Processes and outcomes of stillbirth and neonatal death audit as a quality improvement tool in the southern region of Malawi

Thesis submitted in accordance with the requirements of the Liverpool School of Tropical Medicine for the degree of Doctor in Philosophy

by

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November 2022

DECLARATION

I, Mtisunge Joshua Gondwe, declare that this thesis: “Processes and outcomes of stillbirth and neonatal death audit as a quality improvement tool in the southern region of Malawi”, is submitted for the degree of Doctor of Philosophy in Global Health of the Liverpool School of Tropical Medicine. This thesis has not been submitted for any other degree or award at this or any other institution. I confirm that this thesis is the result of my own work, and all materials used from other sources have been appropriately acknowledged and referenced in the thesis.

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DEDICATION

I dedicate this work to God Almighty for love, protection, grace and wisdom. May His name receive all the honour and glory forever.

To my dad and mum, your advice, encouragement and reassurance kept me going on the Journey. You have been a greater motivator to my aspirations, and you keep telling me that the sky is the limit.

To my loving, caring, and supportive husband, Mabvuto Baxter Gondwe and my beloved children, Gracious and Glory, your support, sacrifice, encouragement, and prayers at every stage gave me the energy and courage to press on towards achieving this goal. Your understanding that I had left you home and neglected my duties as a wife and a mother helped me achieve this dream.

ACKNOWLEDGEMENTS

I thank the Almighty God for his grace, power, protection and wisdom throughout my PhD journey. It is not by my own understanding or wisdom to achieve this goal but through His grace and mercy.

I am grateful to the Commonwealth Scholarship Commission for the full funding for my PhD programme in the United Kingdom, World Friendship in Liverpool and Malawi Liverpool Wellcome Trust training committee for additional financial support towards my fieldwork in Malawi.

I would like to extend my sincerest gratitude and appreciation to my supervisory team Prof. Stephen Allen (primary supervisor), Dr Mamuda Aminu, Dr Nicola Desmond and Progress Assessment Panel members, Dr Joanna Raven and Dr Florence Mgawadere, for their tremendous support, timely feedback, advice and constructive criticism during my PhD research work. Their expertise, guidance, and support contributed to completing this research work and thesis. Special gratitude goes to Prof. Stephen Allen, who kept on inspiring me, provided an opportunity for career growth and checked on my wellbeing in all aspects of life throughout my study. You have not only been a supervisor but a great motivator, mentor and even a father. My study journey has been smooth and healthy due to your support.

I am also grateful to Malawi Liverpool Wellcome Trust, Clinical Research Programme through core grant 206545/Z/17/Z, the director and supporting departments and colleagues for providing a supportive and enabling environment during my field work in Malawi. Special thanks go to Prof. David Lissauer for hosting me in the Maternal and Fetal Health group at MLW and providing an opportunity for career growth and Prof. Henry Mwandumba for support to secure a school placement at LSTM and encouragement. Many thanks to Mtundu Khongono for support during field work.

I would also like to say thank you to the PGR team Charlotte Blakeburn and Richard Madden, Ismaela Abubakar from the Clinical Trials Unit, my officemates, Helen Wong, Tracy Seddon, Julie Franco and Cheryl Giddings and my colleagues, Adama Ladu, Lilian Boateng,

Doreen Sakala and Wezzie Lora at the Liverpool School of Tropical Medicine and Juwo Lwesya Sibale from the University of Liverpool for their support.

Special thanks go to all participating hospital management teams and all staff who took part in this research. I would also like to thank Hendrina Kaliati, Emily Joshua, Lophina Sitima and Thokozire Joshua for assisting with the research work.

Finally, my special and heartfelt gratitude goes to my dad and mum Mr and Mrs Joshua, my father and mother In-law, Mr and Mrs Gondwe, my brothers Geresom, Mphatso and Mtendere, my sisters, Rebecca, Ruth, Chimwemwe, Tiyamike and Emily, my niece Thokozani, my in-laws Lusungu and Martha and my best friends Eluby and Fanny for their support and encouragement during my studies.

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LIST OF ABBREVIATIONS

ANC	Antenatal care
CBR	Crude Birth Rate
CI	Confidence Interval
CD4	Cluster Differentiation 4
CDR	Crude Death Rate
CHAM	Christian Organisation of Malawi
COIN	Care of Infants and Newborn
COM-B	Capability Opportunity Motivation Behaviour
CPAP	Continuous Positive Airway Pressure
DAMA	Data Management Association
DHMT	District Health Management Team
DHIS 2	District Health Information Software 2
DHO	District Health Officer
DOI	Diffusion of Innovation
ENAP	Every Newborn Action Plan
ENC	Essential Newborn Care
FGD	Focus Group Discussion
HBB	Helping Babies Breathe
HBM	Health Belief Model
HDI	Human Development Index
HMIS	Health Management Information System
HAS	Health Surveillance Assistant
ICD	International Classification of Diseases
IDI	In-depth Interview
IMNC	Integrated Maternal and Neonatal Care
ISS	Integrated Support Supervision
KMC	Kangaroo Mother Care
LBW	Low Birth Weight
LMIC	Low and Lower-Middle-Income Country
LSTM	Liverpool School of Tropical Medicine
MDSR	Maternal Death Surveillance and Response
MPDSR	Maternal Perinatal Death Surveillance and Response
MOH	Ministry of Health
MPs	Members of Parliament
MUSIQ	Model of Understanding Success in Quality
NMR	Neonatal Mortality Rate
NSO	National Statistical Office
PDSR	Perinatal Death Surveillance and Response

PIPP	Perinatal Identification Problem Programme
PNC	Postnatal Care
QECH	Queen Elizabeth Central Hospital
QI	Quality Improvement
QIST	Quality Improvement Support Team
QMD	Quality Management Directorate
QoC	Quality of Care
RCT	Randomised Controlled Trial
RECORD	Reporting of studies Conducted using Observational Routinely-Collected Health Data
RMNCH	Reproductive Maternal Neonatal and Child Health
SBR	Stillbirth Rate
STC	Social Cognitive Theory
SDGs	Sustainable Development Goals
SEM	Social Ecological Model
SMART	Specific Measurable Achievable Realistic and Time Bound
SPSS	Statistical Package for the Social Science
SSA	Sub-Saharan Africa
TA	Traditional Authority
TPM	Theory of Planned Behaviour
TRF	Total Fertility Rate
TTM	Transtheoretical Model
UK	United Kingdom
UN IGME	United Nations Inter-Agency Group for Child Mortality Estimation
WHO	World Health Organization
WIT	Work Improvement Team
WRA	Women of Reproductive Age
ZHSO	Zonal Health Support Office

PUBLICATIONS AND SUBMISSIONS

Paper	Chapter	Title	Publication status
1	2	Literature Review-Approaches, enablers, barriers and outcome of implementing stillbirth and neonatal death audit in LMICs: a systematic review	Published in BMJ Open Quality-Open access
2	4	Resources available and barriers to delivering quality care for newborns in health facilities in the southern region of Malawi: a multisite observational study	Submitted to PLOS Global Public Health
3	5	Quality of stillbirth and neonatal death audit in Malawi: a descriptive observation study	Published in the Journal of Clinical Pediatrics and Neonatology-Open access
4	6	Factors impacting on stillbirth and neonatal death audit in Malawi: a qualitative study	Published in BMC Health Services Research Journal-Open access

DEFINITION OF TERMS

1. **Stillbirth (fetal death)**: is defined as a baby born dead at ≥28 weeks of gestation, or with a birth weight of ≥1000 grams, or a body length of ≥35cm (WHO., 2016b).
2. **Antepartum stillbirth (macerated stillborn)**: is defined as a death of a fetus before the onset of labour characterised by skin changes and peelings (WHO., 2016b).
3. **Intrapartum stillbirth (fresh stillborn)**: is defined as a death of a fetus which occurs after the onset of labour but before birth (Lawn *et al.*, 2016b).
4. **Neonatal death:** refers to a death of a baby within the first 28 days of life (WHO., 2016a).
5. **Early neonatal death**: refers to a death of a baby within the first seven days of life.
6. **Late neonatal death**: refers to a death of a baby between 7—28 days of life (WHO., 2016a).

   Perinatal death: refers to fetal death occurring between 28 completed weeks of gestation to term or newborn death within the first week of life (stillbirth and early neonatal mortality) (WHO., 2016a).

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ABSTRACT

Title: Processes and outcomes of stillbirth and neonatal death audit as a quality improvement tool in the southern region of Malawi

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Stillbirth and neonatal death audits are suggested interventions to help meet the Sustainable Development Goals of reducing stillbirth and neonatal mortality. Many interventions aimed at improving treatment do not achieve their desired change, with few efficiently implemented and sustained due to health system constraints such as poor infrastructure, insufficient resources and poor leadership. To address these gaps, I assessed the quality, facilitators and barriers associated with stillbirth and neonatal death audit processes in seven public hospitals in Malawi. The ultimate goal was to provide evidence for recommendations on how the health system may better support staff so that the audit process can be improved.

The research approaches were guided by a conceptual framework which I developed based on health system strengthening, quality improvement theories, and a systematic literature review. I tested the framework in practice through three cross-sectional descriptive studies to evaluate its strengths and limitations.

In a systematic literature review, I evaluated ten studies from low and lower middle-income countries (LMICs) that implemented stillbirth and neonatal death audits. I found that audits improved structure, process and health outcomes in maternal and neonatal care. I identified 18 enablers and 23 barriers with the majority identified at the health provider and facility levels.

The first study assessed the resources available for neonatal care. I discovered that the hospitals' ability to provide newborn care was universally low due to inadequate Infrastructure, staff training, medications and supplies, clinical protocols and leadership support. The second study assessed the quality of stillbirth and neonatal death audits and discovered that they were of poor quality due to challenges in audit tools and guidelines, WHO audit cycle stages, action plans and patient load. In the last study, I used the conceptual framework to identify facilitators and barriers at system levels to performing death audits in practice. I discovered that the elements that influence staff engagement in audit meetings and the implementation of recommended solutions were interrelated.

In my research, I discovered that a number of structure and process factors contribute to low-quality audits. Rather than simply gathering information, I have emphasised that facility audits should aim at improving practice. This can be accomplished by implementing suggested actions and evaluating the process. However, this will only be possible if facility and national leadership provide adequate support in terms of resources, supervision and guidelines. A comprehensive approach guided by behavioural theory that tackles variables at all system levels is more likely to be successful. The findings contribute to the evidence base required to develop strategies that ensure the audit cycle is completed and contributes effectively to improving patient outcomes. The conceptual framework was deemed to be suitable for use in the Malawi context and should now be tried in other facilities across Malawi, as well as in other LMICs.

CHAPTER 1: INTRODUCTION

1.1 Chapter Overview

Reducing stillbirths and neonatal deaths is a global agenda to end preventable deaths by achieving the national target of 12 or fewer stillbirths and neonatal deaths by 2030 (World Health Organization, 2014). Despite implementing evidence-based interventions to promote maternal, perinatal and neonatal care, facility quality of care in Malawi falls significantly short of global evidence-based care standards despite these standards being both accessible and widely utilised (Leslie *et al.*, 2016). This likely contributed to the high number of stillbirths and significant neonatal morbidity and mortality in the country (National Statistical Office (NSO) [Malawi] and ICF Macro, 2017). Further research is required to understand how to improve the quality of perinatal and neonatal care especially for vulnerable groups in whom most perinatal and neonatal deaths occur. WHO has recommended auditing stillbirths and neonatal deaths by capturing necessary information on all births and deaths and a more in-depth analysis of the critical factors involved in selected cases to identify and implement ways to improve the quality of maternal and newborn care. Despite some Sub-Saharan Africa (SSA) countries conducting stillbirth and neonatal death audits, it is unclear whether the data collected were linked to improved quality of perinatal and neonatal care considering the high numbers of deaths in facilities (Lusambili *et al.*, 2019).

There are few published studies on perinatal and neonatal death audits in SSA (Sandakabatu *et al.*, 2018) and most have focused on describing causes of death and modifiable factors rather than describing the process of implementing the change or documenting the effect of death audit on service use and maternal or newborn health outcomes (Nakibuuka *et al.*, 2012). Interventions in healthcare facilities need to extend beyond clinical micro-systems and engage in system improvements for long-term sustainability (Kruk *et al.*, 2018). Clinical micro-system refers to a small group of professionals who collaborate regularly or as needed to provide care to patients in clinical units, departments and wards (Likosky, 2014). It is important to understand how, when and why health workers change (or do not change) their practice including as a response to the findings of stillbirth and neonatal death audits.

Using a conceptual framework, this thesis evaluates the quality of stillbirth and neonatal

death audit, and the facilitators and barriers to conducting audits, in seven public health facilities in the southern region of Malawi. It focuses on the resources available to support appropriate care for newborns, the quality of stillbirth and neonatal death audit process according to WHO guidelines and facilitators and barriers in implementing stillbirth and neonatal death audit. In this chapter, the background and rationale for this work presented in this thesis are outlined. The chapter ends with presentation of the conceptual framework, aims, objectives and structure of the thesis.

1.2 Background

1.2.1 Burden and trends of stillbirths and neonatal deaths

Each year, an estimated 2.0 million babies are stillborn (uncertainty range 1.9- 2.2 million), and more than 2.4 million babies die within 28 days of birth (uncertainty range 2.3- 2.7 million) (UN IGME, 2020a; UN IGME, 2020b). The highest mortality burdens are seen in low - and lower-middle-income countries (LMICs), with the two regions, SSA and Central and Southern Asia, contributing about 84% of all stillbirths and almost 80% of all neonatal deaths (Blencowe *et al.*, 2016; Lawn *et al.*, 2016a; UN IGME, 2021; UN IGME, 2020b). Almost half of all global under-five deaths in 2020 were attributed to newborn deaths (UN IGME, 2021). According to the National Statistical Office (NSO) [Malawi] and ICF Macro (2017), Malawi significantly contributes to global stillbirth and neonatal deaths, with an estimated 1 in every 48 babies being stillborn or dying within the first seven days of life (perinatal deaths) and 1 in every 37 children dying in the first month of life (neonatal deaths). About 43% of all under-five deaths in Malawi in 2016 were newborn deaths (National Statistical Office (NSO) [Malawi] and ICF Macro, 2017). The greatest burden is also experienced by families yet many prenatal and newborn outcomes still rely on common data systems, such as household survey data and modelling adjustments, leaving most outcomes unaccounted for (Lawn *et al.*, 2016a).

Despite widespread consensus on terminology, there are regional variances, with high-income countries generally differing from low- and middle-income countries (Lawn et al., 2016). For purposes of international statistical comparison, stillbirth is defined as a baby born dead at ≥28 weeks of gestation, or with a birth weight of ≥1000 gram, which is in line

with the international Classification of Diseases (WHO., 2016b). The International Classification of Diseases (ICD) advises collecting data on all babies born dead with a birthweight of 500 g or more. However, where birthweight is unknown, the ICD suggests using a gestational age threshold of 22 weeks or more for recording and 28 weeks or more for international comparison (WHO., 2016a).While review of the terminology is underway, the use of gestational age at birth rather than weight is preferred especially in LMICs where weighing may be limited (World Health Organization, 2018; Blencowe *et al.*, 2016). Stillbirths can be further differentiated into antepartum stillbirths (macerated stillborn) and intrapartum stillbirths (fresh stillborn). Antepartum stillbirth refers to a death of a fetus before the onset of labour characterised by skin changes and peelings (WHO., 2016b). Intrapartum stillbirth refers to the death of a fetus during labour and childbirth with no maceration or skin changes (Lawn et al., 2016). However, a study conducted in Ghana and a recent Every Newborn– Birth Indicators Research Tracking in Hospitals (EN-BIRTH) multi-country validation study found that use of fresh or macerated stillbirth appearance was a poor proxy for timing of stillbirth as it underestimated intrapartum stillbirths. In order to accurately identify true intrapartum stillbirths, the study recommended measuring, recording, and using the presence of fetal heart sounds as a standard of care (Peven *et al.*, 2021; Gold *et al.*, 2014). About 40 per cent of all stillbirths in 2019 were intrapartum (UN IGME, 2020b). Globally, an estimated stillbirth rate (SBR) has decreased substantially from 21.4 (uncertainty range 20.0-23.7)per 1000 total births in 2000 to 13.9 (uncertainty range 13.5-15.4) in 2019, representing a 35% decrease (UN IGME, 2020b). Despite this significant decrease at the global level, the number of stillbirths stagnated or even increased in many SSA countries, and SBR has decreased by only 23% from 28.1 (uncertainty range 25.5-32.8) to 21.7 (uncertainty range 19.8-24.8) per 1000 total births (UN IGME, 2020b). In Malawi, an estimated SBR has decreased from 22.2 (uncertainty range 17.2-29.0) to 16.3 (uncertainty range 14.7-18.1) per 1000 live births in 2019 (UN IGME, 2020b). This represents only a 26.6 % decrease between the two time periods, which is markedly lower than the 35% global decrease in SBR (UN IGME, 2020b).

Neonatal mortality is defined as a death occurring within the first 28 days of life (WHO., 2016a). Neonatal mortality can be further differentiated into early neonatal deaths (END) occurring within the first seven days of life (WHO., 2016a) and late neonatal deaths (LND)

occurring between the seventh and the 28th day of life (WHO., 2016a). Globally in 2019, an estimated 1 million newborns died on the first day of life, and almost 2 million died in the first seven days of life (World Health Organization, 2020b). The global Neonatal Mortality Rate (NMR) has steadily decreased from an estimated 37 (uncertainty range 36-38) deaths per 1000 live births in 1990 to 17 (uncertainty range 17-19) in 2020, representing a 54% reduction between two time periods (UN IGME, 2021). The SSA region has the highest NMR and a slower decrease from 46 (uncertainty range 44-48) deaths per 1000 live births to 27 (uncertainty range 25-32) in 2020 (41% decrease) than has occurred globally (UN IGME, 2021). With a greater fall in under five deaths outside of the neonatal period, the share of neonatal deaths among under-five deaths in SSA increased from about 26% in 1990 to 38% in 2020; this 46% increase in the share of neonatal mortality among under-5 mortality is alarming (UN IGME, 2021).

In Malawi, neonatal mortality declined from an estimated 42 deaths per 1,000 live births in 2000 to 27 deaths per 1,000 live births in 2004 and has remained at the same level since then (National Statistical Office (NSO) [Malawi] and ICF Macro, 2017). Furthermore, the share of neonatal mortality in under-5 mortality increased from an estimated 22% in 2000 to 43% in 2016, representing an alarming 95% increase in the share of neonatal mortality among under-5 deaths in a specified period (National Statistical Office [Malawi] and ORC Macro, 2001; National Statistical Office (NSO) [Malawi] and ICF Macro, 2017).

Stillbirths and neonatal deaths are also linked to negative psychological impacts on mothers, families, and healthcare professionals as well as to significant direct and indirect economic costs (Heazell *et al.*, 2016). In addition, it can take years and often decades for families to recover from the immediate and long-term effects of losing a baby (Cacciatore, 2013). Fear, shock, numbness, and a desire to "escape" are among the immediate impacts (Trulsson and Rådestad, 2004). While long term impacts include depression, anxiety, obsessive-compulsive behaviours, suicidal ideation, guilt, shame, substance use, marital conflict, and posttraumatic stress that can last for years (Cacciatore, 2013). The health care providers might also experience levels of distress when confronted with sudden deaths such as depression, anxiety, anger, helplessness and nightmares (Halbesleben and Rathert, 2008; West *et al.*, 2006), These experiences may affect patient-provider interaction and communication, which will decrease both patient and provider satisfaction and may

therefore, impact on quality of care (Halbesleben and Rathert, 2008). In a recent study conducted in Ghana and Kenya regarding parents' perceptions about the care and support they received after experiencing a stillbirth, the parents reported that they were deeply shocked, confused and distressed when their baby died (Mills *et al.*, 2021) and while hoping to get compassionate care and support from health providers, barriers like poor communication, environmental restrictions and hospital policies limited such support (Mills *et al.*, 2021). Even their last hope, community support after discharge, proved to be unsupportive with increased stigma that exacerbated their stress, sense of guilty and loneliness (Mills *et al.*, 2021). In a recent systematic review for LMICs, most symptoms of grief that women experience after stillbirth may go unnoticed by healthcare workers or in their communities which might lead to loss of social status. The systemic review suggested that improving the health care system and well-trained staff to support women after the loss and as well as from family and ensuring staff are well-trained to support women after their loss, in addition to support from family and communities, are required to provide better care during bereavement (Shakespeare *et al.*, 2019). According to the Lancet series, stillbirths are overlooked both at global, regional, district, facility and community level with stigma and taboos hiding the burden (de Bernis *et al.*, 2016). To combat the stigma connected with stillbirth, more voices from the community, families and women are required (de Bernis *et al.*, 2016). Parents in a study conducted in United Kingdom endorsed that they would like to participate in perinatal audits and recommendations for parental engagement in perinatal mortality were developed later in a consensus study (Bakhbakhi *et al.*, 2019; Bakhbakhi *et al.*, 2017). Similar interventions should be considered in LMICs where the stillbirth and neonatal death burden is estimated to be high. Given the high rate of stillbirth and newborn mortality, the slow rate of reduction and the psychological, social, and economic impact of stillbirths, I will now discuss the causes and important period during which deaths occur in order to inform actions.

1.2.2 Causes of stillbirth and neonatal deaths

1.2.2.1 Causes of stillbirths and risk factors

Due to a lack of data and comparable death classification systems, it is difficult to generate causes of stillbirths that are globally comparable. However, the available data indicate that about half of stillbirths occur during labour and birth and most result from preventable

conditions Lawn *et al.* (2016a). The commonly reported causes of stillbirth include intrapartum complications (hypoxia), antepartum haemorrhage, infections, maternal conditions and fetal growth restriction (Reinebrant *et al.*, 2018; Aminu *et al.*, 2014; Hoyert and Gregory, 2020).

It is vital to understand the differences in causes, risks and contributing factors associated with stillbirth to improve the quality of care. According to McClure and Goldenberg (2009), the cause of stillbirth refers to a maternal or fetal condition with a probable mechanism likely to have led to the death of the fetus (e.g. maternal diseases, placental condition and congenital abnormalities). A risk factor is either a maternal or fetal characteristic associated with, but not obviously causal for, stillbirth (e.g., maternal age, socioeconomic status). Contributing factors refer to health system factors contributing to a stillbirth (e.g., inadequate staff and poor quality of care).

Due to inadequate prenatal care and resources in LMICs, the causes of stillbirth have been mostly derived from verbal autopsy or clinical symptoms reported by the mother or caregiver (Ahmed *et al.*, 2018). In stillbirth surveillance and review in rural districts of Bangladesh, Halim *et al.* (2018) identified maternal hypertension or eclampsia and antepartum haemorrhage as the most frequent causes of stillbirth accounting for 15.2% and 13.7% respectively. Maternal infection was the third most common cause and accounted for 8.9 % of stillbirths. Similarly, Aminu *et al.* (2014), in their systematic review of 142 studies in LMICs, described maternal diseases (syphilis, hypertensive disorders, positive HIV status with low CD4 count, malaria and diabetes) as frequently reported causes of stillbirth resulting in between 8-50% of deaths. Other reported causes of stillbirth were congenital anomalies (2.1–33.3%), placental causes (7.4–42%), asphyxia and birth trauma (3.1–25%), umbilical problems (2.9–33.3%) and amniotic and uterine factors (6.5–10.7%). However, the studies used different classification systems and a high percentage of stillbirths remained 'unclassified' (3.8–57.4%) (Aminu *et al.*, 2014).

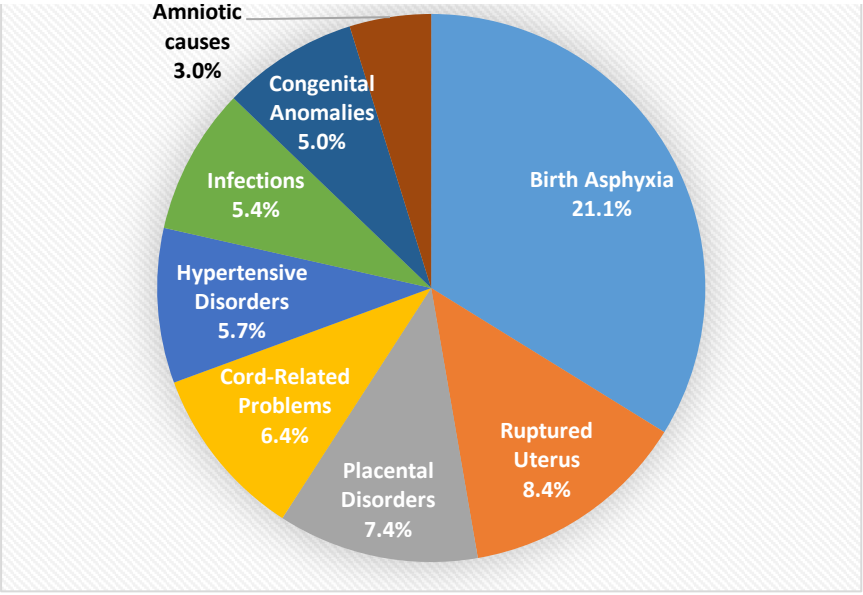
Reported risk factors for stillbirth include maternal factors (age <20 or >35 years, poor nutritional status, history of previous stillbirth, lack of antenatal care, complicated and multiple pregnancies, poverty, high parity and lack of education) (McClure and Goldenberg,

2009; Watson-Jones *et al.*, 2007; Aminu *et al.*, 2014). Fetal risk factors include prematurity, low birth weight and congenital malformations (Aminu *et al.*, 2014).

Studies have also described health system factors contributing to stillbirths. Poor quality of care during birth and suboptimal health systems have been described as significant factors contributing to stillbirths (Darmstadt *et al.*, 2009). In LMICs, quality of health care, lack of access to antenatal care services, poor quality of care during childbirth and delayed caesarean sections are important contributing factors for stillbirth, alongside other factors (Lawn *et al.*, 2009a).

In an observational study conducted at Queen Elizabeth Central Hospital (QECH), Blantyre, Malawi, for 21 months, many stillbirths occurred during the process of labour and birth and a high percentage of early neonatal deaths were due to a complication arising during labour and birth (Metaferia and Muula, 2009). In the prospective observation multi-country study on causes of stillbirths, the major causes of stillbirth in Malawi were birth asphyxia (21.1%), ruptured uterus (8.4%), placental disorders (7.4%), cord-related problems (6.4%), hypertensive disorders (5.7%), infections (5.4%) and congenital anomalies (5.0%) (Figure 1) (Aminu *et al.*, 2019). Improving the quality of care during the antenatal period, labour and birth could reduce mortality.

Figure 1: Causes of stillbirths in Malawi



Source: Aminu *et al.* (2019)

1.2.2.2 Causes of neonatal deaths

The three leading causes of neonatal deaths worldwide are preterm birth complications, intrapartum conditions and infections (Lawn *et al.*, 2014). In a global estimate of causes of neonatal deaths in 2018, preterm birth complications accounted for 35%, birth complications 24%, sepsis 15% and congenital abnormalities 11% (WHO, 2019). A prospective cohort study conducted in 11 community-based research sites in South Asia and SSA reported that perinatal asphyxia (40% of neonatal deaths in South Asia; 34% in SSA), severe neonatal infections (35%; 37%), and complications of preterm birth (19%; 24%) were the most common causes of neonatal deaths (Ahmed *et al.*, 2018). Despite the same leading causes of neonatal death for both the early and late neonatal periods, the distributions of causes differ between these periods. Early neonatal deaths are mostly due to intrapartum-related conditions and preterm birth (Lawn *et al.*, 2014). Oza *et al.* (2015), in their cause of neonatal death estimation study in 165 countries, reported that in the early period, preterm birth and intrapartum complications account for two-thirds of deaths while infections account for 14% of deaths.

In contrast, in the late neonatal period, around a third of deaths are due to preterm birth or intrapartum complications, while almost half are from infections (Oza *et al.*, 2015). Targeting these three causes must be prioritised to reduce neonatal mortality in LMICs. Since approximately 80% of all neonatal deaths occur during the early neonatal period (before seven days of age), this period requires focused attention on prematurity and birth asphyxia— the leading causes of death during that period (UN IGME, 2020a).

In 2015, Malawi had approximately 18,090 neonatal deaths, with prematurity (33%), asphyxia (26%) and sepsis (19%) the leading causes (Government of Malawi, 2015). Similarly, in a case-specific analysis of neonatal deaths in 4 countries, including Malawi, the leading causes in 3 districts of Malawi were: prematurity (29.4%), asphyxia (26.8%) and infection (25.7%) (Fottrell *et al.*, 2015). Recently, there has been a shift in the leading cause of neonatal death in Malawi from prematurity to birth asphyxia. According to a recent situation analysis of causes of neonatal deaths published in the Malawi Child Survival and Health Development document, birth asphyxia (48%), complications of preterm birth (40%) and sepsis (5%) have been listed as the leading causes of neonatal deaths (Government of

Malawi., 2021). Given that preventable intrapartum problems cause the majority of stillbirths and neonatal fatalities during labour and the first week of life, the following section outlines evidence-based measures to improve care quality and reduce mortality.

