THE MEASUREMENT OF THE QUALITY OF MATERNAL AND NEWBORN CARE IN MALAWI:

COMPARATIVE ANALYSES OF HEALTH WORKER PERFORMANCE MEASUREMENT METHODS AND AN EXPLORATION OF EVIDENCE OF RESPECTFUL MATERNITY CARE

By

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Abstract

Background: Global evidence suggests that better quality of care is associated with reductions in maternal and newborn mortality. The routine measurement of the quality of care is important to ensure the proper functioning of a health care system but there is no consensus on the best way to measure quality of care, especially relating to the process of care. While the direct observation of clinical care (especially as it relates to labor, delivery and essential newborn care) may be a gold standard, the routine use of this method is not feasible in most resource poor settings. This dissertation examines the relationship between different process quality of care measurement methods for selected maternal and newborn care services in Malawi including adherence to clinical guidelines, consistency and quality of health worker performance, and the provision of respectful maternity care. The results of an analysis of the quality of essential newborn care and respectful maternity care are also provided.

Methods: Using data from an evaluation of a neonatal resuscitation program (Helping Babies Breathe or HBB) in Malawi, Paper One examines the validity of clinical simulations as a measure of health worker performance of essential newborn care, self-reported provision of the active management of the third stage of labor, and partograph use when compared to the gold standard of direct clinical observations. Paper Two assesses the consistency and overall quality of health worker performance of essential newborn care practices. Paper Three uses direct clinical observation data to provide estimates of prevalence of disrespect and abuse during childbirth and develops and validates a scale to routinely measure respectful maternity care.

Results: Results from Paper One show that clinical simulations are a valid measure of most processes involved in providing essential newborn care (other than hand hygiene) while self-report is a valid measure of the active management of the third stage of labor. Paper Two shows that health workers did not always perform all essential newborn care steps consistently on every

newborn they were observed providing care for and that there was variation in performance between health workers. Paper Three shows that health worker communication with clients during labor and delivery was generally low. The overall prevalence of physical and verbal abuse was low but privacy and the encouragement of a support person to be present during labor and delivery were also low. Results from the development of a scale to measure respectful maternity care showed that two factors (provider to client communication and provider encouragement during the first stage of labor) could be used to assess the provision of respectful maternity care using direct clinical observation data.

Conclusions: Through the generation of valid data using feasible methods, measurement can be a key driver in improving the quality of maternal and newborn care. This dissertation used clinical simulation data and direct clinical observation data to show that a low cost measurement method (clinical simulations) can be a valid proxy for direct clinical observations to measure the provision of essential newborn care. This finding has implications from the level of policymakers, quality improvement specialists, facility-level supervisors and even researchers who can confidently use this method to measure most of the processes involved in effectively managing a newborn when resources are limited or when data need to be generated routinely. This dissertation has also added to the set of tools available to measure respectful maternity care through the development of a scale using direct clinical observations. The tool has its limitations in terms of the type of data that can be generated from it, but it if used in conjunction with other tools, it can provide an estimate of the prevalence of disrespect and abuse during facility-based deliveries that adhere to international human rights guidelines. Finally, the findings also show that there are still improvements to be made in the overall provision of maternal and newborn care in Malawi. Health workers were not always adhering to clinical guidelines for essential newborn care, were not always following evidence-based maternal health practices (use of a partograph and provision of the active management of the third stage of labor) and were not always treating their patients with dignity and respect. The findings

provide evidence that further work needs to be done to ensure that women who deliver in these facilities are receiving the best care possible.

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List of Terms and Abbreviations

AAP	American Academy of Pediatrics
AMDD	Averting Maternal Deaths and Disabilities
AMTSL	Active Management of the Third Stage of Labor
ANC	Antenatal Care
BEmOC	Basic Obstetric Emergency Care
CEmOC	Comprehensive Emergency Obstetric Care
CFA	Confirmatory Factor Analysis
COMREC	College of Medicine Ethical Review Committee
CV	Coefficient of Variation
D&A	Disrespect and Abuse
DCO	Direct Clinical Observation
DHMT	District Health Management Team
EFA	Exploratory Factor Analysis
EHP	Essential Health Package
EmOC	Emergency Obstetric Care
ENAP	Every Newborn Action Plan
FASQ	Facility Audit of Service Quality
HBB	Helping Babies Breathe
HSSP	Health Sector Strategic Plan
ICC	Intracluster Correlation Coefficient
IQR	Interquartile Range
KMO	Kaiser--Meyer-Olkin test of sampling adequacy
KR-20	Kuder -Richardson 20
L&D	Labor and Delivery
MCHIP	Maternal Child Health Integrated Program
MDG	Millennium Development Goal
MOH	Ministry of Health

MNH	Maternal and Newborn Health
PPH	Postpartum Hemorrhage
QoC	Quality of Care
RMC	Respectful Maternity Care
SAM	Service Availability Mapping
SBA	Skilled Birth Attendant
SPA	Service Provision Assessment
TBA	Traditional Birth Attendant
TFR	Total Fertility Rate
UNFPA	United Nations Fund for Population Activities
USAID	United States Agency for International Development
WHO	World Health Organization

Chapter 1: Introduction

Every year, nearly nine out of ten maternal deaths and more than 75% of the 3.6 million neonatal deaths in the world occur in Sub-Saharan African and South Asia (Ameh et al., 2012). The provision of emergency obstetric and newborn care by skilled birth attendants is among the evidence-based strategies developed to address maternal and newborn mortality and ultimately achieve Millennium Development Goals 4 and 5. In Malawi, complications that occur during pregnancy and childbirth are the leading cause of death among women of reproductive age (Chirwa, 2010). Although the skilled birth attendance rate has increased there in recent years and the overall number of newborn deaths has decreased (National Statistical Office & Macro, 2011), the maternal mortality ratio remains high and the proportion of newborn deaths that occur during the intrapartum period has increased. This suggests that high coverage of skilled birth attendance and training of health workers in emergency obstetric and newborn care is not enough—the process of care (both clinical and interpersonal) provided during those encounters should be of high quality if reductions in maternal and newborn mortality are to be made.

Quality is one of the key elements in the right to health and also represents an essential component of the World Health Organization's (WHO) health systems building blocks. The performance of health workers is a critical element of a successfully functioning health system and is a key determinant in the quality of care. Because of increasing emphasis placed on methods to improve quality of health care, especially in low-resource settings, there is a need to efficiently measure changes in quality on a routine basis even when faced with limited program budgets. Measurement tools and methods for assessing health worker performance exist but the cost of using them on a regular basis may be prohibitive. Valid quality measurement options should be available to efficiently and inexpensively assess health worker performance on a routine basis.

In 2013, the USAID-funded Maternal Child Health Integrated Program (MCHIP) conducted an evaluation of the Helping Babies Breathe program in Malawi. The purpose of this study was to measure the performance of health workers who had been trained in Helping Babies Breathe (HBB) in managing

birth asphyxia. Through the generosity of the Principal Investigator, the study team and the funders of the evaluation (USAID), there was an opportunity to integrate a dissertation into this evaluation by using data that were generated on health worker knowledge and performance and through the opportunity to add additional questions to the health worker observation tools that were used as part of the program evaluation.

Divided into three parts, the main objective of this dissertation is to provide clear and programmatically relevant evidence about the validity of lower cost methods to measure health worker provision of maternal and newborn clinical services and respectful care during labor and delivery. The secondary objective is to present information about the quality of the management of labor and delivery in Malawi, focusing on essential newborn care and respectful maternity care. More specifically, the aim of the first part of this dissertation is to validate the use of less resource-intensive measurement methods (clinical simulations and health worker interviews) against data collected through a more labor and resource intensive method that is often thought of as a gold standard (direct clinical observation) to measure the process quality of care. The aim of the second part is to examine the variability and overall quality of health worker performance of essential newborn care. These results can guide program staff and evaluators to select the most practical and accurate method to routinely measure the quality of health worker performance in the context of maternal and newborn health in a low income setting. The analysis of the quality of health worker performance of essential newborn care provides public health practitioners with evidence that can be used to focus programmatic strengthening efforts.

The aim of the last part of this dissertation—the assessment of the prevalence of disrespect and abuse during childbirth and the development of a scale to measure respectful maternity care (or care that is centered on the individual and is based on principles of ethics and respect for human rights) (Reis, Deller, Carr, & Smith, 2012)—will add to the limited evidence base for this emerging topic. High coverage of emergency obstetric care services and availability of trained health workers who adhere to clinical standards during labor and delivery will not be beneficial if women are deterred from using those services for fear of being disrespected or abused during facility-based care. Much of the data available

for the examination of respectful maternity care has been generated through qualitative methods but the development of a scale using direct clinical observations will be a starting point in the use of quantitative (direct clinical observation) data to contribute to the methods available to measure respectful maternity care. The results from the analysis of the prevalence of disrespect and abuse during labor and delivery will provide policymakers with quantitative evidence that can be used to drive actions to correct gaps in provision of respectful maternity care.

Reflecting the central theme of the measurement of the quality of essential newborn care, the specific aims of this study are:

1.) To validate the use of clinical simulations and self-report against the gold standard of direct clinical observations to measure health worker provision of essential newborn care and key labor and delivery practices in Malawi;
2.) To assess the variability and overall quality of health worker provision of essential newborn care in Malawi using direct clinical observation data;
3.) To describe the prevalence of disrespect and abuse during childbirth and to develop a scale to measure the provision of respectful maternity care in Malawi using direct clinical observations.

Organization of this dissertation

The first chapter of this dissertation provides background information on maternal and newborn health worldwide and in Malawi. It explains the importance of measuring the quality of care related to labor and delivery services and essential newborn care in low resource settings and how the process quality can and has been measured. Information is also included about possible barriers to high quality performance and about gaps between knowledge and practice. Chapter 2 explains the details of the study from which the data have been analyzed. Chapters 3, 4 and 5 have been developed as stand-alone papers, where Chapter 3 presents the results from the validation of clinical simulations of essential newborn care in Malawi against direct clinical observations and the validation of self-reported use of a partograph and the active management of the third stage of labor against direct clinical observations. Chapter 4 looks at

the variability and overall quality of health worker provision of immediate newborn care among newborns born without complications. Chapter 5 presents the results from the analysis of the prevalence of disrespect and abuse during childbirth the results of the development of a scale to measure respectful maternity care using direct clinical observations. The last chapter brings the results of the papers together and presents the overall public health importance of the findings.

Background of Maternal and Newborn Health

Overview of maternal health in low and middle income countries

Every day, nearly 800 women die from childbirth or pregnancy related complications, with 99% of these deaths occurring in low income countries (WHO, 2012a). The four major causes of maternal mortality are hemorrhage, infections, unsafe abortion, and hypertensive disorders (pre-eclampsia and eclampsia) (WHO, 2012a). Most of these maternal deaths occur during childbirth and in the immediate postnatal period, which is also when most stillbirths and newborn deaths occur. However, many of these deaths are largely preventable through skilled care during childbirth (WHO & UNICEF, 2010). Maternal mortality tends to be higher in rural areas and among poorer and less educated communities, highlighting disparities in access to quality health services even within a population (WHO, 2014).

Overview of newborn health in low and middle income countries

Approximately 4.4 million children in sub-Saharan Africa die every year, with 27% of these deaths occurring among newborns. The three main causes accounting for 88% of newborn deaths are infection, intrapartum-related conditions and preterm births (Kinney et al., 2010). Child survival programs have tended to focus on the reduction of mortality after the first month of life, when pneumonia, diarrhea, malaria and vaccine-preventable conditions are the most important causes of death. Although child mortality after the first year of life fell between 1980 and 2000, the decrease in the neonatal mortality rate has not been as large and has resulted in an increase in the proportion of child deaths that take place during the neonatal period (Lawn, Cousens, & Zupan, 2005). During the neonatal period, which lasts from birth to 28 days, the daily mortality rate is 30 times higher than during the entire postnatal period and is especially high in the first 24 hours after birth (Lawn et al., 2005). Approximately 75% of all neonatal deaths occur during the early neonatal period (the period before 7 days of age), requiring focused attention on the main causes of death during that period—birth asphyxia and prematurity (Lawn et al., 2005). Also, failure to immediately warm and dry newborns can cause hypothermia and this condition

compounds the inadequate respiratory effort at birth that is found globally in at least 10% of otherwise healthy newborns (Gill, Mazala, Guerina, Kasimba, & Mulenga, 2011).

Birth asphyxia, or the failure to establish breathing at birth, is the third leading cause of neonatal death in low and middle income countries and accounts for approximately 23% of the 4 million annual neonatal deaths (ICDDR,B, 2006). Among neonates who survive asphyxiation during birth, the consequences can range from cerebral palsy, mental retardation and epilepsy among severely asphyxiated newborns to cognitive and behavioral alterations (e.g. hyperactivity, autism, attention deficit, low intelligence quotient score, schizophrenia and development of psychotic disorders in adulthood) among those with mild to moderate asphyxia (Morales et al., 2011).

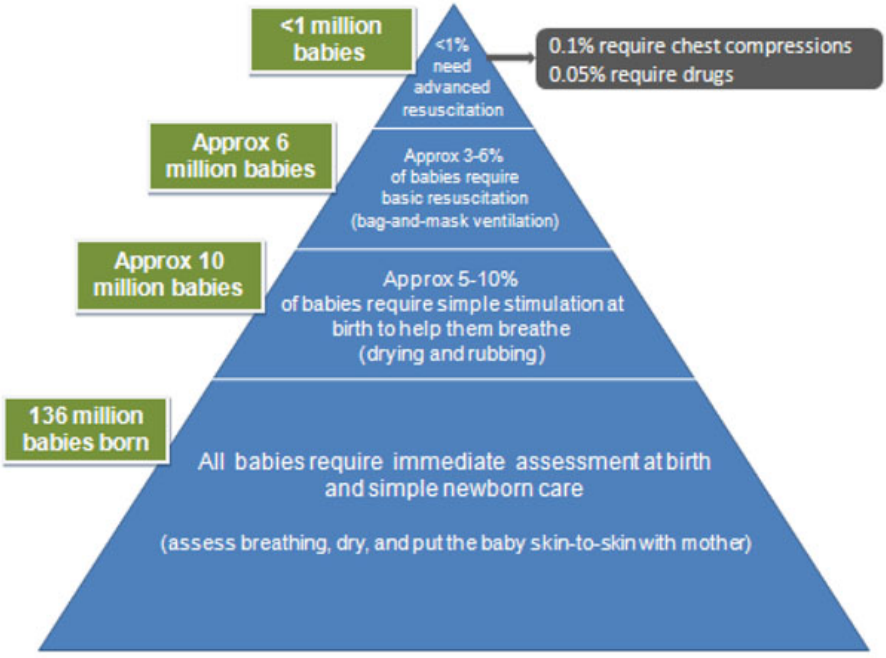


Figure 1: Estimated number of newborns who need assistance to breathe at birth and varying levels of neonatal resuscitation. Figure directly from Lee et. al. (2011).

According to guidelines from the American Academy of Pediatrics and the American College of Obstetrics, the following criteria are used to diagnose asphyxia: profound metabolic or mixed acidemia (pH>7.00) in an umbilical artery blood sample; persistence of an Apgar score of 0-3 for longer than 5 minutes; neonatal neurologic sequelae; and multiple organ involvement (Morales et al., 2011). However, diagnosis of asphyxia using these guidelines is unlikely to be feasible in most low income settings (e.g. blood gas analysis cannot be done in most health centers in low and middle income countries because of lack of facilities and trained staff).

Events that occur during the antepartum, intrapartum or postpartum period (or combinations) can cause birth asphyxia (Azra & Bhutta, 2006). Lee et al., (2008) provided a summary of antepartum,

intrapartum, and infant risk factors for birth asphyxia reported previously from hospital-based studies (Figure 2).

Antepartum Risk Factors	Intrapartum Risk Factors	Infant Factors
Multiparity	Malpresentation	Prematurity
Maternal Fever	Prolonged labor	Low birth weight
Pregnancy-induced hypertension	Meconium stained amniotic fluid	Intrauterine growth restriction
Anemia	Preeclampsia	
Antepartum hemorrhage	Premature rupture of membranes	
History of previous neonatal death	Oxytocin augmentation of labor	
	Umbilical cord prolapse	

Table from Lee et al, 2008

Figure 2: Risks factors for birth asphyxia

In a community-based study in Nepal published in 2008, maternal infections, prematurity, and multiple births were found to be important risk factors of birth asphyxia mortality. This study also found low socioeconomic status to be strongly associated with birth asphyxia mortality through possibly influencing maternal nutritional status, care seeking and access to health services during the antenatal and intrapartum periods (Lee et al., 2008). Another study in rural Nepal from 2009 found that the risk of neonatal asphyxia was higher among women with maternal stunting and wasting and among infants with large infant head circumference (through maternal-fetal or cephalopelvic disproportion) (Lee et al., 2009). In low and middle income countries, intrapartum causes are likely to account for a larger proportion of cases of birth asphyxia, given a higher incidence of complications in labor and a lower availability of skilled care during delivery (Azra & Bhutta, 2006). The absence of skilled care during delivery was also found to be an issue in high income settings, as was reported in recent nationwide study in Norway which found that human error (e.g. lack of fetal monitoring and lack of clinical knowledge and skills) was a common cause of birth asphyxia among reported cases of birth asphyxia between 1996 and 2008 (Andreasen, Backe, & Oian, 2013).

However, properly skilled health workers can usually manage newborn asphyxia. According to Wall et al (2009), basic resuscitation—simulation and ventilation—are the most important steps of resuscitation that can help to reduce deaths during the intrapartum period. Basic newborn resuscitation is required on approximately 3-6% of all newborns and only a very few (~.1%) require advanced

resuscitation. Although many obstetrical conditions that are associated with intrapartum hypoxia cannot be predicted, they can be detected during the intrapartum period by clinical signs (including maternal bleeding and abdominal pain and obstructed labor) and the use of a partograph. To detect these conditions, however, requires access to quality emergency obstetric care (Wall et al., 2009). The specific steps in the management of obstetric emergencies will be discussed in greater detail later in this chapter.

Maternal health in Malawi

The leading cause of death among women of reproductive age in Malawi is complications of pregnancy and childbirth (Chirwa, 2010). The main direct causes of maternal death are hemorrhage, sepsis, ruptured uterus and eclampsia; the main indirect causes are HIV, malaria and anemia (Colbourn et al., 2013). According to the 2010 Malawi Demographic and Health Survey (MDHS), the maternal mortality ratio in Malawi is 675 maternal deaths per 100,000 live births, while the neonatal mortality rate was reported as 31 deaths per 1,000 live births. The institutional delivery rate in Malawi is 73% (57% in public facilities and 16% in private facilities) (National Statistical Office & ICF Macro, 2011). Of facility births, 44% occur in hospitals and 56% take place in health centers (Malawi MOH, 2010). The skilled birth attendance (SBA) rate in Malawi is 71%, with a skilled birth attendant being defined by the World Health Organization (WHO) as "[a]n accredited health professional-such as a midwife, doctor or nurse-who has been educated and trained to proficiency in the skills needed to manage normal (uncomplicated) pregnancies, childbirth and the postnatal period and in the identification, management and referral of complications in women and newborns" (National Statistical Office & ICF Macro, 2011; WHO, 2004). In Malawi, at least four antenatal care (ANC) visits are recommended for women without complications using the following schedule: 1st ANC visit before the end of 16 weeks of pregnancy; 2nd ANC visit between 24 and 28 weeks of pregnancy; the 3rd ANC visit at 32 weeks and the 4th visit at 36 weeks (National Statistical Office & ICF Macro, 2011). The antenatal care (ANC) attendance rate is 45.5% for four or more visits, with only 12% of pregnant women attending their first ANC visit before the end of their first trimester as recommended (Kongnyuy, Hofman, Mlava, Mhango, & van den Broek, 2009;

National Statistical Office & ICF Macro, 2011). The MDHS 2010 found that almost 2% of women did not attend ANC at all; 3% had only one visit; and nearly 50% had two to three visits (National Statistical Office & ICF Macro, 2011). The increase in the skilled birth attendance rate (from 56% in the 2004 MDHS to 71% in the 2010 MDHS) may be related to the 2008 ban of traditional birth attendants (without the accompanying increase in resources) that was later rescinded in 2010 (Gulland, 2013; National Statistical Office & Macro, 2011; National Statistical Office & ORC Macro, 2005; Rosato et al., 2012).

Although more women are now delivering in health facilities in Malawi, the maternal mortality ratio still remains high, leaving the country unable to meet the goal of MDG5 (reduction of maternal mortality by 75%). Delivery in a health facility may not automatically equate to positive health outcomes because of substandard quality of care and because reducing maternal deaths requires all parts of a health system to function in coordination (Kumbani, Bjune, Chirwa, Malata, & Odland, 2013; Parkhurst et al., 2005). A 2008 study in Malawi found some problems with the quality of care at health facilities that included a lack of technically competent staff; interpersonal problems between health staff and patients; and shortage of drugs (Leigh, Mwale, Lazaro, & Lunguzi, 2008). This same study found that many women were delivering in facilities that did not offer all of the life-saving services that are required to treat obstetric emergencies. Suboptimal obstetric care was found to contribute to over half of the maternal deaths in Southern Malawi (Seljeskog, Sundby, & Chimango, 2006).

Newborn health in Malawi

The neonatal mortality rate is 29 per 1,000 live births which is a significant reduction from ten years ago when it was 40 deaths per 1,000 live births (National Statistical Office, 2014). While the country has made significant strides in reducing neonatal mortality and has reached its MDG goal, the number still remains high

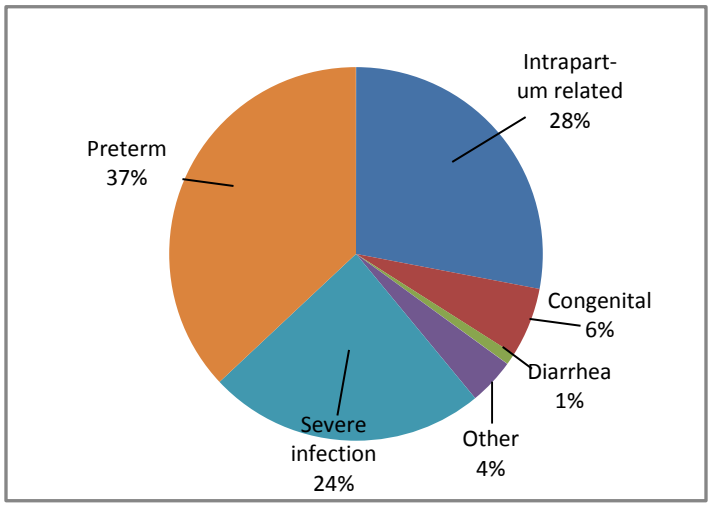


Figure 3: Causes of Neonatal Death in Malawi. Source: Zimba et. al. (2012)

when compared to higher income countries (e.g. the United States where it is estimated to be 4 deaths per 1,000 live births and Japan where it is estimated to be 1 death per 1,000 live births) (UN Inter-agency Group for Child Mortality Estimation, 2015). In Malawi in 2010, there were approximately 17,700 newborn deaths, with prematurity, asphyxia and sepsis being the main causes of neonatal death (Colbourn et al., 2013; Zimba et al., 2012). Nearly 1 out of every 4 neonatal deaths is a result of birth asphyxia (MaiKhanda Trust, 2013). When asked about the most important problems facing neonates, women's groups in Malawi mentioned asphyxia as well as infections, indicating there is community-level awareness of issues facing newborns (Rosato, Lewycka, Mwansambo, Kazembe, & Costello, 2009). Although there can be many biological causes of birth asphyxia, proper management by health workers can result in reviving more than 75% of newborns with asphyxia, resulting in the possibility of reducing all causes of neonatal mortality by 6%-42% if programs implemented neonatal resuscitation (ICDDRB, 2006). Figure 3 presents the causes of neonatal death in Malawi.

Strategies to reduce maternal mortality

It was not until the mid-1980s that strong efforts were made to address maternal mortality in low income settings, precipitated by a 1985 article by Rosenfield and Maine that asked where the "M" was in in MCH (maternal and child health) (Rosenfield & Maine, 1985). During a meeting held in Nairobi, Kenya in 1987, the World Bank, WHO and United Nations Fund for Population Activities (UNFPA) focused their attention on the causes and contributors to maternal morbidity and mortality and strategies to address these problems. A call to action resulted in the development of the Safe Motherhood Initiative, which was one of the earliest international strategies to address maternal mortality and morbidity (Mahler, 1987). In 1995, the Fourth World Conference on Women adopted the Beijing Declaration and Platform for Action which stated their determination to, "[e]nsure equal access to and equal treatment of women and men in education and health care and enhance women's sexual and reproductive health as well as education" (The United Nations, 1995). In 2000, the global community made a commitment to eradicate extreme poverty and improve the health and welfare of the world's poorest people within 15 years by

fulfilling 8 Millennium Development Goals (MDGs). Health is explicitly represented in three of the eight goals and makes an acknowledged contribution to the achievement of all the other goals (WHO, 2005). The goal of MDG 4 is to reduce under-5 mortality by two-thirds by 2015, and the goal of MDG 5 is to improve maternal health by reducing the maternal mortality ratio by 75% and by achieving universal access to reproductive health. International organizations and country governments launched additional strategies to address maternal and newborn mortality. The Every Woman Every Child strategy was launched in 2010 during the United Nations Millennium Development Goals Summit and aims to save the lives of 16 million women and children by 2015 and in June 2012, the governments of India, Ethiopia and the United States with UNICEF convened the Child Survival Call to Action in which they challenged the world to save 45 million additional children's lives by 2035 (The Partnership for Maternal, Child and Newborn Health, 2012; The United Nations, 2010).

It is known that most maternal deaths can be prevented with appropriate care that includes access to skilled birth attendants and quality emergency obstetric and newborn care (EmOC) (Paxton, Maine, Freedman, Fry, & Lobis, 2005). There is also a close relationship between women's health and health care (especially at the time of birth) and early neonatal deaths (Lawn et al., 2011). Since newborn health is intrinsically linked to the mother's health, incorporating newborn care into existing safe motherhood programs has been suggested as a cost-effective way to integrate interventions to improve neonatal, maternal and child health outcomes simultaneously (Haws, Thomas, Bhutta, & Darmstadt, 2007). According to Freedman et al., 2007,"(t)he ultimate goal is to ensure that every birth is attended by a skilled health professional and that every woman who has an obstetric complication receives care either in a basic emergency obstetric care facility (typically a health centre) or in a comprehensive emergency obstetric care facility (typically a district or subdistrict hospital)" (Freedman et al., 2007).

Emergency obstetric care (EmOC) is divided into two levels of care: 1.) basic emergency obstetric care (BEmOC) in which seven signal functions are performed (administration of parenteral antibiotics; administration of uterotonic drug; administration of parenteral anticonvulsants for preeclampsia and eclampsia; manual removal of the placenta; removal of retained products of conception;

assisted vaginal delivery; and basic neonatal resuscitation) and 2.) comprehensive emergency care(CEmOC) in which two signal functions are performed in addition to BEmOC (surgery (e.g. C-sections) and blood transfusions) (WHO, 2009). The WHO EmOC guidelines state that there should be at least 1 facility offering CEmOC services and at least 5 facilities offering BEmOC services per 500,000 population.

According to these guidelines, Malawi should have 134 BEmOC facilities, with 26 of those facilities offering CEmOC (Malawi Ministry of Health et al., 2010). In 2005, the Ministry of Health in Malawi developed a Road Map to reduce maternal and neonatal mortality and morbidity, with one objective being the improvement of EmOC throughout the country (Kongnyuy, Leigh, & van den Broek, 2008). Even though a plan was made to reach the required number of EmOC facilities, results from a 2010 EmOC survey showed that Malawi did not have the recommended number of EmOC facilities per 500,000 population and that there has been no improvement in the number of available EmOC facilities since 2005. However, the country has exceeded the target of having at least 26 CEmOC facilities (with 42 facilities offering CEmOC). This survey also showed that out of 155 government health centers conducting deliveries, only 3% were fully functioning BEmOC sites and 23% were partially functioning (Malawi Ministry of Health et al., 2010). It should be noted that this survey found that 64% of births took place in health facilities and out of these, 22% took place in BEmOC facilities. While the suggested number of CEmOC facilities may exist, they are not all fully functioning and the quality of the services offered is limited,

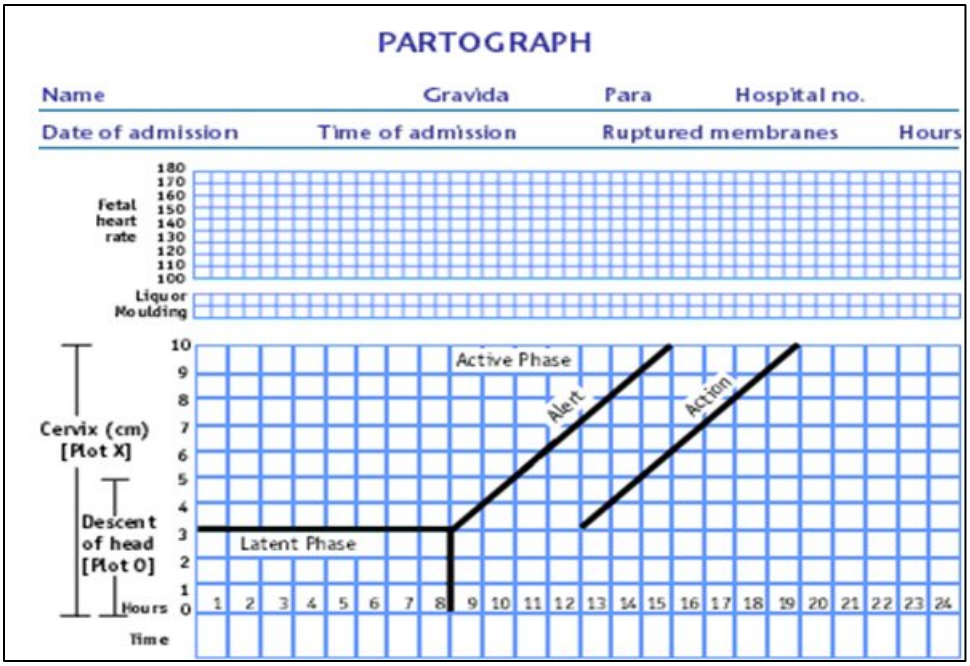


Figure 4: WHO Partograph

ultimately affecting maternal and newborn health outcomes.

As briefly mentioned earlier, hemorrhage is one of the most important direct causes of maternal death, accounting for 25% of maternal deaths mostly from hemorrhage during the postpartum period (Walraven, Wanyonyi, & Stones, 2008). Postpartum hemorrhage (PPH) is defined as blood loss of 500ml or more within 24 hours after giving birth (WHO, 2012b). The active management of the third stage of labor is an evidence based practice used to manage PPH that includes the administration of a uterotonic; controlled cord traction; and uterine massage after the delivery of the placenta and is recommended for all women who deliver in maternity hospitals (Mukherjee & Arulkumaran, 2009). One of the EmOC signal functions is the administration of a uterotonic to reduce the risk of postpartum hemorrhage. The updated 2011 Cochrane Review of active versus expectant management for women in the third stage of labor states that irrespective of their risk of bleeding, active management reduced severe bleeding and anemia for all women in the reviewed studies (Begley, Gyte, Devane, McGuire, & Weeks, 2011). In settings where the health worker does not have the technical skills to manage this complication or the necessary drugs, postpartum hemorrhage can result in maternal death.

Another method to prevent adverse obstetric outcomes related to childbirth is through the continuous monitoring of labor, as one of the factors that can lead to an increased risk of postpartum hemorrhage is prolonged labor (Anderson & Etches, 2007). In 1954, E.A. Friedman introduced the partogram (or partograph) to graphically depict the dilation of the cervix during labor. Then, in 1972, Philpott and Castle added "action" and "alert" lines to the tool to make it more useful for monitoring the progress of labor. The current version of the WHO partogram includes variables (fetal heart rate, dilation of cervix, contractions and mother's pulse rate) plotted on pre-printed paper. The plotted, pre-printed paper allows the health care provider to identify deviations in expected parameters and to identify possible complications (Soni, 2009). A picture of the WHO partograph is presented in Figure 4.

In 1994, The Lancet published the results from a WHO trial of partograph use in three countries in Asia. The study showed that the use of a partograph resulted in a 54% reduction in labor of more than 18 hours; a 9% reduction of instrumental deliveries; a 3% reduction in emergency caesarean sections; and

a 59% reduction in postpartum sepsis. The authors concluded that their results provided evidence that the use of the WHO partograph with a simple management protocol improves the outcome of labor (WHO, 1994). According to the article, "[t]he impressions of the principal investigators and their staff of the partograph as a management tool were unanimously favourable. It was felt that observation of the progress of labour was clearer and this helped in interpreting findings and communication between members of the maternity-care team. The reduction of intravenous infusions for augmentation of labour was appreciated by the midwives as they could give more supportive care to the women (WHO, 1994)." Bosse, Massawe, & Jahn (2002) reported that delivery outcomes in Tanzania were improved with the use of partographs but that implementing the use of this monitoring tool requires continuous reinforcement and quality assurance. Further evidence suggests that partograph use improves maternal and neonatal outcomes during labor in India and Ghana (Tayade & Jadhao, 2012 and Gans-Lartey, O'Brien, Gyekye, & Schopflocher, 2013). However, use of the partograph in low income countries tends to remain low and is oftentimes incorrect. For example, in a study in Nigeria, approximately half of the midwives in a Federal Medical Center and nearly 100% of midwives in Nigeria Delta University Teaching Hospital reported routine use of partographs. Further investigation of the partograph charts indicated that actual utilization was less than reported and that among the partographs reviewed, only one third were properly filled-in (Opiah, Ofi, Essien, & Monjok, 2012). Another recent study in two maternity units in Lilongwe, Malawi found that only 3.9% of 464 partographs were correctly filled-in. The author found that some of the barriers to the use of the partograph were shortage of human resources, high workloads, inadequate supervision and lack of motivation (Khonje, 2012). Additional reasons for low and incorrect use include shortage of staff; lack of knowledge on how to properly fill it out and use it; lack of supplies; and lack of time to fill it out (Opiah et al., 2012; Qureshi, Sekadde-Kigondu, & Mutiso, 2010).

Strategies to reduce newborn mortality

The *Every Newborn* action plan (ENAP) was approved by Ministers of Health throughout the world in May 2014 at the World Health Assembly. ENAP presents a clear vision of how to improve

newborn health and prevent stillbirths by 2035 and builds on the United Nations Secretary General's Global Strategy for Women's and Children's Health and the Every Woman Every Child movement by supporting government leadership and providing guidance on how to strengthen newborn health components. Strategic objective two is stated as "*Improve the quality of maternal and newborn care. Substantial gaps in the quality of care exist across the continuum for women's and children's health. Many women and newborns do not receive quality care even when they have contact with a health system before, during and after pregnancy and childbirth. Introducing high-quality care with high impact, cost-effective interventions for mother and baby together – delivered, in most cases, by the same health workers with midwifery skills at the same time – is key to improvement*" (WHO & UNICEF, 2014). The plan also presents specific actions that should be taken by various constituencies, including the following for health workers: "Health workers: provide quality and respectful integrated services to babies and women through accelerated training, retention and motivation approaches." The plan calls for the prioritization of interventions around the time of birth, including basic newborn care (WHO & UNICEF, 2014). A critical step in ensuring that goals of ENAP can be met is through ensuring the availability and use of valid measurement methods for routine monitoring of process quality of clinical care.

Essential Newborn Care

Universal access to essential newborn care may result in the greatest reduction in global newborn mortality (St Clair, Batra, Kuzminski, Lee, & O'Callahan, 2014). According to the WHO, "essential newborn care," consists of a bundle of provisions including thermal care (drying, warming, skin-to-skin, and delayed bathing), hygienic cord and skin care (hand washing, delayed cord care, chlorhexidine), and early and exclusive breastfeeding. Care of the newborn immediately after birth includes immediate drying and additional stimulation and skin-to-skin contact (World Health Organization (WHO), 2013a). Evidence for the importance of these critical steps in the provision of essential newborn care is presented below.

Hand hygiene: One of the World Health Organization's "six cleans" is hand washing of the birth attendant before birth, with the others being a clean surface; a clean blade; clean cord tie; clean towels to dry the baby and then wrap the baby; and clean cloth to wrap the mother (Pearson, Larsson, Faveau, & Standley, 2006). Blencowe and colleagues (2011) conducted a systematic review and Delphi estimation of the mortality effects of clean birth and postnatal care practices, which included hand washing by birth attendants. They included the results of a 2008 study in Nepal that found that birth attendant hand washing before assistance with delivery was associated with a lower rate of neonatal mortality (RR: 0.66 [0.46-0.95]) (Rhee et al., 2008). In sub-Saharan Africa, the WHO reports that clean childbirth practices could avert six to nine percent of the 1.16 million newborn deaths (Pearson et al., 2006).

Thermal care: Ensuring that the newborn is dry after birth, covering the baby and skin-to-skin contact all reflect proper thermal care of the newborn. After a newborn is delivered, the baby's skin temperature can decrease at a rate of up to 0.3°C per minute as the newborn loses heat from multiple causes (evaporation, convection, conduction and radiation, and possibly humidity and the temperature of surrounding surfaces) (Waldron & Mackinnon, 2007). When a newborn does not have enough heat, the baby's body tries to maintain body temperature through thermogenesis (Salam et al., 2014). Thermogenesis results in increased energy expenditure, which can result in reduced weight gain (Salam et al., 2014). The recommendation to prevent newborn heat loss is to immediately dry the baby (under radiant heat if available) and discard the wet towel and replace it with a dry warm towel (Waldron & Mackinnon, 2007).

Skin-to-skin contact: In addition to being a source of thermal care for the newborn, Mullany et al. (2006) found that infants in Bangladesh who received skin-to-skin contact were 36 percent less likely to have umbilical cord infection. They also report that skin-to-skin contact has been associated with a decreased risk of infectious morbidity among infants, especially low-birth-weight infants (Mullany et al., 2007).

Delayed cord clamping: During the third stage of labor, the infant becomes separated from the placenta by clamping the umbilical cord. There is evidence that delayed cord clamping increases early

hemoglobin concentrations and iron stores in infants (McDonald, Middleton, Dowswell, & Morris, 2014). More specifically, it has been associated with decreased iron-deficient anemia and increased iron stores along with possible effects on long-term neurodevelopment after the newborn period (McAdams, 2014).

Chlorhexidine for clean cord care: The recently-cut umbilical cord is an entry point for bacteria that can colonize the moist stump cord and access the newborn's bloodstream and can cause newborn sepsis and death (Chlorhexidine Working Group, 2014). In settings with high neonatal mortality (30 or more neonatal deaths per 1000 live births) or a large proportion of home births, the application of daily chlorhexidine (7.1% chlorhexidine digluconate aqueous solution or gel, delivering 4% chlorhexidine) to the umbilical cord stump is recommended during the first week of life ((WHO), 2013). This recommendation is based on evidence from several cluster randomized controlled trials that took place in South Asia. The study in Nepal found that neonatal deaths were reduced by 34% if chlorhexidine was first applied within 24 hours of birth; that single chlorhexidine applied on the first day of life in Bangladesh reduced newborn deaths among those enrolled in the study by 20%; and that in Pakistan, neonatal deaths were 38% lower in the chlorhexidine group compared to the dry cord care group (Arifeen et al., 2012; Mullany et al., 2006; Soofi et al., 2012).

Immediate, exclusive breastfeeding: Since 2001, the WHO has recommended exclusive breastfeeding for 6 months (World Health Organization (WHO), 2013c). In Malawi, breastfeeding should be initiated within a half hour of delivery (Malawi Ministry of Health, 2013b). Evidence from a Cochrane review of two controlled trials and 21 other studies suggests that exclusive breastfeeding (defined as no solids or liquids besides human milk, other than vitamins or medications) for six months is associated with a lower risk of gastrointestinal infection and prolonged lactational amenorrhea among mothers (Kramer & Kakuma, 2012). Exclusive breastfeeding, preferably within the first hour of birth is also associated with reduced neonatal mortality, with the possibility of averting 22% of neonatal deaths if started within the first hour after birth (Edmond et al., 2006; Mullany et al., 2009).

Management of babies not breathing at birth

Another specific newborn intervention that has been hypothesized to avert approximately 30% of intrapartum related deaths is neonatal resuscitation training at the facility level in low- and middle-income settings (Wall et al., 2009). At the health facility level in Malawi, there are several interacting factors that are necessary in order to ensure the optimal management of asphyxiated newborns: availability of appropriate resuscitation equipment; availability of skilled health workers in general (in Malawi, these providers are generally nurses and midwives); and availability of providers who are specifically trained in newborn resuscitation and who can perform these skills at a satisfactory level. The majority of EmOC facilities in Malawi report performing neonatal resuscitations, even though 75% of these facilities also lack three or more EmOC signal functions and report shortages in staff and basic drugs and supplies (Zimba et al., 2012). If given the right medical attention, however, any child born alive after seven months of pregnancy in Malawi could be expected to survive (van den Broek et al., 2003). Correct medical attention in this case is one aspect of quality of care.

