Improving Perinatal Health in Low-Resource Settings:
A Framework for Effective Translation of Training into Practice

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Abstract

One common method of addressing poor quality care in low-resource settings is clinical training programs. However, despite clinical training programs' ability to improve provider knowledge and skills, a single educational experience does not consistently result in improved health outcomes in low- and middle-income countries. Additional elements are essential to effective translation of training programs into practice including maintaining knowledge and skills, monitoring and evaluation and continuous quality improvement with supportive supervision. Knowledge and skills can be maintained with refresher training, low-dose high-frequency practice of complex skills and point-of-care checklists. Processes of care and health outcomes can be continuously monitored and evaluation of this data reflected back to providers. Continuous quality improvement methods can be used to address local barriers to evidence based care with context-driven solutions, and is most successfully employed with the facilitation of a supportive supervisor. In sum, a training program must be embedded in a self-consciously orchestrated context of pre- and post-program initiatives, all of which are designed to turn the knowledge and skills imparted by the training program into instrumental processes of care.

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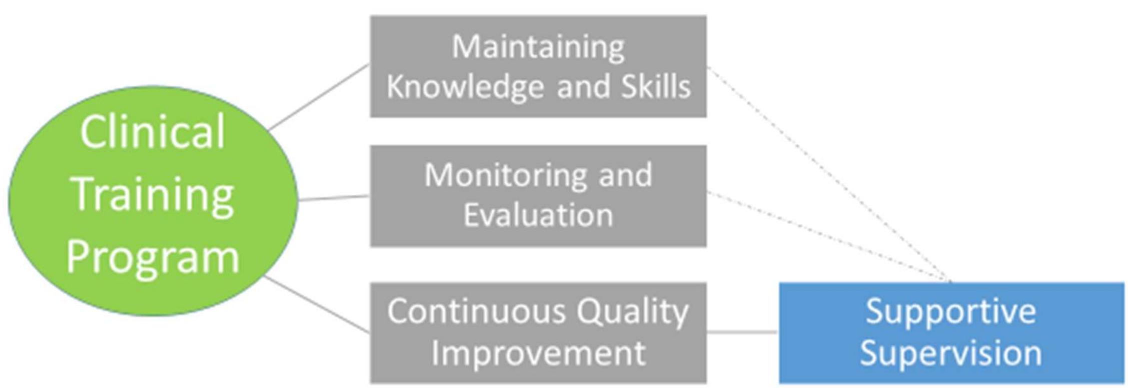
Introduction

Maternal and neonatal health outcomes in low- and middle-income countries (LMIC) lag far behind those of high-income countries (HIC). The LMIC maternal mortality ratio in 2015 was 237/100,000 live births compared to only 10/100,000 live births in HIC.[1] Similarly, the LMIC neonatal mortality rate in 2015 was 21/1,000 live births compared to only 3/1,000 live births in HIC.[2] The disproportionate burden of maternal and neonatal mortality in LMIC is partially attributable to inadequate commodities and staffing, poor infrastructure for health care delivery, and limited access to advanced medical technology. Solutions to these structural deficiencies are resource-intensive and difficult to implement on a large scale. However, lack of knowledge and skills among providers also contributes to deficiencies in health outcomes in these settings. Strong evidence suggests that poor provider knowledge and skills may be ameliorated by clinical training programs.

Clinical training programs have been used in LMIC to improve knowledge and skills of providers in such evidence-based practices as active management of the third stage of labor, newborn resuscitation and early newborn care.[3-7] Many of these programs have been specifically designed for low-resource settings both in their clinical content and their method of instruction. One such example is *Helping Babies Breathe* (HBB), a clinical training program that teaches basic newborn resuscitation with bag mask ventilation using a low-tech newborn simulator.[8] This program uses paired simulation and group learning, with dissemination of the training via a train-the-trainer model. With over 400,000 trained, HBB has consistently demonstrated improvements in knowledge and skills of providers.[9-16] However, concomitant reduction of stillbirths and neonatal mortality following a one-time HBB training has been inconsistently achieved.

Despite clinical training programs' ability to improve provider knowledge and skills, a single educational experience does not consistently result in improved health outcomes in LMIC.[17-19] Implementation of clinical training programs in low-resource settings can be enhanced by additional elements beyond training that support the translation of knowledge and skills into practice and improved health outcomes. Clinical training programs are more likely to produce a change in practice and thus improved outcomes when paired with regular practice of skills, continuous collection and review of data and removal of barriers using quality improvement (QI) methodology with supportive supervision (Figure 1). What follows is an analysis of a framework for effective implementation of clinical training programs, highlighting the following critical elements: maintaining knowledge and skills, monitoring and evaluation and continuous quality improvement (CQI) with supportive supervision. Literature supporting these critical elements is reviewed from both HIC and LMIC. This framework and analysis is designed to aid clinicians who are implementing education in low-resource settings in order to improve health outcomes.