1.3 Strategies to prevent stillbirths and improve neonatal survival

A systematic literature review on risk for stillbirths in LMICs reported that improving care during antepartum, labour, birth and postpartum could prevent stillbirths and maternal and neonatal deaths (Di Mario, Say and Lincetto, 2007). It is estimated that half of stillbirths occur during labour and birth and most result from conditions which could be prevented with low-cost life-saving interventions and high-quality health care during childbirth (Lawn *et al.*, 2016a; UN IGME, 2020b). Every Newborn Action Plan (ENAP) was developed and endorsed by 194 states in 2014 to guide interventions to improve newborn health and prevent stillbirths by 2035. Its vision is "*a world of no preventable deaths of newborns or stillbirths and that every pregnancy is wanted, every birth celebrated and women, babies and children survive, thrive and reach their full potential*' (World Health Organization, 2014). Its goal is to end preventable stillbirths and newborn deaths. Implementing the plan and achieving its goals and targets could save 3 million lives each year (World Health Organization, 2014). Five strategic objectives have been proposed to achieve the ENAP vision and goal (World Health Organization, 2014). These included strengthen and invest in care during labour, birth and the first day and week of life; improve the quality of maternal and newborn care; reach every woman and newborn to reduce inequities; harness the power of parents, families and communities and count every newborn through measurement, programme-tracking and accountability (World Health Organization, 2014).

A large number of interventions before conception, during pregnancy, during labour and birth, postpartum and after pregnancy have been suggested to prevent stillbirths and newborn deaths (World Health Organization, 2014). These include reproductive health care, family planning, nutrition, management of maternal infection, pregnancy complications, birth preparedness, use of antenatal corticosteroids to manage preterm labour, use of antibiotics for prolonged premature rupture of membranes (PROM), hygienic birth practices and access to safe and high-quality care during labour (UN IGME, 2020b; World Health Organization, 2014). Similarly, In the review of strategies to reduce the global burden of

stillbirths, five interventions that could reduce stillbirths included syphilis screening and treatment, use of insecticide-treated bed nets during pregnancy in malaria-endemic areas, administration of heparin for certain maternal conditions including autoimmune and clotting disorders and emergency obstetric care, including planned caesarean section for breech delivery in settings where access to referral-level care is good (Bhutta *et al.*, 2009).

Every Newborn Action Plan (ENAP) has focused on care packages with the most significant impact on ending preventable neonatal deaths and stillbirths during labour, around birth and the first week of life and caring for the small and sick newborn (World Health Organization, 2014). The labour and birth interventions include skilled care at birth, basic or comprehensive emergency obstetric and newborn care, home birth with skilled care and clean practices and postnatal care, including essential newborn care, care for small and sick newborns and postnatal visits (World Health Organization, 2014). The essential newborn care recommended at primary level facilities include immediate and thorough drying, immediate skin-to-skin contact, delayed cord clamping, skin cleansing and cord care, neonatal resuscitation where required, initiation of breastfeeding in the first one hour and exclusive breastfeeding, routine care (vitamin K, eye care, vaccinations, weighing and clinical examinations) and prevention of mother to child transmission of HIV. Additional procedures include the management and referral for bacterial infections, jaundice, diarrhoea, feeding problems, congenital abnormalities and other problems; pre-discharge advice on mother and baby care and follow up (WHO., 2018). Special newborn care at the secondary level in addition to essential newborn care include thermal care, comfort and pain management, kangaroo mother care, assisted feeding, oxygen or continuous positive airway pressure (CPAP) administration, prevention of apnoea, detection and management of hypoglycaemia, jaundice, anaemia and neonatal encephalopathy, seizure management, fluids administration and follow-up care for high-risk babies (WHO., 2018). Intensive newborn care at the tertiary level includes advanced feeding support, assisted ventilation, surfactant treatment and surgery (WHO., 2018). All these factors should be assessed during the audit process to understand gaps in care and highlight areas for improvement to be implemented after audit.

Malawi has made significant improvements in implementing some of these interventions recommended by WHO. Neonatal tetanus vaccination coverage, intermittent preventive

therapy for malaria in pregnancy, Kangaroo mother care (KMC) for low birth weight babies and neonatal resuscitation using the Helping Babies Breathe algorithm, district level neonatal units and use of Bubble CPAP have been widely introduced (Government of Republic of Malawi, 2017; Government of Malawi., 2021; Government of Malawi, 2015). Despite the implementation of these evidence-based initiatives, the quality of care (QoC) provided to women and newborns in Malawi and other LMICs remains sub-optimal (Leslie *et al.*, 2016; Kruk *et al.*, 2018). The QoC frameworks and gaps in providing quality care are discussed in the sections below.

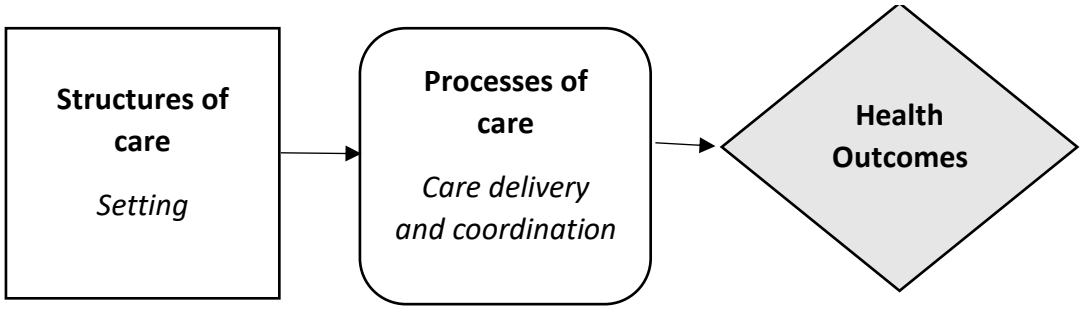
1.4 Quality of care

Quality of care (QoC) is defined as "the extent to which health care services provided to individuals and patient populations improve desired health outcomes. Health care services must be safe, effective, timely, efficient, equitable and people-centred" (Tuncalp *et al.*, 2015). Recently, a focus on QoC has been advocated to attain the SDG 2030 goal of ensuring healthy lives and promoting well-being for all ages. Poor QoC is harmful and wastes resources that could have been used in other sectors to improve the lives of citizens. In a recent review by Kruk *et al.* (2018), providing high QoC in LMICs remains a challenge, and performance varies across providers.

1.4.1 Measures of quality of care

Donabedian (1988) proposed using the triad of structure, process, and outcome to evaluate the quality of health care (Figure 2). The structure component includes the infrastructure, skills, and qualifications of health care professionals and administrative systems to deliver health care. The process encompasses the individual components of care and their interactions. The outcome is recovery, restoration of function, and survival. The model is essential in understanding structural and process factors that may facilitate or hinder quality care in an organisation. These structure and process factors could also affect death audit implementation. The staff could use this model in understanding the factors that affect audit processes and identify solutions.

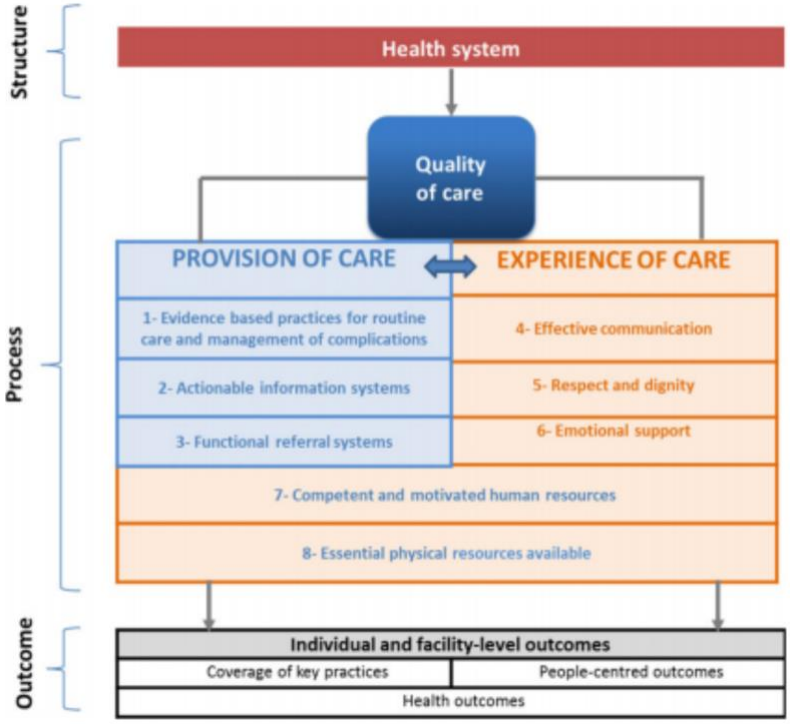
Figure 2: Triad of quality of care



Source: Donabedian (1988)

The WHO quality of care framework for maternal and newborn health (Figure 3) identified eight domains of quality of care for pregnant women and newborns in facilities that increase the likelihood of achieving desired individual and facility outcomes (World Health Organization, 2016c; Tuncalp *et al.*, 2015). In order to provide high quality of care during childbirth and improve user experience, the health system must be well prepared in terms of available physical infrastructure, supplies, management and staff with the knowledge, skills and capacity to deal with both normal and complicated pregnancy and childbirth (Tuncalp *et al.*, 2015)**.** Following the eight domains of the WHO quality of care framework, eight quality standards for maternal and newborn health were developed with 31 quality statements in 2016 (World Health Organization, 2016c). Recently, eight standards for improving the quality of care for small and sick newborns in health facilities have been also developed with 78 quality statements (World Health Organization, 2020c). Appendix 1 summarises eight maternal and newborn health and small and sick newborns care standards and their 31 and 78 quality measures respectively.

Figure 3: WHO quality of care framework for maternal and newborn health



Source: Tuncalp *et al.* (2015)

1.4.2 Quality of care for newborns

The WHO health system framework describes health systems thinking by identifying six building blocks: service delivery; health workforce; information; medical products, vaccines and technologies; financing and leadership/governance. These building blocks create a structure from where health systems analysis and intervention points can be established (WHO, 2007). All health systems must carry out some essential functions regardless of how they are organised: they must provide services, develop health workers and other vital resources, mobilise and allocate finances and ensure health system leadership and governance (WHO, 2007). These functions will improve health system performance resulting in better outcomes (WHO, 2007). Death audits aimed at strengthening service delivery and implementation of audit solutions could be affected by other components of the system building blocks.

Neonatal survival depends on key elements such as competent care during labour and birth, staff skilled in basic neonatal resuscitation, management of sepsis and kangaroo mother care for low birth weight (LBW) infants (Dickson *et al.*, 2014). However, all these

interventions require qualified health workers and facility infrastructure and resources, which are inadequate in settings like Malawi. Implementing QI is possible even in LMICs through identifying the challenges in care and improving and adopting best practices to improve the QoC (Leslie *et al.*, 2016). A focused change programme can impact health professionals' behaviour, but individual, social and organizational contexts play an important role in producing significant change (Smith *et al.*, 2004).

A study on obstetric facility QoC and newborn mortality conducted in 476 birth facilities in Malawi reported that birth facilities were both accessible and widely utilised (Leslie *et al.*, 2016). However, QoC delivered by the facilities falls significantly short of global standards of evidence-based care (Leslie *et al.*, 2016). Malawi's health care system faces many challenges in delivering quality services (Cushing and Dielemans, 2015). These challenges include a shortage of skilled and motivated health workers, deteriorating facilities and equipment, a lack of drugs, and inadequate health information data to guide decision-making (Cushing and Dielemans, 2015).

1.4.3 Gaps in the quality of care

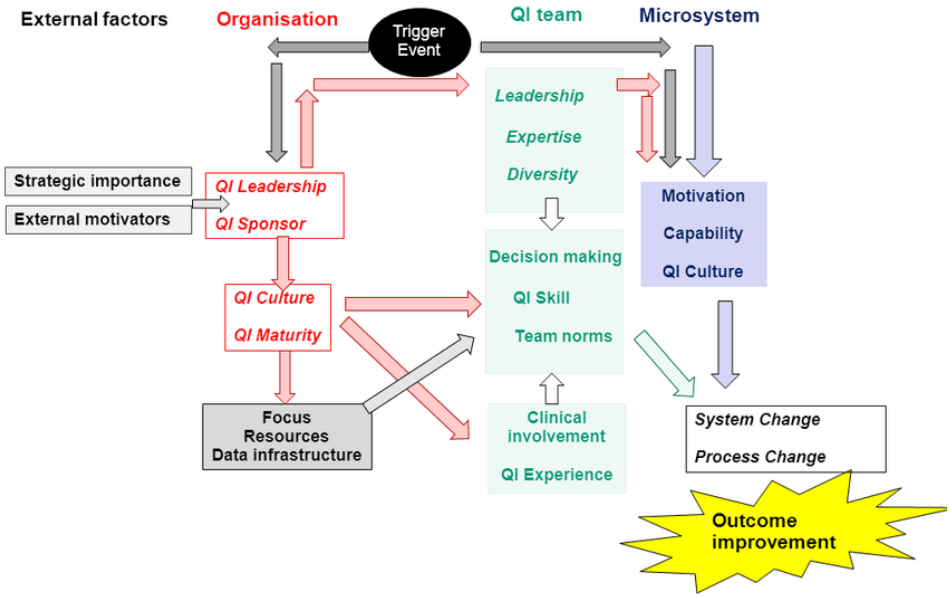
Challenges remain to reduce perinatal and neonatal mortality rates. With high antenatal attendance and institutional birth rates in Malawi (95% pregnant women attend for ANC and 91% have facility births) (National Statistical Office (NSO) [Malawi] and ICF Macro, 2017), improving QoC in health facilities is of great value to address challenges at this level. To accelerate progress in reducing neonatal deaths, Darmstadt, Shiffman and Lawn (2015) propose three key elements: improve care at birth and for small and sick newborns; improve equity for maternal and newborn care; reach every woman, newborn and achieve impact at scale.

Implementing QI in facilities of Malawi can improve the quality of care (Leslie *et al.*, 2016). QI initiatives can optimise the use of limited resources available from governments and global initiatives targeted at achieving shared aims in LMICs (Leatherman *et al.*, 2010). The section that follows examines quality improvement programmes and their impact on the quality of care.

1.5 Quality Improvement

QI initiatives improve health outcomes for small and sick newborns (Zaka *et al.*, 2018). In India, 125 public health facilities supported by the USAID ASSIST Project used QI approaches to provide better care to women and babies before, during and immediately after birth (Sarin *et al.*, 2017). Similarly, In Ghana, QI improved intrapartum and postnatal care for mothers and neonates using available resources in the 27 networked rural health facilities (Twum-Danso *et al.*, 2013). While in a retrospective descriptive study in Uganda, conducting perinatal death audits as a QI tool improved perinatal outcomes (Nakibuuka *et al.*, 2012). Through the mortality review process, facilities are encouraged to identify gaps in practice and engage in QI initiatives to address gaps and monitor success. However, QI might fail due to challenges such as inadequate leadership, and resources and poor health care worker behaviour. Nambiar *et al.* (2017) recommended approaching systems at the facilities as they are operating at the micro- (care providers), meso- (health facility team) and macro-level (health care system). Furthermore, a model of understanding success in quality (MUSIQ) (Figure 4), described how context influences the success of individual QI projects in terms of system and process change and outcome improvements (Kaplan *et al.*, 2012). The model described the macro-level (national/sponsors/political) as external motivators that stimulate the organisation to improve the performance in QI projects. At the meso level (institution-facility, red in Figure 4) lies the responsibility for QI leadership, culture support, guidance and direction that shapes the behaviour of staff pursuing QI projects. Senior leaders' commitment to champion QI projects is of value. At the micro-level (purple), motivated care providers who have the capability and desire to improve performance will be of great value to the system. The QI team characteristics (green), workforce focus, resource availability and data infrastructure (dark grey) exist across all system levels and trigger and influence the success of QI projects (Kaplan *et al.*, 2012). The model will assist in understanding the contextual factors at these different levels, which are likely to influence the implementation, success and sustainability of interventions.

Figure 4: Model of understanding success in quality (MUSIQ)



Source: Kaplan *et al.* (2012)

There is evidence that QI initiatives improve the quality of maternal and neonatal care in Malawi (Kinney, Corbett and Wall, 2020; Colbourn, Nambiar and Costello, 2013). In a QI project implemented by Save the Children between 2014 to 2016, use of clinical teaching, training, audits, and capacity-building strategies to address healthcare provision gaps that they had identified at facilities improved structure, process and health outcomes for newborn care (Kinney, Corbett and Wall, 2020). The notable changes in Thyolo District Hospital included newborn beds increased from three to 40, the number of non-rotating staff in the newborn care unit increased from zero to six, availability of low birthweight data increased from 24% to 64% in two years and routine data indicated a reduction in mortality among admitted newborns from 15.5% to 9.5% in one year (2015–2016) (Kinney, Corbett and Wall, 2020). According to Colbourn, Nambiar and Costello (2013), the Maikhanda programme worked with 879 communities, nine hospitals and 29 health centres across three districts in Malawi to identify and implement local strategies for maternal and newborn healthcare improvement. The Maikhanda programme combined a cluster randomised controlled trial (RCT) design using four approaches in different locations. Overall, the evaluation estimated that each year during the 27-month intervention period,

the community-based intervention alone averted 933 (95% CI: 159-1609) perinatal deaths while the combined approach (community mobilisation and healthcare improvements) averted 384 (95% CI: 14-695) neonatal deaths. The results suggest that the observed effects on the mortality of both interventions occurred mainly in the community. This might lead to a lack of observed effects on deaths at the health centres and hospitals (Colbourn, Nambiar and Costello, 2013) and also facility level limitations. There are many limitations in facilities such as resources, supervision systems, staff morale, and motivation that can limit impact. Several external influences (sponsors, political and external supervisors) exist that need to be considered and used to drive improvements in quality. Engaging a wider health system creates awareness and commitment to quality, which leads to ownership of QI initiatives introduced at the facility.

In a qualitative study to assess perceptions of obstetric critical incident audit held by health workers in Thyolo district, Malawi, staff considered that audit and feedback were valuable tools to enhance the QoC that they provide (Bakker *et al.*, 2011). Through critical incident audit and feedback in the same district, the incidence of uterine rupture and major obstetric haemorrhage reduced considerably (from 3.5 to 0.2 and from 5.9 to 2.6 per 1000 facility deliveries) respectively, within two years (van den Akker *et al.*, 2011).

In Malawi, the Ministry of Health (MoH) institutionalised quality management in the health sector and developed an effective leadership approach by creating a Quality Management Directorate (QMD) in 2016. Through this, QI Support Teams (QIST) and Work Improvement Teams (WIT) have been created to champion the implementation of QI initiatives in facilities (Ministry of Health, 2017). The QIST is a multidisciplinary team comprising members from various specialties and departments responsible for leading and coordinating quality management activities within their institutions. At the same time, WIT is a small team of staff that meets regularly to solve the problems related to their work in the ward or department (Ministry of Health, 2017). Death audits or reviews, which are covered in the next section, are one of the QI methods that have helped improve the quality of treatment and minimize stillbirths and newborn deaths around the world.

1.6 Stillbirths and neonatal death audits or reviews

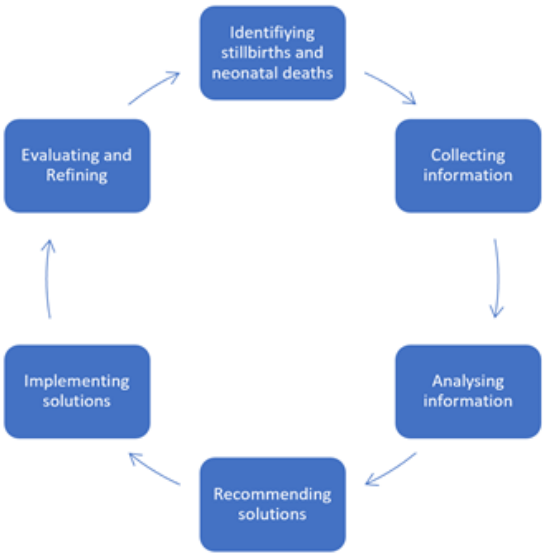
The audit process identifies and reviews deaths to identify the medical cause of death and avoidable factors on a case-by-case basis. Recommendations for avoiding such deaths in the future are implemented and changes made in the system are evaluated (Willcox *et al.*, 2018; Pattinson *et al.*, 2009).

Maternal and perinatal mortality audits apply to objective two of improving the quality of maternal and newborn care and five of counting every newborn within the five strategic objectives defined by the ENAP to end preventable deaths as outlined in section 1.3 above (World Health Organization, 2014). Studies have demonstrated that perinatal death reviews improve health care quality and health outcomes in LMICs (Nakibuuka *et al.*, 2012; Pattinson *et al.*, 2005). In a meta-analysis of seven before–after studies, perinatal mortality audit was shown to be associated with up to a 30% (95% confidence interval, 21%–38%) reduction in perinatal deaths. In South Africa, perinatal death audits were associated with a reduction in perinatal mortality (42-29 per 1000 live births over 5 years), early neonatal mortality (by 50%), intrapartum asphyxia (by 26%) and informed the introduction of interventions such as a perinatal education programme for midwives and Perinatal Identification Problem Programme (PIPP) (Pattinson, 2007). A study in Moldova reported that perinatal audits resulted in a significant reduction in mortality from 5.1 per 1000 in 2006 to 3.6 per 1000 in 2013 with 1.5 per 1000 or 29.4% reduction (95% CI 0.6-2.4; P=0.0015) among fetuses/newborns ≥ 37 weeks and birth weight ≥ 2500g (Stratulat *et al.*, 2014; Nakibuuka *et al.*, 2012). A study in Uganda reported perinatal mortality reduction (52.8% in 2007 to 47.9% in 2008) following perinatal audit implementation but this difference was not statistically significant (Nakibuuka *et al.*, 2012). In a recent study in Uganda, the introduction of a perinatal death audit showed no statistically significant effect on perinatal mortality or stillbirth, a significant decrease in the early neonatal mortality rate (IRR (95% CI)=0.35 (0.22 to 0.56), p<0.001), and no effect on case fatality rates for prematurity, intrapartum related hypoxia or infections (Kirabira *et al.*, 2020). These findings indicate the need for more research on the effectiveness of stillbirths and neonatal audits in LMICs (Kirabira *et al.*, 2020).

Evidence suggests that audit may be a useful tool for decreasing mortality and improving

quality, but only if the audit and feedback loop links to action at the point of care (Pattinson *et al.*, 2009). Auditing alone does not necessarily imply that there will be a reduction in deaths. This requires a functional system with constant monitoring and evaluation, with the feedback loop in place as per the audit cycle (Rhoda *et al.*, 2014). Audits in facilities empower staff to learn from mistakes and initiate significant changes in the care of the patients or the health system (Pattinson *et al.*, 2009). The use of the WHO mortality audit cycle described in Figure 5 is advocated and involves: identifying cases (stillbirths and neonatal deaths), collecting information, recommending solutions, implementing solutions, evaluating and refining (World Health Organization, 2016b).

Figure 5: Mortality Audit Cycle



Source: Adapted from World Health Organization (2016b)

A study conducted in Malawi showed that maternal death audits and standard-based audits promoted essential obstetric care services and reduced maternal deaths from acute obstetric complications. However, the study did not evaluate if the improvements were due to one type of audit or a combination of both (Kongnyuy, Leigh and van den Broek, 2008).

1.6.1 Perinatal death reviews in Malawi

Stillbirths and neonatal reviews/audits in Malawi are not as well established as maternal death audits. Stillbirths and neonatal death audits are performed in the facilities, but there

is no guideline document at the national level. In collaboration with the Liverpool School of Tropical Medicine (LSTM), the Malawi MoH developed Perinatal Death Surveillance and Response (PDSR) guidelines to support healthcare providers and managers, but this has not yet been used in Malawi (Government of Malawi., 2019). Recently Malawi has launched child health strategy II, and one of its strategic objectives emphasized the need to support neonatal death audits in facilities (Government of Malawi., 2021).

1.6.2 Stillbirth and neonatal death audit process implementation challenges

Although WHO recommended auditing stillbirths and neonatal deaths to identify and implement ways to improve newborn care (World Health Organization, 2016b), progress in LMICs, including countries in SSA, has not been optimal compared to high-income countries (Lusambili *et al.*, 2019). The following section reports challenges with completing the WHO stillbirth and neonatal death audit cycle, which are critical for successful audits (World Health Organization, 2016b).

1.6.2.1 Identifying perinatal deaths

This step aims at recording all births, stillbirths and neonatal deaths occurring either in health facilities or in the community, capturing a minimum set of perinatal indicators and deciding which deaths, being a sample or all, to collect more information (World Health Organization, 2016b). This information may come from either paper-based or electronic birth or death registers depending on the availability of Health Management Information System (HMIS) support at the institution and in communities. In a study in Rwanda, source documents from postnatal, outpatient and antenatal care were largely not used to identify stillbirths and neonatal deaths for audit (Tayebwa *et al.*, 2020). Studies done in Zimbabwe and Rwanda found a well-established system to collect maternal death information across hospital clinical departments but limited information for stillbirths and neonatal deaths (Tayebwa *et al.*, 2020; Om'Iniabohs *et al.*, 2017).

1.6.2.2 Collect information

This step aims to empower staff to collect a standardised set of information from patient files or a register as soon as possible after the stillbirth or neonatal death (World Health

Organization, 2016b). A few individuals can be identified to collect this information that can be reviewed during the larger team meeting for causes and modifiable factors. Challenges such as poor record-keeping, poor documentation, missing charts and incomplete information have been reported in Rwanda and Tanzania (Tayebwa *et al.*, 2020; Kashililika and Moshi, 2021). In a study conducted in Zimbabwe (Om'Iniabohs *et al.*, 2017), participants reported that the standard data collection form was usually available and that they were able to complete the audit form as soon as death occurred. However, when the standardised form was not available, filling information in a blank workbook could miss essential parameters and maternal history or files were rarely incorporated in the neonatal death review process (Om'Iniabohs *et al.*, 2017).

1.6.2.3 Analysis of information

This step aims to identify problems in the system that might have contributed to stillbirth or neonatal death, especially those that could have been prevented or avoided (World Health Organization, 2016b). The data analysed include quantitative components such as trends in rates, causes of deaths, geographical area and qualitative analysis of modifiable factors (World Health Organization, 2016b). Decisions on the cause of death depends on reviewers' subjective judgement as most hospitals in LMICs could not do neonatal post-mortems due to lack of resources, family consent and interest (Om'Iniabohs *et al.*, 2017). However, studies introducing minimally invasive tissue sampling approaches to paediatric autopsy are gaining acceptance in Malawi (Lawrence *et al.*, 2022; Lawrence *et al.*, 2021). A study done in Tanzania found that while other facilities used the international classification of disease-10 (ICD 10) to classify causes of deaths, other facilities did not use a classification system (Kashililika and Moshi, 2021). A similar problem was identified in Rwanda and Zimbabwe (Tayebwa *et al.*, 2020; Om'Iniabohs *et al.*, 2017). Other challenges identified in Rwanda were incomplete notification forms, action plans not completed correctly, and some preventable deaths were classified as not preventable deaths due to inadequate capacity for staff to complete the form and analyse the deaths (Tayebwa *et al.*, 2020). A study in Tanzania found inconsistent use of mortality trends during audit and incorrect assignment of causes of deaths (Kashililika and Moshi, 2021).

1.6.2.4 Recommending and implementing solutions

The effectiveness of stillbirth and neonatal death audit depends on the ability to close the audit loop; without effectively implementing the planned actions based on the problems identified, audit alone cannot improve QoC (Pattinson *et al.*, 2009). Step 4 aims to identify actions for identified problems that are specific, measurable, attainable, relevant and time-bound, while step 5 aims to implement immediate, medium-term or long term actions to prevent stillbirths and neonatal deaths (World Health Organization, 2016b). Studies have reported challenges in formulating appropriate recommendations based on modifiable factors and implementing changes (Sandakabatu *et al.*, 2018; Nyamtema *et al.*, 2010). An assessment done in Tanzania reported that most facilities did not have a mechanism to assign responsibilities during action planning and the action plans developed were not specific. There was also no formal process to monitor the follow up of actions and national guidelines were not clear on monitoring action plans (Kashililika and Moshi, 2021; Om'Iniabohs *et al.*, 2017). In the Zimbabwe assessment, recommendations ranged from being very specific, time-bound and feasible to broad and long term with no official document for tracking follow-up (Om'Iniabohs *et al.*, 2017). In Zimbabwe, although the maternal death audit meeting achieved a multidisciplinary team composition, it was impossible for the perinatal audit team to achieve this, resulting in challenges linking up with the quality improvement team to implement actions (Om'Iniabohs *et al.*, 2017).

1.6.2.5 Refining and Evaluating

Looking back at what has worked or not is key that will help in replanning and ensuring that future recommendations are informed by the collected data and lead to action (World Health Organization, 2016b). The challenges identified in Zimbabwe and Tanzania included no formal process of documenting and reporting successful stories and facilities did not report targets for reducing mortality and complications that could have been used as a benchmark and link to quality improvement to improve health outcomes (Om'Iniabohs *et al.*, 2017; Kashililika and Moshi, 2021).

1.6.3 Health system challenges in sustaining stillbirth and neonatal death audit

Despite the fact that stillbirths and neonatal death audits can improve the quality of care,

many challenges have been reported relating to the implementation of audits and implementing changes suggested during audit (Gondwe *et al.*, 2021). This section reports challenges to sustain stillbirth and neonatal death audit according to the WHO health system building blocks of leadership and governance, health financing, health workforce, essential medical products and technologies, health delivery system and health information system (WHO, 2007).

