
Madge E. Buus-Frank

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Madge E. Buus-Frank, DNP
University of Connecticut, 2014

Abstract

Introduction

The Helping Babies Breathe® (HBB®) program is designed to improve neonatal resuscitation knowledge and skills for birth attendants in resource-limited settings.

Purpose and Research Design

This prospective, longitudinal, quasi-experimental study with a control group hold-back design evaluated the effect of HBB® training on resuscitation knowledge and psychomotor skills in healthcare providers in Zambia (N = 52).

Subjects

The sample included nurses (85%); clinical officers, medical licentiates, and physicians accounted for the remaining 15%.

Methods

Resuscitation knowledge and bag-mask ventilation (BMV) skills were measured using the HBB® Multiple Choice Test and the HBB® BMV OSCE. The BMV OSCEs were performed at baseline, 1 and 3 months, using a low-
technology simulator (NeoNatalie), videotaped using iPads, and scored by blinded independent raters. The intervention group received a 2.5 day HBB® training post baseline measures.

Results

Baseline knowledge scores (HBB® MCQ) had pass rates of 71%. The baseline HBB® BMV OSCE had a pass rate of 0% (Median = 2.5 of 7 points). To examine the effect of the HBB® training on knowledge, a repeated measures mixed model ANOVA compared the HBB® MCQ scores between subjects (control versus intervention) and within subjects (changes in scores over time; at baseline, 1 month, 3 months) on the M knowledge score. There was a significant effect of group assignment on knowledge (HBB® MCQ scores), $F(1,50) = 13.62$, $p = <0.001$ and of group and time on knowledge (HBB® MCQ scores), $F(2,50) = 20.76$, $p = <0.001$. Both group assignment and time were significantly correlated with the HBB® MCQ Scores. The intervention group’s knowledge scores increased over time; the control group’s scores did not. The intervention group’s mean scores for the HBB® BMV OSCE increased from 2.8 to 5.8 ($p = 0.01$) in the post-test period and remained higher (4.6 at 1 month; 5.2 at 3 months); however, competency was not uniformly achieved. Atypical and potentially dangerous resuscitation practices, not previously well described, were noted in 43% of the videos at baseline and persisted in 35% of the videos post-training.

Implications for Practice

This study explores baseline levels of newborn resuscitation knowledge and BMV skills in Zambia. Although the HBB® training improved both knowledge
and BMV scores, only two participants demonstrated BMV competency; neither sustained competent scores over time. Our findings highlight the complexity of both teaching and learning BMV and have practical applications for both the developed and developing world context.
Pilot Testing the Effectiveness and Stability of a Structured Curriculum for Newborn Resuscitation—Helping Babies Breath®—

Using Videotaped Simulations

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2014
Doctor of Nursing Practice Dissertation

Pilot Testing the Effectiveness and Stability of a Structured Curriculum for Newborn Resuscitation—Helping Babies Breath®—
Using Videotaped Simulations

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Dedication

Zambian Nights

On the darkest of Zambian nights, we saw you practicing . . .

Sans electricity, the room dimly lit by a flickering flashlight.

Held by one, and then another, each in turn.

You were breathing life into NeoNatalie

celebrating each rise of her chest - as a victory of sorts.

Not like the others – the stories you told me –

when there was simply nothing you could do.

Unfettered by the oppressive heat,

your faces gently cloaked by the ethereal veil of the white mosquito net,

furrowed brows, intense concentration

sweat dripping from your upper lip.

We were but voyeurs

Who could not help watching through the open air window.

Transfixed at the site.

First one, then another, no my turn, unrelenting

You drilled each other deep into the night,

Celebrating this new found skill, committing to memory the steps.

Your voices breaking the vow of silence

As we slipped away into the night, invisible but ever changed.
Dedication

Life is fragile — and death sometimes comes far too early, especially to those in the developing world. During the four years it took to conceptualize, design, complete and analyze the data for this study we have suffered three tragic deaths – lives ended too soon – long before their full potential or contributions could be realized. This dissertation is dedicated to three important members of our Zambian research team. We know that your powerful spirit lives on through your undying investment in the education and training of others.

- Margaret Nachela Mulimine  
  CMMB Assistant Administrative Officer / Research Assistant HBB®  
  Died of complications related to cerebral malaria.

- Baby Nachela Mulimine  
  Preceded Margaret in death due to complications related to mild prematurity.

- Moses Sinkala MBChB, MPH  
  CMMB Zambian Country Director / HBB® Co-investigator / Trusted colleague

And finally, I further dedicate this work to an incredible man who has loved me for 39 years, my husband, friend and chief advisor - Ken. He has walked with me down each and every highway and byway, and has been the steadfast force, encouraging me to do work that really matters, even when it takes me to the other side of the world and back. Ken, your sense of commitment to the cause of improving newborn lives, and your sacrifice, is in many ways far deeper than mine. I am forever grateful for your love and laughter and for the beautiful and precious family that has been our incredible gift to each other.
Table of Contents

Front Matter
Abstract.................................................................................................................. i
Copyright Page ..................................................................................................... v
Approval............................................................................................................... vi
Acknowledgements ............................................................................................ vii
Dedication .......................................................................................................... viii
Table of Contents ................................................................................................. x
List of Tables ....................................................................................................... xiii
List of Figures ....................................................................................................... xiv
Chapter One: Background and Significance
Background and Significance ................................................................................ 1
Overview of Helping Babies Breathe® (HBB®).......................................................... 12
Significance to Nursing ....................................................................................... 23
Theoretical Framework: Social Cognitive Theory.................................................. 26
Purpose of the Study ............................................................................................. 36
Research Questions ............................................................................................. 37
Definition of Key Study Variables ....................................................................... 30
Summary .............................................................................................................. 42
Chapter Two: Integrated Review of the Literature
Introduction ......................................................................................................... 45
Aim of the Systematic Review of the Literature.................................................... 49
Table of Contents – Continued

Research Question 2 ........................................................................................ 163
Research Question 3 ........................................................................................ 168
Research Question 4 ........................................................................................ 172
Research Question 5 ........................................................................................ 175

Chapter 5: Discussion
Discussion by Research Question .................................................................... 179
Implications for Education, Practice, and Research .......................................... 199
Strengths/Limitations ........................................................................................ 200
Conclusions........................................................................................................... 205
References............................................................................................................. 210

Appendix A: Demographic Survey Version 1 .................................................... 224
Appendix B: Short Demographic Survey Version 2........................................... 227
Appendix C: HBB® Knowledge Instrument Multiple Choice Question Test……228
Appendix D: HBB® Bag and Mask Ventilation Psychomotor Skills OSCE........... 231
Appendix E: IRB Documentation....................................................................... 232
Appendix F: HBB® Training Program Brochure and Agenda......................... 235
List of Tables

Table 1. Participant Demographics

Table 2. Prior Exposure to Resuscitation Training Programs

Table 3. Comparisons of Baseline Resuscitation Knowledge

Table 4. Comparisons of Baseline Resuscitation Knowledge By Group

Table 5. Baseline Resuscitation BMV Psychomotor Competency

Table 6. Resuscitation BMV Psychomotor Competency All and By Group

Table 7. Influence of HBB® on Knowledge Over Time

Table 8. Mixed Model Analysis of Variance For HBB® MCQ Total Score

Table 9. Resuscitation BMV Psychomotor Competency; Baseline vs. Post-test

Table 10. Influence of HBB® on BMV Psychomotor Skills Over Time

Table 11. Influence of HBB® on BMV Psychomotor Skills Over Time
List of Figures

Figure 1. The Global Need for Resuscitation by Stratum
Figure 2. Social Cognitive Learning Theory
Figure 3. The Formula for Enhanced Survival
Figure 4. Research Design
Figure 5. Distribution of Knowledge Measure at Baseline: Control Versus Intervention Group
Figure 6. Resuscitation Knowledge Multiple Choice Questions Scores Over Time
Chapter One

Background and Significance

Health is a fundamental human right, and as a global community we will be judged on the health of mothers and children, our most vulnerable citizens. In the next hour, 450 newborns will die, mostly from preventable causes (Lawn, Cousens, Zupan & Lancet Neonatal Survival Steering Team, 2005). Recently maternal, child and newborn health has received unprecedented attention. In part, this attention stems from the ratification of Millennium Development Goal 4 (MDG 4), signifying the international community’s commitment to reduce the mortality of infants and children under five by two-thirds between 1990 and 2015 (United Nations MDG Report, 2013).

Significant progress has been made towards this global goal with infant and child mortality on the decline (Darmstadt, 2010); however, during this same time period, deaths during the first month of life are decreasing at a much slower overall rate. Consequently, the annual 3.6 million neonatal deaths worldwide now account for a higher proportion (41%) of deaths under the age of five than previously reported. Minimal progress has also been made in reducing preterm births and/or other fetal intrapartum deaths; both of these factors are significant contributors to neonatal and childhood deaths worldwide (Bhatta & Black, 2013; Darmstadt, 2010; Lawn, Kerber, Enweronu-Laryea & Cousens, 2010). A clear strategy to decrease neonatal deaths, particularly those in the first hour, day and
week of birth is needed in order to achieve MDG 4 in the next decade.

**Neonatal Mortality on the Day of Birth**

According to the World Health Organization (2005), over 136 million infants are born each year; births are expected to peak at 137 million worldwide births annually by 2015. “Across the entire human lifespan, the day of birth is the day of greatest risk of death” (Lawn et al., 2010). Each year, one million newborns will not survive the first, and only day of their life (Save the Children, 2014). Therefore, any global health efforts aimed at reduction of childhood mortality must include interventions that decrease the mortality and morbidity of newborns.

Birth is a natural process with significant potential risks and consequences. Birth is a natural process and should be a time of celebration; however, the transition from the womb to extra-uterine life is a time of great vulnerability. Problems with transition to extra-uterine life may relate to preexisting maternal conditions, such as preeclampsia, anemia, or infections, leading to fetal distress during the labor process, and may result in delays in the initiation of the first breath for the newborn. Fetal distress and subsequent birth asphyxia can occur due to unexpected intrapartum events such as umbilical cord prolapse, placental abruption, fetal malposition, shoulder dystocia, or cephalopelvic disproportion resulting in obstructed labor. Additionally, cultural practices, such as those described by Zambian traditional birth attendants, including administration of herbs to “open the birth canal or initiate labor” are also
suspected of contributing to obstructed labor and fetal distress (Maimbolwa, Yamba, Diwan & Ransjo-Arvidson, 2003).

Asphyxia is defined as the state in which either placental or pulmonary gas exchange are compromised or absent. Asphyxia is often associated with end-organ ischemia (i.e. decreased or cessation of blood flow). Infants affected by birth asphyxia have an altered respiratory pattern at birth. The infant’s initial response is a rapid respiratory rate; however, with continued asphyxia (either in utero or at birth) the infant develops primary apnea. Infants with primary apnea will often begin breathing in response to tactile stimulation. However, if the insult is not resolved expeditiously, the infant begins to gasp irregularly. If the asphyxia persists the frequency of the gasps slows and the infant proceeds to secondary apnea. Secondary apnea is more difficult to treat – the infant will not respond to tactile or noxious stimulation – and some form of positive pressure ventilation is required to rescue the infant. Longer durations of fetal distress or asphyxia, result in longer delays in spontaneous respirations (Bissinger & Rosenkrantz, 2012).

If prolonged or unmitigated, asphyxia at the time of birth may result in hypoxic ischemic encephalopathy, death and/or survival with disability. Historically birth asphyxia has been estimate to account for 25% of neonatal morality. These estimates are imprecise, and likely under estimate the magnitude of the problem, given challenges with recording births and deaths in the developing world. A recent report from rural hospital in Tanzania evaluating 2470 births reported that birth asphyxia was the cause of 60% of the newborn deaths in the first 24 hours of life (Ersdal, Mduma, Svenson & Perlman, 2012).
Although intrapartum risk assessments to identify high-risk deliveries and prompt rapid sequence triage to more advanced care settings are recommended, the reality in the developing world is that these options are limited. The quality of the roads, limited transportation options (i.e., bicycle ambulance), and the distance to more advanced care settings often make this triage impossible or lead to prolonged delays in seeking or receiving care (Lawn et al., 2010). A report conducted in Nigeria focused on material resources in the developing world context, revealed that 60% of the primary health facilities and 50% of the secondary facilities did not have a functioning ambulance and were, therefore, unable to refer and transfer newborns from primary care to secondary care. Many facilities did not have a functioning landline telephone. Healthcare workers reported using their personal funds and cell phones in order to organize care within facilities and to refer patients for increased levels of care outside of the facility (Ogbolu, 2011).

**Preparation of Birth Attendants for Basic Newborn Resuscitation**

Because intrapartum risk assessments alone do not reliably predict which infants will require newborn resuscitation, and options to refer mothers to a higher level of care are limited, all delivery personnel must be ready to provide resuscitation at every birth, irrespective of the site at which the birth takes place (Lee et al., 2011; Wall et al., 2009).

Every newborn requires care immediately after birth to assess their health and wellbeing. Wall et al. (2009) suggests that somewhere between three to five percent of all births, approximately ten million infants yearly, do not breathe
spontaneously and will require some form of breathing assistance at the time of birth. Infants with perinatal depression and birth asphyxia may be born with poor respiratory effort and have a sometimes imperceptible, slow, or absent heart rate. When initiated promptly in the first minute of life, simple measures, including careful drying to limit evaporative heat loss, warming the infant using skin-to-skin maternal care and/or other measures to preserve body heat, as well as opening and clearing of the airway and breathing passages, are often all that are required to effectively resuscitate most infants (Newton & English, 2006; Wall et al., 2009).

A subgroup of infants, estimated to include another three to six percent of births - approximately six million infants born worldwide annually - may require more aggressive assistance at birth, often in the form of artificial respiration, which must be provided until spontaneous breathing is well established by the infant (Wall et al., 2009). Figure 1 highlights the resuscitation pyramid, illustrating the frequency of resuscitation support needed by infants at birth.

With basic training and practice any birth attendant can provide effective artificial respiration using a simple self-inflating bag and mask resuscitation device. In developed settings, concentrated oxygen is provided, commonly at doses as high as 100% FiO$_2$. However, evolving evidence reflected in a Cochrane meta-analysis demonstrated that bag-mask ventilation with room air is safe, highly effective, and may in fact be preferable to the use of high concentrations of inspired oxygen (Davis, Tan, O'Donnell, & Schulze, 2004; Saugstad, 2005; Saugstad, Ramji, & Vento, 2005).
Evidence for the Presence of a Skilled Birth Attendant for Both Hospital and Home Births

Worldwide, at least 60 million births occur outside of health facilities (Wall, et al., 2010). Irrespective of the site of birth, the presence of a birth attendant
who is skilled in newborn resuscitation skills is of critical importance to the survival of both mothers and infants. More than 99% of all births in developed countries are attended by at least one skilled health worker. However, international data suggest that only 65.7% of births worldwide occur with the assistance of a skilled health worker (WHO, 2008). Save the Children (2014) reports that 40 million women gave birth without any assistance from a midwife or trained healthcare worker; of these, 2 million were completely alone.

Dramatic variations in the presence of skilled birth attendants exist between countries and within regions. In many parts of the developing world, skilled birth attendance is much lower than the reported worldwide average. For example, only 14% of births in Afghanistan, 20% of births in Bangladesh, and 33% of births in East Africa occur with the presence of a skilled birth attendant (WHO, 2008). In Zambia, 47% of all births are attended by skilled birth attendants, over half of all births are outside of health facilities, and this contributes to significant mortality disparities between poor, rural mothers with low levels of education, and their urban counterparts who have more access to facility births, and whose facilities are typically better equipped (WHO, 2013). The absence of a skilled birth attendant has negative implications for the mortality and morbidity of both mothers and infants. Countries that have successfully increased their rates of skilled birth attendance at delivery have shown substantial sustainable decreases in deaths of both childbearing women and their infants (WHO, 2005).
Gaps in the Skill Level of “Skilled” Birth Attendants

Additionally, clear differences in the education and skill levels of “skilled” birth attendants exist. Literacy rates are low (< 50%), and 80% of these caregivers had one month or less of formal training. Most SBAs do not have basic equipment (e.g., blood pressure apparatus, stethoscopes, infant bag and mask manual resuscitators) (Garces et al., 2012).

An important qualitative study, undertaken by a Zambian nurse midwife-led research team, described the beliefs of mbusas, or traditional birth attendants (TBAs) in Zambia (N = 36) who conduct home births and advise childbearing women on culturally appropriate childbirth practices. They concluded that this cadre of providers lacked knowledge about complications related to birth. The TBAs or mbusas relied on traditional beliefs and witchcraft to explain mishaps in labor, and blamed maternal or paternal infidelity as the cause of poor birth outcomes. When describing routine newborn resuscitation and care, notably absent from the TBAs descriptions of important practices and priorities were concepts related to clearing the airway, skin-to-skin care as a mechanism of thermoregulation, or early breastfeeding (Maimbolwa et al., 2003).

A National Service Provision Assessment, which included estimates of newborn resuscitation capacity in six African countries, revealed that even when births occur in health facilities rather than at home, only 2 to 12% of personnel conducting these births had been trained in neonatal resuscitation techniques. The availability of basic equipment for newborn resuscitation was also
inconsistent. Only 8 to 22% of facilities reported that they had equipment to provide newborn respiratory support (Wall et al., 2009). A recent cross sectional survey of 124 birth centers in Africa and Asia evaluated access to the “WHO child-birth related essential technologies,” critical equipment that supports birth and infant resuscitation. The survey revealed significant gaps in access to basic equipment for newborn resuscitation (BMV devices and warming devices) with wide variations in access to critical equipment that were most notable in small centers with < 100 deliveries per year (Spector, Reisman, Lipsitz, Desai & Gwande, 2013).

Significant variation in the availability of skilled resuscitation at birth exists from region to region even in high-income countries in the developed world. Data from rural settings in the United States, reported by Jukkala & Henly (2007, 2009), demonstrates suboptimal and inconsistent skills in newborn resuscitation. In Canada, increased infant mortality rates in native Inuit populations, has also been reported by Smylie, Fell, & Ohlsson (2010).

The gap between a newborn’s need for resuscitation at birth, and the universal availability of simple newborn resuscitation skills and equipment, is most urgent in low resource settings, primarily in the developing world (Meaney et al., 2010; Ogbolu, 2011). Although best practices for newborn resuscitation specific to low-resource settings have been developed (Newton & English, 2006), they have not been systematically disseminated or adopted in the developing world. Evidence suggests that simple inexpensive but highly effective resuscitation measures could be provided in a variety of birth settings worldwide,
from the hospital to the home.

**Impact of Delayed or Suboptimal Resuscitation**

Delays in initiating resuscitation or suboptimal resuscitation may result in death. Additionally, a proportion of infants who are compromised and survive birth asphyxia will suffer from the long-term impact of hypoxic ischemic encephalopathy, which may result in the development of cerebral palsy, learning disabilities, cognitive disabilities and ongoing seizure disorders. Potentially preventable morbidities affect over one million children worldwide according to WHO estimates. Of those infants who suffered serious intrapartum events and survive beyond one year of age, 18% will have a major disability (WHO, 2005).

In low-resource settings, newborns who initially survive birth asphyxia, have high mortality rates in the first year of life; 45% will die by one year of age. The actual prevalence of birth-related disabilities worldwide is unknown; however, in Katmandu, Nepal, a representative developing setting, the estimated prevalence of neurological impairment attributable to birth asphyxia was measured at 1 per 1000 live births (Ellis et al., 1999).

The 2004 Global Burden of Disease assessment estimated 41,683,855 disability-adjusted life years due to birth asphyxia (WHO, 2005). Resuscitation training is a very cost-effective strategy with direct costs of approximately US $208 per life saved and approximately US $5.24 per disability-adjusted life year. This cost indicates that neonatal resuscitation is among the most cost-effective perinatal care strategies available, and among the most cost-effective of all child health interventions (Manasyan et al., 2011).
Invisible Mortality: An Evolving Understanding of Stillbirths

Clearly both mothers and infants are at high risk for mortality in the perinatal period. Of the 535,900 maternal deaths that occur each year, 42% occur in the highly vulnerable intrapartum period. In many parts of the world, infant births are not officially “counted” or registered with a birth certificate; reporting of live born infants who later die may be equally problematic. Without an accurate account of birth and death rates, the cause and contributing factors for all early neonatal deaths are extremely difficult to discern.

However, maternal and neonatal mortality rates, even if accurately reported, fail to tell the whole story. Some infant deaths are invisible in traditional reports of mortality rate statistics because the infants do not survive labor, or they are so severely depressed at birth, that they are misclassified as “stillborn” or sometimes, more specifically, classified as “fresh stillbirths.”

Stillbirths are technically defined as a baby (>1000 grams) that is born with no signs of life during the last 12 weeks of pregnancy or after 28 weeks gestation (Lawn et al., 2009). Current data, based upon the best estimates available, suggest that 3.9 million stillbirths occur worldwide with the highest rates, almost 98%, occurring in the developing world (Lawn, Shibuya & Stein, 2005). Of the 3.9 million yearly stillbirths, 1.02 million stillbirths occur during the intrapartum period. This staggering statistic is in addition to the 904,000 intrapartum-related neonatal deaths already reported.

Where a baby is born matters, as illustrated by intrapartum-related
neonatal mortality rates that are 25-fold higher in the lowest income countries stillbirth rates that are up to 50-fold higher than in higher resource settings (Lawn et al., 2009). Despite the magnitude of the burden of stillbirths in the developing world, until very recently these deaths have been largely invisible in global health indicator reports. There is a clear mismatch between the mortality burden, and evolving international policies and programmatic responses. The stillbirth data further amplify the challenges in providing newborn resuscitation. It is postulated that many births that are misclassified as “stillbirths” may actually be full-term infants, who are suffering from perinatal depression, many of whom would likely respond to simple resuscitation measures initiated in the first minute or minutes of life.

Overview of the Proposed Intervention:

Testing a Structured Educational Curriculum

Helping Babies Breathe®(HBB®) Designed for Low Resource Settings

In response to the urgent need for effective newborn resuscitation, irrespective of the site of birth, a new evidence-based neonatal resuscitation curriculum for use in low resources settings, titled Helping Babies Breathe® (HBB®), has been developed (AAP, 2010). This skills-based curriculum is the concerted work of a team of neonatal and perinatal experts, which was undertaken as an initiative of the American Academy of Pediatrics with input from the World Health Organization and developed in association with a number of
key partners. The work was partially funded using an unrestricted educational grant from the Laerdal Foundation for Acute Medicine, Stavanger, Norway. The Latter-Day Saints Charities, Salt Lake City, Utah provided support for evaluation of the program materials. Implementation and evaluation of the curriculum was also supported by the US Agency for International Development (USAID). The HBB® program represents a unique collaboration between clinicians from the United States and the developing world. The training reemphasizes the importance of the presence of a skilled birth attendant. In addition, the HBB® training provides a structured educational curriculum that integrates the International Liaison Committee on Resuscitation (ILCOR) evidence-based neonatal resuscitation strategies that have been pragmatically adapted for use in low-resource settings.

The emphasis of HBB® is on the early recognition of newborns in distress. This is followed by the prompt initiation of simple but effective low-technology resuscitation efforts that can be initiated in the first minute of life, regardless of the birth setting. The focus of the interventions, aptly titled “The Golden Minute®,” is a carefully structured care sequence that can be taught to and provided by a wide range of skilled birth attendants wherever babies are born.

The Helping Babies Breath® Resuscitation Program (AAP, 2010) includes a scripted structured curriculum, standardized educational materials, and low-technology resuscitation training simulator. The program uses low technology
educational tools and visuals including a flip chart, a handheld pocket-sized resource manual, along with culturally sensitive flowcharts as structured teaching aides and a consistent script for the trainers. The educational model uses the train-the-trainer methodology, with a combination of didactic teaching, and an emphasis on small group learning facilitated by a master trainer who works with two to three trainee learning dyads.

Psychomotor and clinical decision-making skills are evaluated using both pretests and post-tests to identify knowledge and practice gaps and to quantify and reinforce learning. The testing uses a plastic inflatable mannequin, NeoNatalie (Laerdal, 2010) that is the size and shape of a newly born infant and serves as an effective low-technology simulator. NeoNatalie can be filled with warm water, emulating the average birth-weight in the developing world (2 kilograms) a dimension that further enhances the fidelity of the simulations. The tactile dimension and fidelity of the simulation are enhanced by the doll’s inherent laxity; this replicates the “feel” of an infant with significant hypotonia from perinatal birth depression.

This structured educational curriculum and unique educational modality has an emphasis on the following: dyad peer-to-peer teaching and learning, expert faculty facilitation with a six to one faculty to student ratio, ongoing practice and return demonstrations, and integration of both formative and summative objective structured clinical evaluations / examinations (OSCEs). The HBB® program was developed primarily by expert consensus by members of the
Global Implementation Task Force of the AAP. Content validity testing included two rounds of review by a panel with expertise in global health and neonatal resuscitation, using the Delphi technique. An additional review was conducted by a regional technical expert at the World Health Organization (Singhal et al., 2012).

The HBB® program underwent preliminary field testing in low resource settings in Bangladesh, India, Kenya, Pakistan, and Tanzania, during which participants demonstrated improved skill acquisition on specific critical resuscitation competencies. The first published formative evaluation of the HBB® program published in the peer reviewed literature focused on the development and formative evaluation. It was conducted independently at two international field-testing sites (Kenya and Pakistan) with learners who had not been formally trained in neonatal resuscitation at baseline (Singhal et al., 2012).

The “dose” of the field-testing educational intervention included 1.5 days (10 hours) in training, with 6 hours of instruction and 4 hours spent on pretest and post-test evaluations. The evaluation team focused on a 7-stage hierarchal evaluation model including: participant numbers, satisfaction, learning, competence and performance. Secondarily, they evaluated whether participants achieved acceptable levels of knowledge and/or performance of skills. They noted that higher levels of evidence for the efficacy of such training might include patient and community health outcomes, which were not performed in the initial assessments. The research team evaluated facilitator and learner perceptions of
the course structure and learning materials using a five point Likert scale and structured focus groups. The empiric evaluation of the utility and performance of the assessment tools (HBB® Knowledge Multiple Choice Question Test and the HBB® BMV Checklist) were not well described in this publication.

Singhal et al.’s (2012) results suggested that even after the intensive training the majority of participants still did not demonstrate mastery of bag and mask ventilation. They noted achieving competency for this critical skill is challenging, and virtually none of the participants demonstrated competency, and summarized their results by stating:

Participants . . . demonstrated high satisfaction, high self-efficacy and gains in knowledge and skills. Mastery of ventilation skills and integration of skills into case management may not be achievable in the classroom setting without additional practice, continued learning, and active mentoring in the workplace.

After international field-testing, the HBB® Task Force made key modifications before unveiling the program curriculum in June of 2010. Two complimentary additional curriculums have been developed: Helping Babies Survive, focused on essential newborn care beyond the first hour of life, and Helping Mothers Survive, focused on reducing maternal mortality.

**Considerations in the Scale-Up and Dissemination of HBB®**

Countrywide implementation of HBB® has been supported in Tanzania, an African country with a population of 42 million, 1.4 million births annually, and a
neonatal mortality rate of 32 per 1000 live births. Of neonatal deaths in Tanzania, 50% occur in the 24 hours around birth and 75% in the first week of life. Approximately 30% of these deaths can be attributed to birth asphyxia.

Despite efforts to meet MDG 4 rates of infant mortality have been static in this region. In 2009, the United Republic of Tanzania adopted a well-harmonized cascade strategy, led by the Ministry of Health and Social Welfare, with a goal of universally training 1332 master trainers and 10,000 providers, over a very aggressive timeline of 18 months. The Tanzanian plan included a research arm, with reporting of HBB® data organized through four research hospitals, which collected and entered data into a standardized central repository. The long-range goal is a countrywide full-scale implementation aimed at reducing neonatal mortality by 50% by 2015 (Tanzania Ministry of Health, 2013; Wall et al., 2010).

Initial reports from this work, included evaluation of the impact of a 1-day HBB® training program, that resulted in significant improvements in the performance of birth attendants (N = 39) during simulated neonatal resuscitations. The research team was one of the first to report the use of videotaped, independently rated assessments. The proportion of caregivers that passed the simulated scenarios increased from 41 to 74% (p = 0.016) for routine care, and from 8 to 74% (p ≤ 0.0001) for the more detailed neonatal resuscitation scenarios (OSCEs A & B). Simultaneously, observations of actual resuscitation care provided at all births were also made both before (n = 2745) and after (n = 3116) the HBB® training. Although the providers’ simulated performance improved, and these improvements persisted seven months later, the use of
resuscitation skills did not translate into improvements in real-world clinical practice. Specifically, the number of infants being suctioned and/or ventilated at birth did not change, and the use of stimulation in the delivery room decreased after HBB® training (Ersdal et al., 2013).

A second study, Msemo et al. (2013), evaluated a strategy for national dissemination of HBB® in Tanzania, that included systematic training for healthcare providers from three major referral hospitals, four associated regional hospitals and one district hospital. The before \((n = 8124)\) and after \((n = 78,500)\) study did not examine educational outcomes but instead focused on important downstream indicators, including fresh stillbirth rates and early neonatal deaths during the first 24 hours of life. This team reported a significant reduction in neonatal deaths with a relative risk \([RR] 0.53; 95\% \text{ confidence interval } [CI] 0.43-0.65; p \leq 0.0001)\) and rates of fresh stillbirth \((RR \text{ with training } 0.76; 95\% \text{ CI } 0.64-0.90; p = 0.001)\).

Beyond the Tanzania context, a third study reported on a before-and-after evaluation of the effectiveness of the HBB® structured educational curriculum to improve healthcare providers’ knowledge and skills while measuring the impact on stillbirth and neonatal mortality in Karnataka, India (Goudar et al., 2013). This prospective study included 4187 births before and 5411 births after the HBB® training. A total of 599 birth attendants from rural primary health centers, as well as district and urban hospitals, received HBB® training using a train-the-trainer cascade. A pre-post written evaluation of trainee knowledge, post-training performance and skills, stillbirth rates, pre-discharge mortality, and neonatal
EFFECTIVENESS OF HELPING BABIES BREATHE®

mortality rate before and after HBB® training were assessed. The study was confounded by grouping first time HBB® trainees, with those who were receiving a “refresher course.” The content, dose, and duration of the refresher course were not clear from the published report.

Knowledge scores, as measured by the HBB® MCQ, had a 46% pass rate on the pretest and 88.6% pass rate on the post-test \( (p < 0.001) \) for those being trained for the first time; HBB® MCQ scores began at 69% and increased to 90.4% for those in the refresher course \( (p < 0.001) \). Unfortunately, no baseline measures of BMV skills or competency were obtained in this study. The post-test level of BMV competency was 58% for first-time attendees and 68% for those attending the refresher course, suggesting ongoing low rates of competency of this skill despite two educational interventions.

When HBB® trained providers were observed in clinical practice, actual resuscitation rates went down (similar to the reports from Tanzania) with a mean of 28% of infants receiving resuscitation in the pre-training period versus 11.9% in the post-training period \( (p < 0.001) \). Actual use of BMV remained low (mean 3.1% versus 4% \( [p = 0.01] \)). The authors postulated that the emphasis on drying and vigorous stimulation may have decreased the actual need for BMV in infants this cohort, although this was speculative as drying efforts were not tracked in the study. When BMV was required, it was primarily provided by physicians; nurses and midwives only initiated BMV in 3% of the pretest cases and 7.5% of the post-test cases. This is an intriguing finding, given the fact that physicians do not attend most births in the developing world.
Evidence Regarding Educational Strategies

Figure 2. The Utstein formula for enhanced survival. Adapted from Søreide et al., 2013. Resuscitation 84 (2013) 1487–1493.

The original Utstein Summit Report highlights the extremely limited evidence for and gaps in our understanding of both the acquisition and stability of resuscitation skills. Furthermore, the studies cited are now 15 to 20 years old, and as such may fail to reflect the complexity of current practice (Chamberlain & Hazinski, 2003) substantiating the need for further research. In addition to good quality evidence regarding the efficacy of various clinical resuscitation strategies, we also need empiric evidence regarding the efficacy of educational strategies, as well as research to guide local implementation efforts (Hunt, Fiedor-Hamilton & Eppich, 2008; Søreide et al., 2013).

In summary, there is limited published data to fully understand either the effectiveness or efficacy of the HBB® training, the stability of knowledge and skills, and the uptake and clinical application of these skills, particularly in culturally diverse settings with a wide range of types of healthcare providers.
(HCPs). To date the effectiveness of this educational program has been evaluated in a limited number of settings and regions, with mixed results.

At the most basic level, the research to date has not demonstrated competency in BMV at the completion of the training. In some circumstances, newly trained trainers have been used to train others, without objective validation of their knowledge and skills, calling into question the both skill level of trainers in the train-the-trainer rollout as well as their ability to train others. Until basic resuscitation skills like BMV are mastered, the time spent on more complex scenarios (OSCEs A & B) in the training may be misplaced. Furthermore, challenges in moving critical resuscitation skills like BMV, from the simulated learning and testing environment, to a clinical environment need to be addressed, given early data that suggests that simulated skills may not routinely translate into clinical practice in both the developed (Spillane, Hayden, Fernandex, Adler, Beeson, Goyal, Smith-Coggins, et al., 2008) and the developing world context (Goudar et al., 2013). Beyond the initial delivery of training, strategies to assure HCPs maintain ongoing competency are needed, and these should be based upon a clear understanding of the stability of resuscitation knowledge and psychomotor skills specific to the local context and setting.

The HBB® Global Implementation Task Force, in concert with their international collaborators, now faces the enormous task of dissemination of the HBB® program worldwide using a train-the-trainers model. The challenge is to
develop trainers with both sufficient technical and educational skills, while increasing trainer capacity given the large number of master trainers that will be needed to build critical resuscitation capacity in various regions around the developing world. These needs must be carefully balanced with the need to maintain a high standard of educational quality and consistency, and to establish some methods and rigor in monitoring program outcomes.

As illustrated by the example in Tanzania, it is critical that, whenever possible, the HBB® training be carefully integrated into the countrywide, strategic health plan. Building upon the experience in India, ongoing monitoring is required to assure knowledge and skill retention, as well as timely performance in the clinical setting. On a larger epidemiologic scale, more data is needed to measure the impact of this program on stillbirth rates and neonatal mortality rates in various regions of the world.

**Significance of the Problem to Nursing**

The active engagement in the health and wellbeing of mothers and newborns around the world is self-evident, as nurses provide or oversee the majority of healthcare worldwide (Buchanon & Calman, 2005). The right to basic healthcare knows no boundaries, and the need for expert nursing care is both basic and universal (Kenner, Sugrue, Mubichi, Boykova & Davidge, 2009; Rosenkoetter & Nardi, 2007). Nursing has a strong historical tradition of global citizenship and collaboration dating back to Florence Nightingale’s work. From 1854 to 1856, Nightingale worked tirelessly to train professional nurses to impact
clean air and water, to advocate for nutritious food and safe housing, and to solve a myriad of epidemiologic and infectious problems (Dossey, 2010). Only now, over 100 years after her death, can we fully appreciate the magnitude of Nightingale’s master collaboration skills, and her revolutionary vision for the future of nursing. Florence Nightingale, 1893, p. 1998.

Shortly after Florence Nightingale recorded her vision for the future of nursing, the International Council of Nurses (ICN) was founded in 1899. The ICN has evolved into a federation of more than 130 national nurses associations (NNAs), representing more than 13 million nurses worldwide. Operated by and for nurses, ICN works to ensure quality nursing care for all, advocates for equitable and sound health policies globally, promotes the advancement of nursing knowledge, and cultivates the worldwide of a professional, competent and respected nursing workforce (International Council of Nurses, 2012).