In order to address challenges specific to low-income countries, the Global Implementation Task Force of the American Academy of Pediatrics (AAP) developed the Helping Babies Breathe (HBB) curriculum. HBB is an educational program designed to teach neonatal resuscitation techniques to health workers in resource-limited areas. The objective of HBB is to train health workers in the essential skills of one of the BEmOC signal functions, newborn resuscitation, with the goal of having at least one person who is skilled in neonatal resuscitation at the birth of every baby. The curriculum is based on the recognition that in many countries, only one birth attendant is available to care for the mother and the newborn. The training materials went through two rounds of review by a Delphi panel of experts as well as a regional technical expert review conducted at the WHO (Singhal & Bhutta, 2008). The HBB curriculum emphasizes assessment of the newborn at birth, stimulation to breathe, and assisted ventilation for babies who are not breathing well by 1 minute after birth. Ventilation and bag and mask resuscitation are the most critical life-saving skills taught through HBB (Singhal & Bhutta, 2008). The HBB program has been incorporated into clinical guidelines in Malawi and is being implemented at a national level.

Quality and the achievement of MDGs 4 and 5

Significant progress has been made towards the achievement of MDGs 4 and 5 but most low income countries were projected to be unable to achieve both targets (Lozano et al., 2011). What is missing from the goal of access to skilled birth attendance and EmOC is the word "quality." In fact, saving the most lives will require more than increasing coverage of care alone; quality of care, or the availability of people with appropriate skills and the essential equipment and drugs, must be improved and must remain high in order to maintain demand for these services (Kinney et al., 2010). Service statistics and information about the coverage of interventions only tell part of the story; e.g. whether a woman delivered with a skilled birth attendant does not indicate the quality of the services she received, including whether she was provided with all of the services that she was supposed to receive. There are instances where skilled staff are available but maternal mortality remains high, indicating that the availability of trained staff alone is not enough to improve maternal health (Shiferaw, Spigt, Godefrooij, Melkamu, & Tekie, 2013). While the coverage of skilled birth attendance may be increasing in some countries, maternal mortality rates remain high, indicating that this indicator only provides information about contact with an SBA, not the content or quality of that contact. Is it enough to assume that by using the word "skilled," the health worker is capable and motivated to provide clinical care at or above standard and has the equipment needed to perform the necessary procedures adequately? How does a health worker manage multiple births and provide quality clinical care to each woman and newborn while working in an understaffed, undersupplied health facility? Do these health workers treat their patients with dignity and respect? The next section of this dissertation will discuss the complications of defining and measuring quality of care.

Background of Quality of Care

What does "quality of care" actually mean?

During the 1978 International Conference on Primary Health Care in Alma Ata, health was declared to be a fundamental human right of which attainment at its highest level was the most important

world-wide goal (International Conference on Primary Health, 1978). In 2000, the UN Committee on Economic, Social and Cultural Rights adopted a General Comment on the Right to Health that included "quality" as one of the elements in the right to health. The comment stated that: "[h]ealth facilities, goods and services must be scientifically and medically appropriate and of good quality" (WHO, 2013). The definition of quality, however, was not clearly defined in that comment.

The term quality of care (QoC) is used widely throughout the literature, but the actual definition of this term is not always so clearly stated. There is a dearth of recent peer-reviewed literature of definitions of quality of care whereas literature actually applying this term is readily available (Goldenberg, 2012). Quality is not defined in a standardized way and actually providing concrete definitions of the term is often overlooked because the meaning may be implied. However, "[e]ven without a concrete understanding of what quality means, everyone seems to agree that it is something worth organizing ourselves around, and that it ought to be monitored, measured and improved" (Goldenberg, 2012). So while there seems to be consensus that quality is important, there is a lack of consensus on what is meant by the actual term.

Quality depends on perspective, location and clinical focus, among other factors. Quality of care is a multidimensional concept that includes appropriate use of effective clinical and non-clinical interventions; strengthened infrastructure; attitudes of health workers; satisfaction of patients and providers; and improved health outcomes (Souza et al., 2013). For a patient at Johns Hopkins Hospital, perception of high quality care may differ greatly from a patient receiving care for the same medical issue in a rural hospital in Malawi. The health worker in each of these communities will likely also have different perceptions of quality based on known resources available in each setting, and communities may have different perspectives about the services that they find to be acceptable. At the government or Ministry of Health level, quality may be related to efficiency and the most judicious use of scarce resources.

Definition of quality in low-income settings

The World Health Organization suggests six areas or dimensions of quality and in doing so, requires that health care be: effective; efficient; accessible; acceptable/patient-centered; equitable; and safe (WHO, 2006). These areas of quality overlap somewhat with Donabedian's Seven Pillars of Quality (efficacy; effectiveness; efficiency; optimality; acceptability; legitimacy; and equity) (Donabedian, 1990). In low income countries, Frater found that quality of care "…is about proper management of organisations, cultural values, and building an integrated approach to providing access to care among front line staff, agreeing on appropriateness and deciding on standards for effective delivery of services" (Frater, 1997). Hulton, Matthews, & Stones (2000) defined quality of care in the context of maternal health as "…the degree to which maternal health services for individuals and populations increase the likelihood of timely and appropriate treatment for the purpose of achieving desired outcomes that are both consistent with current professional knowledge and uphold basic reproductive rights." They also presented a framework (Figure 5) that identifies six elements related to the provision of care: human and physical resources; the referral system; management of information systems; the use of appropriate technologies; internationally recognized good practice; and the management of emergencies. The framework also includes four aspects that relate specifically to the experience of care: human and physical resources; cognition; respect, dignity and equity; and emotional support.

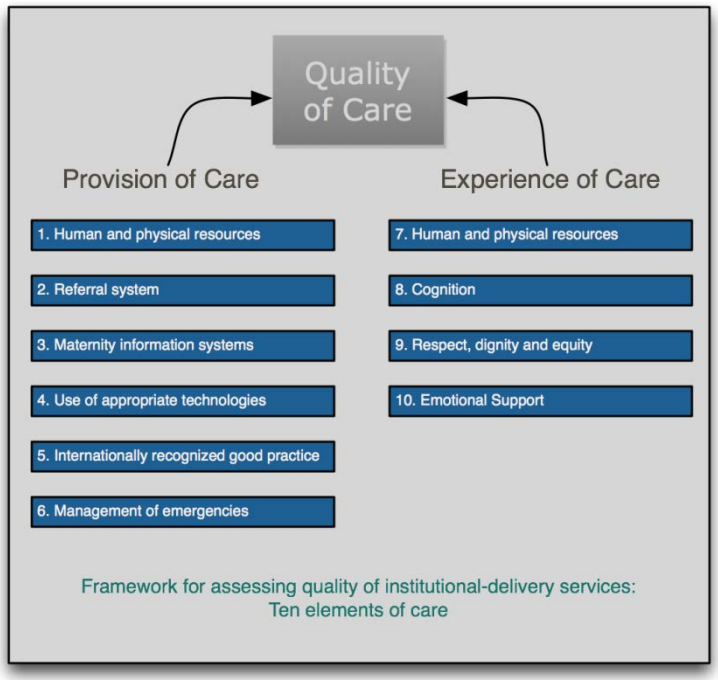


Figure 5: Framework for assessing the quality of institutional delivery services. Figure taken directly from Hulton et al., 2000.

Bruce and Jain defined quality in the context of international family planning as "…the way individuals and clients are treated by the system providing services" (Creel, Sass, & Yinger, 1994). Bruce

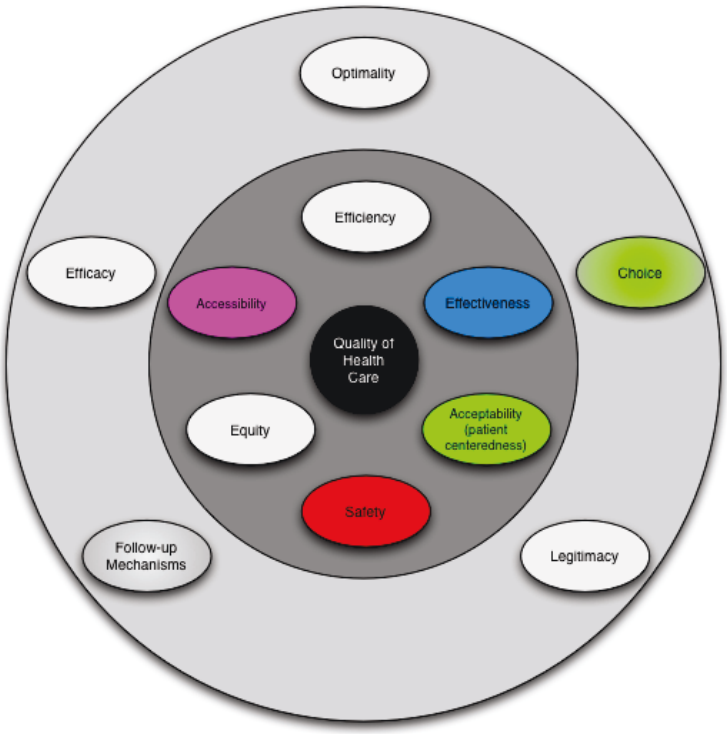
also defines the elements that constitute quality in family planning to include "…choice of methods, information given to users, technical competence, interpersonal relations, follow-up or continuity mechanisms and appropriate constellation of services" (Bruce, 1990).

In the context of labor and delivery, choice may not always be as relevant when it comes to medical interventions as compared to choice in family planning (e.g. a woman should be given the choice of contraceptive method but does not necessarily need to choose whether the active management of the third stage of labor or management of newborn asphyxia is performed during life-threatening conditions). But at the same time, the woman should be given the option of choosing her birthing position or of having a companion with her during labor. Pittrof, Campbell, & Filippi (2002) proposed the following definition for quality of care in maternity services: "High quality of maternity care services involves providing a minimum level of care to all pregnant women and their newborn babies and a higher level of care to those who need it. This should be done while obtaining the best possible medical outcome, and while providing care that satisfied women and their families and their care providers. Such care should maintain sound managerial and financial performance and develop existing services in order to raise the standards of care provided to all women."

The Institute of Medicine defines quality of care as "[t]he degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge" (Institute of Medicine, 2001). This definition seems to succinctly capture the key concepts from the other QoC definitions without presenting specific components. And while there are some overlapping components in the definitions of QoC, there are likely to be some characteristics that have greater application in low and middle income country settings when both financial resources and choices in care are limited. In particular, safety and choice are components of quality that are not explicitly stated in Donabedian's Pillars of Quality, but these components can be especially important in settings in which there is coercion (e.g. forced sterilizations) or in settings where patient safety in a facility-based setting is an issue (e.g. high risk of nosocomial infections because of lack of infection prevention procedures). Having the ability to select which products to use (e.g. family

planning) may be more closely related to having choice as an important part of quality in situations where the life of the mother and her baby are at not at immediate risk. Human resources are also not mentioned in the Pillars of Quality but in settings like Malawi where there is a shortage of human resources, issues related to the motivation and retention of skilled health workers may affect the quality of care received by a patient. Figure 6 presents the overlap of dimensions of quality of care from multiple sources, with the non-greyed circles representing the dimensions of most interest for this dissertation.

Figure 6: Dimensions of Quality (Adapted from WHO, Donabedian, Bruce)



Why does quality matter?

In higher income settings, one of the reasons that quality matters is because people generally have more choices about where they go to receive care. In the context of family planning, Bruce (1990) noted that "[t]he interpersonal dimensions of care are strongly influenced by the quantity of care—the amount and nature of contact between the client and the provider system." These same choices may not be available in low income settings where there are fewer clinics or health staff available to provide services. And when choices are offered, perceived quality about an individual provider can affect the client's willingness to receive and pay for services, in part due to mistrust (Andaleeb, 2001; Bruce, 1990). Perceptions of quality can in fact take precedence over concerns about distance and cost (Onah, Ikeako, & Iloabachie, 2006). This is especially important in settings where out-of-pocket expenditures can take up a significant proportion of a family's income. The health care system can in effect be segmented according to who can pay for services and who cannot, and this affects care-seeking, the quality of care that they receive and

ultimately their health outcomes. Although health services may also be free in public facilities, there are still costs related to transportation to the facility, food, and supplies in some cases. Indirect costs can include loss of time when waiting for services. In Malawi, the government provides free health services for all residents through the Essential Health Package (EHP) but there are there are still out-of-pocket costs that need to be covered by the client (Levin, Mangini, McEuen, Chaweza, & Chizani, 1999). Lack of trust in the formal health care system and mistreatment by providers could also encourage people to seek alternative care that could result in more harm.

One of the major contributors to maternal mortality in resource-poor settings is poor quality of maternity care (Kongnyuy, Mlava, & van den Broek, 2009). This is because women's experience of maternity care affects both the actual birth process and future utilization of health services (Kongnyuy, Mlava, et al., 2009). Even though the availability of appropriate essential obstetric care is the only way to manage complications that could lead to death, the quality of care that the woman receives during antenatal care or normal delivery may have negative impacts on overall health outcomes if there are delays in seeking care because of perceived poor quality. Quality maternity care gives women dignity in childbirth and also helps to avoid aspects of care that are disrespectful and may negatively impact patterns of use (Hulton et al., 2000).

Respectful maternity care as an important aspect of quality

In order to receive EmOC (regardless of whether the services themselves are of good quality), a pregnant woman and/or her support persons must take action and seek care at a formal health facility. However, there are barriers that can prevent this from occurring. The three-delays

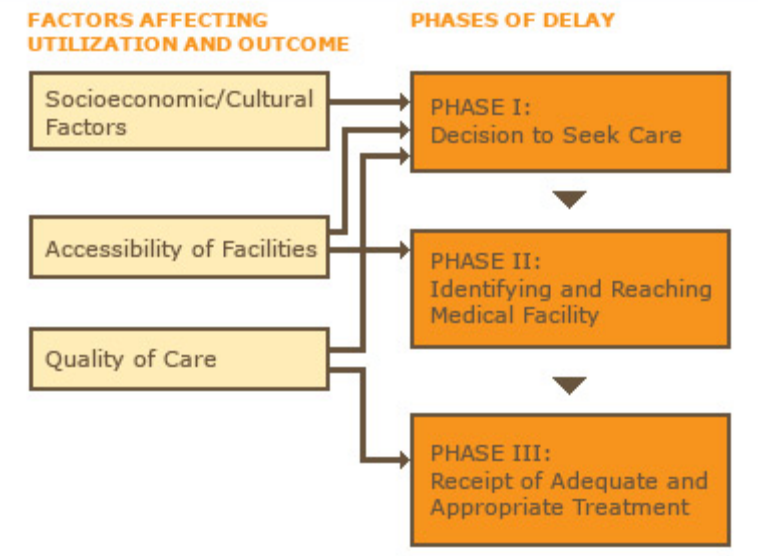


Figure 7: Diagram of the 3 Delays Model. From UNFPA: http://www.unfpa.org/public/home/mothers/pid/4385

model described by Thaddeus and Maine in their 1994 paper, "Too far to walk: maternal mortality in context," provided a framework (Figure 7) within which to understand the factors that can affect health care utilization and health outcomes among pregnant women that contribute to maternal mortality (Thaddeus & Maine, 1994). Poor quality of maternity care contributes to both the Phase I delay (Decision to seek care) and the Phase III delay (Receipt of adequate and appropriate treatment). The receipt of respectful care can have an effect on both a woman's decision to seek care (e.g. fearing ill-treatment may prevent her from seeking care at a health facility) and quality of care (e.g. the act of being mistreated or cared for inappropriately).

In 2010, Bowser and Hill conducted a landscape analysis of disrespect and abuse in facility-based childbirth. The purpose of the report was to review evidence related to the definition, scope, contributors and impact of disrespect and abuse in childbirth because there was a relative lack of formal evidence around this important topic (Bowser & Hill, 2010). The results of their review led to the development of seven categories of disrespect and abuse as seen in Figure 8. The White Ribbon Alliance then led a multi-sectoral collaboration in producing a consensus document--the Respectful Maternity Care Charter: The Universal Rights of Childbearing Women (presented as Annex A).

In 2014, the WHO released a statement of actions that should be taken to prevent facility-based disrespect and abuse during childbirth that included 1.) greater support from governments and development partners for research and action on disrespect and abuse; 2.) programs that are designed to improve the quality of maternal health care, with a strong focus on respectful care as an essential component of quality care; 3.) an emphasis on the rights of women to dignified, respectful health care throughout pregnancy and childbirth; 4.) generation of data related to respectful and disrespectful care practices, systems of accountability and meaningful professional support; and 5.) involvement of all stakeholders, including women, in efforts to improve quality of care and eliminate disrespectful and abusive practices (World Health Organization (WHO), 2014c). Figure 9 below also presents the RMC components that are included in the QoC frameworks described earlier.

Figure 8: Seven Rights of Childbearing Women. From the White Ribbon Alliance Respectful Maternity Care Charter.

Seven Rights of Childbearing Women		
Category of Disrespect and Abuse		Corresponding Right
1	Physical abuse	Freedom from harm and ill treatment
2	Non-consented care	Right to information, informed consent and refusal and respect for choices and preferences, including the right to companionship of choice wherever possible
3	Non-confidential care	Confidentiality, privacy
4	Non-dignified care (including verbal abuse)	Dignity, respect
5	Discrimination based on specific attributes	Equality, freedom from discrimination, equitable care
6	Abandonment or denial of care	Right to timely healthcare and to the highest attainable level of health
7	Detention in facilities	Liberty, autonomy, self-determination and freedom

The seven categories of disrespect and abuse are described below:

Physical abuse: Physical abuse is causing pain, injury, and bodily harm as well as conducting un-indicated medical procedures. Examples include slapping, punching and hitting the woman as well as conducting unnecessary episiotomies and doing so without anesthesia (Bowser & Hill, 2010).

Non-consented care: Bowser and Hill reported that there is "…evidence of widespread absence of patient information processes or informed consent for common procedures around the time of childbirth in many settings (e.g. caesarean sections, episiotomies, hysterectomies, blood transfusions, sterilization, or augmentation of labor)" (Bowser & Hill, 2010). There is extensive literature that reports the physical and psychological benefits for women when they are able to adopt upright birthing positions of their choice (Priddis, Dahlen, & Schmied, 2012).

One example of non-consented care is not having a choice of birthing positions. There is extensive literature that reports the physical and psychological benefits for women when they are able to adopt upright birthing positions of their choice. Women in Malawi are aware of two birthing positions: the supine position (or lying down, face-up) that is used in health facilities and the semi-recumbent position (with backrest elevated at 45 degrees) used mainly during births attended by traditional birth attendants (TBAs). The preference for semi-recumbent births among some women partly explains births that occur outside of health facilities (Kongnyuy, Mlava, et al., 2009).

Non-confidential care: Non-confidential care refers to both a physical lack of privacy as well as a lack of privacy related to sensitive personal information. Privacy is generally valued by pregnant women but can be difficult to achieve in a health facility because of cultural barriers or lack of private delivery wards (Bohren et al., 2014). Women who feel threatened by their birthing environment (especially because of a lack of privacy or respect) may go through unnecessary medical interventions because of high catecholamine levels that rise during stress and slow down the labor process (Kongnyuy, Mlava, & van den Broek, 2009). Privacy according to Malawian women includes confidentiality and being screened and spoken to quietly (Kumbani, Chirwa, Malata, Odland, & Bjune, 2012).

Framework	RMC component from QoC frameworks
WHO	Acceptability/patient-centeredness
Donabedian	Acceptability
Hulton et al	Respect, dignity and equity

Figure 9: Respectful Maternity Care Components from Quality of Care Frameworks

Non-dignified care: Bowser & Hill (2010) describe non-dignified care during childbirth as intentional humiliation, blaming, rough treatment, scolding, shouting and publicly divulging private information. Non-dignified care can include verbal abuse in hospital-based settings such as …"threatening, scolding, ridiculing, shaming, coercing, yelling, belittling, lying, manipulating, mocking, dismissing, and refusing to acknowledge behaviors that undermine the recipient's self-esteem while

enhancing the abuser's sense of power, typical of bullying" (Hodges, 2009). A qualitative study in Malawi identified good reception by women as not being shouted at, spoken to harshly or spoken to with anger and that in general, they expected health workers to show kindness towards their clients (Kumbani et al., 2013). A section further below in this proposal provides numerous examples of qualitative studies that report humiliation and harsh treatment of women during labor and delivery in different countries.

Discrimination based on specific attributes: Discrimination because of specific patient attributes such as race, ethnicity, age, religion, HIV/AIDS status, socioeconomic status and other characteristics can affect care-seeking behavior. The women who are most often in need of skilled attendance—those in poor health who come from rural and/or impoverished areas—are likely to be ones that are given less respect because of their social status. Also, women from rural areas who are more likely to be illiterate and of low social status, tend to receive harsher treatment (Bazzano, Kirkwood, Tawiah-Agyemang, Owusu-Agyei, & Adongo, 2008). In a study in Uganda, young midwives were said to abuse mothers if they had not attended ANC before or if judged that the woman had many pregnancies before (Amooti-Kaguna & Nuwaha, 2000).

Abandonment or denial of care: Abandonment of care refers to leaving women alone during labor and birth and failing to monitor women and intervene in life-threatening situations (Bowser & Hill, 2010). Unavailability of a health worker during labor and delivery in Malawi may result in a woman delivering alone and the stress of potentially delivering alone could also result in preterm delivery (Dole et al., 2003; Igboanugo & Martin, 2011; Kumbani et al., 2013; Seljeskog et al., 2006). Restricting a woman's ability to ambulate during labor can also affect cervical dilation, maternal comfort and need for analgesia (Khayat & Campbell, 2000). Not having a health worker available to manage possible maternal or newborn complications can lead to adverse outcomes including death.

The restriction of a birth companion is also included under abandonment or denial of care. The use of a companion to support women during labor has been shown to be associated with a safe and satisfying birth experience and has been recommended by the WHO as one of the main aspects of

humanized care (Ballen & Fulcher, 2006; Behruzi et al., 2010). A Cochrane review found that women who had continuous intrapartum support were more likely to have a shorter labor and spontaneous birth and has benefits for infants (Hodnett, Gates, Hofmeyr, Sakala, & Weston, 2011). Companionship during labor was also found to promote self-esteem and a positive mother-infant relationship while reducing cesarean section rates, the need for analgesia or medication for pain relief, and the duration of labor (Kongnyuy et al., 2009; Wolman, Chalmers, Hofmeyr, & Nikodem, 1993).

Detention in facilities: Detention in facilities usually involves recently delivered women who cannot pay for their health services. This may occur less in government-run or public health facilities where services may be offered at no cost.

Experiences with respectful maternity care in low income countries

The relationship between seeking maternity care and perceptions of quality as they relate to provider behavior towards maternity patients has been explored mostly through qualitative studies. These studies have shown that disrespect and abuse during labor and delivery does not just occur in Malawi.

In Tanzania, Kruk et al (2009) found that women in their study valued respectful, attentive providers among other facility based features like cost or distance, suggesting that provider characteristics may be a more important deterrent to seeking facility-based maternity care than the other more commonly recognized barriers. An earlier study in rural Tanzania found that staff attitudes and poor treatment (including a lack of privacy, abusive language, denying women service, lacking compassion and refusing to assist properly) discouraged women from delivering in health facilities (Mrisho et al., 2007). Positive clinical interaction in another Tanzanian study was said to be influenced by a sense of kindness, understanding and active listening (Mselle, Moland, Mvungi, Evjen-Olsen, & Kohi, 2013).

A qualitative study in Guatemala that sought to identify factors that influenced care-seeking for maternal health among indigenous Mayan women found that the decision to seek care was based on knowing that they could receive care that was culturally appropriate, safe and secure and that they would be treated with dignity at the facility (Schooley, Mundt, Wagner, Fullerton, & O'Donnell, 2009). In the

Dominical Republic, patients also reported abandonment and denial of care during labor and delivery (S. Miller et al., 2003).

A study on adolescent maternal health care seeking services in Uganda found that respondents were discouraged from seeking ANC and delivery services because of rude and abusive health workers, with physical abuse being reported by some adolescent mothers in labor. Among this group of women, the perception of good quality of care included having empathy from the health workers (Atuyambe, Mirembe, Annika, Kirumira, & Faxelid, 2009). In another study in Uganda, women reported that health workers in hospitals were insensitive to their pain and were unable to communicate their pains to health workers who did not offer a sympathetic response. This study described the feelings of rural women towards health workers, who were said to be, "…rude, poorly trained and unwilling to dispense drugs." They were also said to deliberately avoid maternity patients, abandon them in critical situations, expect to be bribed, give false information and lack ethics. Most mothers in this study reported only going to the hospital or health center in emergency situations to avoid having embarrassing questions asked of them, not being able to deliver in their preferred position and not having their pain dismissed (Kyomuhendo, 2003).

In Nigeria, the friendliness of staff was a significant factor that affected maternity care utilization; the lack of compassion and friendliness was said to create social and psychological distance between maternity clients and health workers and the hostility and impersonal treatment from nurses and midwives was one reason why women preferred to deliver with traditional birth attendants (C. B. Okafor & Rizzuto, 1994; Onah et al., 2006). Through interviews with postnatal mothers, it was discovered that women in southeastern Nigeria received non-consented services and were subject to physical abuse during facility-based childbirth (I. Okafor, Ugwu, & Obi, 2015).

A study in rural Ghana reported that nursing staff were overheard shouting and berating women during maternity ward observations (Bazzano et al., 2008). In Benin, women reported that corporal punishment was used to control women who were thought to be disobedient during childbirth and that midwives in hospitals were impatient and did not give women respect and comfort. Most of the women

in that small qualitative study in Benin reported being humiliated by midwives; did not have information or were misinformed about medical procedures; and one woman reported that she was forced to remain hospitalized for an entire month because she did not have money to pay her hospital bills. The authors of this study also pointed out that "[a]ccess to emergency obstetric care is a priority in the battle against maternal mortality, but it should not be at the expense of improvements in the quality of the interaction between women and health personnel and the challenges in ameliorating this interaction" (Grossmann-Kendall, Filippi, De Koninck, & Kanhonou, 2001).

Treatment of women can also influence from whom they seek care. Findings from a different small qualitative study in Ghana suggested that the utilization of maternity care was affected by the psychosocial and emotional support needs of pregnant women, resulting in preference for traditional birth attendants (TBA) over facility-based providers (Dako-Gyeke, Aikins, Aryeetey, McCough, & Adongo, 2013). Similarly in Ethiopia, women who preferred to deliver at home indicated that some facility-based health professionals did not offer them privacy or psychosocial support when needed. In this same study, a respondent said the following: "*I am afraid of delivering in a health facility. They [health professionals] don't allow my family members (who are the main source of psychological support and comfort) to accompany me in the labor ward. They leave us alone on the delivery couch and everybody who comes in and out of the delivery room watches our naked body which is quite embarrassing. We get little respect from health workers. I won't have these problems if I go to a traditional birth attendant. I seek help from a health facility only as a last resort (i.e. if I encounter difficulty to deliver in my home)* (Shiferaw et al., 2013)." This statement seems to summarize the client-side issues related to RMC described by women in the studies mentioned above and reasons for not seeking maternity care in health facilities as described in Figure 7. The results are similar in Cambodia as well where women reported seeking care at private health facilities rather than public facilities because of abandonment during delivery, unfriendly, impolite and rude staff, physical abuse, lack of privacy, and refusal to allow a birth companion (Ith, Dawson, & Homer, 2013). In rural China, women reported that barriers to a hospital birth (and preference for home deliveries) included the fear of being left alone without the newborn or

family members and that nurses did not provide assistance to the woman after delivery (Gao, Barclay, Kildea, Hao, & Belton, 2010).

Disrespect and abuse during delivery is also recognized in higher income settings. In Spain, women not only wanted health workers to be technically skilled, but also wanted them to be respectful of the woman's autonomy and values and to be trustworthy and empathetic in order to develop an effective therapeutic relationship. Women could distinguish between technical quality and interpersonal skills but there was dissatisfaction when providers were not friendly or said something hurtful to the client (Goberna-Tricas, Banús-Giménez, Palacio-Tauste, & Linares-Sancho, 2011).

The results of these studies suggest that there should be a focus both on ensuring that health workers adhere to clinical guidelines but also that the interaction between the health worker and the patient is considered an important quality of care issue. Freedman and Kruk (2014) point out that disrespect and abuse represents a breakdown in accountability of the health system to not only its users but also to the people that it employs. Furthermore, they state that disrespect and abuse in a health system that tolerates the devaluation of women is a signal that the system is facing a crisis of both accountability and of quality (Freedman & Kruk, 2014). This is even more of a reason to ensure that measurement methods are available to develop baselines and track improvements. Both clinical quality and treatment of the client affect care seeking and should be measured routinely.

Practice variation

Clinical guidelines are "systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances" (Committee to Advise the Public Health Service on Clinical Practice: Institute of Medicine, 1990). Successful implementation of clinical guidelines should improve quality of care by decreasing variation through the application of evidence-based practices to each patient. One way to reduce unwarranted variation is through the availability and regular implementation of evidence-based clinical practice guidelines. The interest in the use of clinical practice guidelines was partially fueled by the discovery of unexplained variations in

clinical practice so clinical practice guidelines were developed to limit the inappropriate variation among and between clinicians for a given condition or situation (Cabana et al., 1999; Shaneyfelt, Mayo-Smith, & Rothwangl, 1999). The regular use of these guidelines can facilitate the improvement of quality of care and subsequently patient outcomes (Francke, Smit, de Veer, & Mistiaen, 2008; Grol, 2001). Practice variations in situations that do not warrant them can also imply that some patients are not receiving the best care possible so uncovering the extent of variations and possible reasons why they exist can help to ensure that optimal care is received by all patients.

Factors affecting the quality of health worker performance

There are a number of reasons why health workers may not always comply with clinical guidelines, even when the guidelines are clear. In 1999, Cabana et al. conducted a systematic review of the literature to identify barriers to guideline adherence. Although their focus was on physicians, it seems reasonable to assume that the barriers may be similar among nurses and midwives in Malawi since the availability of physicians there is quite limited and nurses and midwives provide the majority of labor and delivery services. The authors found the following barriers to adherence: lack of awareness and lack of familiarity affect physician knowledge of guidelines; lack of agreement with guidelines, lack of self-efficacy, and lack of outcome expectancy (or the belief that a behavior will lead to a particular outcome). External barriers due to the patient, guidelines itself or environmental barriers may also limit a provider's ability to perform the recommended behavior. The persistence of these barriers may ultimately affect the health worker's self-efficacy, outcome expectancy or motivation (Cabana et al., 1999).

Focusing specifically on nurses, in 1959, Benne and Benne postulated that there were four factors that affect their ability to perform: 1) expectations of the health care institution; 2) expectations of work colleagues; 3) expectations of reference groups such as professional organizations, and 4) own expectations, that is one's own role image (Benne & Bennis, 1959). These factors correspond to the factors mentioned by Cabana et al. In 1968, Harrington and Theis suggested three additional factors: 1.) attitudes and expectations of superiors; 2.) nature of work assignment; and 3.) quality and amount of

work-related communication. Other factors include honesty, judgment, work habits, maturity, psychological stability and adaptive capacities, anxiety, low motivation and fatigue (While, 1994). Additional reasons why there may be a difference between clinicians' knowledge and actual practice could be time constraints; environmental concerns (e.g. privacy issues), or organizational issues (Dresselhaus, Peabody, Lee, Wang, & Luck, 2000). Westert and Groenwegen (1999) also suggest that differences in health worker practice style are formed by the social context in which they work and that they conform to local standards within a medical group in order to obtain social approval from their colleagues (Westert & Groenewegen, 1999).

In low resource settings, mid-level providers (that have two to three years of post-secondary school health training) are often called-upon to perform the roles and tasks of higher level providers. While there is evidence that these providers are often capable of performing these tasks, including the provision of emergency obstetric care, there is also evidence that maintaining their effectiveness is contingent on having a supportive working environment that includes adequate supportive supervision (McAuliffe et al., 2013). The absence of supervision may contribute to lower job satisfaction, which may in turn affect health worker performance (McAuliffe et al., 2013).

Rowe et al. (2005) addressed the issue of achieving and maintaining high-quality performance of health workers in low-resource settings and found similar determinants of performance. Examples of factors or environments that might influence health-worker practices include: health worker factors (e.g. knowledge, skills, motivation, job satisfaction, remuneration, experience); patient or client level factors (e.g. severity of illness and sociodemographic characteristics); attributes of work (complexity of guidelines, topics addressed by guidelines); environment of the health facility (e.g. leadership, supervision, caseload, availability of supplies, health facility type, location); professional environment; educational environment; and administrative environment (e.g. salary and regularity of payment, supervision, rules governing working conditions) (Rowe, De Savigny, Lanata, & Victora, 2005).

In Tanzania, health workers reported that a lack of equipment and a shortage of necessary supplies for delivery hindered their ability to provide quality care and that they felt disempowered and

unsupported (Mselle et al., 2013). In the case of providing respectful care to women during labor and delivery, it is possible that the leadership (at the facility or government levels) does not emphasize client focus and accountability towards clients (Mavalankar, 2003).

The availability of adequate human resources for health service delivery is a big concern in Malawi and can affect the quality of care received by women and their newborns. Not only is there a shortage of skilled health workers, there are also geographic imbalances that result in urban areas having higher concentrations of staff than rural areas (Chirwa, 2010). This may result in less support to providers working in rural areas, less routine availability of essential supplies and potentially higher workloads. A shortage of qualified staff and unequal distribution of staff in Malawi have resulted in more staff in hospitals, leaving health centers severely understaffed (Kongnyuy, Hofman, et al., 2009). There is also a challenge in Malawi with internal migration—or the movement of health workers into the private sector from the public sector. Some of the factors that are said to contribute to internal migration include low pay, lack of resources, poor working conditions, inadequate supervision and lack of career movement (Chimwaza et al., 2014). Other issues are an imbalance of skills' mix and a high degree of absenteeism among staff (Chirwa, 2010). Doctors may spend their time as administrators who work at the district level rather than providing clinical care while medical assistants and clinical officers do the work that is traditionally done by doctors just to meet the overwhelming needs (Seljeskog et al., 2006).

A qualitative study in Malawi found that some of the reasons why attitudes of providers may have been negative is that these providers "…may have other aspirations for their life than what is currently available, and may use their relative indifference as a coping mechanism for fatigue and helplessness in the real situation in which they work with little supervision, poor feedback, and few prospects for any improvement in the near future" (Seljeskog et al., 2006). Inadequate staffing and high workloads may influence the behavior of nurse midwives towards their clients (Kongnyuy et al., 2009).

The knowledge-practice gap

Assessing clinical performance in the workplace can provide important evidence on the availability of quality health services and may help to further explain gaps in the application of guidelines. In 1990, George Miller developed a framework for assessing clinical competence that is represented through a pyramid (Miller's Pyramid), shown in Figure 10. Located at the bottom of the pyramid is knowledge (or what a health worker has to know in order to carry out his or her professional functions effectively); competence is the next level above (or whether the health worker knows how to perform the skill); performance (or whether the health worker can show how to perform the skill) is above competence; and finally, what the health worker does (or whether the provider takes the action when functioning independently in clinical practice) is at the top of the pyramid (Miller, 1990).

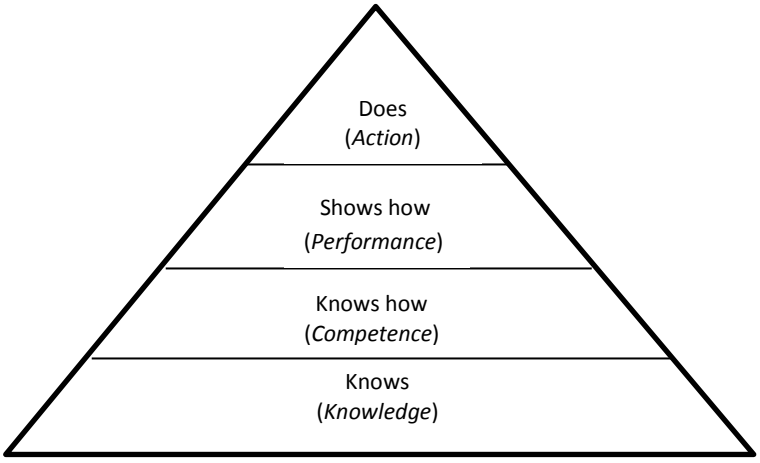


Figure 10: Miller's Pyramid. From Miller (1990).

Although there is global consensus on the effectiveness of many maternal and newborn interventions, implementation gaps still exist and can result in suboptimal quality of care. This "know-do" gap (the difference between what is known to be effective and what is actually done in practice) may be related to a lack of resources in some cases but even when resources are available, a gap can still be found that can result in poor quality of care (St Clair et al., 2014). Leonard and Masatu (2010) measured the know-do gap among health workers in Tanzania and found that one fifth of health workers behaved professionally (where professionally was defined as …"an individual who embodies the stated characteristics of his or her profession, specifically to serve the interests of the public (in particular, the patient) above his or her own immediate interests)." This gap was measured in two ways: by looking at the difference between what the clinician knew how to do (using a vignette) and what the clinician did (using direct observation) and by looking at the difference in what the clinician did when first observed

and what the clinician did after becoming accustomed to the presence of a data collector (Leonard & Masatu, 2010). The difference in clinicians' knowledge and actual practice could be a result of time constraints, environmental concerns (e.g. privacy issues), motivation, or organizational issues that lead to deviations from recommended practices (Dresselhaus et al., 2000; Leonard & Masatu, 2010). So while a health worker may know what to do in certain situations, performance may vary based on some of the factors mentioned.

Although it may be assumed that a true reflection of the process quality of clinical care will ideally come from observing what the clinician does while functioning in a true clinical setting, there are several reasons why it may not be feasible to routinely use this method, especially in low-resource setting. Cost is a big factor as well as unavailability of clinical observers in some settings. Given the knowledge that there may be a discrepancy between knowledge and practice but also that the observation of practice in a real clinical setting may not be feasible on a routine basis, the question then is whether performance (or shows how) is a valid proxy for doing (action) when faced with these constraints.

Methods to measure quality

Measuring the quality of care can offer evidence on whether care was provided in the most timely, skillful and efficacious way. Routine assessment using performance measures derived from evidence-based guidelines is also an important step in transforming health systems (Kilbourne, Keyser, & Pincus, 2010) and strengthening the ability of health systems to respond to the health needs of a population. Donabedian's seminal 1966 article, "Evaluating the Quality of Medical Care" presented the structure-process-outcomes classification system as a way to assess quality (Donabedian, 1966). This framework allows for the collection of information about the necessary attributes that need to be in place to obtain quality medical care and is one of the main frameworks of reference for the dissertation. These domains are described in more detail below and Annex B provides further information about strengths and weakness of different measurement methods.

Structure "…is concerned with such things as the adequacy of facilities and equipment; the qualifications of medical staff and their organization; the administrative structure and operations of programs and institutions providing care; fiscal organization and the like" (Donabedian, 1966). It also represents the organization of care and includes legal mandates, accreditation and administrative regulations. McClure et al. found that even if training is available that improves knowledge and practices, this training will not be as effective if inadequate structures limit the possibility of improving the process and outcomes of care, so the assumption is that having the necessary equipment and staff in place can lead to better quality of care (Goldenberg, McClure, & Bann, 2007).

Structure can be measured through facility audits, review of human resources management systems, review of stock-out reports, and policy reviews, for example. There are many tools available that can be used to assess the availability of supplies and equipment at the health facility level. Some of these tools include the Service Provision Assessment (SPA), which looks at the availability of infrastructure and resources for providing a given service as well as information on staff training and adherence to best practices; the Facility Audit of Service Quality (FASQ), which looks at facility infrastructure and readiness to provide quality of maternal/delivery care; and the WHO's Service Availability Mapping Tool (SAM), which is a district-owned facility monitoring system that quantifies, estimates and maps services and resources available (Hozumi et al., 2006).

Process refers to the actual activities that occur when a patient receives care. This includes technical competency and adherence to clinical standards (including use of a partograph, the active management of the third stage of labor, and the provision of essential newborn care) as well as the interpersonal aspects of care (including respectful maternity care). This can also include the degree of variation within and between health workers. The ultimate goal in measuring the process of care is to answer the question of whether or not medicine was properly practiced (Donabedian, 1990).

Examples of process measurement methods include health worker interviews; patient interviews; direct clinical observations and the use of clinical vignettes (both with actors and with anatomic models). Three additional process measures—self-report (through a health worker interview), direct clinical

observations and clinical simulations—have been compared in Chapter 3 and are described in greater detail.

Self-report: With self-report, the respondent is directly asked for information. The accuracy of self-report as a measure of actual behavior is difficult to establish because of differing methods that have been used that have resulted in differing results (Hrisos et al., 2009). There is also evidence that health workers tend to over-report their delivery of some services (Stange et al., 1998).