Figure 1: Framework for Effective Translation of Training into Practice. The boxes indicate activities that enhance the translation of training into practice. The success of continuous quality improvement may depend upon supportive supervision (solid line). The influence of supportive supervision on maintaining knowledge and skills and monitoring and evaluation is less certain (hatched lines).



Maintaining Knowledge and Skills

Although a single educational experience can improve knowledge and skills of providers, it does not ensure long-term retention of knowledge nor mastery of skills. Strategies that address declines in knowledge over time as well as the acquisition of complex skills through repetition are critical to the translation of knowledge and skills into practice following a clinical training.

Knowledge decay has been repeatedly demonstrated following single educational experiences in LMIC. Newborn resuscitation education using both the Neonatal Resuscitation Program (NRP) and HBB is illustrative of this decline. While early implementation of NRP in China and India achieved modest success,[20-22] a time-related decay in knowledge of nurse-midwives in Zambia was evident just six months after NRP training.[23] Similarly, despite initial improvement of knowledge following HBB training in Tanzania, declines in knowledge ensued as early as 4 to 6 weeks, with on-going declines out to 4 to 6 months.[24]

One strategy that can be used to address this common falloff in knowledge is refresher training. Refresher training has long been accepted as beneficial in HIC in the context of resuscitation programs, and has been increasingly adopted in LMIC. For example, in the United States, intermittent recertification via refresher training is required for life support credentialing including Basic Life Support, Advanced Cardiac Life Support, Pediatric Advanced Life Support and NRP. In LMIC, implementation of HBB has increasingly been paired with refresher training, resulting in a reduction in knowledge decay.[24-31] The optimal frequency and duration of refresher training is poorly studied in these contexts, but likely depends upon the content of the clinical training program and the context of health care delivery, including clinical expertise of the providers, frequency of use of specific knowledge or a particular skill and frequency of provider turnover.

Point-of-care checklists have also been used as a resource to promote knowledge retention resulting in more consistent compliance with evidence-based practices in both HIC and LMIC. For example, in HIC, the consistent use of checklists has dramatically reduced central line-associated bloodstream infections (CLABSIs) in intensive care units.[32-36] In LMIC, a 29-item checklist for safe institutional birth developed by the World Health Organization (WHO) called the Safe Childbirth Checklist has improved compliance with evidence based childbirth practices.[37,38] Additionally, point-of-care checklists in the Standards-Based Management and Recognition approach used by Jhpiego (a non-profit organization that works in LMIC to improve the health of women and families) have improved provider performance in a variety of evidence based practices in maternal and newborn health.[39] Although these examples are not in the context of a clinical training, they suggest that point-of-care checklists are an important strategy to maintain knowledge and can improve provider performance and health outcomes.

Point-of-care checklists can be useful in reminding providers of the elements of routine perinatal care. They can also be useful in reminding providers of symptoms and signs of disease. For example, checklists to reduce CLABSIs in HIC list routine, evidence based insertion and maintenance practices for central lines. Similarly, portions of the Safe Childbirth Checklist highlight standard care for childbirth regardless of the woman's presentation. Both of these examples support application of point-of-care checklists for care delivered to every woman and newborn, such as active management of the third stage of labor or early newborn care practices. In these cases, the checklist can be a simple but powerful bedside reminder of routine care. Alternatively, other portions of the Safe Childbirth Checklist highlight detection of a woman's symptoms and signs and the appropriate provider response, such as diagnosing and treating postpartum hemorrhage. This example illustrates that point-of-care checklists can also be helpful for evidence based care that responds to a patient's symptoms and signs. In this cases, the checklist is a reminder of the symptoms to assess and the appropriate response, serving as a ready resource for complex algorithms. Whether used for routine care or care that responds to a patient's symptoms and signs, point-of-care checklists are useful tools for maintaining knowledge following a clinical training.

In addition to knowledge retention strategies, the acquisition of some complex skills may not be possible in a single educational experience and may require repetitive practice for mastery. For example, for the complex skill of bag mask ventilation (BMV), adequate performance following a one-time training is unattainable for the majority of HBB participants.[15,40,41] For providers attending births in low-volume centers, structured practice is particularly important to maintain their skillset given their infrequent use of BMV in clinical interactions. For example, it is estimated that 3-6% of newborns require positive pressure ventilation at birth,[42] suggesting that providers who attend less than two hundred deliveries per year are unlikely to use BMV more than once per month. On-the-job simulation practice of BMV in health facilities has been accomplished with the use of newborn simulators and the development of a newborn care corner where providers can practice BMV at frequent, regular intervals. This repetitive simulation, referred to as low-dose high-frequency (LDHF) practice, has shown significant promise as a strategy for BMV skill acquisition and retention. [9,26,30,43,44] Simulation immediately preceding the delivery of care, referred to as "just-in-time" simulation, has been more recently explored in HIC as a mechanism to improve care. It has shown promise in improving central line dressing changes, lumbar punctures, cardiopulmonary resuscitation and post-operative management of congenital heart disease.[45-49] While not yet studied in the context of BMV, "just-in-time" structured practice of neonatal resuscitation is another strategy that may be particularly effective in supporting skills acquisition and retention. Similar to refresher training, the optimal frequency of LDHF practice is poorly studied in LMIC, but likely depends upon the complexity of the skill and context of health care delivery, including the volume of births at the facility and clinical expertise of the providers.