1.6.3.1 Leadership and governance

A study conducted in South Africa described managers and health workers as drivers, champions or agents of change in perinatal audit (Belizán *et al.*, 2011). Similarly, MUSIQ model emphasized the need for senior leadership's commitment to champion the projects (Kaplan *et al.*, 2012). A current evidence study for facility-based mortality audit identified the absence of a national policy or audit strategy, lack of data collection tools, lack of audit prioritisation by policymakers, culture of blame, lack of awareness and use of data by government officials and unavailability of champions as main factors challenging leadership and governance during audit implementation (Kerber *et al.*, 2015). The involvement of key stakeholders in the health system such as external agencies, managers, heads of departments and health policymakers is key to sustaining changes in practice (Pattinson *et al.*, 2009; Nair *et al.*, 2014). A Tanzanian study investigating facilities that implemented perinatal audits found that some facilities had discontinued clinical audits due to the failure of hospital administration to implement audit recommendations (Nyamtema *et al.*, 2010). Strong leadership across all levels is needed for a successful audit. A systematic review for LMICs found that audit-suggested solutions that require administration or hospital management to respond are less likely to be implemented than others (Kerber *et al.*, 2015). This calls for wide engagement of facility, district and national level leadership and managers to promote accountability at health system levels (Kerber *et al.*, 2015). Learning from maternal and perinatal death surveillance and response implementation factors in a scoping review for LMICs, the countries where leadership was strong and engaged resulted in better performance than countries where leadership was less engaged (Nakibuuka *et al.*, 2012). A study done in Uganda found that District Medical Officers (management members) had many competing priorities and the lack of district leadership and ownership affected the institutionalization of maternal death reviews (Kinney *et al.*, 2021; Nam, 2011). A

qualitative evidence synthesis of health workers' views on audit in maternal and newborn health care in LMICs reported that the absence of key staff in leadership roles made audit meetings and discussions irrelevant, but their presence helped isolate mistakes and guide corrective actions appropriately (Rousseva *et al.*, 2020).

1.6.3.2 Health financing

There is limited evidence regarding cost as a barrier to implementing a mortality audit system. Although mortality review is a low-cost activity, a space for meetings, training stationery and software maintenance may require funds as well as the provision of training to clinical staff (Pattinson *et al.*, 2009; World Health Organization, 2016b). In two west African countries, Burkina Faso and Benin, the cost of conducting audit meetings was estimated at US$154 and US$217 per meeting, respectively, which seemed to be affordable (De Brouwere *et al.*, 2013). However, although changes in practice that are identified during audit meetings may require funds to be implemented, as they require essential supplies, drugs and equipment that are key for facility functioning. Although audit implementation may be relatively low cost, LMICs still struggle to identify funds. For example, in a multi-country obstetric audit project, a hospital manager in Ghana pleaded with the audit committee to stop making recommendations that required money (Filippi *et al.*, 2004). In a similar study, much of the cost was related to staff incentives in the form of allowances. A near-miss audit project in Ghana, Benin and Cote d'Ivoire gave a generous stipend to core members of hospital audit teams for audit meeting preparations and completion of research data collection forms (Filippi *et al.*, 2004). This has a significant impact on the sustainability of audit activities if similar incentives are not available in the future.

1.6.3.3 Health workforce

A systematic review of facility-based perinatal mortality audits in LMICs reported that ward staff tended to hide behind their busy schedules rather than plan and attend audit meetings (Kerber *et al.*, 2015). Integrating audit into routine practice, whereby staff view audit as part of their job description and daily work, could strengthen sustainability (Kerber *et al.*, 2015; Belizán *et al.*, 2011). In hospitals in LMICs, the high patient load, including emergencies and inadequate staff presents a barrier to participate in audit meetings (Filippi *et al.*, 2004;

Rousseva *et al.*, 2020). Lead personnel sacrifice their time and effort to prepare for audit meetings, prepare cases, summaries and reports, which is an extra burden on their working time. Furthermore, due to professional power hierarchies occurring in a multidisciplinary team, junior staff might feel out of place among seniors, less likely to contribute to the process, unwilling to speak if the death concerns their senior, feel blamed and may likely not attend (Rousseva *et al.*, 2020; Kerber *et al.*, 2015). Staff rotations to other departments or hospitals, especially those trained or in a leadership position also affected the sustainability of audit initiatives (Rousseva *et al.*, 2020).

1.6.3.4 Essential medical products and technologies

Although mortality audits require little equipment, the lack of stationary essential to conducting audit meetings in LMICs has been identified as a critical barrier (Kerber *et al.*, 2015). Essential medical products and technologies may be needed for the implementation of proposed changes. Non-implementation of audit demotivates staff as they do not see a need for continuing audit when proposed changes are not implemented due to inadequate resources (Rousseva *et al.*, 2020).

1.6.3.5 Health delivery system

While some health system building blocks such as health workforce, leadership and governance support audit, the core aim of audit is to strengthen the health delivery system as a whole by identifying gaps in the care and implement changes to improve practice. In a qualitative synthesis of maternal and newborn audits, health workers reported improvements in health service delivery, especially in structure and care processes (Rousseva *et al.*, 2020). However, few facilities reported having an official documentation system for tracking progress and follow-up of improvements in care resulting from audit implementation (Tayebwa *et al.*, 2020; Om'Iniabohs *et al.*, 2017).

1.6.3.6 Health information system

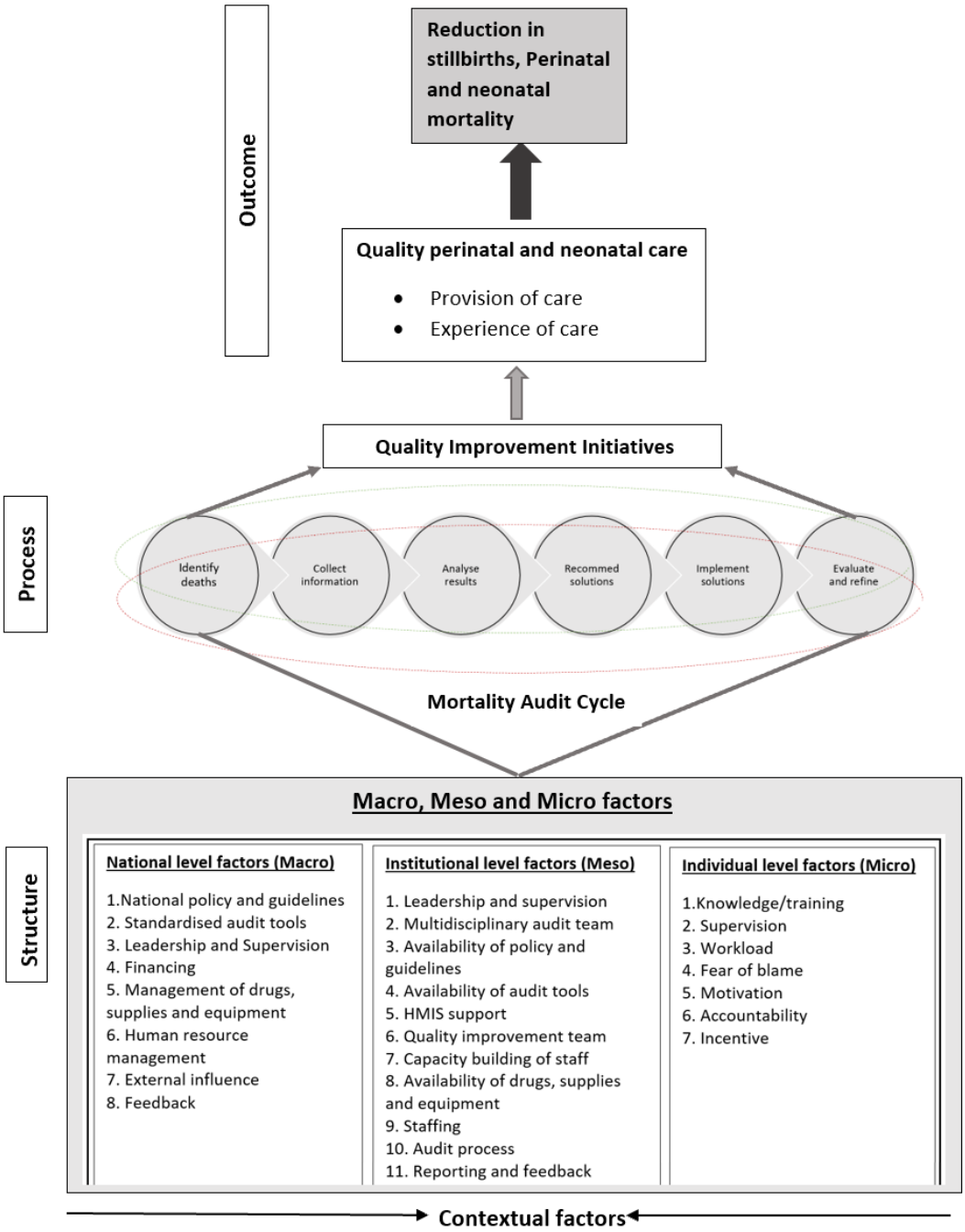
In a systematic review on stillbirths and neonatal death audit in LMICs, health information system challenges included a limited capacity to capture neonatal deaths outside the hospital setting, use and interpretation of statistics and the limitations of paper-based

systems (Kerber *et al.*, 2015). Although paper-based is less costly, it may lead to inaccurate information, lost files, difficulty aggregating and sharing data, and require more people and time to manage (Kerber *et al.*, 2015). South Africa has provided evidence on the feasibility, acceptability and benefit of using a centralized database system, although only a few hospitals could manage it due to cost (Rhoda *et al.*, 2014; Buchmann, 2014). A review of maternal and perinatal mortality and morbidity audits in sub Saharan Africa found that data reporting during the audit meeting was poor and incomplete, with no standards set and clinical records lacking in some audits, which made analysis and identification of cause and modifiable factors incomplete (Lusambili *et al.*, 2019). After describing the difficulties in completing the WHO death audit cycle phases and problems in the health system during the audit process, I built a conceptual framework to guide this study's methodologies and future audit implementation, as indicated in the following section.

1.7 Conceptual framework for the study

A conceptual framework is the composition of different concepts developed from theoretical foundations that guide and better explain the proposed research work (Jabareen, 2009). The framework for this study (Figure 6) brings together the findings from multiple conceptual frameworks as described above: the WHO framework for the quality of maternal and newborn healthcare, Donabedian's structure-process-outcomes framework, WHO health system framework and MUSIQ- a model of understanding success in quality. The conceptual framework captures the associations described in the literature between factors that affect the implementation of successful facility-based perinatal and neonatal death audits at different levels (macro-level: national/political factors; meso level: institutional; micro-level: individual/personal factors). These factors are linked to the process of conducting perinatal and neonatal deaths audits, which inform QI initiatives to improve QoC (both the provision of care and the experience of care). QoC is then linked to the expected outcome of a reduction in perinatal and neonatal mortality.

Figure 6: The study conceptual framework



1.8 Study aim

Using this framework, the study aims to evaluate the quality of stillbirth and neonatal death audits, the facilitators and barriers to conducting audits, in seven public health facilities in the southern region of Malawi.

1.9 Specific objectives

The specific objectives of the study are to:

1. Assess the resources available to support appropriate care for newborns (Chapter 4)
2. Assess the quality of stillbirth and neonatal death audit processes (Chapter 5)
3. Identify facilitators and barriers in implementing stillbirth and neonatal death audit (Chapter 6)

1.10 Study significance

The study will add new knowledge on the processes and conduct of stillbirth and neonatal death audit in Malawi. The findings and recommendations will provide insights to help develop and implement sustainable mortality audit processes that effect change and improve health outcomes. This is because the study approach of understanding issues around mortality audit processes and outcomes, as well as the context in which audits are undertaken, are based on health system strengthening and QI theories. These theories describe factors to consider when implementing QI programmes in health systems (Tuncalp *et al.*, 2015; World Health Organization, 2016b; Kaplan *et al.*, 2012; Donabedian, 1980; Donabedian, 1988; WHO, 2007; Aragón and Giles Macedo, 2016).

The study will also provide a conceptual framework developed by combining the abovementioned theories to guide facilities, managers, QI researchers, policymakers and health care workers in understanding and optimising contextual factors affecting the success of mortality audits and other QI initiatives. The next section illustrates the organisation of this thesis after defining the conceptual framework that guided study methods, study aim, objectives and importance.

1.11 Thesis structure

The thesis comprises seven chapters. The current chapter, **Chapter 1,** presents a background regarding stillbirth and neonatal deaths, quality of care and the role of access to care in reducing mortality, quality improvement approaches with a focus on facility-based mortality audits, a study conceptual framework and the study objectives and its potential significance.

Chapter 2 presents a systematic review of approaches, enablers, barriers and outcomes of stillbirth and neonatal death audit in LMICs highlighting gaps regarding stillbirth and neonatal death audit implementation.

Chapter 3 describes the study setting and research methodology.

Chapter 4 addresses objective 1; resources available to support appropriate care for newborns.

Chapter 5 addresses objective two; quality of stillbirth and neonatal death audit processes.

Chapter 6 addresses objective 3; facilitators and barriers in implementing stillbirth and neonatal death audit.

Chapter 7 summarises the research findings, discusses the study's challenges, strengths, limitations, implications for policy, research and practice and concludes with recommendations. The next section explains my role in the study.

1.12 My roles and responsibilities in the research

In the whole research, my role and responsibilities were as follows:

- I conceived and designed the study, developed the conceptual framework, the research proposal and data collection tools
- I secured approval from the Ethics Committees in UK and Malawi
- I created forms and tables in Microsoft Access to enter the data
- I collected all data with the support of a research assistant
- I analysed the data and drafted all chapters of the thesis and with feedback from the supervisors, I revised and finalised the thesis
- I registered with PROSPERO and conducted a systematic review (Chapter 2) with support from the external reviewer and with feedback from my supervisors. I wrote the first draft of the paper and published the results.
- I drafted two other manuscripts and with feedback from the supervisors, I submitted them for publication

1.13 Summary

I have described in this introduction chapter the information on stillbirth and neonatal mortality, quality care gaps, health system gaps, quality improvement theories, study conceptual framework, broad and particular study objectives and study rationale/significance. Stillbirth and neonatal mortality are still a major health problem, according to the reports. Despite the fact that many ways to improve neonatal care have been proposed, it remains sub-optimal. While stillbirth and newborn mortality audits have been suggested as ways to enhance care, they may be difficult to implement due to a lack of resources, protocols and leadership support. Given the aforementioned problems, this study evaluates the current state of audit implementation to identify gaps and analyse health system facilitators and barriers. This will help to strengthen its implementation and inform the way forward to maximize its effectiveness. This research also offers a conceptual foundation for evaluating audit implementation. The results of a systematic literature review, which also informed the construction of the conceptual framework, are presented in the next chapter.

CHAPTER 2: LITERATURE REVIEW (PAPER 1)

2.1 Chapter overview

In this chapter, I review the existing evidence on the implementation of facility-based stillbirth and neonatal death audit in LMICs to inform this study. The aim of this systematic review was to assess and synthesise the evidence on the approaches and outcomes of the stillbirth and neonatal death audit on QoC in LMICs. Another aim was to identify enablers and barriers to implement successful stillbirth and neonatal death audits in LMICs at health provider, facility and regional or national levels.

The methods section of this chapter describes how the systematic review was conducted. The results section summarises key findings in narrative form with other findings summarized in figures and tables. The discussion section describes what the results mean, comparing the findings with the previous literature, the implications for practice and a systematic review conclusion.
This chapter was published in BMJ Open Quality Journal in 2021. The publication can be found at the link below.
https://bmjopenquality.bmj.com/content/10/1/e001266

I led the study conceptualization, project administration (which included abstract extraction, screening, developing reporting templates, data interpretation, formal analysis) and wrote the original, revised and final manuscripts. The title of the paper is 'Approaches, enablers, barriers and outcomes of implementing facility-based stillbirth and neonatal death audit in LMICs: a systematic review'

2.2 Abstract

Purpose

To identify approaches, enablers, barriers and outcomes of facility stillbirth and neonatal death audit in LMICs.

Data sources

We searched MEDLINE, CINAHL Complete, Academic Search Index, Science Citation Index, Complementary index and Global health electronic databases.

Study selection

Studies were considered eligible when reporting the approaches, enablers, barriers and outcomes of facility-based stillbirth and neonatal death audit in LMICs.

Data extraction

Two authors independently preformed the data extraction using pre-defined templates made before data extraction.

Results of data synthesis

A total of 10 articles from seven countries were included in the final analysis. Facility or external multidisciplinary teams performed death audits on a weekly or monthly basis. A total of 1018 stillbirths and neonatal deaths were audited. Of 18 audit enablers identified, nine were at the health provider level whilst 18 of 23 barriers to audit that were identified occurred at the facility level. The facility-level barriers cited by more than one study included: failure to implement change; inadequate training; limited time; increased workload; too many cases and poor documentation. Six studies reported that death audits resulted in structural improvements in physical structure, training, service organisation, supplies and equipment in the wards. Five studies reported that death audits improved the standard of care, with one study showing a significant improvement in measured standards. One study reported a significant reduction in newborn mortality rate of 29.4% (95% CI 0.6-2.4; P=0.0015) and one study a reduction in perinatal mortality of 4.9% (52.8% in 2007 to 47.9% in 2008) before and after perinatal audit implementation.

Conclusion

Stillbirth and neonatal death audit improve facility structures, processes of care, and health outcomes in neonatal care. There is a need to enhance enablers and address barriers identified at both health provider and facility levels to improve the audit process.

2.3 Introduction

Improving access to health care alone is not enough to improve patient outcomes (Kruk *et al.*, 2018). Recently, a focus on the quality of care (QoC) was advocated to achieve the Sustainable Development Goal (SDG) 2030 of ensuring healthy lives and promoting wellbeing for all at all ages. Poor QoC is not only harmful but also wastes resources that could have been used in other sectors to improve the lives of citizens (Kruk *et al.*, 2018). Despite increased facility-based births, women and babies are still dying or developing lifelong disabilities due to poor QoC (Kieny, 2018). The World Health Organization (WHO) estimates 295,000 women and an estimated 2.4 (uncertainty range 2.3- 2.7) million newborns die every year during childbirth from preventable causes (UN IGME, 2020a; UN IGME, 2020b). Furthermore, an estimated 2 (uncertainty range 1.9- 2.2) million stillbirths occur each year. About 80% of these deaths occur in low and middle-income countries (LMICs) (UN IGME, 2020a; Lawn *et al.*, 2016a; Blencowe *et al.*, 2016). Providing high QoC in LMICs remains a challenge and performance varies across providers (Kruk *et al.*, 2018).

Implementing quality improvement is possible in these countries through identifying problems in care and adopting best practice. The WHO has recommended auditing stillbirths and neonatal deaths to identify and implement ways to improve the quality of maternal and newborn care (World Health Organization, 2016b). However, progress in LMICs has been limited compared with high-income countries (Lusambili *et al.*, 2019). Stillbirth and neonatal death audit is the process of capturing information on the causes of deaths and analysing the QoC received, in a no-blame, interdisciplinary setting to improve the care provided to all mothers and babies (World Health Organization, 2016b). Through the process, the hospital staff have an opportunity to learn from the cases audited and improve care. Many factors hinder or facilitate the successful implementation of auditing stillbirths and neonatal death (Lusambili *et al.*, 2019). Critically, the effectiveness of audit depends on the ability to complete the audit process. Without effectively implementing the planned actions to respond to the problems identified, the audit alone cannot improve QoC (Pattinson *et al.*, 2009). Also, effective audit requires a system-wide effort to support the recommended initiatives. However, challenges related to system support, formulating appropriate recommendations based on preventable factors and implementing changes

have been reported (Sandakabatu *et al.*, 2018; Lusambili *et al.*, 2019).

This systematic review will contribute to the existing evidence base by synthesising data on facility stillbirth and neonatal death audits and provide guidance on how to undertake a successful stillbirth and neonatal death audit initiative in LMICs. We address the following objectives:

- To evaluate and synthesise the evidence on the approaches and outcomes of facility-based stillbirth and neonatal death audit on QoC and perinatal and neonatal health outcomes in LMICs.
- To identify enablers and barriers at health provider, facility and regional or national levels of care, to the implementation of successful stillbirth and neonatal death audits in LMICs.

This work will serve as a guide to facility stillbirth and neonatal death audit implementation by evaluating the evidence on approaches used, outcome measures, opportunities and challenges to guide future health care workers undertaking similar initiatives to ensure that it is evidence based.

2.4 Methods

We registered the review on the International Register of Systematic Prospective Reviews (PROSPERO; registration number: CRD42019148515) and used the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines (Moher *et al.*, 2009).

2.4.1 Search strategy

In September 2019, we searched MEDLINE, CINAHL Complete, Academic Search Index, Science Citation Index, Complementary index and Global health for eligible studies from January 2009 to August 2019. Included search terms were “stillb*” OR “neonat*” OR “perinatal death” OR “neonatal death” AND audit OR review (Appendix 2).

2.4.2 Inclusion and exclusion criteria

We included studies if they met all of the following criteria: (1) studies describing approaches, enablers, barriers or reporting outcomes of stillbirth and neonatal death audit at the facility level; (2) Original research article reporting either quantitative, qualitative

data or both (3) Study done in LMIC(s) defined and identified according to World bank list (World Bank, 2019); (4) Studies which implemented a full audit process; (5) Published in English; (6) published between 1 January 2009 and 1 September 2019 (search date). We selected studies published since January 2009 as many LMICs become proactive in addressing quality problems from this date (Leatherman *et al.*, 2010) and we aimed to focus the review on current practice.

We excluded studies only reporting descriptive findings of audits as such reviews have been well covered elsewhere (Aminu *et al.*, 2014; Halim *et al.*, 2018; Belizan *et al.*, 2012). We excluded systematic reviews as we were only interested in original research articles.

2.4.3 Quality appraisal

We used the checklist for reviewing disparate data developed by Hawker *et al.* (2002) to appraise the studies (Appendix 3). The checklist comprises nine questions, each of which has four sub-categories, permitting summation of a methodological quality score. Each paper was rated on a scale from 9 (very poor) to 36 (good).

2.4.4 Data extraction and analysis

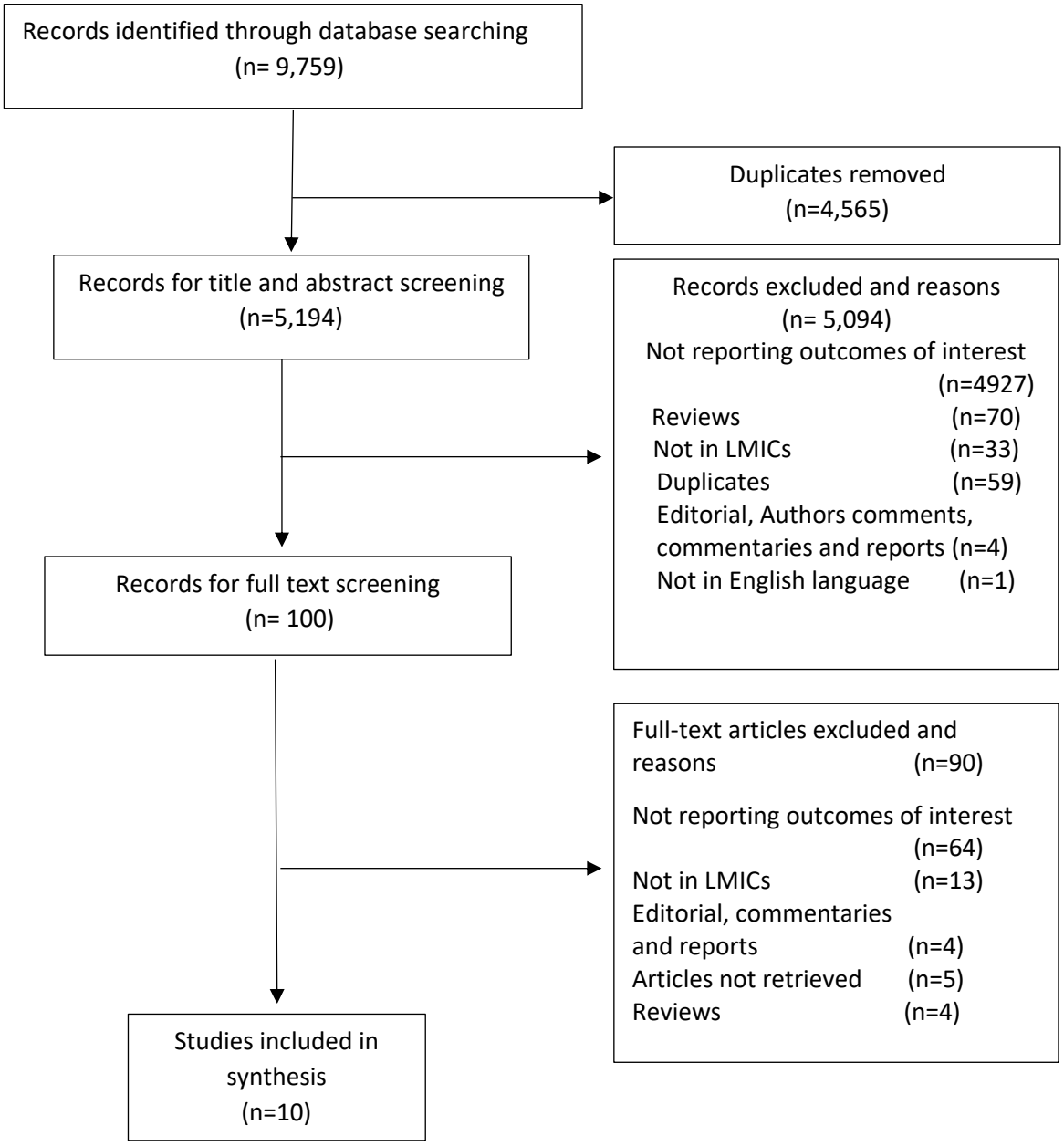
Two authors (M.G and J.M) independently screened titles and abstracts for eligibility (Figure 7). A third author (M.A) resolved any discrepancies. Articles approved for full-text screening were reviewed by the two authors (M.G and J.M) independently by applying the pre-established inclusion and exclusion criteria listed above; if disagreement, we reached consensus through discussion.

One author (M.G) performed data extraction and quality appraisal using pre-defined templates, made by the authors before the literature search. Another author (J.M) consulted in case of uncertainty.

Since the included studies were heterogeneous regarding design and outcomes, we used the narrative approach to synthesise the evidence. We reported characteristics related to (1) publication; (2) study; (3) audit type; (4) approaches; (5) structure outcomes; (6) process outcomes; (7) health outcomes; and (8) enablers and barriers. We classified the approaches, enablers and barriers according to the Kruk and Gage schema ‘synthesising improvement

approaches' (Kruk and Gage, 2017). This guide classifies approaches at micro, meso and macro system levels, meaning health provider level; health facility, district, or clinic level; and across health system or national level, respectively.

Figure 7: Study flow diagram



2.5 Results

2.5.1 Study selection

The searches resulted in 9,759 articles across all the databases. After excluding 4,565 duplicates, we screened 5,194 titles and abstracts. Of these, we excluded 5,094 articles for not meeting the inclusion criteria (Figure 7). The remaining 100 articles underwent full-text review. Common reasons for exclusion at this stage were; not reporting outcomes of interest (n=64) and not done in LMICs (n=13) according to World Bank Classification (World Bank, 2019). All studies were rated fair with a quality score ranging from 23 to 32 (Appendix 4). We finally identified ten studies as appropriate for inclusion in the synthesis.

2.5.2 Characteristics of studies

Ten studies from seven countries met the inclusion criteria: Tanzania (3 studies), Uganda (2) and one study each from Bangladesh, Moldova, Solomon Islands, Ethiopia, and Zambia. Appendix 5 summarises the study designs. Six quantitative (Demise *et al.*, 2015; Stratulat *et al.*, 2014; Sandakabatu *et al.*, 2018; Kidanto *et al.*, 2009; Kasengele *et al.*, 2017; Nakibuuka *et al.*, 2012), two qualitative (Biswas *et al.*, 2015; Armstrong *et al.*, 2014) and two mixed-method studies (Agaro *et al.*, 2016; Nyamtema *et al.*, 2010) were identified. All studies were uncontrolled before and after studies describing the effectiveness of stillbirth and neonatal death audit, with a before or after analysis, except two studies with a qualitative design (Biswas *et al.*, 2015; Armstrong *et al.*, 2014). Audits were conducted either weekly (Sandakabatu *et al.*, 2018; Kasengele *et al.*, 2017; Nakibuuka *et al.*, 2012) or monthly (Demise *et al.*, 2015; Stratulat *et al.*, 2014). Study duration ranged from 1 month (Armstrong *et al.*, 2014) to 48 months (Stratulat *et al.*, 2014) (Appendix 4). The deaths audited in all studies were perinatal deaths (stillbirths and early neonatal deaths) except one study which audited deaths in neonates (0-28 days) and older children (Sandakabatu *et al.*, 2018). The total number of cases audited ranged from a minimum of 5 to a maximum of 146 deaths per month (Appendix 4). A total of 970 perinatal deaths (stillbirths and early neonatal deaths) and 48 neonatal deaths were audited.