Direct clinical observation is the assessment of provider performance in real-life situations. This method provides a reliable measure of actual care (Bessinger, Bertrand, & Bessinger, 2013; Franco, Daly, Chilongozi, & Dallabetta, 1997; Franco, Franco, Kumwenda, & Nkhoma, 2002; Hermida, Nicholas, & Blumenfeld, 1999). A comparative study of three methods for assessment of the quality of primary health care conducted in 1999 by Hermida et al. found that direct observation as a measurement tool offered the best balance of sensitivity and specificity when compared to patient exit interviews and medical record review (Hermida et al., 1999). When recorded on a structured checklist by trained data collectors, direct clinical observations provide one of the most complete and reliable picture of what providers do (Franco, Franco, Kumwenda, & Nkhoma, 2002). For the purposes of this dissertation, direct clinical observation is considered to be a gold standard for the measurement of health worker performance.

The main criticisms of direct observation (that observations are intrusive and can introduce bias, and measuring quality of care can be subjective) calls into question the reliability of the resulting data (Huntington, Miller, & Mensch, 1996). In further exploration of the biases inherent in the direct observation method, Leonard & Masatu (2005) conducted a study in rural and urban Tanzania comparing direct clinician observation with vignettes. They reported that the number of inputs provided for each patient decreases over the course of observations, which suggests that there has to be an adjustment made to the level of quality based if some clinicians are observed for a longer period than others. In that same study, Leonard & Masatu (2005) reported the possibility that shorter observations result in higher clinician average scores than longer observations, suggesting that provider practices change depending on

the length of time of the observation. In addition, the case mix must be analyzed in order to compare providers across health facilities and ensure consistency of severity of cases.

A written case simulation is used to assess the decision making skills and clinical competence of health workers. The use of the written simulation is based on the assumption that a written response to a question will agree with the client's actual behavior during a clinical interaction. The main advantages of this method are that disease and patient factors can be controlled across respondents and that collecting data from a large number of providers can be relatively inexpensive. However, there are also disadvantages to using this method. One disadvantage is that a visual cue that may normally be available during a real provider-client interaction is not available during a written simulation (Jones, Gerrity, & Earp, 1990a). Another potential drawback of this method is the "cueing effect", whereby health workers tend to do more on written simulations that include response options than with simulations that provide patient information but do not provide response options (Jones, Gerrity, & Earp, 1990b). The framing effect involves the possibility of having varying responses based on the format used to present information to respondents because of how the questions are asked and how much non-essential information is provided. Another potential issue with written case simulations is the possibility of social desirability effect (or demand effect) where health workers respond to the simulation as they think is expected rather than how they would actually respond with a real case (Jones et al., 1990b).

Clinical vignettes are designed to both simulate a range of medical conditions and to evaluate the provider's skills in caring for the patient (Shah, Edgar, & Evans, 2007). They are usually developed to simulate patient visits and have been used to measure a practitioner's ability to evaluate, diagnose and treat specific medical conditions" and can be used when large-scale data is needed as part of quality assessments or if ethical or budgetary issues hinder the use of real patients or medical records (Shah et al., 2007).

Using the same vignettes or clinical simulations instead of direct observations to assess all providers eliminates issues related to case mix and severity of illness because the same model, equipment and scenario are presented to each provider. According to Gaba (2004), "[s]imulation is a technique…to

replace or amplify real experiences with guided experiences, often immersive in nature, that evoke or replicate substantial aspects of the real world in a fully interactive fashion. ‘‘Immersive’’ conveys the sense that participants have of being immersed in a task or setting as they would if it were the real world” (Gaba, 2004). Based on the findings of their study, Leonard & Masatu (2005) report that vignettes are a better measure of the best practice of a provider but do not reflect the actual practice of that same provider. They suggest the use of vignettes as a way to measure the impact of training on ability rather than on the quality of care available to the average patient. Perhaps this is because circumstances in which the vignette is used to measure provider performance are often controlled and may not represent the actual circumstances the provider faces in real practice. However, in situations in which direct clinical observations are too expensive to be conducted and case load for the particular health condition to be observed is low, the use of clinical case studies may be a feasible alternative. In fact, results from Peabody et. al. (2004) indicate that vignettes are inexpensive, easy to use, and are a valid tool for measuring the quality of clinical practice, particularly for comparing quality within sites (Peabody et al., 2004). Leonard & Masatu (2005) compared vignettes (unblind case studies with an actor) to DCO of history taking, physical examination and health education for fever, cough and diarrhea in Tanzania. They reported that the vignette and DCO produce the same result 63% of the time (Leonard & Masatu, 2005).

There appears to be no published results comparing provider performance using DCO with clinical simulations or vignettes using an anatomic model. Harvey and his colleagues measured the competence of skilled birth attendants in five countries using knowledge tests and performance on an anatomic model, but these results were not compared to DCO (Harvey, Wong, Mccaw-binns, Sandino, & Urbina, 2007). It should also be noted that the vignettes in the Peabody study were computerized written scenarios and that vignettes in Leonard & Masatu (2005) were done with a researcher acting as a patient. In contrast to these studies, the Malawi HBB evaluation that will be further described in Chapter 2 used an anatomic model as part of a clinical simulation to measure health worker performance in the provision of newborn care and management of birth asphyxia.

Outcomes may be defined as conditions of people (whether at the individual level or population level) that can be attributed to antecedent health care, including changes in health status, changes in knowledge or behavior, or changes to future health status and satisfaction with health care (Donabedian, 1992). They are measures of the results of interventions and health care practices. Outcomes can be assessed through clinical measures, through patient perspectives and through societal perspectives. Some outcomes are fairly concrete and are able to be measured precisely, while others are not directly linkable to structures and processes. In fact, "[o]utcomes do not directly assess the quality of performance. They only permit an inference about the quality of the process (and structure) of care (Donabedian, 1992)." Also, a "good" outcome can also vary by practice. For example, in elder care, a quality outcome may not result in the improvement of health status but rather could be related to slowing down the progression of functional decline or to indicators of comfort.

A reduction in mortality-related indicators is therefore only one type of outcome measurement that can be used to infer high quality. Another important aspect of quality is equity, or the idea that the availability of care and quality of services should not differ between individuals based on their personal characteristics including gender, race, age, ethnicity, income, education, disability, sexual orientation, or place of residence (Institute of Medicine, 2001).

Outcomes have been measured through patient satisfaction surveys, patient exit interviews, review of patient status, and death audits. When available, service statistics can also be used to measure changes in referrals, continuity of care (e.g. completion of TB treatment) and safety (e.g. infection rates and surgical complication rates). Household surveys can also be used to measure coverage and uptake of health services. For maternal mortality as an outcome, various methods are available for collecting this indicator, including vital registration, household surveys, surveillance systems, reproductive-age mortality studies and censuses (S. Brown et al., 2013). Figure 11 provides examples of some of the measurement tools mentioned here as well as data generated through those tools.

Record abstraction or record reviews involve the review of data generated during a clinical encounter and can be one way to potentially measure process or outcomes. For complicated services

where clinical decision making depends on each specific case, record abstraction may require hiring skilled data collectors. One of the main limitations of this method is that record abstractions are subject to results that are carried out but not recorded (Shah et al., 2007). This may especially be the case in countries with poor-record keeping practices. On the flipside, it is also possible that over-documenters record tests or procedures that they did not carry out because of fear of scrutiny (Shah et al., 2007). Other issues with record abstraction are incomplete or illegible records and inability to capture provider-client interactions.

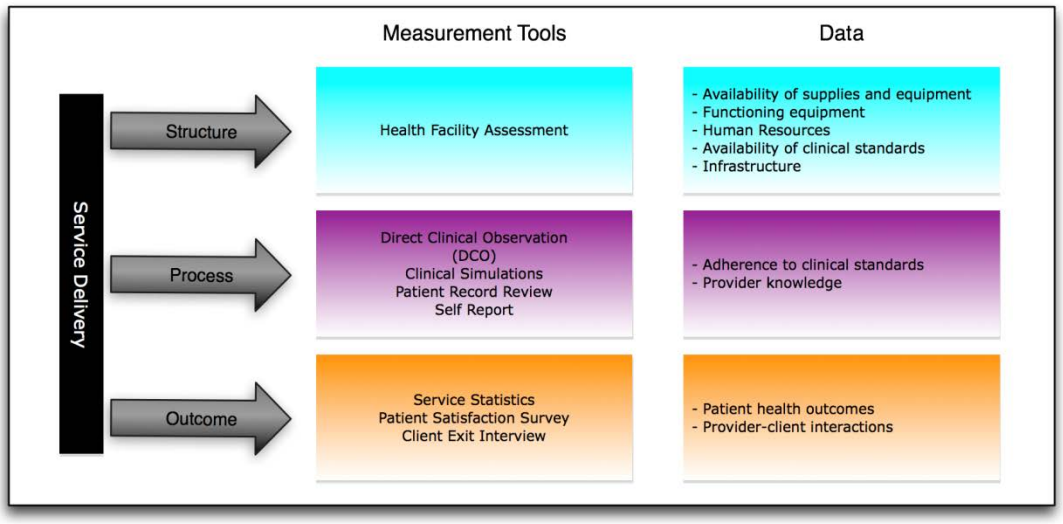


Figure 11: Measurement tools and resulting data

Relating outcomes to structures and processes is challenging because of the many confounding factors that can influence outcomes that may not be directly related to the delivery of health care. A poor health outcome does not necessarily mean that the structure and processes were lacking in the same way that having a high quality outcome cannot be necessarily attributed to structures or processes. Measuring quality through an integrated approach that triangulates data from multiple dimensions of quality assessment may be the best approach to measuring the quality of maternal and newborn care.

Comparison of methods of measuring health worker performance

The availability of results from comparisons of different health worker performance measurement methods is limited, especially in low income settings and especially for provision of essential newborn care. Franco and colleagues examined the reliability and validity of direct observation of patient-provider interactions, provider interviews and simulated patients to measure the quality of health worker

management of sexually transmitted diseases in Malawi. They found under-reporting and over-reporting of management steps when comparing direct clinical observation data with provider interview data and that agreement between direct observation data and interview data was poor. When they compared direct observation data with simulated patient data, they found that providers were likely improving their normal performance when observed. Franco et al. (1997) also state that providers do not forget that they are being observed over the course of a few days and maintain their improved performance in the presence of data collectors (Franco, Daly, Chilongozi, & Dallabetta, 1997).

In 2002, Franco and colleagues compared three different methods (exit interviews, record reviews and provider interviews) to measure the quality of pediatric outpatient health worker performance in Malawi against direct observation. The found that exit interviews with caretakers provided valid data about many of the tasks completed during the patient-provider encounter (though not all); that provider interviews did not provide valid data about what providers were observed to be doing; and record reviews of patient registers only provided a limited amount of information about the encounter (Franco et al., 2002). One of their recommendations was to incorporate case studies into provider interviews (which will be covered in Paper 1 of this dissertation).

In the US, 2000, Dresselhaus et al. compared medical records with reports from standardized patients (who they determined to be the gold standard in their study) and vignettes in the provision of preventive care in two veterans' hospitals in the US. They found that medical abstraction seriously underestimated the quality of care being delivered by physicians in that study and recommended that alternative strategies such as clinical vignettes should be used to more widely to measure preventive care delivery (Dresselhaus et al., 2000). In a follow-up paper, Dresselhaus and colleagues (2004) again compared medical records with standardized patients (gold standard in that study) and computerized clinical vignettes and determined that clinical vignettes more closely approximate the data obtained from their gold standard (standardized patients) than chart abstractions (Dresselhaus, Peabody, Luck, & Bertenthal, 2004).

Measurement of quality of essential newborn care

There are few published studies available that measure the quality of essential newborn care in low resource settings. In Ghana, Vesel et al. (2013) conducted an assessment of the quality of facility newborn care by using vignettes that related to different aspects of newborn care, including resuscitation, essential newborn care and thermal care. They also included a vignette of a very low birth weight baby and breastfeeding advice. Data collectors read the vignettes to the health workers and asked them to describe the steps that would be taken in each particular case. In their paper, they concluded that the vignettes tested the best practice as compared to actual practice, which could have led to an overestimate of quality (Vesel et al., 2013).

Other studies assessed essential newborn care through interviews and record reviews. Opondo and colleagues looked at only the availability of the structural components needed for essential newborn care in eight health facilities in Kenya but did not assess the process component of care (Opondo et al., 2009). A medical record review to assess the process of care was conducted by English et al. in 2009 in the same eight study hospitals in the previously mentioned study. They noted that a large portion of patient records were missing due to the lack of available stationery and that documentation was generally poor when the records were available. Also, these documents related specifically to children from 7 days of age to 59 months and do not reflect the process of essential newborn care (English et al., 2009).

In a study on the frequency of newborn interventions in Nepal, Osrin et al. (2002) used interviews and found that half of the respondents reported that birth attendants washed their hands before the birth of the baby and that 64% reported that their newborns were wrapped within a half hour of birth. It should be noted though that 90% of these deliveries were at home rather than in a health facility (Osrin et al., 2002). In a large cross-sectional community-based study of newborn care practices in Southern Tanzania in which 41% of births in the study took place in a health facility, the authors found that 42% of women reported that her baby was dried and 27% reported that the baby was wrapped within 5 minutes of delivery. More than half (58%) of the respondents reported that the birth attendant wore gloves and 46%

reported that the birth attendant washed his or her hands and used soap before the delivery (Penfold et al., 2010).

Challenges of measuring process quality

There is seemingly no perfect way to assess the process quality of health worker performance; each method has its own advantages and disadvantages. Overall challenge of measuring the quality of maternal and newborn health in terms of process is that different levels of effort and complexity are required to carry out different tasks. For example, delivering a uterotonic as part of the active management of third stage of labor may be a less complicated task than correctly performing controlled cord traction, which may require more training. In fact, the revised WHO guidelines for AMTSL now indicate that controlled cord traction and fundal massage are optional for postpartum hemorrhage prevention, suggesting that uterotonic provision may be the most important component of AMTSL (WHO, 2012). Also, correctly filling out a partograph may not be directly comparable to the process of taking the mother's blood pressure in terms of complexity. When measuring outcomes, case mix and severity also need to be considered.

In general, conclusions about overall quality of care may be difficult to make based on the assessment of adherence to a specific set of clinical steps because there are many steps related to the management of a pregnant woman or newborn that lead up to the observed steps. This makes it challenging to make a comprehensive statement about the quality of labor and delivery practices based on the observation of a small subset of observations. Another potential issue with clinical observations to measure process quality is that some of the clinical assessment conducted by the health worker may be non-verbal, making it difficult for the data collector or clinical observer to know whether or not a certain step was carried out. For these reasons, using clinical simulation to assess provider performance could be a viable measurement method for some clinical processes—but perhaps not all (e.g., the choices that are made as part of a diagnostic decision making process).

Loeb (2004) points out that one of the challenges associated with measuring health care quality is that people are not generally comfortable with being measured and that it …"provokes considerable angst, frustration, and worry among those being measured…" These challenges associated with quality assessment through observations could also ultimately affect how a health worker performs when being observed (e.g. the Hawthorne effect). The Hawthorne effect is when behavior or performance is altered as a result of being observed. The name comes from experimental studies that were performed between 1927 and 1932 in the Hawthorne Works plant of the Western Electric Company in Chicago. Researchers were interested in the relationship between the effects on productivity of rest pauses and work hours. They found that the increase in output was partly caused by the experiment itself (Campbell, Maxey, & Watson, 1995; Wickström & Bendix, 2000). This phenomenon complicates the measurement of process quality through observations—whether observing performance on an anatomic model or on live patients.

Leonard et al. (2006) found that the quality of health worker performance increased by 20% on average when being directly observed but that this was only temporary and 10-15 observations later, the quality returned to the level of quality that existed before the arrival of the research team. They state that the reasons for the change in quality are not understood but they suggest that health workers put in more effort when they knew they were being watched, especially if the observers were their own peers. There is a chance then that the Hawthorne effects upwardly biases "true" quality of care. However, it should be noted that their study was related to outpatient services, not to essential newborn care (Leonard & Masatu, 2006) so the quantification and direction of the bias is unknown in this case.

Conceptual framework for the study

The conceptual framework for this study (Figure 12) links together the objectives, focusing on the health worker as the unit of analysis. It brings together the findings from multiple conceptual frameworks (Donabedian's structure-process-outcomes framework; Hulton et al. quality of MNH care framework; and the Seven Rights of Childbearing Women framework) that were described earlier in this chapter. This framework represents the associations described in the literature between factors that affect health worker

performance at different levels (macro level: national/political factors; micro level: institutional; and individual level: personal factors). These factors are linked to the process quality of care (both the provision of care and the experience of care) and then the process quality of care is linked to the expected outcome (or a reduction in maternal and newborn mortality). The political, institutional and individual factors that were analyzed as part of this study are underlined.

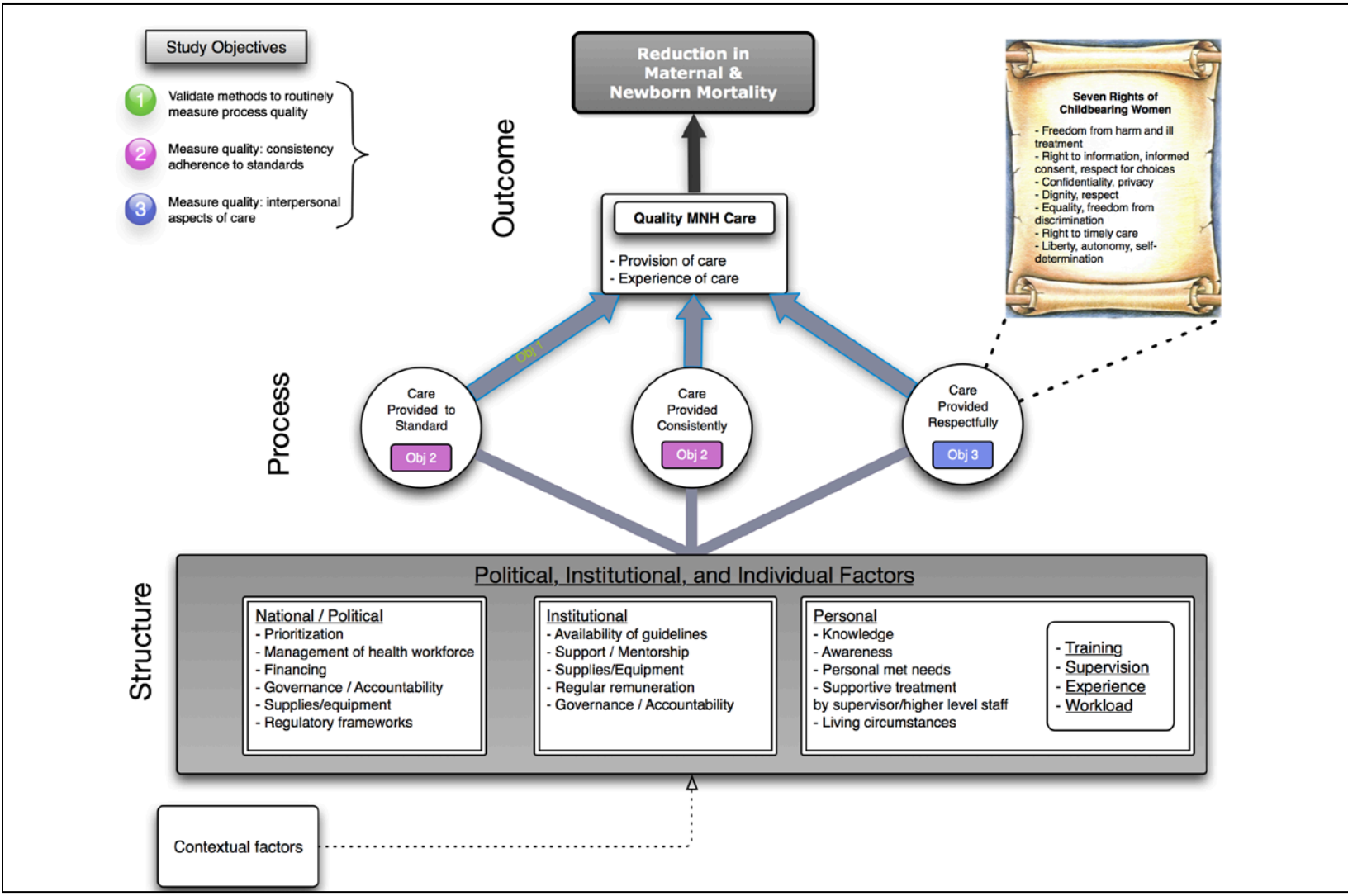


Figure 12: Conceptual Model for the Dissertation

Chapter 2: Study Setting and Parent Study

Malawi is a landlocked country located in Southern Africa—east of Zambia and west and north of Mozambique. Malawi was under British rule until it became an independent nation in 1964. The population of Malawi is estimated at over 17 million people, nearly 80% of who live in rural areas. There are 28 districts in Malawi, with the capital Lilongwe located in Lilongwe district (CIA, 2014).

The crude birth rate is 41.8 births per 1,000 population and the total fertility rate (TFR) is 5.66 children born per woman (the 8th highest TFR in the world). The mother's mean age at first birth is 18.9 years. Challenges the country is facing include a high burden of disease, inadequate finances to support poverty reduction programs and high levels of illiteracy (WHO, 2014a).

Health System in Malawi

More than half (60%) of formal health services in Malawi are provided through the government at three levels—primary, secondary and tertiary. Primary health services are delivered through rural hospitals, health centers and health posts while secondary services are provided in district hospitals and serve as the referral level for obstetric emergencies. The tertiary level includes services offered at the secondary level in addition to surgical interventions. In 2010, there were 361 facilities operated by the Ministry of Health (MOH) of Malawi that offered labor and delivery services including 4 central hospitals; 23 district hospitals; 2 maternity hospitals and 258 health centers (Malawi Ministry of Health, 2011).

The MOH provides overall stewardship for the health sector including the formation of policy, coordination, supervision and human resources planning. Health care in Malawi is financed through a combination of public, private and donor sources, where private sources include social insurance, private insurance enterprises, private household out-of-pocket expenditure and others. Malawi also receives health financing through grants and in-kind contributions from donors (Chirwa, 2010). The country has an essential health package (EHP) that covers most of the population and is delivered free of charge to Malawians. The EHP includes maternal and newborn health services (Malawi Ministry of Health, 2011).

In 1998, a Decentralization Policy was initiated by the MOH. While the MOH central office retains the management of human resources, most functions previously held by the MOH have devolved to the district level, including routine operations and overall management of health facilities. It is the District Health Office that coordinates service delivery at district level but there are also five Zonal Offices that provide technical support to District Health Management Teams (DHMTs) in the planning, delivery and monitoring of health service delivery at the district level (Chirwa, 2010; Malawi Ministry of Health, 2011).

Health Workforce in Malawi

In Malawi, one of the contributing factors to the country's high maternal mortality ratio is the shortage of health workers in government facilities (Chimwaza et al., 2014). There are .02 physicians and .34 nursing and midwifery staff per 1,000 population, leading to a high client volume per health worker (Chimwaza et al., 2014). The Constitution of the Republic of Malawi states that the State must "*provide adequate health care, commensurate with the health needs of Malawian society and international standards of health care"* but the 2011-2016 Health Sector Strategic Plan (HSSP) points out that quality improvement in the health sector is hindered by poor facilities, lack of equipment, lack of qualified human resources, and weak management (Malawi Ministry of Health, 2011). This same strategy reports that there is a critical shortage of health workers and prioritizes further massive investments in human resources as part of the HSSP (Malawi Ministry of Health, 2011). Part of the approach to alleviate the human resources issues in Malawi is to increase salaries for health professionals, which has been designed to improve working conditions and increase retention of public health workers (Manafa et al., 2009).

There is also increasing health worker migration from the public to the private sector resulting from low pay, low resources, poor working conditions, inadequate supervision and lack of career progression (McAuliffe, Manafa, Maseko, Bowie, & White, 2009). The absence of quality supervision also appears to contribute to low levels of job satisfaction in Malawi, which could also have an effect on health worker performance (McAuliffe et al., 2013). Another study in Malawi suggested that a high

workload sometimes affected health worker performance and that health workers were dissatisfied with the supervision they received (Manafa et al., 2009). That same study also reported that poor housing and the absence of basic amenities such as water and electricity negatively affected work performance. Poor remuneration, limited career and educational opportunities, inadequate human resources management systems and the lack of performance-related rewards are additional factors in Malawi (Bradley & McAuliffe, 2009). All of these factors could potentially affect the quality and consistency of health worker performance.

Parent Study

Data for this dissertation come from the second round of data from an evaluation of the Helping Babies Breathe (HBB) program in Malawi. HBB is being rolled out in Malawi with support from USAID/Maternal and Child Health Integrated Program (MCHIP), Johnson and Johnson and other development partners. The MCHIP program started the implementation of HBB in February 2011 in a phased manner over ten districts. By August 2011, Johnson and Johnson Foundation also started HBB implementation in 3 additional districts. There was need to understand both how HBB was being implemented in Malawi as well as the associated results in terms of health system performance, provider competence, quality of care, and outcomes. Data were collected in August 2012 for the first phase of the HBB evaluation in Malawi and in September 2013 for the second and final round of the evaluation. One of the specific questions in this evaluation was whether health workers trained in HBB were able to apply the newborn resuscitation and essential newborn care skills up to a year after they had been trained. One of the methods used to evaluate health worker clinical skills was to ask study participants to complete three clinical case studies or vignettes in which the health worker was given a clinical scenario and was asked to perform the necessary clinical practices on a "Neonatalie" anatomical model. The same data collectors then followed that health worker for clinical observation(s) of labor and delivery.

Study Methodology: A quasi-experimental intervention comparison study design was originally used for this program evaluation. Four main data collection methods were used: health worker interviews and

knowledge and skills assessments that included case studies; direct clinical observations (DCO); key informant interviews; and a facility survey.

The health worker interview included both quantitative and qualitative components. Some background information was collected from each health worker through the health worker interview tool regarding the providers' qualifications, trainings received and frequency of receiving supportive supervision. Additional questions were included to assess the health worker's knowledge, frequency of providing AMTSL and using a partograph, and frequency of practicing with the Neonatalie simulator—which is recommended to keep provider skills up-to-date since newborn asphyxia is a relatively rare event. The simulator was developed by Laerdal to be used in role playing scenarios that cover normal deliveries as well as standard resuscitations. Each standard Neonatalie simulator kit includes: simulation squeeze bulbs with tubing and connectors; an umbilical cord with connector and two ties; and two sheets to simulate towels and a head cap (Laerdal, 2013).

Figure 13: Laerdal Neonatalie newborn simulator

These providers were also asked to complete skills assessments using clinical vignettes that were developed by the American Academy of Pediatrics as part of their HBB training course. A total of 206 health workers were interviewed and were asked to perform clinical simulations using an anatomic model (Figure 13) during the second round of data collection. Of the health workers interviewed, a subset were also observed performing labor, delivery, newborn and immediate postpartum care via direct clinical observations by data collectors trained in the use of a quantitative checklist (Annex C). An additional checklist was used specifically to observe newborn resuscitation skills with real newborns (Annex D). The newborn resuscitation checklist documented adherence to American Association of Pediatrics (AAP) approved protocols for screening, management and treatment of birth asphyxia in newborns.

Participant Selection: Inclusion criteria for health workers included health staff who were directly involved in the management of labor and delivery. Health workers who did not fit this criterion were excluded from the study. The health workers who were included in the study were selected based on convenience and their willingness to participate, whether or not they had been trained in HBB. Inclusion criteria for pregnant women included women presenting for labor and delivery at the health facility during the time of data collection. Non-participation of women was not measured but the data collectors reported that non-participation was rare. If the woman was unable to consent to the observation, consent was requested from her next of kin.

Data Collection: Data for this evaluation were collected from health workers in 92 selected facilities as well as key stakeholders in Malawi who were associated with newborn care including members of the National Ministry of Health, National Professional Society of Obstetrics/ Gynecology and midwifery, and hospital or maternity/ newborn ward directors. The data collection tools for this study were based on the MCHIP Quality of Care survey tools that were developed to complement and build on Columbia University's Averting Maternal Deaths and Disabilities (AMDD) Program's obstetric care facility assessment and on ICF International's Service Provision Assessment (SPA) survey. The MCHIP QoC surveys include direct observation of care using structured, standardized clinical observation checklists in both ANC and L&D care.

The following data collection tools were used as part of the HBB Evaluation though not all of the study data was analyzed for this dissertation:

Tool 1A: Health worker line listing tool—This tool was used by data collectors to assign IDs to health workers who were interviewed and observed.

Tool 1: Health worker interview—This tool was used by data collectors to collect information about the health worker's background and to assess the knowledge and practice of HBB, AMTSL and the partograph.

Tools 2 and 3: These knowledge and skills assessment instruments included three clinical case studies/ simulations which were completed by the providers using an anatomic model to assess their clinical decision making pertaining to screening, management and treatment of newborns, focusing on newborn resuscitation.

Tools 4 & 5: Direct clinical observations of labor and delivery and asphyxiated newborn resuscitation checklist

Tool 6: Key informant interview (was not used for this analysis)

Tool 7: Labor and delivery inventory assessment

Tool 8: HBB staffing and record review that includes service statistics (was not used for this analysis)

Tool 9: HBB rollout documentation review (was not used for this analysis)

Sample size: The total sample size for the study is presented in Figure 14 below but each individual analysis has a different sample size based on the questions of interest and the data needed to answer that question:

Figure 14: Malawi HBB Evaluation Sample

Malawi HBB Evaluation Sample	
	Sample size
Districts	27
Health facilities	92
Health workers interviewed	206
Direct observations of labor and delivery (beginning at first stage of labor)	208
Direct observations of labor and delivery (beginning at third stage of labor)	2109

The number of health facilities for inclusion in this evaluation was originally determined based on selecting twenty five percent (25%) of the health facilities in thirteen of what had been called intervention districts (where the HBB program had been rolled-out in Round 1) and twenty percent (20%) of the health

facilities in the fifteen comparison districts (where HBB had not yet been rolled out as of Round 1). Two central hospitals, 23 district hospitals and 67 health centers were selected for inclusion in this evaluation. The facilities were selected randomly to be representative of the all the intervention and comparison health facilities in the 28 districts. A similar percentage of facilities had been included for primary data collection in other facility based evaluations conducted in Malawi (Msemo et al., 2013) and other low and middle income countries (Lawn et al., 2011). In the second round of data collection, distinctions were not made between intervention facilities and control facilities, as the HBB program had been rolled-out nationally.

Implementation and data collection: The data collectors' training for Round 2 was conducted in August 2013 for one week with 34 individuals (20 of whom had also participated in data collection for the first round of this evaluation). The data collectors were previously trained health care workers who had experience in Basic Emergency Obstetric and Neonatal care (BEmOC). Most of these data collectors had also been previously trained in the Helping Babies Breathe curriculum. The data collector training included briefings on background and rationale of the study, a description and technical instructions on completion of data collection tools. The training included practice until the inter-rater reliability across all observers was at least 80%, as per the Clinical Observer Training Guidelines developed by MCHIP (Rawlins, Christianson, & Bluestone, 2013). The trainees also had an opportunity for field practice using the data collection tools at health facilities to interview health workers and observe actual maternity clients. The data collection was monitored on an ongoing basis by a trained team of supervisors and was overseen by a study coordinator. The supervisors checked the data collection plans, observed data collection, and reviewed completed forms during their monitoring visit. The fieldwork for the second round of data collection occurred between September 2nd and September 28th, 2013. There were challenges with linking data collection tools in Round 1 of data collection. These issues were corrected prior to the second round of data collection so only data from Round 2 has been analyzed for this dissertation. These corrections allow for the comparison of data from the different tools used to collect

information on health worker performance (e.g. health worker interview tool, health worker clinical simulation tool, and direct clinical observation tools).

Data Analysis and Management: Data collected as part of this evaluation were kept secure in the Jhpiego/Malawi office. Data were entered into an MS ACCESS database by trained data entry clerks. Annex F presents a summary of the sample size, tools used for data collection, analysis methods, and inclusion criteria for each of the analyses described in Chapters 3, 4 and 5.

Ethical Considerations: The Malawi HBB Evaluation protocol was reviewed and approved by the JHSPH IRB on August 2, 2012 (IRB # 4318). The study was also approved locally by the University of Malawi, College of Medicine's Ethical Review Committee (COMREC). Participants were provided with information about the study's purpose, procedures, risks and benefits and were assured confidentiality and the right to end the interview or observations at any time without any repercussions. To maintain confidentiality of health workers, a health worker inventory tool was used to generate identification numbers for each health worker. These health workers identification numbers were used on the labor and delivery observation checklist, the health worker interview tool and the clinical simulation checklist. There were no personal identifiers collected on the women who were observed.

Chapter 3: Validation of clinical simulation and self-reported management of labor, delivery and essential newborn care against direct clinical observations to measure health worker performance in Malawi (Paper One)

Abstract

The routine measurement of the process quality of care can help to ensure that health services are being offered according to evidence-based guidelines, resulting in desired health outcomes. This purpose of this paper was to examine the validity of clinical simulation with an anatomic model and health worker self-report as proxies for direct clinical observations to measure the process quality of key obstetric and newborn care services in Malawi. Direct clinical observation and simulation data were collected as part of an evaluation of the Helping Babies Breathe (HBB) program, where the performance of 85 health providers was observed. Self-reported data on the use of a partograph and the provision of active management of the third stage of labor was collected from 84 health workers. Using direct clinical observations as a gold standard method to measure performance, sensitivity and positive predictive values for key essential newborn care steps (hang hygiene, drying of the baby, removing of the wet cloth, covering the baby, delayed cord clamping and initiating skin-to-skin contact) were calculated. The results showed that the sensitivities and positive predictive values for most essential newborn care steps were high, ranging from 73.3% sensitivity for initiating skin-to-skin contact and a positive predictive value of 86.5% to a sensitivity of 96.3% for drying the baby and a positive predictive value of 95.2%, indicating that clinical simulating using a model may be a valuable method that can be used for the routine quality assessment of providers for steps other than hand hygiene when direct clinical observations are not feasible to undertake. The sensitivity and positive predictive values for self-reported use of a partograph was low 79.3% (CI: 60.3%-92.0%) but was higher for self-reported provision of the active management of the

third stage of labor (94.6%, CI: 85.1%-98.9%), indicating that this method of data collection can be a valid measure of some aspects of maternity care when compared directly observed provision of care.

Introduction

Approximately 4.4 million children in sub-Saharan Africa die every year, with 27% of these deaths occurring among newborns (Kinney et al., 2010). During the neonatal period, which lasts from birth to 28 days, the average daily mortality rate is 30 times higher than during the entire postnatal period and is especially high in the first 24 hours after birth (Lawn et al., 2005). Approximately 75% of all neonatal deaths occur during the early neonatal period (the period before 7 days of age), requiring focused attention on the main causes of death during that period (Lawn et al., 2005).

In Malawi, the newborn mortality rate is 27 deaths per 1,000 live births—a significant decrease from 38 deaths per 1,000 live births in 2000, but still higher than in most higher income settings (Zimba et al., 2012). One of the factors that may explain why the country has been successful is the Government of Malawi's promotion of neonatal health by identifying an essential health care package to promote maternal and neonatal health in health care facilities. This health package is based on the National Reproductive Health Standards including care of the newborn (Kumbani et al., 2012). When implemented routinely, these essential newborn care standards should also result in a reduction in newborn mortality (St Clair et al., 2014).

Essential newborn care

Universal access to essential newborn care may result in the greatest reduction in global newborn mortality (St Clair et al., 2014). According to the World Health Organization (WHO), "essential newborn care," consists of a bundle of provisions including thermal care (drying, wrapping skin-to-skin contact, and delayed bathing), hygienic cord and skin care (hand washing, delayed cord clamping, and chlorhexidine umbilical cord care), and early and exclusive breastfeeding. Care of the newborn immediately after birth includes immediate drying, additional stimulation and skin-to-skin contact (World

Health Organization (WHO), 2013a). Evidence for the importance of these critical steps in the provision of immediate newborn care was in Chapter 2.

Quality of care and the measurement of the process of care

The Institute of Medicine defines the quality of care as "[t]he degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge" (Institute of Medicine, 2001). Measuring health worker performance can provide insight into the quality of care provided in clinical settings and offers evidence on whether care was provided in the most timely, skillful and efficacious manner. A commonly used measurement framework proposed in Donabedian's seminal 1966 article, "Evaluating the Quality of Medical Care" presented the structure-process-outcomes classification system as a way to assess quality (Donabedian, 1966). The process quality of care refers to the actual activities that are performed when a patient receives care and includes technical competency, adherence to clinical standards as well as the interpersonal aspects of care. Assuming that there is evidence for the association of a particular process with an outcome, the ultimate goal in measuring the process of care is to answer the question of whether or not medicine was properly practiced (Donabedian, 1990).

Process measurement methods include health worker interviews; patient interviews; direct clinical observations (DCOs), medical chart abstractions and the use of clinical vignettes (both with actors and with anatomical models). Direct clinical observation is the assessment of performance in real-life situations. DCOs may be considered to be the gold standard for the measurement of health worker performance (Franco, Franco, Kumwenda, & Nkhoma, 2002). However, the cost of routinely conducting direct observation of management of labor and delivery (including essential newborn care) may make this method prohibitive in most low income settings.

Clinical simulations—especially using an anatomic model—may be a reasonable alternative to the gold standard. In the context of observing essential newborn care practices, simulations require less time conducting fieldwork, provide a standardized approach that allows for measurement within and

across facilities, can be conducted on a more frequent basis, and can even be used in low caseload facilities.

Reliably measuring healthcare processes as insight for quality of care can be challenging to do routinely, especially in low-resource settings. There appear to be no published results that compare the measurement of health worker performance using DCO with clinical simulations or vignettes using an anatomic model to observe the quality of essential newborn care among health workers in low-resource settings, and there is limited evidence comparing self-reported provision of care to direct clinical observations of care. The main objective of this analysis was to validate the use of clinical simulations with an anatomic model as a proxy for direct clinical observations of essential newborn care. The secondary objective was to validate the use of self-reported adherence to partograph use and the active management of the third stage of labor with directly observed use.

Methods

Study Design

This study included direct observations of labor and delivery and health worker interviews that were part of the evaluation of the Helping Babies Breathe (HBB) Program in Malawi conducted by the USAID-funded Maternal Child Health Integrated Program (MCHIP), led by Jhpiego (an NGO-affiliate of Johns Hopkins University) during August and September of 2013. Detailed methodology can be found in Chapter 2 of this dissertation and results of the evaluation will be available elsewhere. A direct clinical observation tool in the form of a standardized checklist was used during observations of labor and delivery; this standardized checklist had also been used in multiple quality of care surveys conducted by MCHIP across Africa (MCHIP, 2014). The direct observation tool was developed based on the experience of expert maternal health technical advisors at Jhpiego, review of the labor and delivery observation tool developed by the USAID-funded Prevention of Postpartum Hemorrhage Initiative (POPPHI) Project and the international WHO Guidelines on Managing Complications in Pregnancy and Childbirth (MCHIP, 2013). This tool (presented in Annex C) was divided into sections, where the first

section covered the observation of the initial client assessment, including history taking, complications associated with current pregnancy, complications associated with previous pregnancies and an initial abdominal examination. The second section of the tool covered the intermittent observation of the first stage of labor and included observation of the progress of labor, vaginal examinations and preparation for delivery. The third section of the tool covered the second and third stages of labor and included the observation of delivery, the active management of the third stage of labor (including the administration of a uterotonic, timing of the administration, dose, time of cord clamping, cord traction and uterine massage), immediate newborn care (including the management of birth asphyxia if necessary) and postpartum care. The final section of the tool was used to document the condition of the mother and newborn at the end of the observation and documentation of delivery. This section included information about the use of a partograph (including the completeness of the partograph and whether the action line of the partograph was reached).

Health workers were interviewed and asked to participate in clinical simulations of newborn care with an anatomic model prior to the direct clinical observations. Up to five health workers in the sampled facility were given a clinical scenario and were asked to perform the corresponding clinical practices on a "Neonatalie" anatomical model. The Neonatalie simulator is used for training of and regular practice by health workers in the Helping Babies Breathe curriculum and was developed by Laerdal Medical to be used in role playing scenarios that cover normal deliveries as well as resuscitations (Laerdal, 2013). A picture of the simulator and further details can be found in Chapter 2 of this dissertation. The clinical scenarios used in the simulations covered basic essential newborn care as well as the management of complications including birth asphyxia. However, the focus of this analysis was on essential newborn care, partograph use and the active management of the third stage of labor (AMTSL).

Background information regarding the health workers' age, qualifications, trainings received and frequency of receiving supportive supervision was collected from each health worker through a health

worker interview tool. Additional questions were included to assess the health workers' knowledge of maternal and newborn care and frequency of using a partograph and of providing AMTSL.

Sample

Sample for overall HBB Evaluation

Malawi has four central hospitals, 24 district hospitals and 328 health centers across 28 districts. Central hospitals are referral hospitals for the region while district hospitals receive referral cases from health centers (Malawi Ministry of Health, 2013a). For the larger Helping Babies Breathe evaluation, 40 government-run health facilities were selected from a list of facilities that offered labor and delivery services and that had at least five deliveries per day. The selection of 40 high volume labor and delivery sites was determined based on consultation with local partners and to ensure the efficient utilization of resources within a restricted time frame.