A one-time clinical training paired with additional elements such as refresher training, point-of-care checklists and/or LDHF practice enhances provider retention of knowledge and acquisition of skills.

Careful consideration of the content of the training program, complexity of skills and context in which health care is delivered can help guide the choice of method(s) that best support maintaining knowledge and skills.

Monitoring and Evaluation

In addition to supporting providers with strategies to maintain knowledge and master skills, empowering front line workers with data regarding the care they provide and the outcomes of their patients is critical to identification of gaps in quality and reinforcement of knowledge. In HIC, providers of maternal and newborn care are usually aware of the outcome of their care because data on key outcome indicators are collected as part of the routine medical recordkeeping system. Providers also usually have access to information about their performance of specific practices. By comparing observed practices to recommended practices and observed outcomes to expected outcomes, providers can identify gaps in the quality of their care. Gaps identified in this manner can be addressed using quality improvement methods (see below). In addition, providing analyzed data directly to providers (and particularly data describing processes of care) may be another strategy for re-enforcing knowledge and skills. Systematic engagement in continuous collection of key process and outcome indicators is often referred to as monitoring, and the comparison of analyzed data to standards or expected outcomes referred to as evaluation.

Monitoring, most often without evaluation, is a relatively common practice in LMIC. It is usually *intermittent* and performed at the level of the health facility in response to a mandate by health ministries. These data are rarely reflected back to providers in these settings. There is no evidence that this strategy of monitoring improves health care or outcomes. A more effective approach to monitoring is continuous monitoring. A common example of *continuous* monitoring in low-resource settings is the tracking of immunization delivery to the pediatric population by non-governmental organizations or ministries of health. Immunization programs are among the most successful programs in LMIC, and it is likely that continuous monitoring has contributed to this success. Unfortunately, similar continuous monitoring of perinatal health indicators at the facility level in LMIC is uncommon.

Monitoring and evaluation require resources. With infrastructure for continuous monitoring often lacking in low-resource settings, success of monitoring strategies may depend upon the selection of data. The most useful indicators are those that are collectable without extraordinary cost or time involved, and that are clearly defined so that they are consistently measureable across time and place.[50] At its best, monitoring in LMIC may be accomplished via national data systems. However, in many cases, tracking indicators may require data collection from facility-level delivery registers. In some circumstances, data collected from direct observation of care may be required. The use of cellular and online technologies can facilitate timely and efficient data collection in these settings. In practice, particularly in settings with minimal infrastructure for data collection, supportive supervision can assist with implementing monitoring and evaluation, as the next pages make clear.

Ideal strategies for monitoring and evaluation make the best use of scarce resources by identifying the minimum set of perinatal process and outcome indicators for monitoring following a clinical training program. Process and outcome indicators should be selected for their relevance to the clinical content of the intervention. Additionally, process indicators should be chosen for their likelihood of affecting health outcomes. For example, while the process of measuring newborn weight is an important part of early newborn care, it is unlikely to have a large effect on a particular health outcome; alternatively, the process of eye ointment application clearly reduces the incidence of newborn eye infections and thus is a better process indicator to measure. Outcome indicators should be chosen for their responsivity to changes in the system in the context of the timeframe of implementation. For example, if neonatal death is relatively rare in a small health center with a low volume of deliveries, neonatal mortality is unlikely to change in response to an intervention that occurs over the space of months rather than years; alternatively, exclusive breastfeeding rates could be more responsive to a shorter intervention focusing on early newborn care and is a better outcome indicator to measure. Mortality may still be one of the most important indicators, but it may be more useful for defining population health (i.e. at the national or regional level) rather than being used as a determinant of the quality of care at a facility.

Based on these principles, the following is an example of a minimum set of process and outcome indicators that might be monitored following an educational program to improve knowledge and skills necessary to provide early newborn care:

- percent of neonates receiving skin-to-skin exposure for the first hour of life;
- percent of neonates receiving vitamin K injection;
- percent of neonates receiving eye ointment prophylaxis;
- percent of neonates initiating breastfeeding in the first hour of life;
- percent of neonates exclusively breastfeeding at discharge; and
- percent of neonates with hypothermia (defined as a temperature <36.5 C)

Each of these measures directly reflects best practices in newborn care interventions, with process indicators having a direct effect on health outcomes. Alternatively, "tracer indicators" that objectively measure a specific health service are another approach to lean measurement in low-resource settings. For example, the WHO has established early initiation of breastfeeding as the tracer indicator for early newborn care following the appearance of strong evidence that links this process to reduced newborn morbidity and mortality, primarily through reduction of infections.[51] In the present case, the list of process and outcome indicators above could be distilled to the one tracer indicator of percent of neonates initiating breastfeeding in the first hour of life.