Four studies with qualitative design (Biswas *et al.*, 2015; Armstrong *et al.*, 2014; Nyamtema *et al.*, 2010; Agaro *et al.*, 2016) interviewed facility staff and key informants to understand

the process of stillbirth and neonatal death audit in the hospitals. The following data collection methods were used; document review (Biswas *et al.*, 2015; Armstrong *et al.*, 2014); focus group discussion (FGD) (2015); in-depth interviews (IDIs) (Biswas *et al.*, 2015; Armstrong *et al.*, 2014; Agaro *et al.*, 2016; Nyamtema *et al.*, 2010). The staff and key informants interviewed for IDIs and FGD varied between studies. However, they included facility staff involved in the process of audit at the private hospital, health centre, district hospital and central hospital level. Staff included were doctors, nurses, administration staff, civil surgeons, family planning officer, health managers and other members of the audit committee. The number of participants in each study for IDIs ranged from 29 to 66 participants (Nyamtema *et al.*, 2010; Agaro *et al.*, 2016). Five doctors and six nurses participated in FGD conducted by one study (Biswas *et al.*, 2015).

2.5.3 Stillbirth and neonatal death audit approaches

Two approaches were reported by six studies in this analysis (Demise *et al.*, 2015; Nakibuuka *et al.*, 2012; Sandakabatu *et al.*, 2018; Kidanto *et al.*, 2009; Kasengele *et al.*, 2017; Stratulat *et al.*, 2014). The first three studies used multidisciplinary facility teams to audit deaths and develop and implement recommendations (Demise *et al.*, 2015; Nakibuuka *et al.*, 2012; Sandakabatu *et al.*, 2018). In the first three studies, the chair of the audit team was either a senior obstetrician or paediatrician. Although the composition of multidisciplinary teams differed between studies, in all three studies it consisted of obstetricians, paediatricians, medical officers, midwives, administrators, nurses, neonatologist, neonatal fellow, and neonatal and labour ward in charges. One study had only senior members in the audit team (Demise *et al.*, 2015). All studies used standard mortality auditing forms adapted from the WHO for gathering clinical information. One study also included verbal autopsy questions for guardians and staff (Demise *et al.*, 2015).

While the second three studies used a confidential inquiry approach (Stratulat *et al.*, 2014) or external researchers (Kidanto *et al.*, 2009) or external and internal auditors (Kasengele *et al.*, 2017), these external multidisciplinary teams were not involved in the care of patients, they audited the cases and give feedback to facility staff to implement recommendations.

Of six studies that reported audit approaches (Demise *et al.*, 2015; Nakibuuka *et al.*, 2012; Sandakabatu *et al.*, 2018; Kidanto *et al.*, 2009; Kasengele *et al.*, 2017; Stratulat *et al.*, 2014),

five studies were prospective audits, while only one was a retrospective then prospective during re-audit (Kasengele *et al.*, 2017). Most of these approach activities were implemented at the facility level (e.g., conducting audits, implementing recommendations and training). Four studies reported engagement at the national level and two studies (Nakibuuka *et al.*, 2012; Stratulat *et al.*, 2014) reported national stakeholder engagement through developing guidelines, coordinating audit and disseminating the findings. In contrast, two studies (Kidanto *et al.*, 2009; Kasengele *et al.*, 2017) reported the use of external panel members or researchers at the national level. Appendix 6 summarises the approaches.

2.5.4 Outcomes of stillbirth and neonatal death audit

2.5.4.1 Structure

Six studies (Demise *et al.*, 2015; Nakibuuka *et al.*, 2012; Sandakabatu *et al.*, 2018; Kidanto *et al.*, 2009; Kasengele *et al.*, 2017; Stratulat *et al.*, 2014) reported structural improvements in one or more areas that improved the care of women in labour and neonates in the wards. Most changes were related to the physical structure of the ward; purchasing of essential supplies and equipment; training, staffing and organisation of services in the ward.

2.5.4.2 Process

Five studies reported changes in the process of care. One study (Kasengele *et al.*, 2017) cited quantitative process outcomes against eight pre-defined standards, and all eight standards showed some significant improvement (Table 2). Another study (Stratulat *et al.*, 2014), reported improvements in standard care and case management of complications during labour and birth . Other process outcomes reported by three studies (Stratulat *et al.*, 2014; Agaro *et al.*, 2016; Kidanto *et al.*, 2009) were improved fetal heart rate monitoring, doppler device use, data documentation, partograph use, clinical decision-making for complicated cases, referral system, the involvement of other professionals (social workers and psychologist) in the audit and international collaboration.

2.5.4.3 Outcomes (Health)

Newborn outcomes were reported in only a few studies (Table 2). Only two studies reported reductions in newborn/perinatal mortality (Stratulat *et al.*, 2014; Nakibuuka *et al.*, 2012) with only one study reporting a statistically significant reduction (Stratulat *et al.*, 2014). Proportional mortality rates among fetuses/newborns (≥ 37 weeks and birth weight ≥ 2500g) significantly decreased from 5.1 per 1000 in 2006 to 3.6 per 1000 in 2013 (with 1.5 per 1000 or 29.4% reduction, 95% CI 0.6-2.4; P=0.0015) (Stratulat *et al.*, 2014). Another study (Nakibuuka *et al.*, 2012) reported overall perinatal mortality reduction (52.8% in 2007 to 47.9% in 2008) before and after perinatal audit implementation (Table 2). Demonstrated changes were attributed to improved standards of care following implementation of stillbirth and neonatal death audits. No study reported newborn morbidity outcomes. One study (Kasengele *et al.*, 2017) reported a reduction in the incidence of maternal obstetric complications such as obstructed labour and antepartum haemorrhage, which contribute to stillbirths, following the implementation of fresh stillbirth audit by setting standards as a benchmark (Table 2).

2.5.5 Enablers and barriers of implementing stillbirth and neonatal death audits

Four studies (Sandakabatu *et al.*, 2018; Biswas *et al.*, 2015; Armstrong *et al.*, 2014; Agaro *et al.*, 2016) reported enablers (Table 3) and five studies (Agaro *et al.*, 2016; Biswas *et al.*, 2015; Armstrong *et al.*, 2014; Nyamtema *et al.*, 2010; Sandakabatu *et al.*, 2018) reported barriers (Table 4). In total, 18 enablers were identified with nine at health provider, seven at the facility and two at national or regional system levels (Table 3). Only one enabler at the health provider level was mentioned by more than one study (Table 3). Twenty-three barriers were identified with one at health provider, 18 at facility and four at national system levels (Table 4). Eight barriers at a facility level and one barrier at a national level were mentioned by more than one study (Table 4)

2.5.5.1 Enablers

Most enablers (9) were identified at the health provider level. Audit meetings provided opportunities for teaching and learning was the only enabler mentioned by more than one study (Sandakabatu *et al.*, 2018; Armstrong *et al.*, 2014) at health provider level (Table 3).

The rest of the enablers at both levels were mentioned by a single study (Table 3). One study (Agaro *et al.*, 2016) assessed the statistical significance of changes in enablers at both the health provider and facility levels. The enablers with statistical significance of changes at health provider level included: attendance record of review meetings ($p < 0.001$), knowledge of objectives of maternal and perinatal death review (MPDR) ($p < 0.001$), an observed improvement in care ($p < 0.001$) (Agaro *et al.*, 2016). While at facility level included: feedback ($p < 0.001$), implementation of action ($p < 0.001$) and the existence MPDR committee ($p < 0.001$) (Agaro *et al.*, 2016).

2.5.5.2 Barriers

Out of 23 barriers identified at three levels by five studies (Agaro *et al.*, 2016; Biswas *et al.*, 2015; Armstrong *et al.*, 2014; Nyamtema *et al.*, 2010; Sandakabatu *et al.*, 2018), 18 were identified at the facility level only (Table 4). Barriers mentioned by more than one study at facility level were: inadequate formation and implementation of action plans (Sandakabatu *et al.*, 2018; Armstrong *et al.*, 2014; Agaro *et al.*, 2016; Nyamtema *et al.*, 2010); audit facility team members not trained (Armstrong *et al.*, 2014; Agaro *et al.*, 2016; Sandakabatu *et al.*, 2018); limited time led to the postponement of meetings (Sandakabatu *et al.*, 2018; Biswas *et al.*, 2015; Armstrong *et al.*, 2014); increased workload in the ward (Agaro *et al.*, 2016; Sandakabatu *et al.*, 2018; Armstrong *et al.*, 2014); health workers not aware of the death audit process (Agaro *et al.*, 2016; Nyamtema *et al.*, 2010); too many cases to review (Sandakabatu *et al.*, 2018; Agaro *et al.*, 2016); poor documentation and inadequate information management systems (Biswas *et al.*, 2015; Nyamtema *et al.*, 2010) and inadequate human resource (Sandakabatu *et al.*, 2018; Biswas *et al.*, 2015). While at a national level, lack of broader engagement was the only barrier mentioned by more than one study (Sandakabatu *et al.*, 2018; Nyamtema *et al.*, 2010) (Table 4)

Table 1: Structural outcomes

Author/Year	Physical structure	Staffing	Equipment and supplies	Training, mentoring and supervision	Local policies and organisation of services
Demise *et al.* (2015)	Increased use of radiant warmers to maintain a the thermoneutral environment in the neonatal Intensive Care Unit	_	_	Refresher training on neonatal resuscitation for midwives and physicians	Improved administration of antepartum steroids Implementation of Kangaroo mother care Using transport incubators and cellophane wraps to keep babies warm during transfer Improved interdepartmental communication
Stratulat *et al.* (2014)	_	_	_	_	Established audit sessions as a routine part of clinical reflective practice Motivated midwives to be actively involved in audit meetings Adaptation of audit guidelines and tool used at national level National level coordinating confidential enquiry of audit meetings Developed 15 clinical practice protocols for neonatal care

Author/Year	Physical structure	Staffing	Equipment and supplies	Training, mentoring and supervision	Local policies and organisation of services
Nakibuuka *et al.* (2012)	Created Space for resuscitation in labour wards and special Neonatal care unit.	Recruited more anaesthetists. Doctors involved in pre-operative preparation of patients	Ambu-bags and masks provided in the labour ward and newborn unit	Trained midwives and doctors on labour management and partograph use Trained Intern Doctors and midwives on neonatal resuscitation Trained midwives in newborn unit on respiratory distress and CPAP.	New standards developed to reduce the time interval between a decision to do the caesarean section Disseminated the standards to all staff involved in the care of women in labour Neonatal resuscitation protocols displayed in the labour wards and neonatal special care unit
Sandakabatu *et al.* (2018)	_	_	_	Teaching opportunities during child death review meetings	Quality improvement team established to implement the action plans.

Dash (-) = Not reported, CPAP= Continuous Positive Airway Pressure

Author/Year	Physical structure	Staffing	Equipment and supplies	Training, mentoring and supervision	Local policies and organisation of services
Kidanto *et al.* (2009)			Purchased New sets) of vacuum and Doppler machines	120 midwives and doctors trained in the use of partograph, abnormal labour and newborn resuscitation Nurses/midwives routine CPD sessions weekly	Established an audit committee to do regular perinatal audits monthly Introduced daily and monthly assessments of all perinatal deaths by the team on call and audit team Management protocols for eclampsia and other obstetrics emergencies prepared and displayed in the wards notice boards Established a record tracing the patient from the labour ward to the theatre to reduce delays Obstetrician on call stationed in the labour ward
Kasengele *et al.* (2017)	_	_	_	_	Doctors began sleeping in the hospital when on call Weekly perinatal reviews and feedback

Dash (-) = Not reported, CPD= Continuous Professional Development

Table 2: Process and health outcomes

Author/Year	Mortality Perinatal, neonatal and stillbirths	Morbidity (Incidence) and other health outcomes	Improvement of the standard of care	Other process outcomes
Stratulat *et al.* (2014)	Proportional mortality rates among foetuses/ newborns with a gestational age of ≥37 weeks and with a birth weight of ≥2500g for the years 2005 to 2013. The proportional mortality rate decreased from 5.1 per 1000 in 2006 to 3.6 per 1000 in 2013 (with 1.5 per 1000 or 29.4% reduction, 95% confidence interval [95% CI] 0.6–2.4; z-value 3.2; P = 0.0015).		Improvements in the standards of care through multidisciplinary audit sessions and a no-blame approach Improved management of cases (breech presentation, cord pathology and Intrauterine growth retardation monitoring)	Improved birth records through data standardisation Partograph updated and modernised to include monitoring in the second stage of labour Improved documentation tools for the pathology of perinatal deaths Partograph used correctly and appropriate Improved clinical decision-making for complicated cases from 44% in 2007 to 82% in 2010 Recognised the role of other professionals (social workers and psychologist) in preventing prenatal deaths Strengthened collaboration across borders
Nakibuuka *et al.* (2012)	The overall Perinatal mortality rate in 2008 was	_	_	_

Author/Year	Mortality Perinatal, neonatal and stillbirths	Morbidity (Incidence) and other health outcomes	Improvement of the standard of care	Other process outcomes
	47.9 compared with 52.8 per 1000 total births in 2007			
Kidanto *et al.* (2009)	_	_	_	Improved referral system to reduce delays Improved documentation
Kasengele *et al.* (2017)	_	Obstructed labour accounted for 55.7% (n=64) in the initial audit and 38.7% (n=12) in the re-audit Antepartum haemorrhage accounted for 23.5% (n=27) at baseline and 16.1% (n=5) at re-audit. Unknown causes increased from 14.8% (n=17) in the initial audit to 38% (n=12) in the re-audit.	Increases occurred in: Partograph usage (from 36 (31.3%) to 20 (65%)) All Severe pre-eclampsia/eclampsia cases received correct treatment of magnesium sulphate at both initial and re-audit Referral of women with obstructed labour (31(48%) to 11 (92%)); Women catheterised (22(38%) to 7(58%)); Women reviewed within 15 minutes (2 (3%) to 4 (33%)); C/S operating staff notified (31(37%) to 16 (100%)); C/S done within 10	

Author/Year	Mortality Perinatal, neonatal and stillbirths	Morbidity (Incidence) and other health outcomes	Improvement of the standard of care	Other process outcomes
			minutes (31(37%) to 12 (78%))	

Dash (-) = Not reported, C/S= Caesarean Section

Table 3: Enablers of implementing stillbirth and neonatal death audit

Level	Enabler	Total	Citation
Health provider	Audit meetings provided opportunities for teaching and learning	2 Studies	(Armstrong *et al.*, 2014; Sandakabatu *et al.*, 2018)
	Confidentiality nature of discussion	1 Study	(Sandakabatu *et al.*, 2018)
	Positive atmosphere of voluntary participation and no blame	1 Study	(Sandakabatu *et al.*, 2018)
	Attendance of review meetings ($p < 0.001$)	1 Study	(Agaro *et al.*, 2016)
	Knowledge of objectives of MPDR ($p < 0.001$)	1 Study	(Agaro *et al.*, 2016)
	Observed improvement in maternal and newborn care ($p < 0.001$)	1 Study	(Agaro *et al.*, 2016)
	Strengthened responsibilities of the healthcare providers	1 Study	(Biswas *et al.*, 2015)
	Documentation process of patient records enriched	1 Study	(Biswas *et al.*, 2015)
	Facility providers committed to the process of reviewing	1 Study	(Armstrong *et al.*, 2014)
Facility	Existence of MPDR committees ($p < 0.001$)	1 Study	(Agaro *et al.*, 2016)
	Implementation of MPDR recommendations ($p < 0.001$)	1 Study	(Agaro *et al.*, 2016)
	Provision of feedback ($p < 0.001$)	1 Study	(Agaro *et al.*, 2016)
	Created a discussion platform of deaths	1 Study	(Biswas *et al.*, 2015)
	Discovered gaps and challenges related to deaths	1 Study	(Biswas *et al.*, 2015)
	Corrective measures were taken after an audit	1 Study	(Biswas *et al.*, 2015)
	Improved supervision and monitoring systems	1 Study	(Biswas *et al.*, 2015)
National	MPDR part of the medical school curriculum	1 Study	(Armstrong *et al.*, 2014)
	National and decentralised administrative levels were both engaged in the MPDR process	1 Study	(Armstrong *et al.*, 2014)

MPDR= Maternal and Perinatal Death Review

Table 4: Barriers to implementing stillbirth and neonatal death audit

Level	Barrier	Total	Citation
Health provider	Care providers not aware of actions implemented following audit recommendations	1 Study	(Nyamtema *et al.*, 2010)
Facility	Health workers not aware of the death audit process	2 studies	(Nyamtema *et al.*, 2010; Agaro *et al.*, 2016)
	Audit facility team members not trained	3 Studies	(Agaro *et al.*, 2016; Armstrong *et al.*, 2014; Sandakabatu *et al.*, 2018)
	Inadequate supportive supervision	1 Study	(Agaro *et al.*, 2016)
	Lack of financial motivation	1 Study	(Agaro *et al.*, 2016)
	Increased workload in the ward	3 Studies	(Agaro *et al.*, 2016; Armstrong *et al.*, 2014; Sandakabatu *et al.*, 2018)
	Too many cases to review	2 Studies	(Agaro *et al.*, 2016; Sandakabatu *et al.*, 2018)
	Inadequate formation and implementation of action plans	4 Studies	(Agaro *et al.*, 2016; Sandakabatu *et al.*, 2018; Nyamtema *et al.*, 2010; Armstrong *et al.*, 2014)
	Poor documentation and poor information management systems	2 Studies	(Biswas *et al.*, 2015; Nyamtema *et al.*, 2010)
	Cause of deaths not followed International Classification of Disease (ICD-10)	1 Study	(Biswas *et al.*, 2015)
	Inadequate human resource	2 Studies	(Biswas *et al.*, 2015; Sandakabatu *et al.*, 2018)
	Limited time led to the postponement of meetings	3 Studies	(Armstrong *et al.*, 2014; Biswas *et al.*, 2015; Sandakabatu *et al.*, 2018)
	Lack of clarity in its intended purpose	1 Study	(Armstrong *et al.*, 2014)
	Weak analysis and discussion of the cases	1 Study	(Armstrong *et al.*, 2014)
	Lacks specific measurable action plan	1 Study	(Armstrong *et al.*, 2014)
	Lack of key hospital decision-makers in the audit committees	1 Study	(Nyamtema *et al.*, 2010)

Level	Barrier	Total	Citation
	Failure to disseminate audit reports to the national authorities	1 Study	(Nyamtema *et al.*, 2010)
	Inadequate material resources (equipment for resuscitation)	1 Study	(Sandakabatu *et al.*, 2018)
National	Reporting forms not systematically analysed at the national level	1 Study	(Armstrong *et al.*, 2014)
	Technical committee meetings not held	1 Study	(Armstrong *et al.*, 2014)
	Funding Guidelines not adequately disseminated	1 Study	(Armstrong *et al.*, 2014)
	Lack of broader engagement at the national level	2 Studies	(Nyamtema *et al.*, 2010; Sandakabatu *et al.*, 2018)

2.6 Discussion

2.6.1 Summary

Overall, the ten studies included in this review support the key role that death audit plays in improving care and outcomes in perinatal and newborn care. Stillbirth and neonatal death audits improve structures, processes, and health outcomes in neonatal care. Facility or external multidisciplinary teams are mostly utilised to perform death audits. More enablers have been identified at the health provider level. In contrast, more barriers have been identified at the facility level. As the majority of barriers are related to the availability of staff to perform death audit, our review has also shown that even auditing one death per week is essential in identifying gaps in the care.

The published research strengths in this review include adding the latest evidence on how the audits are performed, their outcomes on quality of care and perinatal and neonatal health in the LMICs. In addition, the present review has identified enablers and barriers and categorised them according to system levels to guide future implementers. The present review assembled evidence from 7 different countries, located in 4 different regions, thus: Sub-Saharan Africa, South Asia, Europe/Central Asia and East Asia and Pacific.

The published research in this review is limited in the way that only ten studies were identified. All included studies audited stillbirth and early neonatal deaths (0-7days) except one study that included neonates from 0 to 28 days. Despite included studies resulted in significant improvement in care, it is essential to note that, all studies were uncontrolled before and after studies. A review by Schouten *et al.* (2008) found that uncontrolled before and after studies tend to exaggerate the effects than controlled design. With regards to the impact of audit on neonatal outcomes, only two studies reported newborn and perinatal mortality and no newborn morbidity outcomes were reported, suggesting this area could be explored further.

2.6.2 Stillbirth and neonatal death audit approaches

This review has shown the usefulness of the facility and external multidisciplinary team in performing stillbirths and neonatal death audits in the included studies. Studies on maternal

audits reported that involving facility staff in the audit process promoted successful implementation, ownership and sustainability of the process (Weeks *et al.*, 2005; Mgaya *et al.*, 2016). Most audits were done prospectively. The number of audited cases varied among the studies in this review, from a minimum of 5 cases to a maximum of 146 cases per month. As large numbers of cases reviewed may result in an in-depth analysis of gaps in the care, but it might pose a challenge in developing and implementing recommendations due to inadequate human and material resources in this context. In this context, it might be unrealistic to audit all stillbirths and neonatal deaths per month as they are many in numbers. Depending on the staffing and workload at the facility, it may be practical for the mortality audit team to review a selection of stillbirths and neonatal deaths or increase the frequency of meeting (World Health Organization, 2016b). Performing stillbirth and neonatal death audit at the departmental level is also essential in identifying gaps in care and interventions.

The majority of the approach activities were implemented at the facility level. Nambiar *et al.* (2017) recommended approaching system at the facilities as they are operating at the micro- (health providers), meso- (health facility team) and macro-level (regional or national level). Despite all system levels being of value, facility-level activities are central to the successful implementation of stillbirth and neonatal death audits. As described by Kaplan *et al.* (2012) in their model of understanding success in quality, facility-level is responsible for quality improvement leadership, culture support, senior leadership commitment, guidance and direction that shapes behaviour of staff pursuing quality improvement projects. Proper training of staff involved in death audits ensures quality implementation of audits and its recommendations. However, structural adjustments are required to facilitate the death audits. These adjustments include audit team characteristics, workforce focus, resources availability and data infrastructure that exist across all system levels to trigger and influence the success of death audit process (Kaplan *et al.*, 2012).

While at the health provider level, the participation of individual staff is essential in the audit process. However, a motivated care provider who has the capability and desire to improve performance will be of great value to the system (Kaplan *et al.*, 2012). Whereas, national or regional level activities like regulation, tool development, governance and dissemination need incessant coordination; as they act as external motivators that stimulate

the organisation to improve the performance in death audit or any quality improvement projects (Kaplan *et al.*, 2012).

2.6.3 Outcomes of stillbirth and neonatal death audit

The previous systematic review on effects of perinatal mortality audits in low- and middle-income countries reported a reduction in perinatal mortality of 30% (95% CI, 21%–38%) after the introduction of facility-based perinatal audit (Pattinson *et al.*, 2009). However, this previous review focused on perinatal mortality audits (stillbirths and early neonatal deaths, 0-7 days old), which may miss late neonatal death audits or early neonatal deaths occurring in neonatal wards after discharge from labour ward, which might give a false impression about overall neonatal mortality audits (age 0-28 days). The current review retrieved the latest evidence on outcomes of stillbirth and neonatal death audits. Overall findings varied both within and between studies. Most of the articles reported a mixture of outcomes that fell into the category of structure, process, and health outcomes. Only two studies reported a significant decrease in perinatal and neonatal deaths.

2.6.4. Enablers and barriers of implementing stillbirth and neonatal death audits

Identification of enablers and barriers are essential for hospital management and programme planners to implement successful stillbirth and neonatal death audits that improves the quality of care. In this review, four studies reported 18 enablers and five studies reported 23 barriers at health provider, facility and national system level, with more enablers (9) cited at the health provider level and more barriers (18) cited at facility level. Similar barriers have been reported in the previous review on maternal and perinatal death audits (Lusambili *et al.*, 2019). The hospital management should prioritise in enhancing enablers identified at the health provider level to maintain staff morale and resolving barriers at the facility level as they demotivate staff involved in audits to effect change. In this review, Nyamtema *et al.* (2010) found that other facilities had discontinued audit meetings due to failure by hospital management to implement audit recommendations.

2.6.5 Limitations

The current systematic review has some limitations, mainly relating to scope. The search was limited to literature describing approaches, enablers, barriers or reporting outcomes of

stillbirth and neonatal death audit at the facility level and to English Language papers only. This limited search might have missed information regarding other elements of death audits and also studies reported in other languages. Five articles could not be retrieved, which may have included important additional information to the review. The search only included original research articles; more information may be available in the grey literature, organisation reports, reviews, dissertations and theses, and conference proceedings. Although two authors conducted screening and eligibility assessment, data extraction and quality appraisal were primarily conducted by one author, which might have led to selection bias.

2.7 Conclusions

Implementation of stillbirth and neonatal death audits improves structure, process and health outcomes in maternal and neonatal care. Using a multidisciplinary facility team to conduct audit contributes to the success of the process. Despite all system levels being of value, facility-level activities are central to the successful implementation of stillbirth and neonatal death audits. Even auditing a single death is useful in the process of improving care at the facility level. The hospital management should prioritise strengthening enablers at the health provider level to improve staff morale and resolving barriers at the facility level as they demotivate staff to effect change. Researchers should aim at generating more evidence on how to effectively implement stillbirth and neonatal death audit, sustain the practice and further improve its impact on newborn outcomes in LMICs.

CHAPTER 3: METHODOLOGY

3.1 Chapter overview

Having described the gaps in the literature, study aim and objectives, this chapter describes Malawi, where this study was conducted, and research methodology used. First, I discuss the demographic characteristics and economic context of Malawi, focusing on the topics relevant for this study such as health indicators. I specifically focus on health system challenges both general and those affecting newborn care, which provides a basis for analysing factors affecting the audit process in Malawi. Then, I describe the research methodology used in this study to achieve the objectives outlined in Chapter 1. I present descriptions of the methods and their use in the field. After that, I discuss how the instruments were developed and outline the study preparation procedures, data collection methods, data management and data analysis. I also discuss the ethical issues that arose while conducting this study and how I addressed them. I describe how trustworthiness was addressed in the qualitative part of this study. I also reflect on my position in undertaking the research.

Further details of methods are provided in chapter 4 (resource availability), which details resource availability and barriers to the delivery of quality care for newborns; chapter 5 (quality of audit), which describes the quality of stillbirth and neonatal death audit; and chapter 6 (facilitators and barriers), which presents factors impacting on stillbirth and neonatal death audit. Please note that there are some repetitions for background and methodology sections in chapters four, five and six due to the thesis by publication approach which I used in compiling this thesis.

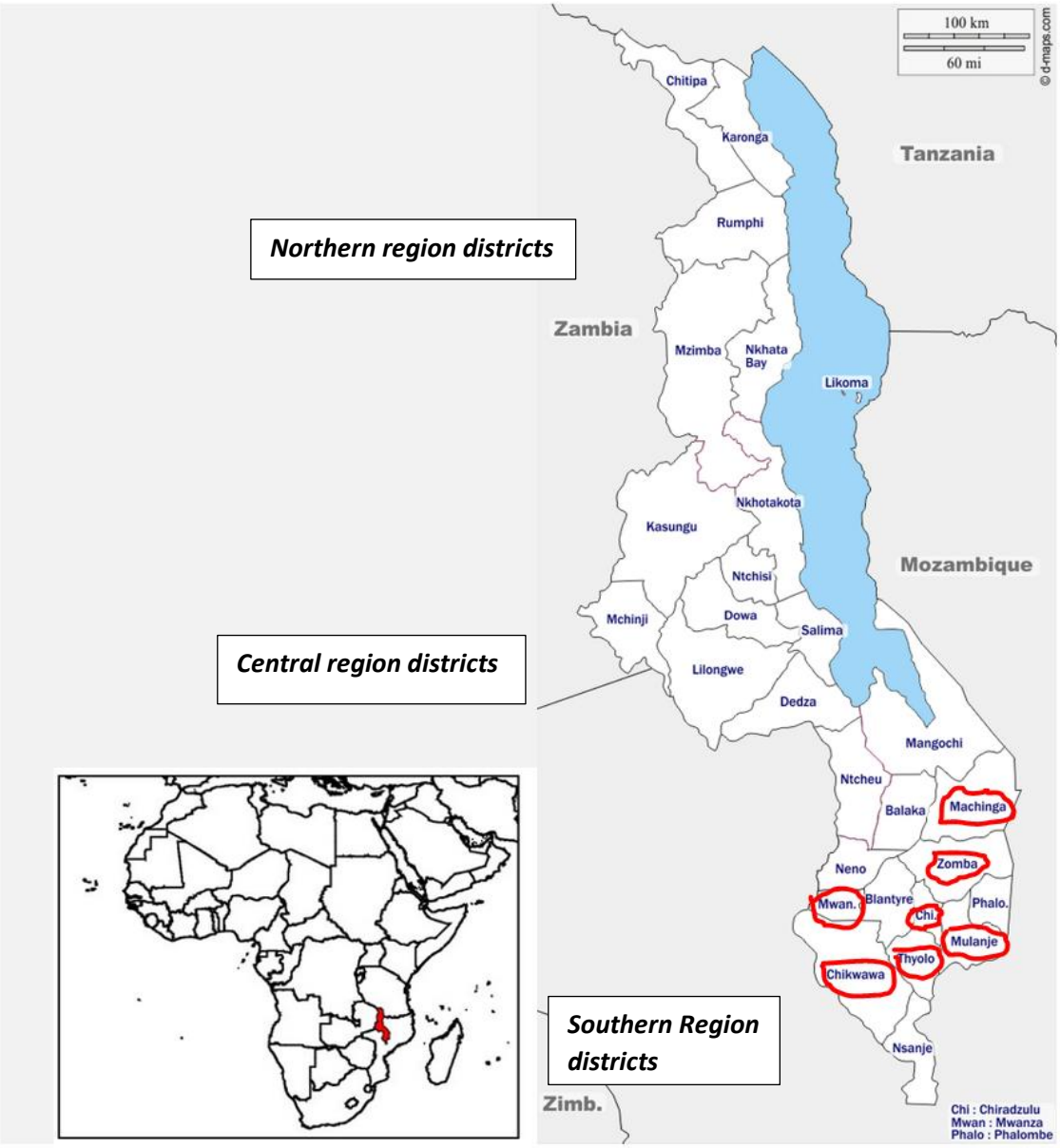
3.2 Study setting

3.2.1 Demographic characteristics and socio-economic context

Malawi is a landlocked country located in southeastern Africa. Administratively, the country is divided into three regions; the northern, central and southern regions (Government of Republic of Malawi, 2017). These regions are further divided into districts. There are 28 districts, 6 in the northern region, 9 in the central region and 13 in the southern region. The

districts are divided into traditional authorities (TA) ruled by chiefs. The TAs are sub-divided into villages, which form the smallest administrative units. Politically, each district is divided into constituencies that are represented by Members of Parliament (MPs) in the National Assembly and constituencies are divided into wards, which are represented by local councillors in District Councils (Government of Republic of Malawi, 2017). Zomba, Thyolo, Chiradzulu, Chikwawa, Machinga, Mwanza and Mulanje districts where this study took place are in the southern region of Malawi (Figure 8).