The main objective of the HBB Evaluation was to evaluate the quality of management of birth asphyxia in newborns, resulting in a sample size calculation that was based on observation of asphyxiated newborns delivered at health facilities. The HBB Evaluation sample size was based on assumption that 8% of the deliveries resulted in asphyxiated newborns and there would be a 30 percentage points difference between intervention and comparison arms for a number of indicators related to the management of birth asphyxia. The sample size was calculated to detect this difference between the intervention and comparison areas with a power of 80%, 5% significance level, and design effect of 1.5 to account for within-facility correlation of responses. This translated into a sample of 2084 observations of labor and delivery. The sample size for the number of health workers interviewed in the HBB Evaluation was calculated to detect a difference in health workers knowledge between the intervention and comparison areas of 30% with a power of 80% and 5% significance level. Since this was a cluster survey, the estimated sample size was multiplied by an assumed design effect of 2, resulting in a sample size of 200 health worker interviews (Lwanga & Lemeshow, 1991).

Sample for validation study

For this validation study, the prevalence of the essential newborn indicators and use of a partograph and ATMSL were unknown but should have been universal across patients and across facilities. Conservatively assuming a 75% performance (or prevalence) for each of the indicators, 70% sensitivity (with precision at +/-10.0%) and 95% confidence level, the sample size needed for this analysis was calculated using Buderer's formula (Malhotra & Indrayan, 2010):

$$\text{Sample size } (n) \text{ based on specificity} = (Z^2_{1-\alpha/2} \times S_N \times (1-S_N)) / (L^2 \times \text{Prevalence})$$

where n = required sample size,

S_N = anticipated sensitivity,

S_P = anticipated specificity,

α = size of the critical region ($1 - \alpha$ is the confidence level),

$z_{1-\alpha/2}$ = standard normal deviate corresponding to the specified size of the critical region (α), and

L = absolute precision desired on either side (half-width of the confidence interval) of sensitivity.

Based on these assumptions, a minimum sample of 50 unique health providers was required for this analysis.

Data Collection

One trained data collector (or clinical observer) was deployed to the selected health facility to observe 5-6 full deliveries and 50-55 deliveries starting from the third stage of labor over the course of 10-11 days. The clinical observers were health professionals who had prior experience with providing labor and delivery services and newborn care (including the management of newborn asphyxia) in Malawi and had also received training in emergency obstetric and newborn care. A one-week clinical observers' training was held to standardize the clinical observers in the study tools, including the health worker interview tool, direct clinical observation tool, simulation scenarios and use of the anatomic model. The training included practice until the inter-observer reliability across all observers was at least 80%, as per the Clinical Observer Training Guidelines developed by MCHIP (Rawlins et al., 2013).

During data collection, each clinical observer worked alone in his or her assigned facility to observe both labor and delivery cases with actual patients and with the simulator. Health workers were assigned to collect data from facilities outside of their own normal living or work areas.

The key essential newborn care practices that should have been observed on all healthy newborns included hand hygiene; immediate drying of the newborn; removal of the wet cloth or towel from the newborn after drying; covering the baby clamping the cord two to three minutes after delivery; and skin-to-skin contact (Table 1). The clinical simulation consisted of three scenarios performed on Neonatalie anatomic model but not all clinical scenario steps directly corresponded to all observations. For this reason, the relevant and comparable steps related to essential newborn care in the clinical simulations presented in Table 1 were validated against the health worker's performance under direct clinical observation. For the validation of self-reported provision of AMTSL and use of a partograph, health workers' responses were compared to the actual directly observed provision of AMTSL and use of a partograph. These steps are presented in Table 2 and the clinical simulation scenario is presented in Figure 15.

Figure 15: Essential newborn care scenario for simulation

Observer to read: "I am going to read a role play case. Please listen carefully, and then show me the actions you would take. I will indicate the baby's response with the stimulator (or in words), but I will provide no other feedback until the end of the case."

"You are called to assist the delivery of a term baby. There are no complications in the pregnancy. The baby will be born in less than 10 minutes. Introduce yourself and prepare for the birth and care of the baby."

Table 1: Essential newborn care steps compared between clinical simulations and direct clinical observations

Essential Newborn Care Step	Clinical Simulation	Direct Clinical Observation
Hand hygiene	Cleans hands and maintains clean technique throughout	Washes his/her hands with soap and water or uses antiseptic before any examination of woman
Drying baby	Dries thoroughly	Immediately dries baby with towel

Removing wet cloth	Removes wet cloth	Discards the wet towel
Covering baby	Covers baby with dry cloth	Covers baby with dry towel
Delayed cord clamping	Clamps or ties cord	Ties or clamps cord when pulsations stop, or by 2-3 minutes after birth (not immediately after birth)
Skin-to-skin	Positions skin-to-skin	Places baby on mother's abdomen "skin to skin"

Table 2: Self-reported provision of AMTSL and partograph use compared with direct clinical observations

Variable Name	Description	Type
Partograph use (self-reported)	The health provider was asked about the frequency of use of a partograph during deliveries. Response options were never, rarely, sometimes, most of the time, and always.	Dichotomized (reported always using vs. reported not always using)
Frequency of performing AMTSL (self-reported)	The health provider was asked about the frequency of performing AMTSL during deliveries. Response options were never, rarely, sometimes, most of the time, and always.	Dichotomized (reported always using vs. reported not always using)
Partograph used to monitor labor (observed)	Clinical observers were asked to observe if a partograph was used to monitor labor.	Binary (yes/no)
Administers uterotonic (observed)	Clinical observers were asked to observe whether a uterotonic was administered.	Binary (yes/no)
Cord traction (observed)	Clinical observers were asked if the health workers applied traction to the cord while applying suprapubic counter traction.	Binary (yes/no)
Uterine massage (observed)	Clinical observers were asked if the health workers performed uterine massage immediately following the delivery of the placenta.	Binary (yes/no)
All AMTSL (observed)	This indicator was calculated from the uterotonic + controlled cord traction + uterine massage indicator. If all 3 were performed, the health provider	Binary (yes/no)

	was said to have performed AMTSL.	

The health workers who were observed were selected using convenience sampling based on availability during the observation period at the health facility. Oral consent was obtained from the health workers for the interview, observation of the simulation and direct observation of labor and delivery cases. Oral consent was also obtained from the patients who were observed. The data collectors were flexible in terms of the timing of the observations and conducted the observations up to 7 days per week at any time of the day so that they could observe all shifts. The clinical observer interviewed up to five health workers in each facility, observed health workers performing the simulated management of newborn care on an anatomic model once and then observed the health workers on one or more actual patients. Information about the actual use of a partograph and provision of the active management of the third stage of labor was recorded on the observation checklist by the same observer and was also included in the health worker interview tool. As part of the HBB evaluation, health workers who were interviewed were asked to perform three clinical scenarios on an anatomic model, where one scenario included the management of a healthy newborn and was used for this analysis. Results from observations (both with actual patients and on the simulator) and health provider interviews were recorded on paper-based forms and data were entered into an MS Access database.

Analysis

Statistical analysis was performed using Stata statistical software (Version 13, College Station, Texas USA). Exploratory data analyses were conducted to examine the extent of missing data and distribution of the outcome and explanatory variables in the sample. Descriptive statistics including frequencies, percentages and proportions were calculated and used to produce tables and figures that describe health worker characteristics and overall performance.

For the validation analysis, sensitivity and specificity and their 95% confidence intervals were calculated assuming clinical observations were a "gold standard" method for measuring health worker performance. In diagnostic testing, sensitivity is defined as the ability of a test to correctly identify those people who truly have a disease while specificity is the ability of the test to correctly identify those who do not have the disease (Figure 16) (Park, Goo, & Jo, 2004).

		DCO (Gold Standard)	
Simulation		Done	Not Done
	Done	TP	FP
	Not done	FN	TN

Figure 16: Calculation of sensitivity and specificity

- Sensitivity= TP/(TP+FN), where TP is the number of true positives and FN is the number of false negatives.
- Specificity=TN/(TN+FP), where TN is the number of true negatives and FP is the number of false positives.

Figure 17 presents the validation analyses that were conducted as part of this study.

Figure 17: Validation analyses for clinical simulation and self-report

Validation of simulation	Sensitivity	Proportion of health providers who completed a specified step (shown in Table 1) during DCO who also completed the step during the clinical simulation
	Specificity	Proportion of health providers who did not complete specified step during DCO who did not complete the step during the clinical simulation
Validation of self-reported partograph use	Sensitivity	Proportion of health providers who always initiated the use of a partograph during DCO who reported always using a partograph
	Specificity	Proportion of health providers who did not always use a partograph during DCO who reported not always using a partograph
Validation of self-reported AMTSL use	Sensitivity	Proportion of health providers who always performed AMTSL during DCO who reported always performing AMTSL (all 3 steps and by step)
	Specificity	Proportion of health providers who did not always perform AMTSL during DCO who reported not always performing AMTSL

The positive predictive value and 95% confidence intervals for each step were calculated using the following calculation: TP/ (TP+FP).

Because health workers may have been directly observed more than once (and in fact, most workers were observed conducting more than one labor and delivery case), the proportions of completion of each step in the direct clinical observations are also presented by whether the observation was the first one that was made on that provider, the last one that was made, or was a randomly selected observation from among all of the observations made on that health worker. Sensitivity, specificity and the positive predictive value for each clinical step were calculated, comparing the simulation result with the "gold standard" of direct clinical observation. Health workers were only observed once using the clinical simulator.

Finally, McNemar's test was used to assess whether there were statistically significant differences between the performance of items in the simulation as compared with direct clinical observations. This test is applied to analyze marginal frequencies of performance of a dichotomous trait among matched pairs of subjects (Dwyer, 1991).

Results

For this analysis, secondary data was used from a total of 85 health workers in 37 public hospitals and health centers across Malawi that had delivery volumes of at least five deliveries per day. These health workers were interviewed (and were asked about use of a partograph and provision of AMTSL), were observed using the direct clinical observation tool and also completed the clinical simulations in September 2013.

Health Worker Background Characteristics

Table 3 presents the background characteristics of health workers included in this analysis. A majority of the health workers (77.9%) were nurse/midwife technicians that completed a three-year integrated training program in nursing and midwifery, with the median age of 31.6 years and the median

number of years practiced after graduation being 3.3 years. A majority (88% of those with responses) of the health workers interviewed had been trained in HBB so should have had familiarity with the anatomic model used in the simulations as part of that training.

Table 3: Background characteristics of health workers

	Number (n)	Percent (%)
Health worker sex (n=85)		
Male	25	29.4
Female	60	70.6
Qualifications (n=85)		
Nurse/Midwife Technician	66	77.7
Registered Midwife	9	10.6
Enrolled Nurse/Midwife	7	8.2
Other	2	2.4
Medical Assistant	1	1.2
Median age (n=67)	31.7	SD (8.7)
Median years practicing after graduating (n=85)	3.4	SD (5.2)
Training in the last two years on*:		
Emergency Obstetric Care (EmOC) (n=51)	39	76.5
Management of pre-eclampsia/eclampsia (PE/E) (n=51)	41	80.4
Routine labor and delivery (n=58)	40	69.0
Partograph use (n=58)	43	74.1
Management of sepsis (n=58)	37	63.8
Management of postpartum hemorrhage (n=57)	45	78.9
Essential newborn care (n=60)	46	76.7
Helping babies breathe (n=59)	52	88.1

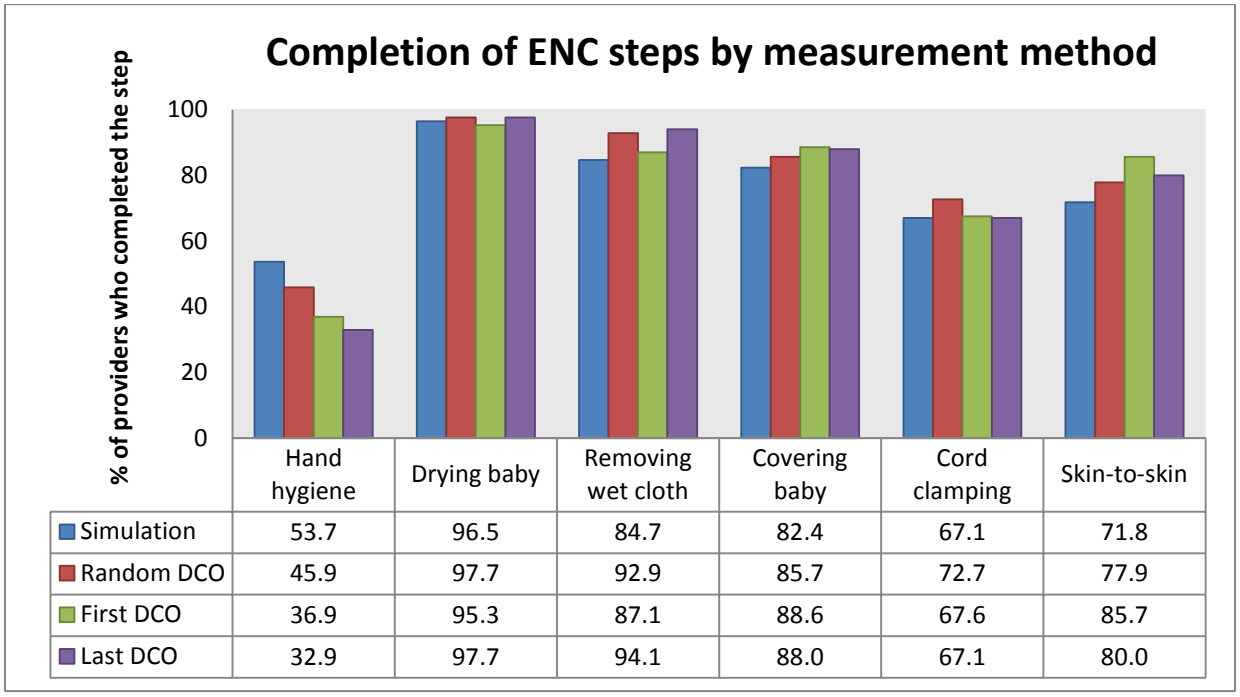
*Among those who received training in the last two years

Overall Performance by Essential Newborn Care Step

Almost all health workers (>95%) dried the baby thoroughly in both the simulation and under direct observation. The lowest observed practice was hand washing which was 33% and 54% in the direct clinical observation and in the simulation, respectively. Figure 18 shows the proportion of health providers who completed each of the steps, comparing simulation with the first DCO, a randomly selected

DCO and the last DCO. Hand hygiene was completed more in the simulation compared with the DCO but removing the wet cloth, covering the baby and ensuring skin-to-skin contact between the mother and newborn were done more with higher frequency in the DCOs as compared with the simulations

Figure 18: Proportion of health workers who completed an essential newborn care step by measurement method (simulation vs. DCO)



	Hand hygiene	Drying baby	Removing wet cloth	Covering baby	Cord clamping	Skin-to-skin
Simulation	53.7	96.5	84.7	82.4	67.1	71.8
Random DCO	45.9	97.7	92.9	85.7	72.7	77.9
First DCO	36.9	95.3	87.1	88.6	67.6	85.7
Last DCO	32.9	97.7	94.1	88.0	67.1	80.0

Validation of clinical simulation against DCO

Table 4 shows the sensitivity (Sn), specificity (Sp) and positive predictive values (PPV) for the comparison of simulation results against the gold standard of direct clinical observations for essential newborn care. Performance on the clinical simulation was compared against a randomly selected direct clinical observation (from among all of the health worker's DCOs), against the first clinical observation made on the health worker and against the last clinical observation made on the health worker. The 95% confidence intervals for each of these values are presented below. The confidence intervals overlap and, therefore, indicate that there is no statistically significant difference in the sensitivity or specificity of each essential newborn care item based on which direct clinical observation is being used to validate performance on the corresponding step of the clinical simulation. In other words, the sensitivity and

specificity did not change when performance on the simulation was compared with a randomly selected DCO, the first DCO or the last DCO of that health worker.

The positive predictive value, or the probability of the health worker adhering to the clinical step in simulation if he or she adhered to the clinical step under DCO, is also presented in the table. In all cases except for drying of the baby in the first case scenario, the positive predictive values do not differ by the timing of the observation. However, in the second case scenario, the positive predictive value for drying is not different by the timing of the observation. In general, the positive predictive values for removing the wet cloth and for drying and covering the baby were the highest at around 90% or higher. The clinical step with the lowest positive predictive value was hand hygiene, ranging from 34.1% to 52.8%.

Table 4: Comparison of essential newborn care steps using direct clinical observations and clinical simulation

	DCO								
	Randomly selected			**First observation selected**			**Last observation selected**		
	Sn	**Sp**	**PPV**	**Sn**	**Sp**	**PPV**	**Sn**	**Sp**	**PPV**
	n=82			n=81			n=82		
Hand hygiene	Sn=57.9% (CI: 40.8%-73.7%)	Sp=50.0% (CI: 34.6%-65.4%)	PPV: 50% (CI: 34.6%-65.4%)	Sn=71% (CI: 52.0%-85.8%)	Sp=56% (CI: 41.3%-70.0%)	PPV: 50.0% (CI: 52.0%-85.8%)	Sn=55.6% (CI: 35.3%-74.5%)	Sp=47.3% (CI: 33.7%-61.2%0	PPV: 34.1% (20.5% - 49.9%)
	n=85			n=85			n=85		
Drying baby	Sn=96.4% (CI: 89.8%-99.2%)	Sp=0% (CI: 0%-84.2%)	PPV: 50.0% (CI: 40.8%-73.7%)	Sn=96.3% (CI: 89.6%-99.2%)	Sp=0% (CI: 0%-60.2%)	PPV: 95.1% (CI: 88.0-98.7%)	Sn=96.4% (CI: 89.8%-99.2%)	Sp=0% (0%-84.2%)	PPV: 97.6% (CI: 91.5%-99.7%)
	n=85			n=85			n=85		
Removing wet cloth	Sn=87.3% (CI: 78.0%-93.8%)	Sp=50% (CI: 11.8%-88.2%)	PPV: 95.8% (CI: 88.3%-99.1%)	Sn=86.5% (CI: 76.5%-93.3%)	Sp=27.3% (CI: 6.0-61.0)	PPV: 88.9% (79.3% - 95.1%)	Sn=85% (CI: 75.3%-92.0%)	Sp=20% (CI: .51%-71.6%)	PPV: 94.4% (CI: 86.4%-98.5%)
	n=77			n=70			n=75		
Covering baby	Sn=84.8% (CI: 73.9%-92.5%)	Sp=36.4% (10.9%-69.2%)	PPV: 88.9% (CI: 78.4%-95.4%)	Sn=88.7% (CI: 78.1%-95.3)	Sp=62.5% (CI: 24.5%-	PPV: 94.8% (CI:	Sn=84.8% (CI: 73.9%-	Sp=44.4% (CI: 13.7%-	PPV: 91.8% (CI:

					91.5)	85.6%-98.9%)	92.5%)	78.8%)	81.9%-97.3%)
n=77				n=71			n=76		
Cord clamping	Sn=69.6% (CI: 55.9%-81.2%)	Sp=52.4% (CI: 29.8%-74.3%)	PPV: 79.6% (CI: 65.7%-89.8%)	Sn=72.9% (CI: 58.2%-84.7%)	Sp=52.2 % (CI: 30.6%-73.2%)	PPV: 76.1% (CI: 61.2%-87.4%)	Sn=72.5 % (CI: 58.3%-84.1%)	Sp=48.0 % (CI: 27.8%-68.7%)	PPV: 74.0% (CI :59.7% - 85.4%)
n=77				n=70			n=75		
Skin-to-skin contact	Sn=78.3% (CI: 65.8%-87.9%)	Sp=64.7% (CI: 38.3%-85.8%)	PPV: 88.7% (CI: 77.0%-95.7%)	Sn=73.3% (CI: 60.3%-83.9%)	Sp=60% (CI: 26.2%-87.8%	PPV: 91.7% (CI: 80.0%-97.7%)	Sn=75.0 % (CI: 62.1%-85.3%)	Sp=53.3 % (CI: 26.6%-78.7%)	PPV: 86.5% (CI: 74.2%-94.4%)
Tool 3: Case 2									
n=83				n=82			n=83		
Hand hygiene	Sn=50.0% (CI: 33.4%-66.6%)	Sp=62.2% (CI: 46.5%-76.2%)	PPV: 52.8% (CI: 35.5%-69.6%)	Sn=54.8 % (CI: 36.0%-72.7%)	Sp=62.7 % (CI: 48.1%-75.9%)	PPV: 47.2% (CI: 30.4%-64.5%)	Sn=51.9 % (CI: 31.9%-71.3%)	Sp=60.7 % (CI : 46.8%-73.5%)	PPV: 38.9% (CI: 23.1%-56.5&)
n=85				n=85			n=85		
Drying baby	Sn=97.6% (CI: 91.6%-99.7%)	Sp=0% (CI: 0%-84.2%)	PPV: 97.6%(91.6%-99.7%)	Sn=97.5 % (CI: 91.4%-99.7%)	Sp=0% (CI: 0%-60.2%)	PPV: 95.2% (CI: 88.1%-98.7%)	Sn=97.6 % (CI: 91.6%-99.7%)	Sp=0% (CI: 0%-84.2%)	PPV: 97.6% (CI: 91.6%-99.7%)
n=85				n=85			n=85		
Removing wet cloth	Sn=87.2% (CI: 77.7%-93.7%)	Sp=57.1% (CI: 18.4%-90.1%)	PPV: 95.8% (88.1%-99.1%)	Sn=86.5 % (CI: 76.5%-93.3%)	Sp=36.4 % (CI: 10.9%-69.2%)	PPV: 90.1% (80.7% - 95.9%)	Sn=86.1 % (CI: 76.5%-92.8%)	Sp=50% (CI: 11.8%-88.2%)	PPV: 95.8% (CI: 88.1%-99.1%)
n=77				n=70			n=75		
Covering baby	Sn=87.9% (CI: 77.5%-94.6%)	Sp=27.3% (CI: 6.0%-61.0%)	PPV: 87.9% (CI: 77.5%-94.6%)	Sn=91.8 % (CI: 81.9%-97.3%)	Sp=33.3 % (CI: 7.49%-70.1%)	PPV: 90.3% (CI: 80.1%-96.4%)	Sn=86.4 % (CI: 75.7%-93.6%)	Sp=22.2 % (CI: 2.81%-60.0%)	PPV: 89.1% (CI: 78.8%-95.5%)

Table 5 presents the lowest bounds for the calculated sensitivities and positive predictive values for each of the validated essential newborn care steps. Even considering the lowest bound of the confidence interval for each compared step, the lowest calculated sensitivities of using simulation as a proxy for a direct clinical observation for cord clamping, skin-to-skin contact; removing the wet cloth, covering the baby and drying the baby are all above 70% while the lowest positive predictive values are

above 74%. The lowest bounds of sensitivity and positive for hand hygiene, however, were low at 35.3% and 30.4% respectively.

Table 5: Lowest bounds of sensitivity and positive predictive value for each essential newborn care step

Step	Lowest bound of Sn	Lowest bound of PPV
Hand hygiene	35.3%	30.4%
Drying baby	96.3%	95.2%*
Removing wet cloth	75.3%	88.9%
Covering baby	86.1%	87.9%
Cord clamping	69.6%	74.0%
Skin-to-skin contact	73.3%	86.5%
*Among observations for which there was no difference in performance by timing		

Validation of self-report against DCO

Table 6 presents the results from comparing health workers' self-report of partograph use and the active management of the third stage of labor with directly observed use. While almost three quarters (72.2%) of health workers interviewed reported always using a partograph, only 36.7% of these health workers were observed using a partograph during direct clinical observations that took place during the data collectors' observation period of that health worker. Self-reported active management of the third stage of labor was validated against directly observed provision of oxytocin as part of the active management of the third stage of labor and also against all three steps of the active management of the third stage of labor (provision of oxytocin, controlled cord traction and uterine massage). While 96.4% of health workers reported always providing the active management of the third stage of labor, 92.8% provided oxytocin but only 66.7% provided all three steps. The positive predictive value for using self-reported provision of the active management of the third stage of labor was high at 96.2% when compared with only directly observed oxytocin provision but became substantially lower (65.4%) when all 3 steps of AMTSL were observed. The positive predictive value for partograph use was low at 40.4%, indicating

that self-reported partograph use was not a good predictor of actual partograph use across all observed cases.

Table 6: Self-report of partograph use and the provision of AMTSL compared to directly observed use and provision

	Self-report	Directly observed partograph use during all of the health worker's observed cases	Sn	Sp	PPV
Partograph use (always)	n=79 72.2%	n=79 36.7%	79.3% (CI: 60.3%-92.0%)	32.0% (CI: 19.5%-46.7%)	40.4% (CI: 27.6%-54.2%)
Active management of the third stage of labor (always)—oxytocin only	n=84 96.4%	n=84 92.8%	96.2% (CI: 89.2%-99.2%)	0% (CI: 0%-45.9%)	92.6% (CI:84.6%-97.2%)
Active management of the third stage of labor (always)—all 3 components	n=84 96.4%	n=84 66.7%	94.6% (CI: 85.1%-98.9%)	0% (CI: 0%-12.3%)	65.4% (CI: 54.0%-75.7%)

Discussion

The findings of this analysis showed that clinical simulation using an anatomic model was a valid method to measure the provision of some of the critical essential newborn care steps: drying the baby (with the highest sensitivity); removing the wet cloth after drying the baby and covering the newborn with a dry cloth. Simulation was less valid for cord clamping and positioning the newborn for skin-to-skin contact and was not valid for hand washing. The results also showed that self-reported use of a partograph was not a valid predictor of what was observed in actual labor and delivery cases but that sensitivity was higher for self-reported provision of the active management of the third stage of labor.

Overall performance of essential newborn care tasks was generally high in both the simulation and in the direct clinical observations. However, adherence to hand washing in this analysis was low at 38% across all clinical observations. Surprisingly, hand washing during the clinical simulation was

higher than the DCO at 54%, though the difference between the simulation and DCOs was not statistically significant.

As previously mentioned, there are no published results available for the comparison between simulations of essential newborn care using an anatomic model and direct clinical observations in low resource settings. Franco and colleagues examined the reliability and validity of direct observation of patient-health worker interactions, health worker interviews and simulated patients to measure the quality of health worker management of sexually transmitted diseases in Malawi. They found under-reporting and over-reporting of management steps when comparing direct clinical observation data with health worker interview data and that agreement between direct observation data and interview data was poor (Franco et al., 1997). The results of the validation of self-reported partograph use and AMTSL provision are similar in that the health workers over-reported adherence to these clinical standards.

Leonard & Masatu (2005) compared vignettes (unblind case studies with an actor) to DCO of history taking, physical examination and health education for fever, cough and diarrhea in Tanzania. They reported that the vignette and DCO produced the same result 63% of the time. Although they also presented an item-by-item analysis, their approach differed from this paper in that they did not designate the DCO to be the gold standard with which to compare performance on the vignette. Rather, they assessed correlation and found that the inputs provided in the vignette were not highly correlated with the inputs that would have been provided in an actual consultation (Leonard & Masatu, 2005). While they concluded that behavior on vignettes did not predict actual behavior as observed through the DCO in their study, in this analysis, the overall level of performance did not vary widely between performance of the simulation on an anatomic model and DCO. It should be noted that there was a difference in how the vignette or case scenario was presented; in their study, the 'patient' described her own symptoms through six vignettes and in the current study, health providers were prompted to react to three scenarios on the anatomic model.

When Franco et al. (1997) compared direct observation data with simulated patient data, they found that health workers were likely improving their normal performance when observed (Franco, Daly,

Chilongozi, & Dallabetta, 1997). This potential issue was addressed in the current analysis by presenting the proportion of health workers who completed a particular step and the sensitivity, specificity and positive predictive values by whether the observation used in the analysis was randomly selected from among all direct clinical observations made on the health worker; was the first observation that was conducted or was the last observation that was conducted. There was no difference by timing of the observation; this by itself is a key finding.

Aung and colleagues (2012) validated the use of an observed simulated patient—the combination of a trained actor playing the role of a mother and a life-size doll to represent a 5 year old boy, along with a clinical vignette for the diagnosis and treatment of malaria. They found that there was 90% agreement between the two methods on almost all tasks. While an anatomic model was used during simulation in this analysis, the clinical observer did not play the role of the mother. Using a similar hybrid approach for the assessment of newborn care could potentially result in greater agreement than was seen in this study where the anatomic model was presented without a caretaker in the scenario—but this would require further investigation (Aung, Montagu, Schlein, Khine, & McFarland, 2012).

Each of the clinical steps that were included in this analysis is a key evidence-based essential newborn care practice that should be done during the birth of a healthy, live newborn, while the use of a partograph and AMTSL are also evidence-based practices to ensure the proper care of the mother during labor and delivery. Based on this analysis and depending on the selected cut-off values that are required by the assessor, simulations can be used to routinely measure health worker performance when it comes to adherence to clinical standards related to drying the baby; removing the wet cloth after drying the baby; covering the newborn with a dry cloth; and slightly less so for cord clamping and positioning the newborn for skin-to-skin contact. However, performance of a simulation using an anatomic model was not a valid predictor of hand washing and the self-reported provision use of a partograph was not a valid predictor of actual use. In diagnostic testing, sensitivity may be affected by prevalence (or performance in this case), suggesting that the lower performance of these items in general could have resulted in lower sensitivity. It should be noted that the direction of this covariance is not always systematic (e.g. higher prevalence

does not always lead to either higher or lower sensitivity) (Leeflang, Bossuyt, & Irwig, 2009). High sensitivity indicates that the clinical simulation is able to correctly identify the ability of health workers to adhere to standards when managing a real labor and delivery case. However, specificity was consistently much lower, indicating that the clinical simulation is less able to able to identify non-compliance under direct clinical observations.

One of the main advantages of using clinical simulations to measure health worker performance is the lower cost of data collection and the ability of this method to be used on a routine basis. Clinical simulations are especially useful in low caseload facilities where supervisors or data collectors may not be able to observe actual performance on a case within a short amount of time. The cost of the anatomic model used in this analysis is roughly $50-$70 depending on the type of accessories included, but in Malawi, government health centers and hospitals should have received a Neonatalie simulator as part of the scale-up of the Helping Babies Breathe evaluation. Therefore, the model should already be available in the facilities in Malawi for routine assessments. Another important advantage of using clinical simulations is that there is no threat to patient safety if poor performance is observed. Also, if the clinical simulation is administered through a standardized method (i.e. scenario is delivered through a video on a tablet or mobile phone), then it should create a more standardized experience for all health workers assessed.

Limitations

This analysis has several limitations that should be considered. The health facilities included in this analysis were all government-run health facilities. Although the health workers assessed likely had exposure to an anatomic model at some point during their training, it is possible that some health workers were more familiar with the Neonatalie models than others. One of the overall limitations of using direct observation methods is the subjectivity that is inherent in measuring the process of care and the question of whether all clinical observers interpreted the providers' behavior and actions in the same way. While a single observer was collecting data in a particular facility, aggregation of these results from multiple

observers assumes that the inter-rater reliability remained high after the training but this was not formally assessed again during data collection. However, it should be noted that the clinical observer who conducted the simulation was the same person who observed the health worker in practice and that clinical observers received periodic supervision visits during data collection from study team members who were also clinicians.

Because the items on the direct observation tool were coded as completed or not completed, the quality of the provision of some items could not be ascertained. For example, the completeness and accuracy of the partograph was not assessed—only whether the clinical observer indicated that a partograph was used or not used during labor. The health worker's compliance with proper hand hygiene (e.g. rubbing technique, length of time spent, etc.) was also not assessed but rather, it was noted only whether the health worker washed his or her hands (or used antiseptic cleanser).

There was some incomplete data in the dataset and given the small number of health workers available for this analysis, data from health workers was included if data were available on at least 80% of the steps of the clinical simulations and of the direct clinical observations. The time between the observation of simulation of the case scenarios on the anatomic model and the direct clinical observations varied from provider to provider since the timing of the first DCO depended on when a labor and delivery case arrived at that facility. Given that there was no statistically significant difference between sensitivity, specificity and positive predictive values based on the DCO used in the analysis (first, last or randomly selected), this issue may not be a large limitation. The clinical simulation was only administered once, so further validation studies should be conducted to also assess the reliability of performance on the model.

Conclusion

The findings from this analysis provide preliminary indication that overall, clinical simulation with an anatomic model can be a valid measure of health worker performance of most essential newborn care steps (specifically drying the baby, removing the wet cloth and covering the baby) when compared

against the gold standard of direct clinical simulations in this setting. However, the simulation of hand hygiene and the self-reported use of a do not validly measure actual provision or use. Given these findings, self-reported provision of some aspects of care may not be recommended to assess health worker performance. The findings for clinical simulation, however, are more promising. Since simulation of health worker provision of thermal care of the newborn was a valid measure of actual thermal care, simulation can be used to assess routine performance of this essential newborn care intervention. Although there is a cost to purchasing an anatomic model and training a clinical assessor (e.g. a supervisor) to administer the scenario, these costs are likely less prohibitive than undertaking direct clinical observations in low case load facilities, where the clinical assessor may need to wait until an actual case is available for observation. The use of clinical simulations as a health worker performance measurement method can be included as part of a clinical supervisor's training (whether at the national, district of health facility level) and as part of a quality improvement process. Simulations can replace direct clinical observations for specific aspects of newborn care in facilities where labor and delivery caseloads are small and where there may not be an opportunity to observe the health worker managing an actual delivery case, allowing clinical supervision to occur more frequently.

These analyses should be replicated in other settings to see if the results remain the same and should also be used with more complex cases or interventions (e.g. the management of postpartum hemorrhage or the active management of the third stage of labor using a birthing simulator). Additional clinical steps should be compared between the simulations and DCOs to understand if the use of simulations is a valid proxy for DCOs for adherence to other clinical guidelines. After further validation, it may be possible to apply clinical simulations in cases where resources for a larger evaluation are limited, the outcome to be observed is rare (e.g. birth asphyxia or postpartum hemorrhage) but where assessment of skills is crucial.

Chapter 4: The consistency and quality of health worker performance providing essential newborn care in Malawi (Paper Two)

Abstract

There is limited evidence available on the technical quality of essential newborn care and the factors influencing the quality of these services in Malawi. The purpose of this paper was to analyze and present results related to the consistency of health worker performance as an important variable that should be measured when quality of care assessments are undertaken. Using data from 576 clinical observations of labor and delivery observations and interviews with health workers from an evaluation of the Helping Babies Breathe program in Malawi, this analysis was conducted among health workers in public facilities in Malawi and focused on the measurement of health worker's adherence to key evidence-based essential newborn care clinical standards, the consistency of health worker performance in general and the consistency of good performance of essential newborn care. The results showed that there was room for improvement in the technical quality of care; hand hygiene was performed in only 37.9% of the direct observations of labor and delivery and all six essential newborn care steps assessed (hand hygiene; drying the newborn; removing the wet cloth; covering the baby; cord clamping; and initiating skin-to-skin contact) were performed in only 26.9% of the observations. There was also and inconsistency in performance (within-health worker variation) when none would have been expected (median coefficient of variation of 15.5%), as these guidelines would have applied to every newborn included in the analysis. Further research should be conducted to understand factors that may influence the technical quality of care, including the consistency of high performance.

Introduction

The Institute of Medicine (IOM) defines the quality of healthcare as the "degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge" (Committee on Healthcare Quality in America, 2001).

The application of current professional knowledge through consistent health worker performance is an important component of quality, assuming that a health worker will perform equally for all similar cases.

However, the assumption that there will be no variation in how a health worker performs may be unreasonable in some cases. In 2002, Wennberg introduced the idea of 'unwarranted variations', or variations in clinical practice that cannot be explained by the type of illness, severity of illness, or by patient preferences (Wennberg, 2002). In a review of literature related to medical practice variations, Mercuri et al. conclude that …"[i]t would appear that unwarranted variations are those differences in care that exist despite compelling evidence or agreement among health workers as to the (evidence-based) best course of treatment" (Mercuri & Gafni, 2011).

There is limited published evidence available on health worker-level variations in care. Fung et al. (2010) conducted a systematic review of articles that examine variability and reliability of health worker performance measures and found that variation has most often been reported at the facility level. Other articles focus on a geographic area as the unit of analysis rather than the individual health worker. Although evidence is limited, there is some suggestion that health workers do not always perform consistently even when the situation calls for it (Chakraborty & Frick, 2002; Holmboe et al., 2010; Palmer et al., 1996; Rethans & Saebu, 1997). There is even less published evidence available about variations in care at the health worker-level in resource-limited settings. In an analysis of the technical quality of care of acute respiratory infection (ARI) in India, Chakraborty and Frick (2002) calculated within-health worker variation using the rationale that "…[t]o improve quality of care on a sustainable basis, it is necessary for health workers to comply with expected technical quality of care guidelines for all cases seen by providers." They found that health worker performance was inconsistent, with some health workers having a coefficient of variation of 15% while others had a coefficient of variation of 66% (Chakraborty & Frick, 2002). There is no similar published evidence available on variations in care at the health worker-level in sub-Saharan Africa.

Quality of essential newborn care in Malawi

Although the majority (71%) of births in Malawi are attended by a skilled professional, the newborn mortality rate remains high at 31 deaths per 1,000 live births (National Statistical Office & Macro, 2011). While universal access to essential newborn care may result in the greatest reduction in global newborn mortality (St Clair et al., 2014), evidence-based essential newborn care needs to be applied consistently. According to the WHO, "essential newborn care," consists of a bundle of provisions including thermal care (drying, wrapping skin-to-skin contact, and delayed bathing), hygienic cord and skin care (hand washing, delayed cord clamping, and chlorhexidine umbilical cord care), and early and exclusive breastfeeding. Care of the newborn immediately after birth includes immediate drying, additional stimulation and skin-to-skin contact (World Health Organization (WHO), 2013a). Evidence for the importance of these critical steps of essential newborn care is presented in Chapter 1 of this dissertation.

No published literature could be found to assess the consistency of health worker performance of essential newborn care in a low resource setting. Therefore the purpose of this analysis was to understand the level of variation within and across health providers of the application of essential newborn care procedures to newborns without complications using data from direct clinical observations (DCOs) of labor and delivery from 36 government-run health facilities in Malawi. The secondary objective was to uncover factors that were associated with the quality of health worker performance.

Methods

Study Area

Malawi is a low income country that is located south of the equator in sub-Saharan Africa. The life expectancy at birth for women is 52.3 years and 49.6 years for men (NMCP & ICF International, 2012). The institutional delivery rate in Malawi is 73% (57% in public facilities and 16% in private facilities) but the maternal mortality ratio in Malawi is 675 maternal deaths per 100,000 live births (National Statistical Office & ICF Macro, 2011). The major causes of newborn death include

prematurity, asphyxia and sepsis (Colbourn et al., 2013; National Statistical Office, 2014; Zimba et al., 2012).

More than half (60%) of formal health services in Malawi are provided through the government at three levels—primary, secondary and tertiary. Primary health services are delivered through rural hospitals, health centers and health posts while secondary services are provided in district hospitals and serve as the referral level for obstetric emergencies. The tertiary level includes services offered at the secondary level in addition to surgical interventions (Malawi Ministry of Health, 2011).

Study design and data collection

This study was conducted in 36 government-run health centers and hospitals in Malawi covering 27 out of 28 districts. Using a structured observation checklist, direct clinical observations were made on any available health worker who provided labor and delivery services and was willing to participate in the evaluation during the time of data collection. A structured observation checklist was part of the evaluation of the Helping Babies Breathe intervention in Malawi conducted by the Maternal Child Health Integrated Program (MCHIP) and Jhpiego and funded by the US Agency for International Development (USAID). Clinical observers were assigned to two facilities each in which they were asked to observe 5-6 full deliveries (starting at the first stage of labor) and 50-55 deliveries starting from the third stage of labor over the course of 10-11 days. A one-week clinical observers' training was held to standardize the clinical observers in the study tools, including a health worker interview tool and direct clinical observation tool. The training included practice until the inter-observer reliability across all observers was at least 80%, as per the Clinical Observer Training Guidelines developed by MCHIP (Rawlins et al., 2013). Clinical observers were health professionals who had been trained in basic emergency obstetric and newborn care. More detailed information about the study design can be found in Chapter 2 of this dissertation and the data collection tools can be found in the Annex.

Interviews were also conducted with up to five health workers in each facility to obtain information on background characteristics, including the health worker's qualifications, age, years of

practice and whether the health worker had been supervised. A total of 77 health workers who provided essential newborn care and who were also interviewed were included in this analysis. This resulted in 576 direct clinical observations of normal deliveries in which background information about the health worker was also available through the health worker interview. The focus of this analysis is on health worker application of essential newborn care standards on newborns born alive and breathing at birth.

Dependent variable

The main dependent variable for this analysis was a direct clinical observation (DCO) score: a performance score was generated for each DCO based on six essential newborn care clinical steps that the health worker should have performed, listed in Table 7. The essential newborn care steps were selected based up their inclusion in essential newborn care guidelines distributed by the World Health Organization (World Health Organization (WHO), 2013a). Evidence for each of these essential newborn care steps is provided in Chapter 1 of this dissertation. This score was considered to be a count of performed steps and ranged from 0 to 6, where 0 indicates that none of the clinical steps were observed being done and 6 indicates that all clinical steps were observed being done. In this definition of the dependent variable, steps were given equal weight when calculating the score since all of the steps are both required and critical for the proper provision of essential newborn care according to WHO guidelines and the country's own newborn care guidelines (Malawi Ministry of Health, 2013b; World Health Organization (WHO), 2013a). If the health worker did not perform an action required in the observation checklist, the health worker was given a zero for that item. Health workers were observed more than once so each health worker was also given an average DCO score based on his or her individual DCO scores.