The ICN Code of Ethics for Nurses, first published in 1953, clearly sets the standard for nurses global responsibility and identifies four fundamental responsibilities of the nurse:

1. To promote health.
2. To prevent illness.
3. To restore health.
4. To alleviate suffering.

The Code further emphasizes that “inherent in nursing is respect for human and cultural rights, the right to life and choice, and the right to dignity and to be
treated with respect. Nursing care is respectful of and unrestricted by considerations of age, color, creed, culture, disability or illness, gender, sexual orientation, nationality, politics, race or social status” (International Council of Nurses, 2012). Contemporary nursing scholars continue to emphasize the important role of nurses in impacting health disparities, poverty, and global health (Kenner, Sugrue, & Finkelman, 2007). Falk-Rafeal (2006) writes, “Nursing’s fundamental responsibilities to promote health, prevent disease, and alleviate suffering call for the expression of caring for humanity and environment through political activism at local, national, and international levels to bring about reforms of the current global economic order.” Some nurse scholars are calling for academic partnerships to support doctoral preparation of nurses interested in working the developing world (Ketefian, 2008).
Theoretical Framework: Social Cognitive Theory

The social cognitive theory (SCT) provides a strong theoretic foundation to ground research focused on the efficacy of a structured curriculum, such as Helping Babies Breathe®. This theory provides guidance regarding teaching methods, learning theory, and factors that influence both the transfer and the stability of knowledge. Social cognitive theory has been identified as the basis for early curriculums developed to teach cardiopulmonary resuscitation.

![Diagram of Social Cognitive Theory](image)

*Figure 3. Albert Bandura’s social cognitive theory. Adapted from Bandura, A. (1997). Self-efficacy: The exercise of control. New York: W.H. Freeman.*

The relevance of SCT is further magnified, in the setting of global health interventions, where dramatic variations in both the content and context of care exist, and where diverse cultural differences abound. A brief history of SCT, as well as its meta-paradigm concepts and philosophical claims, will provide further insight into how this theoretical framework will support and inform the proposed research plan.
Albert Bandura is the father of SCT. His first seminal work was published in 1953, based upon portions of his doctoral dissertation. Recent updates on Dr. Bandura’s Facebook page indicate that he continues to be connected to the community of scholars and students, publishing prolifically. His body of work now spans 61 years, a testament to the magnitude and durability of his contribution to the science of understanding human behavior and learning, and his ongoing curiosity and commitment that fuels further exploration in a wide variety of disciplines (Pajares, 2010).

Bandura (2001) elegantly summarizes the overarching focus of his life’s work by stating, “My research focus is on the analysis of basic mechanisms of human agency through which people exercise control over their level of functioning and events that affect their lives”. Social cognitive theory has been broadly applied by multiple disciplines and focuses on the following:

1. How people regulate their own motivation, thought patterns, affective states and behavior through beliefs of personal and collective efficacy.

Relevance of Human Agency

Social cognitive theory was born from the efforts to understand what it means to be human. *Human agency* is the key tenant upon which SCT is based. Bandura (2001) describes human agency in simple terms stating:
To be an agent is to influence intentionally one’s functioning and life circumstances. In this view people are self-organizing, proactive, self-regulating and self-reflecting. They are contributors to their life circumstances not just products of them.

This theoretical framework can be carefully linked to the purpose of the HBB® curriculum, which is to empower local care providers and communities to develop a more organized, systematic, and sustainable system of care for newborns and to facilitate self-organizing and self-regulating behaviors. The model of instruction, using dyad and peer-to-peer teaching with ongoing return demonstrations, skillfully integrates the principle of self-reflection. Local providers are encouraged to monitor their clinical practices with the goal of improving infant mortality one birth at time.

The key principles of intentionality, forethought, future-directed planning are critical to applying this theory in teaching newborn resuscitation. Intentionality encompasses actions that are achieved by proactive plans and strategies, and the commitment to bring them about; both of which are extensions of forethought and future-directed planning. Additionally, forethought provides direction, cohesion, and enhanced meaning to life.

In essence, SCT teaches us that we must plan for a future that does not yet exist. However, planning is not enough. We then must execute the plan to create that future. We must learn to transcend the present, to be able to create the future. In this way, each of us serves as the architect of our preferred future.
According to Bandura (2001), “The capacity to exercise control over the nature and quality of one’s life is the essence of humanness”.

On a very pragmatic level, the HBB® curriculum strongly emphasizes the importance of intentional forethought and planning. The following excerpt from the HBB® workbook foreword states that:

Planning for birth begins in the family and the community. The pregnant woman prepares a birth and emergency plan. Health workers and community leaders urge women to have a skilled birth attendant at the birth. Health units maintain enough skilled people and equipment. With planning and skills you can make sure every baby has a chance to breathe at birth. (AAP, 2010)

In addition to forethought and future planning in SCT, self-reactiveness, or self-regulation, is identified as a key principle of human agency. Personal standards, actions, and behavioral choices are examples of self-regulation. Self-regulation is evident when an individual focuses on actions that provide satisfaction and self-worth, refraining from actions that are detrimental and harmful, and continuously reflecting on and making corrective actions to their behaviors.

Active self-reflection is an additional principle of human agency. Social cognitive theory is based on the premise that, “People are not only agents of action but are also self-examiners of their own functioning. The meta-cognitive
capability to reflect upon oneself and the adequacy of one’s thoughts and actions is another distinctly core human feature of agency” (Bandura, 2001).

In building upon this theoretic framework, the HBB® Master Training program will begin with an evaluation of current skill level, integrating the use of objective, structured, clinical evaluations. Master trainers will learn how to effectively reflect on their own skill level and model this to their students.

Relevance of Efficacy and Self-Efficacy to Newborn Resuscitation

Social cognitive theory is intrinsically linked to the second meta-paradigm, efficacy, which is often referred to as the foundation of human agency (Bandura, 2001). Bandura (2001) defines self-efficacy as the, “belief in one’s capabilities to organize and execute the course of action required to produce given attainments.” The paradigm of self-efficacy is a powerful and multi-faceted one. Unless people believe that they can make a difference, they have little impetus or incentive to act; furthermore, when actions are met with barriers, they have little fuel for perseverance. Self-efficacy requires internal regulation of motivation, thought processes, and affective states, as well as external regulation of actions and environment. Self-efficacy can be considered both a cause of and an effect on human behavior.

The absence or lack of self-efficacy is explored extensively in SCT. Regardless of the specific circumstances, people who doubt their capabilities in a specific realm may avoid that realm and may also find it hard to motivate
themselves. Furthermore, these thought processes may lead to overt or covert procrastination, or alternatively the individual may simply disengage, lower their aspirations and efforts, as their energy and internal resources are depleted. When faced with obstacles, they may give up quickly, as their mental model is one of failure versus success (Bandura, 1997).

Imagine that you worked in a setting where the loss of mothers and infants during the birth process was the norm, where births and deaths were not carefully accounted for, and where infants were often not named until they reached one month of age, largely because of the risk of dying in the first hour, week, or month of life. Reflecting on these circumstances that are quite typical in the developing world, one can begin to understand the potentially devastating toll that low self-efficacy can take, and the paralyzing sense of helplessness that could result.

Low self-efficacy is not just an esoteric score on a scale; low self-efficacy actually interferes with or impedes performance. Low self-efficacy decreases the ability to analyze critically and thoughtfully. In the face of low self-efficacy, thought processes are diverted away from the predetermined goals and a positive mindset that failure is not an option, and leads to an exaggerated focus on deficiencies, anticipatory worries, and drain of energy, all counterproductive strategies (Bandura, 1997). In one of his famous and pithy public appearances Bandura summed it succinctly by saying, “self-belief does not necessarily ensure success, but self-disbelief assuredly spawns failure”.

In testing a structured curriculum, measurements of self-efficacy have the potential to provide important determinants of outcomes; therefore, a measure of self-efficacy may be an important step in understanding the impact of the HBB® structured curriculum. Self-efficacy influences the initiation, performance and maintenance of human behaviors and is a pivotal factor in performance, in that it mediates how people apply their knowledge and skills in a specific circumstance. Maibach, Schieber & Carroll (1996) published a review of the literature on self-efficacy in the context of pediatric resuscitation. Using 3 case exemplars, they highlight that self-efficacy is moderately correlated with the quality of global performance, noting that even clinicians who are knowledgeable and skilled in resuscitation techniques may fail to apply these techniques in the absence of adequate self-efficacy. They also propose key strategies for influencing self-efficacy in modern resuscitation training programs.

Other authors have confirmed that self-efficacy seems to be predictive of a HCP’s willingness to attempt specific resuscitation skills during a simulated resuscitation – not just knowing what to do, and being prepared to do it, but daring to do it, to actually attempt a potentially life-saving procedure. An important distinction is that self-efficacy does not correlate with skill (quality of performance of these resuscitation skills). The authors conclude that self-efficacy might serve as a predictor of the application of learning; however, it is not well suited for self-assessment given that competency and self-efficacy may not be well calibrated (Turner, Lukkassen, Bakker, Draaisma, & ten Cate, 2009).

To be useful, self-efficacy instruments must be situation- and population-
specific (Bandura, 2006). Carlo et al. (2009) measured self-efficacy in the developing world setting; however, the validity and psychometric properties of the instrument they used remain untested. Recently published methodological work by Roh, Issenberg, Chung & Sun (2012) shows progress on developing and evaluating the properties of the Resuscitation Self-Efficacy Scale for nurses in a sample of 509 Korean nurses. Their final instrument includes 17 items with four structural components, including the following domains: recognition; debriefing and recording; responding and rescuing; and reporting. This scale, with its focus on high-technology interventions (e.g. electrocardiogram [ECG], pulse oximetry, chest compressions, and defibrillation), would require significant modification and testing to have relevance to low-resource settings. In summary, there are no well-developed, self-efficacy instruments appropriate for use in low-resource settings available at this time, and this is an important limitation in our ability to understand the critical relevance of self-efficacy to resuscitation.

**Relevance of Proxy and Collective Agency**

Expanding the theoretic lens from one’s personal agency, to that of society, SCT states that human agency is deeply rooted in social systems. In that context, personal agency is subject to a myriad of social, structural influences. These influences and transactions are bidirectional and reciprocal in nature. The social structures and systems in which behavior is learned and carried out are important modifiers and influencers of future behavior. Given this, the concept of agency has three distinct levels: personal, proxy, and collective agency
(Bandura, 2001). Most of life’s pursuits are a symphony, not a solo performance.

This symphonic performance that we call “healthcare” requires not simply cooperation but also more complex behaviors, including collaboration, shared intention, and intense coordination of interdependent team members and patients.

To be successful, global health endeavors must understand the “score” in the region where the intervention takes place. Global interventions must build upon existing social, educational, and health systems, in order to make a sustainable and enduring impact on outcomes. Social cognitive theory provides guidance here; in addition to individual intentionally, there is a focus on engaging participating agents, on teaching collaboration, and on developing collective works. As Bandura (2001) states, “The challenge in collaborative activities is to meld diverse self-interests in the service of common goals and intentions collectively pursued in concert.”

*Collective agency refers to “people's shared belief in their collective power to produce desired results. Group attainments are the product not only of the shared intentions, knowledge, and skills of its members, but also of the interactive, coordinated, and synergistic dynamics of their transactions”* (Bandura, 2001). Again, the training priorities for the HBB® rollout are focused
on first training individuals and groups who have the strategic ability to impact care at the local level.

**Critical Linkages Between Social Cognitive Theory and Nursing**

In summary, SCT is based upon the continuous, triadic, reciprocal interactions of cognitive factors (e.g., knowledge, expectations, and attitudes) and behavioral factors (i.e., skills, practice, and self-efficacy), in context with the environmental factors (social norms and the ability to modify the environment). The theory enhances our understanding of how human behavior is determined and, more importantly, how it can be modified in very intentional and structured ways. As outlined, SCT can provide an important theoretical perspective and grounding for both the current and future study of the HBB® structured curriculum.

The social cognitive theory has clear relevance for nursing. Nurses are both caregivers and teachers in virtually every action and interaction in which they engage. On an individual level, nurses must develop multiple competencies, strong self-efficacy and moral agency; however, they are also members of the complex social network of healthcare, where collective agency is needed for effective collaboration and teamwork. Further, in the context of nursing as a profession fueled by life-long learning, SCT is a powerful motivator to pursue higher levels of competency (Axley, 2009).

The developmental infrastructure and rich paradigms of SCT provides a solid framework for nursing practice on many levels. Clinicians can seek guidance at any stage of their development, from first year nursing students to
reasoned and seasoned clinicians and academicians. Nurse educators can seek guidance for structuring both formal and informal learning activities. Nurse researchers can and are testing the predictive value and power of SCT, which has applicability in virtually any patient or clinical population. These explorations reveal and will continue to reveal layers of intriguing questions regarding the nature of human behavior and its interface with health.

On a societal level, SCT provides a theoretic perspective and framework, making explicit the interdependency of human lives, the duality of our individual human agency, as well as the power of our collective human agency to create a more human and meaningful existence. It also fuels the hope that we can create our preferred future. As Bandura (2001) taught “Theories are judged by explanatory and predictive power . . . In the final analysis they are judged by their ability to change lives.”

**Purpose of This Study**

Given the background of serious neonatal mortality and morbidity in the developing world related to birth asphyxia, and the context of MDG 4, aimed at improving this neonatal mortality, and building on key principles of Albert Bandura’s theoretical framework of social cognitive theory, this study is proposed.

**Pilot Testing the Effectiveness and Stability of a Structured Educational Curriculum for Newborn Resuscitation—Helping Babies Breath®—**
Using Videotaped Simulations

This prospective, longitudinal, quasi-experimental study with a control group (hold-back design) will evaluate the effect of HBB® training on the knowledge and psychomotor skills of healthcare providers in a low resource setting in Zambia. There are three major areas of inquiry in this study:

1. Baseline resuscitation knowledge.

2. Baseline resuscitation-related psychomotor skills (bag and mask ventilation).

3. Stability of knowledge and skills, as defined as retention of resuscitation knowledge and BMV skills over time.

Additionally, the feasibility of the unique testing methods, specifically the use of videotaped objective structured clinical evaluations to assess BMV psychomotor skills will be described.

Research Questions

In healthcare providers (HCPs) who routinely attend deliveries in Zambia at baseline:

1. What are the levels of knowledge about newborn resuscitation?

2. Do healthcare providers demonstrate BMV competency?

In healthcare providers (HCPs) who routinely attend deliveries in low-resource settings who have received the HBB® training intervention:
3. Do intervention group participants demonstrate increased knowledge about newborn resuscitation when compared to control group participants at 1 and 3 months?

4. Do intervention group participants demonstrate improved BMV psychomotor skills when compared to control group participants at 1 and 3 months?

5. Do intervention group participants achieve increased rates of BMV competency, compared to control group participants?
Definition of Key Study Variables

Conceptual and Operational Definitions of Structured Resuscitation Curriculum

A structured resuscitation curriculum is defined conceptually in the literature by example, using courses such as the American Heart Association (AHA) Basic Life Support, Advanced Cardiovascular Life Support (ACLS), Pediatric Advanced Life Support (PALS), and Neonatal Resuscitation Program (NRP™) (Hunt, Fiedor-Hamilton, & Eppich, 2008). In this study, the structured resuscitation curriculum was operationally defined as Helping Babies Breathe® (HBB®) Neonatal Resuscitation Curriculum (AAP, 2010).

Conceptual and Operational Definition of Resuscitation Knowledge

A clear and explicit conceptual definition of resuscitation knowledge was not found in the literature, although work to identify the content universe and essential dimensions of neonatal resuscitation knowledge have been published, and attempts to develop instruments to measure resuscitation knowledge have been reported (Jukkala & Henley, 2007). For the purpose of our study, neonatal resuscitation knowledge was operationally defined as the core concepts included in the HBB® curriculum (AAP, 2010) and was measured by scores on the HBB® Multiple Choice Question Test (See Appendix C).

Conceptual and Operational Definition of Resuscitation Psychomotor Skills

The conceptual definition of psychomotor skills includes linking cognitive knowledge and functions and sequentially performing physical actions that
encompasses both gross and fine motor movement, coordination, manipulation, dexterity, grace, strength, speed, skills and precision in the use of instruments or tools (Wikipedia, 2011). For this study, we used a simulation based assessment. The operational definition of psychomotor skills needed for resuscitation was defined as those skills identified in the HBB® curriculum as those most important in newborn resuscitation and the provision of bag and mask ventilation including: preparing equipment for the birth, warming and drying the infant, assessing the presence and adequacy of breathing, suctioning and clearing the airway, and providing effective bag and mask ventilation (HBB®, 2010). This was measured using the HBB® BMV Checklist, which was further enhanced by the development of an objective item-by-item criterion-based scoring rubric and administered as an objective structured clinical evaluation (OSCE) in a simulation-based testing model (Spillane, Hayden, Adler, Beeson, Goyal & Smith-Coggins, et al., 2008).

**Conceptual and Operational Definition of Global BMV Competency**

In addition to the criterion based scoring for BMV competency global BMV competency will be explored. Global assessments (GAs) are defined as “gestalt impression of competent performance” performed by an experienced rater, with content specific expertise in area being assessed (Spillane, Hayden, Adler, Beeson, Goyal & Smith-Coggins, et al., 2008). Although global rating scales have been used in the literature to describe both holistic and analytical scales, in our study the global competency was assigned as a dichotomous variable (pass
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= competency; fail = not competent) and this score was assigned after item-by-item scoring of the videotaped BMV OSCEs, via the criterion-based scale.

**Conceptual and Operational Definition of Stability of Knowledge and Psychomotor Skills Over Time**

Stability is defined as the opposite of decay, which is the loss of skills or knowledge over time, potentially related to nonuse (Arthur, Bennett, Stanush, & McNelly, 1998). A recent longitudinal cohort study evaluating the retention of knowledge and skills in UK healthcare providers, conduct by Mosley & Shaw (2013), continues to raise serious questions with only 39% of the participants achieving passing scores at 3 to 5 months post-training on airway and non-invasive ventilation skills. Consistent with other studies, those who failed the test had equivalent self-assessment of competence, than those that failed. Similar decays in skills were found in another UK sample of junior and senior trainees, in a longitudinal study conducted over eight years (Cusak & Fawke, 2012).

For the proposed study, the operational definition of stability of knowledge and psychomotor skills over time was defined as the ability to recall key resuscitation knowledge (as previously defined) and demonstrate critical psychomotor skills (also previously defined) using a simulation-based OSCE. The stability of knowledge and psychomotor skills was measured by performance on the multiple choice question examination and performance on the HBB® BMV OSCE evaluation of psychomotor skills for BMV measured at baseline, 1 month, and 3 months.
Chapter One Summary

Significant opportunities for improvement exist in the area of newborn and infant mortality. The Millennium Development Goal 4 (MDG 4), aimed at reducing child mortality, has been widely sanctioned in the global healthcare community. Neonatal mortality accounts for 42% of all under-five deaths; therefore, impacting neonatal deaths is essential to achieving MDG 4 (Lawn, 2011).

The gap between a newborn’s need for resuscitation at birth and the universal availability of simple newborn resuscitation skills and equipment, contributes significantly to infant and neonatal mortality rates; this gap is most urgent in low-resource settings, primarily in the developing world (Meaney et al., 2010; Ogbolu, 2007). Recently the ability to impact neonatal resuscitation has been demonstrated in a variety of developing world settings (Wall et al., 2009).

Healthcare disparities are not just a function of the wealth of the nation. They are, however, a function of how a nation chooses to use its resources. Numerous examples exist demonstrating that countries at the same level of income perform very differently in areas of infant and child mortality; therefore, some countries are clearly more effective in converting their wealth into improved conditions for women and children (Save the Children, 2014).

Although the landmark 1999 Institute of Medicine Report was focused on care in the United States, clearly some of the principles articulated have application to care in developing and middle-income countries. Trying harder is clearly not enough. Rather than merely trying harder, a redesign of the content of care, the systems and processes to deliver that care, as well as increasing the
capacity to provide care to newborns, are desperately needed to effectively improve the health of newborns and infants worldwide (Kitson, 2009; Kumar, Kumar & Darmstadt, 2010). As nurses and global citizens, we have an obligation to assure that safe, effective, timely, patient-centered, efficient care is available to any baby, born anytime, and anywhere.

Finally, perhaps one of the serious gaps in our design and delivery of education in both the developed and developing world is a failure to use theory to ground and guide our work. The prospective application of Bandura’s social cognitive theory is a powerful albeit under-utilized tool to guide the design, development, delivery and evaluation of resuscitation education science.

Dissemination of theoretically sound, evidence-based resuscitation strategies and universal access to basic resuscitation for every birth has the potential to save hundreds of thousands of newborn lives currently lost each year. It is imperative to remember that 60 million births worldwide do not occur in hospitals; in low resource settings, trained healthcare providers do not attend most births. Therefore, in order to impact neonatal and infant mortality rates, basic resuscitation skills are needed in the community setting (Wall et al., 2009). Community-based intervention packages for reducing maternal and neonatal morbidity and mortality and improving neonatal outcomes need to be carefully considered and implemented (Lassi, Haider, & Bhutta, 2010). Global health efforts must consider the urgent need to build critical resuscitation capacity in the areas of the world where basic resuscitation resources are most limited and most infants are born in the home. This must be balanced with the thoughtful use of
resources and the best available evidence regarding the effectiveness of proposed educational strategies and curriculums and the durability and sustainability of these efforts over time.
Chapter Two

Integrated Review of the Literature

This review of the literature examines empiric studies focused on effectiveness of structured neonatal educational interventions in general and their associated theoretical frameworks. The review also includes an additional focus on educational interventions related to resuscitation, stabilization, and early newborn care that are congruent to the design and execution of a study on this topic area.

Background Summary

The need for assistance during the critical transition to extra-uterine life has been well documented in the literature. Estimates suggest that somewhere between three to five percent of all births, approximately ten million infants yearly, do not breathe spontaneously and will require some resuscitation, typically in the form of assistance with initiation or establishment of effective breathing, at the time of birth (Wall et al., 2009). Furthermore, many of the deaths attributed to infant mortality, happen either in the immediate newborn period, or in the first week of life. Programs focused on essential newborn care during this period could play a significant role in decreasing infant mortality rates (Schiffman, Darmstadt, Agarwal, & Baqui, 2010; Wall et al., 2010). The intrapartum period is an extremely hazardous time period for infants born in resource limited settings in the developing world. The universal challenge in improving outcomes is designing a system of care that assures safe passage for every newborn, with
critical linkages between the home, the community, and facility services (Bahl, Qazi, Darmstadt, & Martines, 2010; Save the Children, 2014).

One essential element in improving perinatal outcomes is the presence at birth of at least one provider who is knowledgeable about and skilled in newborn resuscitation. In the developing world, >60% of births do not take place in hospitals, and when births occur in the home, skilled birth attendants may or may not be in attendance. In these settings, the challenge of access to effective newborn resuscitation is exponentially magnified. Additionally, communities or health systems that provide structured universal follow-up care during the first weeks of life have demonstrated improved outcomes, yet in most regions of the developing world, this universal follow-up care may not be available (Lawn et al., 2010; Save the Children, 2014).

Structured Educational Programs: Systematic Reviews and Meta-Analysis

Some guidance for structuring international educational programs can be found in two recent systematic reviews of the literature (Meaney et al., 2010; Opiyo & English 2010) that relate to this topic. The 2010 Opiyo and English study is a Cochrane Systematic Review that examined the impact of in-service training of health professionals to improve the care of seriously ill newborns or children in low- and middle-income countries. The review found limited evidence of effectiveness. This review was extremely limited in focus; there were only two randomized controlled trials (RCTs) published before May of 2009 that met their rigorous inclusion criteria. Notably, the current version of the review fails to include the most recent randomized controlled trials, Carlo et al. (2009) and
Carlo et al. (2010), two papers of critical importance to the topic.

The second systematic review, Meaney et al. (2010), was not restricted to RCTs and had broader overall patient inclusion criteria including studies in adults (primarily focused on trauma triage training), studies in pediatric patients, as well as some studies dealing with the population of interest – newborns. The aim of the Meaney et al. (2010) systematic review was to evaluate the published evidence on the impact of non-specific, resuscitation training programs on the short-term outcomes of cognitive knowledge, psychomotor skills, self-efficacy, and simulated team behavior. They also attempted to examine the more difficult to assess outcomes including operational performance, clinical patient outcomes, cost-effectiveness and sustainability. The Meaney et al. (2010) systematic review cited 44 relevant papers, of which 38 empiric studies met their inclusion criteria and are included in their review. Outcome variables that measured self-efficacy (15 studies) and student satisfaction (8 studies) consistently reported improvement; notably, high self-efficacy was inversely related to performance at 6 months. However, the studies included in the Meaney et al. (2010) review were fraught with inconsistent, inadequate, and untested methods to test both educational outcomes as well as measure relevant patient outcomes. The evaluation of psychomotor skills, such as bag-mask ventilation – a skill critical to newborn resuscitation – was particularly weak across all of the studies.

Inconsistent reporting of baseline skills and failure to use validated scoring systems were prevalent in the studies included in this systematic review.
specifically, and in the literature at large.

The Meaney et al. (2010) systematic review did not include studies examining the acquisition of psychomotor skills, nor did they test whether the classroom-skill acquisition translated into performance in a real-world setting. More importantly, the question of whether or not resuscitation and/or other educational programs make a difference on patient mortality and/or morbidity was incompletely answered in the studies reviewed. Although the Meaney et al. (2010) review did attempt to include studies evaluating team training, these studies were conducted in the trauma or adult settings. In the final analysis, although the goal was to evaluate the cost-effectiveness of resuscitation training, none of the 38 studies evaluated was designed to measure the true value proposition, that is, costs per lives saved, of the training interventions.

Both the Cochrane and Meaney et al. (2010) systematic reviews are silent on important issues related to the stability and/or retention of knowledge and skills over time; this clearly reflects the paucity of literature in this area. Both reviews focused heavily on training of healthcare providers; notably absent were studies that evaluated the impact of community-based, educational interventions on neonatal mortality and morbidity. Furthermore, neither systematic review comprehensively addressed the impact of combined interventions (i.e., impact of both the Essentials of Newborn Care and NRP™ training program). In summary, despite the fact that two systematic reviews have recently been published, notable gaps exist in the literature. An additional Cochrane Review, titled “Formal resuscitation training courses for reducing mortality and morbidity in newborn
infants,” is at the protocol stage, and when published should provide additional information on both the acquisition and retention of knowledge and skills.

The most recent, relevant systematic review, Schiffman et al., published in December 2010, focused primarily on community-based intervention packages, combining and integrating antepartum, intrapartum, and postnatal educational and care packages into the existing healthcare system in an attempt to improve perinatal health in the developing world. This paper analyzed ten, large-scale, controlled studies conducted in rural, developing settings. These studies included rural sites in Bangladesh, Pakistan and Southeast Asia; notably absent are similar trials in urban settings or on the continent of Africa. Although some overlap exists, many of the studies included in the Schiffman et al. (2010) review were published after the Opiyo (2010) and Meaney et al. (2010) systematic reviews. Each of the community-based, intervention packages will be analyzed individually, rather than in the aggregate, in the review of the literature that follows.

**Aim of the Systematic Review of the Literature**

This systematic integrated review of the literature was undertaken in preparation for an upcoming study designed to further evaluate the HBB® program. The aim of this review is to explore, compile, critique, and synthesize empiric literature related to the following questions:

1. What empiric evidence exists to assess the efficacy and/or effectiveness of common, structured, educational interventions for
newborn resuscitation and early newborn care, specifically the existing
NRP™, Helping Babies Breathe®, and Essential Newborn Care?

2. Do structured neonatal educational programs impact healthcare
providers’ knowledge of self-efficacy and/or perceived competence or
actual performance of neonatal resuscitation at birth?

3. Do structured neonatal educational programs, alone or in combination,
impact neonatal outcomes, such as mortality and morbidity?

4. What is known about the stability and retention of resuscitation
knowledge and psychomotor skills over time?

5. What is known about the use of existing technology (i.e., videotaping)
to deliver educational interventions and/or perform assessments of
competency in the developing world?

6. Is there a basis for the use of Bandura’s social cognitive theory, as a
conceptual foundation for neonatal educational interventions?

**Design, Methods and Search Strategy**

A series of sequential comprehensive searches were performed, using the
following electronic data bases:

- Cochrane Register of Controlled Trials (complete edition).
- CINAHL (1982 to December 2014).
- Pro-Quest (1990 to current).
Keywords for the literature search included the following: newborn, neonate, infant, newly born infant, stillbirth, perinatal mortality, perinatal depression, hypoxic ischemic encephalopathy, infant mortality, resuscitation, neonatal resuscitation program, Neonatal Resuscitation Program (NRP™), Helping Babies Breathe (HBB®), essential newborn care, Essentials of Newborn Care, self-efficacy, Bandura’s social learning theory, continuing medical education and effectiveness, CME, continuing nursing education and effectiveness, health provider training, international infant mortality, developing countries, developing world, emergency training, resuscitation and education, clinical competence, effectiveness, telesimulation, and Skype. These keywords were used alone, in combination and using the MESH features of the various databases in an effort to uncover relevant studies and theoretic works.

Once relevant articles were located, a careful historical search was performed using their reference lists, in an effort to locate all of the important and relevant empiric research for inclusion in this review. Additionally, once relevant sources were located electronically in the PubMed and CINAHL databases, as well as in the systematic, historical bibliographic search, each of the relevant citations were reviewed, in abstract form, to assess relevancy. These search strategies were employed until the principle of saturation was met.
Inclusion and Exclusion Criteria

Published studies, conducted in humans, and focused on the neonatal population that were relevant to the structured questions were included irrespective of their quality or methodology. Furthermore, a broad search strategy was used, searching back to 1980 whenever possible, in an effort to capture relevant studies that date back to the launch, or prelaunch phase of the NRP™.

This integrated review excludes empiric studies not translated into English and made no systematic effort to locate unpublished abstracts except for those published by the HBB® research team. However, the following, which were included in the Cochrane Review, were all excluded from this review based on their lack of direct relevancy to the stated questions: other in-service and child health training courses that deal primarily with resuscitation in the pediatric setting, such as Pediatric Advanced Life Support (PALS); courses designed for high-resource settings, post-resuscitation stabilization and transport (STABLE); and those focused on triage for serious illness, such as Emergency Triage, Assessment and Treatment (ETAT), Control of Diarrheal Diseases (CDD) and Acute Respiratory Infections (ARI) case management programs and/or the training components of the Integrated Management of Childhood Illness (IMCI) strategy. A limited number of studies relative to the retention of knowledge after CPR, or other structured educational curriculums, were included in the review for illustrative purposes.
Search Outcomes

The ProQuest on-line database search yielded a total of seven dissertations related to neonatal resuscitation; three had some potential links to the search questions as outlined. One focused on the preliminary development of an instrument to measure neonatal resuscitation competence, based upon a novice to expert continuum (Mitchell, 1997) the second examined hospital preparedness for and outcomes of neonatal resuscitations in rural hospitals in Minnesota (Jukkala, 2005); and the third explored the use of discrete event modeling using a neonatal simulation tool (ANAKIN) in the context of the NRP resuscitation algorithms (Wilson, 2006). Findings from these studies provide contextual and background information; however, they were not directly relevant to the review questions. An additional dissertation on material capacity in Nigeria, provided relevant background information and is previously cited (Ogbolu, 2012). In total >500 abstracts were reviewed electronically for potential relevancy; the majority of these were identified from PubMed and historical bibliography searches.

Data Extraction, Synthesis and Quality Appraisal

A data extraction table was created pro forma to aide uniform analysis of each study. A single reviewer manually extracted the data reported from each of the individual studies and organized the data into a comparison table. No systematic efforts to locate missing data points were undertaken. The studies were appraised based upon the following: the design; the fit between their stated
purpose and measures, methodology, clarity and statistical significance; as well as their overall generalizability to the population and their relevance to the stated questions.

**Results / Characteristics and Organizing Framework of the Review**

The published literature was organized into six categories based upon either the educational intervention(s) employed and/or the focus of the studies (healthcare worker, healthcare system, or community; or use of telesimulation). The first category includes seven studies conducted in low-resource settings that focused on the education and training of healthcare providers (typically nurses, midwives and physicians) using a single, standardized, educational curriculum. The majority of these studies used the same program, Essentials of Newborn Care (ENBC), developed by the World Health Organization (WHO) developed specifically or use in low-resource settings. Two of the studies in this category tested slightly different, albeit related, educational interventions, including one locally developed Perinatal Education Program with similar content themes (Woods & Theron, 1995) and another that used a three phase interactive educational intervention (Jeffery *et al.*, 2004).

The second category of studies included those that evaluated the impact of the simultaneous implementation of two complementary, educational interventions, namely NRP™ and the WHO Essential Newborn Care (ENBC), both in low-resource settings (Carlo *et al.*, 2009; Carlo *et al.*, 2010).

The third category includes six studies that evaluated the impact of a single, educational intervention surrounding neonatal resuscitation. These
studies typically used NRP™. However, other short, one day, resuscitation educational interventions, as well as studies focused on the development and pilot testing of a unit-based, nurse-led, resuscitation team were also grouped under this theme and reviewed (Boo, 2009; Carlo et al., 2009; Deorari, Paul, Singh, Vidyasagar & The Medical Colleges Network, 2001; Duran, Aladağ, Vatansever, Süt, & Acunas, 2008; O’Hare, Nakakeeto, & Southall, 2006; Opiyo et al., 2008).

The fourth category of studies included a total of four studies that focused primarily on educational interventions aimed at existing community-based healthcare workers, specifically community-based, traditional birth attendants, dais, or other providers that might attend the birth of a newborn or provide post-birth care and follow-up in the community in low-resource settings (Bang, Bang, Baitule, Reddy, & Deshmukh, 2005a; Bang, Reddy, Deshmukh, Baitule, & Bang, 2005b; Bhutta et al., 2008). Two of these studies report longitudinal data reflecting improvements in populations over time; therefore, they provide some insights into the impact of community-based, educational interventions.

The fifth group of studies is uniquely focused on educational interventions in general, and resuscitation, educational interventions specifically, with an emphasis on not just the short-term acquisition of knowledge and psychomotor skills, but also the stability of these measures over time. A number of these studies were conducted in the United States and Canada, rather than in low-resource settings (Carbine, Finer, Knodel, & Rich, 2000; Mitchell, Niday, Boulton, Chance, & Dulberg, 2002; Jukkala & Henly, 2007; Jukkala & Henly, 2009). Select
studies examining retention of skills after CPR structured curriculums were included, given potential relevance to the stability of resuscitation knowledge and skills over time (Gass & Curry, 1983; McKenna & Glendon, 1985; Berden, Wilems, Hendrick, Pijls, & Knape, 1993; Broomfield, 1996). A more detailed evaluation of the NRP™-specific studies relative to knowledge and skill retention include the RCT performed by Dunn, Niday, Watters, McGrath, and Alcock (1992), as well as work by Skidmore and Urquhart (2001), and Bookman et al., (2010).

One widely referenced and methodologically sound systematic review, performed by Jabbour, Osmond and Klasse (1996), evaluated the published evidence for the effectiveness of life support courses taught to doctors, nurses, or laypersons. This research team was specifically interested in the ability to demonstrate reductions in mortality and morbidity after a life-threatening event. They also sought to include studies that examined the retention of knowledge or skills by course participants, and/or those that examined changes in practice behavior among course participants. Relevant life support courses incorporated in this review include Basic Cardiac Life Support (BCLS), Advanced Cardiac Life Support (ACLS), Pediatric Advanced Life Support (PALS), modified advanced pediatric life support (APLS), ATLS, or the Neonatal Resuscitation Program (NRP™). The authors reviewed 67 relevant studies published between 1975 and 1992 of which 17 met the inclusion criteria, and five of these were randomized controlled trials. The authors concluded that retention of knowledge and skills acquired by participation in structured, educational curriculums was poor overall;
however, the evidence suggested that refresher courses or activities seem to be effective in increasing knowledge retention.

The final category of empiric studies reviews the evidence to support the use of existing technologies (i.e., cell phones, web-based education, and web-based teleconferencing) to both teach knowledge and psychomotor skills, as well as assess ongoing competency.