Figure 8: Showing map of Malawi, bordering countries and study sites



Source: Worldometer

Malawi's current population size is estimated at 17.5 million; 13% of the population is from the northern region, 43% from the central region and 44% from the southern region (National Statistical Office, 2019). An estimated 84% of the population lives in rural areas and 16% in urban centres (National Statistical Office, 2019). Fifty-one percent of the population are female of whom 47% are women of reproductive age (WRA; age 15-49 years) (National Statistical Office, 2019). Life expectancy at birth is 60.7 years for men and 66.9 years for women (UNDP, 2019). Malawi has a young population with 44% of the total population under the age of 15, 15% under the age of 5 and only 4% above 65 years (National Statistical Office, 2019). The unadjusted Total Fertility Rate is 4.2 children per woman. The unadjusted Crude Birth Rate (CBR) is 32.8 births per 1000 population; regional CBR is 30.5, 32.5 and 33.8 births per 1000 in the northern, central and southern regions, respectively (National Statistical Office, 2019). The total Crude Death Rate (CDR) is 6.3 deaths per 1000 persons (7.3 deaths per 1000 persons for males and 5.4 deaths per 1000 deaths for females). The CDR is higher in rural areas (6.6 deaths per 1,000 persons) than in urban areas (4.9 deaths per 1,000 persons). At regional level, CDR is highest in the southern region (6.7 deaths per 1,000 persons), then the northern region (6.5 deaths per 1,000 persons) and central region (5.8 death per 1, 000 persons) (National Statistical Office, 2019).

Malawi is one of the poorest countries in the world with a Human Development Index of 0.485 (UNDP, 2019). About half of the Malawi population lives below the national poverty line of K165,879 ($205) per year, which is equivalent to K454.46 ($0.56) per day (deemed by the country) (Government of Malawi, 2021) and 70.3% of the population lives below the international poverty line of $1.90 in purchasing power parity terms a day (UNDP, 2019). About half (52.3%) of the population aged between 15-64 years are working, of which 72% have formal employment and 28% informal employment (National Statistical Office, 2019).

Literacy level is higher among men (83%) than women (72%) (National Statistical Office (NSO) [Malawi] and ICF Macro, 2017). The literacy rate amongst women (90%) and men (96%) aged 15-49 years living in urban areas is higher than women (68%) and men (80%) living in rural areas (National Statistical Office (NSO) [Malawi] and ICF Macro, 2017). Table 5 summarises trends in key demographic and health indicators relevant to women and

newborns in Malawi which shows the slow progress in reducing the SBR and NMR. The proportion of deliveries by caesarian section (6%) and postnatal checks (42%) within 2 days were low. After describing demographic characteristics, socio-economic status and health indicators, I will now discuss how Malawi's health-care system operates and its impact on provision of care.

Table 5: Trends of key demographic and health indicators

Indicator	2000	2004	2010	2015-2016
SBR per 1000 births	22.2	-	20.0	-
PMR per 1000 births	46	34	40	35
NMR per 1000 live births	42	27	31	27
IMR per 1000 live births	104	76	66	42
U5MR per 1000 live births	189	133	112	63
MMR per 100000 live births	1123	984	675	497
Received ANC from skilled attendant (%)	91	92	95	95
Deliveries by skilled attendant (%)	56	56	71	90
Health facility deliveries (%)	55	69	73	91
Delivery by caesarian section (%)	3	3	4.6	6
Postnatal checks within 2 days (%)	-	31.4	43	42
Access to a safe water source (%)	65	64	80	87

Source: adapted from National Statistical Office [Malawi] and ORC Macro (2001); National Statistical Office (NSO) [Malawi] and ORC Macro (2005); National Statistical Office (NSO) [Malawi] and ORC Macro (2011); National Statistical Office (NSO) [Malawi] and ICF Macro (2017)

3.2.2 The Malawi health care system

Malawi's health care system is organised at four levels: community, primary, secondary and tertiary (Government of Republic of Malawi, 2017). The different levels are linked through an established referral system. Health services in Malawi are mainly provided by the public sector free of charge. The private sector includes private for-profit and private not-for-profit providers (Government of Republic of Malawi, 2017).

Health Surveillance Assistants (HSAs) provide health services at the community level, which include health posts, dispensaries, village clinics and maternity clinics. Each HSA is meant to be responsible for a catchment area of 1,000 people and there are currently 7,932 HSAs supported by 1,282 Senior HSAs in post. HSAs mainly provide promotive and preventive health care through door-to-door visits, village and outreach and mobile clinics (Government of Republic of Malawi, 2017). At the primary level, health services are provided by health centres (PHCs) and community hospitals. PHCs offer outpatient and maternity services. With a population of about 17,000,000 and 542 health centres in Malawi, each health centre serves a population of more than 30,000 against the recommended population of 10,000 (Government of Republic of Malawi, 2017; National Statistical Office, 2019). In Malawi, health centres are mainly managed by clinical technicians or medical assistants and nurses with an average training duration of 2-3 years. Community hospitals, with a bed capacity of 250 beds, are larger than health centres and offer outpatient and inpatient services and conduct minor procedures (Government of Republic of Malawi, 2017). Whilst HSAs are recruited to run community-based services, they spend a substantial amount of time supporting PHC services.

The secondary level of care consists of district hospitals and Christian Health Organisation of Malawi (CHAM) hospitals of equivalent capacity. This level accounts for 9.5% of all health care facilities. These hospitals provide referral services for health centres and community hospitals within the catchment area as well as providing outpatient and inpatient services to the local population.

The tertiary level consists of central hospitals. They ideally provide specialist health services and referral services for district hospitals within their region. In practice, around 70% of their services are primary or secondary services due to a lack of a gate-keeping system, where PHCs are at a distance or there is no secondary level facility where regional hospitals are allocated (Government of Republic of Malawi, 2017). There are only four tertiary hospitals in Malawi: two in the Southern Region, Queen Elizabeth Central Hospital (QECH) in Blantyre, Zomba Central Hospital in Zomba; one in the Central Region, Kamuzu Central Hospital in Lilongwe; one in the Northern Region, Mzuzu Central hospital in Mzimba.

The four system levels are supported by the Ministry of Health Headquarters situated in the capital city of Malawi, Lilongwe. Its functions include policymaking, standard-setting, quality assurance, strategic planning, resource mobilization, technical support, monitoring and evaluation and international representation. There are also five quality satellite offices, previously known as Zonal Health Support Offices (ZHSOs), which extend the central level and provide technical support to districts on quality management. Each district in Malawi has a district health office (DHO). The functions of DHOs include managing all public health facilities at the district level and directing the provision of primary and secondary level health services. The DHOs report to the District Commissioners under the Ministry of Local Government. At the technical level, DHOs receive technical backstopping from the quality satellite zones. Having described the different levels of the health system in Malawi and their respective functions, I move on in the next section to discuss the challenges faced by the health system in delivering quality of care.

3.2.3 Health system challenges in Malawi

Many problems have been identified in the Malawi health care system. Issues presented in this section are based on bottleneck analysis done when developing *''Every newborn action plan: an action plan to end preventable neonatal deaths in Malawi''* in 2013, Health Sector Strategic Plan (HSSP) II for 2017-2022 in 2017 and Human Resources for Health Strategic Plan in 2018 (Government of Malawi, 2015; Government of Republic of Malawi, 2017; Government of Republic of Malawi, 2018).This section will present general health system issues and those affecting newborn care.

3.2.3.1 General Issues

3.2.3.1.1 Health care workforce

Malawi faces a critical shortage of human resources for health despite the increased training of health care workers. The gaps exist across all cadres, districts and health care levels within Malawi's public sector (Government of Republic of Malawi, 2017). Only 67% of established posts for clinical staff (Medical Officer, Clinical Officer, Nursing Officer, Nurse/Midwife Technician, Medical Assistants, Pharmacy Technician, Laboratory Technician and Health Surveillance Assistants) are filled. With 1.49 health workers (clinical, nursing and

allied staff) per 1,000 population (Government of Republic of Malawi, 2018), capacity is far below the recommended ratio of 4.45 health workers per 1,000 population (World Health Organization, 2016a). Other challenges include staff deployment and retention, particularly among staff serving hard to reach populations (Government of Malawi, 2015).

3.2.3.1.2 Essential medical products and technologies

Although the MoH has put in place a national coordination mechanism with a technical working group on medical products, facilities still face a critical shortage of medical products. On average, only 24% of health facilities were able to maintain sufficient stocks to cover 1 to 3 months for the 23 essential tracer medicines and medical supplies described in the HSSP against a national target of 60% (Government of Republic of Malawi, 2017). Challenges include the absence of quantification at health centres, poor forecasting and procurement planning, inadequate funding, high disease burden, high purchasing prices, weak supply chain management, lack of drug storage spaces, unreliable information systems, irrational use of medicines, leakage, stealing, chronic stock-outs and inadequate generation and use of data (Government of Republic of Malawi, 2017; Government of Malawi, 2015). Given these critical deficiencies across the health system in Malawi, combined with the high burden and low priority previously given to newborn care, I will now introduce how some of these issues have impacted particularly on the provision of high-quality new-born care.

3.2.3.2 Health system issues affecting newborn care

3.2.3.2.1 Leadership and governance

Existing Reproductive, Maternal, Newborn and Child Health (RMNCH) intervention guidelines do not address and prioritise the leading causes of neonatal mortality (prematurity, asphyxia and infection) (Government of Malawi, 2015). There is also a lack of a MoH district-level focal person for RMNCH, unavailability of terms of reference for district-level coordinators, weak coordination between national- and district-level RMNCH programmes, challenges in the countrywide rollout of the birth registration policy and very few newborn indicators included in the Health Management Information System (HMIS) (Government of Malawi, 2015). Furthermore, poor accountability for newborn health at all

levels has been identified: there was no identified person accountable for newborn deaths, there were no regular perinatal death audits and until 2015 there was no policy on QI (Government of Malawi, 2015). Although the government introduced a policy on QI in 2017, (Ministry of Health, 2017) its impact on health care is not yet known. There was also poor coordination between MoH and some partners and between partners. Donors often work directly with districts thus there is no central accountability or equity in service provision. Even though the MoH tries to create accountability and equity through the requirement for quarterly Integrated Support Supervisions (ISS) at all levels, they are rarely done (Government of Republic of Malawi, 2017).

3.2.*3*.2.*2* Health financing

Malawi operates a public health system that is free for all with service level agreements with mission owned hospitals for maternal health and under-five children (Government of Republic of Malawi, 2017; Government of Malawi, 2015). However, the major challenge is that the health sector is grossly underfunded by the Government with 89% of the health sector funded externally by donors. With donors working directly with districts, the challenges with health care financing are evident in the frequent stock-outs of essential supplies (Government of Malawi, 2015).

3.2.3.2.3 Health care workforce

Malawi has no speciality training for neonatal nurses and doctors or clinical officers. Most nurses and doctors/clinical officers who work in neonatal units have general nursing or clinical or paediatric backgrounds and mostly they learn on the job. The lack of skilled health workers for newborn care in Malawi, as well as poor leadership and governance impact on health service delivery as described in, the next section.

3.2.3.2.4 Health service delivery

Quality of newborn care in health facilities was poor (Leslie *et al.*, 2016). Health service delivery challenges identified by the team involved in adapting Malawi ENAP highlighted that supervision was underfunded and not systematically implemented and there was limited availability of newborn care services in health facilities, especially for sick newborns

and complicated labour and deliveries. There was a lack of adequate guidelines and poor adherence to standard practices, inadequate utilization of key newborn survival interventions and no accountability system in place (Government of Malawi, 2015).

3.2.3.*2.5* Health information systems

The MoH has harmonized the Health Management Information System (HMIS), which includes the District Health Information Software (DHIS2), to improve data collection and reports (Government of Republic of Malawi, 2017). However, data quality is still inadequate due to challenges in recording, extracting and reporting data and submissions from the facilities. Other challenges include ineffective data use and validation systems at the point of generation, undeveloped surveillance and response guidelines for newborns and a lack of data collection systems in both private for-profit and non-profit facilities (Government of Malawi, 2015).

3.2.3.2.6 Community ownership and partnership

The challenges in community involvement include harmful cultural beliefs that prevent care seeking for sick newborns, particularly during the first seven days of life and beliefs that do not value and honour the life of a newborn, especially low birth weight or preterm babies (Government of Malawi, 2015). Having discussed issues affecting the Malawi health system, the next section presents demographic and health indicators specific to the study sites and describes how they were selected.

3.2.4 Study sites

The number of health facilities included was initially determined by selecting from thirteen government facilities implementing stillbirths or neonatal death audits, representing 54% of government district/tertiary facilities in the southern region of Malawi. Facilities were purposively selected to represent a wide range of neonatal mortality rates by including lowest, medium and highest district neonatal mortality rates (15-30 per 1000 live births). In order to compare how audits were conducted according to different death rates and likely case mixes from the chosen hospitals, I used mortality rate ranges in selecting facilities. The selection process only took into account hospitals that conducted stillbirth or newborn

death audits (intervention under review). Due to time and cost constraints, the researcher only considered hospitals in Malawi's southern area as a feasible option. The study was conducted in seven public hospitals in the seven districts of the southern region, Malawi, namely Zomba central (Figure 9), Thyolo (Figure 10), Chiradzulu (Figure 11), Chikwawa (Figure 12), Machinga (Figure 13), Mwanza (Figure 14) and Mulanje (Figure 15) hospitals. All hospitals are district hospitals except Zomba Central Hospital that serves the population from the east of the southern region of Malawi. The hospitals will be referred to as hospital 1, 2,3,4,5,6 and 7, respectively in chapters 4, 5 and 6 which have been submitted or are ready to submit manuscripts for anonymisation purposes.

Figure 9: Front view of Zomba Central Hospital

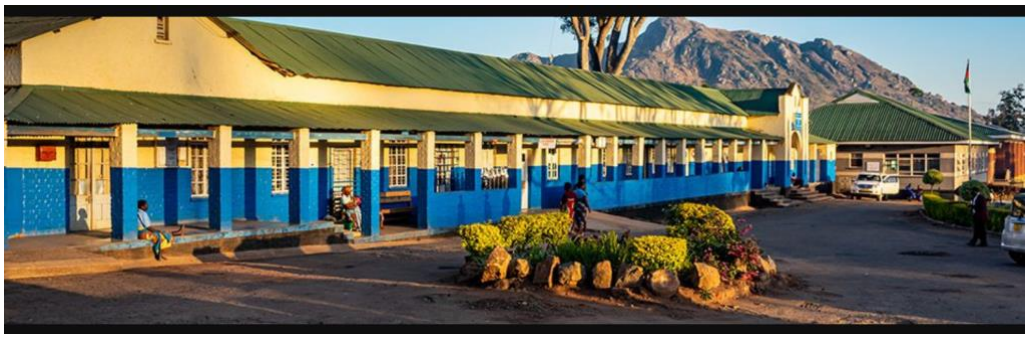


Figure 10: Rear view of Thyolo District Hospital

Figure 11: Front view of Chiradzulu District Hospital

Figure 12: Front view of Chikwawa District Hospital

Zomba is the largest district (851,737) with a mainly rural population (88%) (National Statistical Office, 2019). The second-largest district is Machinga (population 735 438), then Thyolo (721,456) and least populated district is Mwanza with 130 949 people in 2018 (Table 6). The population density is high in Zomba city followed by Chiradzulu district and the least is Chikwawa district. Machinga has the highest annual projected population inter-censual growth rate of 3.9% followed by Mwanza district (3.4%) and least is Chiradzulu district (2.1%) (National Statistical Office, 2019).

Figure 13: Side view of Machinga District Hospital

Figure 14: Front view of Mwanza District Hospital

Table 6 summarises population, demographic and health indicators for the seven districts. Chikwawa and Machinga are the districts with the lowest literacy levels for both men and women (Table 6). Childhood mortality rates (neonatal, infant and under-five rates) are highest in Mulanje district and lowest in Mwanza district. Machinga district has the highest and Thyolo the lowest fertility rate at 6.6% and 3.5% respectively (Table 6). Skilled ANC attendance ranged between 86.9% (Thyolo district) to 99% (Chiradzulu district), while skilled attendants' availability at birth ranged from 88.5% (Mulanje) to 96.3% (Mwanza). Facility birth ranged from 88.1% (Mulanje) to 96.2% (Mwanza) (National Statistical Office (NSO) [Malawi] and ICF Macro, 2017).

All seven districts had a caesarian rate of less than 7% in 2016 (National Statistical Office (NSO) [Malawi] and ICF Macro, 2017), which is below WHO recommendation of 10-15% (Betran *et al.*, 2016). The proportion of mothers who had a postnatal check within two days of giving birth ranged from 40.5% (Zomba) to 72.6% (Mwanza), while postnatal check for newborns ranged from 48.0% (Mulanje) to 72.3% (Zomba). The percentage of women who breastfeed within 1 hour of birth ranged from 70.6% (Mulanje) to 92.9% (Mwanza). Overall, Mwanza district has the most positive maternal and newborn indicators and Mulanje district the least. Having described specific characteristics of the respective study settings, the next section will present the overall study methodology.

Table 6: Population, demographic and health indicators for seven districts

Indicator	Zomba	Thyolo	Chiradzulu	Chikwawa	Machinga	Mwanza	Mulanje
Population*	851 737	721 456	356 875	564 684	735 438	130 949	648 107
Population density	2511-City 316-Rural	433	469	116	205	173	341
Population Inter-censual growth rate (%)	2.5	2.0	2.1	2.5	3.9	3.4	2.6
Literacy rate men (%)	87.7	87.5	93.3	78.2	71.1	76.8	82.9
Literacy rate women (%)	77.9	74.0	77.8	53.8	56.3	69.4	70.9
NMR per 1000 live births	22	27	29	27	28	15	30
IMR per 1000 live births	36	38	45	42	46	33	61
U5MR per 1000 live births	54	59	68	62	81	51	103
Fertility rate (%)	4.1	3.5	4.2	5.6	6.6	4.4	4.5
ANC by skilled attendant (%)	92.1	86.9	99.0	85.1	96.7	97.4	94.6
Deliveries by skilled attendant (%)	91.3	89.8	94.5	90.9	90.9	96.3	88.5
Health facility deliveries (%)	92.8	93.3	95.4	92.9	91.8	96.2	88.1
Delivery by caesarian section (%)	4.2	5.7	5.1	2.4	4.4	4.0	6.7
Postnatal checks within 2 days for mother (%)	40.5	45.1	60.4	53.3	49.9	72.6	63.0
Postnatal checks within 2 days for newborn (%)	72.3	59.7	59.2	56.5	55.3	61.1	48.0
Percentage of women breastfeed within 1 hour of birth (%)	91.4	78.4	86.2	77.1	79.8	92.9	70.6

Source: National Statistical Office (NSO) [Malawi] and ICF Macro (2017), *National Statistical Office (2019)

NMR-Neonatal Mortality Rate, IMR-Infant Mortality Rate, U5MR-Under-Five Mortality Rate, ANC-Antenatal Care

Figure 15: Side view of Mulanje District Hospital

3.3 Study methodology

3.3.1 Study design

A cross-sectional descriptive study using mixed methods collected retrospective and prospective data to evaluate the processes and outcomes of stillbirth and neonatal death audits. Both prospective and retrospective methods have merits and limitations in terms of data, control, accuracy, time, cost, bias, practicality and usefulness (Kessels-Habraken *et al.*, 2009). The prospective method is associated with generation of more reliable data than the retrospective method (Kessels-Habraken *et al.*, 2009). While retrospective method is less time consuming, cheaper and no risk of lost to follow up. With retrospective methods, challenges include underreporting, incomplete data and recall bias (Kessels-Habraken *et al.*, 2009). We used both prospective and retrospective methods to minimize bias as the strengths for both methods are combined and weaknesses minimized (Kessels-Habraken *et al.*, 2009). Mixed methods and different data collection techniques were used to complement each other and increase the reliability and validity of the findings (Dahlgren, Emmelin and Wingren, 2007).

I developed a conceptual framework (Figure 6) informed by the literature to guide the audit process and tested it in Malawi. Seven main data collection methods were used: 1) health facility assessments using facility resource surveys, (2) prospective review of audited deaths

and monthly facility surveillance data for maternal and newborn outcomes, (3) audit documents review, (4) direct observation of audit meetings, (5) a semi-structured questionnaire to assess knowledge, attitudes and practices of audit among ward staff, (6) semi-structured interviews (SSIs) and (7) focus group discussions (FGDs) with stillbirth and neonatal death audit committee members. Detailed information on each data collection approach will be described in the subsequent chapters.

3.3.2 Participant selection

The inclusion criteria for survey interviews included staff directly involved in managing pregnant women antenatally, during labour and birth, postnatally and those working in nursery wards. The SSIs and FGDs included staff working in these wards and participating in stillbirth and neonatal death audits. The DHMT members were also included. Staff who did not fit these criteria were excluded from the study. The included staff in the study were selected based on purposive and convenience sampling and their willingness to participate. I used purposive and convenience sampling for survey interviews to obtain descriptive data rather than for the calculation of statistical significance or odd ratios. I also used the same sampling method for qualitative semi-structured interviews because I wanted to reach staff who had participated in stillbirth and neonatal death audit to explore their lived experiences. I pre-defined a stratified purpose sample criteria of staff participating in SSI. The criteria included staff working in maternity and nursery wards either nurses, doctors or clinical officers who participate in audit meetings. I also included administration and management team members who are responsible for decision making at facility. Then, based on these criteria, I conveniently selected them for the interview (Cresswell and Plano Clark, 2011). The staff comprising DHMT members, doctors, midwives, nurses, clinical officers and administrative staff participated in the study. Figure 16 shows staff conducting an audit in one facility.

Figure 16: Staff attending a neonatal death audit at hospital 5

3.3.3 Data collection

Data were collected from DHMT members and staff who work in maternity and nursery wards in the seven facilities from August 2019 to December 2020. The following data collection tools were used in this study:

- Tool 1: Health Facility Resource Survey – I adapted the WHO Service Availability and Readiness Assessment (SARA) tool and a facility assessment questionnaire (Appendix 7). This questionnaire was previously used by the Maikhanda evaluation study on maternal and neonatal QI in Malawi (World Health Organization, 2015; Colbourn, Nambiar and Costello, 2013). This tool was used to collect information on facility characteristics, infrastructure, transport and communication, staff availability in labour, postnatal and neonatal wards, staff training in the last 12 months, material inventories (essential supplies, drugs, equipment and laboratory), treatment guidelines, leadership and governance.
- Tool 2: Facility Surveillance Data– I adapted the WHO audit and review of stillbirths and neonatal deaths guidelines form (World Health Organization, 2016b) (Appendix 8) to collect monthly facility data on the number, place and mode of deliveries, the number of births, neonatal admissions, neonatal complications, stillbirths and neonatal death rates.
- Tool 3: Newborn Perinatal Death Audit Form – For audited stillbirths, I used the newborn and perinatal death audit form used in Malawi to collect information on

audited stillbirths and early neonatal deaths (Appendix 9) which mainly occurred in the labour ward. The audit form captures data on maternal characteristics, type of delivery and fetal/neonatal characteristics, classification of perinatal deaths, avoidable factors and details of the action plan to address avoidable factors. Stillbirths were audited in only three hospitals and, although each used a different form, they captured most of the required information.

- Tool 4: Neonatal Death Audit Form– I used a neonatal death audit form (Appendix 10) used in Malawi to collect information on audited neonatal deaths in nursery wards during the study period. The audit form captured data on maternal and neonatal characteristics, care in nursery, classification of neonatal deaths, avoidable factors and an action plan to address avoidable factors.
- Tool 4A: Quality of Action Plan Assessment – I adapted criteria for assessing an action plan from Kimambo (2008), which analysed perinatal death reviews in Tanzania (Appendix 11 A-C). The parameters on the action plan are similar to action plan templates in the neonatal death audit form used in Malawi and covered modifiable factors, proposed solutions, responsible person and timeframe (Appendix 10).
- Tool 4B: Quality of Data Collection Assessment Form– captured completeness, accuracy, validity and consistency of data (Appendix 11D).
- Tool 5: Direct Observation Checklist – I developed a structured observation checklist (Appendix 12) based on six mortality audit cycle parameters described in WHO audit and review of stillbirths and neonatal deaths guidelines (World Health Organization, 2016b).
- Tool 6: Questionnaire Interview Guide – I adapted a questionnaire interview guide (Appendix 13) from Nyamtema *et al.* (2010), who used some of the questionnaires in Tanzania. The questionnaire covers awareness of the audit and QI teams, attitude and practice of audit using both open and closed-ended questions.
- Tools 7 and 8: Semi-Structured Interview (SSI; Appendix 14) and Focus Group Discussion (FGD; Appendix 15) topic guide. I developed the topic guides informed by six WHO stillbirth and neonatal death audit cycles and processes (World Health Organization, 2016b). The topic guides for SSI and FGD used the components of an

ideal model of mortality audit to assess composition, timing and frequency of audit meetings, selection of cases, feedback provision, dissemination of recommendations, record keeping, analysis of results and use of audit recommendations for institutional planning and budgeting, implementing changes and evaluating the process to improve quality of care (World Health Organization, 2016b). Use of the group approach (FGD) allows for collective norms to be identified and debated and individual approaches (SSI) for personal experiences and perceptions (Setia, 2017).

- Document Review Process– I reviewed audit data collection tools, reporting tools, recommendations follow up tools and national guidelines.

3.3.4 Sample size

The sample size for the overall study is summarized in Table 7 below. A sample size of seven hospitals were reached on the basis of feasibility and also compatibility with other similar studies (WHO *et al.*, 2009). A description of the sample size for each analysis is presented in the results chapters four, five and six. The labour ward, neonatal ward in-charges and neonatal focal persons from each hospital, totaling to 21 participated in both facility survey or SSIs and FGDs.

Table 7: Summary of sample size

	Sample Size	**Sampling approach**
District	7	Purposive
Health facilities	7	purposive
Facility survey	7	Purposive
Staff participated in semi-structured interviews (SSI)	38	Purposive and convenience
Number of Focus group discussions (FGD)	7	Purposive and convenience
Staff participated in FGD	49	Purposive and convenience
Staff participated in a questionnaire interview survey	35	Purposive and convenience
Neonatal death audit forms reviewed	438	All neonatal deaths audited
Stillbirth audit forms reviewed	8	All stillbirths audited
Audit action plans reviewed	996	All action plans reviewed
Direct neonatal death audit meeting observations	12	Random (at least 3 at each facility)

3.3.5 Data collection process

I first visited and informed participating hospitals about the study. I booked a meeting with 6 District Health Officers and 1 Hospital Director, and, through them, I organised and convened sensitization meetings with hospital staff. A minimum of 10 members from each hospital participated in these meetings and included nurses, clinical officers and doctors working in labour, postnatal and nursery wards, ward clerks, safe motherhood coordinators, neonatal focal persons and maternal and neonatal death audit teams.

After sensitisation meetings, I conducted a pilot study with participants from 2 participating facilities (hospitals 1 and 3) to test the facility Assessment tool, Structured Observation tool for observing audits and Questionnaire Interview Survey. Adjustments were made, especially on the survey questionnaire where some questions were unclear or asked similar things. For the Facility Assessment Survey, the essential drug Aminophylline used for preterm in the nursery was missed. I updated the tools accordingly.

After the pilot, I visited each hospital for two days and collected data for the health facility survey and of deaths audited between August 2019 to January 2020. After seeking permission from the ward in-charges, I collected the facility survey data from 3 wards (labour, postnatal and nursery wards), safe motherhood coordinators, neonatal focal persons, administration and laboratory personnel. I reviewed available death audit documents and death audit forms from patients' files for the next nine-month period. I redacted identifiable information, scanned the form and saved it on a password secured laptop.