Table 7: Essential newborn care steps included in each DCO

Clinical Step	Direct Clinical Observation
Hand hygiene	Washes his/her hands with soap and water or uses antiseptic before any examination of woman

Drying baby	Immediately dries baby with towel
Removing wet cloth	Discards the wet towel
Covering baby	Covers baby with dry towel
Delayed cord clamping	Ties or clamps cord when pulsations stop, or by 2-3 minutes after birth (not immediately after birth)
Skin-to-skin	Places baby on mother's abdomen "skin to skin"

Independent variables

The independent variables that were included in the bivariate analyses and regression models are listed in Table 8. These variables included the sex of the health worker; age (in years); the health worker's professional qualifications, the health worker's experience providing newborn care (in years); whether the health worker had been trained in the past two years in newborn care; whether the health worker received supervision; and the number of direct observations that were made on the health worker (as a proxy for case load).

Table 8: Independent variables included in the analyses

Variable Name	Description	Data Collection Method	Type
Sex of health worker	Sex of the health worker	Health worker interview	Binary
Age of the health worker	The self-reported age of the health worker	Health worker interview	Continuous
Health worker's professional qualifications	This variable provided information on health worker's current professional, technical or medical qualifications. Categories in the questionnaire included doctor, medical assistant, clinical officer, registered midwife, enrolled nurse/midwife, nurse midwife technician, and other	Health worker interview	Categorical
Years providing newborn care services	This was the total number of years that the health worker had been providing newborn care services either the current facility or in another facility	Health worker interview	Continuous
Newborn care training	Whether the health worker received training in essential newborn care in the past 2 years (in-service or pre-	Health worker interview	Binary (yes/no)

	service)		
Supervision	Whether the health worker received technical support or supervision at the facility	Health worker interview	Binary (yes/no)
Number of DCOs	Number of DCOs of essential newborn care that were made on that health worker to serve as an indirect proxy for workload	Direct clinical observations	Count

Analysis

Statistical analysis was performed using Stata statistical software (Version 13, College Station, Texas USA). Exploratory data analyses were conducted to examine the extent of missing data and distribution of the outcome and explanatory variables in the sample. Descriptive statistics including frequencies, percentages and proportions were calculated and used to produce tables and figures that describe health worker characteristics and overall performance. Medians and interquartile ranges (IQR) are presented for continuous variables.

The coefficient of variation (CV) was calculated to assess the variation in performance within observed health workers. The coefficient of variation is a measure of dispersion in a variable and is the ratio of the standard deviation to the mean where the smaller the CV, the less dispersed the variable is than a variable with a high CV (UCLA: Statistical Consulting Group). The distribution of the CV was also assessed and the CVs were fit to a linear regression model for CV at the dependent variable (represented as a percentage) along with health worker background characteristics as independent variables to assess predictors of variation in health worker performance.

CV=Standard deviation of performance scores /Mean performance score

The intracluster correlation coefficient (ICC) or ρ (rho) was calculated for each essential newborn care item to measure the within-health worker correlation of performance by comparing the variance within health workers with the variance between health workers. ICC or $\rho = s_b^2 / (s_b^2 + s_w^2)$ where s_b^2= variance between health workers and s_w^2=variance within a health worker (Killip, Mahfoud, &

Pearce, 2004). An ICC close to one implies a reliable health worker performance for the given item because the between-health worker variation is relatively larger than the within-health worker variation, whereas a rho of zero shows that there is no correlation of responses within a health worker. To calculate rho, a two level random effects logistic regression model was used in Stata to model the binary outcome (done or not done) for each essential newborn care performance item with a random intercept for health worker. The two level random effects logistic regression model analyzes error variance structures.

Commonly-cited cutoffs for qualitative ratings of agreement based on ICC values suggest that poor consistency includes values less than .40, fair consistency includes values between .40 and .59, good consistency includes values between .60 and .74, and excellent consistency includes values between .75 and 1.0 (Cicchetti, 1994). By excluding newborns with complications, adjustments did not have to be made for case-mix since all of the essential newborn care steps should have been observed for every labor and delivery case.

A two-level random effects Poisson regression model was then used to assess the relationship between the independent variables related to health worker characteristics and the dependent DCO score. This model was selected for use because the DCO scores were treated as a count and were correlated within (or clustered by) health worker. Random intercept models recognize the hierarchical structure of this data by allowing residual variance to be partitioned into between cluster and within-cluster components, where clustering is at the health worker level (Hesketh & Skrondal, 2012). Poisson regression coefficients were interpreted as the ratio of average DCO scores for a one unit increase in the independent variable, controlling for other independent variables in the models. The following equation represents the random effects Poisson regression model:

$$\log(\mu_{ij}) = \beta_0 + \beta_1 \text{Sex}_{ij} + \beta 2 \text{Age}_{ij} + \beta_3 \text{Qualification}_{ij} + \beta_4 \text{Years of service}_{ij} + \beta_5 \text{Training in ENC}_{ij} + \beta_6 \text{Supervision}_{ij} + \beta_7 \text{Number of DCOs}_{ij} + u_j$$

for j = 576 direct observations i = 77 health workers. The random effects intercept for each health worker $j = u_j$ and $u_i \sim \text{Normal}(0, \sigma^2_u)$

And where:

μ_{ij} = average DCO score for j^{th} observation and i^{th} health worker, where DCO score is assumed to be distributed as a Poisson random variable

β_1=health worker-specific difference in log average DCO score between males and females (ref=males) adjusted for age, qualification, years of service, training, supervision and number of DCOs

β_2= health worker-specific difference in log average DCO score for each additional year of age adjusted for qualification, years of service, training, supervision and number of DCOs

$\beta_3 - \beta_k$= health worker-specific difference in log average DCO score between health providers with different qualifications (ref=nurse midwife technician) where k is number of different qualifications – 1 , adjusted for age, years of service, training, supervision and number of DCOs

β_4= health worker-specific difference in log average DCO score for each additional year of service adjusted for age, qualification, training, supervision and number of DCOs

β_5= health worker-specific difference in log average DCO score between health workers trained in ENC compared to those who have not been trained in ENC in the past two years adjusted for age, qualification, years of service, supervision and number of DCOs

β_6= health worker-specific difference in log average DCO score between health workers who received any supervision compared to those who have not received any supervision adjusted for age, qualification, years of service, training, and number of DCOs

β_7= health worker-specific difference in log average DCO score for each additional DCO adjusted for age, qualification, years of service, training, and supervision

Multilevel analysis addresses the concern that health worker estimates from health workers with a few patients are less reliable by "dispersing" the shrinkage. In other words, estimates from multilevel analysis for smaller caseload health workers regress more towards the mean and have wider confidence intervals compared to estimates for health workers with higher caseloads (Tan, Freeman, & Freeman, 2007).

Finally, linear regression models were used to assess the relationship between the independent variables related to health worker characteristics and the dependent coefficient of variation score of the health worker. Logistic regression models were used to identify health worker characteristics that were associated with "consistently good" performers, where "consistently good" performance was classified as having a coefficient of variation less than or equal to 20% and a mean DCO score of 80% or higher.

The linear regression model (for CV scores) is represented by the following equation:

$$E[Y_i] = \beta_0 + \beta_1 Sex_i + \beta 2 Age_i + \beta_{3\text{-}K} Qualification_i + \beta_4 Years\ of\ service_i + \beta_5 Training\ in\ ENC + \beta_6 Supervision_i + \beta_7 Number\ of\ DCO_i$$

Where:

Y_i =CV score for i^{th} health worker

β_1=difference in average CV score between males and females (ref=males) adjusted for age, qualification, years of service, training, supervision and number of DCOs

β_2=difference in average CV score for each additional year of age

$\beta_{3\text{-}k}$=difference in average CV score between health providers with different qualifications vs. reference qualification (ref=nurse midwife technician), where K is number of qualifications - 1

β_4=difference in average CV score for each additional year of service

β_5=difference in average CV score between health workers trained in ENC compared to those who have not been trained in ENC in the past two years

β_6=difference in average CV score between health workers who received any supervision compared to those who have not received any supervision

β_7=difference in average CV score for each additional DCO

The logistic regression model is represented by the following equation:

$$Odds\ (good\ performance_i) = \beta_0 + \beta_1 Age_i + \beta_2 Training\ in\ ENC_i + \beta_3 Supervision_i$$

Where:

Odds= ((probability of good performance) / (1 – probability of good performance))

β_1=change in expected log odds of being a consistently good performer for each additional year of age of health worker

β_2= change in expected log odds of being a consistently good performer between health workers trained in essential newborn care in the past two years

β_3= change in expected log odds of being a consistently good performer between health workers who have received any supervision

Results

Health worker background characteristics

All of the health workers in this sample worked in one of 36 health facilities in Malawi that were included in the Helping Babies Breathe evaluation. The maximum number of health workers observed in any one health facility was four and the minimum was one. Most of the health workers were women (70.1%) and more than three quarters (76.2%) were nurse/midwife technicians that had completed a three-year integrated training program in nursing and midwifery. The median age of these health professionals was 32.0 years (IQR: 25 to 34 years of age) and the median number of years of professional experience was 3.0 years (IQR: 2 to 6 years). Nearly half of the health workers interviewed had two or fewer completed years of experience. More than half of the health workers (64%) reported ever receiving technical support or supervision for their work (Table 9).

Table 9: Health worker characteristics

	Number (n)	Percent (%)
Health worker sex (n=77)		
Male	23	29.9
Female	54	70.1
Health Worker's Qualification (n=77)		
Nurse/Midwife Technician	59	76.2
Registered Midwife	8	10.4
Enrolled Nurse/Midwife	7	9.1
Other	2	2.6
Medical Assistant	1	1.3
Median age (n=61)	32.0	IQR: 9.0
Median years of work experience (n=77)	3.0	IQR: 4.0
Training in essential newborn care in the past two years (n=56)	42	75.0
Health worker has received technical support or supervision (n=75)	48	64.0

Health worker performance on DCOs

Figure 19 shows the number of direct clinical observations of labor and delivery cases in which the newborn did not need to be resuscitated and was not stillborn, and was therefore included in this analysis. The number of DCOs per health worker ranged from two to 25 observations per health worker;

the median number of observations was six (IQR: 4 to 10). Most health workers completed between two to five DCOs while there were only three health workers who were observed on twenty or more labor and delivery cases within the observation period.

Figure 19: Histogram of the number of DCOs performed by health workers

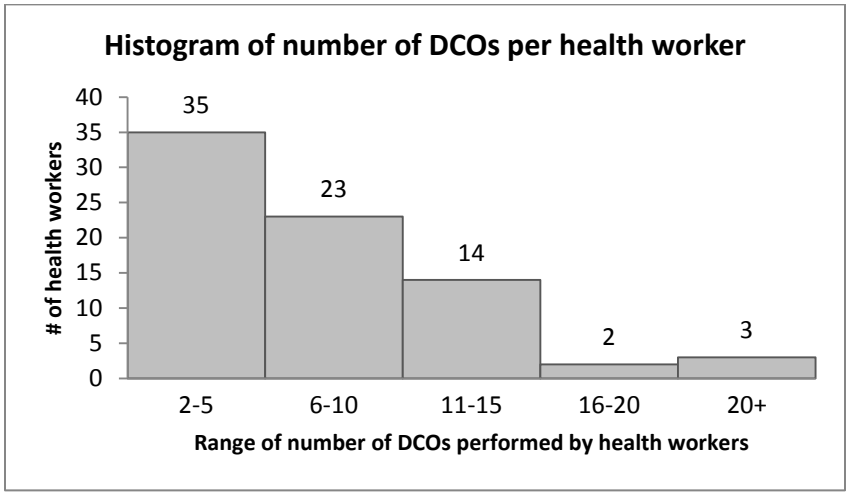


Table 10 shows the step-wise performance of essential newborn care among all DCOs. Among all DCOs, the most frequently completed essential newborn care step was drying the baby (98.1%) and the least frequently completed step was washing hands or using an antiseptic (37.9%).

Table 10: Overall step-wise DCO performance among all DCOs (n = 576)

Clinical Step (n=576 DCOs)	% of DCOs in which step was done
Hand hygiene	37.9
Drying baby	98.1
Removing wet cloth	93.8
Covering baby	84.2
Cord clamping	74.0
Skin-to-skin	79.6

The proportion of DCOs with a given score is presented in Figure 20. In over one quarter (26.9%) of the essential newborn care cases observed, all six steps were done. In only one direct clinical

observation of labor and delivery (0.2%) did the health worker not perform any of the six essential newborn care steps. The median DCO score among all observations was 5 (IQR: 4 to 6).

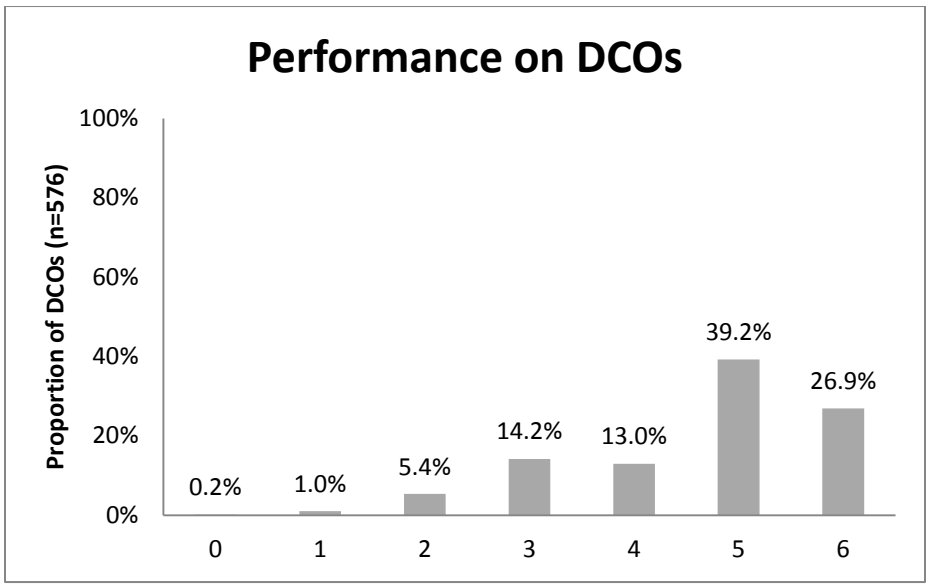


Figure 20: Performance scores on direct clinical observations of essential newborn care.

Table 11 shows the proportion of observations in which an essential newborn care step was missed and provides information on which steps were most frequently missed. Health workers performed all six essential newborn care steps in 155 DCOs (29.6% of all DCOs and score=6). In 226 DCOs (39.2%), one step was not performed (score=5). Among the observations with a score of 5, health workers did not wash their hands in 81% of the cases and did not delay clamping the newborn's cord in 15% of cases. The least missed step in observations with a score of 5 was drying of the newborn (0% missed) (Table 11). There were five health facilities in this sample that did not have soap available during the time of assessment and one that did not have water for hand washing. However, the one facility that did not have soap and water had antiseptic available at the time of data collection. Taking these factors into account, there were 69 direct clinical observations made by 9 health workers where the health worker

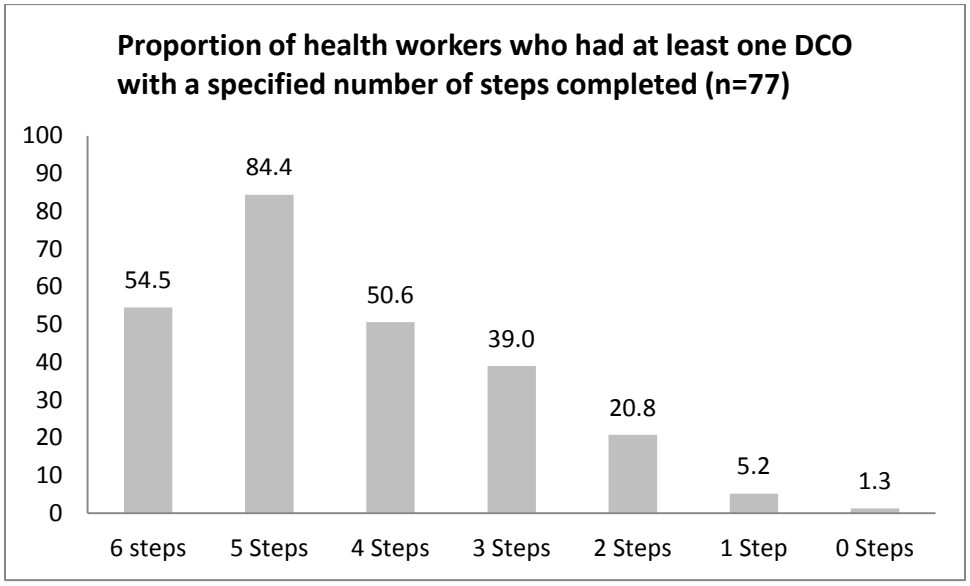
did not have access to soap, water or antiseptic. These observations were not excluded in the analysis because all six steps should ideally be performed.

Table 11: Proportion of observations in which the essential newborn care step was not done (by score)

Score (n=# of DCOs)	Did not wash hands No. (%)	Did not dry baby No. (%)	Did not remove wet cloth No. (%)	Did not covers baby No. (%)	Did not delay cord clamping No. (%)	Did not initiate skin-to-skin contact No. (%)
6 (n=155)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
5 (n=226)	183 (81.0)	0 (0.0)	1 (.44)	1 (.44)	34 (15.0)	7 (3.1)
4 (n=75)	64 (85.3)	0 (0.0)	3 (4.0)	11 (14.7)	53 (70.7)	19 (25.3)
3 (n=82)	74 (90.2)	4 (4.9)	8 (9.8)	48 (58.5)	41 (50.0)	71 (86.6)
2 (n=31)	30 (96.8)	4 (12.9)	17 (54.8)	30 (96.8)	23 (74.2)	20 (64.5)
1 (n=6)	6 (100.0)	2 (33.3)	6 (100.0)	6 (100.0)	5 (83.3)	5 (83.3)
0 (n=1)	1 (100.0)	1 (100.0)	1 (100.0)	1 (100.0)	1 (100.0)	1 (100.0)

Additional descriptive analysis was conducted to quantify the number of health workers who receive at least one perfect score on a labor and delivery observation, presented in Figure 21. Slightly more than half (54.5%) of observed health workers performed all essential newborn care steps in at least one observation while 84.4% of health workers had at least one observation in which they completed 5 steps out of 6. Only one health worker observed had at least one observation in which he or she did not complete any of the essential newborn care steps.

Figure 21: Proportion of health workers who had at least one DCO where the specified number of steps was completed



Consistency of performance of direct clinical observations

Within-health worker variations in DCO scores were represented by whether or not the health worker performed consistently on all of the newborns they were observed managing. A coefficient of variation was calculated for each health worker and the CV ranged from 0% to 73.1% with a median of 15.5% (IQR: 9.2% to 27.0%). A histogram of the CVs is shown in Figure 22. Eleven health workers had a CV of 0, indicating that they did not have any variability in their DCO scores while five health workers had a CV that was greater than 50%, indicating a relatively high amount of variability between DCO scores. It should be noted that the CV only indicates consistency of performance but does not differentiate between consistently "good" or consistently "poor" performance.

Using a two-level random-effects logistic regression model, ICC was calculated for each clinical step and is presented by item in Table 12. The ICCs range from .54 (CI: .38-.69) for consistently ensuring skin-to-skin contact of the newborn with the mother to .72 (CI: .25-.95) for consistently drying the baby. Using the cutoff values cited by Cicchetti (1994), the ICC for ensuring skin-to-skin contact of the newborn to the mother was fair while the ICCs were good for the other clinical steps. However, the

confidence intervals for the ICCs were wide, indicating that the overall sample size was too small to produce precise estimates. To be conservative, the lower bounds of the ICC confidence intervals indicated poor consistency for drying the baby, removing the wet cloth and ensuring skin-to-skin contact. The ICCs were fair for the remaining steps.

Figure 22: Histogram of Coefficient of Variation (CV) scores (shown as a %) for health workers (n=77)

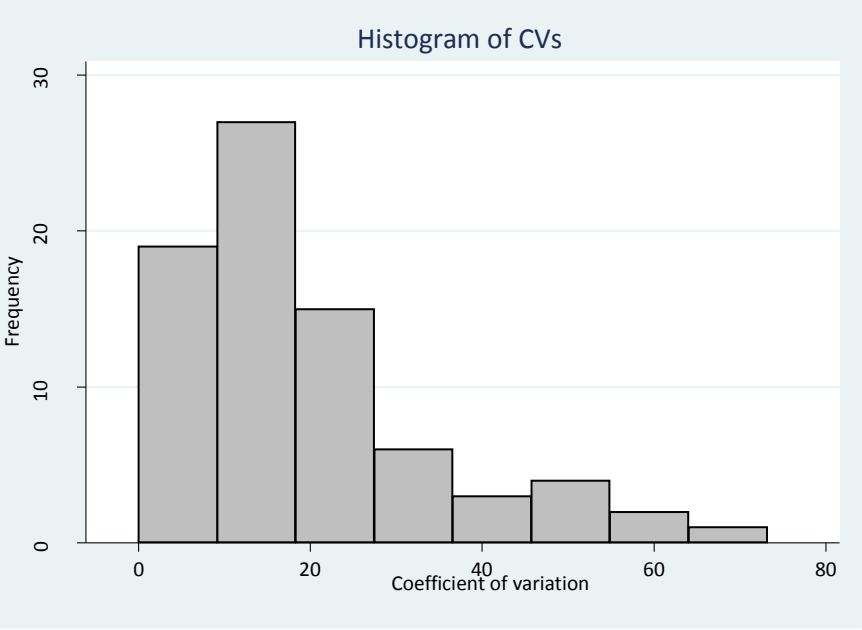


Table 12: ICCs for each essential newborn care step

Clinical Step	ICC	CI
Hand hygiene	0.61	(.47-.73)
Drying baby	0.72	(.25-.95)
Removing wet cloth	0.62	(.39-.80)
Skin-to-skin contact	0.54	(.38-.69)
Covering baby	0.60	(.43-.75)
Cord clamping	0.63	(.48-.76)

Determinants of mean DCO score and variation in health worker performance on DCOs

The goal of subsequent analysis was to identify variables that were significantly associated with a health worker's DCO scores, where each score is modeled as a count from 0 to 6. The results of the

bivariate random-effect Poisson regression analysis and multivariate random-effect Poisson regression model shown in Table 13 indicate that none of the independent variable tested were significantly associated with DCO scores.

Table 13: Unadjusted and adjusted Poisson regression coefficients for the relationship between health worker characteristics and health worker's DCO scores, represented by the incidence rate ratio

	Bivariate Random Effects Model			Multivariate Random Effects Model		
	Unadjusted IRR	95% CI	p-value	Adjusted IRR	95% CI	p-value
Health worker's sex (Ref: male)	1.01	(.910-1.13)	0.791	.965	(.819-1.13)	0.672
Health worker's age (for each additional year)	.995	(.988, 1.00)	0.155	.995	(.987-1.00)	0.202
Health worker's qualification*						
Medical assistant	.950	(.517-1.74)	0.868	.863	(.491-1.51)	0.607
Registered midwife	1.07	(.887-1.29)	0.485	1.08	(.887-1.32)	0.442
Enrolled nurse midwife technician	1.17	(.977-1.40)	0.089	1.09	(.739-1.62)	0.654
Other	1.00	(.673-1.49)	0.990	.983	(.669-1.45)	0.932
Years providing newborn care services (for each additional year)	.995	(.989, 1.00)	0.158	1.00	(.987-1.02)	0.839
Trained in essential newborn care	.993	(.899,1.10)	0.895	1.04	(.870-1.23)	0.693
Receives supervision (any)	.967	(.868, 1.08)	0.536	1.05	(.992-1.01)	0.512
Number of DCOs	.998	(.989,1.01)	0.655	1.00	(.992-1.01)	0.612

Two-level random effect Poisson regression model testing with random intercept for health worker; *Reference category for health worker qualification was nurse midwife technician; $p<0.05$ Level of significance

The purpose of the second regression analysis was to identify variables that were significantly associated with the coefficient of variation for each health worker. The result of this analysis shown in Table 14 indicated that the number of DCO was statistically significant in the unadjusted logistic regression model but was no longer statistically significant in the adjusted model; this finding was not unexpected because the more DCOs the health worker performs, the higher the potential the health worker has for variability of performance.

Table 14: Unadjusted and adjusted linear regression coefficients for the relationship between worker characteristics and CV (n = 77)

	Unadjusted Coefficient	95% CI	p-value	Adjusted Coefficient	95% CI	p-value
Health worker's sex (Ref: male)	0.004	(-.075-.083)	0.918	0.0001	(-.129, .131)	0.991
Health worker's age	0.004	(-.0003-.008)	0.069	-0.003	(-.015, .101)	0.635
Health worker's qualification*						
Medical assistant	0.081	(-.024-.400)	0.617	0.175	(-.138, .488)	0.263
Registered midwife	-0.025	(-.145-.094)	0.672	-0.016	(-.256, .224)	0.895
Enrolled nurse midwife technician	0.095	(-.032-.222)	0.141	0.068	(-.196, .332)	0.602
Other	-0.060	(-.288-.168)	0.602			
Years providing services	0.003	(-.002-.008)	.0254	0.002	(-.005,.029)	0.171
Trained in essential newborn care	0.045	(-.047.137)	0.329	0.036	(-.071, .144)	0.494
Receives supervision (any)	-0.021	(-.098-.055)	0.577	-0.026	(-.129, .076)	0.599
Number of DCOs	0.011	(.005-.018)	**0.001**	0.008	(-.002, .019)	0.132

Linear regression model; *Reference category for health worker qualification was nurse midwife technician; $p<0.05$ Level of significance

The purpose of the third regression analysis was to identify health worker level characteristics that are associated with "consistently good" performance, where "consistently good " was defined as having a coefficient of variation of 20% or less and a mean DCO score of 80% or more. There were 34 health workers who met these criteria. Bivariate analysis using logistic regression was conducted with the outcome as the odds of being a consistently good performer alongside health-worker level characteristics and the results of the multivariate logistic regression model are also shown in Table 15. The multivariate analysis between consistently good performance and health worker's age, whether the health worker trained in essential newborn care in the past two years, and whether the provider receives supervision did not show significant relationships between the outcome and these variables. It should also be noted that the confidence intervals for the odds ratios presented in the table are wide, indicating that the small effective sample size does not allow for precise estimates of the odds ratios.

Table 15: Unadjusted and adjusted logistic regression coefficients of the relationship between worker characteristics and consistently good performance (n = 77)

	Unadjusted Odds Ratio	95% CI	p-value	Adjusted Odds Ratio	95% CI	p-value
Health worker's age	0.95	(.882,1.02)	0.171	0.97	(.896,1.05)	0.490
Trained in essential newborn care	0.74	(.216,2.54)	0.356	0.84	(.191,3.90)	0.850
Receives supervision (any)	1.08	(.387,3.01)	0.884	3.09	(.688,13.9)	0.141

Logistic regression model; *Reference category for health worker qualification was nurse midwife technician; p<0.05 Level of significance

Discussion

The main objective of this analysis was to assess consistency and quantify the level of variation in performance of key essential newborn care steps by health workers in 36 government-run health facilities in Malawi. The secondary objective was to explore factors that may influence intra-health worker variation, performance score across all observations, and performing consistently well. By calculating the coefficient of variation (CV), this analysis found that health worker performance varied both within and between health workers, where some health workers had a variation factor of 0% (indicating consistent performance in their DCOs) while the highest variation factor was 73.1% (indicating inconsistent performance). Taking this a step further, it was found that 34 health workers performed consistently well (described as a coefficient of variation of <=20% and a mean DCO score of >=80%), whereas 15 health workers performed consistently, but did have a high mean DCO score, indicating consistent "poor" performance. The overall provision of all essential newborn care steps across all DCOs was relatively low (27% across 576 DCOs) even though all six steps should have been observed being performed on these newborns by all providers.

Although the type of health services being examined in this analysis was different than in the Chakraborty and Frick study in 2002 **(**the management of ARI vs. the provision of essential newborn care), this analysis also found that health worker performance was inconsistent across different patients and among different essential newborn care steps. Inconsistency in health worker performance was also

found through direct observations among health workers in Malawi who offered care for sexually transmitted diseases (Franco et al., 1997).

While zero variation in performance cannot be expected, especially when observing a larger number of cases, there are no known cutoffs for how much variation in health worker performance is acceptable (Chakraborty & Frick, 2002). This makes it difficult to draw firm conclusions from this analysis other than to note that further attention should be paid to the evaluation of consistency as an indicator of quality of care. However, if one is just looking at consistency alone, these results show that within-health worker variations were high given that the essential newborn care items observed are part of the national guidelines and should have been applied universally to each newborn included in this analysis. For the same reason, between-health worker variations also are higher than expected.

The results from the analysis of the absolute performance of health workers across all clinical observations showed that clean delivery practices (hand washing) was the step most often missed overall (completed in 38% of DCOs) and also when only one step was missed. Clean delivery practice is strictly recommended by the WHO but low compliance has been reported from labor wards in various low-income countries as well as in this analysis (Asp, Sandberg, Ezechi, & Pettersson, 2011). While the lack of availability of soap in five facilities and lack of water in one facility likely prevented those 11 health workers from completing this particular step, there is no explanation for why the health workers who had access to soap and water were unable to complete this step. The low adherence to hand hygiene practices in Malawi is in line with a recently published study that found adherence to hand hygiene to be 23% in in Queen Elizabeth Central Hospital in Malawi (Kalata, Kamange, & Muula, 2013). Other Quality of Care surveys under the MCHIP project found hand washing compliance to be low in Africa (64% before examinations during labor in Zanzibar; 11% before initial assessment of labor in Rwanda; and 2% before initial assessment in Ethiopia) (Plotkin et al., 2010; Ngabo et al., 2012;Getachew et al., 2011). One possible reason is because of time constraints, especially if the health worker was the only person available to conduct the delivery. Lack of awareness of the importance of hand washing is another possible reason even though hand washing is part of the basic obstetric and newborn care training.

Pressures of work were also said to be a reason why midwives do not consistently wash their hands during clinical practice in another study of midwives in Malawi (Mondiwa & Hauck, 2007), but this data was not available in this study. It is also interesting to note that there is a wide assumption that the Hawthorne effect increases hand hygiene compliance when health workers are being observed but the results of this analysis shows that this was not the case in this group of health workers (Srigley, Furness, Baker, & Gardam, 2014).

The results of the random-effects Poisson regression analysis showed that DCO scores were not associated with the health workers' age, qualification, years of experience providing newborn care, recent training in newborn care, supervision, or number of DCOs (as a proxy for caseload) that the health worker performed during the time of data collection. Further research should be conducted to explore other relationships with other possible health worker and facility-level characteristics. That there was no effect on DCO score by caseload is unexpected but not unique; Maestad et al. (2010) assessed the relationship between workload and health worker assessment on consultations of patients who presented with fever, cough and/or diarrhea in Tanzania and found that a high workload did not affect the quality of health worker performance in that study (Mæstad, Torsvik, & Aakvik, 2010). Unlike the results from this analysis, the authors of that study noted that there was a significant difference in quality based on health worker's qualifications but that this difference was not large, suggesting that there are other measures that are needed to improve quality than just the health worker's qualifications. It should also be noted that the overall demand for services in that study was low, resulting in health workers spending less than two hours of their day with patients (Mæstad et al., 2010). Labor and delivery can be a much longer process so care must be taken when extrapolating finding from the Maestad study to other settings and clinical areas.

The lack of association between DCO score, recent training in essential newborn care and supervision are not surprising either. Although a lack of training was once assumed to contribute to poor health worker performance, Rowe (2009) et al. point out that evidence on the long-term effect of training is disappointing and that performance problems cannot be solved by training alone. They also point out

that while supervision has been shown to improve performance in the short-term, supervisors often lack the skills to supervise. Even though regular supervision may be planned, issues with other administrative duties and with transportation may preclude them from making the visits. Supervision may also be unwelcome when the assessment is perceived as fault-finding, takes up too much of the health worker's time and when the visits are not thought of as being helpful (Rowe et al., 2005). Information on the quality of supervision and health worker perceptions about supervision were not collected as part of this study.

There are few studies that specifically assess within-health worker variation in the provision of clinical care. The findings of this analysis are in line with most of those studies. Using the same standardized patients at two time points, Rethans et al. (1997) assessed the consistency of 23 doctors in providing care for angina pectoris and found that when analyzed at a group level, performance was consistent but that the performance of individual doctors was subject to variation (Rethans & Saebu, 1997). Palmer et al. (1996) analyzed inter- and intra-physician differences in performance on the basis of review criteria for eight patient care guidelines related to pediatric care and internal medicine and found that health workers' scores were not consistent from one case to the next in conforming to the same guideline (Palmer et al., 1996). Holmboe and colleagues assessed between- versus within-variation in ambulatory care in 236 patients by quantifying by intraclass correlation coefficients (ICC) and found that performance varied substantially between and within physicians (Holmboe et al., 2010). However, Kaplan et al. (2009) assessed physician performance of diabetes care and found that physicians appeared to behave consistently across patients in their practices for the process measures (Kaplan, Griffith, Price, Pawlson, & Greenfield, 2009). Unlike the direct clinical observations that were used for the health workers in Malawi, the Kaplan et al. (2009) study asked physicians to submit quality of care data to the researchers rather than observing the health workers providing care in real-time.

There are likely numerous factors that can help to explain why health worker performance is not always consistent even when clinical guidelines are available. In Wennberg's seminal article published in 1984, he introduced the idea of "practice style" that suggested that medical practice variations can be

caused by health workers themselves (Wennberg, 1984). Additional evidence is available to suggest that variation in medical practice can be due to differences in geographic region; evolution of medical knowledge; individual health worker characteristics (including medical training, time constraints, distractions and levels of stress); the complexity of human disease and behavior; and errors in judgment (James & Hammond, 2000). Other possible causes include factors at the environmental level, including workload; the availability of staff; and the proper functioning of equipment (Palmer et al., 1996). In this study sample, there were no significant differences in consistency of performance based on the health worker's qualification and observed workload.

Failure to apply the correct skills and to consistently use correct techniques in accordance with evidence-based guidelines could have negative effects on the newborn. Uncovering the extent of variation and identifying deficiencies in the provision of clinical care are essential for understanding whether trained health workers are applying their skills based on guidelines and also provides an opportunity to identify needs for continued learning and professional development. Evaluating the consistency at which a health worker operationalizes evidence-based guidelines and the factors that affect within-health worker variation and overall process quality of care can help health programs managers make decisions about how to best reduce clinical practice variations when resources are limited.

Strengths and Limitations

One of the strengths of this analysis is that an adjustment did not need to be made for case-mix. Wennberg's (1984) seminal article mentions that some variations in practice exist because of scientific controversies and differing opinions related to best practices, but for the case of essential newborn care, there hardly seems to be any disagreement on the importance of the six steps that were examined in this analysis (Wennberg, 1984).

It should also be noted that gaps in practice at the health worker level usually reflect systems-related issues and not only the performance of health workers (Kitson & Straus, 2010). Therefore, one of the major limitations of this analysis is that missing data on some health worker characteristics, (e.g.

stress levels, exact workload (though DCO number was used as an indirect proxy), and other potential factors) precluded their use in the regression models. Due to the small sample size, practice variations between health facilities could not be adequately assessed. While there may be facility-level differences that could help to explain some of the variation in performance, it is important to note that the essential newborn care steps that were assessed do not require specialized equipment and are expected to be performed on all healthy newborns. It should also be noted that observations provided information about whether a step or task was done but not how well it was done. For hand hygiene for example, there was information about whether the health worker washed his or her hands but not whether the health worker followed the proper technique (e.g. rubbed hands in the recommended way or for the recommended amount of time). The overall sample size may have limited the associations that could be seen between health provider characteristics and performance.

All of the data were collected from public, government-run facilities so variations between public and private facilities and among health workers in private facilities could not be assessed. Data on the characteristics of the women being observed was not collected but by excluding newborns with complications, practice should not have varied by newborn given that all of the essential newborn care steps would still apply.

Conclusions

In conclusion, this analysis provides evidence on the overall quality of essential newborn care in 36 government-run health facilities in Malawi, focusing on six key components: hand hygiene, thermal care, cord clamping and facilitating skin-to-skin contact between the newborn and mother. This analysis also provides information on the consistency of health worker performance of these key steps and explored the relationship between health worker characteristics and consistency, performance, and consistently good performance. Results show that overall adherence to evidence-based essential newborn care practices assessed under direct clinical observation in this analysis was high for most steps except for hand hygiene. The results also showed that nearly half of the health providers performed consistently, but the proportion

of health providers who performed well consistently was lower. In this sample, health worker background characteristics could not be used to explain variations in performance.

The findings raise concerns about the quality and consistency of the provision of essential newborn care in the sampled facilities in Malawi, especially when no variations in care were expected, either within or between health workers. This suggests the need for further in-depth investigation of causes of variation to better understand how other factors may affect health worker performance (e.g. structural, contextual and personal factors) and using the subsequent analysis to develop appropriate solutions.

Chapter 5: Respectful maternity care in Malawi: Direct observations of labor and delivery in health facilities and scale development (Paper 3)

Abstract

Not only is published evidence on the extent of disrespect abuse (D&A) during facility-based delivery in Malawi limited, measurement methods to quantify the D&A are even more limited. When evidence is available, it has generally been collected through qualitative data collection methods. For this analysis, a scale using direct clinical observations of labor and delivery was developed and its validity and reliability were assessed. Guided by the 2010 Bowser and Hill landscape analysis and the Seven Rights of Childbearing women, the prevalence of disrespect and abuse across 40 health facilities in Malawi is presented. The results show that while women were frequently greeted respectfully (86.1%), they were not encouraged to ask the health provider questions (73.1%), were not given privacy (58.2%) and were not encouraged to have a support person present with them (83.2%). The results from the development of the scale resulted in a model with two factors: provider-client communication and provider encouragement during the first stage of labor measured through direct clinical observation. Further research should be done to assess the reliability and validity of the tool in other settings and to consider the use of the tool alongside other data collection methods for a more complete picture of respectful maternity care.

Introduction

While the availability of quality clinical obstetric services is a key determinant of the delivery outcome of a mother and her newborn, a pregnant woman and/or her support person must first take action and seek care in a health facility to receive basic emergency obstetric care (BEmOC). However, there are well-described barriers that can prevent this from occurring. The three-delays model described by Thaddeus and Maine in their 1994 paper, "Too far to walk: maternal mortality in context," provided a framework within which to understand the factors that can affect health care utilization and health outcomes among pregnant women that contribute to maternal mortality (Thaddeus & Maine, 1994).

Delay one is a delayed decision to seek care, delay two is the delayed arrival to a health facility and delay three is delayed provision of care. Poor quality of maternity care contributes to both delay one (decision to seek care) and delay three (receipt of adequate and appropriate treatment). The receipt of respectful care can affect both a woman's decision to seek care (e.g. fearing ill-treatment may prevent her from seeking care at a health facility) and quality of care (e.g. the act of being mistreated or cared for inappropriately).

Conceptual model

In 2010, a landscape analysis of disrespect and abuse in facility-based childbirth reviewed evidence related to the definition, scope, contributors and impact of disrespect and abuse in childbirth (Bowser & Hill, 2010). The results led to the development of seven categories of disrespect and abuse (Figure 23). The White Ribbon Alliance then led a multi-sectoral collaboration in producing a consensus document--the Respectful Maternity Care Charter: The Universal Rights of Childbearing Women. These rights are relevant to all pregnant women around the world but are of particular interest in low resource settings where women may have less choice about where to deliver and less legal recourse to address and challenge disrespectful treatment. Further information about each of component of this framework is presented in Chapter 2.

Figure 23: Seven Rights of Childbearing Women. From the White Ribbon Alliance Respectful Maternity Care Charter.

Seven Rights of Childbearing Women		
Category of Disrespect and Abuse		Corresponding Right
1	Physical abuse	Freedom from harm and ill treatment
2	Non-consented care	Right to information, informed consent and refusal and respect for choices and preferences, including the right to companionship of choice wherever possible
3	Non-confidential care	Confidentiality, privacy
4	Non-dignified care (including verbal abuse)	Dignity, respect

5	Discrimination based on specific attributes	Equality, freedom from discrimination, equitable care
6	Abandonment or denial of care	Right to timely healthcare and to the highest attainable level of health
7	Detention in facilities	Liberty, autonomy, self-determination and freedom

Mother- friendly care in Malawi

The Integrated Maternal and Newborn Care Training Manual for Malawi is part of the training curriculum for health workers who provide labor and delivery services in government facilities. This manual contains modules that cover the knowledge, skills and attitudes required for skilled birth attendants to provide emergency obstetric and newborn care. Module 8 of this manual describes "Mother and Family Friendly Care Guiding Principles" and includes mother friendly care actions that should be taken during the management of labor (Malawi Ministry of Health, 2013b). This manual was finalized in 2006 and training on the manual was rolled out in 2007. Any health worker who provides labor and delivery services and who graduated after 2008 will have received training that includes mother friendly care actions (Tauzi & Lwesha, 2015). Figure 24 provides examples of the mother friendly care actions that are included in the training manual that reflect respectful maternity care and the corresponding category of disrespect and abuse as per the Seven Rights of Childbearing Women.