The history, evolution, testing of, and lessons learned from the NRP™ program have important implications for work surrounding HBB®. Therefore the review of the literature will be preceded by a brief discussion of the history and evolution of one of the primary interventions in many of the relevant studies in the published literature, the NRP™ program, to provide adequate context for the review.

**The History and Evolution of The Neonatal Resuscitation Program**

In the United States, the Neonatal Resuscitation Program (NRP™), which is taught using a train-the-trainer model has been the universal standard of care for neonatal resuscitation since its initial development by the American Academy of Pediatrics (AAP) and the American Heart Association (AHA) in 1987 (Kattwinkel, 2001). The course, designed to standardize and optimize hospital-based resuscitation, is universally taught to nurses, physicians, trainees, and relevant intra-disciplinary members of the healthcare team. Certification is provided after successful completion of a written test, a performance checklist,
and a mega-code scenario. A mandatory recertification every two years is required; however, the term of the certification was not based on any evidence.

Since its inception, NRP™ has been widely adopted across the United States. In the U.S. alone, there are 26,000 active NRP instructors and over three million certified healthcare providers, of which more than 80% are nurses (Kattwinkel, 2001; Halamek, 2008). Attitude and resource changes were demonstrated after NPR™ training programs (Singhal, McMillan, Lockyer & Gondosz, 1992).

The rapid expansion of US perinatal care units in the 1980s created an urgent need for providers skilled in newborn resuscitation in both community and regional birth centers. Despite the large-scale nature of the NRP™ educational program, the clinical urgencies of the time did not allow for comprehensive, prospective testing to evaluate the impact of this educational program on knowledge and/or skill acquisition before the dissemination of NRP™.

As with many educational endeavors, competency is an elusive concept. The NRP™ course materials contain the following disclaimer:

Completion of the program does not imply that an individual has the competence to perform neonatal resuscitation. Each hospital is responsible for determining the level of competence and qualifications required for someone to assume clinical responsibility for neonatal resuscitation (AAP, 2011).
Recent work to develop and validate a checklist to assess neonatal resuscitation megacode skills has been developed, tested and integrated into current NRP™ updates (Lockyer et al., 2006).

In addition to challenges in establishing initial competencies faced by resuscitation training programs like NRP™, to date very little is known about the stability of resuscitation knowledge and skills over time. The mandated, biannual NRP™ recertification process has little if any empiric grounding. The Utstein Report highlights the fact that limited evidence for the stability/durability of resuscitation skills exists, and further, most of the studies that are cited are now 15 to 20 years old, and as such may fail to reflect the complexity of current practice (Chamberlain & Hazinski, 2003).

In the 20 years since the wide dissemination of NRP™ nationally, it has evolved from guidelines based on “accepted practice” and expert opinion to an increasingly sophisticated focus on the integration of the evolving science of both resuscitation and the more theoretically based science of education. Recently integrating human factors and simulation into the NRP™ training program, has resulted in a major paradigm shift in training providers for neonatal resuscitation (Halamek et al., 2000; Halamek, 2008). A number of focused evaluations of the impact of NRP™ have been performed. These testing efforts have been supported, in part, by the NRP™ research award program, which supports basic, clinical, educational or epidemiological research pertaining to the broad area of neonatal resuscitation.
In addition to the widespread use of NRP™ in the United States, the curriculum has been translated into 24 different languages and disseminated internationally in 130 countries; currently there are over 500,000 providers trained worldwide (Cash, 2006). Once again, the ethical balance of urgent clinical needs for newborn resuscitation in the developing world, prompted the generalization of the NRP™ curriculum to low-resource settings, without robust pro forma testing of educational outcomes, clinical outcomes, or cost-effectiveness.

Some have been critical of the exportation of both North American and European Resuscitation Council programs, such as the American Heart Association’s (AHA) Cardiopulmonary Resuscitation Program, to the developing world arguing that this model may have discouraged developing countries from developing their own structured training programs. Furthermore, the costs associated with royalties for AHA and European Resuscitation Council accreditation, teaching materials, and copyright represent a tremendous proportional cost for many of the countries that need it most. These disincentives serve to further limit access to uniform, high-quality training in developing countries; the net result may be a small, elite group of health professionals who can pay for such courses and many in the frontlines of care who cannot (Urbano, et al., 2010). Such disincentives could also preclude nurses, who are the largest cadre of frontline healthcare providers, from being trained in the numbers
needed. Additionally, these costs represent ongoing barriers to sustainability of the resuscitation programs over time.

The evolution of NRP™ has focused on building and integrating the science behind the clinical recommendations. The methodology behind the reviews of the evidence is now a transparent process with a consistent level of evidence model (Morley, 2009). It is important to note that the AAP, AHA, and the 1997 creation of the International Liaison Committee on Resuscitation (ILCOR) have also led efforts to infuse evidence into the design and delivery of the structured curriculum. Also, efforts have been made to design courses that more simply and effectively translate this science of resuscitation into clinical practice. In concert with the Utstein Symposium recommendations, the NRP™ curriculum continues to evolve, and the 2010 guidelines have placed increased emphasis on the use of simulation and imbedded, active, adult learning in efforts to enhance the effectiveness of the program.

**Evaluations of Real-World Resuscitation Practices Compared to NRP™ Standards**

The application of neonatal resuscitation skills in clinical practice was evaluated in a prospective, real-time analysis using systematic assessment and scoring of videotaped resuscitations. The study was conducted in a busy tertiary newborn intensive care (NICU) and high-risk delivery service in the United States, where neonatal resuscitations occur frequently and are led by NRP™ certified providers. The findings revealed that 54% of the 100 resuscitations recorded had significant deviations relative to the NRP™ guidelines (Carbine et
Furthermore, they found that the more complicated the resuscitation process, the more likely deviations occurred, suggesting that the translation of resuscitation science and education into practice is challenging even in high-resource settings, that are impeccably equipped and with sufficient and proficient NRP™-trained staff.

A research team from a regional referral center in Canada conducted a prospective systematic audit of neonatal resuscitation practices in 56 Level I, II, and III centers (Mitchell et al., 2002). They reported clear differences between the NRP™ guidelines and actual clinical practice. A high rate of the use of delivery room medications (14%) and chest compressions (8%) are two key findings of this study. Further concerns included extremely high rates of post-resuscitation hypothermia (27%) or hyperthermia (25%). Maintaining normal body temperature is a basic concept that applies to every newly born infant, and thermal management skills are emphasized in the NRP™ curriculum. These authors affirmed the premise that NRP™ certification, “does not assure competency, nor does it ensure compliance with established standards of care” (Mitchell et al., 2002).

A descriptive, correlate study, conducted in 36 hospitals in a rural Midwest region of the United States, used two newly developed scales, the Neonatal Resuscitation Index (a measure of knowledge of critical elements of NRP™) and the Neonatal Resuscitation Experience Index (a measure of “comfort” with and recent performance of neonatal resuscitation) (Jukkala, 2009). These measures
were performed on a sample of 224 rural healthcare providers comprised of 165 (79.3%) NRP™-certified nurses and 50 (45.8%) NRP™-certified physicians; all were responsible for newborn resuscitation in their delivery centers. The knowledge scores on the Neonatal Resuscitation Index ranged widely, from 16% to 100% (M = 69%; SD = 15.4). This study illuminated the unique challenges of rural providers in maintaining knowledge related to infrequent, but extremely high-stakes events such as newborn resuscitation. The study did not attempt to evaluate psychomotor skills or higher-order integration of complex decision-making skills.

**Teaching Resuscitation in Low-Resource International Settings**

Failure to fully understand the level of education and training of the primary caregivers for mothers and newborns, who are nurses, as well as understating the role of nurses in society and their often relative subordinate position in the healthcare system is problematic and may lead to assumptions about the baseline levels of knowledge and skills in a particular setting.

A recent descriptive study highlighting CPR knowledge among nurses working in Bahrain reported that only 7% of the respondents passed the general knowledge test, despite the fact that 75.6% described themselves as confident, moderately confident, or extremely confident while performing CPR. The author concluded that nurses’ knowledge and ability to respond were of concern as was their false sense of confidence regarding their CPR competence (Marzooq & Lyneham, 2009).
A more complex range of questions emerge when evaluating the effectiveness of resuscitation and other educational programs exported to low-resource settings in the developing world. In rural settings, caregivers share the challenges of preparing for low volume and infrequent events. In busy urban and tertiary settings, the need for services overwhelms the system. Both rural and urban caregivers function in settings with extremely low resources.

In response to these concerns, and in response to the extremely high rates of neonatal mortality in the first hours of life worldwide, in June 2010 the AAP launched a new program focused on neonatal resuscitation in low-resource settings, titled Helping Babies Breathe® (HBB®). Preliminary testing of this newly emerging educational tool is underway; however, considerable work remains to establish the effectiveness and maximize the potential impact of this international initiative.

Critique of Existing Research

Effectiveness in Low Resource Setting

Question 1: Effectiveness of Educational Interventions Focused on Resuscitation and Care of the Newborn Infant in Low-Resource Settings

Single-Intervention Studies: Essentials of Newborn Care

This pre-post intervention study, using a clinical audit technique (Allen & Jeffery, 2006) evaluated the impact of a low-cost, evidence-based educational program, consisting of four, 90-minute, teaching sessions given to a combination of hospital nurses \((N = 7)\), junior physicians \((N = 10)\) and community-based nurses \((N = 6)\) on newborn care practices \((N = 236 \text{ infant charts})\), at the United
Mission Hospital, a tertiary level facility in the Tansen Palpa District of Nepal. Pre- and post-intervention audits of newborn care practices were performed using a structured checklist for chart audits performed in the six weeks after training. They evaluated knowledge acquisition using multiple-choice questions, and skill competency was tested using an objective, structured clinical evaluation (OSCE). Additionally, a post-intervention evaluation of participant satisfaction yielded high results with >80% of the participants rating the program as “good or excellent.” The Wilcoxon Signed-Rank Tests compared p values for pre- and post-test MCQ tests and showed improvement in all groups (p < 0.05). The OSCE scores (post-intervention only n = 22) were 76% (SD = 14.7) overall, with junior doctors scoring 87% (SD = 7.3), hospital nurses 65% (SD = 7) and community based nurses scores of 70% (SD = 21.4). The chart audit evaluating actual performance showed 100% improvement in history, exam and measurements. Vitamin K administration increased from 24.5% to 95.8%; hypoglycemia risk assessment increased from 0.90% to 95%; and blood sugar measurement in at-risk infants increased from 0.9% to 59.1% respectively.

The short time period of the study did not allow testing of the stability of the knowledge and skills beyond six weeks, and they were unable to evaluate the sustainability of the intervention. Despite these limitations, the linkage of a structured educational program to an audit of care practices in a resource-limited setting represents a unique model to test knowledge translation into real-world clinical practice and performance.
A second pre- and post-intervention study, evaluated the effect of a more structured educational intervention. In this study, a 15-module training program, extracted from the WHO Essentials of Newborn Care, was provided to maternity ward staff \((N = 59\) nurses and doctors) in a four day training program format, and examined the impact on newborn care practices after hospital discharge in two participating hospitals in the District of Puttalam, in the North Western province of Sri Lanka (Senarath, Fernando, & Rodrigo, 2007). Pre-intervention baseline data was collected on 144 mother-newborn pairs who were followed up and interviewed in the home 28 to 35 days after delivery \((n = 150\)). Maternal “satisfaction” with care increased from 56.7% to 92.5%. The opportunity for mothers to ask questions and clarify doubts increased from 47.9% to 84.7% post-intervention. Unwanted cord practices (dressings) went from 13.9% to 5.3% \((p < 0.05\)), and covering the cord with a nappy went from 31.9% to 14% \((p = 0.01\)), while consistently high rates of breastfeeding were maintained. Limitations of the study included the following: the failure to evaluate neonatal resuscitation practices or outcomes; the lack of a control group; and the large loss to follow-up, given that 35% of the sample could not be followed due to geographic constraints.

The same research team conducted a carefully designed, more comprehensive, multi-site study (Senarath, Fernando & Rodrigo, 2007). This pre- and post-intervention study with a control group was designed to evaluate the effect of the educational program (ENBC, provided over a four day training period, with 32 hours total training), administered to maternity ward healthcare
providers \((N = 27 \text{ midwives, 19 nurses, and 13 doctors})\) and examined the impact on improving newborn care practices in inpatient hospital obstetrical units. The study was conducted in the District of Puttalam in the North Western province of Sri Lanka from 2003 to 2004, a region where there are 12,513 total births per year.

The sample consisted of five hospitals; each hospital was randomly assigned to one of two groups. The sample was drawn using a stratified random sampling method proportionate to the number of deliveries in the hospital, and included 892 mother/newborn pairs (pre-intervention baseline data collected on \(N = 446\) mother-newborn pairs and post-intervention data on \(N = 446\) mother-newborn pairs). Outcome measures included direct observation of care practices related to the ENBC curriculum. Approximately 10% were selected for direct labor room observation pre- and post-intervention; structured maternal interviews were also conducted, and data were extracted from the chart regarding undesirable health events.

Handwashing, a skill emphasized in the hygiene portion of ENBC, improved in the intervention group from 62.5% to 100% compared to the control (66.7% to 87.5%). Significant improvements were also noted in preparation for resuscitation: readiness of bag-mask equipment increased from 25% to 95.8%; emergency tray preparation increased from 20.8% to 87.5%; and newborn breathing assessments increased from 25% to 95.8% \((p < 0.001)\). The stability of this intervention was assessed, and found that four out of five practices remained
improved three months post-intervention. Undesirable events decreased from 32 to 21 per 223 newborns; however, this decrease was not statistically significant.

The study’s ability to evaluate resuscitation practices was limited by the small numbers of infants who required active resuscitation; however, the authors were able to demonstrate improvements in preparation for resuscitation. The presence of an observer at delivery may have led to “best practice” rather than “usual practice.” This study was also confined to low-risk newborns; therefore, more data are needed regarding the impact of ENBC on higher-risk scenarios.

Strengths of this study include an attempt to perform a formal power analysis; however, this was difficult as there were no other studies in similar settings on which to base the sample size. The research team estimated that care practices were happening approximately 50% of the time; in order to detect a 15% increase in care practices with a power of .90 and an alpha error of 0.05, it was estimated that 223 mother/infant pairs were needed. The fact that the educational intervention was based upon a baseline needs assessment survey with high priority given to self-identified high needs areas is an additional strength. Furthermore, there was a three-month lag between the educational intervention and measurement of the outcome variables and this design allowed the team to evaluate the stability of information and sustainability of the effort. The study also employed the complementary use of direct observation and maternal interviews.
A third research study, structured as a before and after intervention study, tested the WHO ENBC curriculum. It was delivered using a train-the-trainer model and measured differences in the knowledge and skills of 114 college-educated nurse midwives employed in first-level delivery clinics in Lusaka and Ndola, Zambia (McClure et al., 2007). Knowledge was tested using a 22-item MCQ examination and performance was evaluated using an 18-item, instructor-observed, performance measure. The course participants were evaluated (\( n = 114 \) written and \( n = 98 \) performance). Knowledge scores improved for 78% of the participants, and performance scores improved for 81% of the participants; average improvements in the written scores were 12% (\( SD = 15 \)), and average improvements in performance were 29% (\( SD = 22 \)).

A small convenience sub-sample of the study was used to test the stability and durability of this knowledge (\( N = 53 \) participants) 6 months after the intervention. These findings will be discussed in the stability section of the review. Strengths of the study included careful psychometric evaluation and factor analysis of the test questions, as well as the subscale development.

Another research team (Vidal et al., 2001) compared the effectiveness of two training strategies, comparing group one given the conventional five day WHO ENBC training course and group two given the same course and manual. It was organized as a self-directed learning program over five weeks, in a cluster trial design, in Pernambuco, Brazil. Researchers used multiple regression and two-way ANOVA to compare tests scores between tests and groups and found that knowledge improved with both teaching methods; however, they found
essentially no difference between the two training strategies. Self-directed learning was estimated to be 20 to 25% less expensive.

It is important to note that unlike the previous studies of the WHO ENBC interventions, in this study, overall practice improved marginally between the two groups. Neither strategy brought about the expected improvements in the quality of care. This study must be interpreted in light of some notable limitations. The lack of random assignment to the cluster or group made it impossible to discern whether the measured effects are hospital effect or intervention effects. Although the intent was to enroll both nurses and physicians, only 14 to 22% of the trainees were nurses in each group. Because physicians in this healthcare system contract with multiple hospitals, and move among and between institutions, the study results may have been confounded by this crossover effect. Furthermore, testing was not conducted on all enrollees; and post-training testing was not done due to unspecified “administrative problems” at two of the research sites.

Woods and Theron (1995) also used a “correspondence” or self-directed cooperative learning course, comprised of locally developed, perinatal educational manuals and cooperative learning led by a site coordinator. They then tested the cognitive knowledge of 114 midwives from primary, secondary, and tertiary settings situated in nine regions of South Africa who volunteered to participate in this study. This research team demonstrated mean pretest and posttest cognitive knowledge scores related to maternal and newborn care
improved significantly ($p < 0.001$). The study did not attempt to measure psychomotor skills and/or what, if any, impact this increased knowledge had on patient outcomes over time. It does suggest the possibility that structured content can be taught locally in a disseminated learning model.

**Single Intervention Studies: Neonatal Resuscitation Program (NRP™)**

One of the most comprehensive studies to date evaluated the impact of the NRP™ training on knowledge and performance in Zambia (Carlo et al., 2009). The course participants in the original training group included 127 experienced, college-educated midwives (range 3 to 30 years of practice; $M = 14$ years) who were working in low-risk clinics in Zambia and who had previously received training in neonatal resuscitation but had not been exposed to the NRP™ program. The initial group ($N = 15$ midwives in Phase 1) was trained by the study’s primary investigator; the subsequent, 112 nurse midwives were trained by the train-the-trainer midwives who were trained during Phase 1. This study used three scales to measure baseline status and post-NRP™ outcomes: (a) knowledge evaluation was based upon the 2000 written NRP™ evaluation, split into sub-scales by grouping related items; (b) performance evaluation was based upon the 29 items in NRP™ lessons 1 to 4 relevant to low-resource settings and performance (judged by a trained, unmasked observer using a structured checklist); and (c) self-efficacy was measured based upon a newly developed 14-item, 5-point Likert scale. These three items were measured with a pretest to measure baseline knowledge and two posttests; one conducted immediately after the initial training and another follow-up testing six months
later. The internal consistency of all three evaluation scales was demonstrated using Cronbach’s alphas. The written scale administered pre-test, post-test and at six months was 0.8, 0.84, 0.87; the performance scale administered pretest, posttest and at six months was 0.87, 0.6, 0.87; and the self-efficacy scale scores 0.9, 0.84, 0.87 at pre-test, post-test and six months respectively.

Interestingly, the initial testing (N = 127) showed low written scores 57%; however, post-intervention scores rose to 80% (p < 0.001). Similar patterns were demonstrated with low baseline performance scores (43% pre-intervention) that rose to 88% post-intervention (p < 0.001). The increase in performance scores was higher than the knowledge scores, perhaps reflecting the very low initial psychomotor skills scores and/or the NRP™ program’s emphasis on psychomotor skills.

In sharp contrast to the pre-intervention knowledge and performance scores, the pre-intervention self-efficacy scores were 3.7, indicating that the nurse midwives rated their knowledge and skills higher than the actual pre-intervention testing of knowledge and skills indicated. Those with high self-efficacy had the largest decline in performance scores compared to those with low pre-intervention self-efficacy scores, whose performance scores remained higher.

At the six month testing, there was an overall decline or degradation in written performance from 86% (SD = 10) to 62% (SD = 16), which was statistically and, likely, clinically significant (p < 0.05) given that they regressed almost to their pre-intervention levels of 59%. Performance scores declined less,
from 90% ($SD = 8$) to 80% ($SD = 19$), which was also statistically significant ($p < 0.05$). Self-efficacy scores stayed stable, from 4.3 to 4.2. Those with initial high self-efficacy had the largest decline in performance scores; those with low self-efficacy pre-training had performance scores that remained high.

The Carlo et al., 2009 study is consistent with others in demonstrating that NRP™ can significantly increase neonatal resuscitation knowledge and performance in a group of well-educated midwives with extensive clinical experience. The study was limited by the instruments and outcome measures, which were newly developed and incompletely tested for reliability. Furthermore, failure to blind, and the potential for inter-rater differences between those scoring the performance measures was not evaluated and could have impacted performance scores. Additionally, the wide range of midwife years of practice (ranging from 3 to 30 years) may have been a confounding variable.

**Single Intervention Studies: Neonatal Resuscitation United Kingdom ABC Model**

A cluster randomized controlled trial evaluated the effectiveness of a simple one day newborn resuscitation training program, that provided focused lectures and mannequin training to teach psychomotor skills, with content based on the ABC model from the United Kingdom Resuscitation Council. The study evaluated the impact on healthcare provider resuscitation practices in a public hospital (Pumwani Maternity Hospital) in Nairobi, Kenya where over 17,000 infants are born each year. The study randomly assigned ward and operating
room staff ($N = 90$ nurses/midwives) to either early or late training (Opiyo et al., 2008).

This study was unique in that actual real-time resuscitation events in the hospital were recorded by trained observers (nursing students). The observers received a three day training program and remained in-house to capture 24-hour shift patterns. The observers were blinded to the training of the healthcare worker. They observed and scored each newborn resuscitation ($n = 256$ resuscitations observed). Two blinded resuscitation instructors subsequently reviewed the scores and relevant descriptive documentation from the resuscitations.

The primary outcome measure was the proportion of resuscitation events in which appropriate initial steps were provided. The primary outcome measure was the proportion of resuscitation events in which appropriate initial steps were provided. Resuscitations classified as perfect (no deviations) occurred in 24% of the trained HCW versus 10% with untrained [RR 2.27, CI 1.23-4.22; $p = 0.009$] and adequate (minor deviations) 66% (trained) versus 27% (untrained) [RR 2.45, 95% CI 1.75-3.42, $p < 0.001$].

Secondary outcomes included analyzing the number of inappropriate or potentially harmful measures detected decreased significantly (trained 0.53 versus control 0.92; $MD = 0.40$, 95% CI [0.13, 0.66], $p = 0.004$). Inappropriate and dangerous practices were classified as the following: “inappropriate breathing support” or oxygen use, oxygen administered by placing the tubing
directly into the nostril, blowing or exhaling intentionally on the infant’s face,

inappropriate stimulation performed before drying, shaking the whole baby,

patting or slapping the baby’s back, flicking or slapping the baby’s feet,

vigorously rubbing the baby’s chest and back, and squeezing the chest. The
results illuminated the extremely poor baseline knowledge and skill present in
HCPs who frequently encounter neonatal resuscitation. Group comparisons for
the overall mortality of resuscitated infants were not statistically significant, and
there were no differences in birth asphyxia admissions and fatality rates before
and after the resuscitation education.

This study was limited by a lack for power; specifically, it was not powered
to detect differences in mortality. The study was unable to enact the “cluster”
design of the RCT because few HCPs met the inclusion criteria. Given the short
period of observation, they were also unable to evaluate the stability of the
intervention.

**Single Intervention Studies: NRP™ and Birth Asphyxia**

Another study evaluating the impact of a single educational intervention,
NRP™, was a retrospective chart review focused on a critical outcome, birth
asphyxia-related morbidity and mortality, pre-NRP™ and post-NRP™ training.
The study was conducted in the Trakya region of Turkey with approximately
12,000 annual births and one regional perinatal referral center. Infants diagnosed
with hypoxic ischemic encephalopathy (HIE), using a standardized definition,
who were transferred to the tertiary neonatal unit, were included in the study (Duran et al., 2008).

In this study, the NRP™ course was provided to 50% of staff in 2003 and 45% of staff in 2004, and data were collected over a three year period. The number of patients with birth asphyxia (N = 66) decreased significantly during the NRP™ transition and post-implementation year: in Group 1 (pre-implementation) n = 35; in Group 2 (transition year) n = 18; and in Group 3 (post-training) n = 13. The number of patients with no resuscitation decreased sequentially from 10 in Group 1 (31.2%), three in Group 2 (16.7%), and one in Group 3 (7.8%) in the three consecutive periods (p < 0.05) suggesting that more active resuscitation measures were being undertaken. One minute Apgar scores improved significantly (p = 0.01); however, improvements in the five minute Apgar scores were not statistically significant.

The number of patients with Stage One and Stage Two HIE decreased more in the third group. Ischemic lesions on magnetic resonance imaging (MRI) also decreased from 32 (91.4%) in Group 1 to nine (50%) in Group 2 (transition period) to eight (61%) in the post-training period (p = 0.02). Although morbidity related to birth asphyxia appeared to improve, the overall survival of referred infants did not change over time. The length of stay (LOS) was 15.1 ± 10.3 days in Group 1, 12.0 ± 8.9 days in Group 2, and 6.1 ± 1.2 days in Group 3 (p < 0.05) showing decreases over time.
One of the strengths of this study was the team's attempt to correlate diagnosis of birth asphyxia using standardized definitions of HIE, with longer-term outcomes (i.e., CNS examination and radiologic MRI findings) in addition to simple mortality. Limitations of this retrospective include a small sample drawn from a single referral region over time. It is unclear if other changes in referral patterns may have led to changes in the numbers and types of infants referred; however, this was the only NICU in the geographic region, making this less likely. Unfortunately, there was no report or data available on infants who were not referred in any of the time sequences. Outcomes were reported; however, there was no attempt to determine the quality of the NRP™ guided resuscitations.

A second study (Deorari et al., 2001) was designed to evaluate the impact of regional NRP™ education on the incidence, management and outcomes of infants with birth asphyxia was conducted as a pre- and post-intervention study in India. Participating hospitals were randomly selected from regions of India. Two faculty members from each institution attended an NRP™ certification course and then trained staff in their respective hospitals. Outcome measures included monthly data review of asphyxia-related morbidity and mortality with details of the resuscitation. This data was collected for three months pre-intervention and 12 months post-intervention (Deorari et al., 2001) and then analyzed and compared.

Study findings included an increase in the documentation of asphyxia as measured by Apgar scores following introduction of NRP™ ($p < 0.001$ at one minute; $p < 0.01$ at five minutes). Marked changes in resuscitation practice were
also noted. For example, the use of bag-mask ventilation increased \((p < 0.001)\) and concurrently the use of medications and chest compression decreased significantly \((p < 0.001)\). The findings suggest that, despite increased reports of compromised newborns, in the post NRP\textsuperscript{TM} training period, infants were effectively resuscitated with bag-mask ventilation. Overall neonatal mortality did not decrease; however, asphyxia-related, cause-specific deaths declined significantly \((p < 0.01)\).

This report did not elaborate on the details of the providers trained (specifically how many, what roles, and whether 24-hour attendance at deliveries was achieved). They also did not attempt to evaluate the knowledge or skills of those trained at baseline and after training, nor was the study designed to test the stability of knowledge or sustainability of outcomes over time. Furthermore, the nature of the study (prospective/retrospective comparisons) does not allow establishment of causality. However, the strength of the association, and the findings in concert with other studies, lends credence to the hypothesis that NRP\textsuperscript{TM} training could be an effective tool to decrease morbidity from birth asphyxia in the developing world.

Stronger evidence for the impact of national implementation of NRP\textsuperscript{TM}, was reported by Boo in 2009. This was a prospective, observational before-and-after measure evaluating the nationwide impact of implementation of a single educational intervention (NRP\textsuperscript{TM}), which was championed by the Malaysian Perinatal Society in collaboration with the Ministry of Health. Data were collected from 1996 to 2004.
The NRPTM materials were translated into the Malay language. Initially 37 core instructors were trained to support the train-the-trainer rollout. Thereafter, NRPTM training and certification was provided to 14,575 healthcare providers (95% were doctors and nurses) by the original train-the-trainer instructors. All doctors working in Labor and Delivery (L/D) or the NICU received “full certificates.” Only 80% of nurses in these areas received “full certificates.” The report provided a ratio of annual live births per certified NRPTM instructor. Before NRPTM, the perinatal mortality rate (PMR), neonatal mortality rate (NMR) and stillbirth rates were already decreasing. After NRPTM implementation, the NMR decreased significantly from 6 to 3.8. Stillbirth rates remained unchanged and the PMR decreased from 9.1 to 6.8. This study demonstrated the feasibility of a well-orchestrated, nationwide implementation of NRPTM. The magnitude of the effect of NRPTM training is unclear given the pre-existing decrease in mortality that was observed.
Single Intervention Study:

Educational and Implementation of a Nurse-Led Resuscitation Team

One unique study reported a pilot test of a single innovative intervention. The authors sought to determine if a team dedicated to basic neonatal resuscitation situated in an extremely busy delivery ward (22,000 deliveries per year) at Mulago Hospital, in Kampala, Uganda, a resource-limited setting, would reduce mortality and/or morbidity (O’Hare et al., 2006). Basic resuscitation training was provided to five members of the nursing staff. The educational program consisted of a five day classroom course (didactic and hands-on), followed by five days of supervised training in the delivery unit. The authors did not report whether a pre-existing, structured, educational curriculum was used, nor did they report any educational outcomes from the study. The pilot test also established 24:7 coverage of the delivery unit with a five member team of specially trained resuscitation nurses. During the study period, this team attended 1046 deliveries over a 31-day period.

The overall number of stillbirths was unchanged. The program reduced the incidence of infant mortality from 16.8% to 6.4% ($p = 0.006$) for infants > 2 kg. Given the volume of births in this setting, logistically, not all births requiring resuscitation could be attended. The authors noted that very few hospitals in low-resource settings would have the volume to warrant this level of resuscitation team staffing. They also reported anecdotally that the success of the program has led to enduring funding that has allowed the model to continue successfully beyond the confines of the study.
Single Intervention Studies: Helping Babies Breathe Program (HBB®)

From a theoretic perspective, the HBB® skills-based neonatal resuscitation program, incorporating the ILCOR evidence-based resuscitation science, a program which has been designed specifically for teaching resuscitation in low-resource settings, may have an advantage over other resuscitation programs like NRP™. The educational field testing of HBB® reports the results of the Kenyan facilitators and learners who tested the curriculum, program design, and instructional tools including flip charts, print materials, and the low-technology infant simulator (Bucher et al., 2010). Structured questionnaires designed for formative evaluation were used to critique the course organization, teaching efficacy, and materials. Multiple-choice questions (MCQs) evaluated knowledge of birth asphyxia and neonatal resuscitation. Performance of specific resuscitation skills, such as mechanical ventilation using a self-inflating bag-mask ventilator and room air, was evaluated using OSCEs, while both knowledge and performance were measured before and immediately after the educational intervention.

The investigators prepared four master trainers, and together they trained 16 facilitators and 48 learners (pediatricians, obstetricians, medical officers, midwives, and nurses). After completing training, 100% of the facilitators felt that they had enough information to lead the HBB® course (they agreed or strongly agreed). Of the learners, 97.8% agreed or strongly agreed that they could provide bag-mask ventilation (BMV).
One very important finding of this study was that at baseline none (0%) of the participants had adequate BMV skills. Post HBB® intervention, 96.9% (62 of 64) demonstrated competency in bag-mask ventilation, suggesting that the hands-on teaching strategies and mannequin were effective. The authors concluded that Kenyan birth attendants had good baseline knowledge of birth asphyxia and neonatal resuscitation; however, they demonstrated profound deficits related to critical psychomotor skills such as BMV. Given the large gap between “knowing” and “doing,” the authors suggested that OSCEs should be used as both formative and summative evaluations in teaching neonatal resuscitation.

A second abstract was presented by the HBB® research team at the Pediatric Academic Society meeting in 2010. This abstract focused on the more qualitative evaluation of the acceptability and efficacy of the HBB® program and its feasibility in low-resource settings. Of the 68 trained, 52 participants engaged in seven focus group discussions, led by experienced facilitators and conducted primarily in English, and transcribed in both English and Kiswahili. Electronic transcriptions were analyzed using the QSR 8 program (QSR International). The data were analyzed using a Grounded Theory approach; coding was used to identify relationships between the codes and create categories. Selective coding helped to collapse categories and identify core concepts.

Many participants expressed gratitude and excitement at learning bag-mask ventilation, compared and contrasted “old” and “new” neonatal resuscitation skills, and expressed an eagerness to disseminate and teach the
program. Primary concerns focused on the need for more time for training and to practice skills and role-playing. The authors concluded that “HBB® is an overwhelmingly acceptable curriculum for neonatal resuscitation training. It was met with universal enthusiasm by Kenyan birth providers, who expressed confidence that the curriculum, materials, and equipment were feasible at both health facility and community levels”. These two preliminary reports focused on the field-testing of HBB® providing early and limited data about this program. The results are limited by the methods (qualitative methods) and measures that are not yet fully tested and without normative data (Keenan, 2010; Little, Keenan, Niermeyer, Singhal, & Scheon, 2009).

The stability of the participants’ knowledge and skills were not tested in these studies. The findings can best be generalized to other settings in Kenya. The investigators did not report the proportion of each type of healthcare provider that was present, their level of education, years of experience, English proficiency or other relevant demographics that may have influenced both the acceptance of, as well as the performance of, these resuscitation skills.

The HBB® development team recently published more detailed program results (Singhal et al., 2012). Knowledge and skill assessments included pre- and post-scores from multiple choice questions (MCQ) and post-training assessment of bag-mask skills, as well as two objective structured clinical evaluations (OSCE) in two geographic settings (Kenya and Pakistan) where 31 facilitators and 102 learners were trained. Assessment of participant knowledge and skills pre- and post-program demonstrated significant gains; however, the majority of
participants could not demonstrate mastery of bag-mask ventilation on the post-training assessment without additional practice. They concluded:

Despite demonstrated high satisfaction, high self-efficacy and gains in knowledge and skills, mastery of ventilation skills and integration of skills into case management may not be achievable in the classroom setting without additional practice, continued learning, and active mentoring in the workplace. (Singhal et al., 2012)

A second publication from a HBB® implementation team reported that although birth attendants in a rural hospital in Tanzania performed significantly better in simulated neonatal care and resuscitation seven months after one day of HBB® training, this improvement did not transfer into improvements in clinical practice (Ersdal et al., 2013).

Conversely, a more global evaluation of HBB®, performed by Msemo et al. (2013), evaluated a strategy for national dissemination of HBB® in Tanzania, that included systematic training for healthcare providers from three major referral hospitals, four associated regional hospitals and one district hospital. This large-scale before and after study (n = 8124 before and n = 78,500 after) examined important downstream indicators, including fresh stillbirth rates, and neonatal deaths during the first 24 hours of life. They reported a significant reduction in neonatal deaths: \( RR \) with training = 0.53, 95% CI [0.43, 0.65], \( p \leq 0.0001 \). They also reported a significant reduction in the rates of fresh stillbirth: \( RR \) with training = 0.76, 95% CI [0.64, 0.90], \( p = 0.001 \). To date the effectiveness of this educational program has not been well tested in other areas of the developing
world; and furthermore, the stability of knowledge and psychomotor skills has not been demonstrated. More research will be needed to better understand the educational strategies, clinical outcomes, and impact on mortality, morbidity, and cost-per-lives saved of this educational intervention.

**Studies That Evaluated Combined Interventions (ENBC and NRP™)**

One of the most powerful studies in the developing world was a recently published, large, controlled, population-based, multi-center study using a pre-post intervention model that combined two structured educational interventions, the WHO ENBC and NRP™ (Carlo et al., 2010). The research team tested the hypothesis that the two training programs, ENBC and NRP™, would incrementally reduce seven day neonatal mortality rates for low-risk institutional deliveries that occur at eight low-risk, first-level, urban community, public-sector, delivery clinics/health centers in Lusaka and Ndola, Zambia. This sample accounted for 98% of institutional, low-risk deliveries in the region. They enrolled 71,689 in the three study periods. Mothers were 99% African; 98% married; 63% multipara; and 55% with < eight years of education. Using a train-the-trainer model, certified research midwives trained local midwives \( n = 18 \), allocating one research midwife per clinic. The midwife trainees were practicing midwives who performed deliveries in low-risk, first-level, urban, community health clinics in two cities in Zambia. A total of 123 practicing midwives were trained in both educational programs.