I informed and collected the contact information for all safe motherhood coordinators or neonatal focal persons responsible for organising neonatal or stillbirth audits for easy communication about which audit meetings to observe. I followed up with them through phone calls and messages, reminding them to inform me when they were doing audits. Some hospitals had fixed days, others not, and timings kept changing.

When I was invited to attend an audit meeting, I observed and recorded information on the observation checklist. I observed three meetings in hospitals 1,2 and 5, two meetings in

hospital 3 and one in hospital 4. Although hospitals 6 and 7 held two meetings during the study period, I was not informed and, therefore, these meetings were not observed. After observing a meeting, I approached audit team members and ward staff and booked them for either questionnaire interview, SSI or FGD. Staff working in maternity wards and nursery wards were invited for questionnaire interview to assess knowledge, practice and attitude towards stillbirth and neonatal audits. I invited staff who participated in stillbirth or neonatal audits, hospital management members for SSI and FGD. For the participants who had accepted to take part, I secured informed consent and conducted the interviews. I moderated FGDs accompanied by a note-taker who was experienced and trained in note taking. The note-taker worked as a field worker at Malawi Liverpool Wellcome Trust-Clinical Research Programme (MLW), and this was her first contact with the participants. Being an outsider, the note taker was advantaged of not judging the individual staff member's capabilities or professional values but objectively observed and gathered the data (Bonner and Tolhurst, 2002). Characteristics of staff were collected at the beginning of each interview and included cadre, age, ward, years of experience and other roles using the recruitment log form in Appendix 16.

3.3.6 Data analysis and management

Data were anonymized from the point of collection and stored in a secure password-protected system, ensuring and maintaining confidentiality and anonymity throughout the study process. All hard copies and consent forms were kept in a locked drawer provided at MLW, where this study was hosted. Raw data has been stored in a password protected computer and will remain protected for at least five years before it is deleted.

I entered quantitative data in a Microsoft access database (MS ACCESS). I created forms and tables in the MS-ACCESS before data collection. MS ACCESS was chosen to reduce errors in data entry as variables were labelled and defined; any entry that did not match the variable definition was rejected. I checked all entries for accuracy. I exported the tables from MS ACCESS to IBM SPSS Statistics 26 for analysis. The data were then subjected to a rigorous cleaning process. The frequency of all variables was generated to identify outliers and address errors following data entry. Duplicate records were also identified and fixed. Hospital names were anonymized in the reporting of data.

Distribution tables were used to indicate the district and facility identifier where the data came from. Frequency and distribution tables and charts were used to analyse demographic characteristics, antenatal, maternal, and fetal/neonatal factors. The mean and standard deviation were calculated for birth weight, gestational age and parity. The factors contributing to deaths (avoidable factors) were analysed qualitatively using thematic analysis to identify emerging themes. Each SSI and FGD were recorded digitally, and recordings transcribed and coded using NVivo 12.0 qualitative software (QSR International). Framework c analysis was used to generate meaning to the data (Richie and Spencer, 1994). The analysis was guided by five phases of framework analysis; familiarisation, identifying a thematic framework, indexing, charting and mapping and interpretation (Richie and Spencer, 1994). Detailed information on sample size, tools used for data collection, analysis methods and inclusion criteria for each analysis are described in chapters four, five and six. Following a description of methods and how they were applied in the field, the next section examines ethical issues that arose and how they were mitigated.

3.4 Ethical considerations and confidentiality

3.4.1 Confidentiality

I redacted all forms with identifiable participant information before making copies. Hard copies of audit forms, questionnaires, action plans, audit notes or minutes, facility assessments and transcripts were kept in a secure location in MLW, and electronic transcripts were stored on a password protected computer accessible only to the researcher. The FGDs included co-workers and, therefore, confidentiality could not be completely guaranteed in this setting. However, at the beginning of each FGD, I secured an agreement with the participants that the content of the FGD findings would not be shared with anyone who did not attend. The participants were given numbers that were used during the discussion to avoid referring to them by name during the interview or transcription. It is not possible to link this number to a participant's identity. The participants for semi-structured and ward interviews were ensured of privacy and confidentiality with interviews conducted in a private room. The participants were ensured that the results would be presented in a general manner and all identifiable information would be redacted.

3.4.2 Informed consent

Informed consent was obtained before the interviews. The participants were approached and given the information sheet (Appendix 17) to read and their understanding of the aims of the study and what it involves were checked. If they agreed to participate, a consent form (Appendix 18) was given for them to sign. Each participant in SSIs, FGDs and survey questionnaires was asked for individual consent. Only those who agreed to participate took part.

3.4.3 Compensation for participation

The hospitals did not receive any formal compensation for participating in the study. The participants involved in SSIs, FGDs and semi-structured questionnaire respondents were compensated for their time at $10 per session as per College of Medicine Research Ethics Committee (COMREC) regulations.

3.4.4 Ethical approval

Permission was sought from the head of the facility, either the District Health Officer or Hospital Director before any data collection. I applied for and secured ethics approvals from the following ethics committees:

1. Liverpool: Ethics Committee, Liverpool School of Tropical Medicine. Reference number 19.076; dated 14th February 2020 (Appendix 19).
2. Malawi: Kamuzu University of Health Sciences formerly called College of Medicine Research & Ethics Committee (COMREC) Malawi. Reference number P.11/19/ 2869; dated 13th December 2019 (Appendix 20).

3.5 Trustworthiness

The relevance and integrity of the findings are dependent on the study's conduct being transparent. In this section, I will review the components of trustworthiness and how I managed them in this study. Munhall (2007) defined trustworthiness as the degree to which the participants have been fully included in the research process and have had the opportunity to reflect and comment on their story as retold by the narrative researcher. I

enhanced the trustworthiness for the qualitative part of this research by using the Lincoln and Guba framework (1986), which recommends using four parameters: credibility, dependability, confirmability, and transferability.

3.5.1 Credibility

Credibility refers to confidence in the truth and interpretations of the data *(Polit and Beck, 2010)*. I used different strategies to enhance it. The required sample size followed the principle of saturation and the interviews and discussions were continued until no new data were generated *(Fusch and Ness, 2015)*. I triangulated different parameters to enhance credibility *(Breitmayer, 1991)*. For example, I used SSIs and FGD to explore both group experience and individual opinions related to expertise and experience in the field of audits and the validation of key issues. In terms of sources, I collected data from different cadres and different wards relevant to newborn care. One research assistant and supervisors were involved in data collection, reviewing and discussing collected data to ensure transparency. Holding weekly supervisory meetings and field team meetings was beneficial for probing issues and helped identify gaps in the study design, data collection and analysis. Member checking was also done with the participants by the researcher to validate information and ensure that there was no misunderstanding and misinterpretation. This was done by inviting members to check their transcripts, although only 20 managed to do this. Participants were also given an opportunity to refuse to participate to ensure that data collection involved only those who were genuinely willing to participate and who stated that they were prepared to answer questions freely and honestly.

3.5.2 Transferability

Transferability concerns how the results will be applicable and meaningful to individuals or contexts not involved in the research (Speziale, Streubert and Carpenter, 2011). Providing sufficient descriptive data in the research methods helps others in evaluating the applicability of the data to other or similar contexts. A comprehensive description of the research setting has been provided in this chapter in section 3.2 and research methods in section 3.3. The detailed methodological section is not only for showing a research process but also for showing how the process or theory has been established and the meaning and

interpretation derived from providing transparency and confirming the validity of the results (Lincoln and Guba, 1986).

3.5.3 Dependability

To ensure the consistency of the research findings if the research was replicated with the same participants in a similar setting (Polit and Beck, 2010), I used triangulation of methods, sources and sites. Using well-trained field assistant experienced in qualitative research was helpful to ensure the quality of the data collected. A detailed description of study sites, data collection and analysis methods also contributed to achieving dependability. All topic guides were in English, but participants were encouraged to use the local language (Chichewa) during interviews. The recorded audio was transcribed but not translated even where Chichewa was used to ensure information accuracy. Also, an audit trail was maintained by documenting all decisions made throughout the study from the conceptualisation through to reporting providing data transparency which helped in achieving dependability (Creswell, 2013; Kitto, Chesters and Grbich, 2008).

3.5.4 Confirmability

Confirmability refers to the degree to which the participants and research setting determined the results rather than biases, motivations, or views of the researcher (Guba, Lincoln and Denzin, 1994). Several approaches were employed to achieve confirmability. A research team from different backgrounds undertook the analysis. The data collection methods, analysis, and triangulation were described in detail. I kept reflective diaries (Vicary, Young and Hicks, 2016; Lincoln and Guba, 1986) and discussed them with the research team to identify challenging established assumptions, circumstances, or events and how best to mitigate them. I have provided a detailed account of my positionality in the following section 3.5.5 as an insider, which could impact the findings. I have also included how I mitigated these assumptions and how they shaped some of the decisions I had to make. Furthermore, all interviews were recorded to help distinguish the participant's data from the interviewer's view. The researcher's role was limited to being an active listener and facilitator to allow participants to give detailed information about their experiences.

3.5.5 Reflexivity

Reflexivity is about being aware of the researcher's role in the practice of research and to provide a favourable environment for a researcher to acknowledge how he or she affects both the research processes and outcomes (Dodgson, 2019). There is the possibility that a researcher's background and position could affect what they choose to investigate, how to investigate, the methods judged to be adequate for the investigation, relevant findings and the framing and communication of what they have found (Dodgson, 2019). As someone born and educated in Malawi who has worked in two public district hospitals for over 14 years as a nurse in charge in a paediatric ward, a similar setting to where study participants came from, I view myself as an insider.

The insider/outsider researcher role has been widely discussed, bringing an understanding that researchers are in a position that constructs both their inside and outside social boundaries (Hodkinson, 2005; Perryman, 2011; Finefter-Rosenbluh, 2017). It might be challenging for an insider to separate their personal experience from that of the participants (Finefter-Rosenbluh, 2017) and my position as a nurse in charge in one of the study sites could have affected how I proceeded with this research due to power relationships. I had also been involved in national roles in paediatrics and child health such as supportive supervisions, emergency training and mentorship, during which I visited all facilities in Malawi, including the study sites. I was aware of these challenges throughout the research process, and I could have considered myself as a nurse in charge or national trainer, supervisor or mentor rather than a researcher. However, being an insider allowed me to offer a diverse and balanced point of view as the participants were freer to express their views on the audit process. Furthermore, being conscious of these challenges and potential biases allowed me to mitigate them to minimise their effects on the quality of data collected, its interpretation and communication.

During introductions with participants, I made it clear that I was not there as a nurse- in charge or a national trainer, supervisor or mentor, but as an independent researcher. Since I was the one conducting the SSIs and FGDs, this could have an impact on how the staff expressed their views or shared their experiences with an expectation to benefit from training and materials. I kept reminding the participants about my positionality at each

interview and interaction with them. I mostly used my car to visit the facilities and staff were interested in knowing where I was working, but I kept reminding them that my workplace was not relevant because I had come as an independent researcher.

3.6 Chapter Summary

This chapter has provided an understanding of the study setting and methods used to achieve the study's objectives. In this chapter I have discussed the socio-economic status and health system challenges that Malawi faces and its impact on the provision of quality newborn care. I have also presented a discussion of the research methodology that I used to assess resource availability, quality of stillbirth and neonatal death audit and explore factors that impact the audit process. I have provided the rationale for the choice of the approaches, data collection techniques and data analysis processes. I have also discussed ethical challenges and their mitigation strategies. I have also explained how I enhanced trustworthiness in the qualitative part of the work and my positionality. The research has generated rich data, which I present in the next three chapters. The first chapter (chapter 4) presents results for resource availability and barriers to delivering quality care for the newborns. The second chapter (chapter 5) presents results for quality of stillbirth and neonatal death audit and the last chapter (chapter 6) presents results for factors impacting on stillbirth and neonatal death audit.

CHAPTER 4: RESOURCES AVAILABILITY AND BARRIERS TO DELIVERING QUALITY CARE FOR NEWBORNS IN HEALTH FACILITIES IN THE SOUTHERN REGION OF MALAWI: A MULTISITE OBSERVATIONAL STUDY (PAPER 2)

4.1 Chapter overview

Having described the health system challenges Malawi is facing and its impact on newborn care, this chapter reports current status of resource availability and barriers to delivering quality of care. Given that different research methods and approaches were used, this chapter reports results for the health facility assessment conducted in all seven hospitals. The study assessed the quality of care in terms of the structural capacity of health facilities to support stillbirth and neonatal death audit implementation and newborn care. It relates to objective number 1 of the study. The conceptual framework for this study (described in Chapter 1, Figure 6) identifies contextual factors (structure) as a key foundation to a successful implementation of death audit as adequate material and human resources are essential for the implementation of service changes following clinical audit.

We assessed the characteristics of the hospital setting in which care was administered such as Infrastructure, staff profile for managing mothers and sick babies, staff training, essential drugs, equipment and supplies, availability of clinical protocols, governance and leadership.

Chapter 4 is ready for publication and was submitted to PLOS Global Public Health Journal on 11th April 2022. I am yet to receive response from the Journal.

I led conceptualization and conduct of this work (data collection and analysis) and was responsible for the original, revised and final manuscript preparation.

4.2 Abstract

Background

Facility-based births have increased in low and middle-income countries, but babies still die due to poor care. Improving care leads to better newborn outcomes. However, data are lacking on how well facilities are prepared to support. We assessed the availability of human and material resources and barriers to delivering quality care for newborns.

Method

We adopted the WHO Service Availability and Readiness Assessment tool to evaluate the resources for delivery and newborn care and barriers to delivering care, in a survey of seven hospitals in southern Malawi between August 2019 and December 2020. Data entered into a Microsoft Access database was exported to IBM SPSS 26 and Microsoft Excel for analysis.

Results

All hospitals had nursery wards with at least one staff available during any 24 hours, a clinical officer trained in paediatrics, at least one ambulance, intravenous cannula, fetal scopes, weighing scales, aminophylline tablets and some basic laboratory tests. However, resources lacking some or all of the time included anticonvulsants, antibiotics, vitamin K, 50% dextrose, oxytocin, basic supplies such as cord clamps and nasal gastric tubes, laboratory tests such as bilirubin and blood culture and newborn clinical management guidelines. Staff reported that the main barriers to providing high-quality care were erratic supplies of power and water, inadequacies in the number of beds/cots, ambulances, drugs and supplies, essential laboratory tests, absence of newborn clinical protocols and inadequate staff, including paediatric specialists, in-service training and support from the management team.

Conclusion

In hospitals in Malawi, quality care for deliveries and newborns was compromised by inadequacies in many human and material resources. Addressing these deficiencies would be expected to lead to better newborn outcomes.

4.3 Introduction

Globally, approximately, every minute nearly four babies are stillborn and five die during the neonatal period (the first 28 days of life) (UN IGME, 2020a; UN IGME, 2020b). About 80% of stillbirths and neonatal deaths occur in low-middle income countries (LMICs) with sub-Saharan Africa (SSA) accounting for 42% of these deaths. A third of stillbirths occur during labour and on the day of birth (Lawn *et al.*, 2014; Sankar *et al.*, 2016). Globally in 2019, neonatal deaths contributed about 47% of all under-five deaths. About a third of all neonatal deaths occur within the first day of life and three quarters within the first week.

Malawi contributes significantly to global mortality, with perinatal and neonatal mortality rates at an estimated 35 per 1000 total births and 27 per 1000 live births in 2016, respectively (National Statistical Office (NSO) [Malawi] and ICF Macro, 2017). To achieve the Sustainable Development Goal 3.2 and the vision and goals of the Every Newborn: an action plan to end preventable deaths (World Health Organization, 2014), a focus on reducing neonatal mortality, especially during birth and first day and week of life is crucial.

Most stillbirths and neonatal deaths result from preventable causes and are associated with poor quality of care during and after birth (UN IGME, 2020a; Lawn *et al.*, 2009b; Kruk *et al.*, 2018; Lawn *et al.*, 2016a; UN IGME, 2020b). Good quality care could prevent almost two neonatal deaths every minute (Kruk *et al.*, 2018). Providing quality care benefits both patient outcomes and the health system (WHO, OECD and World Bank, 2018).
Increased facility births has increased workload in many hospitals (Lawn *et al.*, 2016a) and lack of staff and equipment compromises the quality of care in most LMICs especially for vulnerable groups (WHO, OECD and World Bank, 2018; Kruk *et al.*, 2018). To provide a good standard of care and a better user experience, health systems must be well prepared with material resources and sufficient staff with the knowledge, skills and capacity to deal with normal and complicated pregnancies, childbirths and the newborn (Tuncalp *et al.*, 2015).

Assessing quality of health care using recognised standards, criteria and indicators is key to quality care improvement (Mainz *et al.*, 1992). WHO published a framework for improving the quality of care for mothers and newborns (World Health Organization, 2016c). Building on these frameworks and covering two of WHO's six vision strategic areas of standards of care and measures of quality of care (World Health Organization, 2016c), WHO has published recently standards for improving the care of small and sick newborns (World Health Organization, 2020c). The standards are guided by the eight domains of the WHO quality care framework (Tuncalp *et al.*, 2015) that health facility leaders, planners, managers and providers can use to assess and monitor the availability of resources, performance, areas for improvement and the impact of the intervention (World Health Organization, 2016c). A standard is what is expected to be provided to ensure high-quality care (World Health Organization, 2020c). Quality statements explain how to achieve the standard of care and are accompanied by quality measures used to assess, measure and monitor inputs,

processes, outputs and outcomes (World Health Organization, 2020c).

Malawi adapted all eight WHO quality of care framework standards and added a ninth standard regarding community health care and social accountability in maternal and neonatal health and published these for use in April 2020 (Government of Malawi, 2020a). However, Malawi has not yet adapted recently published WHO standards for improving small and sick newborn (World Health Organization, 2020c).

Little is known on resource availability in LMICs to meet the quality of care standards set by WHO (World Health Organization, 2016c; World Health Organization, 2020c). This study was conducted in the context of evaluating stillbirth and neonatal death audit in the southern region of Malawi. We assessed the availability of human and material resources and barriers to delivering quality care for newborns.

4.4 Materials and methods

4.4.1 Study design and Setting

This survey was done in seven public hospitals in the southern region of Malawi purposively selected to represent health facilities in the region with neonatal mortality at district level ranging from 15 to 30 per 1000 live births (National Statistical Office (NSO) [Malawi] and ICF Macro, 2017). The selected hospitals included one central hospital (tertiary level, hospital 1) and six district hospitals (secondary level, hospitals 2-7). The central hospital provides specialised inpatient and outpatient care at a regional level and serves referrals from the district hospitals and health centres within the region. The district hospitals provides both outpatient and inpatient services and serves referrals from community hospitals and health centres. Health centres were not included as they do not admit neonates.

4.4.2 Adaptation of data collection tools

We adapted the WHO Service Availability and Readiness Assessment (SARA) (World Health Organization, 2013) tool to assess facility readiness to provide quality newborn care during birth and up to 28 days postnatally. Information was collected regarding facility characteristics, infrastructure, transport and communication, staff availability in labour, postnatal and neonatal wards, staff training in the last 12 months, material inventories

(essential supplies, drugs, equipment and laboratory), clinical protocols, leadership and governance (Appendix 7). We piloted the tool in hospital 2 and incorporated appropriate changes such as including pharmacy stock out days to better achieve a comprehensive view of care. The data collection methods included observed availability in a service area, interviews with wards in charge and laboratory and pharmacy staff and stock card checking.

4.4.3 Administering the health facility assessment

Initially, the study team introduced the study to central and district management teams and secured permission to conduct the study. An introductory meeting was then held with facility management and staff. The first author (MG) conducted the health facility assessments between August 2019 and December 2020. The health facility resource survey was carried out with senior or ward nurses in charge of the labour, postnatal and neonatal wards and pharmacy and laboratory staff available on the assessment day. During interviews, staff were asked if resources were always, sometimes, or never available in the previous three months. The health resource survey took two days in each hospital.

4.4.4 Data analysis

Data extracted from paper forms was entered into a Microsoft Access database. Data were checked for anomalies by running descriptive summaries and data entry errors corrected. There was no imputation of missing data. Data were exported to IBM SPSS 26 and Microsoft Excel for analysis. Descriptive statistics were used to summarise scores allowing comparisons between hospitals.

4.5 Results

4.5 1 Hospital characteristics

All seven hospitals offered maternal and neonatal services 24 hours each day. Each hospital had labour, postnatal and nursery wards except hospital 6 where the labour and postnatal wards were combined. All seven hospitals admitted babies up to age 2 months requiring specialised care. Bed capacity and staffing levels for each hospital are shown in Table 8. Although there was a particular shortage of nursing/midwifery officers across all hospitals, overall, there was marked variability between hospitals in the proportion of staff posts

filled. This contributed to marked discrepancies between hospitals in the number of staff in post according to number of beds in all wards. Although none of the hospitals had a full-time paediatrician, all hospitals had at least one general medical officer available for consultation in all wards during both day and night shifts. All hospitals had at least one clinical officer trained in obstetrics and gynaecology or paediatrics, a clinical technician trained at diploma level, at least one registered nurse/midwife trained at degree level and at least three nurse/midwife technicians trained at diploma level and stationed at each ward.

Table 8[1234]**:** Summary of bed capacity and staffing levels

Hospital	**Hospital 1**	**Hospital 2**	**Hospital* 3**	**Hospital* 4**	**Hospital 5**	**Hospital 6**	**Hospital 7**
Number of Labour ward beds	9	8	8	7	8	4	9
Number of postnatal beds	31	88	54	18	38	35	33
Number of nursery beds	52	41	26	10	12	22	20
Number of staff labour ward							
Medical Officer/Specialists	2	1	1	2	3	1	2
Clinical Officer/Technician	1	1	2	3	1	3	4
Nursing/Midwifery Officers	7	1	5	4	2	2	3
Nurse/midwife technician	11	5	9	6	9	5	11
Support staff	9	5	5	7	10	12	12
Number of staff postnatal ward							
Medical Officer/Specialists	0	0	0	0	0	_	0
Clinical Officer/Technician	1	3	2	3	3	_	3
Nursing/Midwifery Officers	6	2	2	2	2	_	2
Nurse/midwife Technician	9	4	4	5	10	_	10
Support staff	9	5	7	6	12	_	12
Number of staff nursery ward							
Medical Officer/Specialists	0	0	0	0	0	0	0
Clinical Officer/Technician	2	1	2	3	5	1	1
Nursing/Midwifery Officers	6	1	2	2	1	3	2
Nurse/midwife technician	8	6	4	3	5	1	5
Support staff	6	6	1	0	0	0	0

[1] One month data for hospital 3- and two-months data for hospital 4 were missing

[2] Dash(-) postnatal ward within labour ward

[3] Nursing/Midwifery Officer trained at degree level while nurse/midwife technician trained at diploma level. Clinical Officers are trained at degree level while clinical technicians are trained at diploma level. Support staff includes patients and hospital attendants

4.5.2 Infrastructure

Inadequate electricity and water supply were noted in all hospitals with an adequate power backup system in hospital 3 only. Water supply failed during power cuts, but all hospitals had reservoir tanks and buckets with a tap for handwashing when piped water was unavailable.

4.5.3 Transport and communication

Although three hospitals were allocated one or more ambulances per 50,000 population, only about two-thirds of ambulances were functional so that only hospital 6 had adequate provision (Appendix 21). All hospitals had at least one functional landline telephone or mobile phone at all times except hospitals 1 and 6, where the mobile phone was not always available for use.

4.5.4 Staff availability and training

Table 8 summarises the number of staff allocated in the wards, while Table 9 summarises the availability of staff during day and night shift in the wards. Nurses/midwife technicians and support staff were the only staff always available during day and night shifts in all wards. One clinical officer or technician was available on call during the night shift. In the previous 12 months, only 22.7% of doctors/clinical officers and nurses across all hospitals had been trained in Integrated Maternal and Neonatal Care (IMNC), 23.1% in Helping Babies Breathe (HBB), 15.6% in Care of Infant and Newborn (COIN), and 25.3% in maternal and neonatal death audit (Appendix 22).

Table 9: Staffing availability

Facility	Labour ward										Postnatal ward										Nursery ward									
	Availability day					Availability night					Availability day					Availability night					Availability day					Availability night				
	Medical Officer	Registered nurse/Midwife	Clinical Officer	Nurse/Midwife	Support Staff	Medical Officer	Registered nurse/Midwife	Clinical Officer	Nurse/Midwife	Support Staff	Medical Officer	Registered nurse/Midwife	Clinical Officer	Nurse/Midwife	Support Staff	Medical Officer	Registered nurse/Midwife	Clinical Officer	Nurse/Midwife	Support Staff	Medical Officer	Registered nurse/Midwife	Clinical Officer	Nurse/Midwife	Support Staff	Medical Officer	Registered nurse/Midwife	Clinical Officer	Nurse/Midwife	Support Staff
Hospital 1																														
Hospital 2																														
Hospital 3																														
Hospital 4																														
Hospital 5																														
Hospital 6											NA	NA	NA	NA	NA	NA	NA	NA	NA	NA										
Hospital 7																														

NA-Hospital 6 had postnatal area combined with labour ward

Availability classification			
Always	Sometimes	Never	NA- Not Applicable

4.5.5 Availability of essential supplies, drugs and equipment

All hospitals had at least one essential drug or supply out of stock in the month preceding the assessment (Appendix 23). Even though some supplies and drugs were available at the pharmacy, their availability in wards varied, with most drugs not always available especially 50% dextrose, diazepam, magnesium sulphate, benzylpenicillin, gentamycin, ceftriaxone and Vitamin K (Table 10). Despite glucometer and blood pressure machines often being available, there were challenges is supplies of glucose test strips and blood pressure batteries for them to function. Basic supplies such as cord clamps, nasogastric tubes and urine dipsticks were not always available in hospitals. Labour and nursery wards had at least one functional essential equipment always available, but postnatal wards lacked essential equipment for the care of the neonate.

4.5.6 Laboratory tests

Basic laboratory diagnostic tests were provided except for haematocrit, bilirubin, blood gas analysis and blood cultures that were uniformly not provided (Table 11).

4.5.7 Clinical protocols

Clinical protocols for neonatal resuscitation, care of small and preterm babies, care of the sick neonate and essential newborn care were available in some of the nursery wards but not in the labour and postnatal wards (Table 12). Infection prevention protocols were absent in 9/21 (43%) wards assessed. Protocols for the management of complications of labour were available in almost all labour and postnatal wards.

4.5.8 Leadership and governance

Neonatal outcome data were summarised and pasted on the wall in wards of hospitals 1, 3, 5 and 7. Staff appraisals had been performed in the last 12 months only in hospital 2. Supportive supervision was done by national-level (Ministry of Health) staff but not by the District Health Management Team (DHMT) in all facilities. All seven facilities reported having functional neonatal death audit teams in place though the frequency of neonatal death audit meetings differed, with only 2 hospitals reported having audits in the month prior to the survey. Quality improvement teams were available but inactive in all facilities.

Table 10: Availability of essential supplies, drugs and equipment

RESOURCES	Hospital 1			Hospital 2			Hospital 3			Hospital 4			Hospital 5			Hospital 6			Hospital 7		
	Labour ward	Postnatal ward	Neonatal ward	Labour ward	Postnatal ward	Neonatal ward	Labour ward	Postnatal ward	Neonatal ward	Labour ward	Postnatal ward	Neonatal ward	Labour ward	Postnatal ward	Neonatal ward	Labour ward	Postnatal ward	Neonatal ward	Labour ward	Postnatal ward	Neonatal ward
ESSENTIAL SUPPLIES																					
Intravenous cannula																	N/A				
Intravenous fluids																	N/A				
Giving sets																	N/A				
Sterile blade																	N/A				
Cord clamp																	N/A				
Nasal gastric tubes																	N/A				
Heaters																	N/A				
Nasal prongs																	N/A				
Guedel airway																	N/A				
Glucometer																	N/A				
Glucose test stripes																	N/A				
Thermometers																	N/A				
BP apparatus																	N/A				
BP Calf batteries			N/U			N/U			N/U			N/U			N/U		N/A	N/U			N/U
Fetal scope		N/U	N/U		N/U	N/U		N/U	N/U		N/U	N/U		N/U	N/U		N/A	N/U		N/U	N/U
weighing scale																	N/A				
urine dipsticks																	N/A				
ESSENTIAL DRUGS																					
50% dextrose																	N/A				

RESOURCES	Hospital 1			Hospital 2			Hospital 3			Hospital 4			Hospital 5			Hospital 6			Hospital 7		
	Labour ward	Postnatal ward	Neonatal ward	Labour ward	Postnatal ward	Neonatal ward	Labour ward	Postnatal ward	Neonatal ward	Labour ward	Postnatal ward	Neonatal ward	Labour ward	Postnatal ward	Neonatal ward	Labour ward	Postnatal ward	Neonatal ward	Labour ward	Postnatal ward	Neonatal ward
Diazepam																	N/A				
Phenobarbitone																	N/A				
Magnesium Sulphate			N/U			N/U			N/U			N/U			N/U		N/A	N/U			N/U
Benzylpenicillin																	N/A				
Gentamycin																	N/A				
Ceftriaxone																	N/A				
Oxytocin																	N/A				
Dexamethasone																	N/A				
Vitamin K																	N/A				
Aminophylline tablets																	N/A				
Artesunate																	N/A				
ESSENTIAL EQUIPMENT																					
Bag and Mask																	N/A				
Resuscitaire																	N/A				
Suction machine																	N/A				
Oxygen concentrator																	N/A				
CPAP																	N/A				
Phototherapy																	N/A				

Availability classification			
1Always	Sometimes	Never	NA- Not Applicable

N/A-Not applicable means- hospital 6 did not had a separate ward. It was combined with labour ward

CPAP-Continuous positive airway pressure

Table 11: Laboratory

Resources	Central hospital	District hospitals					
	1	2	3	4	5	6	7
Full Blood Count							
Bilirubin							
Blood glucose							
Malaria Smear							
Grouping and Crossmatch							
CSF analysis							
Haematocrit (PCV)							
Haemoglobin							
Arterial blood gases							
Urine Microscopy							
Urine dipstick							
HIV							
Syphilis							
Blood Culture							

Key: Green=Test conducted at hospital

Red= Test not conducted at hospital

Table 12: Availability of clinical protocols in wards

	Central hospital			District hospitals																	
	1			2			3			4			5			6			7		
Protocols and governance	Labour ward	Postnatal ward	Nursery ward	Labour ward	Postnatal ward	Nursery ward	Labour ward	Postnatal ward	Nursery ward	Labour ward	Postnatal ward	Nursery ward	Labour ward	Postnatal ward	Nursery ward	Labour ward	Postnatal ward	Nursery ward	Labour ward	Postnatal ward	Nursery ward
Clinical protocols pasted on the wall																					
Neonatal resuscitation																					
Infection prevention																					
Care of small and preterm babies																					
Care of the sick neonate																					
Essential newborn care																					
Management of complications of labour			NA			NA			NA			NA			NA			NA			NA

Classification			
Available		Not available	NA- Not Applicable

4.6 Discussion

4.6.1 Summary of findings

All hospitals provided maternal and newborn health services and had at least one clinical officer trained in paediatrics and one healthcare worker available 24 hours a day to provide care to sick neonates. All hospitals had a separate nursery ward or unit dedicated to neonatal care though bed capacity varied. At least one ambulance for referral transportation was available. All hospitals had clinical protocols for managing labour complications pasted on the walls of the labour and postnatal wards. Some essential supplies and laboratory tests were always available.