Figure 24: Mother Friendly Care Actions listed in the Integrated Maternal and Newborn Care Training Manual (Ministry of Health, Malawi)

MOTHER-FRIENDLY CARE ACTIONS	Corresponding category of disrespect and abuse that is addressed by the action
• Kind and supportive care	Non-dignified care
• Body language that shows kindness (address woman by name, look into the woman's eyes, uses a respectful tone of voice, smiles when appropriate)	Non-dignified care
• Privacy	Non-confidential care
• Clean and attractive facility	Non-dignified care

MOTHER-FRIENDLY CARE ACTIONS	Corresponding category of disrespect and abuse that is addressed by the action
• Permit cultural practices that are not harmful	Non-dignified care/Abandonment or denial of care
• Explain every procedure	Non-consented care
• Episiotomy only if indicated	Non-consented care
• Choice of position for delivery	Non-dignified care
• Give woman and family friendly care. Explain what is happening to the woman and family after each evaluation. Teach the woman and companion how to support the woman in labour: o Urinate every 2 hours o Drink fluids every 1 hour or more often o Eat lightly o Have a birth support/guardian person present o Talk to the woman: give emotional support and educate her about what is happening o Use comfortable positions for labour (walking, sitting, side-lying)	Non-consented care/ Abandonment or denial of care
• Postpartum o No restriction on family members o No separation of mother and baby	Abandonment or denial of care
Figure adapted directly from Module 8 of the Participants Manual in Integrated Maternal and Newborn Care. (2009). Malawi Ministry of Health, Reproductive Health Unit	

The ethical and respectful treatment of maternity clients is an important issue in Malawi, although the extent of the problem has not been formally measured. There are no existing scales available that focus on the measurement of respectful maternity care through non-qualitative data collection methods. A scale that allows supervisors and policymakers to routinely measure key aspects of respectful maternity care yield information needed to ensure that health providers are effectively communicating with clients and if not, to recommend that health providers receive additional training or mentoring in this area. By directly observing health providers' interactions with their clients, healthcare providers may also realize whether their communication with patients is adequate, and, if not, they will know which aspects of the communication that reflect respectful maternity care are problematic.

Therefore the objectives of this paper are: 1.) to describe the prevalence of disrespect and abuse during labor and delivery in Malawi through the secondary analysis of direct clinical observations; 2.) to describe the association between the observation of RMC items with the place of delivery and client background characteristics; and 3.) to describe the development of a scale to measure respectful maternity care and assess the scale's validity and reliability.

Methods

Data for this analysis were collected as part of an evaluation of the Helping Babies Breathe (HBB) program in Malawi conducted in August 2013 that was supported by the USAID-funded Maternal Child Health Integrated Program (MCHIP). More detailed information about the study setting and parent study (Malawi HBB Evaluation) can be found in Chapter 2 of this dissertation.

Study Population

Descriptive analysis: The descriptive secondary analysis of respectful maternity care was conducted by using direct clinical observation of labor and delivery from the HBB evaluation. This data came from 40 health facilities from 27 out of the 28 districts in Malawi. Health workers were selected for observation based on availability at the time of data collection, willingness to be observed and status as a skilled birth attendant (doctor, medical assistant, clinical officer, registered midwife, enrolled nurse midwife or nurse midwife technician). Clinical observers were required to observe an average of five deliveries per day over 12 days in order to be able to make at least 50 observations of labor and delivery starting at the third stage of labor and five deliveries starting at the first stage of labor. Quota sampling was used to select up to five health workers in each facility who were interviewed about their training, supervision and experience providing labor and delivery services. Health worker background information collected through the health worker interview tool was not available for every health worker who was observed, but rather a subset of those health workers who were observed.

A total of 34 clinical observers were trained for one week on the use of a labor and delivery observation (L&D) checklist. They practiced using the L&D checklist until the inter-rater reliability

across all observers was at least 80% as per the Clinical Observer Training Guidelines developed by the Maternal Child Health Integrated Program (MCHIP). As part of the evaluation, there were 2,109 direct clinical observations of labor and delivery beginning at the third stage of labor. Of those 2,109 observations, 208 included data related to the first stage of labor. The remainder of the observations did not include data from the first stage of labor but rather, the observation started at the third stage of labor. Data on potentially harmful practices and on maternal and newborn outcomes was recorded for all observations. Information on the timing of the observation of the item is being presented because the respectful maternity care items are observed in different stages of labor or as part of the overall outcome of the observation. Therefore more data is available on items that occur in the third stage of labor or the outcome than in the first stage of labor. Nearly three quarters (71.3%) of the delivery observations were conducted in a hospital while the rest were made in health centers. Figure 25 shows the RMC items used in the analysis and the timing of the observation during labor and delivery.

Figure 25: RMC items and timing of observation during labor and delivery

Direct clinical observation item	Stage of labor
Non dignified care	
Did not respectfully greet pregnant woman	First
Shouted, insulted or threatened the woman during labor or after	Applies to all observations
Non consented care	
Manual exploration of uterus after delivery when unindicated	Applies to all observations
Used episiotomy (without indication)	Applies to all observations
Did not ask woman (and support person) if she has any questions	First
Did not ask client if there are any other problems the client is concerned about	First
Did not explain procedures to woman (support person) before proceeding	First
Did not inform the woman what will happen before conducting the vaginal examination	First
Did not inform pregnant woman of findings	First
Did not explains what will happen in labor to woman (support person) at least once	First
Did not explains procedures to woman (support person) before proceeding	First
Provider did not give at least one update on status and progress of labor	Third
Non confidential care	

Woman did not have audio and visual privacy	First
Provider did not drape woman (one drape under buttocks, one over abdomen)	First
Woman did not have her own bed	First
Provider did not use curtains or other visual barriers to protect woman during exams, births, procedures	First
Abandonment or denial of care	
Provider did not encourage the woman to have a support person present during labor and delivery	First
Provider did not encourage woman to consume fluids/food during labor at least once	First
Provider did not encourage or assist woman to ambulate and assume different positions during labor at least once	First
Provider did not ask woman which position she would like to deliver in	First
Support person or companion for mother was not present at birth	Third
If support person was not present at birth: Support person was restricted from being present	Third
Woman requested some pain relief for her pain but was not given anything	Third
Woman was not allowed to deliver in her preferred birthing position (if she had a preferred position)	Third
Mother and newborn were not kept in same room after delivery (rooming-in)	Third
Physical abuse	
Provider slapped, hit or pinched the woman during labor or after	Applies to all observations

Scale development: To develop the scale, cross-sectional data from a subset of the labor and delivery observations that included all stages of labor were used. The labor and delivery observations for scale development had to not only include data from all stages of the labor but also had to not have any missing data for the items selected for inclusion in the scale. This resulted in 173 (out of 208) complete observations of labor and delivery in this dataset that included data from the first stage of labor to immediate newborn care.

Questionnaire Development and Item Selection

The main data collection tool used to generate data for this analysis was an L&D observation checklist. This checklist adheres to the World Health Organization's guidelines on Managing Complications in Pregnancy and Childbirth and was adapted from the USAID-funded Prevention of Postpartum Hemorrhage Initiative (POPPHI) Project labor and delivery checklist (MCHIP, 2013). While

the checklist included some items reflecting interpersonal communication between the health provider and the patient, aspects of care related to the seven types of disrespect and abuse and the seven Rights of Childbearing Women that were absent in the original checklist were added. The selection of the additional items was based on a compendium of proposed indicators developed by the Maternal Child Health Integrated Program (MCHIP). These indicators were reviewed by members of the technical team at MCHIP who specialize in respectful maternity care and monitoring and evaluation as well as members of the Reproductive Health Department of Malawi's Ministry of Health.

Statistical methods

Descriptive Analysis: Descriptive analysis was performed using Stata statistical software (Version 13, College Station, Texas USA). Exploratory data analyses were conducted to examine the extent of missing data and distribution of the outcome and explanatory variables in the sample. Descriptive statistics including frequencies and proportions were calculated and used to produce tables and figures that describe health worker characteristics and overall performance. Bivariate analysis that accounted for clustering by health provider was conducted using logistic regression models (where the relationship between the odds of the observation of a RMC item was assessed against facility type (hospital or health center) and client-level factors—woman's age, parity, and HIV status) (Rogers, 1993). Age and parity were continuous variables and HIV status was coded as 0 if the woman was HIV negative and 1 if the woman was HIV positive (based on the woman's delivery record).

Scale Development: Scales are "[m]easurement instruments that are collections of items combined into a composite score, or intended to reveal levels of theoretical variables not readily observable by direct means…" and are developed to measure events or situations that cannot be directly assessed (De Vellis 2003). The measurement of respectful maternity care as a concept requires the use of latent variable analysis methods or qualitative data analysis approaches to observe different aspects of this concept. A scale was developed rather than an index because of the assumption of an association between the potential RMC items based on the Bowser and Hill framework. Also, scales measure a single underlying

concept whereas an index is used to measure more than one concept of items that are not necessarily correlated (Diamantopoulos & Winklhofer, 2001).

The categories of disprespect and abuse from the Bowser and Hill landscape analysis were used as a framework to select items to include in the scale. However, not all of the categories could be represented by direct clinical observations in the current analysis. For example, no direct clinical observations related to detention were included in the observation tool since health maternity services at public, government-run facilities in Malawi are free, so detention for failure to pay for services was unlikely. Also, detention was not assessed since data collection on the direct observation ended immediately after delivery so women were not observed during the duration of their stay in the facility. Discrimination was also not observed directly as there was little information about the client's background characteristics that could be collected via observation (as compared to an interview). There are other items that were intially included in the scale but were dropped because of the very low (or alternatively, very high) frequency of occurrence. For example, physical abuse was not observed in any of the 173 cases labor and delivery cases used for the development of this scale and nearly all pregnant women were informed of the findings of their exams. However, to the extent possible, the latent construct of respectful maternity care is represented through the factors from the RMC charter, which in turn is represented by direct clinical labor and delivery items that were used to explore RMC.

The Kaiser-Meyer-Olkin (KMO) test was conducted prior to conducting exploratory factor analysis (EFA) to determine whether EFA was the appropriate method to use for this analysis. The KMO compares the magnitudes of calculated correlation coefficients to the magnitudes of the partial correlation coefficient and is represented as follows:

$$KMO=\sum (\text{correlations})^2 / [\sum (\text{correlations})^2 + \sum (\text{partial correlations})^2]$$

If common factors are shared between items, then the expectation is that the partial correlation coefficients between pairs of items are small after removing the linear effects of other items (Pett, Lackey, & Sullivan, 2003). Therefore, a smaller value of KMO indicates that a factor analysis is not recommended for that particular set of items.

Bartlett's test of sphericity, which tests the null hypothesis that there is no relationship among the items in the correlation matrix, was then conducted to ensure that the sample size was adequate (Pett et al., 2003). The test is a chi-square test that takes the following form:

$$\chi^2 = - [(N-1) - ((2K +5)/6)] \log_e |R|$$

Where χ^2=calculated chi-square value for Bartlett's test
N=sample size
K=number of items or variables in the matrix
Log_e=natural logarithm
|R|=determination of the correlation matrix

Exploratory factor analysis was then conducted using Stata statistical software (Version 13, College Station, Texas USA) and confirmatory factor analysis was conducted using Mplus version 7.3 (Muthen & Muthen). According to Kim & Mueller (1978), "[f]actor analysis refers to a variety of statistical techniques whose common objective is to represent a set of variables in terms of a smaller number of hypothetical variables" (Kim & Mueller, 1978). For the purpose of developing a scale, exploratory factor analysis (EFA) was used to assess how the indicators grouped together and the relationship of those groupings with the dimensions of RMC as laid out by the latent variables in the rights of childbearing women charter. "A basic assumption of EFA is that within a collection of observed variables, there exists a set of underlying factors, smaller in number than the observed variables, that can explain the interrelationships among those variables" (Pett et al., 2003).

Because the observations were coded as dichotomous responses, tetrachoric correlations were used to compute the factors loadings followed by varimax (orthogonal) rotation procedures to obtain rotated factor loadings. The tetrachoric correlation coefficient is used as an estimate of the correlation of an underlying bivariate normal distribution (M. Brown & Benedetti, 1977). Rotation of the factors is the process of turning the reference axes about their origin to obtain a meaningful factor solution (Pett et al., 2003). The extraction of components was based on eigenvalues, which are direct indices of how much total item variation is accounted for by a particular component (Pett et al., 2003).

Assessment of validity, reliability and model fit

Criterion validity is the correlation of a scale with another measure of the trait under study. Because the lack of a 'gold standard' measure of respectful maternity care is the main reason for developing this scale, it was not possible to test its criterion validity against a gold standard due to the lack of relevant criterion variables. As a result, the assessment of external validity relied on an examination of the construct validity of the factor solution. Construct validity was assessed through confirmatory factor analysis to confirm the factor structure after necessary changes were made to the model after EFA. Confirmatory factor analysis (CFA) assesses the degree to which the plausibility (or fit) of a factor solution is empirically confirmed (Kim & Mueller, 1978). The use of the "exploratory-confirmatory" approach was proposed by Jöreskog in 1978 and suggests that EFA can be used first to decide on the number of factors (*m*) in a model and that the subsequent *m*-factor model should be fit again as a confirmatory factor model after finding the largest loadings and constraining all of the other loadings in that row to be zero. Non-significant loadings are then deleted from the model (Jöreskog, 1978).

The reliability (internal consistency) of the scale was evaluated by calculating the inter-item consistency among the items using the Kuder-Richardson 20 formula rather than Cronbach's alpha since the observations were dichotomous, as follows:

$$\boldsymbol{\rho}_{\mathbf{KR20}} = [k / (k+1)](1 - (\Sigma^{k}_{j=1}\ p_j q_j)/\sigma^2)$$

where

k = number of questions

p_j = number of people in the sample who performed the step

q_j = number of people in the sample who did not perform the step

σ^2 = variance of the total scores of all the who were observed

KR-20 alpha ranges between 0 and 1 and was calculated for each of the factors rather than for the entire scale because alpha is being used to confirm whether the items in each factor are actually unidimensional. Acceptable values of KR-20 alpha range from .70 to .95, where the number of test items, item interrelatedness and dimensionality affect this value. Descriptive model fit statistics such as the root

mean square error of approximation (RMSEA) are currently unavailable for categorical data through Mplus or Stata.

Results

Descriptive Analysis of RMC items for all labor and delivery observations

The median age and parity of the observed women and the proportion of observed women who were HIV positive are presented in Table 15. The frequency of the lack of provision of the selected respectful maternity care items is shown in Table 16. The availability of data on the RMC items varied if the item was observed during first stage of labor (as compared to second or third stage only). The overall frequency that an item did not occur ranged from .09% (for manual exploration of the uterus after delivery when unindicated) to 93.7% (for the health provider not asking the woman in which position she wanted to deliver).

Under non-dignified care, women were generally greeted respectfully (86.1%) and most women (98.1%) were not shouted at, insulted, or threatened during labor or after. Non-consented care, including unindicated manual exploration of the uterus after delivery and episiotomy were rarely performed (.09% and .50%, respectively). However, women were not encouraged to have a support person, were not asked if they had any questions, and were not asked if they had any other problems they were concerned about on a much more frequent basis (83.2%, 73.1% and 73.9%, respectively). Under non-confidential care, more than half of women (58.2%) did not have audio and visual privacy. Under abandonment/denial of care, one of third of women (33.7%) observed were not encouraged by the provider to consume fluids/food during labor at least once and most women were not asked about the position in which they wanted to delivery (93.7%). Less than one percent (.20%) of women were slapped, hit or pinched by the provider during labor or after.

Table 16: Characteristics of observed women observed during labor and delivery in 40 health facilities in Malawi in 2013

Characteristics of observed women (n=2109)	
Median age in years (Interquartile range)	23 (IQR: 9)
Median parity (Interquartile range)	1.0 (IQR: 3)

Proportion of women who were HIV positive (%, n)	6.5% (111)*

*Denominator=1,718

Table 17: Descriptive RMC results for all L&D observations from 40 health facilities in Malawi in 2013

Direct clinical observation item	# of obs	# of occurrences	Frequency of occurrence
Non dignified care			
Did not respectfully greet pregnant woman*	208	29	13.9%
Shouted, insulted or threatened the woman during labor or after***	2109	41	1.90%
Non consented care			
Manual exploration of uterus after delivery when unindicated***	2109	2	0.09%
Used episiotomy (without indication) ***	208	1	0.50%
Did not ask woman (and support person) if she has any questions*	208	152	73.1%
Did not ask client if there are any other problems the client is concerned about*	203	150	73.9%
Did not explain procedures to woman (support person) before proceeding*	205	35	17.1%
Did not inform the woman what will happen before conducting the vaginal examination*	205	42	20.5%
Did not inform pregnant woman of findings*	200	20	10.0%
Did not explain what will happen in labor to woman (support person) at least once*	208	43	20.7%
Did not explain procedures to woman (support person) before proceeding*	208	32	15.4%
Provider did not give at least one update on status and progress of labor**	2052	249	12.1%
Non confidential care			
Woman did not have audio and visual privacy during initial client assessment*	208	121	58.2%
Provider did not drape woman (one drape under buttocks, one over abdomen) *	208	152	73.1%
Woman did not have her own bed*	208	5	2.40%
Provider did not use curtains or other visual barriers to protect woman during exams, births, procedures*	206	54	26.2%
Abandonment or denial of care			
Did not encourage the woman to have a support person present during labor and delivery*	208	173	83.2%

Provider did not encourage woman to consume fluids/food during labor at least once*	208	70	33.7%
Provider did not encourages or assist woman to ambulate and assume different positions during labor at least once*	208	58	27.9%
Provider did not ask woman which position she would like to deliver in*	207	194	93.7%
Support person or companion for mother was not present at birth**	2071	1818	87.8%
If support person was not present at birth: Support person was restricted from being present**	1818	210	11.6%
Woman requested some pain relief for her pain but was not given anything**	118	66	55.9%
Woman was not allowed to deliver in her preferred birthing position (if she had a preferred position) **	273	36	13.2%
Mother and newborn were not kept in same room after delivery (rooming-in) **	1722	213	12.4%
Physical abuse			
Provider slapped, hit or pinched the woman during labor or after***	2109	4	0.20%

*applies to first stage of labor; **applies to third stage of labor; ***applies to all observations

Relationship between RMC items, facility type and client background characteristics

The results of the bivariate analysis presented in Table 17 do not show an overarching pattern in the treatment of women based on whether or not they delivered in a hospital or health center. For example, the odds of a health provider shouting at a woman were 81% lower in health centers when compared to hospitals (OR: 0.19; CI: 0.59-0.62) but the odds of a health provider not asking the woman if there are other problems she is concerned about during the initial client assessment were 2.4 times higher in a health center when compared to a hospital (OR: 2.40; CI: 1.06-5.40). The odds of not having a support person present was 2.6 times higher in health centers (OR: 2.61, CI: 1.82-3.73) and the likelihood of a support person being restricted from being present was higher in health centers than in hospitals (OR: 1.62, CI: 1.21-2.19).

The bivariate analysis between age of the woman and RMC items showed even fewer associations; the only statistically significant difference seen was between age and whether the woman had her own bed, where the odds of not having her own bed was 15% lower as the age of the woman increased (OR: .85, CI: 0.79-0.92). There was also an association between the presence of a support person and parity, where there was a 26% higher odds of not having a support person present as the

woman's parity increased (OR: 1.26, CI: 1.13-1.41). For the prevalence of RMC items and HIV status, women who were HIV+ had significantly lower odds of not having audio and visual privacy (OR: 0.34, CI: 0.12-0.97) and of not being asked about her preferred delivery position (OR: 0.17, CI: 0.05-0.65).

Table 18: Results of bivariate analysis of RMC items with facility type and client's age, parity and HIV status

	Unadjusted Odds Ratio							
RMC Item	Facility type[a]	p-value	Age	p-value	Parity	p-value	HIV status[b]	p-value
Non Dignified Care								
Does not respectfully greet woman	2.14	0.10	1.01	0.72	0.94	0.61	1.21	0.79
Shout, insult or threaten the woman during labor or after	0.19	**0.006**	0.99	0.55	0.91	0.36	1.46	0.53
Non-consented care								
Does not ask woman (and support person) if she has any questions	0.51	0.12	0.99	0.80	0.94	0.61	0.81	0.68
Does not ask client if there are any other problems the client is concerned about	2.40	**0.036**	0.98	0.42	1.11	0.26	0.38	**0.04**
Does not explain procedures to woman (support person) before proceeding	1.29	0.52	0.99	0.90	1.02	0.81	0.99	0.90
Does not inform the woman what will happen before conducting the vaginal exam	0.85	0.79	0.96	0.19	1.01	0.91	0.74	0.64
Does not inform pregnant woman of findings	1.15	0.81	1.00	0.99	1.04	0.79	0.46	0.46
Does not explain what will happen in labor to woman (support person) at least once	1.41	0.52	0.96	0.22	0.85	0.09	1.05	0.93
Does not explain procedures to woman (support person) before proceeding	1.15	0.83	0.97	0.34	0.87	0.15	0.62	0.56
Provider does not give at least one update on status and progress of labor	0.64	**0.006**	1.01	0.18	0.95	0.24	1.26	0.43
Non-confidential care								
Woman does not have audio and visual privacy (during initial client assessment)	0.91	0.80	1.00	0.98	1.10	0.36	0.34	0.06
Provider does not drape woman (one drape under buttocks, one over abdomen)	0.98	0.96	0.99	0.66	0.95	0.60	1.13	0.84
Woman does not have her own bed	0.50	0.56	0.85	**<0.001**	0.64	0.24	n/a[c]	n/a
Provider does not use curtains or other visual barriers to protect woman during exams, births, procedures	2.99	**0.020**	1.00	0.88	1.04	0.60	0.38	0.23
Abandonment or denial of care								
Does not encourage the woman to have a support person present during labor and delivery	1.43	0.52	1.00	0.99	1.00	0.98	0.64	0.50
Does not encourage woman to consume fluids/food during labor at least once	0.24	**0.001**	1.00	0.86	0.92	0.40	1.59	0.40
Does not encourage or assist woman to ambulate and assume different positions during labor at least once	0.24	**0.004**	1.03	0.23	1.01	0.89	0.65	0.54
Provider does not ask woman which position she would like to deliver in	2.54	0.28	0.98	0.71	0.91	0.66	0.17	**0.010**

Support person or companion for mother is not present at birth	2.61	**0.001**	1.02	0.11	1.26	**<0.001**	2.00	0.06
If support person was not present at birth: Support person was restricted from being present	1.62	0.18	1.00	0.69	0.94	0.20	0.56	0.16
Woman requested some pain relief for her pain but was not given anything	0.29	0.24	0.96	0.16	0.81	0.06	n/a[c]	n/a
Woman was not allowed to deliver in her preferred birthing position (if she had a preferred position)	0.53	0.26	1.03	0.07	1.06	0.56	0.77	0.68
Mother and newborn were not kept in same room after delivery (rooming-in)	1.44	0.16	0.98	0.12	0.96	0.32	0.89	0.70

[a]Facility type coded 0 for hospital and 1 for health center

[b] HIV status coded 0 for HIV- and 1 for HIV+

[c] n/a: The number of HIV positive women in the subset of data who requested pain relief and did not have their own beds was not computed due to few observations in cell for these two RMC items.

Given that the bivariate results showed that there was a relationship between the presence of a support person and type of facility the woman delivered in, the age of the woman and her parity, a multiple logistic regression model was used to examine the association between all of these predictors. After adjusting for facility type, age, parity and HIV status, the odds of having a support person restricted from being present was 2.10 times higher among health centers compared with hospitals (OR: 2.10, CI: 1.19-3.71) ; 3% lower as the client's age increased (OR: 0.97, CI: .949-.995); and was 36% higher as the woman's parity increased (OR: 1.36, CI: 1.19-1.55). (Table 18).

Table 19: Unadjusted and adjusted odds ratio for restriction of support person by selected client background characteristics

	Support person was restricted from being present					
	Unadjusted odds ratio			Adjusted odds ratio		
	OR	p-value	CI	OR	p-value	CI
Facility	2.61	**.001**	(1.51, 4.51)	2.10	**.010**	(1.19, 3.71)
Age	1.02	0.11	(.995, 1.05)	0.97	**0.015**	(.949, .995)
Parity	1.26	**<.001**	(1.13,1.41)	1.36	.158	(1.19, 1.55)
HIV status	2.00	0.06	(.979, 4.10)	1.69	0.16	(.816, 3.48)

*Facility type coded 0 for hospital and 1 for health center

** HIV status coded 0 for HIV- and 1 for HIV+

Descriptive analysis of RMC for labor and delivery items included in observations used for scale development

Table 20 shows the results from only the labor and delivery items that were used to generate the scale and includes all items originally proposed for inclusion. There were no significant differences

between the entire set of L&D observations and the subset used to develop the scale. Most women (more than 80%) in this subset of observations were respectfully greeted; had procedures explained to them; were informed what would happen before the provider conducted a vaginal examination; were informed of findings; and were given an update on the status of labor. Almost all women (98.3%) did not have to share a bed during labor and delivery and 88.4% were kept in the same room as their newborn immediately after delivery. Conversely, only 18.5% of women were encouraged to have a support person with them during labor and birth and less than 10% of women were asked the position in which they would like to give birth. Only 7% of women requested pain relief so whether or not she was given pain relief when requested could not be adequately assessed. Audio and visual privacy were relatively low at 39.4% and only one quarter of women (25.4%) were draped during delivery. There were no significant differences between the entire set of L&D observations and the subset used to develop the scale.

Table 20: Proportion of direct clinical observations in which the item was not done

Direct Clinical Observation (n=173 observations)	No	%
Respectfully greets the pregnant woman	22	12.7
Encourages the women to have a support person present during labor and birth	141	81.5
Asks women (and support person) if she has any questions	126	72.8
Asks client if there are any other problems the client is concerned about	127	73.4
Explains procedures to woman (support person) before proceeding	30	17.3
Informs the woman what will happen before conducting the vaginal examination	34	19.7
Informs pregnant woman of findings	19	11.0
At least once, explains what will happen in labor to woman (support person)	37	21.4
Explains procedures to woman (support person) before proceeding	27	15.6
Observer: Is a support person (companion) for mother present at birth?	149	86.1
Provider gives at least one update on status and progress of labor	23	13.3
Woman has audio and visual privacy	104	60.1

Drapes woman (one drape under buttocks, one over abdomen)	129	74.6
Woman has her own bed	3	1.7
Provider uses curtains or other visual barriers to protect woman during exams, births, procedures	47	27.2
At least once, encourages woman to consume fluids/food during labor	62	35.8
At least once, encourages/assists woman to ambulate and assume different positions during labor	52	30.1
Provider asks woman which position she would like to deliver in	162	96.4
Mother and newborn kept in same room after delivery (rooming-in)	20	11.6

Factor Analysis

The Kaiser-Meyer-Olkin (KMO) measure of sampling adequacy was calculated to be .69, which is slightly above the recommended value of .6 and the Bartlett's test of sphericity was significant (χ^2 (78) = 374.72, $p < .000$) so EFA was conducted using these variables (Table 21). The results of the factor analysis are presented in Table 20. Initially, the number of factors to be retained was based on the Kaiser-Guttman rule which suggestions that factors with eigenvalues >1 are selected, meaning that these factors account for more than their share of total variance in the items (Pett et al., 2003). However, there is broad consensus that this method is among the least accurate to select the number of factors to retain and can result in overextraction or underextraction (Costello & Osborne, 2005). Therefore, a scree plot, or a graph of eigenvalues, was used to identify 2 factors and 7 items that had been extracted using the principal component factor (PCF) extraction method. The items within the factors were retained after assessing communalities and the uniqueness of factor loadings (where loadings were >.3), and where factor loadings represent the correlation of the items on the factor and the communality of an observed variable is the square of the factor loadings for that variable (Pett et al., 2003). Items with cross-loadings greater than .32, which equates to approximately 10% of overlapping variance with the other items in the factor, were excluded (Costello & Osborne, 2005).

Five items loaded onto Factor 1. All of these five factors related to the communication of the health provider with the client at different stages of labor and delivery. This factor was labeled "Provider-

client communication." Two items loaded onto Factor 2 (encouraging the woman to consume fluids/food during labor and encouraging the woman to ambulate and assume different positions during labor). This factor was labeled, "Provider encouragement during the first stage of labor."

Table 21: Factor loadings and communalities based on a principle components factor extraction and varimax rotation for the scale items (n =173 observations)

Items	Timing of observation	Factor loading		Communality
Factor		**1**	**2**	
Asks woman (and support person) if she has any questions	Initial client assessment	.842		.813
Explains procedures to woman (support person) before proceeding	Initial client assessment	.835		.833
Informs woman what will happen before conducting the vaginal exam	Initial client assessment	.834		.834
At least once, explains what will happen in labor to the woman (support person)	First stage of labor	.818		.805
Provider gives at least one update on status and progress of labor	Second/third stage of labor	.737		.631
At least once, encourages woman to consume fluids/food during labor	First stage of labor		.758	.736
At least once, encourages/assists woman to ambulate and assume different positions during labor	First stage of labor		.766	.747

Assessment of validity, reliability and model fit

The CFA results are presented in Table 22. The KR-20 alpha for Factor 1 was .735 and was .61 for Factor 2, suggesting that the reliability for Factor 1 was acceptable but was less acceptable for Factor 2. Factor 2, however, only includes two items. The chi-square test of model fit was found to be non-significant (p=.9192, df=112), suggesting that the model fit the data adequately since the null hypothesis is that there is no difference between the patterns observed in the data and the model specified. The p-values for the items included in the model indicate that that all non-zero factor loadings of items are significant.

Table 22: CFA: Standardized Model Results

Items	Estimate	S.E.	p-value
Factor 1			
Asks woman (and support person) if she has any questions	0.531	0.120	0.000
Explains procedures to woman (support person) before proceeding	0.857	0.060	0.000
Informs woman what will happen before conducting the vaginal exam	0.977	0.030	0.000
At least once, explains what will happen in labor to the woman (support person)	0.753	0.080	0.000
Provider gives at least one update on status and progress of labor	0.679	0.099	0.000
Factor 2			
At least once, encourages woman to consume fluids/food during labor	0.719	0.128	0.000
At least once, encourages/assists woman to ambulate and assume different positions during labor	0.859	0.135	0.000

Discussion

Descriptive Results of RMC in Malawi

The effects of poor interpersonal communication between health providers and patients on maternal care-seeking practices have been shown in numerous qualitative studies among women in women in low income countries. The goals of this analysis were to provide an estimate of the prevalence of disrespect and abuse during childbirth in Malawi through the secondary analysis of labor and delivery observations, to assess the association of client-level characteristics on the provision of respectful maternity care items, and to develop and validate a scale that can potentially be used to routinely assess the provision of respectful maternity care using direct clinical observations of labor and delivery. More specifically, the hypothesized dimensions were based on observable dimensions of the Bowser and Hill

(2010) landscape analysis of respectful maternity care, including physical abuse, non-consented care, and non-dignified care.

According to the Malawi DHS 2010, 95% of pregnant women in the country receive antenatal care from a skilled attendant but only 71% deliver with a skilled birth attendant, indicating that they may have access to skilled attendants but may choose to avoid delivering in a facility unless they are satisfied with the care that they receive (Kumbani et al., 2013; National Statistical Office & Macro, 2011). A qualitative study in rural Malawi found that staff in the labor and delivery wards did not communicate with patients and kept women waiting for their examinations. This study also cited findings from the Malawi Obstetric Quality of Care assessment which found that one of the major constraints to accessing maternal health services was rudeness of health workers (Seljeskog et al., 2006). In the present analysis of L&D observations, the waiting time for the client to initially receive care was not recorded but communication between the provider and the client was observed. Communication was found to be high in some aspects (e.g. informing the woman of findings from exams) but less so in other aspects (e.g. asking the woman if she has any questions). However, the majority of clients were greeted respectfully. The finding of deficiencies in the quality of interpersonal communication from the health worker to the patient is not surprising, as problems with communication between health workers and patients have previously been reported in the media in Malawi (Madula, 2013).

Regardless of the reason why health worker attitudes are negative, the result may deter women from seeking care in health facilities if they fear being treated poorly. Another study in three districts in Malawi reported that health workers created barriers to care-seeking by being unwilling to assist pregnant women, beating women in labor, acting rudely, performing operations when drunk, using abusive language, discriminating against poor women, delaying treatment and not providing privacy (Bowie & Geubbels, 2013). Discrimination against women was difficult to observe through direct clinical observations in the present analysis but the results of the bivariate analysis showed that there was no systematic difference in the provision of the items based on the woman's HIV status, parity and age. The findings related to treatment of women with HIV are similar to that found by Sando et al. (2014), where

they assessed self-reported disrespect and abuse during childbirth in Tanzania and found no reported differences in the prevalence between HIV positive and HIV negative women (Sando et al., 2014).

Women in the present analysis were not generally given a choice of birthing position, but this could potentially be because health providers may not have been comfortable assisting women in positions other than the orthodox supine position. In Tanzania, it was found that labor position was not a crucial factor in deciding where women chose to deliver (Magoma, Requejo, Campbell, Cousens, & Filippi, 2010) so while these findings are important, it may not be the ultimate deterrent of facility-based births.

A recently published qualitative study in Malawi by Kumbani et al. (2013) found that the major concern for recently delivered women in that study was poor staff attitudes. Women reported that health workers shouted at them and even threatened to beat them if they created problems during delivery. Other participants reported meeting rude health workers that treated them harshly during labor and delivery. "Participants stated that they wanted to be treated like human beings, with respect and not shouted at when they go to health facilities. When women go to a health facility they are in pain and health workers should not shout or ignore them." The women in this study perceived poor care when they were shouted at, there were delays in receiving care, or they were not informed of findings. They did not complain about the technical quality of care (Kumbani et al., 2013). However, the results from the present study using labor and delivery observations showed that most women were informed of findings, and that shouting and threatening or physically abusing women during labor or after did not occur frequently. Lack of privacy was an issue in this study and another study in Malawi also found that privacy was difficult to achieve, that some beds did not have curtains and that many people had access to the ward (Seljeskog et al., 2006). This is an important result because in Malawi, being respected, respectfully greeted, informed of findings, and having confidentiality and privacy are associated with good quality of care (Kumbani et al., 2013).

Scale Development

Using psychometric analysis methods, a scale consisting of a two-factor model with 7 direct clinical observations items was produced. Although the conceptual model that was used to select and develop items to include in the observation tool was based on the Bowser and Hill (2010) landscape analysis that consisted of seven framework components, this analysis using direct clinical observations resulted in the selection of two main factors that could be directly observed and that both relate to communication between the health provider and the clients and provider encouragement during the first stage of labor, which seems reasonable given that the frequency of occurrence of some events (e.g. beating of the woman in labor and unindicated practices) was low. The results of the factor analysis suggested that the direct clinical observations did not discriminate between the specific framework components that were laid out by Bowser and Hill and that were used as the conceptual framework for selecting the direct clinical observations.

Although the scale is short with only 7 items categorized into two factors, it reflects a multidimensional view of a key aspect of respectful maternity care. The scale demonstrated good psychometric properties and can provide a more objective measure of respectful maternity care through direct clinical observations than self-report for those specific factors. The items in the scale relate to the initial stages of labor and delivery and could indicate that direct clinical observations are able to measure the client-provider interaction at that time period better than in later stages of delivery.

This is the first scale developed using direct clinical observations based on sample of labor and delivery cases across Malawi. While Kruk et al. (2014) measured the frequency of reported abusive experiences in Tanzania, they did so using a client exit interview and re-interview of a subset of clients (Kruk et al., 2014). Okafor (2015) used a survey to assess disrespect and abuse among women delivering in one teaching hospital in Nigeria (Okafor et al., 2015). Given the high maternal mortality in other countries in Sub-Saharan Africa, there is great interest in ensuring that pregnant women seek facility-based maternity care and are treated appropriately when using those facilities so the availability of

additional quantitative measurement methods that can be routinely used to measure the provision of respectful maternity care is an important gap that needs to be filled.

The routine use of non-qualitative data collection methods to generate data that can be used assess the provision of RMC may be one way to remove obstacles to facility-based care seeking. The RMC L&D Observation scale presented in this paper may be integrated into existing quality of care surveys and quality improvement tools, and could potentially be used with more frequency than employing qualitative data collection methods. The existence of a scale will allow for the monitoring of changes in provider practices over time and the data can be useful by curriculum specialists (for both pre-service and in-service training) to focus on areas in which there deficiencies related to provider interaction with patients. The scale can also be used by supervisors of individual health providers as well as district level supervisors to assess the provision of RMC within specific facilities.

Limitations

Because of limitations in what can be directly observed, observations reflecting the entire Bowser and Hill Rights of Childbearing Women framework could not be included in the direct clinical observation tool. For example, in this study population of government-run health facilities in which services are offered for free, women may not be detained as frequently as compared with private facilities that require payments. The clinical observer would need to follow the client's care until the time of possible discharge but in this secondary dataset, the clinical observation ended after immediate newborn care so it is not possible to know how the client was treated after the labor and delivery observation ended. Discrimination is also a challenging concept to observe unless the health workers provide verbal cues.

Regarding the data itself, the selection of health workers and labor and delivery cases to observe was a non-probability sample. As was previously mentioned, data related to disrespect and abuse during labor and delivery has generally been collected through qualitative data collection methods. Self-reported data where the patient herself can assess whether she was treated well or not also has its limitations so one

of the reasons for developing a scale to assess RMC through direct clinical observations is to attempt to obtain objective information about whether an item occurred or did not occur. However, this type of data collection method excludes the client and health provider from the process. Information about the client's expectations of the health worker during labor and delivery (and vice versa) in Malawi was not included in the direct clinical observation tool. Rather, the direct clinical observations were based on a framework that was not specific to a particular country but represents a universal approach to human rights during childbirth. Also, while negative associations between the quality of health worker-patient communication and patient literacy and socioeconomic status have been documented, this information was not available in this study (Willems, De Maesschalck, Deveugele, Derese, & De Maeseneer, 2005)

The Hawthorne effect may also be a factor in observing health worker performance, especially related to disrespect and abuse. The method of direct clinical observations could influence the health worker's performance (either negatively or positively). This data was also collected in government-run health facilities so information was not available on whether the treatment by private health providers or traditional birth attendants differed from these government health providers. It is also quite possible that certain items that were more overt under observation (e.g. physical and verbal abuse) were subject to a higher level of the Hawthorne effect, but this was not measured. This has implications for which respectful maternity care items can be included as part of an observation tool vs. which items should be reported on through a client interview.

Regarding the analysis, the small sample size did not allow for further testing of reliability through the split-halves method. The observations were dichotomous, which limited the variability that could be seen in responses. Test-retest reliability could not be assessed, as the labor and delivery observation could only occur once. Also, model-fit statistics are not as readily available for scales using dichotomous indicators so RMSEA could not be calculated.

The scale also cannot provide information on how or why providers communicated or encouraged their clients during labor and delivery (reflected by the items in the scale), but can only quantify whether the specific item was done or not done. Further analysis should be done to understand how many

observations need to be made to provide a true indication of the health provider's communication skills with clients. Health worker data was limited so it was not possible to assess the association between the characteristics of the health worker and their communication with clients. Further analysis should be done to understand the possible facilitators and barriers of a positive relationship.

Conclusions

Although labor and delivery guidelines in Malawi include guidance about mother friendly care, the results from this analysis of labor and delivery observations showed that women are exposed to disrespect and abuse during birth. This suggests that there is further need for more detailed research on the prevalence of disrespect and abuse during delivery—especially including items that may not be directly observable, as well as methods that can be used to measure this concept. For items that cannot be directly observed, other more appropriate data collection methods can be used and this data can be used with observation data. With regards to the scale, exploratory factor analysis should be conducted again to ensure that the same factor solution is found in subsequent data sets in different settings and then this should be followed up with confirmatory factor analysis (Pett et al., 2003). After further validation and testing in other settings, this two-factor scale may serve as a diagnostic tool to measure respectful maternity care at the overall level (using both measures and all items); at the factor level; and at the individual item level. Assessing performance by analyzing data at these different levels will allow for an overall evaluation of the frequency of provision of respectful maternity care through direct clinical observations to identify problems areas and to concentrate resources on improving the provision of those particular non-clinical aspects of labor and delivery care.

Chapter 6: Conclusions

Summary of Findings

The measurement of the quality of essential newborn care and of respectful maternity care are critical for ensuring that populations accessing labor and delivery services in Malawi are receiving appropriate services that are provided according to evidence-based standards. The information presented in this dissertation contributes to the knowledge base of methods to routinely measure the quality of facility-based maternal and newborn care in Malawi and beyond. It also provides valuable information about the quality of maternal health and essential newborn care services and the experience of care during labor and delivery across Malawi.