Evaluation of continuously collected indicators produces its greatest benefit when results of data analyses are made available to providers in a meaningful format. One such strategy is the generation of run charts. These are created for each indicator by plotting the number or percent of patients for whom the process was performed or who experienced the outcome on the y-axis during designated time intervals (typically in days, weeks or months) indicated on the x-axis. Gaps in quality, as evidenced by poorly compliant processes of care or poor health outcomes, are readily seen on the run charts. These run charts can be publicly displayed so that they are accessible to those working at the point of care delivery, thereby engaging providers in the process of improving care. The gaps in quality discovered by monitoring and evaluation are best addressed with CQI.

Continuous Quality Improvement

Engaging providers in improvement work is fundamental to the translation of knowledge and skills into practice and improved outcomes, thus making CQI a critical element of our proposed framework. In 2001, the Institute of Medicine published *Crossing the Quality Chasm*, a report on the status of the United States health care delivery system and six aims for improvement.[52] This report fostered a growing recognition of inconsistent quality care delivered by health systems, and resultant momentum to improve health outcomes. This momentum led to the wholesale adoption of continuous quality improvement methods in hospitals around the country. In contrast, the widespread use of CQI has not permeated the health care infrastructure of LMIC.

While the term QI can be understood to encompass many different strategies, in this paper, I use the more specific term continuous quality improvement (CQI) to refer to methods that continuously address gaps in quality through problem-analysis followed by the development and testing of tailored solutions. Even when providers are knowledgeable and skilled in delivery of care, monitoring and evaluation will identify gaps in quality including non-compliance with evidence based practices and poor health outcomes. Systems are perfectly created to produce the results they produce. For example, a provider who knows the importance of drying and stimulating a newborn immediately following birth may not dry the baby if towels or cloths to dry the baby are not readily accessible in the delivery room.

Alternatively, a provider who knows the benefits of early skin-to-skin care may separate the newborn from the mother to administer vitamin K because it is his or her responsibility to complete this task before transitioning the mother and baby to the postpartum area. Gaps in quality care differ across facilities and require tailored solutions for their removal. Some gaps may be opened by higher systems level barriers such as inadequate staffing, insufficient supplies and poor health infrastructure—barriers which are resource-intensive to address, and often require interventions beyond the facility level. However, additional performance barriers causing gaps in quality may exist within the facility itself, such as poorly organized processes, misaligned incentives, provider's convenience and challenges with management/leadership. CQI is best suited to address context-specific barriers such as these.

The success and widespread use of CQI in perinatal care in HIC is illustrative of its power as a tool to improve health care delivery. CQI has been successfully employed by perinatal quality collaboratives in the United States to reduce CLABSIs, late onset newborn sepsis and elective deliveries before 39 weeks gestation, as well as to increase antenatal steroid use for premature birth and breast milk feeds for premature newborns.[32,53-64] However, its generalizability to single centers in low-resource settings may be limited by the context-specific nature of improvement work and the dependency on learning collaboratives to achieve these results. Despite these factors that limit drawing inferences about CQI in low-resource settings, the success of CQI in HIC supports consideration of its use in LMIC.

The importance of QI science in improving health outcomes in LMIC is increasingly being recognized at the international level, as evidenced by the recently published WHO quality of care framework for pregnant women and newborns, as well as development of guides for auditing stillbirths and neonatal deaths.[65,66] At the national level, the Early Newborn Action Plan has encouraged many ministries of health in countries with the highest newborn mortality rates or highest number of neonatal deaths to focus on improving care by defining national newborn plans, allocating resources and defining target outcomes.[67] In comparison, QI at the facility level has been adopted more slowly in the face of limited staffing, poor support from health facility and national leadership, lack of electronic record keeping, and limited exposure to QI methodology.[68-70] Successful strategies of implementation of CQI at the facility level in LMIC have entailed the use of an external QI facilitator or coach, involvement of front-line health care workers in the development and testing of solutions, and selection of low-cost solutions.[67]