Data collected in the post-intervention phase, after initial ENBC training, revealed that the all-cause, seven day neonatal mortality rate decreased from
11.5 deaths per 1000 live births to 6.8 deaths per 1000 live births ($p < 0.001$). This was primarily attributable to decreases in the post-discharge mortality rate. The decrease in mortality rate after ENBC training was attributable to decreases in the rates of deaths from birth asphyxia, which went from 3.4 to 1.9 deaths per 100 live births ($p = 0.02$). The perinatal mortality rate decreased from 18.3 deaths per 1000 live births to 12.9 deaths per 1000 live births. The rate of stillbirths did not change significantly. After implementation of the NRP™ training, the seven day neonatal mortality rate increased ($p = 0.01$); the increase in mortality rate was attributable to unknown or other causes of death, escalating from 1 to 2.5 deaths per 100 live births ($p < 0.001$). This was presumed to be a function of changes in the follow-up data and disappears with statistical “correction.”

This study was unique given its size, scope, and population-based data, as well as measurement of the relevant clinical outcomes (infant mortality in the first seven days of life). Furthermore, the exclusive use of local midwives in a train-the-trainer model lends credibility to the potential for larger scale implementation and sustainability. A clear limitation of this study lies in the differences in the follow-up rates throughout the study that had the potential to bias results.

A second, large, multi-center, multi-national, cluster-randomized controlled trial, evaluated the same 2 interventions (WHO ENBC and modified NRP™) in a before and after study once again led by Dr. Carlo and his research team (Carlo et al., 2010). The study focused on births in rural communities in Argentina, the Democratic Republic of the Congo, Guatemala, India, Pakistan, and Zambia, and
reported that up to 20% of the births in these settings were attended only by a family member (Carlo et al., 2010).

This study once again tested the hypothesis that the combination of the two training programs would incrementally reduce seven day mortality rates for infants (>28 weeks gestation and >1500 grams) born in developing countries. In this study, the educational intervention was targeted at trained birth attendants (nurses, midwives and physicians). Training using NRP™ was conducted in 88 communities located in five countries. Sequential teaching and evaluation of the two educational programs, both of which employed the train-the-trainer model, occurred.

The primary outcome measured was death from all causes within seven days of birth (NS $p = 0.60$). Secondary outcomes included death in the first seven days due to birth asphyxia. Overall rates of stillbirth and “fresh” or very recent stillbirth declined from 23 per 1000 births to 15.9 per 1000 births ($p = 0.003$). Furthermore, morbidity related to birth asphyxia, as measured by abnormal neurologic examinations on day seven, decreased from 8 to 6.4% ($p = 0.01$).

Both the Journal of Pediatrics and New England Journal of Medicine population-based Carlo study support the hypothesis that improvements in seven day neonatal morbidity and mortality related to birth asphyxia are possible in low-resource settings.
Summary of Findings Related to Question 1: Evidence Regarding Efficacy
and/or Effectiveness

In summary, the evidence surrounding the use of structured educational curriculums to impact newborn care in low-resource settings, is based upon a small number of studies of varying quality; seven studies evaluated ENBC only, and six studies focused on NRP™ only, and the two Carlo et al., studies focused on combining ENBC and NRP™. The evidence for HBB® is limited to the following: a two part abstract evaluating the education program, curriculum, methodology, and feasibility of the train-the-trainer methodology; early preliminary reports from global implementation teams; and three follow-up implementation studies with mixed results. None of the studies includes randomization, blinding, control group data, or careful analysis of individual knowledge or skill acquisition or retention over time.

The sample sizes of the early studies were small overall; furthermore, in many reports, the samples are not well described, and when described they often included a mix of doctors, junior doctors and nurses. Although HBB® purports to be appropriate for TBAs, allowing for community-based resuscitation capacity, TBAs uptake of this program has not been well studied. One of the unexpected and intriguing findings in these studies is the almost universal integration of inter-professional education imposed by the research teams, despite local, low-role esteem given to nurses in these settings and the paucity of collaborative practice environments (Mickan, Hoffman, & Nasmith, 2010; Petri, 2010).
Notably, those studies that performed a power analysis had larger sample sizes and were more frequently able to detect improvements in care. The strongest evidence for the use of ENBC comes from the Senarath, Fernando and Rodrigo (2007b pre- and post-intervention study in Sri Lanka, which demonstrated improvements three months post-intervention. One study (McClure et al., 2007) used significant rigor to evaluate the performance of the multiple-choice measure used for knowledge. Most of the studies focused on the short-term acquisition of knowledge. However, several studies (Carlo et al., 2009; Carlo et al., 2010) also looked at knowledge and performance six months after the intervention, and in the most recent study implemented a “refresher course” at six months in response to degradation of knowledge over time.

Carlo et al. (2009) provides the most rigorous evaluation of NRP™ to date, and the findings support implementation of NRP™ as a single intervention; however, educational measures to guard against the degradation in knowledge over time are likely needed in order to maximize enduring impact. The two most recent Carlo et al. (2010) studies, using both NRP™, a program which focuses primarily on resuscitation at birth, and ENBC, a program that focuses on post-birth stabilization and care measures, show the most promise for the ability to impact the clinical outcomes of interest, mortality and morbidity rates.

When the literature is reviewed chronologically, it appears that the research methods are evolving with a trend towards looking at changes in clinical performance in the hospital environment, moving from educational effectiveness to clinical efficacy, moving away from initial methods reliant on clinical audit
methodologies, to evaluating wide-scale population-based outcome measures. Furthermore, the use of more rigorous and sophisticated measurement techniques, as well as the incorporation of repeated measures over time are emerging themes in this body of research. The number and quality of the studies does not provide enough data to guide whether the potential benefits of face-to-face programs outweighs their costs; however, this is an area where further exploration is needed.

Critique of the Research

Impact of Standardized Neonatal Educational Programs on HCP

Knowledge, Self-Efficacy and/or Actual Performance

Question 2: Do standardized neonatal educational programs impact healthcare providers’ knowledge of, self-efficacy and/or perceived competence, or actual performance of neonatal resuscitation at birth?

The resounding answer is yes – at least in the short-term. Almost universally the programs were able to show “satisfaction” with the course program as well as increases in knowledge scores using a variety of MCQ measures. However, only a small number of studies were able to demonstrate that knowledge was translated into practice and that knowledge positively impacted outcomes.

The data surrounding self-efficacy is fascinating and complex. In some studies measuring self-efficacy, the self-reported perceived abilities and confidence were grossly over-estimated when compared to their actual competency. More careful, systematic and methodologically sound work on
developing and testing self-efficacy measures specific to neonatal resuscitation in the developing world context is needed. Furthermore, an understanding of the potential interaction between self-efficacy and actual performance, which may differ by role and setting, is needed to better understand this concept. Finally, cultural differences in self-efficacy may exist, making comparisons across countries and cultures challenging.

Measurements of performance are critical to measuring the effectiveness of resuscitation. The use of OSCE assessments appeared to be effective. The baseline levels of performance of key resuscitation skills were extremely low in the developing world; therefore, the ability to demonstrate significantly improved performance was a universal finding. The interaction between knowledge, pre-existing experience, curriculums that emphasize skills-based learning, developing and maintaining competency, and the potential degradation of critical skills like bag-mask ventilation over time deserves careful attention and longitudinal evaluation.

Critique of the Research

Impact of Structured Neonatal Educational Programs on Mortality and Morbidity

Question 3: Can structured neonatal educational programs impact neonatal outcomes, such as mortality and morbidity?

Studies demonstrating outcomes on neonatal mortality and morbidity require intense collaboration, large reliable data sets, and these studies are resource-intensive to design, conduct and monitor. The data to date suggest
potential reductions in either morbidity, mortality, or both, as demonstrated in Macedonia (Jeffery et al., 2004), Zambia (Carlo et al., 2010), South American, India, Pakistan and Africa (Carlo et al., 2010), Turkey (Duran et al., 2008), Malaysia (Boo, 2009), Uganda (O’Hare et al., 2006) and Tanzania (Msemo et al., 2013).

The evidence for the effectiveness of community and/or home-based neonatal care, is largely based on the work of Abay Bang and his team of collaborators published in the two 2005 papers. This team performed a field trial of home-based neonatal care in rural India with before and after evaluation of outcomes. They evaluated the effect of home-based neonatal care on birth asphyxia and compared the effectiveness of two types of workers and three types of resuscitation breathing techniques in home deliveries. Outcome measures included the following: the proportion of deliveries where the village healthcare worker (VHW) attended the delivery; the incidence, case fatality (CF) and asphyxia-specific mortality rate; as well as, the “fresh” stillbirth rate during the different phases of field testing.

The study was set in 39 villages in Gadchiroli, India whose total population at the time of the study was 38,998. During the study period, there were 5033 home deliveries; 84% of the infants were attended by the VHW, who were paid a $1.00 incentive for attending the home birth. Beginning in 2000, the government began encouraging institutional deliveries, with a $15.00 incentive paid to the family of infants born in an institution. Infant deaths were assessed using verbal
autopsy reports. The modes of resuscitation were changed over the longitudinal studies. Traditional birth attendants used mouth-to-mouth resuscitation during baseline years (1993 to 1995), and the VHWs only observed from 1995 to 1996. During the intervention years, the delivery attendants used tube-mask ventilation (1996 to 1999) and bag-mask ventilation (1999 to 2003). The incidence of mild birth asphyxia decreased by 60%, from 14% in the observation year (1995 to 1996) to 6% in the intervention years \((p < 0.0001)\). The incidence of severe asphyxia did not change significantly; however, the case fatality with severe asphyxia decreased by 47.5%, from 30% to 20% \((p < 0.07)\) and further reduced the asphyxia-specific mortality rate (ASMR). The implementation of mouth-to-mouth resuscitation reduced ASMR by 12%, and the use of tube-mask ventilation further reduced the CF by 27% and the ASMR by 67%. The bag-mask showed an additional decrease in CF of 39%. The proportion of institutional deliveries increased from 0.5% to 2% during the incentive year.

A second report by this research team, which is a longitudinal extension of their initial field trial of home-based neonatal care, included a large population-based sample followed meticulously over seven years. In this paper, the intervention was implemented and before and after comparisons in 30 intervention villages in Gadchiroli, India (nested) were compared to 47 randomly assigned control villages in the region. The study was designed to evaluate the effect of home-based neonatal care on two main outcome variables: neonatal mortality rate (NMR) and sepsis-specific NMR, using baseline, standardized, community vital statistics in both control and intervention regions. A uniform
cause of death analysis using verbal autopsy was used and performed by a single neonatologist. Three phases were described: baseline phase (1993 to 1995); observational phase (1995 to 1996); and 7-year intervention (1996 to 2003).

The second and more comprehensive intervention focused on providing 8 to 12 home visits, recognition and treatment of sepsis, management or prevention of birth asphyxia, and management of low birth-weight infants. The study provided careful education and close supervision and training of VHWs with payment linked to work done. Data analysis compared two years of baseline data to the most recent two years of data. The study reported a decrease in the perinatal mortality rate by 56%; stillbirth rate decreased by 16%; NMR decreased by 44 points (70% reduction), which was contributed almost equally by early and late reductions. All changes described were significant ($p < 0.05$). The authors estimate that 161 neonatal deaths were averted. The relative contribution to averted deaths of each aspect of the intervention was as follows: sepsis management (36%); asphyxia management (19%); supportive care (34%); primary prevention (7%); and “other” (4%). This longitudinal study is an important example because of the sustained decreases in mortality meticulously demonstrated over time. There was no change in mortality rates in the control villages.

The work of Bang et al. (2005 a/b) clearly demonstrated the importance of community support for any childbirth intervention, and documented a very high rate of compliance with >90% of neonates receiving home-based neonatal care.
The paper very carefully described and reported methods and statistics. Although the interventions were parsed for the purpose of analysis, these interventions are clearly interdependent in the real world context. One of the strengths of this study was the potential sustainability of a community-based intervention and the longitudinal follow-up, tangibly demonstrated by this region's success in meeting MDG-4. The authors described the critical and “curative role” of the VHW who was trained to give injections of Vitamin K and Gentamicin.

One of the criticisms of the Bang et al. (2005) field trials was on the ability to achieve sustainable reductions in neonatal mortality, specifically, with the increased emphasis on care for sick and fragile infants, the potential to decrease NMR while postponing death in biologically frail infants. This was not seen; decreases in NMR were sustained with ongoing decreases in infant mortality rates as well. The study was limited by the field nature of the intervention and the reliability of data sources and verbal autopsy. The estimation involved many assumptions (untested). The demonstration of HBNC was feasible on a small-scale; however, scale up considerations would need to be carefully planned and executed to achieve similar results.

A study-by-study analysis of community-based intervention packages (CBIPs) for improving perinatal health in the developing world is beyond the scope of this literature review. A recent systematic review of CBIPs identified nine large-scale studies with control groups and concluded that these interventions can have a substantial effect on both neonatal and perinatal mortality (Schiffman et al., 2010). The authors noted that further large-scale
studies to test evidence-based CBIPs are needed, particularly in Africa where no large-scale studies have been undertaken. They also emphasized the urgent and competing need to focus on neonatal health in urban settings.

**Critique of the Research**

**Stability of Resuscitation Knowledge and Psychomotor Skills Over Time**

**Question 4: What is known about the stability of resuscitation knowledge and psychomotor skills over time?**

We understand a great deal about teaching and learning; however, less is known about retention or “forgetting.” This can be restated as the stability of knowledge and discrete procedural skills over time. The early work of educational psychologists demonstrated that when humans are taught discrete procedural skills, these skills are rapidly forgotten (Adams, 1987). Examples outside of medicine and nursing include research on aircraft pilots, which demonstrated that in the absence of continued training, the pilots recall of discrete cockpit procedures could decay to unsafe levels within a matter of weeks (Schendel, Shields, & Katz, 1978). However, they emphasized that the initial degree of learning and opportunities to practice could modulate the decay of skills.

A meta-analysis of skill degradation noted that this degradation is magnified in settings where skills are taught, and then potentially not used routinely or for long periods of time. Although this study examined skills from many settings, including military training, they noted that the skill loss “ranges from a $d$ of -0.1 less than one day after training, to a $d$ of -1.4 after more than 365
days of non-use,” showing that the “average participant was performing at 92% of their peak performance level and further amplifying the need for over-learning and refresher training” (Arthur et al., 1998).

The only study that evaluated the “stability” factor in HBB® training was performed by Ersdal et al. (2013). They demonstrated that a one day HBB® course improved simulated performance but not clinical management of neonates. The authors concluded that, “birth attendants in a rural hospital in Tanzania performed significantly better in simulated neonatal care and resuscitation seven months after one day of HBB® training. Unfortunately, this improvement did not transfer into clinical practice”.

**Degradation of Knowledge and Skills with CPR Training**

The CPR literature is replete with examples of skills degradation over time. Further reports highlighting challenges with the stability of CPR instruction include a study by Gass & Curry (1983). This team evaluated the knowledge and skills over time of participants in physicians and nurses ($N = 39$; 19 nurses and 20 physicians) who completed a one day CPR structured educational intervention. They assessed knowledge using a MCQ, self-perception of knowledge, and CPR related skills (assessed using performance on a mannequin). Consistent with the findings of others, they demonstrated substantial decay in knowledge and skills of both physicians and nurses during
the longitudinal follow-up at 6 and 12 months. They suggested that the body of research supports the need for ongoing training at intervals more frequent than 6 to 12 months.

The classic reference illustrating rapid degradation of resuscitation skills is a study of 124 occupational first aid providers who had received standard CPR testing and were evaluated at subsequent intervals. Only 12.1% of the subjects were able to successfully provide CPR. Those trained within two years had success rates of 32.5%, and those whose training took place three years earlier had rates of 2.4% (\(X^2 = 20.37, DF = 1, p < 0.050\)). Performance scores also declined from 4 (of possible 8) at two months to < 1 after three years (\(p < 0.001\)). The loss of skills was rapid (within months of training) and the result was that very few individuals could carry out effective CPR, and led to the conclusion that recertification every three years was insufficient (McKenna & Glendon, 1985).

Bergen, Wilems, Hendrick, Pijls, & Knape (1993) published a randomized controlled trial (\(N = 141\) nurses enrolled and 96 analyzed at 12 months). The trial was designed to assess how different intervals between CPR reinstruction affect the maintenance of basic skills. Nurses were randomly assigned to reinstruction at 3, 6 or 12 months with pre-instruction testing at each interval. Performance of CPR was measured using a two minute structured CPR scenario with key variables recorded on a resuscitation mannequin.

Group scores were similar after first instruction indicating similar baseline skills; however, an increased number of “penalty points” awarded for improper CPR was noted before the second instruction, suggesting a decline in skills.
Reinstruction led to improvement in baseline scores. There was inconsistent reporting of their sample, methods, and statistics; however, at face value the findings suggest that a training interval as short as two months could lead to insufficient clinical skills.

Building upon this work a quasi-experimental study designed to evaluate the retention of CPR knowledge and skills and speed of deterioration was conducted by Broomfield (1996) with a goal of identifying the need for regular CPR updates. This convenience sample of 19 registered nurses in England received the intervention, which consisted of a three hour CPR course. CPR skills were measured using an eight point checklist. Scores on the knowledge measure (MCQ) rose from a pre-test $M = 4.895$; post-test $M = 23.895$. Knowledge scores, tested at ten weeks, regressed significantly ($M = 19.421$), demonstrating degradation of knowledge over a short time period. There was also a degradation in skills with overall low pretest $M$ scores (1.053); post-test $M$ scores were 7.211 and these scores degraded to means of 5.053 at the ten week retesting. All results were statistically significant ($p = 0.0001$).

**Degradation of Knowledge and Skills With NRP™ Training**

In 1992, Dunn *et al.* evaluated the effectiveness of a one day neonatal resuscitation program (NRP™ with Canadian modifications) to improve knowledge and skills. More importantly, they looked at the stability of knowledge and skills, using the same measures, reassessing both control groups and intervention groups for the retention of knowledge and skills at six months. They
also compared participants’ self-assessment of knowledge and skills with actual performance.

The samples included ten hospitals (four teaching and 16 nonteaching hospitals) in Canada. Hospitals were randomized into experimental and control groups with ten in each, and each hospital provided ten subjects for NRP\textsuperscript{TM} education and testing. A total of 190 nurses were tested initially, and 166 were retested at six months. The study documented overall low baseline resuscitation knowledge and skills (36% passed the knowledge pretest and 0% passed the skills pretest). Given these low baseline scores the research team was readily able to demonstrate knowledge transfer. During the post-test phase 91% of the nurses passed the knowledge test and 100% passed the skills test (McNemar $\chi^2[1] = 42.07, p < 0.001$). At six months they demonstrated a marked disparity between knowledge and skills; 85% passed the knowledge test; however, 0% passed the skills test (McNemar $\chi^2[1] = 37.02, p < 0.001$). Notably, when evaluating self-assessments of competence, 23% of the subjects rated themselves as competent despite failing the tests. Control subjects were monitored, and there was no change in performance over time.

Another Canadian research team performed an NRP\textsuperscript{TM} program evaluation using a before and after cohort study (Skidmore & Uruquhart, 2001). Their stated goal was to evaluate the impact of an NRP\textsuperscript{TM} course on the theoretical knowledge and practical skills and to evaluate the stability of knowledge and skills at 6 and 12 months in birthing room personnel. Their sample was comprised of $N = 737$ healthcare providers (included medical staff,
nurses, respiratory therapists) who work in birthing settings across Canada. They measured knowledge using a 55-item MCQ. To test psychomotor skills and application, a practical test was scored using a performance checklist with a standardized scoring rubric as well as data from an electronic mannequin that could identify appropriate chest compressions and ventilation techniques. Of the 737 NRP™-trained healthcare providers, a cohort of 108 (15%) participants received testing before and after the course; the theoretical knowledge and practical performance of 62 of these participants was then retested at 6 and 12 months. These authors echoed concerns by Dunn et al. (1992) related to degradation of skills (primary) and knowledge (secondary) to sub-competent levels over time and state that “every nursery and intrapartum unit should have newborn mannequins, space and dedicated practice time to facilitate skills maintenance”.

The most recent study of NRP™ retention as conducted in West Africa, in a high-volume, tertiary, high-risk referral birth facility in Ghana with a small sample (N = 14) of college-educated, highly experienced midwives (years in practice M = 25) using a before and after observational methodology. The midwives participated in a three hour structured educational program using modified NRP™ materials (Chapter 1-4) and combining didactic and practical teaching. The goal of the study was to assess the midwives’ baseline cognitive knowledge of evidence-based neonatal resuscitation practices and secondly to measure short- and long-term educational effects (retention of NRP™ learning).
Knowledge was measured using a 22-item MCQ test; additionally, practical scores on the AAP/AHA NRP™ Mega-code, comprised of a 27-point evaluation, were also obtained. The NRP™ instructors were blinded to the scores. Retention of knowledge and skills were reassessed using the same measures at 9 to 12 months after the initial training. Consistent with other studies, both the written and practical evaluation of neonatal resuscitation skills increased after training. Written scores were 56% pre-training and 71% post-training ($p < 0.01$). Practical scores increased from 58% pre-training to 81% ($p < 0.01$). However, contrary to the findings of other authors, no degradation of skills was seen. At 9 to 12 months, the written scores remained high at 79% and the practical scores remained high at 85%. The authors speculated that the sustained retention of skill and knowledge in the present study occurred because participating midwives worked in a high-risk referral hospital and used these new skills daily, performing over 7000 deliveries per year. The authors called for “an adequately powered RCT to study the impact this form of training has on neonatal mortality in resource limited settings” (Bookman et al., 2010).

This study is in direct contrast to the degradation of knowledge over time found in Carlo (2009), an NRP™ intervention study on midwives in Zambia. In the Carlo study, at six month testing, there was a significant decline in written performance from 86% ($SD = 10$) to 62% ($SD = 16$) which was statistically, and likely clinically significant ($p < 0.05$) given that the midwives knowledge scores...
degraded to almost pre-intervention levels which were 59%. Carlo’s findings were contrary to the findings of most in that the midwives’ performance scores declined less, from 90% \((SD = 8)\) to 80% \((SD = 19)\), which was also statistically significant \((p < 0.05)\). Self-efficacy scores stayed stable, from 4.3 to 4.2. Those with initially high self-efficacy had the largest decline in performance scores; those with low self-efficacy pre-training had performance scores that remained high.

Critique of the Research

Exploring The Use of Simulation and/or Videotaping in the Developing World

Question 5: What is known regarding the use of existing technology (i.e., videotaping) to deliver or assess educational interventions and/or perform competency assessments in the developing world?

Educational interventions are challenging, complex, and labor intensive; studies situated in the developing world are fraught with feasibility issues. Long-distance relationships are difficult to establish and nurture; cultural and language barriers exist; and logistical challenges of time, distance, political visa restrictions, and the pure economics of travel to distant locations are all significant barriers faced by research teams engaged in international work.

Participant burden—that is the time, money and effort required of HCWs in resource-limited areas—is another important consideration. Many nurses, physicians, and village healthcare workers or traditional birth attendants are
working in remote regions and the cost and burden of traveling to a central site for training are significant. Many of these caregivers see large numbers of patients per day (estimates range from 50 to 100 contacts) and often have no one to “cover” for them while they are away for training, thereby leaving their already underserved communities without access to care in their absence.

The use of innovative methods that harness existing technology, such as the cell phone, Internet, and videotaped technology, for use as mobile educational delivery devices have been reported. Early pilot work by Canadian research teams demonstrated that it was possible to assess neonatal resuscitation skills using the NRP™ Mega-code format, remotely even in the days before fiber-optic technology allowed for more instantaneous high-quality video transmission (Cronin, Cheang, Hlynka, Adair, & Roberts, 2001).

Exploration of the use of mobile technologies (phones, video-cams, and videophones) is a fascinating concept. As evidenced in the recent revolution in Egypt, mobile devices have changed the social, political and economic playing fields of the world through the instantaneous exchange of meaningful information. Since the year 2002, the number of worldwide mobile phone subscribers outnumbered traditional phone lines; cell phones are rapidly bridging the digital divide. Recently, the term “m-learning” has been coined to describe the evolving use of existing mobile technologies, such as cell phones, portable or handheld computers, to promote learning in a highly mobile society.

In exploring the potential for the use of mobile phones and Internet technology in a research site like Africa, local conditions must be analyzed. The
mobile phone revolution in Africa has transformed commerce, healthcare, and the everyday lives. Mobile subscriptions in Africa have risen from 54 million in 2003 to almost 350 million in 2008, the most rapid expansion of this technology on the planet. The mobile phone penetration rate in South Africa is 84%; however, actual access to cell phones likely exceeds “subscribers” due to a number of common cell phone sharing schemes in the region.

The World Health Organization has created a new focus on M-Health, or the use of mobile phones to deliver or improve access to health care services (WHO, 2011). The access to the Internet parallels the growth in the cell phone industry. The percentage of growth of Internet access in Africa is exponential – up 2357.3% from 2000 to 2010; however, despite these “advances,” in 2011, best estimates suggested that only 10.9% of the population currently had Internet access. There is also wide variability of Internet access in different countries within the African continent. The highest area of Internet access appears to be in Nigeria (39.6%) with rates as low as 0.6% in poorer regions such as Malawi (Internet World Stats, 2011).

The access to, reliability of, and speed of Internet connections are rate-limiting factors to the diffusion of knowledge using Internet-based technologies in resource-limited settings. For example, to use the freely available and widely accessible Skype technology for videoconferencing, a tool that has been used for both teaching and evaluating students, a minimum Internet speed of 60 kb/s is required for audio calls. For “medium quality” video calls, 256 kb/s is recommended. Prospects for improved Internet bandwidth are on the immediate
horizon. The West Africa Cable System is in the process of installing under-the-sea, fiber-optic cables that will serve western Africa. Given the rapid growth in existing technologic tools, it is important to review the literature to better assess how these tools have been applied, and their relative feasibility and utility for teaching and assessing learners.

**Critique of the Research**

**Exploring the Use of Existing Technology for Teaching, Learning, Health Monitoring or Assessments of Provider Knowledge and Skills**

One innovative example of the use of cell phone technology as a platform for learning equipped 20 physicians who worked in urban HIV/AIDS clinics in Peru with individual Smartphones (Nokia 95 and iPhones), as well as a portable solar charger. The HCWs received a series of 3-dimensional learning scenarios, interactive clinical cases, and access to a discussion forum with HIV specialists. Education was delivered on and tracked through the phone. Learning outcomes were assessed using mobile quizzes and multiple-choice questions. Outcomes of the study evaluated both technical feasibility and user satisfaction with the program. Overall the program was well-received by the end users. Barriers cited included lack of interoperable software and the high initial capital investment as potential limiting factors (Zolfo et al., 2010).

A short descriptive paper by Klock and Gomes (2008) described and provided photographs illustrating the use of web conferencing systems, specifically Skype and MSN, demonstrating the feasibility of these technology platforms as a potential new mode for remote surgical telepathology. The use of
voice transmission and image capture allowed for adequate transmission of images from countries or remote locations where no pathologists exist to volunteer expert pathologists across the world (Klock & Gomes, 2008).

Tele-simulation (TS) is a novel and evolving strategy that couples the principles of and contextual learning of simulation. Tele-simulation provides access to these interactive environments to remote regions via the Internet and could be used to teach clinical and procedural skills, as well as to assess learners’ competency and skill retention over time, as well as to provide refresher courses or training. One team of researchers compared the use of standard simulation with the use of Internet-based TS for fundamental laparoscopic surgical training. The use of TS is an innovative educational strategy that links simulators to learners in remote locations. The study enrolled 16 surgeons from two centers in Botswana, Africa, who participated in the eight-week training program. Half of the surgeons were trained on a standard in-person simulator, practicing independently using a DVD trainer, and were deemed “the self practice group.” The other half (TS group) had one remote training session per week with a remote proctor using telesimulation. Post-test scores were compared at the end of the training. Participants in the TS group had significantly higher post-test scores than those in the self-practice group (440 +/- 56 vs. 272 +/- 95, p = 0.001). All trainees in the TS group achieved a simulator certification passing score, whereas only 38% in the SP group did so (p = 0.03), suggesting that remote telesimulation may be an effective method for teaching complex skills (Okrainec,
Directly building upon the methodology of Okrainec et al. (2010), another team of Canadian researchers collaborated with their physician partners in Botswana, Africa to test the hypothesis that a relatively new and life-saving technique for administering intra-osseous fluids (IO) during pediatric resuscitations could be successfully taught and the psychomotor skills mastered using telesimulation. The IO technique was taught using one simulator that was located in Toronto, Canada and the other located in Gaborone, Botswana. The education was delivered to 22 physicians using a real-time synchronous format where both instructors and trainers could see each other and communicate freely in real time. The study used a pre-test/post-test design and learners’ knowledge and procedural skills were evaluated before and after completion of the training. The competency was scored both locally and via the Internet trainers. This was a new therapeutic tool and technique; therefore, the pretest scores were low as expected (ranging from 1 to 12 out of 15). The post-test scores ranged from 10 to 15 out of 15 correct answers; furthermore, the $SD$ on pre- and post–multiple choice testing increased by $+5 (±2.75; 95\% CI for MD = 3.92 \text{ to } 6.35)$.

Participants also reported a significant improvement in their comfort and knowledge inserting IO needles ($p < 0.01$), and familiarity with the EZ-IO infusion system and equipment ($p < 0.01$). Also, 95% reported they “felt more prepared” to manage pediatric resuscitations. Local versus remote Internet scores were
comparable ($\text{mean \pm } SD$ score difference = -0.11 \pm 1.22 with 95% CI [-0.66, 0.43]; mean \pm SD time difference = 0.01 \pm 0.15 seconds with 95% CI [-0.06, 0.08]). The authors demonstrated that it was possible to score the IO placement from a remote location; furthermore, their conclusions stated that this methodology, with the focus on multisensory input and options of multi-modal learning (visual, audio, hands-on) has potential for teaching and/or evaluating other procedural skills using distance techniques (Mikrogianakis et al., 2011).

A more formal feasibility and reliability analysis of the use of remote technology to assess complex Pediatric Advanced Life Support (PALS) psychomotor skills via interactive video-conferencing was performed by Weeks & Molsberry in 2008. They compared two remote and two on-site instructors who independently rated the performance of PALS participants using the shock and emergency core cases. A total of 2584 ratings of individual skills were provided across all raters and participants and disagreement was noted in 21 cases (0.8%). The inter-class correlation for overall agreement (pass/fail) was 0.997 for the cardiac cases and 0.998 for the shock cases, and perfect agreement was reached on 52 of 54 pass/fail decisions. They concluded that video-conferencing technology provided adequate spatial and temporal resolution for the assessment of PALS psychomotor skills.

This research team expanded the work by performing a two-armed, prospective randomized controlled trial with repeated measures, designed as a non-inferiority trial focused on not just assessing but delivering a PALS retraining
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program using interactive video-conferencing techniques. The learners’ \( (N = 73) \) outcomes were assessed at the course conclusion and one year after the retraining. There were no significant differences (all \( p \) values > 0.10) in knowledge, psychomotor skills, or confidence based upon method of instruction (face-to-face versus video-conference). Consistent with other resuscitation training programs, they did demonstrate significant degradation in psychomotor skills and knowledge at one year in both groups (Weeks & Molsberry, 2009).

A demonstration project with medical students in remote areas of New Zealand described the use of free Internet-based tools such as Skype (previously described) and Moodle, a free open-source courseware management system designed to create rich interactive dialogues between teachers and learners. The combination of the Skype and Moodle platforms have been used to create both synchronous and asynchronous learning environments with which remote students, equipped with webcams and headsets, can interact. To evaluate the program, qualitative data from two student focus groups were taped, transcribed and analyzed. Students reported variability in the quality of phone calls and videos (some were excellent, others were poor quality). They also voiced concerns related to dropped calls. This initiative saved approximately 7000 km of travel distance and approximately 70 hours of travel time for the 12 students that were enrolled. The study concluded that distance education can be provided at minimal cost with substantial savings in student travel costs and time (Lillis, Gibbons & Lawrenson, 2009).

A medical school faculty team from Australia has done substantial work in
demonstrating that practical clinical procedural skills (for example suturing) can be taught to students, and evaluated by faculty, simply by combining existing technologies such as video recording, networked laptop computers, and content management software. They have developed the Imperial College Feedback and Assessment System (ICFAS) that represents a standardized method to observe, record, assess and provide feedback on multiple contextualized simulated encounters (Kneebone et al., 2008). The learner engages with a standardized patient and moves through the clinical encounter or procedure. After the simulated encounter, the learner can access the collated results, on a password-protected web site, where he or she receives feedback from an expert clinician, recorded feedback from the standardized patient, as well as their own self-assessment.

In the United States, an illustrative demonstration project focused on a cohort of 25 family nurse practitioners, who received extensive training in emergency room triage and management, and were then mobilized to rural Mississippi to improve emergency care in remote areas. This program showed promise in both the use of technology to train and provide real-time consultation and support to provide high-level complex care in remote and underserved geographic regions (Hendersen, 2006). This group is now using telesimulation scenarios, with a remote tester and a nurse practitioner in their local emergency room setting, to remotely assess competency in history and physical skills, procedural skills, team leading skills, and collaboration and triage skills.

In summary, the use of distance education, cell phones, videotaping and
telesimulation are in their infancy; however, a rapidly growing body of literature suggests that these methods are being adopted to both teach and assess competency across a variety of content areas, specialties and complex procedures in varying settings and contexts, including the developing world. In addition to assessment of skill competencies using direct video capture at the research site, which is the methodology employed in the authors’ proposed study, the use of videoconferencing shows promise for the delivery of educational interventions in the future. To achieve adequate quality and fidelity, careful attention to technical specifications, lighting, camera angles and the nature and sequence of the training and testing are needed. More robust research and testing using control groups, and/or randomized studies would provide further insight into the efficacy of these methods.

Critique of the Research

Evidence to Support Theoretical Linkages to Bandura’s Social Cognitive Theory

Question 6: Is there a basis for the use of Bandura’s Social Cognitive Theory, as a conceptual foundation for neonatal educational interventions?

The vast majority of the studies included in this review of literature do not cite an explicit theoretical framework for their study design; further theoretical foundations for the structured curriculum are notably absent in the literature as well. This notable absence may, in and of itself, be a critical finding of this literature review. One author team (Maibach et al., 1996) presented a
provocative argument for the critical link between self-efficacy and resuscitation education, asserting that resuscitation knowledge and skill may not be sufficient to act, stating that, “Even clinicians who are knowledgeable and skilled in resuscitation techniques may fail to apply them successfully unless they have an adequately strong believe in their capability.” Although the authors made a passionate case for focusing on self-efficacy in resuscitation training, they did not provide any empiric studies to support this argument, and instead used three case studies to support their argument. Furthermore, the authors provided minimal guidance on how to measure self-efficacy related to neonatal resuscitation, with the exception of a reference to another publication that serves as a general guide to developing self-efficacy measures and further emphasizing that self-efficacy measures must be developed specifically to the construct of interest (Maibach & Murphy, 1995).

Despite the lack of explicit linkages to a specific theoretic framework, and the notable absence of studies testing this theory, clear themes emerge from both the design and delivery of common structured resuscitation curriculums that can be at least retrospectively be linked to Bandura’s social cognitive theory (SCT). Moving from the aforementioned paucity of explicit linkages in the literature, this author will attempt to strengthen the need for linking theory to practice.