The first section of this dissertation showed that simulations of essential newborn care using an anatomic model are a valid measure of data collected through direct clinical observations for most of the immediate newborn care steps (except for hand washing). The assessment of health worker performance during labor, delivery and essential newborn care using direct clinical observations is resource-intensive and cannot be done on a regular basis in most settings. Clinical simulations were found to be a generally sensitive and predictive indicator of a health worker's performance on actual patients compared to observations, suggesting that this data collection method can be used with more frequency during periodic supportive supervision visits rather than being done only during full-scale evaluations. This is especially important in low-income settings where resources for evaluations are already limited. To my knowledge, analyses comparing these specific data collection methods have not been published in the literature to date. The validation of self-report of adherence to obstetric clinical guidelines also showed that directly asking a health worker about his or her use of a partograph is not a sensitive measure of actual observed use, suggesting that this method should not be used to assess the performance of this particular process.

The second part of the dissertation provided information about health worker variability in the application of essential newborn care practices by assessing within health worker variations in the provision of care, in the provision of consistently high levels of care, and of overall quality of care. There

are limited results available in the literature that include consistency of performance as part of quality of clinical care assessments. However, consistent application of evidence-based practices is crucial in cases where no variability should exist, indicating that the calculation of variability is an important indicator in measuring the process quality of care. The results showed that consistent health worker performance of essential newborn care was generally fair but given that these essential newborn care practices should have been carried out on all newborn observed, the results are a cause for concern. Also, disregarding individual health worker-level performance, the provision of essential newborn care practices was unsurprisingly low for hand hygiene but was nearly universal for drying the newborn. No associations were found between health worker characteristics and performance, but further investigation should be done.

And finally, the third part of this dissertation--the quantification of respectful maternity care provides information about disrespect and abuse during labor and delivery in public health facilities in Malawi. The results showed that overall, women were generally greeted respectfully and were informed of procedures, but women were not encouraged to ask questions, were not given privacy, and were not encouraged to have a support person with them. The Ministry of Health of Malawi has been proactive in addressing issues of disrespect and abuse during labor and delivery by incorporating the Seven Rights of Childbearing Women into the Malawi National Reproductive Health Service Delivery Guidelines, presented in Annex G (2014-2019) (Malawi Ministry of Health, 2014). The data analyzed as part of this dissertation were collected in 2013, so it will be interesting to see whether the inclusion of the categories of disrespect and abuse as well as the impact of disrespectful maternity care on safe motherhood will affect the receipt of respect care by pregnant women in the future.

The development of scale using a limited set of direct clinical observations to measure the provision of respectful maternity care will be useful for stakeholders to identify areas for more focused interventions during pre-service and in-service maternal and newborn health (MNH) trainings and to also identify areas in the health system that need to be strengthened to create an enabling environment for the provision of RMC. The scale could also be used more frequently by supervisors at both the facility and

district levels in Malawi for routine assessments. The scale development method should also be applied and tested in other settings. The importance of providing respectful maternity care is gaining more attention but the quantification of this latent construct is not available, so the development of a scale is just a first step in thinking about how to effectively measure a complicated, multifaceted issue.

Implications for policies and programs

As we move from the MDGs to the Sustainable Development Goals (SDGs), some of the MDG indicators have been carried over while additional indicators have been added to monitor progress. Evidence suggests that skilled birth attendance (in which a health provider has the minimum knowledge and skills to manage normal childbirth and provide basic emergency obstetric care) could eliminate between 13% to 33% of maternal deaths, so it follows that one of the key MDG indicators (and now and SDG indicator) is the percentage of births attended by skilled health personnel (Carlough & McCall, 2005; Sustainable Development Solutions Network (SDSN), 2015). In settings like Malawi, where a high proportion of women seek labor and delivery care in health facilities, the maternal mortality ratio is 675 deaths per 100,000 live births and the and newborn mortality rates is 31 deaths per 1,000 births—numbers that are unacceptably high when compared to higher income settings (National Statistical Office & Macro, 2011). These numbers suggest that the programmatic focus should shift from addressing barriers to care-seeking, increasing facility delivery rates, and increasing the coverage of skilled birth attendance to focusing on the quality of services that a woman and her newborn in a health facility. The results of this dissertation show that we need to routinely look beyond coverage indicators that do not provide information about the quality of services offered but are often used because they are relatively easy to collect on a regular basis. Having additional feasible and valid measurement methods that can be used on a more frequent basis and using limited resources will provide policymakers with data needed to develop strategies to address the fact that high coverage of services does necessarily correspond with lower morbidity and mortality.

If we consider health worker performance of essential newborn care as an indicator of process quality, wherein essential newborn care guidelines--which apply to all uncomplicated births--are not always followed, it seems fair to conjecture that heath workers may not be strictly adhering to more complicated guidelines. This is a troubling finding, given that 70% of maternal and 85% of newborn deaths are a result of complications for which evidence based management guidelines exist (Tunçalp et al., 2015). These results indicate that there are deficiencies in the health system but the main underlying causes of these deficiencies need further exploration so that appropriate interventions can be designed.

Recommendations for the applications of findings and further research

Given the findings of the validation analyses, simulation of essential newborn care with an anatomic model can be incorporated into health worker supervision tools. Further validation work should be done on the use of adult simulators (e.g. the MamaNatalie birthing simulator) to assess performance of the management of other health complications, including postpartum hemorrhage.

Related to the performance quality of essential newborn care, further work should be done to understand and improve consistent compliance with clinical guidelines—especially with handwashing procedures. Analysis of direct clinical observations showed that hand hygiene was poor, even in cases when health workers had access to soap, water and antiseptic cleansers. This indicates that we need to look deeper to understand why health workers did not follow guidelines, even when the necessary supplies were available. Depending on the underlying causes of poor compliance, targeted educational interventions, more frequent/high quality supervision, or even the use of periodic SMS reminders could be potential strategies. Patient empowerment in demanding better hand hygiene could also be a driver of change. Although the adherence to the remaining essential newborn care steps was higher, further evidence that considers personal factors, health facility factors and policy level factors must be collected to understand why health workers did not always comply with the guidelines in this setting.

With regards to respectful maternity care, the analysis presented in Paper 3 is an initial account of both the development of a scale and of measurement of the prevalence of disrespect and abuse during

facility-based births in Malawi. Further attention to this topic is required. The limitations in the use of direct observations to measure respectful maternity care were noted in Paper 3 but the RMC DCO scale can be used in conjunction with other measurement methods (e.g. self-report for some of the RMC indicators). Discrimination and detention were not measured through DCOs so further work needs to be done to develop and validate methods to assess these aspects of the Rights of Childbearing Women.

Conclusion

Ultimately, a woman delivering in a health facility in rural Malawi should have the same right to effective clinical care and respect as a woman delivering at Johns Hopkins Hospital, and her newborn has the right to the same basic care. The findings of this dissertation are a contribution to moving towards that goal by presenting evidence on the utility of different measurement methods when the quality of maternal and newborn care must be assessed routinely but programs face resource constraints. The findings also provide information on the current quality of care that can be used by policymakers and implementers to focus their improvement efforts.

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Annexes

Annex A: Respectful Maternity Care Poster from the White Ribbon Alliance

Annex B: Table of measurement methods, research questions, tools and strengths and weaknesses of the methods

Measure	Question	Tool	Strengths	Weaknesses
Structure	Does the health facility have the necessary equipment to perform essential newborn care?	Facility audit	Easy to define and measure	May depend on time of data collection and validation with facility equipment records may not be possible
Structure	Does the health facility have enough trained staff available to handle the patient load?	Human resources assessment (through facility audit)		
Process	Does the health worker follow specific clinical guidelines?	Direct clinical observation tool (DCO)	Can be used when medical records are poor or not available Can be used when HMIS systems are weak Clinician is providing services in familiar environment	Need to ensure standardization of data collectors to avoid data collector disagreement about if process was conducted satisfactorily Limits to human resources availability and qualifications for data collection (e.g. nurses, etc.) Possible Hawthorne effect (change in behavior due to being observed) May Have to take into account case-mix when comparing across providers and/or facilities
Process	Does the provider know	Clinical vignettes/case	Could take less time to collect data	Performance in a controlled

	what to do and how to provide care when faced with a case study?	scenarios	because data collector is not waiting for a particular real-life scenario to emerge	environment may not truly reflect performance under real-life circumstances Some providers may be observed longer than others
Process		Patient Records	Can use existing data	May have incomplete data Process measurement limited to what data are actually collected in the patient records Measurement of a process may be based on available data, which may not be the most important process
Outcomes	Is the client satisfied with the services received? Did the client receive the services s/he was supposed to receive (e.g. were standard clinical practices followed)?	Client exit interviews	Inexpensive to administer Can sample health facilities and develop simple sampling protocols Patients are already available after receiving services	Courtesy bias can result in overestimation of satisfaction If provider knows client will participate in exit interview, Hawthorne effect may result in providers performing better because they know they will be observed or their patient will be interviewed Clients may not be aware of or understand the standard of care so

				could result in overestimation or underestimation of results
Outcomes		Household survey	May suffer from less Hawthorne effect	More expensive to administer Can require complex sampling approach Courtesy bias Recall bias
Outcomes	Patient-specific outcomes	Medical record review	May be less subjective than direct clinical observations Less intrusive than DCO and interviews	Possible inaccuracies in records (data quality issues) could lead to false conclusions Requires risk adjustment

ANNEX C: Malawi HBB Evaluation Health Worker Interview Tool

Tool ID#:

MALAWI HBB EVALUATION
Tool 1: Health Worker Interview & Knowledge Test

Cover Sheet			
H1: Facility name		**H2: Facility number**	**|__C/I__|____|____|____|**
H3: Observer number	**|____|____|**	**H4: Today's date** **DD/MM/YY**	**|__D__|__D__|__M__|__M__|__Y__|__Y__|**

EXPLAIN TO THE HEALTH WORKER THAT HIS/HER NAME WAS PROVIDED AS A KNOWLEDGEABLE MATERNAL AND/OR NEONATAL HEALTH PROVIDER AVAILABLE ON THAT DAY. VALIDATE WITH THE HEALTH WORKER THAT HE/SHE DOES PROVIDE SOME MATERNAL AND/OR NEONATAL HEALTH SERVICES IN THIS FACILITY.

H6: Health worker line number (from worker line listing in Tool 1A, column 1)	**|___|___|**	**H7: Sex of health worker**	**Male**	**1**
			Female	**2**

Section 1: Interview	
READ THE FOLLOWING QUESTIONS TO THE HEALTH WORKER. IF HEALTH WORKER DOESN'T KNOW THE YEAR, PROBE USING PAST EVENTS AND RECORD YOUR BEST ESTIMATE.	
Question	**Code**
Section 1: EDUCATION AND EXPERIENCE	

H8: What is your current professional/technical/medical qualification?			
Obstetrician/Gynaecologist	**1**		
Doctor	**2**		
Medical Assistant	**3**		
Clinical Officer	**4**		
Registered Midwife	**5**		
Enrolled Nurse/Midwife	**6**		
Nurse/Midwife Technician	**7**		
Other (Specify)_____	**9**		
H100: What year did you graduate (or complete) with this qualification?	**|___|___|___|___|**		
H101: In what year did you start working in this facility?	**|___|___|___|___|**		
H102: In what year did you start working in your current position in this facility?	**|___|___|___|___|**		
H103: What is your age? *(Observer: if health worker doesn't want to give age, ask them to give you a range, i.e. between age 40 and 50. If they refuse to give an age range, enter "00" in the "Age in years" boxes)*	**Age in years:** **Age range:** **< 18 years of age** **18-24** **25-34** **35-44** **45-54** **55-64** **65+**	**|___|___|** **1** **2** **3** **4** **5** **6** **7**	
TRAINING AND SERVICES PROVIDED			
Question	**Yes**	**No**	**Go to**
H106: During the past 2 years have you received any pre-service (basic) or in-service training on subjects related to antenatal care?	**1**	**0**	**No→H108**
H107: In the past 2 years, did you receive any training on the following topics:			
01) ANC screening (e.g., blood pressure, urine glucose and protein)?	**1**	**0**	
02) Counseling for ANC (e.g., nutrition, FP and newborn care)?	**1**	**0**	
03) Emergency obstetric and newborn care (EmONC)	**1**	**0**	
04) Management of pre-eclampsia/eclampsia	**1**	**0**	
05) Any topic related to pregnancy and HIV/AIDS or PMTCT?	**1**	**0**	
H108: In your current position, and as a part of your work for this facility, do you personally provide any delivery services? By that I mean conducting the actual delivery of newborns	**1**	**0**	**No→H114**

H109: How many years in total have you provided such services? Service may have been here or in another facility *(Observer: ENTER 00 IF LESS THAN 1 YEAR OF SERVICE)*	**|___|___|**		
Question	**Code**		
H110: How often do you use a partograph *(READ EACH ANSWER ALOUD)*:			
Never	**1**		
Rarely	**2**		
Sometimes	**3**		
Most of the time	**4**		
Always	**5**		
H111: How often do you use active management of the third stage of labor (AMTSL) during normal vaginal births *(READ EACH ANSWER ALOUD)*:			
Never	**1**		
Rarely	**2**		
Sometimes	**3**		
Most of the time	**4**		
Always	**5**		
Question	**Yes**	**No**	**Go to**
H112: During the past 2 years have you received any pre-service (basic) or in-service training on subjects related to delivery care?	**1**	**0**	**No→H114**
H113: In the past 2 years, did you receive any training on the following topics *(read each answer aloud)*:			
01) Routine care for labor and normal vaginal delivery	**1**	**0**	
02) Use of partograph	**1**	**0**	
03) Active management of third stage of labor (AMTSL)	**1**	**0**	
04) Emergency obstetric care (EmOC)/Life saving skills (LSS) - in general	**1**	**0**	
05) Management of sepsis, including use of parenteral antibiotics	**1**	**0**	
06) Administer magnesium sulfate for the treatment of severe pre-eclampsia or eclampsia	**1**	**0**	
07) Management of postpartum hemorrhage	**1**	**0**	
08) Removal of placenta or products of conception? (D&C, vacuum aspiration, etc.)	**1**	**0**	
09) Manual removal of placenta	**1**	**0**	
10) Special delivery care practices for preventing mother-to-child transmission (PMTCT) of HIV/AIDS	**1**	**0**	
11) Assisted vaginal delivery (apply vacuum extractor/ventouse or forceps)	**1**	**0**	

12) Resuscitate a newborn with bag and mask	**1**	**0**	
13) Maternal death or near miss reviews/audits	**1**	**0**	
14) Quality improvement approaches such as standards based management	**1**	**0**	
15) Respectful maternity care	**1**	**0**	
H114: In your current position, and as a part of your work for this facility, do you personally provide care for newborns?	**1**	**0**	**No→H118**
H115: How many years in total have you provided such services? Service may have been here or in another facility *(Observer: enter 00 if less than 1 year of service)*	**|___|___|**		
H116: During the past 2 years have you received any pre-service or in-service training on subjects related to newborn care?	**1**	**0**	**No→H118**
H117: In the past 2 years, did you receive any training on the following topics *(READ EACH ANSWER ALOUD)*:			
01) Essential newborn care (e.g., cord care, warming, early and exclusive breastfeeding)	**1**	**0**	
01a) Did you practice your skills on an anatomic model that was filled with water or air?	**1**	**0**	
02) Resuscitation of newborns not crying or breathing at birth	**1**	**0**	**No→H118**
2a) Did you receive this newborn resuscitation training as part of the Helping Babies Breathe (HBB) Initiative?	**1**	**0**	**DK**
2a1) Approximately when did you receive this training?	**|___|___|___|___|**		
2b: Did you ever have the opportunity to practice resuscitating a newborn using a newborn anatomic model/doll (NeoNatalie) after you were trained?	**1**	**0**	**No→H118**
2c: Have you had the opportunity to practice resuscitating a newborn using a newborn anatomic model/doll (NeoNatalie) in the last 3 months?	**1**	**0**	
2d: Have you had the opportunity to practice resuscitating a newborn using a newborn anatomic model/doll (NeoNatalie) in the last 1 month?	**1**	**0**	
WORKING CONDITIONS IN FACILITY			
NOW I WOULD LIKE TO ASK YOU SOME QUESTIONS ABOUT SUPERVISION YOU HAVE PERSONALLY RECEIVED. THIS SUPERVISION MAY HAVE BEEN FROM A SUPERVISOR EITHER IN THIS FACILITY, OR FROM OUTSIDE THE FACILITY.			
H118: Do you receive technical support or supervision in your work at this facility?	**1**	**0**	**No→H121**
H118a: Was this supervision from someone inside or outside of this facility?	**Inside**		**A**
	Outside		**B**
H119: When is the most recent time you were supervised?	**Last 3 months**		**1**
	Last 6 months		**2**
	More than 6 months ago		**3**

H119a: When is the most recent time you were supervised by someone from the DHMT?	**Last 3 months** **1** **Last 6 months** **2** **More than 6 months ago** **3** **Never** **0**
H120: The last time you were personally supervised, did your supervisor do any of the following *(read each aloud)*:	
01) Check your records or reports	**1** **0**
02) Observe your work	**1** **0**
03) Give you verbal feedback about how you were doing your job	**1** **0**
04) Provide any written comment about how you were doing your job	**1** **0**
05) Provide updates on administrative or technical issues related to your work	**1** **0**
06) Discuss problems you have encountered	**1** **0**
07) Participate in quality of care improvement activities	**1** **0**
08) Observe you performing newborn resuscitation with a newborn anatomic model/doll (NeoNatalie)	**1** **0**

FOR QUESTION H121, DO NOT READ THE ANSWER CHOICES ALOUD. IF YOU ARE NOT SURE WHETHER AN ANSWER GIVEN BY HEALTH WORKER MATCHES THAT LISTED, PROBE FOR MORE DETAIL. IF THEY GIVE AN ANSWER THAT IS NOT LISTED, MOVE ON TO THEIR NEXT ANSWER. USE THE PROBE TO ENCOURAGE HEALTH WORKER TO GIVE 3 ANSWERS. IF THEY CANNOT GIVE AN ANSWER, OR GIVE ONLY ANSWERS THAT DO NOT APPEAR IN LIST, CIRCLE DON'T KNOW.	
H121: Among the various things related to your working situation that you would like to see improved, can you tell me the three that you think would most improve your ability to provide good quality of care services? (PROBE: Anything else?)	**Code**
More support from supervisor	**A**
More knowledge/ updates / training	**B**
More supplies/drugs	**C**
Better quality equipment	**D**
Less workload (more staff)	**E**
Better working hours / flexible times	**F**
More incentives (salary, promotion, holidays, transportation)	**G**
Increased security	**H**
Better facility infrastructure	**I**
More autonomy / independence	**J**
Emotional support for staff (verbal encouragement)	**K**
More job aids / guidelines / standards	**L**
Don't know / None of these	**Z**
END OF SECTION 1	

Section 2: Maternal Health Knowledge Questions		
FOR THE FOLLOWING QUESTIONS, READ THE QUESTION ALOUD TO THE HEALTH WORKER. DO NOT READ THE ANSWER CHOICES ALOUD. IF YOU ARE NOT SURE WHETHER AN ANSWER GIVEN BY HEALTH WORKER MATCHES THAT LISTED, PROBE FOR MORE DETAIL. IF THEY GIVE AN ANSWER THAT IS NOT LISTED, MOVE ON TO THEIR NEXT ANSWER. USE THE PROBE TO ENCOURAGE HEALTH WORKER TO GIVE AS MANY ANSWERS AS THEY CAN THINK OF. IF THEY CANNOT GIVE AN ANSWER, OR GIVE ONLY ANSWERS THAT DO NOT APPEAR IN LIST, CIRCLE DON'T KNOW.		
READ ALOUD: Please answer the following questions on maternal health to the best of your knowledge. Most of the questions I ask you will require multiple responses from you. Assume all needed supplies, medications, and equipment are available. When thinking about your answers, you should include actions or interventions that could be done at your facility and at a referral facility. I will probe sometimes to help you remember some more information. Please provide all responses that come to mind.		
Question		**Code**
H200: What actions during labor and delivery would you take in an HIV+ woman to prevent/ reduce mother-to-child transmission of the virus?		
	PMTCT counseling	**A**
(PROBE: Any other actions or interventions?)	**Provide ARV prophylaxis to woman in early labor**	**B**
	Wipe nose, mouth, eyes of newborn with gauze, avoid suction	**C**
	No routine episiotomy	**D**
	Minimize instrument delivery	**E**
	Hibitane vaginal cleansing	**F**
	Minimize vaginal exam	**G**
	Minimize artificial rupture of membranes	**H**
	Avoid milking cord/ immediate clamp cord	**I**
	Appropriate use of partograph	**J**
	Active management of 3rd stage labor	**K**
	Provide ARV prophylaxis to infant	**L**
	Don't know	**Z**
H201: What are the key steps for performing active management of the third stage of labor?		
	Administration of a uterotonic immediately/ within 1 minute of delivery	**A**
(PROBE: if health worker mentions uterotonic, ask when should uterotonic be given?)	**Administration of a uterotonic with delivery of anterior shoulder**	**B**
	Administration of a uterotonic after delivery of placenta	**C**
	Controlled cord traction	**D**
	Uterine massage	**E**
	Don't know	**Z**
END OF SECTION 2		

Section 3: Newborn Health Knowledge Questions		
FOR THE FOLLOWING QUESTIONS, READ THE QUESTION ALOUD TO THE HEALTH WORKER. DO NOT READ THE ANSWER CHOICES ALOUD. IF YOU ARE NOT SURE WHETHER AN ANSWER GIVEN BY HEALTH WORKER MATCHES THAT LISTED, PROBE FOR MORE DETAIL. IF THEY GIVE AN ANSWER THAT IS NOT LISTED, MOVE ON TO THEIR NEXT ANSWER. USE THE PROBE TO ENCOURAGE HEALTH WORKER TO GIVE AS MANY ANSWERS AS THEY CAN THINK OF. IF THEY CANNOT GIVE AN ANSWER, OR GIVE ONLY ANSWERS THAT DO NOT APPEAR IN LIST, CIRCLE DON'T KNOW.		
READ ALOUD: Please answer the following questions on newborn health to the best of your knowledge. Most of the questions I will be asking you will require multiple responses from you. Assume all needed supplies, medications, and equipment are available. When thinking about your answers, you should include actions or interventions that could be done at your facility and at a referral facility. I will probe sometimes to help you remember some more information. Please provide all responses that come to mind.		
Question		**Code**
H301: What basic equipment and supplies must be available to ensure the baby receives appropriate immediate care after birth?		
	2 dry warm towels or cloths	**A**
(PROBE: Anything else?)	**Sterile blade or scissors**	**B**
	Sterile or disposable cord ties/ clamps	**C**
	Cap for baby	**D**
	Source of warmth: heating lamp or incubator	**E**
	Self-inflating ventilation bag	**F**
	Newborn face mask size 1	**G**
	Newborn face mask size 0	**H**
	Mucus extractor/ suction/ bulb syringe	**I**
	Flat surface	**J**
	Clock or watch with seconds	**K**
	Don't know	**Z**
H302: Please tell me, when a baby is delivered and there is no complication, what care is important to give them immediately after birth and in the first hour?		
	Wipe face after birth of head	**A**
(PROBE: Anything else?)	**Ensure baby was breathing/ crying**	**B**
	Provide thermal protection: place skin to skin with mother	**C**
	Provide thermal protection: wrap baby in a towel/cloth	**M**
	Bathe newborn shortly after birth	**D**
	Suction newborn with bulb	**E**
	Ensure mother initiates breast feeding within 1 hour	**F**
	Assess/examine newborn within 1 hour	**G**
	Weigh newborn	**H**
	Provide eye prophylaxis /antibiotic ointment	**I**

	Give prelacteal feed/ water	**J**
	Cut cord with sterile blade/scissors	**K**
	Apply antiseptic or other material to cord stump	**L**
	Don't know	**Z**

H303: Can you please tell me the signs and symptoms of severe infection (sepsis) in a newborn?		
	Poor/ no breastfeeding	**A**
(PROBE: Any other signs or symptoms?)	**Restlessness/irritability**	**B**
	Breathing difficulties	**C**
	Hypothermia	**D**
	Hyperthermia	**E**
	Breathing rating >60/minute	**F**
	Convulsions	**G**
	Pus/ redness around umbilicus	**H**
	Abscess on any part of body	**I**
	Skin pustules	**J**
	Lethargy/ no movement (conscious)	**K**
	Unconscious	**L**
	Don't know	**Z**
END OF INTERVIEW. MOVE ON TO CLINICAL SIMULATIONS OF NEWBORN RESUSCITATION (TOOL 2 AND 3)		

ANNEX D: Malawi HBB Evaluation Labor and Delivery Observation Checklist

Tool ID#:	Q12	

Cover Page	
Q1: Facility name	**Q2: Facility code**
Q3: Observer code	**Q4: Today's date** D D M M Y Y **(day/month/year)**

BEFORE OBSERVING THE CONSULTATION, MAKE SURE TO OBTAIN PERMISSION FROM BOTH THE SERVICE PROVIDER AND THE CLIENT. ALSO MAKE SURE THAT THE PROVIDER KNOWS THAT YOU ARE NOT THERE TO EVALUATE HIM OR HER, AND THAT YOU ARE NOT AN "EXPERT" TO BE CONSULTED DURING THE SESSION.

READ THE CONSENT SCRIPT TO HEALTH WORKER LOCATED ON SEPARATE CONSENT FORM

Q5: *Ask health worker* Do I have your permission to be present at this consultation?

☐ Yes, consent is signed→ go to Q6

☐ No, consent is not signed→ observation of this health worker must END; if available, approach another health worker for participation.

Q6a: Health worker line number (From tool 1A colmn 1)	**Q6b: Health worker line number (**From tool 1A colmn 1**)**
Q7a: Sex of health worker	**Q7b: Sex of health worker**
Male 1	Male **1**
Female	Female **2**

	2		
Q8a: Health worker category		**Q8b: Health worker category**	
Obstetrician/Gynaecologist	**1**	**Obstetrician/Gynaecologist**	**1**
Doctor	**2**	**Doctor**	**2**
Medical Assistant	**3**	**Medical Assistant**	**3**
Clinical Officer	**4**	**Clinical Officer**	**4**
Registered Midwife	**5**	**Registered Midwife**	**5**
Enrolled Nurse Midwife	**6**	**Enrolled Nurse Midwife**	**6**
Nurse Midwife Technician	**7**	**Nurse Midwife Technician**	**7**
Other (Specify)_____	**9**	**Other (Specify)_____**	**9**
Q8a1: Trained in HBB (tool 1A colmn 7)?		**Q8b1: Trained in HBB (**Check tool 1A colmn 7)**?**	
Yes	**1**	**Yes**	**1**
No	**0**	No	**0**

READ THE CONSENT SCRIPT TO CLIENT. IF CLIENT IS INCAPACITATED, NEXT OF KIN OR FAMILY FRIEND ACCOMPANYING CLIENT MAY GIVE CONSENT. CONSENT FOR CLIENT CANNOT BE GIVEN BY HEALTH WORKER OR FACILITY IN-CHARGE. CLIENT OR PROXY CONSENT MUST BE OBTAINED PRIOR TO START OF OBSERVATION.

Q9: *Ask client* Do I have your permission to be present while you are receiving services today?

☐ Yes, consent is signed→ go to Q10

☐ No, consent is not signed→ observation of this client must END; if available, approach another client for participation.

Q10: Who gave consent	**Client**

	1	
	Next of kin/family friend 2	
Q11: Client code		***Start client code at 1 for the first client observed at a given facility.***
Q12: Client initials or other identifier		***Write client initials or identifier in box at top right of cover first page (marked Q12) to help identify this client's case when observing multiple cases***
Q13: Record time the observation started (*Observer:* Please use 24 hr clock)	**H H M M**	
GO TO SECTION 1 TO BEGIN THE OBSERVATION		

Section 1: Initial Client Assessment (TOOL 4)

Question	Yes	No	DK	Go to
RECORD WHETHER THE PROVIDER CARRIED OUT THE FOLLOWING STEPS AND/OR EXAMINATIONS: (SOME OF THE FOLLOWING STEPS MAY BE PERFORMED SIMULTANEOUSLY OR BY MORE THAN ONE PROVIDER)				
INTRODUCTION AND HISTORY TAKING				
Q101: Respectfully greets the pregnant woman	**1**	**0**	**8**	
Q102: Encourages the women to have a support person present during labor and birth	**1**	**0**	**8**	
Q103: Asks women (and support person) if she has any questions	**1**	**0**	**8**	**No/DK→Q103b**
Q103a: If the woman or support person asks a question, the provider answers the questions in a polite manner	**1**	**0**	**8**	
Q103b: Woman has audio and visual privacy	**1**	**0**	**8**	
Q104: Checks client card OR asks client her age, length of pregnancy, and parity	**1**	**0**	**8**	
Q105: Asks whether she has experienced any of the following for current pregnancy:				
01) Vaginal bleeding	**1**	**0**	**8**	
02) Fever	**1**	**0**	**8**	
03) Severe headaches and/or blurred vision	**1**	**0**	**8**	
04) Swollen face or hands	**1**	**0**	**8**	
05) Convulsions or loss of consciousness	**1**	**0**	**8**	
06) Severe difficulty breathing	**1**	**0**	**8**	
07) Persistent cough for 2 weeks or longer	**1**	**0**	**8**	
08) Severe abdominal pain	**1**	**0**	**8**	
09) Foul smelling discharge	**1**	**0**	**8**	
10) Frequent or painful urination	**1**	**0**	**8**	
11) Whether the client has felt a decrease or stop in fetal movement	**1**	**0**	**8**	
12) If there are any other problems the client is concerned about	**1**	**0**	**8**	**No/DK→Q106**
12a) The provider takes the time to discuss the clients concerns adequately	**1**	**0**	**8**	

Q106: Checks woman's HIV status (checks card or asks woman)	**1**	**0**	**8**	
Q107: Offers woman HIV test	**1**	**0**	**8**	
Q108: Is woman HIV positive?*(observer: listen and record answer; circle Don't Know if status is unknown or is not discussed)*	**1**	**0**	**8**	**No/DK→Q110**
Q109: Asks about or counsels on the following topics for HIV positive mothers:				
01) Asks if client is currently taking ARVS	**1**	**0**	**8**	**No/DK → 109_02**
01a) Asks client when she took last dose ARVs	**1**	**0**	**8**	
02) Explains why the mother should take ARVs	**1**	**0**	**8**	
03) Explains when and how the mother should take ARVs	**1**	**0**	**8**	
04) Administers ARVs to mother	**1**	**0**	**8**	
05) Explains why the newborn should take ARVs	**1**	**0**	**8**	
06) Explains when and how newborn should take ARVs	**1**	**0**	**8**	
07) Provider actively protects woman's privacy and confidentiality when discussing the woman's HIV status	**1**	**0**	**8**	
Q110: Client has any previous pregnancies? *(Observer: LISTEN AND RECORD)*				**No/DK → Q112**
Q111: Asks about complications during previous pregnancies:				
01) Heavy bleeding during or after delivery	**1**	**0**	**8**	
02) Anemia	**1**	**0**	**8**	
03) High blood pressure	**1**	**0**	**8**	
04) Convulsions	**1**	**0**	**8**	
05) Multiple pregnancies (twins or above)	**1**	**0**	**8**	
06) Prolonged labour	**1**	**0**	**8**	
07) C-section	**1**	**0**	**8**	
08) Assisted delivery (forceps, ventouse)	**1**	**0**	**8**	
09) Prior neonatal death (death of baby less than 1 month old)	**1**	**0**	**8**	
10) Prior stillbirth (baby born dead that does not breathe or cry)	**1**	**0**	**8**	

11) Prior abortion/miscarriage (loss of pregnancy)	1	0	8	
EXAMINATION				
Q112: Washes his/her hands with soap and water or uses disinfectant before any initial examination	1	0	8	
Q113: Explains procedures to woman (support person) before proceeding	1	0	8	
Q114: Takes temperature	1	0	8	
Q115: Takes pulse	1	0	8	
Q116: Takes blood pressure	1	0	8	No/DK → Q117
01) Take client's blood pressure in sitting or lateral position	1	0	8	
02) Take blood pressure with arm at heart level	1	0	8	
Q117: Asks/notes amount of urine output	1	0	8	
Q118: Tests urine for presence of protein	1	0	8	
Q119: Performs general examination (e.g. for anemia, edema)	1	0	8	
Q120: Performs the following steps for abdominal examination:				
01) Checks fundal height with measuring tape	1	0	8	
02) Checks fetal presentation by palpation of abdomen	1	0	8	
03) Checks fetal heart rate with fetoscope/doppler/ultrasound	1	0	8	
Q120a: Informs the woman what will happen before conducting the vaginal examination	1	0	8	
Q121: Performs vaginal examination	1	0	8	
Q122: Wears high-level disinfected or sterile gloves for vaginal examination	1	0	8	
Q123: Informs pregnant woman of findings	1	0	8	
Q123a: End of initial client assessment	H	H	M	M
END OF SECTION 1				

Section 2: Intermittent Observation of First Stage of Labor (TOOL 4)

Question	Yes	No	DK	Go to
RECORD WHETHER THE PROVIDER CARRIED OUT THE FOLLOWING STEPS AND/OR EXAMINATIONS: (SOME OF THE FOLLOWING STEPS MAY BE PERFORMED SIMULTANEOUSLY OR BY MORE THAN ONE PROVIDER)				
PROGRESS OF LABOR				
Q201: At least once, explains what will happen in labor to woman (support person)	**1**	**0**	**8**	
Q202: At least once, encourages woman to consume fluids/food during labor	**1**	**0**	**8**	
Q203: At least once, encourages/assists woman to ambulate and assume different positions during labor	**1**	**0**	**8**	
Q204: Observer: Is a support person present at some point during labor?	**1**	**0**	**8**	
Q205: Drapes woman (one drape under buttocks, one over abdomen)	**1**	**0**	**8**	
Q205a: Woman has her own bed	**1**	**0**	**8**	
Q205b: Provider asks woman which position she would like to deliver in	**1**	**0**	**8**	
Q206: Partograph used to monitor labor	**1**	**0**		**No→Q212**
Q207: Action line on partograph reached	**1**	**0**	**8**	**No/DK→Q212**
Q208: Record time action line was reached (*Observer:* PLEASE USE 24 HR CLOCK)				
Q209: If action line reached on partograph, was any <u>definitive</u> action taken?	**1**	**0**	**8**	**No/DK→Q212**
Q210: Record time action was taken (*Observer:* PLEASE USE 24 HR CLOCK)				
Q211: What definitive action was taken (CIRCLE ALL THAT APPLY):	**Code**			
Consult with specialist	**1**			
Refer to other facility for specialist	**2**			
Prepare for assisted delivery	**3**			
Prepare for c-section	**4**			

Other (specify_____)	**6**			
EXAMINATION & PROCEDURES				
Question	**Yes**	**No**	**DK**	**Go to**
Q212: Washes his/her hands with soap and water or uses antiseptic prior to any examination of woman	**1**	**0**	**8**	
Q213: Wears high-level disinfected or sterile surgical gloves	**1**	**0**	**8**	
Q214: Puts on clean protective clothing in preparation for birth (goggles, gown or apron)	**1**	**0**	**8**	
Q215: Explains procedures to woman (support person) before proceeding	**1**	**0**	**8**	
Q215b: Provider uses curtains or other visual barrier to protect woman during exams, birth, procedures	**1**	**0**	**8**	
Q216: Number of vaginal examinations *(observer: to the best of your ability, update the answer to this question during intermittent observation of first stage of labor)*				
Q217: Augments labor with oxytocin	**1**	**0**	**8**	**No/DK → Q219**
Q218: Oxytocin administered intravenously (IV)	**1**	**0**	**8**	
Q219: Performs artificial rupture of membrane	**1**	**0**	**8**	
Q220: Administers antibiotics	**1**	**0**	**8**	**No/DK → Q223**
Q221: Why were antibiotics administered (CIRCLE ALL THAT APPLY)?	**Code**			
Treatment for chorioamnionitis	**1**			
Management of pre-labor rupture of membranes	**2**			
Preparation for C-section	**3**			
Routine/prophylactic	**4**			
Don't know	**8**			
Q222: Which antibiotic was administered? (CIRCLE ALL THAT APPLY)				
Penicillin	**A**			

Ampicillin	**B**
Gentamicin	**C**
Metronidazole	**D**
Cephalosporin	**E**
Other	**X**
Don't know	**Z**

PREPARATION FOR DELIVERY

CHECK TO SEE IF THE FOLLOWING EQUIPMENT AND SUPPLIES ARE LAID OUT IN PREPARATION FOR DELIVERY. IF SOME SUPPLIES ARE IN A BIRTH KIT, LOOK/ASK TO DETERMINE WHICH ITEMS ARE INCLUDED.