Application of CQI at the facility level has demonstrated improved compliance with perinatal processes of care and outcomes in both single center case studies[71-73] and multi-center and national level studies in LMIC.[74-76] Many methods of CQI at the facility level have been explored in low-resource settings, including improvement collaboratives, Total Quality Management, Lean and Six Sigma, and Client-Oriented, Provider-Efficient services.[77-79] One example of a multi-center study demonstrating success with CQI and coaching is the maternal newborn health program in Niger and Mali, implemented by the United States Agency for International Development through Applying Science to Strengthen and Improve Systems. The study involved continuous, shared learning across multiple facilities with baseline assessment of quality care, on-site training in improvement, monitoring and evaluation, and support through intermittent site visits.[74] Examples of changes implemented by QI teams in this study included "low-hanging fruit" such as maintaining essential commodities in designated care areas to improve compliance with care (e.g. keeping oxytocin in the delivery room rather than in the pharmacy) and purchasing coolers to maintain oxytocin during power outages. More complex changes implemented by QI teams included staff-led 24-hour call schedules to ensure presence of a skilled birth attendant at every birth, modifying facility records to remind providers to implement best practices, and reorganizing care to delay bathing of newborns. These examples highlight the benefit of implementation of relatively low-cost interventions using CQI methodology.

This framework for effective implementation of clinical training programs recommends using CQI to develop locally relevant solutions to gaps in quality with the help of a QI coach to engage frontline workers in developing and testing low-cost solutions. I recognize that this may be the most challenging element of the framework to implement given the obstacles discussed above. However, CQI remains a powerful tool to address local barriers to evidence based practice, and the increasing focus on QI science at the international and national level suggests it will play an increasingly important role at the facility level in LMIC. In the context of a clinical training, CQI can create local momentum for on-going improvement long after an intervention, empowering health care workers to understand both the value of their own observations and their capacity to improve the care they provide.

Supportive Supervision

All elements of the framework to promote successful translation of education into practice may benefit form support from experts who understand the context of facility-based care and can adapt each element to this context. This type of support is often termed “supportive supervision.” Supportive supervision includes working with staff to set goals, identify and correct problems, and monitor performance. It may occur in all domains of care—management, clinical service, and education.[80] In practice, the role of a supportive supervisor has traditionally involved site visits with health facility staff, with a focus on administration and checking.[81] Less commonly, supportive supervisors also assist with problem solving, feedback and clinical supervision, training, and consultation.[81]

The element that is likely to be most dependent upon supportive supervision for effectiveness is CQI. Although there is clear evidence that QI coaching facilitates successful CQI in low-resource settings, the literature on other functions of supportive supervision is less clear. Inconsistent results with supportive supervision likely result from its diverse implementation, with supervisory visits taking on a variety of functions and being conducted by people with varying clinical background and ability to motivate health care workers.[39,80,82-86] The modest positive effects on knowledge and performance in the context of supervision have been demonstrated in situations where the supervisor supports activities that maintain knowledge and skill or problem-solving. For example, mentorship visits in the context of training in essential early neonatal care practices in district hospitals in Ghana demonstrated improvements in provider knowledge.[25] These visits included review of case management, observation of patient care, coaching and feedback to trained participants, and addressing supply chain issues and management.[25] Additionally, onsite nurse mentoring in primary health centers in South India facilitated provider preparedness as well as facility readiness to support births and birth complications at higher levels than was true in the control facilities.[83] The supportive supervisors in this study conducted onsite mentoring visits and training updates, and gave point-of-care checklists to providers.[83] This evidence prompts the use of supportive supervision of CQI activities, with further focus on maintaining knowledge and skills and monitoring and evaluation as required to support these additional elements of the framework.

Supervision by a QI expert is clearly critical to successful implementation of CQI. Investment in a supportive supervisor for this function should be the focus, but consideration for sustainability of the other elements of this framework may warrant expanding the role to include support of activities that maintain knowledge and skills as well as assistance with monitoring and evaluation. When possible, incorporation of the tasks of a supervisor into the role of personnel already working within the health system, or into the role of ministry of health officials, can facilitate sustainability.

Conclusion

Clinical training programs alone cannot translate knowledge and skills into practice to improve outcomes. The training program must be embedded in a self-consciously orchestrated context of pre- and post-program initiatives, all of which are designed to turn the knowledge and skills imparted by the training program into instrumental processes of care. Knowledge and skills acquired immediately following a training program must be maintained with the support of refresher training, point-of-care checklists and/or LDHF practice. Monitoring and evaluation of a minimum set of quality indicators must guide on-going implementation. CQI with supportive supervision must address context-specific barriers to implementation of evidence based practices. Supportive supervision may assist in the implementation of activities to maintain knowledge and skills as well as monitoring and evaluation to the extent necessary. The success of a clinical training program in LMIC will be enhanced by the deliberate addition of the other elements in this framework.

Appendix 1: Systematic Review

Introduction

Evidence based practices have been shown to improve mortality. Educational programs that teach evidence based practices are a common strategy to address poor health outcomes in low resource settings. One such example is *Helping Babies Breathe* (HBB), an educational program endorsed by the American Academy of Pediatrics that teaches delivery room resuscitation of the newborn using a low-tech newborn simulator and bag-mask.[1] This program uses small group discussion and paired learning with a train-the-trainer strategy for dissemination.