One of the most pragmatic and accessible applications of SCT for nursing in general, and more specifically for nurse educators who are designing,
delivering and evaluating structured educational curriculums such as HBB® or NRP™, relates to the critical determinants of learning that are essential for knowledge transfer. The SCT model highlights four factors that impact learning; attention, retention, motor reproduction and motivation. Social cognitive theory breaks the learning steps down systematically, and concretely illustrates these into key learning principles (Bandura, 1997). In order to learn, one must attend to the information at hand. Attention to modeled events may depend on how distinctive or unique the event is, its affective properties, the complexity of the situation, and the perceived functional value of what is being taught. Each learner comes equipped with unique sensory capacities, arousal levels, perceptions and past exposures or reinforcement that may affect the learning situation.

Retention of learning, or the stability of knowledge and skills, depends on the ability to develop symbolic codes, cognitive organization strategies, symbolic rehearsal, and, for psychomotor tasks, the opportunity for repetitive motor rehearsal. Motor reproduction, or the ability to reproduce psychomotor skills, depends on physical capabilities, self-observation, and good coaching with accurate feedback. One of the most powerful predictors of learning is motivation. Motivation to learn specific content may be intrinsic, extrinsic or self-reinforced (Bandura, 1997).

Social cognitive learning emphasizes the importance of observational learning, a principle that is integrated into the use of simulation. The highest level of observational learning is achieved by:

1. Organizing and rehearsing the modeled behavior symbolically;
2. Enacting this behavior overtly (i.e. simulation);

3. Coding modeled behavior into words, labels, or images that will help the learner retain the behavior, making the learning memorable.

The learner is more likely to adopt a modeled behavior if the learner can relate to the model and if the model is admired or respected. This further enhances the importance of using respected regional caregivers as master trainers for the HBB® curriculum. Lastly, learners need to understand not just what, but why, as this gives functional value to behavior (Bandura, 1997).

To explore the importance of SCT, and the penetration of the theories and concepts, such as self-efficacy, in the nursing and medical literature, a PubMed search was performed and revealed over 580 articles directly related to self-efficacy. The literature includes five discrete published concept analysis papers, as well as one text, titled *Self-Efficacy in Nursing* (Lenz & Shortridge-Baggett, 2002).

Additional evidence of a large body of work linked to SCT, includes six published meta-analyses, linking self-efficacy to promote healthy lifestyle and recreational activities (Ashford, Edmunds, & French, 2010); self-efficacy and smoking cessation (Gwaltney, Metrik, Kahler, & Shiffman, 2009); self-efficacy promoting programs (Cha, Chang, & Sohn, 2004); self-efficacy and job performance (Judge & Bono, 2001); self-efficacy and health-related outcomes (Holden, 1991); and self-efficacy of children and adolescents (Holden, Moncher, Schinke & Barker, 1990).
Measuring Self Efficacy and Identification of Resuscitation Specific Measures

In efforts to empirically test SCT and self-efficacy, >300 situation-specific self-efficacy instruments have been developed. An extensive listing of self-efficacy instruments, as well as Bandura’s instructions for developing new instruments, are available (Bandura, 2006). The depth and breadth of the instruments illustrates the broad scope of SCT. Instruments that measure self-efficacy range from those that focus on specific careers, computers, gifted students, teachers, language arts, writing, foreign language acquisition, math and sciences, spirituality, sports and exercise, medical and health issues, motivation, social, interpersonal, familial and psychological measures, organizational and business measures as well as collective self-efficacy. Some of these measures are in the preliminary stages of construction; however, others are carefully tested, with well-established validity and reliability. This range of instrument development provides evidence for the widespread appeal of and interest in SCT, as well as the unique balance between specificity and generality of this theory.

Three potential resuscitation-specific, self-efficacy instruments were reviewed for potential relevance to the upcoming HBB® study. The first, which was the development of a pediatric skill, self-efficacy scale focused on skills needed to care for pediatric patients in the emergency room setting, has established construct validity; however, only 1 of the 47 items even remotely related to resuscitation (Craven & Froman, 1993). The second scale was an
attempt to assess the validity of a visual analogue scale (VAS) in physicians and nurses, using the technique of known group comparison (Turner, van de Leemput, Draaisma, Oosterveld, & ten Cate, 2008). The known group comparison was a questionnaire developed for paramedics (Spaite et al., 2000) which was designed to measure knowledge and “comfort” related to a myriad of high-technology skills in children with special healthcare needs (Spaite et al., 2000). This questionnaire has some face validity however, prior to use in the Spaite et al. (2009) study it had only undergone incomplete testing with a convenience sample of 24 paramedic students. The questionnaire did not perform well as a measure of self-efficacy for nurses in the Turner et al. (2008) validity study, calling into question its ability to validate the VAS. The authors concluded that there was no correlation between the questionnaire and resuscitation VAS overall when all participations were included (Turner et al., 2008). They did note that the VAS may have some merit for measuring specific skills such as bag-mask ventilation.

The most recent study of a modified version of the NRP™ structured curriculum attempted to integrate a measure of self efficacy, used a new 14-item Likert scale, with responses ranging from 1 (not very confident) to 5 (very confident). Two physicians and a nurse-educator developed the scale specifically for use in the NRP™ research study (Carlo et al., 2009). The scale underwent preliminary testing with 127 subjects who were college-educated midwives in Zambia. To date, there are no reports of validity or reliability of this measure. Six of the 14 items relate to high-technology resuscitations (intubation, chest...
compressions, epinephrine, fluid resuscitation and shock) and would not be
appropriate for use with the HBB® structured curriculum that does not address
these concepts. Unfortunately, to date, there is no well-developed and tested
instrument that measures self-efficacy and resuscitation in general, while
measures of self-efficacy and neonatal resuscitation are, at best, at the early
stages of development.

In summary, Bandura’s SCT holds promise as a theoretic framework for
developing and testing structured curriculums. Perhaps more intentional
educational program designs, and more explicit theoretical linkages could lead to
improved educational, clinical practice, and research outcomes. The ability to
empirically test SCT is limited, in part, by the state of knowledge development
and, even more specifically, by the lack of valid and reliable measures to test one
of the major constructs, self-efficacy.

**Summary of Key Findings From the**

**Integrated Review of the Literature**

One of the most prominent gaps in the literature is the impact of structured
educational program, on nurses. Although many educational programs are
developed for nurses, nurses were notably absent from many of the research
teams. Furthermore, very little is known about the effectiveness of general
continuing education, and/or more skills-based structured educational programs
on experienced nurses. Generalizing data and strategies from the physician
literature, may or may not be universally appropriate.

Other key findings include the following:
1. Little is known about the efficacy or effectiveness of exporting U.S.-
developed curriculums to low resource settings.

2. Initial changes in resuscitation knowledge are demonstrated consistently;
however, the magnitude of the effect size depends upon the baseline
knowledge and competencies of the healthcare provider.

3. More consistent definitions of key terminology are needed to allow
comparisons among and between studies.

4. The studies are plagued by weak methodology and even weaker outcome
measures.

5. Self-efficacy appears to be a critical factor; however, good measures of
resuscitation self-efficacy in the developing world context do not currently
exist.

6. Psychomotor testing is often overlooked, not tested at baseline, and is
tested with even less frequency and rigor both initially and in a longitudinal
fashion.

7. Degradation of knowledge and psychomotor skills both occur; knowledge
appears to have a longer shelf life than psychomotor skills. Exposure to
opportunities to practice or perform skills may impact degradation.

8. Stability of both knowledge and skills is likely much shorter than each of
the structured educational curriculums’ prescribed recertification window.

9. Virtually nothing is known about effective re-dosing interventions.

10. The feasibility of using videotaping or telesimulation to both teach and
assess competency, across a variety of content areas, specialties and
complex resuscitation education and procedures has been demonstrated in the developing world.

11. In addition to assessment of skill competencies, the use of videoconferencing shows promise for the delivery of educational interventions in the future.

12. The use of an explicit theoretical model to guide the structured educational intervention as well as inform further research focused on patient outcomes is notably absent and could represent an opportunity to fundamentally change both the design, delivery and evaluation of resuscitation education in the future.
Ratification of Millennium Development Goal 4 (MDG-4) led to a worldwide focus on the reduction of mortality in children under the age of five with significant progress towards the global goal of a two-thirds reduction targeted between 1990 and 2015 (Darmstadt, 2010). However, during this same time period deaths during the first month of life are also decreasing at a slower overall rate. Consequently the 3.6 million neonatal deaths worldwide now account for a higher proportion (41%) of deaths under the age of five than previously reported. Additionally, minimal progress has been made in reducing deaths during the intrapartum period or preterm births; both of these factors are significant contributors to neonatal and childhood deaths worldwide (Darmstadt, 2010; Lawn, Kerber, Enweronu-Laryea, Cousens & Stat, 2010). Across the entire human lifespan, the day of birth is the day of greatest risk of death” (Lawn, Kerber, Enweronu-Laryea, Cousens, & Stat, 2010); therefore, any global health efforts aimed at reduction of childhood mortality must include interventions that improve the mortality and morbidity of newborns.

Fetal distress during the labor process, due to unexpected intrapartum events such as umbilical cord prolapse, placental abruption, fetal malposition or cephalopelvic disproportion leading to obstructed labor, or shoulder dystocia, may result in a delay in initiation of the first breath, and if unmitigated lead to hypoxic ischemic encephalopathy, death and/or survival with disability. Wall et
al. (2009), suggest that somewhere between 3 to 5% of all births, approximately 10 million infants yearly, do not breathe spontaneously and will require some form of breathing assistance at the time of birth. When initiated promptly in the first minute of life, simple measures such as opening and clearing of the airway and breathing passages are often all that are required to effectively resuscitate most infants (Wall et al., 2009; Newton & English, 2006). Another 3% to 6% or approximately 6 million infants born worldwide annually, may require more aggressive assistance at birth, often in the form of artificial respiration, which must be provided until spontaneous breathing is well established by the infant (Wall et al., 2009).

With basic training and practice every birth attendant could provide effective artificial respiration using a simple self-inflating bag and mask resuscitation device. Current barriers include the absence of a skilled birth attendant, absent or incomplete training and skill in neonatal resuscitation (specifically bag and mask ventilation) in those that do attend deliveries, and the lack of universal access to resuscitation equipment both in and out of the hospital. All of these factors have negative implications for the mortality and morbidity of both mothers and infants and are potentially remediable. Countries that have successfully increased their rates of skilled birth attendance at delivery have shown substantial sustainable decreases in deaths of both childbearing women and their infants (WHO, 2005).

This quasi-experimental study evaluated the efficacy of Helping Babies Breathe® a recently developed evidence-based structured skills-based
educational curriculum designed for dissemination in the developing world, using a train-the-trainer model.

**Overview of the Intervention / A Structured Educational Curriculum (HBB®)**

The HBB® curriculum is a structured educational intervention that includes standardized educational materials to facilitate learning. The illustrated flip chart provides pictures of key learning principles on the learner side, and carefully scripted didactic content on the instructor side. The pocket-sized workbook is designed for use in the classroom and as a hand-held pocket guide that could be used to guide resuscitations in the field. The scripted scenarios are simulated using a low-technology resuscitation training simulator (NeoNatalie, Laerdal, 2010). When filled with warm water NeoNatalie looks and feels like a hypotonic infant with severe perinatal depression, creating sufficient fidelity to enhance learning. Both the teacher and learner are able to demonstrate and practice psychomotor skills using the simulator and the simulator can provide key real-time clinical clues to the learner serving as a feedback mechanism. The simulator is used to:

- Stimulate an infant who is not breathing and requires rapid intervention;
- Demonstrate proper technique to open and maintain an infant’s airway;
- Teach and assess adequate lung inflation by observing the rise and fall of the chest which signifies effective bag and mask ventilation.
technique;

• Perform heart rate assessment using an umbilical cord that can pulsate, indicating the simulated infant’s response to resuscitation efforts.

• Demonstrate how to tie the umbilical cord.

The HBB® program is delivered using the train-the-trainer methodology to enhance integration and assure sustainability. The program is taught in small groups, optimally two to three learning dyads, whose learning is facilitated by a master trainer with a one to six teacher to student ratio. The program includes a combination of didactic teaching, group interaction, and emphasis on hands on practice of psychomotor skills and key care sequences.

The structured curriculum, training materials, and low-technology simulator, as well as the assessment tools (OSCEs and multiple choice test) have undergone preliminary field-testing in low resource settings in Bangladesh, India, Kenya, Pakistan, and Tanzania (Keenan et al., 2010; Bucher et al., 2010). After regional in country testing of the HBB® curriculum to train local care providers in key developing regions of the world, the HBB® Task Force made key modifications before unveiling the program curriculum in June of 2010. To date the effectiveness of this educational program has not been well tested; and further, the stability of knowledge and psychomotor skills has not been adequately demonstrated.
Research Questions

In healthcare providers (HCPs) who routinely attend deliveries in Zambia at baseline:

1. What are the levels of knowledge about newborn resuscitation?
2. Do healthcare providers demonstrate BMV competency?

In healthcare providers (HCPs) who routinely attend deliveries in low-resource settings who have received the HBB® training intervention:

3. Do intervention group participants demonstrate increased knowledge about newborn resuscitation when compared to control group participants at 1 and 3 months?
4. Do intervention group participants demonstrate improved BMV psychomotor skills when compared to control group participants at 1 and 3 months?
5. Do intervention group participants achieve increased rates of BMV competency, compared to control group participants?

Research Design

A prospective, longitudinal, quasi-experimental study with a control group (hold-back design) was used. See Figure 4 for a schematic overview of the research design.

<table>
<thead>
<tr>
<th></th>
<th>Baseline</th>
<th>Intervention</th>
<th>1 Month</th>
<th>3 Month</th>
<th>Intervention</th>
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<tbody>
<tr>
<td>Intervention</td>
<td>$O_{1A}$</td>
<td>$X$</td>
<td>$O_2$</td>
<td>$O_3$</td>
<td></td>
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Figure 4. Research Design: Prospective, Longitudinal Quasi-experimental Study with a Control group (Hold-Back Design). Note: The intervention group had a pre-test / post-test measure.

The study was designed using methods best suited to answer the research questions given the global context. Ethical considerations surrounding the urgent need for resuscitation education in the developing world led to the design of a hold back or delayed treatment group, rather than a pure control group. Further, randomization, although ideal, was not feasible given the setting, location and logistical challenges of this study. For the purposes of this dissertation, data reported will include the HBB® MCQ and HBB® BMV OSCE at baseline, one month and three months for both the intervention and control groups; as well as a pre-test and post-test comparison for the intervention group. Additional data, including videotaped HBB® OSCE A & B, and data collected at a 5 month follow-up are outlined in the IRB applications; however, will not be reported in this dissertation.

Sample

The target population for the use of the HBB® structured educational curriculum was healthcare providers who practice in low resource settings in a developing country. A purposive sampling criterion based strategy was employed. Study inclusion criteria included the following:

- Currently practicing healthcare providers (physician, nurse, midwife,
clinical officer, traditional birth attendant, or village healthcare worker);

- Self-report of routine attendance at births;
- Primary practice site in Zambia;
- Geographic proximity and/or willingness to travel to the data collection site for repeat measures.

Exclusion criteria include:

- Non-English speaking caregivers; or
- Participation in HBB® or other neonatal resuscitation training in the prior six months.

**Research Setting / Study Site**

The study was undertaken in three districts in Zambia. This setting was selected based upon a high infant mortality rate (34 per 1000 live births), low predicted baseline exposure to HBB®, and widespread availability of English-speaking participants and trainers, avoiding translation challenges. And further, the study was designed to be synchronized with pre-existing efforts to roll-out the HBB® training program in Zambia, that are approved by the Zambian Ministry of Health, and supported by the Catholic Medical Mission Board. The HBB® training in Zambia was led by study co-investigators: Dr. George Little (U.S.); Madge E. Buus-Frank RN, MS, APRN-BC, FAAN and Dr. Moses Sinkala Zambia Country Director for the Catholic Medical Mission Board, who served as an on the ground collaborator and provided us with testing sites and research assistants to collect the follow-up measures.

**Power Analysis**
Performing a formal power analysis was challenging given the paucity of HBB® studies published in 2011 at the time of the study design. A statistician who contributed to development of both the study questions and the research design was consulted for the power analysis. The current study is powered as a preliminary pilot study focused on estimating the effect size of the intervention as a basis for more definitive future research. These calculations were based in part on the HBB® pilot data (unpublished data, personal communication G. Little).

The power calculation suggested that 48 subjects (24 in the intervention/treatment group and 24 in the hold/back control group) would be needed to ascertain the effect size of the intervention with a standard error (SE) of < +/- 12.5%. The calculated sample size was derived after considering the study design and the study goal of describing the potential effect size of the educational intervention by comparing the experimental and control groups pre-intervention and post-intervention scores. The intervention’s actual effect size was calculated comparing the means and standard deviations of the treatment and control groups, using Cohen’s $d$, as the difference between the means, $M_1 - M_2$, divided by the pooled standard deviation, $s$, of both groups.

Repeated measures were used to explore both the knowledge scores (MCQ) and psychomotor skills (BMV OSCE) comparing the intervention and the control group, as well as to describe the stability of the research testing measures in the control group. Additionally, the feasibility of using videotaped simulations, and our ability to successfully follow international participants over
time was assessed and attrition rates reported and compared.

Sample Recruitment

Subjects were recruited in collaboration with a local designated research partners from CMMB, all of who have completed the Dartmouth IRB-mandated research training program. Potential participants were contacted via an invitation sent to physicians, clinical officers, nurses, midwives, assistant midwives, and skilled birth attendants who were actively engaged in attending deliveries and responsible for resuscitating infants in the region. Potential participants were invited to attend a 2.5-day HBB® training program and further, offered the option to participate in HBB® research on-site and in the three months following this training program. See Appendix F. for a sample of the training program brochure and agenda.

The call to participate was extended via e-mail messaging, posted paper flyers and informal local channels. Potential training program participants were informed that everyone that participates in the educational program would undergo testing of their current knowledge, skills as well as any changes in their knowledge and skills on-site as part of the standard HBB® curriculum. These testing tools are used for the sole purpose of enhancing participants’ individual learning.

Registered HBB® workshop participants were asked an additional question regarding their interest in participating in research using the following scripted question:

“In addition to the standard HBB® training, we are undertaking a
research study designed to better understand the effectiveness and stability of neonatal resuscitation training. This will involve using the standard HBB® educational tools to collect data on individual resuscitation knowledge and skills before and after completion of the educational program. Would you be open to discussing the potential of participating in this research?"

Participants that registered in advance of the training program were offered the option to consent to participate in the study at the time of HBB® registration. They were also offered the option to request more information or to decline participation. On the day of the HBB® workshop all workshop participants were offered the same information and an additional opportunity to opt in or opt out of the study.

All individuals who participated in the HBB® training underwent the same onsite testing; however, only data from those who consented and were enrolled into the study were scored, analyzed and included in the study results, after careful blinding procedures to protect their identity. Additionally, study subjects were asked to return to a local study site to undergo repeat testing measurements at one and three months after completion of the HBB® educational program. Potential research subjects were informed that they had the right to withdraw from the study at any time during the research period. Also, other than the verbal feedback and coaching that is part of the HBB® standard
workshop training, subjects were informed that they would not be given their final research testing scores or any additional feedback on their performance during the study period.

Once registered for the program, all efforts were made to obtain consent from willing subjects before the educational program. The PI provided preliminary study information to participants at the time of registration. The registration information, including demographics on all workshop and research participants, was collected via SurveyMonkey®-designed instrument, using pencil and paper methods. The workshop opened with remarks form the Ministry of Health and a discussion of the research proposal and plan with questions and answers from local Zambian nurse faculty from the School of Nursing and the Ministry of Health. Participants were given the option to opt in or out; however, after careful dialogue within the group 100% of the workshop participants elected to enroll in the study. Similar procedures were outlined and followed for the recruitment of control subjects. Informed consents were obtained from participants by the research assistants (MN, CK,) with oversight provided by co-investigator Dr. Moses Sinkala.

**Protection of Human Subjects**

The research proposal and Dartmouth IRB application was developed, refined, and approved by the primary investigator with oversight by the dissertation committee. Dartmouth IRB Attachment L, designed for international research settings, was completed in collaboration with the international sites. After formal approval by the dissertation committee the appropriate materials
were submitted to the IRB at Dartmouth Hitchcock Medical Center for consideration via the expedited review process. The UCONN IRB developed a letter of agreement between the two institutions’ IRBs. Once approval was received from the Dartmouth IRB the decision was forwarded to the UCONN IRB for review. The Zambian IRB application was submitted with the assistance of co-investigator, Dr. Moses Sinkala (Appendix E) and subsequently approved.

**Subject Risks and Inconveniences**

Traditionally educational interventions expose subjects to minimal risks during participation. In the context of the HBB® study one potential risk was the discovery of gaps in caregiver competency to resuscitate infants and any potential impact this discovery could have on their current or future employment. The protection of subject identity and individual performance and results, coupled with the reporting of blinded and aggregate rather than individual data, minimized these risks. Further, after the workshops were completed and the research post-test measures are obtained, workshop participants were offered ongoing practice, coaching and opportunities to ensure competency before leaving the workshop setting.

A second risk for subjects is the potential that the training could result in anxiety or stress related to the testing environment, and/or the emotional responses related to recollection of past resuscitation events or infant or maternal deaths. Subjects could have potentially experienced or disclosed personal stories, stressors and traumatic events. The HBB® training team was
experienced in providing support to workshop participants and was instructed to provide personal support and referral for further counseling as deemed necessary.

Research subject inconveniences included the need to travel to the study site for the workshop training and for the follow-up measures. Additionally, given the critical lack of backup healthcare workers and facilities in this region, the research had to remain cognizant and respectful of the subjects’ time away from their typical assigned duties and the potential for unmet needs in the caregivers’ facilities, villages, or regions. The potential enduring regional benefits of improved newborn resuscitation skills and potential projections regarding lives saved outweighs risks and burdens of participation in this study in the experimental and control groups, both of whom ultimately received the educational intervention, one prospectively, and the other after completion of the comparison data. Potential personal benefits to the participants include the opportunity to obtain increased knowledge and skill, potential for increased confidence, and potential for increased status in their respective communities.

Economic Considerations

A small travel stipend (US$20.00 per return trip required) was provided to participants returning for the repeated measures testing. This stipend was based on local standards and the projected costs of travel. Funds were administered through the CMMB local infrastructure and provided to participants in local currency (Kwacha).

Confidentiality and Data Management Plan
The PI (MBF) and co-investigator(s) (GL) (MS) (RC) and any and all individuals involved in obtaining subject consent or in any other way accessing the data have all met the Human Subjects training requirements. All subject data are confidential; only de-identified subject numbers were used on electronic, paper records or forms, or videotapes.

The procedures used to de-identify subjects was conducted by the PI. All subjects received a unique subject identifier. The unique subject identifier was used to track all data collected either in paper and pencil form or electronically via SurveyMonkey® or other electronic means. This unique identifier tied to participants identify was kept in a locked file and/or in an encrypted password protected electronic file, stored on the study laptop, and backed up on a remote hard drive dedicated to the HBB® study and accessible only by the PI.

The unique subject identifier included a nine letter prefix of HBBAFRICA, followed by an observation number (1 for the first observation, 2 for the second observation, 3 for the third observation etc.), followed by a sequential 3 digit code assigned in the order of subject enrollment. For example the first person enrolled in the study would have the unique identifier of HBBAFRICA1-001.

All workshop participants were fully informed regarding the use of videotape technology as part of the educational intervention and research methods. All efforts were made to position the iPad recording device with the video camera focusing on the research subject from the shoulders down; specifically the videotape focused on the participants’ arms, hands and the infant simulator and we successfully avoided capturing the participants face on
Videotapes obtained from research subjects were identified using a tent card with the subject number in the foreground of the video. Immediately at the conclusion of the HBB® on-site training session, the electronic files of the subject videos were downloaded onto the password protected study computer, into a locked file, and backed up on the study designated portable hard drive, and again accessible only to the study PI and research assistant. Once these data are secure the files were then erased from the portable iPads.

Data entry was performed by designated research assistants and/or the PI and conducted at the Children’s Hospital at Dartmouth. The PI performed the data analysis, with assistance of a university-based statistician (DH). Hard copy records with data or participant information were retained in a locked file cabinet in the Regional Program for Women’s and Children’s Health that cannot be accessed by or removed by anyone other than the PI and authorized personnel engaged in the research, in order to protect participant confidentiality. Data will be retained for a period of five years beyond publication of the research results and then will be destroyed.

All data were cleaned prior to coding and data analysis and final copies of the data kept on the PI’s password protected study computer, with back-up of the data burned onto a portable back-up hard drive. Individual level data do not include names, addresses, or other identifying information. All records are
indexed on and labeled by unique study record identifiers only.

Data on the performance of health workers’ resuscitation practices have been handled sensitively. Written reports or presentations will not identify any individual health worker or organization. However, as the interests of patients are also at stake, poorly performing health workers were offered further opportunities for training at the completion of the study.

The results of this research study may be disseminated, with de-identified data, through publications in peer-reviewed journals, and through regional, national, and international professional conferences. Evaluation of the feasibility and logistics, including barriers and/or challenges in the delivering the program in an international setting will be ongoing; therefore, if changes or modifications need to be made, they will be reported to the IRB by the PI per IRB policy.

The research team acknowledges that there are multiple potential confounders that could affect knowledge, skill, and competence in the simulated testing and research setting; further, many of these are challenging to account for in this quasi-experimental design. Therefore, conclusions about the impact of this educational intervention have been made with considerable caution.

**Research Instruments**

A series of educational measurement instruments were developed and used in the original field-testing completed by the HBB® research team (Interim Report to the American Academy of Pediatrics Global Implementation Task Force: Evaluation of the HBB® Educational Program; (Unpublished report,
personal communication George Little). In the interest of consistency and the ability to compare data across studies in future replication and research efforts, the HBB® instruments were adopted with minimal modifications and were used in this study with permission (See Appendices C & D). A standardized mechanism to operationally define and score the BMV checklist, and testing methods that elevated it to the level of an objective structured clinical exam (OSCE) are described. Additionally relevant demographic data was collected to allow for comparisons of the treatment and control group.

Sample Demographics

The sample demographics and characteristics were obtained using HBB® Demographic Survey Version 1 (Appendix A). This information obtained at baseline for both groups using a printed version of SurveyMonkey®. We intended to collect an Abbreviated Demographic Survey Version 2 (Appendix B) at the time of each follow-up measurement interval to monitor for any new exposures to resuscitation education and to identify whether the participant had the opportunity to use or teach the HBB® program to others. However, this data was not reliably collected by the Zambian ground team, and therefore could not be analyzed.

Knowledge Measure

The HBB® Resuscitation Knowledge Measure was obtained using the printed HBB® MCQ Test, created on SurveyMonkey® (Appendix C). This is a 17-item written multiple choice question test (MCQ) test developed and field-tested
by the authors of HBB® and was used to measure the subjects’ newborn
resuscitation knowledge. Although the MCQ questions were developed by a
team of international content experts and were tested with an international
participant pool in the HBB® field-testing, there are no reported reliability
measures for this instruments published to date. The HBB® MCQ test was initially
intended to be administered to participants before HBB® training via an electronic
testing format (SurveyMonkey®, 2011). However, the paper and pencil back-up
option was actually used due to recurrent failures of both the electrical power
supply and Internet during the study period. The HBB® MCQ test was re-
administered immediately after completion of the HBB® training program, and
again at one and three months after the educational intervention by paper and
pencil.

The HBB® Multiple Choice Question test, evaluated knowledge. The
mean, median, range, and the percentage of participants who achieved passing
test scores was calculated and will be reported. Additionally, specific elements of
resuscitation knowledge evaluated by individual MCQ were evaluated by
reporting each item as a percent passed. Higher test scores indicate higher
levels of didactic knowledge about newborn resuscitation. A score of 80% on the
HBB® MCQ indicates the threshold to “pass” and scores 79% or lower indicates a
test “fail.” Individual item analysis was performed to identify group performance by question. To assess for group differences at baseline the intervention versus the control group’s mean baseline scores were compared using a t-test. The percentage that received passing scores were analyzed using chi square test.

**Psychomotor Measure: HBB® Bag-Mask Ventilation OSCE**

The HBB® Bag-Mask Ventilation Objective Structured Clinical Examination was used to measure the critical psychomotor skill for newborn resuscitation, bag and mask ventilation, tested in a simulated environment using the NeoNatalie mannequin and self-inflating bag and mask device (Appendix D). The HBB® Bag-Mask Ventilation Objective Structured Clinical Examination was scored using the Bag and Mask Skill Performance Checklist is based upon the following principles:

- a) Demonstrate appropriate BMV technique;
- b) Demonstrates the appropriate steps and sequences of BMV; and
- c) Demonstrates the corrective maneuvers to employ if BMV is not effective.

This criterion-based instrument includes seven critical items and was scored as “done” with 1 point awarded, or “not done” with 0 points awarded. The critical components of each step are provided on the scoring sheet in a bulleted text detail to assure consistency in scoring with 12 critical items noted. The learner must obtain and maintain an appropriate seal with the mask, use the
correct rate of ventilation, assess for chest rise, and demonstrate how problems with the bag and mask ventilation would be corrected if the baby does not improve. The learner was not given any feedback on performance during the simulation, and s/he is given a single attempt to complete the demonstration. The videotapes captured two to three minutes of BMV before the scripted verbal prompt and two to three minutes of BMV after the structured prompt, when the tester simulates failure of chest rise which is the clinical prompt for the subject to employ BMV corrective maneuvers.

Higher HBB® Bag-Mask Ventilation OSCE scores indicate improved integration of knowledge and psychomotor skills related to BMV. A score of 7/7 is considered a “pass” or demonstrates competency; scores of 6 or less are considered a “fail.” The primary investigator or a trained research assistant administered the HBB® Bag-Mask Ventilation OSCE.

**Global Assessment of Competency and Dangerous Practices**

In addition to the item-by-item scoring HBB® Bag-Mask Ventilation OSCE, videotape raters were asked to provide a “global assessment” of BMV. Global assessments (GAs) are “gestalt” impressions of performance by an experienced rater, with content specific expertise in the area of assessment (Spillane, Hayden, Adler, Beeson, Goyal & Smith-Coggins, *et al.*, 2008). A determination of global competency (pass / fail) was performed after scoring the criterion-based OSCE. It was possible to fail the criterion-based scale and receive a “pass” on
the global competency score. Videotape raters were also asked to code for atypical or potentially dangerous resuscitation practices, defined as shaking, slapping, aggressive stimulation, overall rough handling, head compression, and a non-specific category (other).

**Timing of Measures**

In the treatment group all testing occurred immediately before the intervention ($O_{1A}$) for baseline measures. Thereafter the HBB® Knowledge MCQ, and the HBB® BMV OSCE, and were repeated serially with measures obtained immediately post-training for the intervention group only ($O_{1B}$) and thereafter both groups were tested at one month ($O_{P2}$), and three months ($O_{P3}$) to assess the stability of knowledge and skills over time. Except for the immediate post-test condition, the control group was tested at parallel intervals using the same methods and testing conditions as the intervention group.

**Videotape Scoring Procedures**

The videos were numbered using a standardized method that blinded the scorers to identity, group assignment, and sequence. They were selected randomly from the file and assigned to one of two trained raters. The videotapes were reviewed and scored using a standardized procedure in low light conditions. The computer settings were adjusted to maximize brightness and audio output. The rater also used headphones to augment the audio output and minimize external distractions. The raters reported 100% compliance with these procedures on their data collection instruments.
The videos were scored using a standardized approach consistent with the OSCE model. In preparation for the study the original HBB® scoring sheets were adapted and refined to highlight the following three key components:

a. Sequence

b. Skill

c. Speed (specifically – the rate of the BMV was measured and compared to the recommended rate)

Our research team (MBF, GL, RC) prospectively developed the BMV OSCE criterion-based scoring rubric that both operationally defined each task, as well as outlined discrete task components that must be demonstrated. The tasks could not occur at random; rather, they had a specific clinically relevant sequence. The scorer noted whether each task was performed (done or not done) and secondarily whether it was performed in the proper sequence. Both must occur in order to award points. Further, certain tasks that were deemed “critical” a priori had to be performed in order to achieve a “pass” score on the HBB® BMV OSCE.

Building upon these principles the HBB® OSCE scoring rubric also evaluated the quality or skill of the subjects performing specific procedures. Even when tasks are attempted in the correct sequence, if they were not performed correctly, points are not awarded. Items on the HBB® published BMV skill station had bulleted points highlighting actions required. When specific actions were not
well enough defined on the existing checklist, to allow for independent scoring, the actions were prospectively operationally defined by the research team, using words and actions directly extracted from the HBB® curriculum workbook and flipchart.

**Establishing and Monitoring Ongoing Inter-Rater Reliability**

For the purpose of this study inter-rater reliability was operationally defined and appropriate levels established based upon standard in the literature (Hallgren, 2012; Kottner, Audige, Brorson, Donner, Gajewski, et al., 2011) and included the following key characteristics:

- Reliable raters agree with the "official" rating of a performance during the training phase.
- Post-training reliability is defined as complete agreement with each other: reliable raters will agree with each other about the ratings of the videotapes.
- Reliable raters will consistently achieve an ICC of > 0.75.

Step one in the procedure to establish the expert rating scores was accomplished by review of a sample of representative videotapes by the three content experts from the research team (MBF, GL, RC). Additions to the HBB® OSCE scoring instrument were made as needed to clarify consistent scoring criteria. When scoring discrepancies emerged, they were discussed, reviewed, until consensus was achieved.

Step two in the IRR procedure included a structured training session for both raters with hands on practice scoring multiple videos simultaneously and
comparing scores until complete agreement was achieved. Step three of IRR procedure included comparison of the independent rater-in-training scores to the “official scores”. When discrepancies emerged, they were discussed, reviewed, and consensus achieved. The training videotapes were repeated until consistent scoring was demonstrated. To assure ongoing IRR throughout the scoring period the raters’ scores were obtained on every 10th consecutive videotape and calculation of the ICC coefficient performed. Pro forma plans to assess for statistical drift were established; structured retraining was planned if needed.

The videotapes were independently scored by one of two research assistants; KK is a practicing neonatal nurse practitioner and SS is a second year medical student. Both reviewers were blinded to the intent of the study, as well as the status of the subject (control versus intervention group) and to the order of the observations (pre-test, post-test etc.).
Planned Statistical Analysis

This study aimed to describe changes in resuscitation knowledge and BMV psychomotor skills in subjects who received HBB® training compared to control group subjects. Additionally, subjects were assessed at intervals of one and three months to evaluate the stability of these changes over time. This study was powered to measure an effect size of 6% (Cohen’s $d = 0.5$) of the educational intervention. The power calculation suggests that 48 subjects (24 in the intervention group and 24 in the hold/back control group) are needed to ascertain the effect size of the intervention with a standard error (SE) of $< +/-$ 12.5%.

Statistical Analysis of Sample Characteristics and Comparisons.

Sample characteristics (Appendix A) were obtained and analyzed using descriptive statistics that measure central tendency, such as frequencies, percentages, variance and distribution. The characteristics of the control and intervention group were compared at baseline to identify any potential differences in the sample characteristics (i.e. age, gender, role, level of education, prior resuscitation exposure, English proficiency).

Statistical Analysis of Research Question 1

In healthcare providers (HCPs) who routinely attend deliveries in Zambia at baseline:
RQ 1. What are the levels of knowledge about newborn resuscitation?

Levels of baseline newborn resuscitation knowledge were measured by the 17-item HBB® MCQ test administered to both the control and the intervention groups (N = 52). Scores on the test represented interval level data (ranging from 0 to 17). The overall test score (mean, median, range, and the percentage of participants who achieved passing test scores) was reported. Additionally, specific elements of resuscitation knowledge were evaluated by individual item by reporting the percent passed for each item.

To assess for group differences at baseline the intervention versus the control groups’ mean baseline scores are compared using a t-test. Assumptions for the use of the t-test were met by examining the data for normal distribution and/or the presence of outliers or skewed data. If the scores are not normally distributed, non-parametric analysis was planned and a Wilcoxon rank test applied. The percentage receiving passing scores was a categorical variable that represents independent observations and this data and was analyzed using the chi-squared test.