Question	Yes	No	DK	Go to
Q223: Prepares uterotonic drug to use for AMTSL	**1**	**0**	**8**	**No/DK → Q225**
Q224: Which drug	**Code**			
Oxytocin	**1**			
Ergometrine	**2**			
Syntometrine	**3**			
Misoprostol	**4**			
Question	**Yes**	**No**	**DK**	**Go to**
Q225: Timer (clock or watch with seconds hand)	**1**	**0**	**8**	
Q226: Self-inflating ventilation bag (250 or 500 mL)	**1**	**0**	**8**	
Q227: Newborn face mask size 0	**1**	**0**	**8**	
Q228: Newborn face mask size 1	**1**	**0**	**8**	
Q229: Suction bulb	**1**	**0**	**8**	
Q230: Catheter	**1**	**0**	**8**	
Q231: Suction machine	**1**	**0**	**8**	
Q232: At least two cloths/blankets (one to dry; one to cover)	**1**	**0**	**8**	
Q233: Cap/hat for the newborn	**1**	**0**	**8**	

Q234: Disposable cord ties or clamps	**1**	**0**	**8**	
Q235: Sterile scissors or blade	**1**	**0**	**8**	
Q236: Has the woman completed the first stage of labor?	**1**	**0**		**Yes → Q300**

IF FIRST STAGE OF LABOR IS NOT COMPLETE, CHECK ANSWERS IN THIS SECTION AGAIN 15-30 MINUTES LATER

END OF SECTION 2

Section 3: Continuous Observation of Second & Third Stage of Labor (TOOL 4)

Question	Yes	No	DK	Go to
RECORD WHETHER THE PROVIDER CARRIED OUT THE FOLLOWING STEPS AND/OR EXAMINATIONS: (SOME OF THE FOLLOWING STEPS MAY BE PERFORMED SIMULTANEOUSLY OR BY MORE THAN ONE PROVIDER).				
PREPARATION FOR DELIVERY				
Q301: Washes his/her hands with soap and water or uses antiseptic before any examination of woman*(observer: circle yes if done previously and no contamination)*	**1**	**0**	**8**	
Q302: Wears high-level disinfected or sterile surgical gloves*(yes if no contamination)*	**1**	**0**	**8**	
Q303: Puts on clean protective clothing in preparation for birth(goggles, gown or apron)*(yes if no contamination)*	**1**	**0**	**8**	
Q304: Performs episiotomy if indicated	**1**	**0**		
Q305: Presentation of baby is cephalic (head first)	**1**	**0**	**8**	
DELIVERY & UTEROTONIC				
Q306: As baby's head is delivered, supports perineum	**1**	**0**	**8**	
Q307: Record time of the delivery of the baby **(*Observer:* PLEASE USE 24 HR CLOCK)**				
Q308: Checks for another baby prior to giving the uterotonic	**1**	**0**	**8**	
Q309: Second baby present? *(observer: circle 1 if multiple babies)*	**1**	**0**		
Q310: Administers uterotonic?	**1**	**0**		**No → Q317**
Q311: Record time uterotonic given (*Observer:* Please use 24 hr clock)				
Q312:Timing of administration of uterotonic	**Code**			
At delivery of anterior shoulder	**1**			
Within 1 min of delivery of baby	**2**			
Within 3 min of delivery of baby	**3**			
More than 3 min after delivery of baby AND before delivery of the placenta	**4**			
More than 3 min of delivery of baby and before delivery of placenta	**5**			

More than 3 minutes of delivery of baby and after delivery of placenta	**6**		
Q313: Which uterotonic given			
Oxytocin	**1**		
Ergometrine	**2**		
Syntometrine	**3**		
Misoprostol	**4**		
Q314: Record dose of uterotonic given *(observer: if necessary, ask afterwards)*			
Q315: Units of medication *(observer: if necessary, ask afterwards)*			
IU	**1**		
mg	**2**		
mL	**3**		
mcg	**4**		
Q316: Route uterotonic given:			
IM	**1**		
IV	**2**		
Oral	**3**		
Other	**4**		
Q317: Record time the cord was clamped **(*Observer:* Please use 24 hr clock)**			
Question	**Yes**	**No**	**DK**
Q318: Applies traction to the cord while applying suprapubic counter traction	**1**	**0**	**8**
Q319: Performs uterine massage immediately following the delivery of the placenta	**1**	**0**	**8**
Q320: Was placenta delivered before administration of uterotonic? *(observer: circle Don't Know if no uterotonic was given)*	**1**	**0**	**8**

Q321: Assesses completeness of the placenta and membranes	**1**	**0**	**8**	
Q322: Assesses for perineal and vaginal lacerations	**1**	**0**	**8**	
Q323: Observer: Did more than one health worker assist with the birth?	**1**	**0**	**8**	**No → Q324**
Q323a: How many health workers assisted with the birth?				
Q324: Observer: Did mother gave birth in lithotomy position (on back)	**1**	**0**		
Q325: Observer: Is a support person (companion) for mother present at birth?	**1**	**0**		**Yes → Q325b**
Q325a: If no support person was present at birth: Was a support person restricted from being present?	**1**	**0**		
Q325b: Did the women request some relief from her pain?	**1**	**0**		**No→ Q325d**
Q325c: If the woman requested pain relief, did the provider help manage her pain?	**1**	**0**		
Q325d: Provider gives at least one update on status and progress of labor	**1**	**0**		
Q325e: Did the woman have a preferred birthing position?	**1**	**0**		**No/Don't know → Q401**
Q325f: Woman was allowed to deliver in her preferred birthing position	**1**	**0**		

END OF SECTION 3

Section 4: Immediate Newborn and Postpartum Care

Question	**Yes**	**No**		**Go to**
RECORD WHETHER THE PROVIDER CARRIED OUT THE FOLLOWING STEPS AND/OR EXAMINATIONS: (SOME OF THE FOLLOWING STEPS MAY BE PERFORMED SIMULTANEOUSLY OR BY MORE THAN ONE PROVIDER)				
IMMEDIATE CARE				
Q401: Immediately dries baby with towel	**1**	**0**	**8**	
Q402: Discards the wet towel	**1**	**0**	**8**	
Q403: Is the baby breathing or crying?	**1**	**0**		**No → Q501**

IF BABY IS NOT BREATHING OR CRYING, GO TO RESUSCITATION CHECKLIST GO TO Q501				
Q404: Places baby on mother's abdomen "skin to skin"	**1**	**0**	**8**	
Q405: Covers baby with dry towel	**1**	**0**	**8**	
Q406: If not placed skin to skin, wraps baby in dry towel	**1**	**0**	**3 (NA)**	
Q407: Ties or clamps cord when pulsations stop, or by 2-3 minutes after birth (not immediately after birth)	**1**	**0**	**8**	
Q408: Cuts cord with sterile blade or sterile scissors	**1**	**0**	**8**	
Q409: Observer: Is a support person (companion) for mother present?	**1**	**0**		
HEALTH CHECK				
Q410: Checks baby's temperature 15 minutes after birth	**1**	**0**	**8**	
Q411: Checks baby's skin color 15 minutes after birth	**1**	**0**	**8**	
Q412: Takes mother's vital signs 15 minutes after birth	**1**	**0**	**8**	
Q413: Palpates uterus 15 minutes after delivery of placenta	**1**	**0**	**8**	
FIRST HOUR AFTER BIRTH				
Q414: Mother and newborn kept in same room after delivery (rooming-in)	**1**	**0**	**8**	
Q415: Baby bathed within the first hour after birth	**1**	**0**	**8**	
Q416: Baby kept skin to skin with mother for the first hour after birth	**1**	**0**	**8**	
Q417: Breastfeeding initiated within the first 30 minutes after birth	**1**	**0**	**8**	
Q417a: Breastfeeding initiated within the first hour after birth	**1**	**0**	**8**	
Q418: Provides tetracycline eye ointment prophylaxis	**1**	**0**	**8**	
Q419: Administers Vitamin K to newborn	**1**	**0**	**8**	
Q420: Is the mother HIV positive?*(observer: listen and record answer; circle Don't Know if status is unknown or is not discussed)*	**1**	**0**	**8**	**No/DK → Q422**
Q421: Administers ARVs to newborn	**1**	**0**	**8**	
Q422: Administers antibiotics to mother postpartum	**1**	**0**	**8**	**No/DK → Q425**
Q423: Why were antibiotics administered?	**Code**			

Treatment for chorioamnionitis	**1**
Routine/prophylactic	**4**
Third stage/postpartum procedure	**5**
Don't know	**8**
Q424: Which antibiotic was administered? (CIRCLE ALL THAT APPLY)	
Penicillin	**A**
Ampicillin	**B**
Gentamicin	**C**
Metronidazole	**D**
Cephalosporin	**E**
Other	**X**
Don't know	**Z**
CLEAN-UP AFTER BIRTH	

RECORD WHETHER THE PROVIDER CARRIED OUT THE FOLLOWING STEPS AND/OR EXAMINATIONS: (SOME OF THE FOLLOWING STEPS MAY BE PERFORMED SIMULTANEOUSLY OR BY MORE THAN ONE PROVIDER)

Question	Yes	No		Go to
Q425: Disposes of all sharps in a puncture-proof container immediately after use	**1**	**0**	**8**	
Q426: Decontaminates all reusable instruments in 0.5% chlorine solution	**1**	**0**	**8**	
Q427: Sterilizes or uses high-level disinfection for all reusable instruments	**1**	**0**	**8**	
Q428: Disposes of all contaminated waste in leak-proof containers	**1**	**0**	**8**	
Q429: Removes apron and wipe with chlorine solution	**1**	**0**	**8**	
Q430: Washes his/her hands with soap and water or uses antiseptic	**1**	**0**	**8**	
CLEAN-UP AFTER NEWBORN RESUSCITATION				
Q431: Was there a newborn resuscitation?	**1**	**0**		**No → Q601**
Q432: Disposes of disposable suction catheters and mucus extractors in a leak-proof container or plastic bag	**1**	**0**	**8**	

Q433: Takes the bag and mask apart and inspects for cracks and tears	**1**	**0**	**8**	
Q434: Decontaminates the bag and mask in 0.5% chlorine solution	**1**	**0**	**8**	
Q435: Sterilizes or uses high-level disinfection for bag, valve and mask	**1**	**0**	**8**	
Q436: Decontaminates reusable suction devices in 0.5% chlorine solution	**1**	**0**	**8**	
Q437: Sterilizes or uses high-level disinfection for reusable suction devices	**1**	**0**	**8**	
Q438: Washes his/her hands with soap and water or uses antiseptic	**1**	**0**	**8**	
REMEMBER TO THANK CLIENT AND PROVIDER FOR THEIR PARTICIPATION IN THE STUDY				
END OF SECTION 4 –IF NEWBORN RESUSCITATION IS NOT OBSERVED, THEN GO TO SECTION 6 TO COMPLETE OUTCOME AND REVIEW OF DOCUMENTATION SECTION				

Section 5: Checklist for Newborn Resuscitation (TOOL 5)

Question	Yes	No	DK	Go to
RECORD WHETHER THE PROVIDER CARRIED OUT THE FOLLOWING STEPS AND/OR EXAMINATIONS: (SOME OF THE FOLLOWING STEPS MAY BE PERFORMED SIMULTANEOUSLY OR BY MORE THAN ONE PROVIDER)				
Q501: Record time resuscitation started (*Observer:* Please use 24 hr clock)				
Q502: Clears the airway by suctioning the mouth first and then the nose	**1**	**0**	**8**	
Q503: Stimulates baby with back rubbing	**1**	**0**	**8**	
Q504: *OBSERVER:* Does newborn starts to breathe or cry spontaneously?	**1**	**0**		**Yes→Q531**
Q506: Ties or clamps cord immediately	**1**	**0**	**8**	
Q507: Cuts cord with clean blade or clean scissors	**1**	**0**	**8**	
Q508: Places the newborn on his/her back on a clean, warm surface or towel	**1**	**0**	**8**	
Q509: Places the head in a slightly extended position to open the airway	**1**	**0**	**8**	
Q510: Tells the woman (and her support person) what is going to be done	**1**	**0**	**8**	

Q511: Listens woman and provides support and reassurance	**1**	**0**	**8**	
Q512: Checks mouth, back of throat and nose for secretions, and clears if necessary	**1**	**0**	**8**	
Q513: Places the correct-sized mask on the newborn's face so that it covers the chin, mouth and nose (but not eyes)	**1**	**0**	**8**	
Q514: Checks the seal by ventilating two times and observing the rise of the chest	**1**	**0**	**8**	
Q515: *OBSERVER:* is newborn's chest rising in response to ventilation?	**1**	**0**		**Yes→Q524**
Q515a:Calls for help	**1**	**0**	**8**	
Q516: Checks the position of the newborn's head to make sure that the neck is in a slightly extended position (not blocking the airway)	**1**	**0**	**8**	
Q517: Checks mouth, back of throat and nose for secretions, and clears if necessary	**1**	**0**	**8**	
Q518: Checks the seal by ventilating two times and observing the rise of the chest	**1**	**0**	**8**	
Q519: *OBSERVER:* is newborn's chest rising in response to ventilation?	**1**	**0**		**Yes→Q524**
Q520: Checks the position of the newborn's head again to make sure that the neck is in slightly extended position	**1**	**0**	**8**	
Q521: Repeats suction of mouth and nose to clear secretions, if necessary	**1**	**0**	**8**	
Q522: Checks the seal by ventilating two times and observing the rise of the chest	**1**	**0**	**8**	
Q523: *OBSERVER:* is newborn's chest rising in response to ventilation?	**1**	**0**		**Yes→Q524**
IF NEWBORN'S CHEST IS NOT RISING AFTER TWO ATTEMPTS TO READJUST, OBSERVER SHOULD CALL FOR SUPERVISOR TO INTERVENE. IF A HEALTH WORKER COMPETENT IN RESUSCITATION IS NOT AVAILABLE, OBSERVER MAY CHOOSE TO INTERVENE.				
Q524: Ventilates at a rate of 30 to 50 breaths/minute	**1**	**0**	**8**	
Q525: Conducts assessment of newborn breathing after 1 minute of ventilation	**1**	**0**		**No→Q527**
Q526: Condition of newborn at assessment	**Code**			
Respiration rate 30-50 breaths/minute and no chest indrawing	**1**			**→Q531**

Respiration rate <30 breaths/minute with severe indrawing	**2**			
No spontaneous breathing	**3**			
Q526a: Checks for heart rate	**1**	**0**	**8**	
	Yes	**No**	**DK**	**Go to**
Q527: Continues Ventilation and baby cries before 10 minutes	**1**	**0**		**Yes→Q529**
Q528: Conducts assessment of newborn breathing after prolonged ventilation (10 minutes)	**1**	**0**		**No→Q530**
Q529: Condition of newborn at assessment	**Code**			
Respiration rate 30-50 breaths/minute and no chest indrawing	**1**			**→Q531**
Respiration rate <30 breaths/minute with severe indrawing	**2**			
No spontaneous breathing	**3**			
	Yes	**No**	**DK**	**Go to**
Q530: Continues Ventilation	**1**	**0**		
Q531: Record time that resuscitation actions ended (or time of death if baby died) **(*Observer:* Please use 24 hr clock)**				
Q532: Is the baby alive and breathing spontaneously? *(observer: circle No if newborn died)*	**1**	**0**		
Q533: Arranges transfer to special care either in facility or to outside facility	**1**	**0**	**8**	
Q534: Explains to the mother (and her support person if available) what happened	**1**	**0**	**8**	
Q535: Listens to mother and responds attentively to her questions and concerns	**1**	**0**	**8**	
Q536: Observer: Did you call for help or intervene during the resuscitation to save the life of newborn?	**1**	**0**		

Q537: *PLEASE COMMENT ON THE QUALITY OF CARE PROVIDED:*

Was mother treated respectfully? Informed of procedures to her baby? Was the situation chaotic or calm? Were there any major delays in needed treatment? If so, for what drugs/procedures and why? Were multiple health workers involved? Who were the health worker Who? If newborn did not survive, describe the circumstances.

Was the mother counseled about the death of newborn?

OBSERVER: PLEASE RETURN TOQ410 (CLEAN-UP AFTER BIRTH)

Section 6: Outcome &Review of Documentation

Question	Code
COMPLETE THIS SECTION FOR ALL CLIENTS	
CONDITION OF MOTHER & NEWBORN AT END OF OBSERVATION	
RECORD THE STATUS OF MOTHER AND NEWBORN AT THE END OF FIRST HOUR AFTER BIRTH.	
Q601: Record outcome for the mother	
Goes to recuperation ward	**1**
Referred to specialist, same facility	**2**
Goes to surgery, same facility	**3**
Referred, other facility	**4**
Death of mother	**5**
Q602: Record outcome for the newborn or fetus	
Goes to normal nursery	**1**
Referred to specialist, same facility	**2**
Referred, other facility	**3**
Goes to ward with mother	**4**
Newborn death	**5**
Fresh stillbirth	**6**
Macerated stillbirth	**7**
POTENTIALLY HARMFUL PRACTICES	
Q603: Did you see any of the following harmful or inappropriate practices by health workers that are never indicated (CIRCLE ALL THAT APPLY)	
Use of enema	**A**
Pubic shaving	**B**

Apply fundal pressure to hasten delivery of baby or placenta	C			
Lavage of uterus after delivery	D			
Slap newborn	E			
Hold newborn upside down	F			
Milking the newborn's chest	G			
Excessive stretching of the perineum	H			
Shout, insult or threaten the woman during labor or after	I			
Slap, hit or pinch the woman during labor or after	J			
None of the above	Y			
Q604: Did you see any of the following practices done without an appropriate indication (CIRCLE ALL THAT APPLY)				
Manual exploration of the uterus after delivery	A			
Use of episiotomy	B			
Aspiration of newborn mouth and nose as soon as head is born	C			
Restrict food and fluids in labor	D			
None of the above	Y			
Q604a: Record time L&D observation ended (24 hr clock)				
Question	**Yes**	**No**	**DK**	**Go to**
Q605: Was there a newborn resuscitation? *(observer: CHECK ANSWER Q431)*	1	0		No → Q611
EXAMINE CHART TO DETERMINE WHETHER THE HEALTH WORKER RECORDED THE FOLLOWING INFORMATION:				
Q606: Condition of the newborn at birth	1	0	8	
Q607: Procedures necessary to initiate breathing	1	0	8	
Q608: Time from birth to initiation of spontaneous breathing or time of death if unsuccessful	1	0	8	
Q609: Any clinical observations during resuscitation, including	1	0	8	

baby vital signs				
Q610: Final outcome of resuscitation measures	**1**	**0**	**8**	
EXAMINE PARTOGRAPH IF AVAILABLE				
Q611: Partograph used to monitor labor	**1**	**0**		**No → Q630**

Q612: Which partograph used	Code			
Old WHO partograph (latent phase)	**1**			
New WHO partograph (at 4cm dilatation)	**2**			
Other partograph	**3**			
Question	**Yes**	**No**	**DK**	**Go to**
Q613: Initiated use of partograph at the appropriate time according to partograph used (New WHO partograph starts at 4 cm; old version starts at 3 cm)	**1**	**0**	**8**	
EXAMINE PARTOGRAPH TO DETERMINE WHETHER THE HEALTH WORKER RECORDED THE FOLLOWING INFORMATION WHILE THE WOMAN WAS IN ACTIVE LABOR:				
Q614: Fetal heart rate plotted at least every half hour	**1**	**0**	**8**	
Q615: Cervical dilatation plotted at least every four hours	**1**	**0**	**8**	
Q616: Descent of head plotted at least every four hours	**1**	**0**	**8**	
Q617: Frequency and duration of contractions plotted at least every hour	**1**	**0**	**8**	
Q618: Maternal pulse plotted at least every hour	**1**	**0**	**8**	
Q619: BP recorded at least every four hours	**1**	**0**	**8**	
Q620: Temperature recorded at least every two hours	**1**	**0**	**8**	
Q621: OBSERVER: Did you see provider fill out partograph after delivery (with information that should be entered during labor)? (circle Don't Know if partograph use was not observed)	**1**	**0**	**8**	
Q621a: Was there a delay in receiving care after a decision was made?	**1**	**0**	**8**	
EXAMINE PARTOGRAPH TO DETERMINE WHETHER THE HEALTH WORKER RECORDED THE FOLLOWING INFORMATION ABOUT THE DELIVERY				
Q622: Birth time	**1**	**0**	**8**	
Q623: Delivery method	**1**	**0**	**8**	
Q624: Birthweight	**1**	**0**	**8**	
DATA EXTRACTION FROM PARTOGRAPH AND/OR CHART				
Q625: Was action line on partograph reached?	**1**	**0**	**8**	**No/DK →**

				Q630
Q626: Record time action line was reached **(*Observer:* Please use 24 hr clock)**				
Q627: If action line reached on partograph, was any <u>definitive</u> action taken?	**1**	**0**	**8**	**No/DK → Q630**
Q628: Record time action was taken *(observer: enter 99:99 if unknown)* **(*Observer:* Please use 24 hr clock)**				
Q629: What definitive action was taken:	**Code**			
Consult with specialist	**1**			
Refer to other facility for specialist	**2**			
Prepare for assisted delivery	**3**			
Prepare for c-section	**4**			
Other (specify_____)	**6**			

FOR THE FOLLOWING QUESTIONS: EXAMINE PARTOGRAPH AND/OR CHART TO DETERMINE THE FOLLOWING INFORMATION. IF THE INFORMATION IS NOT IN THE CHART OR PARTOGRAPH, BUT THE OBSERVER KNOWS THE INFORMATION OR PREVIOUSLY RECORDED THE INFORMATION IN ANOTHER SECTION, HE OR SHE SHOULD FILL IN THEIR OWN ANSWER. IF THE INFORMATION IN THE CHART OR PARTOGRAPH DIFFER FROM OBSERVER'S INFORMATION, USE OBSERVER'S INFORMATION.

Q630: Record age of woman	
Q631: Record the gravidity of the woman	
Q632: Record the parity of the woman <u>prior to this delivery</u>	
Q633: Time of admission to labor ward *(observer: enter 99:99 if unknown)* **(*Observer:* Please use 24 hr clock)**	
Q634: Centimeters dilated upon admission to labor ward *(observer: enter 99 if unknown)*	

Q635: Time membranes ruptured *(observer: enter 99:99 if unknown)*	
(*Observer:* Please use 24 hr clock)	
Q636: How did the membranes rupture?	**Code**
Spontaneous	**1**
Artificial	**2**
Q637: Type of delivery	
Spontaneous vaginal	**1**
Assisted (vacuum)	**2**
Caesarean	**3**
Q638: Time of birth *(observer: enter 99:99 if unknown)*	
(*Observer:* Please use 24 hr clock)	
Q639: Birth weight in grams *(observer: enter 9999 if unknown)*	
Q640: Record gestational age at birth in weeks*(observer: enter 99 if unknown)*	

Question	Yes	No	DK	Go to
Q641: Was she diagnosed with severe PE/E?	**1**	**0**	**8**	**No→ Q643**
Q642: Was baby delivered within 24 hours of PE/E diagnosis?	**1**	**0**	**8**	
Q643: Did the mother have blood loss more than 500mL?	**1**	**0**	**8**	**No→ Q645**
Q644: Was she diagnosed with postpartum hemorrhage?	**1**	**0**	**8**	
Q645: Did the mother develop a fever of 38° C or higher during labor?	**1**	**0**	**8**	**No→ Q647**

Q646: Was she diagnosed with chorioamnionitis during labor?	**1**	**0**	**8**	
Q647: Were antibiotics administered to mother at any time?	**1**	**0**	**8**	**No/DK → Q651**
Q648: When were antibiotics administered? (CIRCLE ALL THAT APPLY)	**Code**			
1st stage	**A**			
2nd stage	**B**			
3rd stage	**C**			
Postpartum	**D**			
Q649: Why were antibiotics administered? (CIRCLE ALL THAT APPLY)				
Treatment for chorioamnionitis	**A**			
After prelabor rupture of membranes	**B**			
Preparation for C-section	**C**			
Routine/prophylactic	**D**			
Third stage/postpartum procedure	**E**			
Don't know	**Z**			
Q650: Which antibiotic was administered? (CIRCLE ALL THAT APPLY)				
Penicillin	**A**			
Ampicillin	**B**			
Gentamicin	**C**			
Metronidazole	**D**			
Cephalosporin	**E**			
Other	**X**			
Don't know	**Z**			
Question	**Yes**	**No**	**DK**	**Go to**
Q651: Is mother HIV positive? ***(observer: circle Don't Know if status is unknown or was not discussed)***	**1**	**0**	**8**	**No/DK → Q654**
Q652: Was newborn given ARV(s)?	**1**	**0**	**8**	**No/DK → Q654**

Q653: Record type of ARV(s) given to newborn	Code
NVP	1
AZT	2
3TC	3
Don't know	8

For data entry use only Tool ID#

ANNEX E: Clinical simulation tool
Tool 3: Clinical case studies for Health Workers
Evaluation of a Facility-based scale-up of the HBB Initiative

Cover Sheet			
H1: Facility name		H2: Facility number	|__C/I__|____|____|____|
H3: Observer number	|____|____|	H4: Today's date DD/MM/YY	|__D__|__D__|__M__|__M__|__Y__|__Y__|
H6: Health worker line number (from worker listing tool 1A colmn 1)	|___|___|	H7: Sex of health worker	Male 1 Female 2

Case Scenario 1

Instructions to the Observer:

HAND OVER THE NEONATALIE AND OTHER EQUIPMENT TO THE HEALTH WORKER. IF THE HEALTH WORKER IS NOT FAMILIAR WITH THE NEONATALIE MODEL AND RESUSCITATION EQUIPMENT, IDENTIFY EACH PIECE OF EQUIPMENT AND ALLOW THE HEALTH WORKER TO EXAMINE THE MODEL THOROUGHLY. EXPLAIN HOW THE MODEL WORKS (E.G., THE CHEST WILL RISE WHEN THERE IS A PROPER SEAL WITH THE BAG AND MASK, ETC.). THEN READ ALOUD TO THE HEALTH WORKER THE FOLLOWING INSTRUCTIONS:

READ ALOUD TO THE HEALTH WORKER THE FOLLOWING INSTRUCTIONS AND THE CASE. PROVIDE PROMPT WHERE SHOWN IN UNDERLINE. AS YOU OBSERVE THE WORKER, TICK THE BOXES "DONE" OR "NOT DONE" FOR EACH ACTIVITY. INDICATE THE BABY'S RESPONSE TO THE HEALTH WORKER'S ACTIONS USING THE NEONATAL SIMULATOR OR WORDS IF USING A MANNEQUIN. FOR EXAMPLE, WHEN THE WORKER EVALUATES CRYING, SHOW OR SAY THAT THE BABY IS NOT CRYING.

Observer: PLEASE READ: "I am going to read a role play case. Please listen carefully, and then show me the actions you would take. I will indicate the baby's response with the stimulator (or in words), but I will provide no other feedback until the end of the case."

"you are called to assist the delivery of a term baby. There are no complications in the pregnancy. The baby will be born in less than 10 minutes. Introduce yourself and prepare for the birth and care of the baby. If particular equipment is not available, explain the action in words"

A. Prepares for birth

	Done (1)	Not Done (0)
1. Identify a helper	☐	☐
2. Makes an emergency plan	☐	☐
3. Prepares the area for delivery	☐	☐
4. Cleans hands and maintains clean technique throughout	☐	☐
5. Prepares an area for ventilation	☐	☐
6. Checks equipment	☐	☐

B. Keeps baby warm

Prompt for observer: After 5-7 minutes give baby to worker and say, "The amniotic fluid is clear. Show how you will care for the baby."

1. DRIES THOROUGHLY	☐	☐
2. Removes wet cloth	☐	☐
3. Covers baby with dry cloth	☐	☐

C. Evaluates crying

Prompt for observer: Show or say the baby is not crying.

1. **RECOGNIZES BABY IS NOT CRYING**	☐	☐

D. Clears airway and stimulates breathing

1. **POSITIONS HEAD AND CLEARS AIRWAY**	☐*	☐
2. Stimulates breathing by rubbing the back	☐	☐

E. Evaluates breathing

Prompt for observer: Show or say the baby is breathing well.

1. Recognizes baby is breathing well	☐	☐
2. Clamps or ties and cuts the cord	☐	☐

3. Position skin-to-skin on mother's chest ☐ ☐

4. Communicates with mother ☐ ☐

SCORING:

Please add together the number of activities/ steps that were done and write it in the space below.

Number Done Correctly |____|____|
Observer's code |____|____|

Annex F: Summary of tools, sample size, analysis methods and inclusion criteria per study objective

Objective(s)	Tool(s) used	Sample size	Analysis method(s)	Inclusion criteria
Validation of simulation against DCO	• Health worker interview tool • Direct observation tool • Clinical simulation tool	n=85 health workers;	Calculation of sensitivity/specificity/positive predictive value	Health workers had to have linked data between clinical simulation tool and direct clinical observation tool (linked ID#) (2 tools)
Measurement of consistency of performance	• Health worker interview tool • Direct observation tool	n=77 health workers n=576 DCOs	Calculation of coefficient of variation to measure within health worker variation in performance Intracluster correlation coefficient to measure item-wise performance variation (calculated with a two-level random effects logistic regression model) Two-level random effects Poisson regression model to assess the relationship between DCO scores and health worker characteristics Linear regression model to assess the relationship between health worker's CV score and health worker characteristics Logistic regression model to assess the relationship between the odds of being a consistently good performer and health worker background characteristics	Health workers had to have linked data between health worker interview tool and direct clinical observation tool (3 tools)
Prevalence of respectful maternity care	• Direct observation tool	n=2109 (3rd stage of labor) n=208 (1st /2nd stage of labor)	Proportion of observations in which an item was observed Bivariate analysis (using logistic regression, with vce(cluster) option on health worker ID to assess the association between a single predictor variable and the odds of provision of an item Bivariate analysis (using	All observations were included for each stage (3rd stage of labor and 1st/2nd stage of labor) Missing data per some observation items resulted in different denominators per item rather than excluding the entire observation

			logistic regression, with vce(cluster) option on health worker ID to assess the association between multiple predictor variables and the odds of provision of an item	
Development of RMC DCO scale	• Direct observation tool	n=173 observations	Kaiser-Meyer-Olkin measure of sampling adequacy Bartlett's test of sphericity Factor analysis using principle component factor extraction method Calculation of internal consistency reliability	Observations had to have complete data for all items to be assessed in scale

ANNEX G: Excerpt from Malawi National Reproductive Health Service Delivery Guidelines (2014-2019)

Malawi Ministry of Health

pp. 70-72

Respectful Maternity Care

Introduction

In every country and community worldwide, pregnancy and childbirth are momentous events in the lives of women and families and represent a time of intense vulnerability. The concept of "safe motherhood" is usually restricted to physical safety, but childbearing is also an important rite of passage, with deep personal and cultural significance for a woman and her family. Because motherhood is specific to women, issues of gender equity and gender violence are also at the core of maternity care. Thus, the notion of safe motherhood must be expanded beyond the prevention of morbidity or mortality to encompass respect for women's basic human rights, including respect for women's autonomy, dignity, feelings, choices, and preferences, including companionship during maternity care.

A woman's relationship with maternity care providers and the maternity care system during pregnancy and childbirth is vitally important. Not only are these encounters the vehicle for essential and potentially lifesaving health services, women's experiences with caregivers at this time have the impact to empower and comfort, or to inflict lasting damage and emotional trauma, adding to or detracting from women's confidence and self-esteem. Either way, women's memories of their childbearing experiences stay with them for a lifetime and are often shared with other women, contributing to a climate of confidence or doubt around childbearing.

Growing Evidence of Disrespect and Abuse

Disrespect and abuse of women seeking maternity care is becoming an urgent problem and creating a growing community of concern that spans the domains of health care research, quality, and education; human rights; and civil rights advocacy.

Categories of Disrespect and Abuse

1. Physical abuse
   Hitting, slapping, pushing, or even roughly touching a woman is physical abuse. All physical contact with our patients should be as gentle, comforting, and reassuring as possible. Freedom from physical abuse is the right of each of our patients.
2. Non-consented care
   Language use and level, educational attainment, and cultural background may vary among our patients. All need careful explanation of proposed procedures in a language and at a level they can understand so that they can knowingly consent to or

refuse a procedure. The freedom to consent to or refuse care is the right of each of our patients.

3. Non-confidential care
   Patients have a right to privacy and confidentiality during the delivery of services. This includes privacy and confidentiality during counselling, physical examinations, and clinical procedures, as well as in the staff's handling of patients' medical records and other personal information.
4. Non-dignified care
   Dignity, comfort, and expression of opinion: All patients have the right to be treated with respect and consideration. Service providers need to ensure that patients are as comfortable as possible during procedures. Patients should be encouraged to express their views freely, even when their views differ from those of service providers. Service providers also need to ask the patient for feedback.
5. Discrimination
   All women are equally worthy of our respectful care regardless of ethnic background, culture, social standing, educational level, or economic status. Non-discrimination is the right of each of our patients.
6. Abandonment of care
   A woman in labour or immediately after birth should never be left alone. If you must leave your patient, tell her when to expect your return and how to get help if needed. Attentive care is the right of each of our patients. Women should be able to have a companion of their choice, such as a family or community member, with them throughout labour and birth at the health facility to provide continuous support.
7. Detention in facilities
   A woman or her baby should never be forcibly kept in a facility. Freedom from detention is the right of each of our patients.

Impact of Disrespectful Maternity Care on Safe Motherhood

Reviewed studies suggest that fear of disrespect and abuse may sometimes be a more powerful deterrent to the use of skilled birth care than geographic and financial obstacles. Disrespect and abuse during childbirth is a violation of human rights.

Table 8-1. Categories of Disrespect/Abuse and Corresponding Rights

CATEGORY OF DISRESPECT AND ABUSE		CORRESPONDING RIGHT
1.	Physical abuse	Freedom from harm and ill treatment
2.	Non-consented care	Right to information, informed consent, and refusal, and respect for choices and preferences, including companionship during maternity care
3.	Non-confidential care	Confidentiality, privacy
4.	Non-dignified care (including verbal abuse)	Dignity, respect
5.	Discrimination based on specific attributes	Equality, freedom from discrimination, equitable care

CATEGORY OF DISRESPECT AND ABUSE		CORRESPONDING RIGHT
6.	Abandonment or denial of care	Right to timely health care and to the highest attainable level of health
7.	Detention in facilities	Liberty, autonomy, self-determination, and freedom from coercion

ANNEX H: Curriculum Vitae

Reena Sethi

Education:

The Johns Hopkins University, Bloomberg School of Hygiene and Public Health, Baltimore, MD

Doctor of Public Health, Department of International Health (2015)

Dissertation: The measurement of the quality of maternal and newborn care: Comparative analysis of health provider performance measurement methods and an exploration of evidence of respectful maternity care in Malawi

Master of Health Science, Department of International Health, Division of Disease Prevention and Control

Master's Thesis: High-Dose Postpartum Vitamin A Supplementation: Past Strategies, Current Policies, and Future Approaches for Delivering Vitamin A to Lactating Women in Indonesia

Oberlin College, Oberlin, OH

Bachelor of Arts degrees in Biology and Third World Studies

Professional Experience:

Jhpiego Corporation, Baltimore, MD

Senior Monitoring and Evaluation Advisor
01/13-Present
Monitoring and Evaluation Advisor
10/08-01/13

- Assist Jhpiego staff in the development, implementation, and quality assurance for monitoring and evaluation systems and activities
- Support Jhpiego's program implementation with data-based program decision-making, and prepare results reporting
- Work collaboratively with key Global Program Operations staff in developing program planning that includes M&E scopes of work, budgets, timelines, and level of effort requests
- In collaboration with program and field staff, ensure that necessary M&E planning, budgeting and management activities occur to facilitate smooth and efficient program and evaluation functioning, including the development of research proposals, protocols, data collection tools, and IRB submissions
- Provided M&E support to the USAID-funded MCHIP Program focusing on maternal and child health and malaria in pregnancy in Rwanda, India, South Africa, South Sudan, Malawi and Afghanistan; supported CDC-funded pre-service HIV education project in Botswana and ExxonMobil-funded malaria in pregnancy project in Angola
- Oversaw data collection for malaria in pregnancy assessment in Senegal, analyzed results and wrote report; organized endline facility survey for ACCESS Program in Rwanda; collaborated on evaluation of Jhpiego's QI approach for maternal health services in Afghanistan; on evaluation of Helping Babies

Breathe program in Malawi; on WHO Safe Birth Checklist in India; on Quality of Care Survey in Kyrgyzstan

- Supported USAID Saving Lives at Birth Grant for evaluation of postpartum IUCD model in Pakistan; supported studies in India and the Philippines for evaluation of postpartum IUD services and in India and Mozambique for postpartum systematic screening; developed protocol and tools for evaluation of HIV B+ option in South Sudan; PI for study on postpartum IUDs in the Philippines
- Headquarters M&E lead for a four country Gates supported implants project; Assisted with the development of evaluation plan for evaluation of USAID-funded EMAS project in Indonesia
- M&E backstop for Jhpiego's Myanmar programs; assisted with development of malaria in pregnancy assessment
- Team leader for CDC funded needs assessment on PLWHA in Botswana; oversaw data collection, analyzed data and wrote final technical report
- M&E backstop for the Jhpiego Malaria Core Team and for the Maternal Child Survival Project (MCSP) WASH team

University Research Company, LLC. (URC), Bethesda, MD
6/07-9/08

Project Director for URC's Indefinite Quantity Contract for Global Fund's Data Quality Audits

Program Associate, International Development Group

- Wrote the winning proposal for URC's IQC to implement The Global Fund's Data Quality Audit tool; served as Project Director
- Wrote the winning proposal and assisted in the project start-up activities for a newly awarded USAID project on Malaria Prevention and Control Activities in Cambodia by developing work plan , M&E plan and designing baseline tools in collaboration with numerous stakeholders, including USAID/RDM/A, USAID/Cambodia, WHO, and Cambodia's National Malaria Control Program
- Designed assessment tool to conduct a situational analysis of the malaria situation in 3 provinces on the Thai-Cambodia border
- Used technical knowledge and skills to develop and lead proposals from USAID, CDC, GFATM, and others in the following areas: behavior change communication, social marketing, HIV/AIDS, malaria, tuberculosis, reproductive health, maternal and child health, health policy, private sector partnerships, and other health development activity areas
- Led the writing and coordination of specific parts of domestic and international proposals, including technical, corporate capability, staffing, and past performance components
- Worked closely with Director of Program Development and other Division Directors and prepared and presented internal briefings on selected topical research on opportunities for expansion
- Managed the processes needed to gather strategic information and planned outreach campaigns to clients and collaborators

Macro International/Casals & Associates, Calverton, MD
3/04- 6/07

Research Associate/Biomarker Specialist -MEASURE DHS/MEASURE Evaluation Projects

- Collaborated in the development of HIV testing and anemia testing guidelines for population-based surveys
- Trained health technicians in taking height and weight measurements, in blood collection for HIV (in the form of dried blood spots) and anemia for the Ethiopia Demographic and Health Survey, Zimbabwe Demographic and Health Survey, and India National Family Health Survey (large-scale population-based surveys)

• Assessed the capacity of national laboratory in Ethiopia (EHNRI) to conduct HIV testing on dried blood spots
• Forecasted supply distribution for field work in Ethiopia and Zimbabwe
• Supervised interviewer teams during field work in Ethiopia, Zimbabwe, and India
• Provided administrative support for Secretariat of the Roll Back Malaria Monitoring and Evaluation Reference Group, managed Roll Back Malaria's Malaria M&E listserv, and updated RBM MERG's website
• Received training in malaria diagnosis through microscopy and PCR
• Reviewed DHS questionnaires and Malaria Indicator Survey (MIS) questionnaires for the collection of household, and women's and men's health and demographic data, prepared powerpoint presentations as necessary, conducted literature searches, gathered and compiled DHS data, created factsheets, press releases, publication notices, and other materials for dissemination of DHS data; assisted in development of published reports and papers

Institute of Human Virology, University of Maryland, Baltimore, MD
10/03-3/04

Research Associate-Division of Epidemiology and Prevention

• Supported the management and field implementation of epidemiological and clinical trials research internationally—specifically on an R21 study to determine the incidence and serodiversity of HIV in 5 sites in the Caribbean (Jamaica, Trinidad, Haiti, the Dominican Republic, and Puerto Rico)
• Assisted in the management of the HIV Vaccine Trials Network (HVTN) Training Program
• Edited and prepared technical reports, scientific research papers, and oral presentations related to the Division's research program
• Reviewed and collated scientific literature for citations for the Division's research program

Maryland Department of Health and Mental Hygiene, Baltimore, MD
4/03-10/03

Epidemiologist-Office of Local Health

• Provided support to the Office of Local Health Regional Planning Coordination staff for bioterrorism preparedness assessment, surveillance, evaluation, and related database development and management
• Designed framework for health status monitoring and program evaluation for the Office of Local Health
• Developed measurable standards and outcome indicators as needed for health status benchmarking, health disparities monitoring, and related program evaluation
• Developed and oversaw data collection and analysis of multiple databases
• Generated output in form of graphs, tables, maps, and other displays and compiled output into health status chartbook and for other reports, including bioterrorism grant accountability and webpages

Social and Scientific Systems, Silver Spring, MD
5/02-4/03

Laboratory Science Specialist—International Laboratory Coordinator

• Researched applicable cultural, legal, logistical, and ethical issues in countries participating in Adult AIDS Clinical Trials Group (AACTG) and Pediatric AIDS Clinical Trials Group (PACTG) clinical trials
• Researched laboratory information (certifications, QA/QC procedures, normal lab values, host country regulatory/IRB requirements, etc.) for sites participating in AACTG and PACTG clinical trials
• Identified impediments to protocol implementation in host countries
• Designed, developed, and maintained a database of international program information
• Coordinated and supported Laboratory Group activities

Helen Keller International, Jakarta, Indonesia
7/01-12/01
Researcher, Vitamin A Program
- Conducted comprehensive literature review of international research activities related to postpartum maternal vitamin A supplementation, food fortification, nutrition education, and home gardening
- Developed the report into a policy briefing for the Ministry of Health of Indonesia

Maryland Department of Health and Mental Hygiene, Baltimore, MD
5/99-5/00
Laboratory Scientist, Division of Virology
- Catalogued and prepared patient specimens for laboratory testing
- Performed ELISAs, LCR, and cell culture to test patient specimens for Chlamydia and a number of viruses, including Influenza, Hepatitis A, B, and C, Rotavirus, and others
- Analyzed findings and reported results to clients
- Ensured that lab processes and procedures were performed in compliance with QA/QC procedures

Country Experience:

Afghanistan, Angola, Botswana, Cambodia, Ethiopia, India, Indonesia, Malawi, Mozambique, Myanmar, Nigeria, Pakistan, Philippines, Rwanda, Senegal, South Africa, South Sudan, Tanzania, Zambia, Zimbabwe

Relevant Trainings:

Data Quality Audit Tool (DQA), Global Fund and JSI

Malaria Microscopy and RDTs (Paracheck)-NY Department of Public Health

M&E Fundamentals (MEASURE Evaluation)

Biomarker Collection in Population-Based Surveys (MEASURE DHS)

Institutional Review Board (IRB) Training

Good Laboratory Practices (GLP) Training

Project Management Training Certification for NGOs (PMD1)

Studies

Principal Investigator: Assessment of postpartum intrauterine contraceptive device (PPIUD) services in the Philippines

Co-Investigator: The Health Training Institutions (HTI) HIV and AIDS training needs assessment in Botswana

Co-Investigator: Assessment of postpartum intrauterine contraceptive device (PPIUCD) services in India

Co-Investigator: Evaluation of demand side interventions for revitalization of postpartum family planning in Bihar

Co-Investigator: Evaluation of a postpartum systematic screening tool in Jharkhand, India

Co-Investigator: Linking licensure examinations to nursing practice through task analysis – A case for Botswana

Co-Investigator: Strengthening of postpartum FP services in Bihar: An evaluation of demand side intervention

Co-Investigator: Evaluation of a low cost PPIUD simulation model in Pakistan

Co-Investigator: Secondary analysis of data from the Expanding Maternal and Neonatal Survival program in Indonesia

Co-Investigator: Assessment of maternal health clinical services and emergency referrals in selected districts in Indonesia

Co-Investigator: A qualitative assessment of the acceptability and effects of the EMAS Project in Indonesia

Co-Investigator: Evaluation of ModCAL computerized training package for candidate trainers in Kenya

Co-Investigator: An evaluation of a facility-based scale-up of the Helping Babies Breathe intervention in Malawi

Co-Investigator: Assessing the effectiveness of a Safe Birth Checklist in changing provider practices during institutional deliveries in selected facilities in Rajasthan, India

Co-Investigator: Evaluation of a postpartum systematic screening tool in Maputo, Mozambique

Co-Investigator: Assessment of the implementation of the HIV B+ option in selected facilities in South Sudan

Co-Investigator: Assessment of the pilot phase of the SMSBunda Project

Co-Investigator: Assessment of antenatal care, including malaria in pregnancy, in three regions of Myanmar

Publications, reports, posters and presentations

Sethi, Reena. Respectful Maternity Care: Evidence from East and Southern Africa. (2015). Presentation at the Global Health Mini-University. Washington, DC.

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American Evaluation Association: June 2013—

Washington Evaluators: June 2014—

Water, Sanitation and Hygiene (WASH) Working Group: March 2015--