous upward curve with very minimal fluctuation. By excluding one variable at a time from the risk-adjusted model, adjustment for abnormal fetal heart rate was the most important factor for the differences between the adjusted and the unadjusted plots (table 2).

DISCUSSION

The major finding in this study is that the observed increased perinatal survival, following introduction of the CQI programme including frequent HBB simulation-based resuscitation training, was even higher when adjusting for changes in perinatal risk factors over time than what we recently published with no risk adjustments.[15] With risk adjustments, a calculated 250 extra lives have been saved during the 6-year period as compared with the baseline period. We found that the most influential risk factor for mortality was the increase in newborns with abnormal or not measured fetal heart rate, an observation in concordance to that reported by Langli Ersdal *et al*.[13]

During the period 2013–2016, the number of women giving birth at HLH progressively decreased from around 4800 annually (during the years 2010–2013) to less than 4300 (in 2014) and to around 3750 (in 2015 and 2016). This progressive reduction appears to be related to the introduction of ambulance (2013) and delivery fees

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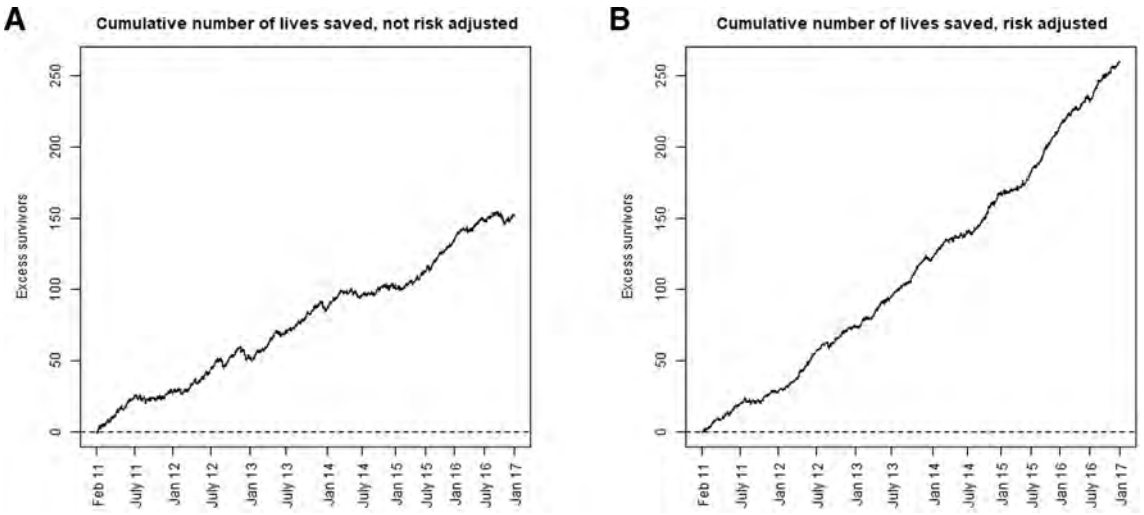

Figure 2 Variable life adjusted display (VLAD) plots displaying the cumulative number of lives saved. (A) Without risk adjustment. (B) With risk adjustment (for birth weight, pregnancy complication, fetal heart rate and fetal presentation).

(2014). Both the ambulance and delivery fees were added to the costs for hospitalisation and hospital management. During the study period before 2013, both ambulance and all delivery services were provided at no cost. The population in this catchment area is scattered with long distances to HLH and with limited means of transport, necessitating the need for ambulance transport of women in labour to HLH. Since the community mostly consists of low social economic status, the reduction in number of births is likely associated with the added economical burden related to the fees, which concur with a qualitative study done by Cephas Sialubanje *et al* in Zambia. This study found that one important reason for home delivery and use of traditional birth attendants was lack of money.[32] We speculate that more women were forced to deliver at home, only proceeding to the hospital if the labour turned out to be complicated. This indicates a more vulnerable cohort from 2013 onwards.

Over the study period, several changes were observed in potential perinatal risk factors for mortality during labour. First, there was a significant increase in the number of cases where the fetal heart rate was not measured, that is, from about 1% between 2010 and 2012, to above 9% in 2013–2016, likely indicating that more women were admitted very late in labour with limited time for fetal heart rate assessment. This may be a consequence of more referrals, often admitted in late labour and/or with severe complications. We also speculate that this is as a result of the above-mentioned fees, making women hesitate to call for an ambulance, and thereby arriving late with complications. Second, the number of CS increased from around 15% in 2010–2012 to above 21% in 2013–2016, likely as a result of increased cases with an abnormal fetal heart rate and/or labour complications. In addition, there was an increase in referred cases from other health facilities during the same period. The increase in CS can also be seen as one of the changes in management, which potentially had a positive impact on ePMR.

The risk-adjusted modelling quantified the level of risk related to each risk factor included in the final model (table 2). The most important risk factor for ePMR was associated with the fetal heart rate, either not detected, not measured or abnormal. We have recently reported that an abnormal fetal heart rate is strongly associated with fresh stillbirths and severely asphyxiated infants.[33] Fetal heart rate abnormalities often indicate fetal hypoxia, raising the possibility that a fetus may require urgent interventions such as intrauterine resuscitation or an expedited delivery. This may translate into the requirement for immediate delivery room resuscitation if the newborn presents without respirations. The number of newborns who received bag mask ventilation remained constant throughout the study period, however newborns

Table 2 Logistic regression model for the risk-adjusted VLAD and CUSUM

Variable	OR	95% CI	P value
Birth weight (Kg)	0.34	(0.23 to 0.51)	<0.001
Pregnancy complications	3.8	(1.1 to 12.9)	0.003
Fetal heart rate			<0.001
Normal	1		Reference
Abnormal	34.6	(19.8 to 60.3)	<0.001
Not detectable	1289	(419 to 3966)	<0.001
Not measured	5.6	(1.6 to 19.6)	0.007
Presentation			<0.001
Cephalic	1		Reference
Breech	2.4	(1.02 to 5.57)	0.045
Shoulder dystocia	0.33	(0.002 to 45)	0.66
Transverse	8.0	(2.4 to 27)	<0.001
Others	1.5	(0.46 to 4.9)	0.50

CUSUM, cumulative sum; VLAD, variable life adjusted display.