Statistical Analysis of Research Question 2

In healthcare providers (HCPs) who routinely attend deliveries in Zambia at baseline:

RQ 2. Do healthcare providers demonstrate BMV competency?

Bag-mask ventilation competency of HCPs was measured using the HBB®
Bag-Mask Ventilation Objective Structured Clinical Examination, adapted from the HBB® BMV Skill Checklist. The HBB® BMV OSCE includes seven critical items; each item was scored as “done” with 1 point awarded, or “not done” with 0 points awarded. Scores on the BMV OSCE represented interval level data (range from 0 to 7) with a pass threshold of 7.

HBB® BMV OSCE scores evaluated competency in a simulated setting, and were calculated and reported at baseline for the entire cohort. The mean, median range, and percent passed are reported. Additionally, specific elements of resuscitation psychomotor competency were reported by percent passed and analyzed on an item-by-item basis.

To assess for group differences at baseline the intervention versus the control group’s mean baseline scores are compared using a t-test. Assumptions for the use of the t-test were met by examining the data for normal distribution and/or the presence of outliers or skewed data. If the scores are not normally distributed, non-parametric analysis was planned and a Wilcoxon rank test applied if needed. The percentage that received passing scores is a categorical variable that represents independent observations and data were analyzed using chi-squared test.

**Statistical Analysis of Research Question 3**

In healthcare providers (HCPs) who routinely attend deliveries in low-resource settings who have received the HBB® training intervention:
RQ 3. Do intervention group participants demonstrate increased knowledge about newborn resuscitation when compared to control group participants at 1 and 3 months?

To identify any potential effect of the HBB® training intervention on knowledge, a repeated measures ANOVA was conducted to compare the effect of HBB® intervention between subjects (control versus intervention) and within subjects (changes in scores over time; at baseline, one month, 3 months) on the mean knowledge score.

A secondary exploratory analysis for relevant covariates, such as actual use of the HBB® (planned to be collected in the short demographics exposure survey) as well as any influence of baseline role and years of experience was planned a priori; however, given the small sample size these data were interpreted with caution.

Statistical Analysis of Research Question 4

RQ 4. Do intervention group participants demonstrate improved BMV psychomotor skills when compared to control group participants at 1 and 3 months?

To identify any potential effect of the HBB® training intervention on psychomotor skills, a repeated measures ANOVA was conducted to compare the effect of HBB® intervention between subjects (control versus intervention) and within subjects (changes in scores over time; at baseline, one month, 3 months)
on the mean score for psychomotor skills.

A secondary exploratory analysis for relevant covariates, such as actual use of the HBB® (reported in the exposure survey) as well as any influence of baseline role and years of experience was planned a priori; however, given the small sample size and missing data these data were interpreted with caution.

Statistical Analysis of Research Question 5

RQ 5. Do intervention group participants achieve increased rates of BMV competency, compared to control group participants?

To identify any potential effect of the HBB® training intervention on overall BMV competency, defined as a passing score on the instrument, a repeated measures ANOVA was conducted to compare the effect of HBB® intervention between subjects (control versus intervention) and within subjects (demonstrating passing scores on HBB® BMV OSCE testing signifying competency) achieved at any time interval.

A secondary exploratory analysis for relevant covariates, such as actual use of the HBB® (reported in the exposure survey) as well as any influence of baseline role and years of experience was planned a priori; however, given the small sample size and missing data these data have been interpreted with caution.
Summary

In summary this pilot study describes the baseline resuscitation knowledge and psychomotor skills of healthcare providers who routinely attend deliveries in Zambia. The comparison of a control and intervention group allows for the evaluation of an effect of the HBB® structured educational curriculum on resuscitation knowledge and psychomotor skills. The pilot study will provide preliminary testing of the feasibility of using a unique combination of simulation testing and videotape scoring methods, as well as the ability to perform repeated measures over time, information that will guide the potential application of these methods in future studies.

Results of this study may be useful to HBB® Master Trainers, or to those who are developing, testing and disseminating other structured educational curricula. Data will provide preliminary insights and assist course developers and course faculty to formulate a better understanding of knowledge transfer, and the predicted stability of knowledge and psychomotor skills over time. A pragmatic model on which to build further understanding and a program of research might mirror the clinical pharmacodynamics model where key factors such as the dose, formulation and route of a drug are important variables. The analogous educational “dose” and “formulation” of the knowledge are reflected in the depth and format of the curriculum, as well as the mode of delivery of the training. Building upon this analogy understanding knowledge transfer (akin to drug administration and absorption), and diffusion of knowledge from the classroom to actual clinical practice (analogous to drug disposition) are both equally important
concepts. Furthermore, just like a drug, knowledge and psychomotor skills may have a predictable half-life. Therefore, the use of repeated measures is essential to measure any potential degradation of knowledge and psychomotor skills over time. If an observable half-life can be discerned, then this could potentially predict the need for additional dosing (use of repeat educational interventions) or could be tested to evaluate the impact of intermittent dosing, versus more continuous forms of learning (i.e. a virtual knowledge pump) – both subjects for future research.

Chapter Four

Data Analysis and Findings

The purpose of this prospective, longitudinal, quasi-experimental study with a control group hold-back design was to evaluate the effect of a structured educational curriculum and training program (HBB®), on resuscitation knowledge and psychomotor skills of healthcare providers who routinely attend births in Zambia. The three major areas of inquiry in this study are baseline resuscitation knowledge, baseline resuscitation-related psychomotor skills (bag and mask ventilation), and the stability of knowledge and skills, as defined as retention of resuscitation knowledge and BMV skills over time. Additionally, the feasibility of the unique testing methods, specifically the use and scoring of videotaped objective structured clinical evaluations (OSCEs) to assess BMV psychomotor skills, is described.

Research Questions

In HCPs who routinely attend deliveries in Zambia at baseline:
• What are the levels of knowledge about newborn resuscitation?

• Do healthcare providers demonstrate BMV competency?

In HCPs who routinely attend deliveries in low-resource settings who have received the HBB® training intervention:

• Do intervention group participants demonstrate increased knowledge about newborn resuscitation when compared to control group participants at 1 and 3 months?

• Do intervention group participants demonstrate improved BMV psychomotor skills when compared to control group participants at 1 and 3 months?

• Do intervention group participants achieve increased rates of BMV competency, compared to control group participants?

Data analysis was completed in collaboration with a biomedical statistician (DH) using Statistical Analysis System (SAS) version 9.3 (Cary, North Carolina) and under the direction of the author’s Major Advisor (RC). An alpha level of 0.05 was used as the threshold for significance for all statistical tests.

**Overview of the Sample**

Study eligibility criteria included currently practicing healthcare providers (nurses, midwives, physicians, clinical officers, medical licentiates), who self-reported routine attendance at births in Zambia, and who were willing to travel to the data collection site for repeat measures. A total of 54 potential participants were recruited to participate in the study, using the purposive sampling strategy outlined in Chapter 3. Of this potential sample, 53 met the eligibility criteria; one
potential participant was excluded for failure to meet the “routinely attends births” criteria. The second participant was enrolled in the intervention group but disqualified as she failed to complete the initial 2.5-day training course. The final analysis was performed on 52 subjects whenever complete data was available; when complete data was not available, the denominator for the analysis is highlighted in the table heading. Exclusion criteria (non-English speaking, and/or participation in HBB® or attendance at other neonatal resuscitation training in the prior six months) were identified pro forma; however, although these circumstances were anticipated, they were not encountered in this study sample, highlighting the limited opportunities for resuscitation training in the region.

Sample Gender, Professional Role and Years in Practice

Table 1 provides an overview of the sample demographics. The participants were predominantly female (85%) with a median age of 41. Gender (p=0.73) and median age (p=0.30) were not statistically different in the intervention versus the control group. The participants were predominantly nurses (85%) and medical providers (15%). The years in practice ranged widely, from 1 to 39, with a median of 8 years of practice experience for the sample at large.

The demographics survey included discrete options for role self-classification; certified nurse midwife, nurse, nurse with some midwifery training, clinical officer, nurse practitioner (NP), physician, skilled birth attendant (SBA), traditional birth attendant (TBA), or respiratory therapist (RT). No participant self-classified as an NP, SBA, TBA or RT. There was lack of precision in the role self-
classification for nurses versus nurse midwives. In the Zambian setting, the widespread use of the word midwife signifies a functional role, rather than an advanced practice educational preparation for such a role. Additionally there is inconsistent use of Zambian Enrolled Midwife (ZEN), the official licensure term for midwives. Further, in the Zambian context virtually all nurses function as “advanced practice nurses” due to the low numbers of physicians; therefore nurses commonly provide medical care and independently oversee births, irrespective of their basic educational preparation and/or training.

For the purpose of data analysis the detailed role classifications were simplified to reflect three basic categories. Category one was a nursing category (inclusive of all nurses with and without formal midwifery training or ZEN distinction); category two was a mid-level practitioner / physician category inclusive of clinical officers medical licentiates, and physicians; and, category three “other” was retained for non-professionals, family, skilled birth attendants, and community health workers, although no one in this category participated in the current study.

**Formal Education**

The highest level of education achieved was self-reported by participants. In the intervention group, 92% had university or technical training (13+ years) and 8% had a university degree (14+years). By contrast, 67% of the control group had secondary school education only; 8% had university or technical training, and 4% had a university degree. At baseline the intervention group had a statistically higher level of education than the control group ($p < 0.001$).

**Language and English Proficiency**
The participants spoke a total of 23 languages and/or dialects in the context of the 70 native languages and dialects of Zambia. English proficiency was self-reported using criteria from the Interagency Language Roundtable (ILR) Scale, (Diamond & Reuland, 2009). The participants had strong English proficiency overall; no differences were found in the intervention versus control groups. The ILR scale provides operational definitions for each level of English proficiency; 0 denotes no proficiency; 1 is elementary proficiency; 2 is limited working proficiency; 3 is professional working proficiency; 4 is full professional proficiency; and 5 is equal to a native or bilingual proficiency.
Table 1

*Participant Demographic Factors Compared by Study Group*

<table>
<thead>
<tr>
<th>Factor</th>
<th>Intervention n=25</th>
<th>Control n=27</th>
<th>Statistical Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Gender</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>4 (16%)</td>
<td>6 (22%)</td>
<td>Fisher’s Exact Test</td>
</tr>
<tr>
<td>Female</td>
<td>21 (84%)</td>
<td>21 (78%)</td>
<td>p = 0.73</td>
</tr>
<tr>
<td><strong>Age</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Median Age</td>
<td>39 (23, 58)</td>
<td>44 (26, 52)</td>
<td>Wilcoxon Test</td>
</tr>
<tr>
<td><strong>Role</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nurses and Midwives</td>
<td>21 (84%)</td>
<td>23 (85%)</td>
<td>Fisher’s Exact Test</td>
</tr>
<tr>
<td>Clinical Officer / Medical Licentiate and/or Physician</td>
<td>4 (16%)</td>
<td>4 (15%)</td>
<td>p = 0.99</td>
</tr>
<tr>
<td>Other</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td></td>
</tr>
<tr>
<td><strong>Years in Practice</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Median Age</td>
<td>4 (1, 39)</td>
<td>10.5 (1, 23)</td>
<td>Wilcoxon Test</td>
</tr>
<tr>
<td><strong>Highest Educational Level Achieved</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Primary school (0-8 yrs.)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>Wilcoxon Test</td>
</tr>
<tr>
<td>Secondary school (9-12 yrs.)</td>
<td>0 (0%)</td>
<td>18 (67%)</td>
<td>Test</td>
</tr>
<tr>
<td>University or technical training (13+ yrs.)</td>
<td>23 (92%)</td>
<td>8 (29%)</td>
<td>p &lt; 0.001</td>
</tr>
<tr>
<td>University or technical training (14+ yrs. and degree granted)</td>
<td>2 (8%)</td>
<td>1 (4%)</td>
<td></td>
</tr>
<tr>
<td><strong>Primary Language</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not Native English Speaking</td>
<td>15 (60%)</td>
<td>19 (70%)</td>
<td>χ² = 0.62</td>
</tr>
<tr>
<td>English only or English and Native Language</td>
<td>10 (40%)</td>
<td>8 (30%)</td>
<td>p = 0.43</td>
</tr>
<tr>
<td><strong>English Proficiency</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Interagency Roundtable Language Scale (ILR)*</td>
<td>4 (3, 5)</td>
<td>5 (1, 5)</td>
<td>Wilcoxon Test</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Test</td>
</tr>
</tbody>
</table>

*English proficiency was self-reported. The ILR scale provides operational definitions for levels of English proficiency: 0 denotes no proficiency; 1 is elementary proficiency; 2 is limited working proficiency; 3 is professional working proficiency; 4 is full professional proficiency; and 5 is equal to a native or bilingual proficiency.*
Prior Exposure to Resuscitation Training

The baseline exposure to any resuscitation training was 26% in the control group and 28% in the intervention group ($p=0.87$), inclusive of even the most basic CPR training (Table 2). In the control group 7 of the 27 participants compared to 1 of 25 participants in the intervention group had been trained in Essential Newborn Care (ENBC) ($p = 0.05$), a four to five-day program that provides a module on basic newborn resuscitation with applied skill sessions. Additionally, 3 of the 7 participants in the control group reported teaching a resuscitation program.

Table 2 Prior Exposure to Resuscitation Training Programs; Both Groups at Baseline

<table>
<thead>
<tr>
<th>Resuscitation Education Exposure</th>
<th>Intervention Group</th>
<th>Control Group</th>
<th>Statistical Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Attended any Resuscitation Education Program</td>
<td>28% (7/25)</td>
<td>25.9% (7/27)</td>
<td>$\chi^2 = 0.03$, $p = 0.87$</td>
</tr>
<tr>
<td>Cardiopulmonary Resuscitation (CPR)</td>
<td>8% (2/25)</td>
<td>11.1% (3/27)</td>
<td>Fisher’s Exact Test, $p = 1.00$</td>
</tr>
<tr>
<td>Neonatal Resuscitation Program™ (NRP™)</td>
<td>12% (3/25)</td>
<td>29.6% (8/27)</td>
<td>Fisher’s Exact Test, $p = 0.18$</td>
</tr>
<tr>
<td>Helping Babies Breathe® (HBB®)</td>
<td>0% (0/25)</td>
<td>11.1% (3/27)</td>
<td>Fisher’s Exact Test, $p = 0.24$</td>
</tr>
<tr>
<td>Pediatric Advanced Life Support (PALS)</td>
<td>4% (1/25)</td>
<td>0% (0/27)</td>
<td>Fisher’s Exact Test, $p = 0.48$</td>
</tr>
<tr>
<td>Essential Newborn Care (ENBC)</td>
<td>4% (1/25)</td>
<td>5.9% (7/27)</td>
<td>Fisher’s Exact Test, $p = 0.05^*$</td>
</tr>
<tr>
<td>Taught Any Resuscitation Training Program</td>
<td>4% (1/25)</td>
<td>11.1% (3/27)</td>
<td>Fisher’s Exact Test, $p = 0.61$</td>
</tr>
</tbody>
</table>

* Statistical significance. Of the 3 control group subjects who taught resuscitation training, 1 taught CPR, 1 taught NRP, and 1 taught ENBC. Exposure to resuscitation training in the prior 6 months was an exclusionary criteria for study entry; no subjects were exposed during this 6 month pre-study time period.
Data Analysis by Research Question

RQ 1. In healthcare providers (HCPs) who routinely attend deliveries in Zambia at baseline - What are the levels of knowledge about newborn resuscitation?

Levels of baseline newborn resuscitation knowledge were measured using the 17-item HBB® MCQ test, which was administered to both the intervention (n=25) and the control group (n=27). The baseline analysis was conducted on 51 of the 52 enrolled participants with complete data. The overall test score (mean, median, range, and the percentage of participants who achieved passing test scores) are reported in Table 3. A passing score of 80% was achieved by 70% of the participants at baseline. Further analysis of specific elements of resuscitation knowledge was completed by question and is described by item and is reported in Table 4.

To assess for group differences at baseline the intervention versus the control group’s mean baseline scores were compared using a t-test, after the assumptions for the test were met. Pass scores were calculated based upon the sum of the number of items correct and divided by the total possible (17), and then compared to the “pass” score threshold of 80% or greater. See Table 3 for the comparisons of baseline resuscitation knowledge as measured by scores on the HBB® Multiple Choice Test.

There were minimal differences between the baseline median and mean scores in the intervention versus the control groups. Participants needed to have 14/17 correct items to achieve a “passing” score defined as >80%; however, of
those who failed, their scores were clustered at 13/17 correct answers achieving scores of 76%. When looking at simply “pass” versus “fail” rates - there was a statistically higher percentage of control group participants that passed (control group 84.6% passing versus 56% of the intervention; \( p = 0.04 \)).

Although statistically significant, this finding must be carefully interpreted in light of the cut-point threshold for passing the exam. Although the intervention group had a statistically significant lower pass rate for the HBB® MCQ measure at baseline, the differences between mean scores is one question. Therefore, “failing” participants were on the cusp of the pass threshold, and the median scores were similar as well, suggesting that the groups’ baseline knowledge was similar as illustrated in Figure 5.

Table 3

*Research Question 1— Comparisons of Baseline Resuscitation Knowledge as Measured by Scores on the HBB® Multiple Choice Test*

<table>
<thead>
<tr>
<th></th>
<th>All</th>
<th>Intervention</th>
<th>Control</th>
<th>Statistical Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N=51</td>
<td>( n = 25 )</td>
<td>( n = 26 )</td>
<td></td>
</tr>
<tr>
<td>Mean Score</td>
<td>14</td>
<td>13.5</td>
<td>14.5</td>
<td>( t = 2.06 )</td>
</tr>
<tr>
<td>( SD )</td>
<td>(1.8)</td>
<td>(1.8)</td>
<td>(1.4)</td>
<td>( p = 0.04 )</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Cohen's ( d = 0.58 )</td>
</tr>
<tr>
<td>Median Score</td>
<td>14</td>
<td>14</td>
<td>15</td>
<td>Wilcoxon test</td>
</tr>
<tr>
<td>Range</td>
<td>(9,17)</td>
<td>(9,17)</td>
<td>(11,16)</td>
<td>( p = 0.04 )</td>
</tr>
<tr>
<td>% Pass</td>
<td>70.6%</td>
<td>56%</td>
<td>84.6%</td>
<td>( \chi^2 = 5.03 )</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>( p = 0.03 )</td>
</tr>
</tbody>
</table>

Note: Passing scores are defined as greater than or equal to 80%; failing scores are defined as less than or equal to 79%.
Figure 5. Note the distribution of the HBB® MCQ test at baseline in the control group versus the intervention group; the mean and median scores are nearly identical; additionally, both have similar ranges.

Further analysis of the HBB® MCQ Test, comparing by group (all, intervention and control) and analyzing by item, is presented in Table 4. Questions 1, 3, 15, and 16 were answered with 100% accuracy by both intervention and control groups. Question 6, related to timing of clamping the umbilical cord, had the lowest pass rate in both groups (intervention 12%; control 0%). Questions related to the appropriate response to an infant who is not breathing (Question 7) and proper BMV technique (Question 11) also had low pass rates as well.
### Table 4

#### Research Question 1—Comparisons of Baseline Resuscitation Knowledge as Measured by Scores on the HBB® Multiple Choice Test Analyzed by Item and By Group

<table>
<thead>
<tr>
<th>Question Number / Content Focus</th>
<th>All N=51</th>
<th>Intervention n = 25</th>
<th>Control n = 26</th>
<th>Statistical Significance</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Priorities in the first minute of life.</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Preparation for birth and emergency planning.</td>
<td>94.1%</td>
<td>92%</td>
<td>96.2%</td>
<td>$\chi^2 = 0.40$</td>
<td>p = 0.53</td>
</tr>
<tr>
<td>3. Preparation for birth: environment.</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Baby can receive routine care.</td>
<td>94.1%</td>
<td>88%</td>
<td>100%</td>
<td>$\chi^2 = 3.32$</td>
<td>p = 0.07</td>
</tr>
<tr>
<td>5. Thermoregulation strategies.</td>
<td>92.2%</td>
<td>84%</td>
<td>100%</td>
<td>$\chi^2 = 4.51$</td>
<td>p = 0.03*</td>
</tr>
<tr>
<td>6. Timing of umbilical cord clamping.</td>
<td>5.9%</td>
<td>12%</td>
<td>0%</td>
<td>$\chi^2 = 3.32$</td>
<td>p = 0.07</td>
</tr>
<tr>
<td>7. Response to limp and apneic baby.</td>
<td>37.2%</td>
<td>32%</td>
<td>42.3%</td>
<td>$\chi^2 = 0.58$</td>
<td>p = 0.45</td>
</tr>
<tr>
<td>8. Response to baby with meconium stained fluid.</td>
<td>58.8%</td>
<td>64%</td>
<td>53.8%</td>
<td>$\chi^2 = 0.54$</td>
<td>p = 0.46</td>
</tr>
<tr>
<td>9. Establish breathing during the golden minute.</td>
<td>90.2%</td>
<td>92%</td>
<td>88.5%</td>
<td>$\chi^2 = 0.18$</td>
<td>p = 0.67</td>
</tr>
<tr>
<td>10. Begin ventilation in a depressed baby.</td>
<td>92.2%</td>
<td>88%</td>
<td>96.2%</td>
<td>$\chi^2 = 1.17$</td>
<td>p = 0.28</td>
</tr>
<tr>
<td>11. Proper bag and mask technique.</td>
<td>66.7%</td>
<td>44.0%</td>
<td>88.5%</td>
<td>$\chi^2 = 11.34$</td>
<td>p &lt; 0.001*</td>
</tr>
<tr>
<td>12. Ongoing monitoring of breathing during the first few hours of life.</td>
<td>96.1%</td>
<td>100%</td>
<td>92.3%</td>
<td>$\chi^2 = 2.00$</td>
<td>p = 0.16</td>
</tr>
<tr>
<td>13. BMV corrective maneuvers.</td>
<td>96.1%</td>
<td>96.0%</td>
<td>96.2%</td>
<td>$\chi^2 = 0.00$</td>
<td>p = 0.98</td>
</tr>
<tr>
<td>14. When to stop BMV.</td>
<td>88.2%</td>
<td>80%</td>
<td>96.2%</td>
<td>$\chi^2 = 3.20$</td>
<td>p = 0.07</td>
</tr>
<tr>
<td>15. Thermoregulation: skin-to-skin.</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>16. Hygiene / cleanliness.</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>17. Normal newborn heart rate.</td>
<td>88.2%</td>
<td>80%</td>
<td>96.2%</td>
<td>$\chi^2 = 3.20$</td>
<td>p = 0.07</td>
</tr>
</tbody>
</table>

* Statistical significance noted.
RQ2. In healthcare providers (HCPs) who routinely attend deliveries in Zambia at baseline: Do healthcare providers demonstrate BMV competency?

Bag-mask ventilation competency of HCPs in a simulated setting was measured using the videotaped HBB® Bag-Mask Ventilation Objective Structured Clinical Examination, adapted from the HBB® BMV skill checklist. Inter-rater reliability was evaluated using 25 videos evaluated by two raters. Rater 1 had a mean score of 2.2 (SD 1.6) compared to rater 2 with a mean score of 2.6 (SD 1.6). For the BMV score, a 2-way mixed model effects Intraclass Correlation Coefficient (ICC) was performed; subjects were randomly assigned to fixed coders evaluating for absolute agreement. The ICC was 0.77, which met our a-priori determination for inter-rater reliability (Hallgren, 2012). Inter-rater reliability for the global competency score (a dichotomous variable) was evaluated using a Kappa score.

The mean, median, range and percent HBB® BMV OSCE scores passed were reported at baseline for the entire cohort. Additionally, each specific element of resuscitation psychomotor competency was analyzed and reported by percent passed by item. Table 5 provides the baseline resuscitation psychomotor competency as measured by the 7-item HBB® BMV OSCE. Overall study participants had low scores on the baseline HBB® BMV competency testing; none of the participants tested demonstrated competency in this simulated testing situation at baseline. Although the scores ranged from 0 to 6, the mean and
median scores at baseline (2.5) were well below the pass threshold of 7 for this test.

Table 5

Research Question 2 — Baseline Resuscitation Psychomotor Competency Measured by Bag-Mask Ventilation OSCE

<table>
<thead>
<tr>
<th></th>
<th>All N=46</th>
<th>Intervention n=25</th>
<th>Control n=21</th>
<th>Statistical Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean Score</td>
<td>2.5 (1.7)</td>
<td>2.8 (1.6)</td>
<td>2.2 (1.8)</td>
<td>t = 1.22</td>
</tr>
<tr>
<td>SD</td>
<td></td>
<td></td>
<td></td>
<td>p = 0.23</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Cohen’s d = 0.36</td>
</tr>
<tr>
<td>Median Score</td>
<td>2.5 (1.6)</td>
<td>3 (0, 6)</td>
<td>2 (0, 6)</td>
<td>Wilcoxon test</td>
</tr>
<tr>
<td>Range</td>
<td></td>
<td></td>
<td></td>
<td>p = 0.25</td>
</tr>
<tr>
<td>% Pass</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
<td>χ² = 5.03</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>p = 0.03</td>
</tr>
</tbody>
</table>

* Control group n = 21 due to the number of analyzable BMV videos at baseline for the control group.

A by-item assessment of resuscitation psychomotor competency as measured by HBB® BMV OSCE at baseline, was performed and compared by group. Items with consistently extremely low scores included item 1 (checking equipment), item 2 (ability to achieve a seal with the mask), item 3 (ventilating at the proper rate) and item 4 (BMV corrective maneuvers; specifically clears secretions, opens the mouth).
### Table 6

**Research Question 2 — Resuscitation Psychomotor Competency as Measured by BMV OSCE at Baseline (% Pass) All and By Group**

<table>
<thead>
<tr>
<th>Item</th>
<th>All (N= 46)</th>
<th>Intervention (n = 25)</th>
<th>Control (n = 21)</th>
<th>Statistical Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Checks equipment / selects correct mask.</td>
<td>13%</td>
<td>12%</td>
<td>14.3%</td>
<td>$\chi^2 = 0.05$</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>$p = 0.82$</td>
</tr>
<tr>
<td>2. Applies the mask to make a firm seal.</td>
<td>34.8%</td>
<td>32%</td>
<td>38.1%</td>
<td>$\chi^2 = 0.19$</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>$p = 0.67$</td>
</tr>
<tr>
<td>3. Ventilates at 30 to 50 breaths-per-minute.</td>
<td>10.9%</td>
<td>0.0%</td>
<td>23.8%</td>
<td>$\chi^2 = 6.68$</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>$p = 0.01$</td>
</tr>
<tr>
<td>4. Looks for chest movement.</td>
<td>65.2%</td>
<td>68%</td>
<td>61.9%</td>
<td>$\chi^2 = 0.19$</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>$p = 0.67$</td>
</tr>
<tr>
<td>5. Improves ventilation: re-applies the mask.</td>
<td>65.2%</td>
<td>80%</td>
<td>47.6%</td>
<td>$\chi^2 = 5.28$</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>$p = 0.02$</td>
</tr>
<tr>
<td>6. Improves ventilation: clear secretions / opens the mouth.</td>
<td>21.7%</td>
<td>28%</td>
<td>14.3%</td>
<td>$\chi^2 = 1.26$</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>$p = 0.26$</td>
</tr>
<tr>
<td>7. Improves ventilation: squeezes the bag harder.</td>
<td>45.7%</td>
<td>60%</td>
<td>28.6%</td>
<td>$\chi^2 = 4.54$</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>$p = 0.03$</td>
</tr>
<tr>
<td>% Pass</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
<td>$\chi^2 = 5.03$</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>$p = 0.03$</td>
</tr>
<tr>
<td>Global Assessment</td>
<td>30.4%</td>
<td>36%</td>
<td>23.8%</td>
<td>$\chi^2 = 0.80$</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>$p = 0.37$</td>
</tr>
<tr>
<td>% Coded as “Potentially Dangerous Practices”</td>
<td>34.8%</td>
<td>40%</td>
<td>28.6%</td>
<td>$\chi^2 = 0.66$</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>$p = 0.42$</td>
</tr>
</tbody>
</table>

**Global Assessment of Competency and Dangerous Practices**

In addition to the item-by-item scoring method, videotape raters were asked to provide a “global assessment” of BMV competency as an exploratory concept. Global assessments (GAs) are “gestalt” impressions of performance by
an experienced rater, with content-specific expertise in the area of assessment (Spillane, Hayden, Adler, Beeson, Goyal & Smith-Coggins, et al., 2008). Although the term “global rating scales” has been used in the literature to describe both holistic and analytical scales, in our study the global competency pass / fail was performed after detailed scoring with a criterion-based scale. It was possible to fail the criterion-based scale and receive a “pass” on the global competency score. The “global competency” results were higher; 30.4% were deemed “competent” using the global competency measure, versus 0% deemed competent using the HBB® BMV OSCE scores, derived by considering individual items on the criterion-based rating scale. The Inter-rater reliability for this measure was low (Kappa 0.23; p = 0.21).

Videotape raters were also asked to code for atypical or potentially dangerous resuscitation practices, defined as shaking, slapping, aggressive stimulation, overall rough handling, head compression, and a non-specific category (other). In total, these potentially dangerous practices were described in 34.8% of the sample videotapes at baseline. The IRR for this measure was low (Kappa 0.27; p = 0.14). To affirm the presence or absence of dangerous practices, the PI reviewed each of the videotapes with dangerous practice coding, and affirmed that indeed, atypical, or potentially dangerous practice(s) were coded appropriately by both raters, despite the low Kappa score achieved.

Some of the practices described as “other” included long delays in initiating or attempting mechanical ventilation (4, 5 and up to 6 minutes), while the participant was rearranging equipment and/or clamping and cutting the cord.
A common theme was incorrect use of the hand-held suction device (squirting into the mouth rather than applying suction to remove secretions), and/or excessive deep suctioning in the posterior pharynx. Other interventions or atypical practices included hanging the baby upside down by the feet, while aggressively slapping the buttocks or feet, or holding the infant upright and shaking aggressively.

Some participants performed “plunger like” movements with the self-inflating device mask on the face, both demonstrating excessive force and head compression, as well as interrupting the mask’s seal with each action, and precluding effective BMV. Others placed the mask intentionally over the mouth verbally stating that they would avoid placement over the nose, while others placed the mask directly over the eyes and nose, using significant force, and leaving the mouth uncovered.

A small number of videos revealed the use of cardiac compressions as a first-line response, before or without any attempts at ventilation. Recordings showed a variety of atypical cardiac compression techniques (three finger method, very deep thrusting actions, and in some cases very gentle “massage” over the heart, as well as one instance of dramatic sub-diaphragmatic or abdominal thrusts).
Statistical Analysis of RQ 3

In healthcare providers (HCPs) who routinely attend deliveries in low-resource settings who have received the HBB® training (intervention group):

Did HCPs demonstrate increased knowledge about newborn resuscitation when compared to control group participants at 1 and 3 months?

A total of 141 of a possible 156 HBB® MCQ tests were returned and analyzed for the three time periods, 46% from the intervention group and 54% from the control group, representing a 90% overall completion rate for this measure. To identify any potential effect of the HBB® training intervention on knowledge, a repeated-measures mixed-model ANOVA was conducted comparing the HBB® MCQ scores between subjects (control versus intervention) and within subjects (changes in scores over time; at baseline, one month, 3 months) on the mean knowledge score. Least Squares Adjusted Means were used to compensate for missing data at each interval (Table 7).
### Table 7

Research Question 3 — *Influence of HBB® on Knowledge Over Time Between Groups Analysis Using Repeated Measures*

<table>
<thead>
<tr>
<th></th>
<th>Intervention</th>
<th>Control</th>
<th>ANOVA</th>
<th>Statistical Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Baseline</strong></td>
<td>13.5 (0.3)</td>
<td>14.5 (0.3)</td>
<td>$F(1,50) = 4.32$</td>
<td>$p = 0.04$</td>
</tr>
<tr>
<td><strong>1 month</strong></td>
<td>15.9 (0.3)</td>
<td>13.7 (0.3)</td>
<td>$F(1,50) = 24.40$</td>
<td>$p &lt; 0.001$</td>
</tr>
<tr>
<td><strong>3 months</strong></td>
<td>16.6 (0.2)</td>
<td>14.7 (0.2)</td>
<td>$F(1,50) = 40.09$</td>
<td>$p &lt; 0.001$</td>
</tr>
</tbody>
</table>

Least squares adjusted means and standard errors (SE)

**Figure 6.** Influence of HBB® on knowledge (MCQ scores) over time between groups analyzed using repeated measures. Differences are statistically significant at each observation; $p = 0.04$ at baseline; $p < 0.001$ at 1 month; $p < 0.001$ at 3 months.
Table 8

Research Question 3 — Mixed-Model Analysis of Variance For HBB® MCQ Total Score

<table>
<thead>
<tr>
<th>Source</th>
<th>df</th>
<th>F</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group Assignment</td>
<td>1, 50</td>
<td>13.62</td>
<td>p &lt; 0.001</td>
</tr>
<tr>
<td>Time</td>
<td>2, 50</td>
<td>28.36</td>
<td>p &lt; 0.001</td>
</tr>
<tr>
<td>Group X Time</td>
<td>2, 50</td>
<td>20.76</td>
<td>p &lt; 0.001</td>
</tr>
</tbody>
</table>

Note: Mixed-model analysis of variance was used because of missing data over time.

Effect of Group Assignment on HBB® MCQ Scores

There was a statistically significant effect of group assignment on knowledge (HBB® MCQ scores), $F(1,50) = 13.62$, $p = <0.001$. See Table 8 for the comparisons; the intervention group, which had a higher baseline level of education, initially had slightly lower knowledge scores. However, the intervention group’s knowledge scores increased post-intervention and over time while the control group’s scores remained flat.

Effect of Time and Group by Time on HBB® MCQ Scores

We hypothesized that there could be a degradation of knowledge over time. There was a statistically significant effect of time on knowledge (HBB® MCQ scores), $F(2,50) = 28.36$, $p = <0.001$. However, the scores for the intervention group appeared to rise rather than decline over the study period, compared to the stability of the control group scores as illustrated in Table 7 and Figure 6. There was also a statistically significant effect of group and time on knowledge (HBB® MCQ scores), $F(2,50) = 20.76$, $p = <0.001$, indicating that both group assignment and time impacted the HBB® MCQ Scores.
Secondary Exploratory Analysis / Resuscitation Knowledge

A secondary exploratory analysis for relevant covariates, such as actual use of the HBB® (reported in the exposure survey) as well as any influence of baseline role, education and years of experience was planned a priori; however, given the small sample size these data have been interpreted with caution.

Although we believe that the actual exposure to opportunities to use resuscitation skills may be an important contributor to either knowledge or BMV competency (Appendix 2) we were unsuccessful in evaluating for this variable due to the extremely inconsistent administration of this instrument in the field. Further, an analysis examining the baseline influence of differing professional roles (physician versus nurse) was not possible given the preponderance of nurses in our sample (85%).

Despite the fact that the subjects were predominantly nurses and midwives (85%) there was an unexpected and statistically significant difference between the educational levels of the control and the intervention group at baseline ($p < 0.001$). This may be a function of geography, as a portion of the intervention group participants came from the metropolitan center (Lusaka), while the control participants, who came from Mazumbuka, had lower educational levels (secondary school versus university training). We were unable to explore education as a covariate because of the markedly unequal distribution of education between the two groups.
Statistical Analysis of Research Question 4

RQ 4. Do intervention group participants demonstrate improved BMV psychomotor skills when compared to control group participants at 1 and 3 months?