With over 400,000 trained, HBB has consistently demonstrated improvement in knowledge and skills of providers.[2-9] However, translation of knowledge and skills into practice and ultimately reduction of neonatal mortality has been inconsistently achieved. Examples of additional elements that support the translation of knowledge and skills into practice following a single educational experience include maintaining knowledge and skills with refresher trainings and low-dose, high frequency (LDHF) practice, as well as supportive supervision.[10-12] This systematic review synthesizes all controlled or observational trials of HBB with or without additional implementation elements in low resource settings, focusing specifically on resultant neonatal health outcomes.

Methods

Any controlled or observational trial of HBB training with or without additional implementation elements occurring in the context of a low-resource population was eligible for review. Additional implementation elements were defined as any intervention designed to improve neonatal processes of care or health outcomes that was implemented in concert with HBB training. These additional implementation elements included but were not limited to refresher trainings, simulation practice and supportive supervision. Any number of comparators were allowed including HBB training alone (when compared to HBB training with additional elements of implementation), pre and post comparisons, a control group without HBB training or no comparator at all. The outcome was defined as fresh stillbirth, neonatal mortality, perinatal mortality or neurodevelopmental impairment (Table One). Given the small body of literature that could address the question under review, there were no time or language restrictions for this review. In addition to studies published in peer-reviewed journals, other gray literature was also eligible for review including abstracts for oral or poster presentations at national meetings and doctoral theses.

Table One: Eligibility Criteria

Patient/Population	Newborns in low-resource settings
Intervention	HBB training +/- additional elements of implementation (including but not limited to refresher trainings, LDHF practice and supportive supervision)
Comparison	HBB training alone, a non-treatment control, a before intervention comparison or no comparator at all
Outcome	Fresh stillbirth, neonatal mortality, perinatal mortality or neurodevelopmental impairment
Study Design	Observational or controlled trial

The following databases were searched for relevant literature: PUBMED, EMBASE, CINAHL, SCOPUS, clinical trials.gov, WHO ICTRP and the Cochrane library. The reference list of studies of particular importance, as well as those of commentaries on HBB, were scanned by the investigator for additional articles of relevance. Furthermore, the HBB website was consulted for other gray literature as were the author's own files. The date of the last search was February 7, 2017.

The search for PUBMED was conducted using "helping babies breathe" as well as its abbreviation, "HBB," in combination with a variety of Medical Subject Heading terms that were noted for articles that were promising for inclusion. The final search strategy entailed the following string of search terms: "helping babies breathe" OR "HBB AND resuscitation" with no additional limits imposed. This strategy was adapted for subsequent databases based on the indexing system for that database.

All studies retrieved during the search of the aforementioned databases were compiled and duplicates excluded. The investigator screened all titles and abstracts for relevance; abstracts with no accompanying full text publication were also excluded. Full text articles were screened for eligibility criteria by answering the following questions in order, with negative responses truncating the screen and making the study ineligible: Was the publication a controlled or observational trial? Was HBB training part of the intervention? Did the study measure fresh stillbirth, newborn mortality, perinatal mortality or neurodevelopmental impairment? Data extraction forms were designed for full text article review with questions regarding the population, intervention, comparison group, outcomes, study design, sample size, length of follow-up and funding source. The investigator extracted data from each article using this extraction form.

Quality was assessed using the risk of bias in non-randomized studies – of interventions (ROBINS-1) assessment tool developed by the Cochrane Review Group.[13] Bias due to confounding, bias in selection of participants into the study, bias in classification of interventions, bias due to deviations from intended intervention, bias due to missing data, bias in measurement of outcomes and bias in selection of the reported result were considered. Studies were classified as low, moderate, severe or critical risk of bias or no information. Given the small number of studies reviewed, results from all studies were reported in the context of their quality classification. Assessment of risk of bias across studies was made by comparing outcomes listed in the methods section to those reported in the results for each article included in this review.