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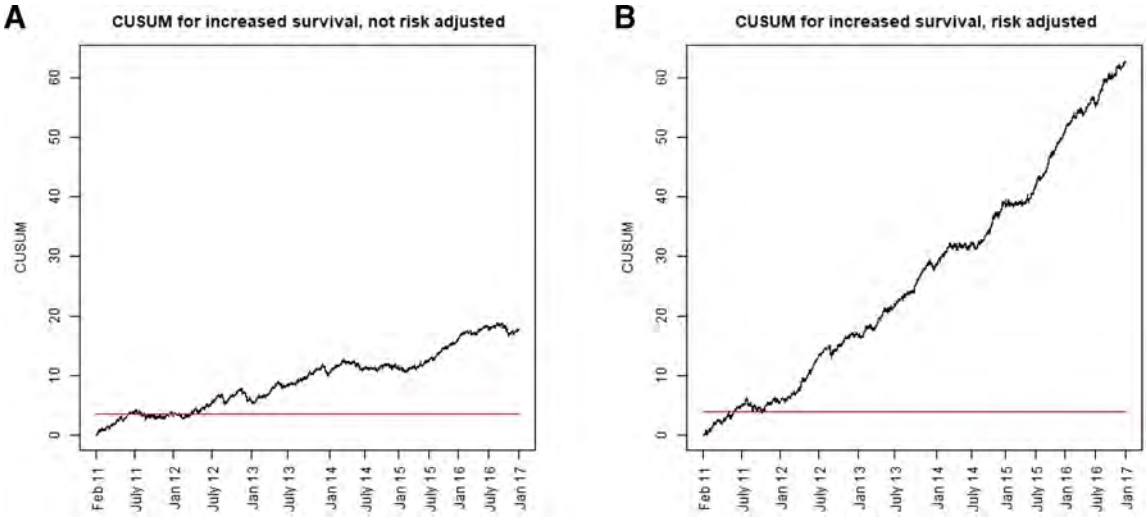

Figure 3 Cumulative sum (CUSUM) for increased perinatal survival. (A) Without risk adjustment. (B) With risk adjustment (for birth weight, pregnancy complication, fetal heart rate and fetal presentation).

being stimulated increased substantially from around 16% in 2010–2014 to above 28% in 2015–2016. This likely is a consequence of intensified resuscitation trainings in 2015 and 2016. Thus, the training focused on immediate stimulation prior to initiating bag mask resuscitation. This simple manoeuvre invariably results in the onset of spontaneous breathing, and thus a relatively lesser need for bag mask ventilation, a finding consistent with that of Msemo *et al*.[11] The HBB refresher training involved all the staff responsible for attending births/resuscitations, reinforcing the existing frequent brief training programme, which we have shown to be associated with a reduction in mortality.[12] This addresses the concern raised by Makene *et al* and Eblovi *et al* on the necessity for on-job practice and strengthening of supportive supervision to ensure quality in resuscitation.[34 35]

Other influences during the study period could also potentially explain the observed changes in perinatal risk factors. The recorded increase in abnormal fetal heart rate could be related to the randomised controlled studies aiming at early detection of abnormal fetal heart rate,[22 23] however, we consider this influence to be minimal since the studies only involved a subset of the cohort and mostly low-risk cases arriving in early labour.

This study indicates a persistent reduction in ePMR after introducing an HBB CQI programme, in spite of an observed increase in high-risk perinatal cases, especially in the last 3 years (2014–2016) of the project. This finding could imply that the newborn management was even better in the 3 last years and indicates the importance of using risk-adjusted models for more reliable estimates.

Strengths and limitations

A major strength of this study is the prospective and detailed collection of data by observers not taking part in the care of the mothers and babies. Earlier studies have shown that CQI based on self-reporting by involved staff may be flawed.[36] The study was done in one setting, which is a limitation for generalising the findings. Additional limitations include some changes in practice not directly related to the HBB CQI, such as increased CS over time that may also have influenced perinatal outcome. However, the duration of the study, which was approximately 7 years, and the high number of newborns observed in the cohort with complete data set, and the continuity of the HBB CQI during the entire period make the findings from this study more convincing. Finally, during the last part of the study period several randomised controlled trials were conducted testing different equipment for fetal heart rate monitoring and newborn ventilation. These studies may have influenced the findings, however, none of them showed any significant individual impact on perinatal survival.

CONCLUSION

To the best of our knowledge, this is the first time risk-adjusted SPC models have been used to estimate effects on ePMR over several years after implementation of an HBB CQI project in a rural sub-Saharan African hospital. The findings indicate a significant improvement in perinatal survival over time, despite a concomitant increase in high-risk deliveries. The estimated number of newborns saved is approximately 40% higher when adjusting for changes in perinatal risk factors than with no risk adjustment. The HBB CQI programme focusing on short refresher HBB training was the only persisting effort throughout the whole period and seems to be the most important factor for improved perinatal survival, despite an increase in high-risk deliveries.

Risk-adjusted VLAD and CUSUM are useful methods to quantify, illustrate and document reliable persistent changes in outcome over time.

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