In an attempt to understand the available data, we did a preliminary analysis of the intervention group only, in whom an immediate post-test measure was performed (Table 9). We do not have parallel data for the control group as a comparison at this interval. The post-test scores revealed statistically significant improvements in all seven discrete items of the BMV OSCE immediately after the educational intervention. Additionally the mean BMV OSCE scores increased from pretest scores of 2.8 (SD 1.6) to post-test scores of 5.8 (SD 1; \( p < 0.001 \)). Competency (defined by a passing score of 7) was not achieved by participants in the immediate post-training testing; however, the global assessment of competency increased from 30.4% to 91.3% (\( p < 0.001 \)). The percentage of dangerous practices observed was 44% in the pretest measure and 35% in the post-test measure (\( p = 0.56 \)).
Table 9

*Resuscitation Psychomotor Competency as Measured by HBB® BMV OSCE at Baseline Versus Intervention Group Only Post-Test*

<table>
<thead>
<tr>
<th>Item</th>
<th>Baseline % Pass n = 23</th>
<th>Post-Test % Pass n = 23</th>
<th>Statistical Significance</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Checks equipment / selects correct mask.</td>
<td>13 %</td>
<td>56.5%</td>
<td>McNemar S = 8.33</td>
<td>p = 0.004*</td>
</tr>
<tr>
<td>2. Applies the mask to make a firm seal.</td>
<td>26.1%</td>
<td>91.3%</td>
<td>McNemar S = 15.00</td>
<td>p &lt; 0.001*</td>
</tr>
<tr>
<td>3. Ventilates at 30 to 50 breaths-per-minute.</td>
<td>0%</td>
<td>52.2%</td>
<td>NA</td>
<td></td>
</tr>
<tr>
<td>4. Looks for chest movement.</td>
<td>65.2%</td>
<td>95.7%</td>
<td>McNemar S = 5.44</td>
<td>p = 0.02*</td>
</tr>
<tr>
<td>5. Improves ventilation: reapplies the mask.</td>
<td>82.6%</td>
<td>100%</td>
<td>NA</td>
<td></td>
</tr>
<tr>
<td>6. Improves ventilation: clear secretions / opens the mouth.</td>
<td>30.4%</td>
<td>91.3%</td>
<td>McNemar S = 14.00</td>
<td>p &lt; 0.001*</td>
</tr>
<tr>
<td>7. Improves ventilation: squeezes the bag harder.</td>
<td>56.5%</td>
<td>91.3%</td>
<td>McNemar S = 5.33</td>
<td>p = 0.02*</td>
</tr>
<tr>
<td>Global Assessment</td>
<td>30.4%</td>
<td>91.3%</td>
<td>McNemar S = 12.25</td>
<td>p &lt; 0.001*</td>
</tr>
<tr>
<td>% with Dangerous Practice</td>
<td>43.5%</td>
<td>34.8%</td>
<td>McNemar S = 0.33</td>
<td>p = 0.56</td>
</tr>
<tr>
<td>Total Mean Score (SD)</td>
<td>2.8 (1.6)</td>
<td>5.8 (1.0)</td>
<td>Paired t = 7.52 Cohen's d = 1.57</td>
<td>p &lt; 0.001*</td>
</tr>
</tbody>
</table>

*Statistical significance demonstrated.

We were unable to answer Research Question 4, a comparison of intervention versus control participants at 1 and 3 months, with confidence, largely due to missing or unusable BMV videotapes over the course of the study in the intervention group, and most notably at Observation 3.
See Table 10 for the ANOVA results; there was no difference at baseline with equivalent group sizes. There was a trend towards improvement at 1 month; however, it was not statistically significant. Interpretation of the 3-month data must be approached with caution, given the extremely small sample at the 3-month follow-up in the intervention group. Of note, one participant from the intervention group did achieve a score of 7 (competency) at 1 month; a second participant achieved a score of 7 at 3 months. Of the participants with usable videotape at 3 months, no participant achieved competency and sustained it. Scores in the control group were stable over time and scores do not appear to increase in relationship to repeated exposures to the BMV OSCE or testing conditions.

Table 10

Research Questions 4 / 5 — Influence of HBB® on Psychomotor Skills Over Time Between Groups Analysis Using Repeated Measures ANOVA

<table>
<thead>
<tr>
<th></th>
<th>Intervention Mean (SE)</th>
<th>Control Mean (SE)</th>
<th>Statistical Significance</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>n=25 2.5 (0.4)</td>
<td>n=21 2.1 (0.4)</td>
<td>F (1,49) = 0.52</td>
<td>p = 0.48</td>
</tr>
<tr>
<td>1 month</td>
<td>n=18 4.6 (0.6)</td>
<td>n=22 3.3 (0.5)</td>
<td>F (1,49) = 3.03</td>
<td>p = 0.09</td>
</tr>
<tr>
<td>3 months</td>
<td>n=9 5.2 (0.6)</td>
<td>n=23 2.8 (0.4)</td>
<td>F (1,49) = 12.60</td>
<td>p &lt; 0.001</td>
</tr>
</tbody>
</table>

Least Squares Adjusted Means and (standard errors)
n = number of usable videos
EFFECTIVENESS OF HELPING BABIES BREATHE®

**Figure 7.** Influence of HBB® on mean BMV scores over time between groups analyzed using repeated measures. Note: Diminishing n’s in the intervention group (n=25 at baseline; n=18 at 1 month and n=9 at 3 months. The stability of the data from the control group (n= 21 baseline; n= 22 1 month; and n = 23 at 3 months) suggests that BMV scores are stable.

<table>
<thead>
<tr>
<th>Question</th>
<th>Intervention</th>
<th>Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Month</td>
<td>1.5</td>
<td>0.5</td>
</tr>
<tr>
<td>3 Months</td>
<td>2.5</td>
<td>1.5</td>
</tr>
</tbody>
</table>

**Table 11 Research Questions 4 / 5 — Influence of HBB® on Psychomotor Skills Over Time Between Groups Analyzed Using Repeated Measures ANOVA**

<table>
<thead>
<tr>
<th>Source</th>
<th>df</th>
<th>F</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group Assignment</td>
<td>1, 49</td>
<td>11.22</td>
<td>p = 0.002</td>
</tr>
<tr>
<td>Time</td>
<td>2, 49</td>
<td>9.18</td>
<td>p &lt; 0.001</td>
</tr>
<tr>
<td>Group X Time</td>
<td>2, 49</td>
<td>2.89</td>
<td>p = 0.065</td>
</tr>
</tbody>
</table>

Mixed model analysis of variance was used because of missing data over time.

**Statistical Analysis of Research Question 5**

**RQ 5. Do intervention group participants achieve increased rates of BMV competency, compared to control group participants?**

We were unable to answer this research question with confidence, due to challenges with missing or corrupted HBB® BMV videotapes over the course of the study, as outlined above. However, we can say, in those subjects for whom we have videotaped measures, although the mean scores increased from 2.8 at
baseline to 5.8 in the post-test period ($p = 0.01$), and were 4.6 at 1 month and 5.2 at 3 months. Only 2 participants ever demonstrated competency over the 3 testing situations. Both of these were from the intervention group, and it is important to note that competent scores were not sustained.

**Feasibility Considerations**

In the current study a number of data collection challenges and feasibility issues were encountered. The primary challenges we encountered were the number of corrupt and/or missing videos. A complete overview of these challenges will be provided in Chapter 5 with a robust discussion of implications for future research.

**Summary**

This prospective, longitudinal, quasi-experimental study with a control group hold-back design evaluated the effect of a structured educational curriculum and training program (HBB®) designed for implementation in low-resource settings in the developing world, on resuscitation knowledge and psychomotor skills of healthcare providers who routinely attend births in Zambia. The sample was comprised primarily of Zambian nurses (85%); clinical officers, medical licentiates, and physicians accounted for the remaining 15%. The participants were linguistically diverse and self-reported English proficiency using a standard measure.

Despite a median of 8 years of experience, and the fact that 26% of the sample had been exposed to some resuscitation training, the levels of baseline newborn resuscitation knowledge were low with pass rates on the knowledge
measure of 70% (N=52). One specific MCQ item, related to timing of clamping the umbilical cord, had the lowest pass rate in both groups (intervention 12%; control 0%). Questions related to the appropriate response to an infant who is not breathing (Question 7) and proper BMV technique (Question 11) also had low pass rates suggesting potential knowledge deficits that could impact both the recognition and treatment of infants with perinatal depression and asphyxia. Baseline measures of psychomotor competency and BMV have rarely been obtained or reported in the literature. This study contributes important baseline data, and highlights that in addition to knowledge deficits, participants also had extremely low psychomotor skill scores, as measured by scores on the baseline HBB® BMV competency testing. Although the baselines HBB® BMV scores ranged from 0 to 6, the scores in both groups (Intervention M=2.8; Control M=3) were extremely low compared to the pass threshold of 7 for the test. None of the participants tested demonstrated competency at baseline in this simulated testing situation.

In terms of achieving BMV competency, in those subjects for which we have videotaped measures, although the mean scores increased from 2.8 at baseline to 5.8 in intervention group, in the post-test period ($p = 0.01$) and remained higher than baseline (4.6 at 1 months and 5.2 at three months), competency was not uniformly achieved. Only 2 participants ever demonstrated competency over the 3 testing situations. Both of these were from the intervention group, and it is important to note that competent scores were not consistent or sustained.
The novel use of videotaped HBB® BMV OSCEs allowed us to demonstrate IRR (ICC of 0.77) and provides a methodology for more objective evaluations of BMV skills. Further, the use of videotaped simulations revealed some unexpected findings including atypical and potentially dangerous resuscitation practices that have not previously been well detailed or described.

Exposure to the HBB® intervention did result in improved knowledge and psychomotor skills. There was a statistically significant effect of group assignment on knowledge (HBB® MCQ scores), $F(1,50) = 13.62, p = <0.001$. We postulated that there could be a degradation of knowledge (HBB® MCQ scores) over time. There was a statistically significant effect of time on knowledge (HBB® MCQ scores), $F(2,50) = 28.36, p = <0.001$. However, the scores for the intervention group appeared to rise rather than decline over the study period, compared to stable scores in the control group. There was a statistically significant effect of group and time on knowledge (HBB® MCQ scores), $F(2,50) = 20.76, p = <0.001$. These data suggest some stability of knowledge gains during the 3-month duration of the study.

We were unable to answer Research Question 4, a comparison of intervention versus control participants at 1 and 3 months, with confidence, largely due to missing and/or corrupted BMV videotapes over the course of the study in the intervention group, and most notably at Observation 3. The ANOVA shows no differences at baseline with equivalent group sizes. There was a trend towards improvement at 1 month, which was not statistically significant.
Chapter Five

Discussion

The purpose of this prospective, longitudinal, quasi-experimental study with a control group hold-back design was to evaluate the effect of a structured educational curriculum and training program designed for use in low resource settings (HBB®), on resuscitation knowledge and psychomotor skills of healthcare providers who routinely attend births in Zambia. A discussion of the findings of this study, in the context of the existing literature follows.

Sample

Gender, Professional Role and Years in Practice

The sample (N=52) was comprised primarily of Zambian nurses (85%); clinical officers, medical licentiates, and physicians accounted for the remaining 15%. They self-reported that they routinely attend births and encounter distressed and depressed newborns in their practice. They have been practicing for a mean of 8 years.

Formal Education

The level of formal education in our sample was consistent with that of trained HCPs in Zambia. Although the level of formal education was higher in the intervention group than the control group, higher levels of education were not associated with improved knowledge or psychomotor skills at baseline in our study. Our study did not include any traditional or skilled home birth attendants; this is an important deficiency, given that TBAs / SBAs attend the majority of births in Zambia and a national initiative to increase the use of community health
workers to address the human resource crisis is underway (Zambian Global Health Initiative Strategy, 2012). Less than half of home birth attendants in the developing world at large are literate; 80% have one month or less of formal training. Additionally, most do not have the basic equipment (e.g., blood pressure apparatus, stethoscope, infant bag and mask manual resuscitator) and or a mechanism to call for backup and assistance. Reporting of births as well as maternal and neonatal deaths to government agencies remains very low in births attended by TBAs or SBAs, further contributing to inaccurate estimates (likely significant underestimates) of neonatal mortality (Garces *et al.*, 2012).

When designing and delivering educational interventions such as HBB® to a global audience with a wide range of roles and skills, it is important to consider that TBAs / SBAs likely have lower rates of formal education, literacy, and, potentially lower rates of English proficiency. These factors may influence both the baseline knowledge and skills, but also the response to and effect size of HBB® or other training programs. There may also be important regional or tribal specific cultural beliefs, and/or differences in birth practices that have the potential to influence the cultural acceptability of resuscitation programs. These beliefs may be more prevalent in birth attendants with less formal education (Maimbolwa *et al.*, 2003).
Language and English Proficiency

Despite the fact that the participants spoke a total of 23 languages, they had high self-reported levels of English proficiency. English, introduced during Zambian colonization, was declared the national language in 1964, and has served as a common language among educated Zambians and healthcare providers. Zambians often learn a native language first - referred to as their “mother tongue”; therefore, English is the first language of only 2% of Zambians.

Our sample was representative of the culturally and linguistically diverse population of Zambia, which has seven officially designated languages and over 70 languages and dialects. The major languages are linked to tribal lineages and are geographically based and include: Bemba (Northern province, Luapula, Muchinga and the Copperbelt), Nyanja (Eastern province and Lusaka), Lozi (Western province), Tonga (Southern province), and Kaonde, Luvale, and Lunda (Northwestern province). The seven official languages are used in conjunction with English, in early primary schooling and in some government publications.

Given this context, establishment of English proficiency was important in our study, to assure that the participants have the English skills to fully comprehend this training program. We were unable to compare the English proficiency of our sample to others, given that none of the NRP™ or HBB® studies to date have reported on this important variable.

Prior Exposure to Resuscitation Training

Prior exposure to resuscitation training may influence baseline or new acquisition of knowledge and skills from the HBB® program. We excluded HCPs
who had been recently exposed to resuscitation education or training (defined as in the prior 6 months). In the current study 26 to 28% of the sample had prior exposure to some form of resuscitation training in a time period > 6 months; notably, 21% of the sample had either NRP™ and/or the WHO Essential Newborn Care (ENBC) training. However, we were struck by the overall low rate of resuscitation training, data that further illustrates the novel nature of resuscitation training and the magnitude of unmet needs in Zambia. Our sample had higher baseline levels of resuscitation training, nearly double those rates reported by others. Wall et al. (2010) reported that even when births occur in health facilities, rather than at home, only 2 to 12% of the personnel conducting the deliveries have been trained in newborn resuscitation. The low albeit higher rates in our Zambian population may reflect recent efforts of the Ministry of Health and others to improve newborn resuscitation capacity.

The critical issue of the stability or durability of resuscitation knowledge and skills over time must be considered in light of the baseline group characteristics. The control group had a statistically significant higher baseline rate of exposure to resuscitation training; however, they did not score higher on measures of knowledge or psychomotor skills. This highlights the well-documented concerns in the literature regarding stability of knowledge and skills from prior resuscitation programs, and raises the issue of timing of appropriate retraining in the future.

There is a paucity of good quality evidence to guide the timing for recertification for both CPR and NRP™ training programs used in the developed
world. The most recent study from the UK (Mosley & Shaw 2014) suggests that when tested in a simulated environment, resuscitation skills deteriorate within a 3 to 5-month period. Furthermore, providers who pass or fail testing often have equal levels of confidence in their resuscitation capabilities, suggesting a lack of insight into their performance. Similar results were found in an 8-year longitudinal assessment of neonatal medical trainees (Cusak & Fawke, 2012). Even less is known about the stability of knowledge and skills in low resource settings in the developing world.

**Baseline Knowledge**

The pass rate for the HBB® Multiple Choice Test (knowledge measure) was 70% overall. There were minimal differences in the mean and median scores in both groups. The statistically significant difference in the baseline pass rate for the intervention group (56%) versus the control group (84.6%) is likely a function of the small number of items on the test (17) coupled with the clustering of test scores at or near the cut-point threshold for the test. This result may be statistically, but not clinically significant because it is unlikely that improved performance on a singular question would translate into clinically important improvements in outcomes. In summary, the baseline knowledge, as measured by this examination, was similar between both groups in our study. However, if an advantage existed, it was conferred to the control group.

To the author’s knowledge, beyond initial field testing, and despite the widespread use, no formal psychometrics have been performed or published on the HBB® MCQ test. A recent study from India evaluating HBB® reported much
lower participant baseline mean scores (46% vs. our sample mean of 70.6%) and reported high post-test scores of 88.6%. Notably, in the Goudar et al. (2013) study, providers who had been trained in the prior year, and who elected to attend an HBB® “refresher” course, had baseline scores of 69%, almost identical to our HBB® novel sample at baseline. Low baseline scores in this refresher group, amplify the concern for the stability and/or retention of resuscitation knowledge over time. Of note, the refresher course participants did demonstrate larger gains in scores than those who attended the program for the first time (90.4%), (Goudar, et al., 2013).

**Varying “Doses” of the HBB® Educational Intervention**

When comparing results of HBB® studies it is important to consider the “dose” of the educational intervention, which varies widely in the published literature. The first report from Singhal et al. (2012) was a training consisting of 1.5 days; a total of 6 hours was spent on instruction and 4 hours in pre- and post-test evaluations, resulting in a total of 10 hours of exposure. The Goudar et al. (2013) study reports a 2-day training for the master trainers, and a 2-day training for the providers; however, they do not provide a breakdown of the time spent in instruction versus testing or detail in hours spent on each day. Our study intervention included content for both the HBB® provider and master trainer level; it was both a larger “dose and duration” of education. Our Zambian participants spent a total of 2.5 days, with 12.5 hours of instruction and 4 hours of testing (total exposure to the intervention was 16.5 hours).
Variations in both the dose of education (time spent in instruction), as well as the quality of the instruction, are potentially important variables for consideration. The clinical and educational skills of the HBB® Master Trainers who conduct the courses, may influence outcomes. Of particular concern, are the studies employing rapid sequence train-the-trainer rollouts; often there does not appear to be a formalized mechanism to establish that the trainers themselves had mastery of BMV and key course concepts, as a prerequisite to teach future courses.

**Exploration of Potential Cultural Influences**

The majority of the published papers failed to explicitly discuss potential cultural influences in the design and delivery of structured educational curriculums in globally based low resource settings. Childbirth is deeply rooted in culture and tradition, and practice variations are the norm (Lewallen, 2010). In the developing world, there may be some local or regional contextual differences that are culturally based and/or health-related, that must be carefully considered when evaluating performance on the HBB® MCQ testing. It may be possible that “incorrect” answers to questions represent differences in culture and/or tradition.

One example of a common birth practice with cultural implications, cord clamping, emerged in our study. The timing of umbilical cord clamping remains controversial both in the developed and developing world (Raju & Singhal, 2014). The HBB® MCQ question about when to clamp the cord (Question 6) had extremely low pass rates (5.9% overall; 12% in the intervention vs. 0% in the
The proper timing of cord clamping was a point of significant controversy in on-site discussions during the training sessions as well.

Anecdotally the Zambian HCPs who attended the HBB® training reported that standard local teaching emphasizes that the umbilical cord should be clamped immediately after birth, in an effort to limit any potential transfer of the Human Immunodeficiency Virus (HIV) from the mother to the infant. HIV transmission is a serious concern Zambia, where HIV rates are extremely high (12.5% overall, 28% in the Lusaka District). Compounding this challenge, access to antiretroviral therapy is variable and inconsistently prescribed. A recent report by Viveo et al. (2010) of active management of the third stage of labor, stated that Zambian midwives “have concerns about risks of maternal to newborn HIV blood transfusion; it is doubtful that they will adopt the currently recommended practice of delayed cord clamping and cutting.”

The practice of early cord clamping is not consistent with the current WHO recommendations that state that delayed cord clamping is safe, even within the context of endemic rates of HIV (Raju & Singhal, 2013). We also could not find data to support rapid cord clamping as an effective strategy to limit mother to infant HIV transfer at birth, and our local co-investigator, an obstetrician and researcher deeply immersed in the field of HIV could not confirm or refute this practice (Personal communication, Moses Sinkala). As evidenced by the answers to the cord clamping question, rapid clamping was an almost universally held local belief, and at a minimum, the biologic plausibility for HIV transmission
exits. This presented a dilemma to the HBB® faculty team, who were reluctant to usurp local context-specific, best practice norms without clear evidence of harm.

We believe that this local tradition and context may have affected the HBB® MCQ scores at baseline. We also documented that the focus on cord clamping, commonly prioritized in the care sequence over helping the baby initiate breathing, led to delays in initiating BMV during the first minute of life on the videotaped HBB® BMV OSCEs.

Another practice with potential cultural implications includes the routine practice of drying the infant. Drying serves both to minimize heat loss, but is also a highly effective mechanism to provide tactile stimulation and trigger spontaneous breathing immediately after birth (Question 5). One report suggests that Zambian TBAs (mbusas) consider vernix to be unclean or “dirty”. They may avoid touching or handling a vernix-covered infant at delivery, and/or request increased compensation to provide care in this circumstance (Maimbolwa, et al., 2003). We did not detect any similar challenges with acceptance of routine drying and stimulation in the professional HCPs enrolled in our current study.

**Baseline BMV Measures**

Other authors have minimized the value of obtaining baseline measures. Our study is one of the first, to report baseline levels of BMV competency in the developing world in general, and in Zambia more specifically. From a theoretic standpoint, BMV testing at baseline, may serve as an intervention of sorts, providing the individual HCP with clear evidence of a critical knowledge or a skill “gap” and providing an immediate opportunity for improvement. There may be a
mismatch between resuscitation self-efficacy (i.e. the perceived versus actual resuscitation skills). Carlo et al. (2009) reported the mismatch of exaggerated confidence versus the actual knowledge and skills related to newborn resuscitation. Obtaining baseline data may serve to identify and address the common HCPs’ assumption that they already know how to perform this life-saving skill. And most importantly, the true measure of BMV competency, might be infants successfully resuscitated using this technique in the field – an important measure beyond the design of our study.

**Patterns of BMV Errors**

The use of videotaped baseline and repeat measures, provided a rich qualitative dimension, with longitudinal evaluations, that have not yet been reported by others. We report not only low baseline scores on BMV, but we were also able to identify patterns of common errors in providing BMV that led to these suboptimal scores. These findings may inform the training staff and present rich learning opportunities.

A common theme noted in the review and scoring of the BMV videos, was failure to check the BMV equipment, which was often not done, or done late in the care sequence, commonly after initiating BMV and with adjustments being made with the face mask on the infant’s face. Failure to achieve a consistent seal with the mask was also commonly observed. Inability to achieve chest rise, due to significant neck hyperextension and airway obstruction, or poor head position was also commonly noted in both groups. Although these findings decreased slightly in the post-training videos they were still present with some regularity.
Careful asynchronous scoring of the videotapes allowed us to actually time the BMV rate; failure to ventilate at the correct rate (30 to 50 breaths-per-minute) was the most common finding that resulted in a “fail,” and this failure to provide the correct numbers of breaths persisted in the post-training period for the intervention group. Excessive chest rise (an item that was observed but was not “officially” scored) and high ventilation rates (which resulted in failing scores) were also noted. Rates of 70, 80 and up to 100 were common; rates as high as 200 breaths-per-minute were recorded in select videotape scenarios.

Hyperventilation, often attributed to the “provider adrenaline affect” is commonly reported during critical care simulations (Niebauer, White, Zinka, Youngblood & Tofil, 2011). A phenomenon of “death by hyperventilation” has also been described in the field with adult rescue teams; additionally, the negative physiologic impact of hyperventilation during resuscitation has been confirmed using animal models in the lab (Aufderheide & Lurie, 2004). Hyperventilation can occur quickly, particularly in an infant with normal lung compliance who has been depressed at birth. Hyperventilation may drive down CO₂ levels (hypocapnia) further depressing the infant’s own respiratory drive and delaying the initiation of spontaneous or effective breathing. Hypocapnia impacts cerebral perfusion and is a known risk factor for central nervous system injuries, such as periventricular leukomalacia, intraventricular hemorrhage, cerebral palsy, cognition developmental disorder, and auditory deficits (Zhou & Liu, 2008).

Excessive chest rise with BMV was not a formal part of the BMV OSCE coding; however, our raters coded this in the “other category” most specifically
when they had audible confirmation of participants activating the pop-off valve on the BMV device with each breath. The BMV pop-off valve activates when pressures in excess of 35 to 45 cm of H₂O are applied. The typical peak inspiratory pressure required to inflate a newborn’s lungs may be high for the initial breath; however, thereafter pressures of 15 to 20 cm of H₂O are typically adequate to achieve good lung inflation. High BMV pressures present a serious clinical concern for the development of an iatrogenic pneumothorax, a known complication of BMV. Treatment of a tension pneumothorax may not be possible in a low resource setting, and its presence may exacerbate pre-existing hypoxia and escalate the risk for mortality.

Although other detailed comparisons could not be found in the literature with respect to the developing world, our findings are consistent with others who have analyzed videotaped real-world resuscitation in the U.S., and found that when BMV was required, 24% of the infants had poor chest expansion, 11% of the BMV episodes had an incorrect rate, and 17% had inadequate reevaluation of the BMV technical and failed to use simple corrective maneuvers such as head repositioning (Carbine, Finer, Knodel, & Rich, 2000). When viewed in concert with the work of others, our findings confirm the complexity of BMV psychomotor skills, and the challenges with translating these skills into action in the clinical setting, irrespective of the developing world context.
Descriptive Findings: Global Assessment of Competency

After reviewing the BMV videotapes, and completing the item-by-item scoring, raters were asked to provide a “global assessment” of BMV competency. This exploratory concept was meant to capture the “gestalt” of the rater, asking them “do you think this HCP could perform this skill?” Although the HBB® training program suggests baseline objective measurement of BMV, using the BMV checklist, it is unclear if formal item-by-item scoring of these measures at baseline and after training is actually occurring in published reports and/or routinely in field training. Some HBB® training programs have used a more streamlined or “gestalt” evaluation approach to this competency.

Our findings suggest that the use of a “global competency assessment” resulted in significant overestimation of actual competency when compared to the item-by-item scoring of the HBB® BMV OSCE. The global competency assessment was significantly higher than the detailed scoring of the BMV OSCE (30.4% versus 0%). Also of concern, was the very low rate of inter-rater agreement of the global competency score (Kappa 0.23; \( p = 0.21 \)) suggesting poor inter-rater reliability of this method.

We compare our results to another published report that used an older generation infant resuscitation mannequin to evaluate the BMV proficiency of pediatric resuscitation personnel in the developed world (Kanter, 1987). An overall global assessment of performance was used, and deemed generally “adequate” in this study. Forty-six of 50 providers achieved adequate minute ventilation, and 48 of 50 operators achieved appropriate tidal volumes. Our
study’s definition of a “pass” on the global assessment differed; Kanter used “adequate” and we used “competent.” This may explain the difference in our findings given Kanter’s “pass” rate of 30% at baseline. Kanter did report wide variations between providers’ performance with an overall tendency to hyperventilate (breathe too fast) and to use excessive pressures, highlighting the need for improved standard training methods, and in this respect our findings were consistent.

**Descriptive Findings:**

**Atypical and Potentially Dangerous Resuscitation Practices**

In the Zambian setting, there is typically at most one HCP for both the mother and the infant. Prioritization of the mother and infant’s needs is challenging. Our use of videotape testing provided us with a unique opportunity to capture resuscitation practices and priorities specific to HCPs practicing in low-resource settings that have not previously been well described.

In some study videotapes a clear lack of urgency in addressing breathing was coded. In others, other clinical tasks, specifically prolonged periods of time tying the umbilical cord, led to delays in initiating ventilation of 4, 5 and 6 minutes. If delays of this nature and magnitude exist in a real-world clinical setting, the lag in initiating breathing could result in an infant rapidly progressing from primary to secondary apnea and or from secondary apnea to death (Pinheiro, 2009). One research team reported that the time to initiate BMV as well as the duration of BMV were significantly longer among infants who died compared with infants with normal outcome in a developing world setting. The
risk for death increased 16% for every 30-second delay in initiating BMV up to 6 minutes of age (Ersdal, Mduma, Svensen, & Perlman, 2011).

In addition to delays in ventilation, the misuse and misapplication of the BMV device were concerning in some of the videotapes reviewed in our study. This raises the issue of an unrecognized and/or potentially under-reported challenge – the potential to cause harm with the BMV device. We speculate that these risks may be highest in the hands of a HCP without adequate initial training and establishment of competency, and/or in those HCPs who might use the skill infrequently and have challenges with maintaining competency.

The risk of occluding the infant’s anatomically vulnerable airway, or suffocating the infant with the mask, in the absence of providing adequate ventilation, exists. Airway obstruction may occur due to manual compression of the soft tissues of the neck, tongue and the trachea, or hyperextension or retroflexion of the head. Additionally airway obstruction may be due to the BMV face mask being held on the face so tightly that it obstructs the mouth and the nose (O’Donnell & Schmölzer, 2012). Excessive head force during simulated neonatal BMV was seen in our videotapes and has been described by an author team from the Netherlands, who evaluated experienced BMV operators who were trying to achieve a seal with a face mask (van Vonderen et al., 2012).

Concerns regarding significant challenges with BMV technique and potential harm from airway obstruction have also been raised by others when reviewing resuscitation videotapes during newborn resuscitations by NRP™ trained providers in a tertiary U.S. setting (Finer, Rich, Wang & Leone, 2009).
This research team used a colorimetric CO2 detection device to detect obstructed breaths during BMV, and recorded the frequency and duration of these events. They reported that “through our review of video recordings, we have observed that airway obstruction is a relatively common phenomenon during initial bag-and-mask resuscitation, particularly in LBW infants.” The authors reported one single videotaped event that lasted 3 minutes and 40 seconds. They also raised the concern that prolonged, or unrecognized airway obstruction could easily lead to further, more aggressive, and hazardous procedures, such as increased pressures and/or cardiac compressions if not rapidly recognized and relieved (Finer et al., 2009; Perlman & Risser, 1995).

Other important findings that emerged from our videotape reviews were dangerous practices, defined in our study as shaking, slapping, aggressive stimulation, overall rough handling, head compression, and a non-specific “other” category. These findings occurred in 44% of the intervention group at sample baseline and remained relatively constant (35%) in the intervention group during the post-test period. The prevalence of these birth practices has not been previously described. Further, the scripted HBB® curriculum does not provide any guidance or teaching to promote identification of unsafe resuscitation practices, or the “unlearning” needs of HCPs.

Historical accounts of neonatal resuscitation techniques describe a host of atypical and dangerous resuscitation practices that were considered “state of the art” for the time. These include brutal shaking, hitting, swinging, electrocuting, hanging upside-down to applying gentle pressures or squeezing of the chest, hot
and cold therapies, and blowing smoke up the infant’s rectum (Raju, 1999). We speculate that some of these practices may persist, particularly in regions of the world where more formal resuscitation training is not universally available.

Atypical and potentially dangerous resuscitation practices were reported in a study focused on characterizing community birth practices in Zimbabwe. Per maternal report, beating/shaking (58%), and/or pouring cold water over the baby (18%) were two of the most common methods of resuscitation (Kambarami, Chirenje, & Rusakaniko, 2000).

Another author team reported on such events in Kenya, where births were directly audited and resuscitation practices rated by trained observers. One of the secondary outcomes of this study was the actual number of inappropriate or potentially harmful practices directly observed (Opiyo, *et al.*, 2007). Their findings suggest observations of “inappropriate breathing support” or oxygen use, oxygen administered by placing the tubing directly into the nostril, blowing or exhaling intentionally on the infant’s face, inappropriate stimulation that was performed before drying, shaking the whole baby, patting / slapping the baby’s back, flicking / slapping the baby’s feet, vigorously rubbing the baby’s chest and back, and squeezing the chest. Of interest, in the Opiyo study these behaviors decreased post-training (trained 0.53 versus control 0.92; mean difference 0.40, [95% CI 0.13-0.66], *p* = 0.004).

**Comparison of Knowledge Between Intervention and Control Groups**

The HBB® training was associated with increased scores, (*M* = 13.5 baseline; *M* = 15.9 at 1 month; and *M* = 16.6 at 3 months. The improved scores
persisted up to 3 months ($p = 0.001$). Group assignment, time and the interaction between group and time all appeared to be important factors. Improvements in knowledge are consistent with the findings of others (Singhal et al., 2012; Goudar et al., 2013).

**Comparison of BMV Skills Between Intervention and Control Group**

Our pre- and post-test data (intervention group only), did suggest improved BMV scores, and this is consistent with the findings of others. Preliminary analysis of the intervention group only showed that the mean scores increased from 2.8 to 5.8. Although scores increased, participants did not achieve competency. This is in contrast to the findings of Goudar, who reported post-test “pass rate” or BMV competency of 58% for first-time attendees and 68% for those attending a “refresher” course. These scores were significantly higher than our post-test scores, in which virtually all of our sample remained well below the pass threshold of the test. Another small study reported that the proportion of caregivers that passed the simulated scenarios increased from 41% at baseline to 74% ($p = 0.016$) for routine care, and from 8 to 74% ($p \leq 0.0001$) for more detailed neonatal resuscitation scenarios (Ersdal et al., 2013). Although this research team reported using videotaped assessments and assigned pass/fail scores their methods for videotape scoring and assessment were not well described, therefore more detailed comparisons are not possible.

We suspect that our videotape acquisition and scoring methods may have contributed to the differences in pass rates between our study and others. Our scoring methods included asynchronous versus real-time “on the spot” scoring.
The scoring in our study was conducted by trained observers using a standardized scoring rubric, with careful attention to both the sequence, skill and speed of the BMV actions, and demonstrated inter-rater reliability. Further, in our study the raters were not engaged in the actual training and were blinded to both the participant, and the group assignment to further limit bias. Scoring occurred with the use of videotaped BMV events, which allowed the scorer to replay the video, and to count the breaths per minute delivered. In summary, we suspect that our scoring methods may have led to more careful scrutiny of the BMV tasks, and perhaps less educator bias. Given this rigor, lower pass thresholds for the test are reported and may be defensible.

We hypothesized that BMV scores would increase after exposure to the training and this was confirmed. We also hypothesized that competency would be possible with HBB® training and this did not appear to be true in our setting. Low rates of BMV competency, in the post-test measures are consistent with the findings of Singhal, et. al, 2012; they reported that 15% of the Kenyan participants and 17% of participants in Pakistan were able to successfully complete the BMV testing on the first attempt.

Individual items in the BMV OSCE with low completion rates in our study included item 1 (checking equipment), item 2 (ability to achieve a seal with the mask), item 3 (ventilating at the proper rate) and item 4 (BMV corrective maneuvers, clears secretions, opens the mouth) and closely mirrored their findings as well. We concur with the findings of Singhal et. al, that careful practice may be needed in order to consistently demonstrate these skills.
BMV Conceptual Knowledge Versus Actual Demonstration of the BMV Psychomotor Skills

Questions related to the appropriate response to an infant who is not breathing (Question 7; 37% pass rate) and proper BMV technique (Question 11; 66.7%) had low and variable pass rates as well. Pass rates on questions 9, 11, 13 and 14 (all relating to specifically to BMV) had pass rates of 90.2%, 66.7%, 96.1%, and 88.2%. It is interesting to compare the knowledge scores related to BMV to the actual BMV scores, which require that the participant applies this knowledge about BMV and demonstrates the psychomotor skills to complete BMV. The HBB® BMV OSCE testing moves beyond “mere knowing” to showing and doing, which is a much higher level of behavioral expectation.

Our study demonstrated persistent longitudinal challenges with the provision of BMV. The mismatch between knowing and showing highlights the complexity of both teaching and learning the critical skills required to provide effective BMV. The need for more focus on BMV skills, and the provision of extended time to practice these skills, both in the training program and beyond, should be considered in efforts to achieve and maintain improve BMV competency.
Implications for Practice, Education and Research

On a local level HBB® faculty and trainers teaching in the developing world need to be both sensitive to and prepared for the potentially extremely low level of baseline skill in their settings. Consistently performing baseline testing, and ongoing formative evaluations, may provide enhanced opportunities to both assess needs and provide increased opportunities for supervised learning with an emphasis on the importance of ongoing practice. We also suggest that the time invested in a structured and rigorous post-test confirmation of skill acquisition is important. This allows for learners to have an objective sense of their competency, and awareness that additional mentorship and learning activities outside of the classroom may be needed (Singahl et al., 2012).