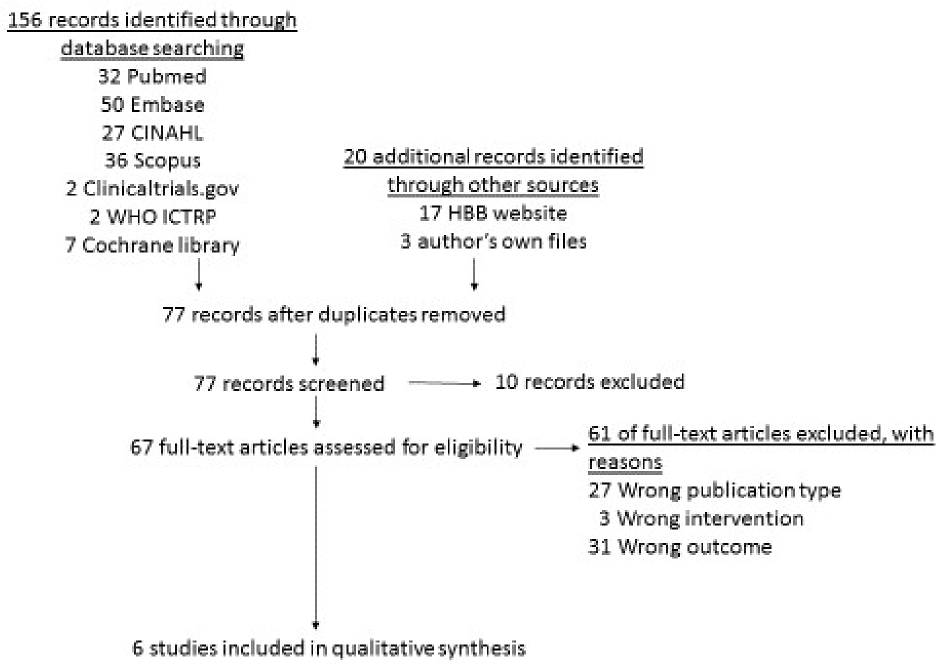
The pre-specified primary outcome measures were fresh stillbirth, newborn mortality, perinatal mortality and neurodevelopmental impairment. Results of each study were described, and only the subset of data related to the primary outcome measures were included.

Results

156 records were identified through database searching and 20 additional records through other sources. After duplicates were excluded, 77 records remained. These 77 were screened for

relevance with ten excluded (Figure One). The remaining 67 full-text articles were assessed for eligibility, and 61 were excluded due to the following reasons: wrong publication type (i.e. the article was not an observational/controlled trial); wrong intervention (i.e. the intervention did not include HBB training); wrong outcome (i.e. the article did not measure fresh stillbirth, newborn mortality, perinatal mortality or neurodevelopmental impairment).

Figure One: Flow of Information Through Different Phases of the Systematic Review.



All studies included in this review were pre-post studies with sample size ranging from 464 births to 86,624 births. Facilities studied included primary, secondary and tertiary level facilities in rural or semi-urban settings located in India, Kenya, Tanzania, Nepal and Nicaragua. The control comparison groups were all HBB naïve other than in the Mduma and colleagues study in which some participants in the control participated in a one-day training in HBB. Intervention groups received HBB with at least one additional element such as refresher trainings, LDHF practice, quality improvement, supportive supervision or Essential Care of Every Baby (ECEB).

All studies in this review carried a low to moderate risk of bias (Table Two). Three studies exhibited potential bias in measurement of the outcome of stillbirth due to differential misclassification; however, this potential bias was mitigated by an unchanged or reduced postnatal mortality rate. One study was considered moderate bias due to potential confounding with low birth weight favoring the comparator, and another moderate bias due to deviation from the intended intervention of 10% of participants, again favoring the comparator.

Table Two: Risk of Bias Within Studies.

Study	Overall Risk of Bias (i.e. low, moderate, severe, critical, no information)	Comments
Bellad et al, 2016[14]	Moderate	Potential confounding favoring the comparator due to increase in low birth weight infants post intervention that could contribute to perinatal mortality. Otherwise low risk of bias in remaining domains.
Goudar et al, 2013[2]	Low	Potential bias in measurement of the outcome of stillbirth due to differential misclassification; however, when taken in context of unchanged neonatal mortality rate pre and post, cannot be the explanation for improved outcomes. Low risk of bias in remaining domains.
KC et al, 2016[15]	Low	Potential bias in measurement of the outcome of stillbirth due to differential misclassification; however, when taken in context of reduced first day mortality pre and post, cannot be the explanation for improved outcomes. Low risk of bias in remaining domains.
Mduma et al, 2015[16]	Moderate	Ten percent of post-intervention participants were not trained in HBB, thus moderate risk of bias due to deviation from intended intervention that favors the control. Low risk of bias in remaining domains.
Msemo et al, 2013[17]	Low	Potential bias in measurement of the outcome of stillbirth due to differential misclassification; however, when taken in context of reduced neonatal mortality rate pre and post, cannot be the explanation for improved outcomes. Low risk of bias in remaining domains.
Perez et al, unpublished[18]	Low	Low risk of bias in all domains.