However, many essential drugs and basic supplies were not always available for mothers and newborns. Clinical protocols for neonatal resuscitation, infection prevention, care of small and preterm babies, care of the sick neonate and essential newborn care were not available in some hospitals. Staff reported several barriers to providing high-quality care including inadequate beds, erratic power and water supplies, inadequate ambulance, inadequate in-service staff training, unavailability of other staff cadres during the night (as only nursing staff is always available), lack of paediatrician specialists, inadequate drugs, supplies and essential laboratory tests, absence of newborn clinical protocols and inadequate support from management teams.

4.6.2 Infrastructure

Our finding regarding nursery ward space is inconsistent with the WHO 2020 standards for providing high-quality care to small and sick newborns (World Health Organization, 2020c) . Limited nursery beds resulted in nursing more than one baby in a single cot increasing the risk of infection and overburdening staff (Zaka *et al.*, 2018; Gondwe *et al.*, 2021; Nair *et al.*, 2014; Souza *et al.*, 2013). Hospital-acquired infections among neonates cause about 30-40% of neonatal deaths (Távora *et al.*, 2008).

We found that power and water supplies were often interrupted despite the adapted Malawi standards for improving quality of maternal and newborn care emphasising the importance of adequate water and energy supplies. Birth asphyxia, prematurity and respiratory distress are common in this setting (National Statistical Office (NSO) [Malawi]

and ICF Macro, 2017) making power-dependent equipment such as oxygen concentrators, continuous positive airway pressure (CPAP) and phototherapy essential for reducing mortality. Inadequate infrastructure has been reported previously in Malawi (Smith *et al.*, 2017; Colbourn, Nambiar and Costello, 2013; Kawaza *et al.*, 2020) compromising compliance with the WHO 2020 standards on supplemental oxygen and CPAP management.

4.6.3 Transport and communication

Timely referral for obstetric emergencies is vital in preventing morbidity and mortality in the newborn. A critical shortage of ambulances was noted in these hospitals despite the adapted Malawi standards which stress having a pre-established plan for timely referrals. The hospitals were compliant with the adapted standards having either a mobile phone, landline or radio that functions all times. Reliable communication channels are crucial as theatre staff, specialists and medical officers are often not available during off-time hours in case of emergency. Referral to higher-level care and communication tools were among proposed signal functions for supporting quality obstetric and newborn care (Gabrysch *et al.*, 2012).

4.6.4 Staffing availability and training

Compared to the WHO-recommended threshold of 4.45 doctors, nurses, and midwives per 1000 population (Scheffler *et al.*, 2018), the Malawi health care system is severely understaffed with 0.5 clinical and nursing staff per 1000 population (Government of Republic of Malawi, 2018), nine times less than recommended threshold. All hospitals had a critical shortage of registered nurses/midwives as the proportion of filled posts were below 50%. At the same time, hospitals 1 and 6 also had a critical shortage of medical officers/specialists (Government of Republic of Malawi, 2018). In comparison to other central hospitals in Malawi, hospital 1 is severely understaffed, with a vacancy rate of 51% for doctors/clinical officers and 58% for nursing/midwifery staff (Government of Republic of Malawi, 2018). This understaffing resulted in only nursing/midwifery and support staff always available during day and night shifts. Studies conducted in Bangladesh and Malawi reported that numbers of nursing/midwifery staff were insufficient with staff facing excessive workloads that surpass their capacity to cope during the night shift, compromising

the quality of care (Bradley *et al.*, 2015). Doctors or clinical officers were not always available during the night shift compromising the required skill mix to manage sick newborns and putting an extra workload on the night duty nurse. These findings are at odds with the adapted Malawi standards on having competent, motivated staff consistently available to provide routine care and manage complications.

Furthermore, we found a lack of specialised paediatricians/neonatologists and few trained clinical officers in obstetrics /gynaecology and paediatrics. In an attempt to compensate for the long-standing shortage of skilled staff (Dogba and Fournier, 2009), Malawi has adopted the use of mid-level cadres like clinical officers, medical assistants, and nurse-midwives at registered, enrolled and technician grades to provide both emergency and routine care (Bradley *et al.*, 2015; Chilopora *et al.*, 2007; Wilson *et al.*, 2011). Recently, Malawi introduced a two-year speciality training programme for qualified clinical officers in obstetrics /gynaecology, paediatric, surgery and internal medicine. This should increase the number of trained clinical officers in obstetric and paediatric specialities to ensure that at least one clinical officer, well equipped with maternal and neonatal care skills, is always available during the day, night and weekend shifts.

Although mid-level cadres can help reduce stillbirths and neonatal deaths in LMICs, these staff require in-service training to update skills and competencies (Baumgartner *et al.*, 2021; Burgoine *et al.*, 2018; Metin Gülmezoglu and Lawrie, 2015). Nurses in LMICs obtain competence in neonatal care through training on the job (World Health Organization, 2020a). In the absence of speciality training in Malawi, some nurses and doctors/clinical officers working in the neonatal unit had benefitted from occasional in-service training such as COIN. However, we found inadequate training in all hospitals for HBB, COIN, IMNC and maternal and neonatal death audits. This is inconsistent with the adapted Malawi standards that recommend regular in-service or refresher training every 12 months. Despite limited evidence that continuous professional development (CPD) reduces mortality (Gitonga, 2016), we suggest incorporating essential training skills in pre-service training and CPD, which are mandatory for clinical and nursing staff to renew their practice licence as the standard guidelines stipulate. We recommend further studies to evaluate the impact of CPD on the outcome of care.

4.6.5 Availability of essential supplies, drugs and equipment

Material resources are vital to providing quality care during childbirth with a better user experience (Tuncalp *et al.*, 2015). Despite the adapted Malawi standards and similar to other LMICs (Souza *et al.*, 2013; Kawaza *et al.*, 2020; Smith *et al.*, 2017; Colbourn, Nambiar and Costello, 2013), we found that facilities were underequipped with many essential drugs, supplies, equipment and laboratory items. Interestingly, despite all hospitals procuring supplies and drugs from the same central medical stores, we observed variations in stocks of essential drugs and supplies between hospitals. For example, one hospital had 8 out of 21 items out of stock in January, while others had only 1-4 items out of stock. This suggests a need to improve drug and supplies needs assessment to ensure continuous availability of items at the hospital level with an adequate budget allocated.

4.6.6 Clinical Protocols

The adapted Malawi standards emphasise the need for written, up to date clinical protocols. These should be consistent with WHO guidelines (World Health Organization, 2016c) and address routine maternal and newborn care, complicated pregnancy and labour, preterm labour, infection prevention, care of small and preterm babies, resuscitation of babies who cannot breathe and essential newborn care. However, clinical protocols were missing in some hospitals. A study in Ethiopia (Rowe *et al.*, 2005) and a systematic review for LMICs (Bolan *et al.*, 2021) found unavailability of protocols on essential newborn care and neonatal resuscitation in hospitals.

4.6.7 Leadership and governance

Good managerial and clinical leadership improve performance by directing staff and creating an environment for support (World Health Organization, 2016c). Supportive supervision and performance appraisal, identified as a gap in this study, accompanying the provision of resources are integral to improving health care, worker job satisfaction, motivation and performance. But supervisors in LMICs often lack skills, tools and transportation, are overburdened with administrative duties, and wait for a financial incentive (per diem). As a result, supervision visits are missed with little accountability as to whether supervision is done or not (Rowe *et al.*, 2005). Despite the adapted Malawi

standards which advocate for competent, motivated staff consistently available to provide routine care and manage complications, we found that district management teams failed to supervise their own facilities.

4.6.8 Guidelines and standards implementation

Despite internationally recognised WHO guidelines and standards, challenges have been reported on the operationalisation of guidelines for maternal health in LMICs (Puchalski Ritchie *et al.*, 2016). WHO recommends the adaption of standards to suit the context of each country (World Health Organization, 2016c) and in Malawi, a multidisciplinary working group comprising doctors/clinical officers nurses, policymakers and development partners adapted the WHO standards and, recognising the importance of community engagement, added a ninth standard on community health care and social accountability for maternal and neonatal health (Government of Malawi, 2020b). Despite these efforts at the national level, this study has revealed deficiencies in the support for delivering quality care during birth and for newborns. WHO has provided an implementation approach for the standard with seven steps according to the 'Plan Do Study Act' model: establishing leadership structures and functions, adapting standards of care, conducting a baseline situation analysis or assessment, ensuring essential infrastructure to get started, building capability and implementing interventions, monitoring progress and refining the strategy (World Health Organization, 2016c). There is a need to conduct a large-scale baseline assessment in Malawi to better understand facility readiness to implement standards and build other structures as recommended in the WHO implementation approach. This study has reported deficiencies that provide a basis for developing interventions to improve standard implementation in Malawi. In addition, the WHO and Malawi adapted standards on maternal and newborn care lack clear monitoring and evaluation plans and tools to improve the implementation guidance and learning platform (World Health Organization, 2016c; Government of Malawi, 2020a).

4.6.9 Strengths and limitations

Strengths of this study were the inclusion of one central and six district hospitals from 7 districts in Malawi increasing the applicability of the findings. We also used a WHO validated checklist (SARA) for assessing service availability and readiness making comparisons with

other studies easier. This tool was also used for the Maikhanda quality improvement project evaluation in Malawi to assess the facility resources (Colbourn, Nambiar and Costello, 2013). The assessed parameters were comprehensive, including maternal and newborn services, physical infrastructure, availability of resources, equipment and supplies, guidelines, staffing, training, leadership and governance. The methods generated a wealth of information to identify gaps and recommend improvement.

This assessment also had limitations. It was only conducted in the southern region of Malawi, which may limit generalisation at the national level. Information was primarily from self-reports; further studies could include direct observation of care to confirm data reliability and semi-structured interviews with staff and women to understand their experience of care (standards 4-6). However, since most of our findings were consistent across the seven facilities, we consider that the study provides information that can guide interventions, implementers, policy, and researchers to improve the quality of care for newborns and outcomes.

4.7 Conclusions

Human and material resources to provide quality care during birth and for newborns were mostly inadequate and inconsistent with the Malawi standards. Assessing the current status of resource availability and barriers to delivering care has highlighted gaps in the system. These provide a basis for health care professionals, policymakers, health service planners, programme managers, regulators, professional bodies and technical partners involved in maternal and newborn care to help in planning, delivering and ensuring the quality of health service delivery. A multi-country evaluation study is needed to better understand and identify ways of mitigating challenges in the implementation of WHO or adapted quality standards.

CHAPTER 5: QUALITY OF STILLBIRTH AND NEONATAL DEATH AUDIT IN MALAWI: A DESCRIPTIVE OBSERVATIONAL STUDY (PAPER 3)

5.1 Chapter overview

Following an initial assessment that evaluated the resources available for neonatal care in seven hospitals, I found that the capacity to deliver neonatal care was uniformly poor across the hospitals with challenges identified in infrastructure, in-service staff training, drugs and supplies, essential laboratory tests, newborn clinical protocol and support from the management team. Following these results, it was necessary to assess the quality of stillbirth and neonatal death audit performed in these facilities. I present these results in this chapter. The section reports: a) maternal and neonatal hospital statistics, b) audit document review— audit guidelines, forms, audit meeting minutes, audit reports and recommendation follow-up records, c) systematic observation of neonatal death audit meeting using WHO audit cycle parameters; d) retrospective review of stillbirth and neonatal death audit charts and e) health care worker factors that affect the conduct of stillbirth and neonatal death audit. This section relates to objectives number 2 and the process component of the conceptual framework for this study (described in Chapter 1, Figure 6). The audit that links to care improvement initiatives can improve neonatal outcomes.

This chapter 5 was published in the Journal of Clinical Pediatrics and Neonatology in August 2022. The publication can be found at the link below: https://probiologists.com/Article/Quality-of-stillbirth-and-neonatal-death-audit-in-Malawi:-A-descriptive-observational-study

I led conceptualization and conduct of this work (data collection and analysis) and was responsible for the original, revised and final manuscript preparation.

5.2 Abstract

Background

WHO developed a guideline for implementing stillbirth and neonatal death audits at healthcare facilities in 2016. Like many other low- and lower-middle-income countries,

stillbirths and neonatal deaths rates remain high in Malawi despite implementation of audit. This paper assesses the quality of facility-based stillbirth and neonatal death audit implementation in Malawian hospitals. The aim was to inform health professionals, facility managers and policymakers of the current status of stillbirth and neonatal death audit and propose recommendations for improvement.

Methods

In accordance with the WHO audit guidelines, we applied mixed methods to determine the quality of audit implementation in seven hospitals in Malawi between August 2019 and December 2020. We reviewed hospital surveillance data, audit documents, used audit forms, audited neonatal deaths and action plans. We sought staff perceptions and opinions through a questionnaire and interviews and observed audit meetings. Quantitative data was analysed using IBM SPSS 26.0 and presented using frequencies and proportions. Qualitative data were analysed using predefined themes in a survey guide.

Results

The frequency of audits and number of stillbirth and neonatal deaths audited varied significantly between hospitals. No hospital had national audit guidelines. Deficiencies included limited information on neonatal death audit data collection and reporting tools, incomplete documentation, lack of senior staff commitment and a blame or shame atmosphere. Audit meetings often did not start with review of ward statistics, previous minutes and follow-up as to whether previous recommendations had been implemented. Challenges in analysing audit information and recommending solutions resulted in low-quality action plans. No objective evidence was found that audit recommendations were implemented.

Conclusion

Assessed according to WHO guidelines, audits were of low quality resulting in challenges in identifying and addressing factors contributing to mortality. We recommend regular audit implementation, with completion of audit cycles for audit to contribute to mortality reduction.

5.3 Introduction

In 2019, an estimated 2 million (uncertainty range 1.9- 2.2) babies were stillborn and 2.4 (uncertainty range 2.3-2.7) million died within 28 days of life (neonatal deaths) (UN IGME, 2020a). About 80% of these stillbirth and neonatal deaths occurred in low- and lower-middle- income countries (LMICs) (UN IGME, 2020a; Hug *et al.*, 2021; UN IGME, 2020b). Despite an increase in the number of births assisted by skilled attendants in LMICs, stillbirths remain common and newborns are still dying from preventable causes due to poor quality of care (Singh, Brodish and Suchindran, 2014; Lawn *et al.*, 2016a; Kruk *et al.*, 2018). Each year, an estimated one million stillbirths and newborn deaths could be prevented if services were of high quality (Kruk *et al.*, 2018). LMICs need to invest in health system strengthening to provide high quality newborn health services.

Stillbirth and neonatal death audit is a widely recommended intervention to improve quality of care and reduce stillbirths and neonatal mortality thereby helping to attain Sustainable Development Goal 3.2 (World Health Organization, 2016b). This approach is also in line with the Every Newborn Action Plan strategic objective 2 and 5 to improve the quality of maternal and newborn care and count every newborn through measurement, programme tracking and accountability to generate data for decision making and action (World Health Organization, 2014). Audits empower staff to learn from mistakes and initiate significant changes in the care of patients or the health system more generally (Pattinson *et al.*, 2009). Stillbirths and neonatal death audit help identify gaps and implementation of ways to improve the quality of newborn care (World Health Organization, 2016b) . However, the audit and feedback cycle need to link to actions at the point of care; audit alone does not necessarily reduce deaths (Pattinson *et al.*, 2009). Effective audit requires a functional system with constant monitoring and evaluation and with the feedback loop in place as per the audit cycle (Figure 5) (Rhoda *et al.*, 2014). In 2016, WHO developed stillbirth and neonatal death audit guidelines to assist facilities in implementing quality audits (World Health Organization, 2016b).

Despite the adaptation of WHO audit guidelines at national level and audit and feedback being widely used, its effectiveness is variable, with some studies reporting positive effects on mortality (World Health Organization, 2014; World Health Organization, 2016b; Allanson

and Pattinson, 2015; Lusambili *et al.*, 2019) while others reporting no effect (Allanson and Pattinson, 2015). Furthermore, in some Sub-Saharan African countries, conducting stillbirth and neonatal death audits, it is unclear whether the data collected are linked to health outcomes considering the high numbers of deaths in facilities (Lusambili *et al.*, 2019). Studies have reported challenges in implementing audits linked to national engagement, organisational support, formulating appropriate recommendations and implementing changes (Sandakabatu *et al.*, 2018; Nyamtema *et al.*, 2010; Lusambili *et al.*, 2019). In Malawi, stillbirths and neonatal reviews/audits are not as well established as maternal audits (Government of Malawi, 2015).

We assessed the quality of facility-based stillbirth and neonatal death audit implementation in seven districts in Malawi based on WHO audit guidelines and provided recommendations on how hospitals in this and similar settings can support staff to improve the audit process.

5.4 Materials and methods

5.4.1 Study design and setting

This descriptive mixed-method study was part of a quality improvement project conducted between August 2019 and December 2020 evaluating processes and outcomes of stillbirth and neonatal death audit and the context in which audits are conducted in public hospitals in the southern region of Malawi. The WHO Making Every Baby Count: Audit and Review of stillbirth and Neonatal deaths guidelines and toolkit comprises of 6 modules. The data collection tools were developed basing on this WHO audit guidelines. We used WHO audit cycle 6 steps to design audit meeting observation checklist, minimum perinatal and neonatal indicators checklist while audit document and audit forms review were based on WHO audit tool kits. The assessment also incorporated aspects of creating enabling environment for audit as per WHO guidelines.

5.4.2 Population and sampling

The study population comprised health workers working in maternity and neonatal (nursery) wards, in-charges of wards, focal persons responsible for neonatal care and members of stillbirths and neonatal death audit committees. Seven hospitals were purposively selected as their neonatal mortality rates fall within the lowest, medium and

highest categories. The seven hospitals included one central hospital (tertiary level; hospital 1) and six district hospitals (secondary level; hospitals 2 to 7).

5.4.3 Measurements and data collection

We reviewed pregnancy and neonatal outcome data (morbidity and mortality) and all audited deaths from August 2019-November 2020 in each hospital. We reviewed audit documents and observed 12 neonatal death audit meetings. Thirty-five health workers in maternity and neonatal wards, available on the interview day, were conveniently selected for a semi-structured questionnaire survey about audit knowledge, practice and impact.

5.4.3.1 Institutional deliveries, stillbirths, and neonatal outcome data review

A standardised form, adapted from WHO guidelines for stillbirths and neonatal deaths (World Health Organization, 2016b), was used to extract monthly data on deliveries, stillbirths and neonatal admissions and deaths from the hospital Health Management Information System department and nursery ward registers (Appendix 8). Data were collected for six months retrospectively from August 2019 to January 2020 and then prospectively and monthly from February 2020 to October 2020.

5.4.3.2 Document review

Based on WHO audit guidelines, we reviewed neonatal death audit national guidelines and a classification list of causes of deaths and modifiable factors for neonatal deaths. In each hospital, data collection templates, reporting templates and follow-up records of action plans were checked and reviewed for their availability, use and type of information captured.

5.4.3.3 Quantitative and qualitative data processing and analysis

All completed audit forms from August 2019-November 2020 were reviewed using a newborn-perinatal audit form for stillbirths (Appendix 9) and neonatal death audit form (Appendix 10). Scanned copies with identifiable information redacted were saved in a password-protected computer. Information extracted included the frequency of audit meetings, proportion of deaths audited, the proportion of forms with complete admission and patient information, the proportion of common causes of deaths audited, summary of

the proportion of deaths that could have been prevented, proportion with modifiable factors and proposed solutions that may prevent deaths, quality of action plans and quality of completed audit forms. Modifiable factors and proposed solutions were grouped into health provider, administrative and caregiver or patient factors as per WHO guidelines. The quality of the action plan was assessed if they were specific, measurable, achievable, realistic and timebound (SMART) as per WHO guidelines and grading of these parameters was guided by a predefined template (Appendix 11A-C) adapted from Kimambo et al. (Kimambo, 2008) which are consistent with WHO SMART description in the guide. Each component of the plan was scored for appropriateness, with scores 1, 2 and 3 representing unsatisfactory, good and very good. The quality of completed audit forms was assessed using a predefined template adapted from the UK Data Management Association working group (DAMA UK working group, 2013) (Appendix 11D). Assessed parameters included completeness (all parts of form filled), accuracy (correct information), consistency (agreement of information within the form) and validity (representing what it aims to measure). A score of 'excellent (100%)' was assigned to complete, accurate, consistent and valid forms, 'good (75%)' if less than 5 items were missing and 'unsatisfactory (50%)' if more than 5 or more items were missing.

5.4.3.4 Observation of audit meetings

Observation of audit meetings was conducted in all hospitals between March 2020 and November 2020 using a pretested observation checklist (Appendix 12). The observations checklist included general meeting organisation and the six WHO mortality audit cycle parameters: identifying deaths, collecting information, analysing information, recommending solutions, implementing solutions, evaluating and refining processes (Figure 5) (World Health Organization, 2016b).

5.4.3.5 Staff interviews

A pretested, semi-structured questionnaire adapted from Nyamtema et al. (Nyamtema *et al.*, 2010) was completed during interviews with nurses and doctors/clinical officers from the maternity and neonatal wards who were audit committee members to assess their perceptions of audit quality (Appendix 13). The questionnaire included their level of knowledge, views, perceived impact of audit and suggestions for improving the stillbirth and

neonatal death audit process. Convenience sampling was used to select at least five staff from each hospital on duty on the interview day. The number of 5 was chosen as a minimum number of staff per shift was between 4 and 6.

5.4.4 Data management and analysis

Pre-coded quantitative data were entered into a Microsoft access database and cleaned and backed-up daily. Data was analysed using IBM SPSS 26.0 software. Quantitative data was described using frequencies and proportions. The qualitative information from the checklist and forms were analysed by thematic analysis using predefined themes in the survey guide in the category of knowledge and impact of audit (Appendix 13).

5.5 Results

5.5.1 Hospital births, stillbirths, and neonatal outcomes during the study period

Of 55,685 births that occurred in the seven hospitals from 1st August 2019 to 30th November 2020, there were 1318 (2.4%) stillbirths. The overall stillbirth rate was 23.7 per 1000 births (95% CI:22.4-24.9) ranging from 20.0 to 26.5 per 1000 births for individual hospitals (Table 13). About 54% of all stillbirths were intrapartum. Amongst 13,113 neonatal admissions, 1732 (13.2%; 95% CI: 12.6-13.8) died. Wide variations were observed in neonatal deaths, with hospitals 4 and 7 having the highest proportion of deaths (18.7 % and 18.0% respectively), while hospital 5 had the lowest (8.3%). Birth asphyxia was the leading cause of deaths overall (45.0%) and in the individual facilities, seconded by prematurity (18.8%). Nearly all neonatal deaths (1636; 94.4%) were early, occurring within seven days of life (Table 13). Detailed information on individual hospital causes of neonatal death, time of deaths, proportion cause of death by age and proportion of neonates dying from each major cause are presented in appendices (Appendix 24 -27, respectively).

5.5.2 Document review

Neonatal admission forms, audit data collection, reporting templates and a classification list of causes of deaths and modifiable factors for neonatal death audit were available in all hospitals. The modifiable factors list did not include any factors from maternity wards (antenatal, labour and postnatal wards) or other departments (Appendix 28). Four hospitals (3, 5-7) did not have any form for stillbirth audit while the other three hospitals (1,2 and 4)

had one, although this was not standardised across these hospitals. The following documents were not available for use in any of the hospitals: national audit guidelines, recommendation follow-up records of action plans template or forms detailing whether or not proposed solutions had been implemented. The reporting template in use did not have a section to report whether a proposed solution was implemented or not.

Table 13: Births, stillbirths, and neonatal outcomes for seven hospitals in Malawi[1,2,3]

Parameters	Hospital 1	2	3	4	5	6	7	Total No. (%)
Births/stillbirths[2]								
Total births	9128	9389	5436	4489	13622	5607	8014	55685
Total stillbirths	225 (2.5)	194 (2.1)	143 (2.6)	105 (2.3)	361 (2.7)	112 (2.0)	178 (2.2)	1318 (2.4)
• Antepartum stillbirths	104 (1.1)	86 (0.9)	56 (1.0)	44 (1.0)	159 (1.2)	52 (0.9)	106 (1.3)	607 (1.1)
• Intrapartum stillbirths	121 (1.3)	108 (1.2)	87 (1.6)	61 (1.4)	202 (1.5)	60 (1.1)	72 (0.9)	711 (1.3)
Stillbirth rate/1000 births (95% CI)	24.6 (21.4-27.8)	20.7 (17.8-23.6)	26.3 (22.0-30.6)	23.4 (19.0-27.8)	26.5 (23.8-29.2)	20.0 (16.3-23.6)	22.2 (19.0-25.4)	23.7 (22.4-24.9)
Stillbirths reviewed	1 (0.4)	7 (3.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	8 (0.6)
Neonatal admissions (inborn and out born)	3418	2223	1604	930	2219	1012	1707	13113
Neonatal deaths[3]	499 (14.6)	293 (13.2)	173 (10.8)	172 (18.5)	186 (8.4)	103 (10.2)	306 (17.9)	1732 (13.2)
• Early neonatal deaths	464 (13.6)	278 (12.5)	171 (10.7)	150 (16.1)	117 (5.3)	101 (10.0)	295 (17.3)	1636 (12.5)
• Late neonatal deaths	35 (1.0)	15 (0.7)	2 (0.1)	22 (2.4)	9 (0.4)	2 (0.2)	11 (0.6)	96 (0.7)
Neonatal death rate (95% CI)	14.5 (13.3-15.7)	13.7 (12.2-15.1)	10.8 (9.2-12.3)	18.7 (16.2-21.2)	8.3 (7.2-9.5)	10.6 (8.7- 12.5)	18.0 (16.2-19.9)	13.2 (12.6-13.8)
Neonatal deaths reviewed	96 (19.2)	223 (76.1)	8 (4.6)	3 (1.7)	74 (39.8)	3 (2.9)	31 (10.1)	438 (25.3)

Causes of neonatal deaths								
Birth Asphyxia	186 (37.3)	117 (39.9)	90 (52.0)	88 (51.2)	94 (50.0)	49 (47.6)	155 (50.7)	779 (45.0)
Prematurity	107 (21.4)	70 (23.9)	14 (8.1)	23 (13.4)	18 (9.7)	21 (20.4)	73 (23.9)	326 (18.8)
Respiratory Distress Syndrome	99 (19.8)	34 (11.6)	43 (24.9)	15 (8.7)	37 (19.9)	12 (11.7)	39 (12.7)	279 (16.1)
Neonatal sepsis	40 (8.0)	42 (14.3)	15 (8.7)	23 (13.4)	17 (9.1)	9 (8.7)	17 (5.6)	163 (9.4)
Pneumonia	5 (1.0)	8 (2.7)	2 (1.2)	9 (5.2)	7 (3.8)	2 (1.9)	1 (0.3)	34 (2.0)
Other causes	62 (12.4)	22 (7.5)	9 (5.2)	14 (8.1)	13 (7.0)	10 (9.7)	21 (6.9)	151 (8.7)

Notes

1. Data are number (%) unless otherwise stated
2. Missing data not included in this analysis: births and stillbirths for 1 month for hospital 3 and two months for hospital 4
3. Missing data not included in this analysis: neonatal outcomes for 1 month for hospitals 5 an

5.5.3 Death audit results

5.5.3.1 Conduct of audit and characteristics of audited neonatal deaths

Only 0.6% (n=8) of all stillbirths were audited with only two hospitals (hospitals 1 and 2) undertaking stillbirth audit (Table 14). Six of the audited stillbirths were born with a normal birth weight of more than 2500g. Five of audited stillbirths were intrapartum (fresh stillbirths), and 3 were antepartum stillbirths (macerated stillbirths). All audited stillbirths occurred due to intrapartum related events that resulted in perinatal asphyxia.