Furthermore, given the consistent trend in failing to establish competency at the most basic level of HBB® training, we question whether the rapid progression to the more complex resuscitation sequences (OSCE A and B activities) may be premature, until basic BMV competency can be reliably established. We hope to address performance on the BMV OSCE A and B, once our complete data set is analyzed. Restructuring of the learning plan, and building in more time for and emphasis on BMV, may be an important consideration for further study and future curriculum updates.

Although our study was focused in Zambia, the review of the literature revealed that similar challenges with BMV competency might also exist in developed world settings, where NRP™ training is the standard of care. The use of simulation, and pretest and post-test competency evaluation deserves further
study and may also have merit in improving performance in higher resource settings in the developed world.

The majority of the published literature failed to identify and integrate a theoretical framework for their studies. The prospective application of Bandura’s social cognitive theory is a powerful albeit under-utilized tool that could be more widely applied to guide the design, development, delivery and evaluation of resuscitation education science.

**Study Limitations and Strengths**

This study was limited by its small sample size. It provides important information about HCPs, but fails to address the use of HBB® in TBAs or SBAs. Although it appears that the groups were equivalent at baseline, lack of randomization may have failed to control for potential group differences that might have existed purely by chance. We were unsuccessful in monitoring the frequency that depressed infants were encountered during the study period; and further, it is possible (albeit unlikely given the low resource setting) that subjects were exposed to additional resuscitation training in the three month study period. Subject attrition presents a potential threat to the internal validity of the study, as we do not know if subject characteristics or competency resulted in differences in return rates for the longitudinal follow-up measures, particularly in the intervention group where loss of subject data was an issue. Therefore, the most important limitation of the study was a technical one. Further, our study was not designed to answer the important questions regarding whether the HBB® training program will translate into real-world changes in clinical practice, an important
question that has been raised by others.

**Study Strengths**

Strengths of the study include recruitment of a sample that exceeded our power calculation (52 vs. 48), and the presence of a strong nursing representation within that sample. Given the key role of nurses in the provision of healthcare the developing world, they are an important group to study. The longitudinal design of the study, with repeated measures, increases confidence in the study findings. The use and rigorous evaluation of the videotaped simulations provides a novel methodological foundation for future research studies.

**Feasibility Challenges: Study Site / Subject Recruitment / Retention**

Research in the developing world is challenging. The following discussion of feasibility challenges may assist other research teams in the design and execution of their work. Exposure to and participation in research was a novel concept to many in our study. We initially had concerns about our ability to recruit subjects. The respect of Dr. Sinkala in this community, as well as engagement of local nurses who were thought and opinion leaders, allowed us to successfully recruit a sample of 52 subjects.

This longitudinal study was significantly impacted by both subject attrition, and to a larger extent data quality. Subject attrition was anticipated. We attempted to minimize travel challenges, by having the research assistants (MN, CK) travel to the remote village locations of Mumbwe and Mazembuka to collect the data en masse. Additionally, participants were paid a small travel stipend, which we hoped would serve as an incentive to return for the repeated
measures.

Two participants reported significant family events / illness as reasons for not returning for the follow-up measures. It is unclear whether local staffing challenges, relocation, or reemployment, or other factors common to the developing world work force contributed to the attrition rates. Furthermore, the attrition rates were higher in the intervention group than the control group. The opportunity to participate in the final resuscitation training may have served as an incentive to continue in the study for the control group, without an equivalent incentive in the intervention group. This disparity in attrition rates between the two groups may have led to significant potential bias and should be addressed in future study designs.

Feasibility of Research Methods – The Use of SurveyMonkey®

The initial research plan included the option for participants to enter their demographic information, and perform the MCQ test directly in SurveyMonkey®, with paper and pencil as the back-up modality. We encountered significant challenges with Internet connectivity, and basic electrical availability and quickly resorted to the more practice modality of paper and pencil measures throughout the study. From the research team’s internal use perspective, SurveyMonkey® served as a very useful data collection instrument, and helped to organize and track the data, as well as allow for simultaneous coding of multiple videotapes. Finally, the ability to download the data and interface directly with the statistical analysis program, was an additional useful feature.
Feasibility of the Research Methods:

Use of the HBB® Curriculum and Low Technology Simulation

The use of a structured educational curriculum, with carefully scripted learning was an important strength of this study. The use of simulation for teaching, learning and testing is a novel concept in Zambia. Based upon our demographic intake survey, a minority of the participants had been exposed to resuscitation training in general, and/or simulation more specifically. Initially participants needed to be encouraged to show (not just tell) how they would provide BMV to an infant. The instructions were followed, in most cases, although the speed of execution varied. The application of simulation was well accepted by the Zambian healthcare providers, and was a cultural fit with their often vivid use of story-telling and re-enactments of important events.

Feasibility of the Research Methods:

Videotaping HBB® BMV OSCEs

Use of videotapes to evaluate resuscitation simulations is a sensitive undertaking. Initial concerns focused on whether participants would consent to participate in such a study. After addressing initial concerns, and our explanations and demonstration that the camera would not show the HCPs’ face, but rather would focus on the baby and HCPs’ hands and arms only, we achieved a 100% enrollment rate.

The quality and fidelity of the videotaped BMV simulations obtained from the study i-Pads were excellent. Raters were both able to see, and to hear the soft-spoken Zambian participants. Further, the angle of the video camera
protected the subjects, that their faces were not captured, as promised, as well as it allowed easy visualization of the infant simulator’s face, mouth, head and airway position, as well and the adequacy of chest rise, and audible sounds when the BMV pop-off valve pressure was exceeded.

The primary challenge we encountered was the number of corrupt and/or missing videos. These were typically obtained at the end of the research day, and we suspect that machine memory may have been a contributing factor. Future studies should develop strict standards about the size of the video files and have hard disc video archiving procedures available during the live video collection to avoid these issues.

**Research Methods: IRR / Videotape Scoring**

As described in detail in Chapter 3 the research team developed an expert-driven operational definition for every item on BMV OSCE (formerly the ® checklist), along with a scoring rubric, integrating key concepts of not just task completion but task skill, task sequence, and speed. Additionally videotape coders were carefully trained and monitored to establish and maintain IRR. We were also able to develop a robust mechanism for scoring the BMV assuring control for distractions, appropriate illumination (low lighting) and adequate sound quality to hear and see the videos. Overall the videotapes documented adequate standardization of testing procedures; however, in select circumstances, the verbal cues, or time allowed to complete the task were incomplete or inadequate. This led to some videotapes which could not be adequately scored and needed to be were excluded from the analysis. Future users would benefit from an even
more detailed video-taping procedure to assure consistent testing circumstances and data acquisition.

**Conclusions**

Our study adds to the body of literature surrounding the use of the structured educational program, HBB® in resource-limited settings such as Zambia. We conclude that the implementation of a focused 2.5-day training program demonstrated both statistically and potentially clinically significant, short-term improvements in HCP performance in a simulated environment in a sample comprised primarily of nurses and medical licentiates.

Despite a median of eight years of experience, and the fact that 26% of the sample had some prior resuscitation training, the levels of baseline newborn resuscitation knowledge were quite low with pass rates on the knowledge measure of 70% (N=52). These data suggest that potential important knowledge deficits exist and these deficits could impact both the recognition and treatment of infants with perinatal depression.

Baseline measures of psychomotor competency and BMV are rarely obtained or reported in the literature. This study contributes important baseline data and highlights that, in addition to knowledge deficits, participants also had extremely low psychomotor skills, as measured by scores on the baseline HBB® BMV competency testing. Although the baselines HBB® BMV scores ranged from 0 to 6, the scores in both groups (Intervention $M=2.8$; Control $M=3$) were extremely low compared to the pass threshold of 7 for the test.
In terms of achieving competency, for those intervention subjects for which we have videotaped measures, although the mean scores increased from 2.8 at baseline to 5.8 in intervention group, in the post-test period \((p = 0.01)\) and remained higher than baseline (4.6 at 1 months and 5.2 at 3 months). Only 2 of the participants tested in both groups over time achieved the defined competency score of 7 in this simulated testing situation.

The novel use of videotaped HBB\textsuperscript{®} BMV OSCEs allowed us to demonstrate IRR (ICC of 0.77) and provided rigorous, objective, and unbiased evaluations of BMV skills. We believe these methods may have relevance for HCP training both in the developed and developing world, given the complexity of achieving and maintaining BMV competency. Furthermore, the use of videotaped simulations revealed some unexpected findings of atypical and potentially dangerous resuscitation practices that have not previously been well detailed or described. More research is needed to better understand the prevalence of these practices in the field. However, HBB\textsuperscript{®} Master Trainers should be aware of local cultural and clinical care practices that may influence the uptake of the program, and future studies should test the effectiveness of structured opportunities to discuss, identify, and unlearn potentially harmful resuscitation practices as an element of the curriculum design.

Exposure to the HBB\textsuperscript{®} intervention did result in improved knowledge and psychomotor skills. There was a statistically significant effect of group assignment on knowledge (HBB\textsuperscript{®} MCQ scores), \(F (1,50) = 13.62, p = <0.001\). We postulated that there could be a degradation of knowledge (HBB\textsuperscript{®} MCQ scores)
over time. There was a statistically significant effect of time on knowledge (HBB® MCQ scores), $F(2,50) = 28.36$, $p = <0.001$. Of particular interest, the scores for the intervention group appeared to rise rather than decline over the study period, compared to stable scores in the control group. There was a statistically significant effect of group and time on knowledge (HBB® MCQ scores), $F(2,50) = 20.76$, $p = <0.001$. These data suggest some stability of knowledge gains during the 3-month duration of the study. Factors that contribute to this rise in scores, such as the frequency of use, warrant further exploration.

Further study will be required to understand if and how newly acquired resuscitation practices are translated from the simulated setting into the clinical environment. A mechanism to reveal and discuss local and regional culturally important birth practices is not well addressed in the HBB® curriculum; these powerful influences may impact uptake and dissemination. Future studies should explore this important element to better prepare teams teaching in diverse regions around the world. And clearly, to impact NMR, widespread use of the training program would be needed to assure that sufficient numbers of trained HCPs / birth attendants exist, and that all birth attendants have sufficient knowledge and proficient resuscitation skills, particularly the safe use of BMV.

Evidence on the stability of knowledge and skills over time is weaker and we were unable to answer these questions with confidence. Further, the sustainability of such efforts remains inconclusive and can only be established by larger trials. We also emphasize that training alone will not be sufficient to improve outcomes. The availability of correctly functioning basic resuscitation
equipment is still a critical missing element for the success implementation of resuscitation training in Zambia and other low-resource settings.

Although, in general, newborn resuscitation training programs are cost-effective, for low-income countries like Zambia, country-wide scale-up of HBB® is both labor and resource intensive, and associated with relatively high direct and opportunity costs (learners'/instructors’ time, equipment purchase, etc.) (Opiyo, et al., 2007). We must proceed thoughtfully, balancing the urgent needs in the region, and pressure to rapidly implement interventions, with the evidence supporting both short-term effects (increased knowledge and skills) in not just simulated but clinical environments, as demonstrated by the Opiyo et al. 2007 trial. Longer-term effects on actual health worker performance, and ideally neonatal morbidity and mortality, must also be established. Studies aimed at investigating these outcomes studies need to be carefully designed and situated in typical, low-income settings, and should include a sample of the types of birth attendants that most frequently attend births in that region.

Context is everything. The local context, where material resources for resuscitation, opportunities for continuous learning, ongoing mentorship, and healthcare resources for post-resuscitation care are limited, must be carefully considered. Novel technologies for learning or practice monitoring, such as the Skype, Smart Phones, Face-Time or other cell phone applications may prove useful in delivering timely and low-cost interventions in the future. Research teams should be encouraged to explore a range of less intensive training models, which could be integrated into local and regional health systems. Further, the
cost-effectiveness of interventions needs to be carefully assessed to inform appropriate health policy decisions, and to assure long-range sustainability.
References


Mosley, C. M., Shaw, B. N. (2013). A longitudinal cohort study to investigate the retention of knowledge and skills following attendance on the Newborn Life support course. *Archives of Diseases in Childhood, 98*(8) 582-586.


Appendix A. Helping Babies Breathe®
Demographic Survey Version 1
Initial Study Enrollment/Registrations

1. My current role / practice preparation is:
   - Nurse
   - Nurse midwife
   - Respiratory Therapist
   - Nurse Practitioner
   - Physician
   - Skilled Birth Attendant
   - Traditional birth attendant
   - Other __________________

2. The primary area of my practice is:
   - Obstetrics
   - Newborn care (primarily well newborns)
   - Newborn care (primarily critically ill newborns)
   - Both maternal and newborn care
   - General pediatrics
   - Family health (generalist)
   - Other __________________

3. I have been practicing in the above primary area of practice for:
   _______ Years

4. My age is: ______________

5. My gender is:
   - Male
   - Female

6. My primary practice setting is:
   - Mothers’ homes
   - Birth attendant’s home
   - Clinic
   - Rural hospital
   - District / secondary level hospital
6. Regional or tertiary level hospital
   ❖ Other. Please describe________________________________________

7. The country of my primary practice is:
   _________________________________

8. I encounter infants who are depressed or not breathing:
   ❖ Very frequently (almost daily)
   ❖ Frequently (weekly)
   ❖ Occasionally (monthly)
   ❖ Infrequently (1 to 2 times year)
   ❖ Never

9. I have had the following training in newborn resuscitation.
   
   Cardiopulmonary resuscitation (CPR) participant  ❖ Instructor  ❖ Participant
   Neonatal Resuscitation Program (NRP)             ❖ Instructor  ❖ Participant
   Helping Babies Breathe (HBB®)                   ❖ Instructor  ❖ Participant
   Pediatric Advanced Life Support (PALS)          ❖ Instructor  ❖ Participant
   Essential Newborn Care (ENBC)                   ❖ Instructor  ❖ Participant
   STABLE Program                                  ❖ Instructor  ❖ Participant
   Other infant resuscitation or life support training

   If other name and describe:______________________________

10. The most recent year/month of my newborn resuscitation training was:

   Month   Year
   _________   _________  Cardiopulmonary resuscitation (CPR)
   _________   _________  Neonatal Resuscitation Program (NRP)
   _________   _________  Helping Babies Breathe (HBB®)
   _________   _________  Pediatric Advanced Life Support (PALS)
   _________   _________  Essential Newborn Care (ENBC)
   _________   _________  STABLE Program
   _________   _________  Other infant resuscitation or life support training
   Name of other program__________________________

11. My level of education is:

   ❖ Primary school (0 to 8 years)
   ❖ Secondary school (9 to 12 years)
   ❖ College or technical training (13+ years)
12. My primary language is: _________________________________

13. In addition to my primary language I also speak: _________________

14. The best description of my English is the following:

- I have no English.
- I can speak and ask and answer uncomplicated questions about familiar topics; however, I need some repetition to understand.
- I can give straightforward instructions; however, I may use awkward or inaccurate phrasing.
- I can communicate effectively in most social and professional situations; however, I may have difficulty communicating some abstract topics.
- I am nearly fluent in English; however I sometimes have trouble with unusual dialects or slang.
- I can communicate like a native speaking individual.
Appendix B. Helping Babies Breathe®
Short Demographic Survey Version 2.
Follow-up Questions

1. Since my last contact with the HBB® research team I have personally:
   - Not used the HBB® training at all
   - Have attempted to help babies breathe 1 to 5 times
   - Have attempted to help babies breathe 6 to 10 times
   - Have attempted to help babies breathe 11 or more times

2. Since my last contact with HBB® research team I have personally successfully resuscitated
   - No infants
   - 1 to 5 infants
   - 6 to 10 infants
   - 11 or more infants

3. Since my last contact with the HBB® research team I have:
   - Not taught the HBB® training program at all.
   - Taught the HBB® training program 1 to 3 times.
   - Taught the HBB® training program 4 to 6 times.
   - Taught the HBB® training program 7 or more times.

4. Cumulative number of people you have trained using HBB® to date: ____________

5. Since my last contact with the HBB® research team I have had the following training in newborn resuscitation.

   Cardiopulmonary resuscitation (CPR) participant
   - Instructor
   - Participant

   Neonatal Resuscitation Program (NRP)
   - Instructor
   - Participant

   Helping Babies Breathe (HBB®)
   - Instructor
   - Participant

   Pediatric Advanced Life Support (PALS)
   - Instructor
   - Participant

   Essential Newborn Care (ENBC)
   - Instructor
   - Participant

   STABLE Program
   - Instructor
   - Participant

   Other infant resuscitation or life support training?
   - Instructor
   - Participant

If other name and describe: _________________________________
Appendix C. Helping Babies Breathe® Knowledge Instrument

Multiple Choice Question Test
AAP / HBB® Modified Version 2010

1. In the first minute after birth you should
   a. Bathe the baby
   b. Help the baby breathe
   c. Feed the baby
   d. Not touch the baby

2. To prepare for a birth
   a. You identify a helper and review the emergency plan
   b. You ask everyone but the mother to leave the area
   c. You prepare equipment only when you need it
   d. You do not need a helper

3. To prepare the area for delivery
   a. Open all the doors and windows to get fresh air
   b. A clean space for the baby will not be required
   c. Make sure the area is clean, warm and well lit
   d. Keep the room temperature cold

4. Which baby can receive routine care after birth?
   a. A baby who is not breathing
   b. A baby who is gasping
   c. A baby who is crying and breathing well
   d. A baby who is limp

5. Routine care for a healthy baby at birth includes
   a. Drying, removing the wet cloth and bathing the baby
   b. Drying, removing the wet cloth and positioning the baby skin-to-skin
   c. Bathing and putting clean clothes on the baby
   d. Drying and wrapping the baby in the wet clothes

6. When should the umbilical cord be clamped or tied and cut during routine care?
   a. After the placenta is delivered
   b. Around 1 to 3 minutes after birth
   c. Immediately after the baby is born
   d. Before the baby has cried

7. A baby is quiet, limp and not breathing at birth. What should you do?
   a. Dry the baby thoroughly
   b. Shake the baby
   c. Throw cold water on the face
   d. Hold the baby upside down
8. A baby is born through meconium-stained amniotic fluid. Which statement is TRUE?
   a. Stimulate the baby and then clear the airway
   b. Meconium cannot be inhaled into the lungs
   c. Clear the airway before drying the baby
   d. All babies born through meconium stained amniotic fluid can receive routine care

9. What should you do in The Golden Minute?
   a. Bathe the baby
   b. Deliver the placenta
   c. Evaluate the heart rate
   d. Help the baby breathe if needed

10. A newborn baby is quiet, limp and not crying. The baby does not respond to steps to stimulate breathing. What should you do next?
    a. Slap the baby’s back
    b. Hold the baby upside down
    c. Squeeze the baby’s ribs
    d. Begin ventilation

11. Which of the following true statements about ventilation with a bag and mask is TRUE?
    a. The mask should cover the eyes
    b. Air should escape between the mask and face
    c. Squeeze the bag to reduce gentle movement of the chest
    d. Squeeze the bag to give 80 to 100 breaths per minute

12. Which of the following signs MUST be monitored in a baby during the first few hours after birth?
    a. Length
    b. Breathing
    c. Smile
    d. Urine output

13. A baby’s chest is not moving with bag and mask ventilation. What should you do?
    a. Stop ventilation
    b. Reapply the mask to get a better seal
    c. Slap the baby’s back
    d. Give medicine to the baby

14. You can stop ventilation if
    a. Baby is blue and limp
    b. Baby’s heart rate is 80 per minute
    c. Baby's heart rate is 120 per minute and the chest is not moving
    d. Baby's heart rate is 120 per minute and the baby is breathing or crying
15. What should you do to keep the baby warm?
   a. Open all the windows to allow warm air to circulate
   b. Give the baby a bath after birth
   c. Place hot water bottles next to the baby’s skin
   d. Place the baby skin-to-skin with mother

16. What should you do to keep the baby clean?
   a. Wash your hands before touching the baby and help mother wash her hands before breastfeeding
   b. Reuse the suction device before cleaning
   c. Keep the umbilical cord tightly covered
   d. Do not touch the baby

17. A newborn baby’s heart rate should be:
   a. 60 beats per minute
   b. 80 beats per minute
   c. > 100 beats per minute
   d. > 200 beats per minute
### Appendix D. HBB® Bag and Mask Ventilation Psychomotor Skills OSCE

**Scripted OSCE Adapted From the Helping Babies Breathe® Curriculum**

**Directions**

1. Provide a flat table / space / and lay out the HBB® training kit.
2. Set up the I-Pad camera and test the angle to assure you can see the baby, chest, rise and the hands and actions of the participant.
3. Use the prompted script, below. Do not provide additional guidance.
4. Allowing adequate time for the participant to complete the steps and bulleted key points.
5. Complete the BMV testing before administering OSCE A and B.

**First Prompt:** “Please show me how you would prepare for and provide bag and mask ventilation for an infant. Continue to demonstrate this skill until further instructions are given.”

<table>
<thead>
<tr>
<th>Psychomotor Skills and Sequences Assessed</th>
<th>Done (1)</th>
<th>Not Done (0)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ALL components must be completely demonstrated and consistently applied to score 1.</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. Checks equipment and selects the correct mask</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>• Test function of bag and mask</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>• Make sure the mask fits the baby’s face</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Applies the mask to make a firm seal</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>• Extends the head</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>• Places mask on the chin</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>• Then places mask over the mouth and nose</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>• A firm seal permits chest movement when the bag is squeezed</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Ventilates at 40 breaths per minute</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>• Rate should be no less than 30 or more than 50 breaths per minute</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Looks for chest movement</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>• Checks that every ventilation breath produces chest movement</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Prompt: After 2 to 3 minutes ... state: “What would you do if the baby’s chest is not rising.”</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Improves ventilation if the chest does not move:</td>
<td>a.☐</td>
<td>a.☐</td>
</tr>
<tr>
<td>• a) Head – reapply mask and reposition the head</td>
<td>b.☐</td>
<td>b.☐</td>
</tr>
<tr>
<td>• b) Mouth – clears secretions and opens the mouth</td>
<td>c.☐</td>
<td>c.☐</td>
</tr>
<tr>
<td>• c) Bag – squeezes the bag harder</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Summary Score on First Attempt**

All steps done correctly __________(facilitator initials) /7 Points
Appendix E: IRB Documentation

THE UNIVERSITY OF ZAMBIA
BIOMEDICAL RESEARCH ETHICS COMMITTEE

Telephone: 260-1-256087
Telegram: UNZAlUNAKA
Telex: UNZAUZA 44370
Fax: +260-1-257053
E-mail: uunrez@unza.zm
Assurance No. FW-080900338
IRB0001131 of ORG0000774

07 November, 2011.

Your Ref: 008-10-11.

Ms Madge E. Baus-Frank,
C/o Dr. Moses Sinkala,
Catholic Medical Mission Board,
PO Box 320146,
Lusaka.

Dear Ms. Baus-Frank,

RE: SUBMITTED RESEARCH PROPOSAL: “TESTING THE EFFECTIVENESS AND DURABILITY OF A STRUCTURED CURRICULUM FOR NEWBORN RESUSCITATION – HELPING BABIES BREATH-USING TELESIMULATION”

The above-mentioned research proposal was presented to the Biomedical UNZA Research Ethics Committee meeting on 26 October, 2011 and the following changes were recommended prior to approval.

CORRECTIONS:

(i) Justify selection of participants aged 21 to 55 years.
(ii) Separate information sheet and consent form.
(iii) Clarify the role of the student since there are so many investigators involved.
(iv) Use the term ‘participant’ and not ‘subject’ when referring to people taking part in the study.
(v) Citation: should be uniform in the text and numbers should tally with ones on the reference list page.
(vi) Appendix E: remove the statement ‘I have no English’.

Approval will only be granted after the above concerns are addressed. Please re-submit one copy of the revised proposal, which should be highlighted with the changes made and a cover letter.

Yours sincerely,

Dr. J.C. Mulitali
CHAIRPERSON

Your Ref: 008-10-11.

Ms Madge E. Buus-Frank,
C/o Dr. Moses Sinkala,
Catholic Medical Mission Board,
PO Box 320146,
Lusaka.

Dear Ms Buus-Frank,

RE: REQUEST FOR AMENDMENT TO THE APPROVED PROPOSAL: “TESTING THE EFFECTIVENESS AND DURABILITY OF A STRUCTURED CURRICULUM FOR NEWBORN RESUSCITATION – HELPING BABIES BREATHE USING TELESIMULATION”

We acknowledge receipt of your letter of 26th January, 2012 requesting for an amendment to the above mentioned protocol.

The amendment to recruit the control group in Zambia is approved as requested.

Yours sincerely,

[Signature]

[Stamp] Dr. J.C. Muwahali
CHAIRPERSON
THE UNIVERSITY OF ZAMBIA

BIOMEDICAL RESEARCH ETHICS COMMITTEE

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Ridgeway Campus
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Lusaka, Zambia

Assurance No. FWA00000338
IRB000001131 of IORG0000774

22 November, 2011.

Your Ref: 008-10-11.

Ms Madge E. Baus-Frank,
C/o Dr. Moses Sinkala,
Catholic Medical Mission Board,
PO Box 320146,
Lusaka.

Dear Ms Baus-Frank,

RE: RE-SUBMITTED RESEARCH PROPOSAL: “TESTING THE EFFECTIVENESS AND DURABILITY OF A STRUCTURED CURRICULUM FOR NEWBORN RESUSCITATION – HELPING BABIES BREATHE USING TELESIMULATION”

The above mentioned research proposal was re-submitted to the Biomedical Research Ethics Committee with recommended changes on 18 November, 2011. The proposal is approved.

CONDITIONS:
• This approval is based strictly on your submitted proposal. Should there be need for you to modify or change the study design or methodology, you will need to seek clearance from the Research Ethics Committee.
• If you have need for further clarification please consult this office. Please note that it is mandatory that you submit a detailed progress report of your study to this Committee every six months and a final copy of your report at the end of the study.
• Any serious adverse events must be reported at once to this Committee.
• Please note that when your approval expires you may need to request for renewal. The request should be accompanied by a Progress Report (Progress Report Forms can be obtained from the Secretary).
• Ensure that a final copy of the results is submitted to this Committee.

Yours sincerely,

Dr. J. C. Muntali
CHAIRPERSON

Date of approval: 22 November, 2011 Date of expiry: 21 November, 2012
Appendix F: HBB® Training Program Brochure and Agenda

DRAFT
SAMPLE PROGRAM BROCHURE / FLYER

Helping Babies Breathe® Master Trainer Workshop

Confirmed Course Faculty

Moeen Shafika MD
Catholic Medical Mission Board

George A. Little MD
The Children's Hospital at Dartmouth-Hitchcock Medical Center, Lebanon NH, USA

Modge E. Buus-Frank RNC, MS, APRO-BC, FAAN
The Children's Hospital at Dartmouth-Hitchcock Medical Center, Lebanon NH, USA

Local HBB® Master Trainers

Course Overview

The World Health Organization estimates that there are approximately 2.0 million neonatal deaths, and another 4 million births characterized as "stillbirths". Birth asphyxia alone is responsible for over 1 million deaths. Neonatal resuscitation training is among the most cost-effective of all child health interventions. This HBB® program is a vital part of the effort to meet Millennium Development Goal 4 (MDG-4), the reduction of under-five child mortality by two-thirds from 1990 to 2015.

Helping Babies Breathe® is an evidence-based neonatal resuscitation curriculum integrating the International Liaison Committee on Resuscitation's (ILCOR) guidelines now pragmatically adapted for use in low-resource settings. The HBB® training emphasizes skilled attendance at birth, establishment of every baby, temperature support,
stimulation to breathe, and assisted ventilation as needed, all within The Golden Minute® after birth. This HBB® Master Trainer Course is designed for clinicians who have an established system and relationships with clinicians and educators in resource-limited regions and who will establish training-of-trainer (TOT) programs for HBB®. These training programs will help to provide essential neonatal resuscitation capacity to achieve the goal of the presence of one person who is skilled in helping babies breathe present at every birth.

During the HBB® workshop, trainees will participate as both providers and facilitators. Each person will demonstrate the skills necessary to complete The Action Plan®, complete checklists, teach action and evaluation steps, participate in simulated case scenarios, as well as identify possible problems and solutions applicable to low-resource global settings. There will also be a group discussion of implementation strategies to assure birth examination and sustainability of the HBB® program in resource-limited settings.

The final portion of the workshop will be devoted to strategies for integration of HBB® into existing maternal and child health programs. This discussion is guided by the principle that improved resuscitation will have its maximum benefit when universally integrated in the continuum of care following birth. The WHO Essential Newborn Care program (ENC) will be used as a model.

**Learning Objectives**

At the end of the HBB® provider component of the training the participant will be able to:

- Discuss the value and roles of the learning dyads.
- Identify key messages and the importance of consistency in HBB® training.
- Successfully complete all the learning exercises: Preparation for birth, Routine care, The Golden Minute, Continued ventilation with normal or slow heart rate.
- Compare regional birth and newborn care practices.
- Demonstrate resuscitation knowledge with a passing score on the multiple-choice test.
- Demonstrate effective bag and mask ventilation and corrective actions.
- Demonstrate integration of resuscitation knowledge and psychomotor skills by successful completion of the Objective Structured Clinical Examinations (OSCE) A and B.

At the end of the facilitator component of the training the participant will be able to:

- Describe the evolution and purpose of the HBB® program.
- Demonstrate ability to present content, including key messages from the facilitator flip chart, integrating all of the components of the learning kit.
- Facilitate active learning in small groups with participants of various ability levels by:
  - Demonstrating skills
  - Leading practice sessions
  - Providing coaching and feedback on skills and performance
  - Moderating the experience of learners and obtain consensus on regional best practices
  - Providing cultural context and interpretation (health beliefs, equipment/supplies, policies)
  - Creating realistic scenarios
- Evaluate the performance of learners
- Score the skills checklist and objective structured clinical exam (OSCEs)
- Access resources to plan and evaluate courses
- Explain the integration of HBB® with existing systems of care
• Identify opportunities for regional implementation

Option To Participate in Ongoing Research

In addition to the standard HBB® training we are undertaking a research study designed to better understand the effectiveness and durability of neonatal resuscitation training. This will involve using the standard HBB® educational tools to collect data on individual resuscitation knowledge and skills before and after completion of the educational program. All individuals who participate in the HBB® training will undergo standardized on-site testing; however, only data on those who have consented and been enrolled into the study will be scored and analyzed (after carefully protecting the research subjects’ identity). Participation in this research is optional and will require written informed consent.

Helping Babies Breathe® Master Trainer Workshop – Day 1

<table>
<thead>
<tr>
<th>Time</th>
<th>Topic</th>
<th>Presenter</th>
</tr>
</thead>
<tbody>
<tr>
<td>11:00</td>
<td>HBB® Master Trainer Workshop&lt;br&gt;• Registration and Small Group Assignments</td>
<td>Faculty</td>
</tr>
<tr>
<td>13:00</td>
<td>Welcome / Introductory Remarks</td>
<td></td>
</tr>
<tr>
<td>13:15</td>
<td>Welcome / Faculty Introductions&lt;br&gt;• Program Overview&lt;br&gt;• Review of Pre-workshop Exercises / Testing</td>
<td></td>
</tr>
<tr>
<td>13:45</td>
<td>Workshop Pre-testing Stations</td>
<td>All Faculty</td>
</tr>
<tr>
<td>15:30</td>
<td>Refreshment Break</td>
<td></td>
</tr>
<tr>
<td>16:00</td>
<td>Reconvene / Participant Introductions</td>
<td></td>
</tr>
<tr>
<td>17:00</td>
<td>Introduction To and Overview of the HBB® Course and Curriculum</td>
<td></td>
</tr>
<tr>
<td>17:30</td>
<td>Overview of the HBB® Learning Kit</td>
<td></td>
</tr>
<tr>
<td>18:30</td>
<td>Opening Scenario: Preparation for Birth</td>
<td></td>
</tr>
<tr>
<td>19:30</td>
<td>Questions / Comments&lt;br&gt;Convene for the Day</td>
<td></td>
</tr>
<tr>
<td>20:30</td>
<td>Dinner</td>
<td></td>
</tr>
</tbody>
</table>
### Helping Babies Breathe® Master Trainer Workshop – Day 2

<table>
<thead>
<tr>
<th>Time</th>
<th>Topic</th>
<th>Presenter</th>
</tr>
</thead>
<tbody>
<tr>
<td>08:00</td>
<td>Continental Breakfast</td>
<td></td>
</tr>
<tr>
<td>09:00</td>
<td>Welcome Back/ Review Plan and Goals of the Day</td>
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</tr>
<tr>
<td>09:15</td>
<td>Routine Care: Demonstration and Scenarios</td>
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</tr>
<tr>
<td>10:00</td>
<td>The Golden Minute®</td>
<td></td>
</tr>
<tr>
<td>11:00</td>
<td>Break</td>
<td></td>
</tr>
<tr>
<td>11:30</td>
<td>The Golden Minute®: Part 2</td>
<td></td>
</tr>
<tr>
<td>12:00</td>
<td>Questions and Answers</td>
<td></td>
</tr>
<tr>
<td>13:00</td>
<td>Break for Lunch</td>
<td></td>
</tr>
<tr>
<td>14:00</td>
<td>The Infant Needing More Extended Resuscitation: Effective Bag-Mask Ventilation</td>
<td></td>
</tr>
<tr>
<td>15:00</td>
<td>HBB® Hands-On Learning Stations</td>
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</tr>
<tr>
<td></td>
<td>Station A: Bag / Mask Ventilation Skills</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Station B: Equipment Cleaning</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Station C: Assessing Hand Hygiene</td>
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<tr>
<td></td>
<td>Station D: Navigating To On-line Resources</td>
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<tr>
<td></td>
<td>Station E: Sharing Local Challenges</td>
<td></td>
</tr>
<tr>
<td>16:30</td>
<td>Questions / Answers / Adjourn for the Day</td>
<td></td>
</tr>
</tbody>
</table>

### Helping Babies Breathe® Master Trainer Workshop Day 3

<table>
<thead>
<tr>
<th>Time</th>
<th>Topic</th>
<th>Presenter</th>
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</thead>
<tbody>
<tr>
<td>08:00</td>
<td>Continental Breakfast</td>
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<tr>
<td>08:30</td>
<td>Planning a HBB® Training Program</td>
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</tr>
<tr>
<td>09:00</td>
<td>Focus on HBB® Sustainability</td>
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</tr>
<tr>
<td>09:30</td>
<td>Hands-On: Mastering the Action Plan®</td>
<td></td>
</tr>
<tr>
<td>11:00</td>
<td>Break</td>
<td></td>
</tr>
<tr>
<td>11:30</td>
<td>Workshop Post-testing Stations</td>
<td></td>
</tr>
<tr>
<td>13:00</td>
<td>Break for Lunch</td>
<td></td>
</tr>
<tr>
<td>14:00</td>
<td>Community Based Applications</td>
<td></td>
</tr>
<tr>
<td>14:45</td>
<td>Integration with Essential Newborn Care</td>
<td></td>
</tr>
<tr>
<td>15:30</td>
<td>Global Linkages For HBB®</td>
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</tr>
<tr>
<td>16:00</td>
<td>Break</td>
<td></td>
</tr>
<tr>
<td>16:30</td>
<td>HBB® Program Wrap-Up</td>
<td></td>
</tr>
<tr>
<td>17:00</td>
<td>Closing Ceremony / HBB® Certificates / Group Photographs</td>
<td></td>
</tr>
<tr>
<td>17:30</td>
<td>Adjourn</td>
<td></td>
</tr>
</tbody>
</table>
To Register

HBB® Workshop registration is limited to maximum of 30 participants. The HBB® Master Trainer Course is designed for clinicians working in developing world settings who have an established system and relationships with clinicians and educators in resource-limited regions and who may establish training-of-trainer (TOT) programs for HBB®. The program will be conducted in English.

- Call
- Register On-line
- On-site Registration available only if space is available.