HBB with refresher training in rural primary health centers, district and urban hospitals in India statistically significantly decreased the odds of fresh stillbirth with a ratio of 0.54 (95%CI 0.37, 0.78), but did not change neonatal mortality (Table Three).[2] The addition of LDHF practice with HBB and refresher training in a rural referral hospital in Tanzania did not change the rate of fresh stillbirths but did reduce first-day neonatal mortality with a relative risk of 0.64 (95%CI 0.41, 0.98).[16] A similar HBB implementation in eight additional hospitals in Tanzania resulted in both a reduction in fresh stillbirths with a RR 0.76 (95%CI 0.64, 0.90) and in early perinatal mortality with a RR 0.67 (95%CI 0.59, 0.76).[17] The implementation of HBB with refresher training and LDHF practice, plus the addition of supportive supervision in semi-urban and rural communities in India and Kenya did not produce a statistically significant change in fresh stillbirths, early neonatal death by 7 days or perinatal mortality following the intervention.[14] However, this study was affected by a moderate risk of bias favoring the comparator due to a substantial increase in low birth weight infants in the intervention phase. An alternative approach of HBB implemented with refresher training and LDHF practice plus quality improvement cycles in a tertiary hospital in Nepal resulted in a decrease in fresh stillbirths with an adjusted OR 0.46 (95%CI 0.32, 0.66) as well as a decrease in first-day neonatal mortality with an adjusted OR 0.51 (95%CI 0.31, 0.83).[15] Finally, implementation of HBB with ECEB and supportive supervision in rural health centers in Nicaragua was inadequately powered to detect differences in mortality.[18] None of the studies in this review measured neurodevelopmental outcomes.

Table Three: Results from Eligible Studies.

Study	Outcomes
Bellad et al, 2016[14]	Fresh Stillbirth: Mean Difference 3.75 (95%CI -0.21, 7.70) Early Neonatal Death by 7 days: Mean Difference -1.41 (95%CI -5.45, 2.64) Perinatal Mortality (fresh stillbirth + early neonatal death by 7 days): Mean Difference 2.34 (95%CI -3.11, 7.80)
Goudar et al, 2013[2]	Fresh Stillbirth: Odds Ratio 0.54 (95%CI 0.37, 0.78) Neonatal Mortality Rate: Odds Ratio 1.09 (95%CI 0.80, 1.47)
KC et al, 2016[15]	Fresh Stillbirth: adjusted OR 0.46 (95%CI 0.32, 0.66) First-day Neonatal Mortality: adjusted OR 0.51 (95%CI 0.31-0.83)

Mduma et al, 2015[16]	Fresh Stillbirth: RR 0.90 (95%CI 0.65, 1.24) First-day Neonatal Mortality: RR 0.64 (95%CI 0.41, 0.98)
Msemo et al, 2013[17]	Fresh Stillbirth: RR 0.76 (95%CI 0.64, 0.90) Early Perinatal Mortality (fresh stillbirth + early neonatal death by 24hours): RR 0.67 (95%CI 0.59, 0.76)
Perez et al, unpublished[18]	Not adequately powered to detect differences in mortality

With respect to risk of bias across studies, Mduma and colleagues did not report on outcome measures in the methods section, so we were unable to note discrepancies. All other studies included in this review had consistency between the outcomes proposed in the methods section and those presented in the results of each article.

Discussion

HBB implemented in the setting of other elements such as refresher training, LDHF practice, quality improvement and supportive supervision reduced perinatal mortality in four large studies compared to pre-intervention groups. One study did not have adequate power to measure mortality; the other study did not demonstrate a statistically significant reduction in neonatal mortality, but had a moderate risk of bias favoring the comparator due to an increase in low birth weight infants in the intervention.

Implementation of HBB targets the newborn from birth onwards, and thus would not be expected to reduce fresh stillbirths. However, misclassification of neonatal deaths as fresh stillbirths is common in low-resource settings because non-breathing, non-moving infants are not always examined for a heartbeat. HBB covers accurate detection of stillbirths, thus a reduction in fresh stillbirths due to prior false classification has been seen following HBB implementation. Studies in this review which demonstrated a reduction in stillbirths also produced a reduction in postnatal mortality, or at least no increase in postnatal mortality, suggesting that HBB was effective in reducing mortality from birth asphyxia.

This literature is limited by a moderate risk of bias in two of the studies, lack of randomized controlled trials, and poor power to detect differences in mortality in one article. Furthermore, conclusions regarding the relative effectiveness of adding refresher training, LDHF practice, quality improvement or supportive supervision to HBB training cannot be drawn given the lack of literature comparing HBB alone to HBB with each of these additional elements. Despite these limitations, the results of these large interventional studies on HBB implementation suggest that the clinical training program is effective in reducing neonatal mortality and may be an appropriate intervention for ministries of health to support.

Further literature on reducing mortality from birth asphyxia with HBB training should explore the relative effectiveness of each of the additional elements: refresher training, LDHF practice, quality improvement and supportive supervision. Additionally, more needs to be discovered about the optimum frequency and timing of refresher training as well as LDHF practice based on the environmental context. Research is also needed to understand the role of supportive supervision and its contribution to the program’s success. Recognizing that the addition of each of these elements is costly, studies should also consider the relative cost-effectiveness of each of these elements to guide ministries of health in their allocation of resources. Finally, there is no literature on the neurodevelopmental outcomes of infants who survive the perinatal period as a result of the HBB intervention. It is possible that reducing death from birth asphyxia through HBB could increase poor neurodevelopmental outcomes. This information is critical to understanding the long-term effect of the program and should also be prioritized for future studies.

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