Only 25.3% (n=438) of all neonatal deaths were audited with hospital 2 accounting for the majority of all audited deaths (50.9%), representing 76.1% of its facility neonatal deaths (Table 14). More than 80% of all neonatal deaths audited were early neonatal deaths. Almost two-thirds of audited neonatal deaths occurred during night shifts. Detailed clinical characteristics of all audited neonatal deaths are presented in the following appendices: Appendix 29–maternal characteristics of neonatal deaths audited; appendix 30–demographic and clinical characteristics of audited neonatal deaths; appendix 31– care provided to audited neonatal deaths and appendix 32– vital signs recorded during care provision in nursery ward.

Table 14: Summary of stillbirths and neonatal deaths audited [5]

Parameters	Hospital							Total No. (%)
	1	2	3	4	5	6	7	
Stillbirths								
Total stillbirths[6]	225 (2.5)	194 (2.1)	143 (2.6)	105 (2.3)	361 (2.7)	112 (2.0)	178 (2.2)	1318 (2.4)
Stillbirths reviewed	1 (0.4)	7 (3.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	8 (0.6)
Neonate (inborn and out born)								
Neonatal deaths[7]	499 (14.6)	293 (13.2)	173 (10.8)	172 (18.5)	186 (8.4)	103 (10.2)	306 (17.9)	1732 (13.2)
Neonatal deaths reviewed	96 (19.2)	223 (76.1)	8 (4.6)	3 (1.7)	74 (39.8)	3 (2.9)	31 (10.1)	438 (25.3)

[5] Data are number (%) unless otherwise stated

[6] Missing data not included in this analysis: births and stillbirths for 1 month for hospital 3 and two months for hospital 4

[7] Missing data not included in this analysis: neonatal outcomes for 1 month for hospitals 5 and 7

5.5.3.2 Completeness of information for audited stillbirths and neonatal deaths

Twenty-nine percent and 20% of admission and critical care pathway forms of audited neonatal deaths were incomplete, respectively. Feeding charts were not used in almost half of the deaths audited, and there was no information available on their usage in 34.2% of deaths audited and no maternal file (labour graph) was attached in 74.9% of audited deaths (Appendix 31). We did not assess these parameters on audited stillbirth as they were not part of the stillbirth audit form.

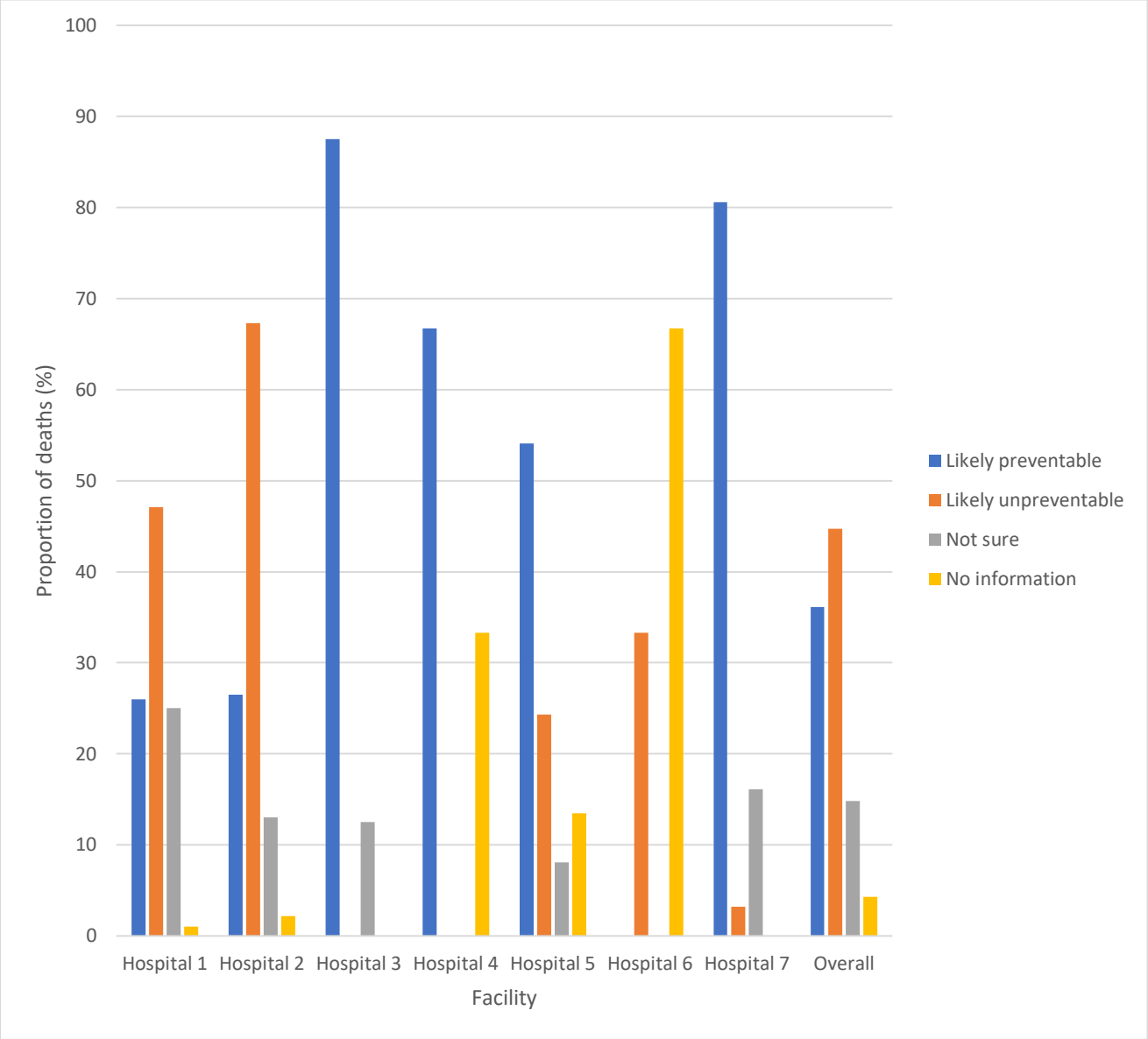
5.5.3.3 Causes of stillbirths and neonatal deaths

Almost all eight stillbirths audited occurred due to intrapartum related events that resulted in perinatal asphyxia. The intrapartum related events included prolonged second stage of labour (n=3), ruptured uterus (n=2), cord accident (n=2) and severe pre-eclampsia (n=1). Appendix 33 shows the aggregated contribution of conditions to the cause of neonatal death audited. Birth asphyxia, prematurity and respiratory distress syndrome were the leading cause.

5.5.3.4 The proportion of neonatal deaths that could have been avoided

Overall, about one third of neonatal deaths audited (36.1%; n=158) were considered preventable, 44.7% (n=196) were considered unpreventable, while the team was unsure in the case of 14.8% (n=16) deaths. No information was included for 4.3% (n=19) deaths (Figure 17). More neonatal deaths were assessed to be likely to be preventable in hospitals 3, 4, 5 and 7 (87.5%, 54.1% and 80.6%, respectively) than in hospitals 1 and 2 (26.0% and 26.5%; Figure 17).

Figure 17: Neonatal deaths according to the likelihood of prevention



5.5.3.5 Modifiable factors and proposed solutions

Stillbirth audits generated 31 modifiable factors of which 93.5% were health provider related factors (Appendix 34). The overall mean number of modifiable factors identified per audited neonatal death was 2.1 ranging from 1.7 (hospital 2) to 4.7 (hospital 4) (Appendix 34). Most factors were health provider related with an overall mean of 1.9 modifiable factors per audited death ranging from 1.3 (hospital 6) to 4 (hospital 4). These health provider related factors included inadequate monitoring of sick neonates, documentation, clinical review, management or treatment, feeding and investigation (Appendix 34). The overall mean number of identified administrative and caregiver factors per audited death

were 0.1 each. The proposed actions for audited neonatal deaths strongly emphasised improving health provider factors at nursery wards, with more than 70% of solutions targeting the management of sick neonates in the nursery ward. The overall mean number of solutions per neonatal death was 2.3 ranging from 1.3 (hospital 4) to 3.4 (hospital 3).

5.5.3.6 Quality of reviews

The overall average score for all neonatal death action plans (n=996) was 2.5 (SD=0.6) indicating the need for improvement (Table 15). Overall, performance was high (very good) in identifying modifiable factors (mean=2.9; SD=0.4) and assigning responsible persons (2.6; 0.7; Table 15). Proposed solution and feasibility of timeframe components scored below standard (2.4; 0.8 and 2.3; SD=0.7 respectively) (Table 15). There was consistency across hospitals in these quality scores. Stillbirth audit only generated modifiable factors and solutions but not full action plan.

5.5.3.7 Quality of completed audit forms

Review of all neonatal audit forms (n=438) revealed that accuracy and consistency were high (Table 16). However, only about 1 in 5 forms scored excellent for completeness (mean score of 77.1%; SD=15.0) and only about half of forms were scored excellent for validity (86.6%; 12.8) with marked variability in these two factors across hospitals.

Table 15: Quality of action plans for identified modifiable factors (n=996) [1,2,3]

Area assessed	Hospital 1	Hospital 2	Hospital 3	Hospital 4	Hospital 5	Hospital 6	Hospital 7	Total
Total action plans reviewed	287	424	28	5	155	9	88	996
Modifiable factor								
Unsatisfactory	10 (3.5)	11 (2.6)	0 (0.0)	0 (0.0)	5 (3.2)	0 (0.0)	0 (0.0)	26 (2.6)
Good	3 (1.0)	32 (7.5)	0 (0.0)	0 (0.0)	13 (8.4)	0 (0.0)	7 (8.0)	55 (5.5)
Very good	274 (95.5)	381 (89.9)	28 (100.0)	5 (100.0)	137 (88.4)	9 (100.0)	81 (92.0)	915 (91.9)
Mean (SD)	2.9 (0.4)	2.9 (0.4)	3.0(0)	3.0 (0)	2.9 (0.4)	3.0(0)	2.9 (0.3)	2.9 (0.4)
Proposed solution								
Unsatisfactory	37 (12.9)	117 (27.6)	11 (39.3)	0 (0.0)	6 (3.9)	3 (33.3)	23 (26.1)	197 (19.8)
Good	107 (37.3)	63 (14.9)	0 (0.0)	3 (60.00	56 (36.1)	0 (0.0)	13 (14.8)	242 (24.3)
Very good	143 (49.8)	244 (57.5)	17 (60.7)	2 (40.0)	93 (60.0)	6 (66.7)	52 (59.1)	557 (55.9)
Mean (SD)	2.4 (0.7)	2.3 (0.9)	2.2 (1.0)	2.4(0.5)	2.6(0.6)	2.3(1.0)	2.3 (0.9)	2.4 (0.8)
Responsible person								
Unsatisfactory	37 (12.9)	29 (6.8)	9 (32.1)	0 (0.0)	24 (15.5)	1 (11.1)	14 (15.9)	114 (11.4)
Good	137 (47.7)	5 (1.2)	0 (0.0)	0 (0.0)	16 (10.3)	0 (0.0)	1 (1.1)	159 (16.0)
Very good	113 (39.4)	390 (92.0)	19 (67.9)	5 (100.0)	115 (74.2)	8 (88.9)	73 (83.0)	723 (72.6)
Mean (SD)	2.3 (0.7)	2.9 (0.5)	2.4(1.0)	3.0 (0)	2.6 (0.7)	2.8(0.7)	2.7(0.7)	2.6 (0.7)
Feasibility of timeframe								
Unsatisfactory	45 (15.7)	29 (6.8)	6 (21.4)	1 (20.0)	40 (25.8)	3 (33.3)	21 (23.9)	145 (14.6)
Good	158 (55.1)	213 (50.2)	0 (0.0)	4 (80.0)	0 (0.0)	0 (0.0)	1 (1.1)	376 (37.8)
Very good	84 (29.3)	182 (42.9)	22 (78.6)	0 (0.0)	115 (74.2)	6 (66.7)	66 (75.0)	475 (47.7)
Mean (SD)	2.1(0.7)	2.4 (0.6)	2.6 (0.8)	1.8 (0.4)	2.5(0.9)	2.3 (1.0)	2.5(0.9)	2.3 (0.7)
Overall Mean (SD)	**2.4 (0.6)**	**2.6 (0.6)**	**2.5 (0.7)**	**2.6(0.2)**	**2.6 (0.7)**	**2.6 (0.7)**	**2.6 (0.7)**	**2.5 (0.6)**

Notes: 1. Data are number (%) unless otherwise stated

Notes: 2. Mean score of 1=Unsatisfactory, Score 2=good and Score 3=Very good

Notes 3. SD=Standard Deviation

Table 16: Quality of completed audit forms (n=438) [1,2,3]

Area	Hospital 1	Hospital 2	Hospital 3	Hospital 4	Hospital 5	Hospital 6	Hospital 7	Total
Total audit forms reviewed	96	223	8	3	74	3	31	438
Completeness								
Excellent	46 (47.9)	25 (11.2)	3 (37.5)	0 (0.0)	15 (20.3)	0 (0.0)	9 (29.0)	98 (22.4)
Good	48 (50.0)	144 (64.6)	5 (62.5)	1 (33.3)	56 (75.7)	3 (100.0)	21 (67.7)	278 (63.5)
Unsatisfactory	2 (2.1)	54 (24.2)	0 (0.0)	2 (66.7)	3 (4.1)	0 (0.0)	1 (3.2)	62 (14.2)
Mean Score %(SD)	86.2 (14.0)	71.9 (14.5)	84.4 (13.0)	58.3(14.4)	78.7 (11.5)	75 (0)	82.3 (13.2)	77.1(15.0)
Accuracy								
Excellent	79 (82.3)	206 (92.4)	8 (100.0)	3 (100.0)	54 (73.0)	2 (66.7)	30 (96.7)	382 (87.2)
Good	17 (17.7)	17 (7.60	0 (0.0)	0 (0.0)	20 (27.0)	1 (33.3)	1 (3.2)	56 (12.8)
Unsatisfactory	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Mean Score %(SD)	95.3(9.8)	98.1(6.6)	100(0)	100(0)	93.2(11.2)	91.7(14.4)	99.2(4.5)	96.8(8.4)
Consistency								
Excellent	80 (83.3)	203 (91.0)	6 (75.0)	2 (66.7)	55 (74.3)	3 (100.0)	28 (90.3)	377 (86.1)
Good	16 (16.7)	20 (9.0)	2 (25.0)	1 (33.3)	18 (24.3)	0 (0.0)	2 (6.5)	59 (13.5)
Unsatisfactory	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	1 (3.2)	2 (0.5)
Mean Score % (SD)	95.3(9.8)	97.8(7.2)	93.8(11.6)	91.7(14.4)	92.9(12.1)	100(0)	97.6(9.9)	96.3(9.2)
Validity								
Excellent	28 (29.2)	128 (57.4)	8 (100.0)	3 (100.0)	12 (16.2)	2 (66.7)	27 (87.1)	208 (47.5)
Good	59 (61.5)	89 (39.9)	0 (0.0)	0 (0.0)	50 (67.6)	1 (33.3)	3 (9.7)	202 (46.1)
Unsatisfactory	9 (9.3)	6 (2.7)	0 (0.0)	0 (0.0)	12 (16.2)	0 (0.0)	1 (3.2)	28 (6.4)
Mean Score %(SD)	81.8(11.7)	89.4(12.4)	100(0)	100(0)	78.0(10.1)	91.7(14.4)	97.6(7.5)	86.6(12.8)

Notes: 1. Data are number (%) unless otherwise stated

Notes: 2. Mean score of 50%=Unsatisfactory, Score 75%= Satisfactory and Score 100%=Excellent

Notes: 3. SD-Standard Deviation

5.5.4 Frequency of audit meetings

There was marked variation in the frequency of audit meetings with weekly or monthly meetings in hospitals 1 and 2 but only occasional and irregular meetings in other hospitals (Appendix 35). Overall meeting frequency increased from July to November 2020 (Appendix 35) as hospitals 1, 2 and 3 were supported by external partners who provided a lunch allowance of approximately $5 per individual and refreshments during audit meetings. Hospital 1 had no external partner in the district from September 2019 to June 2020 and the central management team supported audits from March 2020 to June 2020; the external partners came in July 2020 and funded audits quarterly. Hospital 2 had an external partner in the district who funded audit meetings from January 2019 to November 2019, and again from May 2020. The other districts conducted audits when district management funded the activities (refreshments or lunch allowance), although this support was inconsistent.

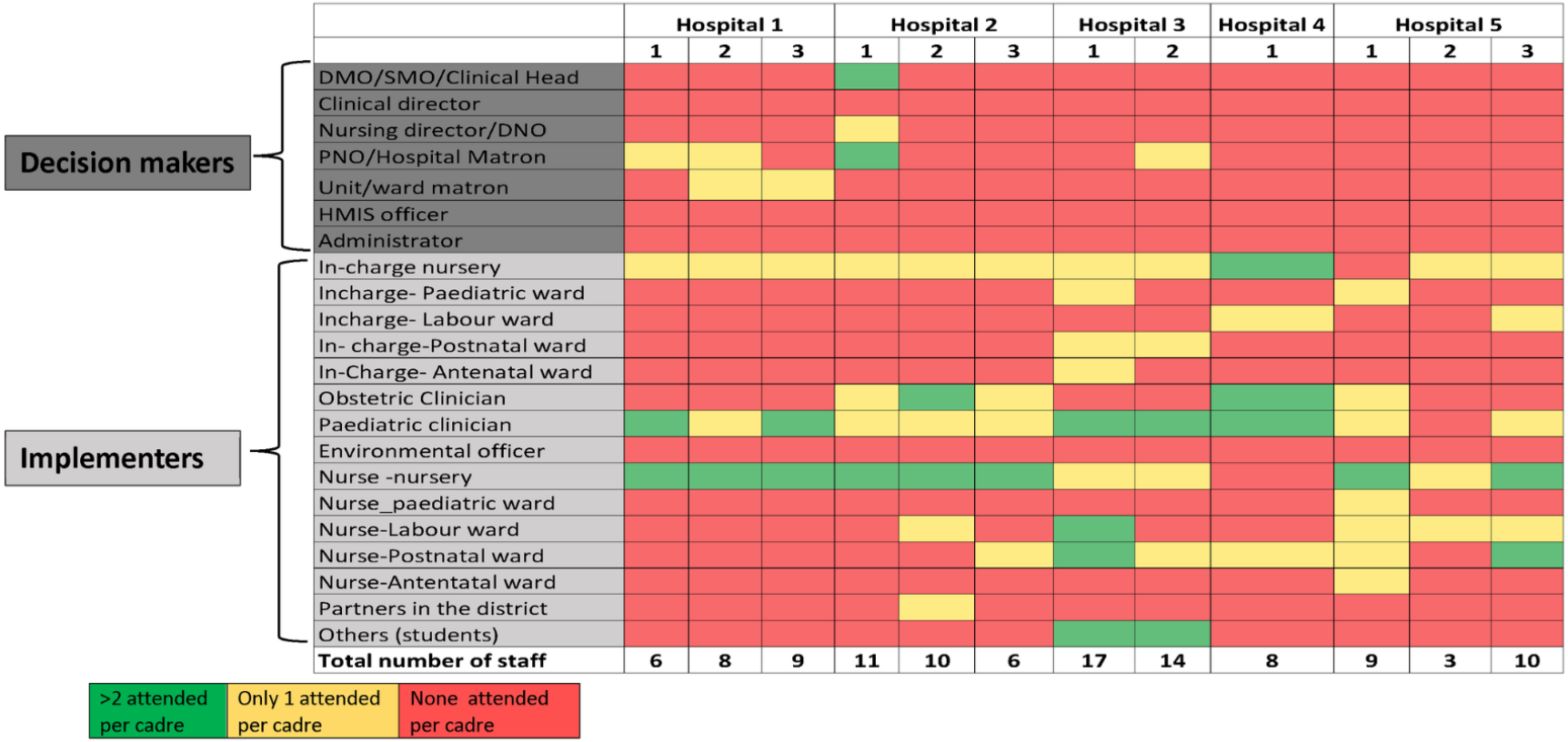
5.5.5 Observation of neonatal death audit meetings

5.5.5.1 Audit organisation

Between March and November 2020, 55 audit meetings were conducted in all hospitals, with the majority of meetings done in hospitals 2 (n=29;52.7%) and hospital 1 (n=15; 27.3%; Appendix 35). Twelve meetings were observed, three meetings each in hospitals 1, 2 and 5, two meetings in hospital 2 and one meeting in hospital 4. No meetings were observed in hospitals 6 and 7 as research staff were not informed of when meetings took place. We did not observe any stillbirth audits.

For 12 observed neonatal audit meetings, all hospitals had a neonatal focal person who coordinated neonatal death audit meetings. Nurses from nursery wards and paediatric clinicians mostly attended the meetings (Figure 18).

Figure 18: Meeting attendance by staff cadre [8,9,10]



[8] Numbers 1,2,3 for each hospital refer to meetings 1, 2 and 3 that were observed at each facility

[9] Decision makers: members of central or district management team who makes decisions at facility level

[10] Implementers: staff in the wards delivering care to patients or implement interventions like audit

5.5.5.2 WHO mortality cycle parameters

All hospitals used audit forms to document causes of death, modifiable factors and action plans. Neonatal deaths were mainly identified from patient files from nursey wards but not source documents from other wards. In one hospital nurses collected demographic and clinical data soon after the death but other hospitals filled this information during death audit meetings. No hospital collected a minimum set of neonatal indicators or used them during analysis. During audit meetings, the patient file was read a loud and background and clinical information documented. Clinical information was verified if already entered. The members discussed causes of death using a national checklist of causes and decided on modifiable factors and actions. None of the meetings started by reviewing ward statistics, previous audit summaries or minutes or checking whether previous recommendations had been implemented. Meetings had a welcoming atmosphere where a chairperson encouraged a 'no blame or shame' approach except in 4 meetings (2 from hospital 1 and one each from hospitals 2 and 3) where staff were identified by tracing or interpreting their signatures. Four meetings (2 from hospital 3 and 1 each from hospitals 4 and 2) included teaching sessions.

Only hospital 3 approached the system as a whole when analysing modifiable factors. The other hospitals focused on identifying factors that could have been prevented in the nursery wards but not from labour, antenatal and postnatal wards. For example, death of a baby that was severely asphyxiated when admitted to the nursery ward was deemed to be unavoidable as no more could have been done at the nursery ward; however, avoidable factors in the labour and birth ward were not considered. As a result, recommended actions mainly targeted nursery wards as guided by the provided modifiable factors list. No written feedback or documentation system for tracking and following up on recommendations was observed in any of the hospitals.

5.5.6 Health worker perceptions about the neonatal death audit process

Almost two thirds of staff interviewed were nurses and one third were doctors or clinical officers working either maternity, nursery, paediatric wards or administrative roles. Only one participant was from the administration department.

The level of awareness of neonatal death audit was high among staff in all seven hospitals: 97.1% mentioned at least one reason why such audits were established, 85.7% knew of the presence of audit committees and 80.0% knew the objective or vision of audit committees (Appendix 39). However, only 67.0% mentioned that the objectives or vision had been shared with the rest of the other ward staff and departmental representatives. Nearly all of the participants knew the permanent members of the maternal or neonatal death audit committee citing 122 nurses and 35 clinicians working in maternity, nursery and paediatric wards.

All hospital staff believed that death audits could improve neonatal health services provided everywhere and at their hospitals (Appendix 36). Nearly all staff knew and remembered at least one recommendation made during maternal or neonatal death audit at their hospital and mentioned at least one action implemented in their ward due to audit. However, 54.3% offered at least one suggestion to improve the audit process and care delivery (Appendix 36).

5.6 Discussion

5.6.1 Summary of findings

Although systematic reviews have shown that well-conducted audits and feedback can improve care and professional practice (Ivers *et al.*, 2012; Nair *et al.*, 2014), we found significant deficiencies in the implementation and quality of stillbirth and neonatal death audits assessed according to WHO guidelines in hospitals in southern Malawi. Audits appeared to be conducted to fulfil requirements for reviewing deaths rather than as internal mechanisms for improving practice. This section discusses the study findings against general literature and WHO audit guidelines, focusing on creating enabling environment and six steps of audit cycle.

5.6.2 Creating enabling environment for audit

A positive enabling environment at national, regional and facility level makes easier to move through phases of mortality audit process (World Health Organization, 2016b). The WHO guidelines stress the importance of the availability of clear national policy and guidelines. Unfortunately, no national guidelines for stillbirth and neonatal death audit were found in

all hospitals to guide health workers on audit process. Only national standardised audit tools for neonatal death audit were available and none for stillbirth audit. The list of neonatal death modifiable factors provided by national level focused on nursery ward related factors rather than other departments like labour and birth where most stillbirth and newborn death causes originates.

Furthermore, the WHO guideline stresses the need for leadership, task-oriented minutes, staff stability, communication and the existence of guidelines and protocols (World Health Organization, 2016b) all of which were deficient in this study. The guideline further reports experience from maternal death reviews in Senegal and Mali that a bundle of approaches is needed to translate recommendations into action (World Health Organization, 2016b; Ndour *et al.*, 2013; Dumont *et al.*, 2013). The bundle included involving leaders, quality improvement committee involvement and strengthening the capacity of health professionals. Leaders are required at both national and facility levels to create an enabling environment as they act as change agents. In our study, although there was good awareness and knowledge among staff about audit and its impact on care, the majority of staff mentioned nurses working in maternity, nursery and paediatric ward as frequent members attending audits and senior facility management staff rarely participated in audit meetings consistent with the findings of other studies (Lusambili *et al.*, 2019; Kongnyuy and van den Broek, 2008; Nyamtema *et al.*, 2010). The guideline further recommends facility-based mortality audits to include representatives of various departments and community liaison officers of which it was deficient in this study.

Another way to create an enabling environment to effect change is to have individual members of staff who are accountable with appropriate follow-ups (World Health Organization, 2016b). We found that the frequency of audit meetings was dependent on the support of partners who provided monetary incentives attached and low when such support was not available. These findings agree with a study done in Uganda, which had difficulties bringing staff to audit meetings during lunch breaks if no lunch or snacks were provided (Agaro *et al.*, 2016).

From audit observations, four meetings had no welcoming atmosphere and failed to follow a no blame and no shame approach in contrast to studies done in Solomon Island and Tanzania, where the meetings had a welcoming atmosphere (Sandakabatu *et al.*, 2018;

Armstrong *et al.*, 2014). Staff who fear blame, judgement or negative consequences may be reluctant to attend mortality audit meetings or suppress information about events, which might affect the effectiveness of the process (World Health Organisation, 2018). The WHO guideline stresses that the committee and facility leadership should nurture a conducive environment of no blame for successful audit process.

5.6.3 Six WHO audit cycle

5.6.3.1 Identify stillbirth and neonatal deaths

To ensure that all birth and death outcomes are recorded and accounted for, the WHO audit and review of stillbirth and neonatal death guidelines emphasises collection of a minimum set of perinatal and neonatal indicators on each birth and death through hospital HMIS register or electronic system (World Health Organization, 2016b). The WHO guidelines advise audit committees to make good use of these outcome data during the audit process and our study confirmed that these indicators were collected in the hospital HMIS system. The guidelines recommend analysing the trend on perinatal and neonatal outcomes and that facility administrators or local policymakers identify particular indicators to focus on, collect more information or follow up after implementing audit recommendation (World Health Organization, 2016b). However, our findings revealed that perinatal and neonatal outcome data were not reviewed during audit meetings.

5.6.3.2 Collecting information

After identifying the deaths, the team decides on deaths that they need to collect more information. Our findings of incomplete documentation regarding maternal information and clinical details agrees with other studies that identified missing information as a barrier to mortality audit (Biswas *et al.*, 2015; Nyamtema *et al.*, 2010; Gondwe *et al.*, 2021). Whilst acknowledging the challenge of locating medical records in low resource settings, WHO recommends extracting relevant medical information using standardised form as soon after the birth and death occur. This occurred in only one hospital in our study where relevant demographic variables and medical history were collected prior to audit meetings.

There was significant variation between hospitals in audit frequency and the number of stillbirth and neonatal deaths audited. We observed a low proportion of audited stillbirths

and variation in the proportion of neonatal deaths audited across hospitals. Only one hospital audited more than half of its neonatal deaths. Given the high numbers of stillbirths and neonatal deaths in this setting, the low audit rate may not be sufficient to identify gaps in care. After implementing regular audits and auditing 75% of all neonatal deaths, a study in Moldova noted a decrease of 1.5 deaths per 1000 births (95% CI 0.6% to 2.4%; p=0.0015) (Stratulat *et al.*, 2014). However, in Uganda, auditing only 34% of all perinatal deaths and implementing local solutions was associated with a reduction of 4.9 deaths per 1000 births (Nakibuuka *et al.*, 2012). In addition, a second study in Uganda which audited only 20% of perinatal deaths due to a high volume of deaths, reported a statistically significant decrease in neonatal mortality although no effect on perinatal mortality or stillbirth rates (Kirabira *et al.*, 2020).

The WHO guideline is not explicit on what proportion of deaths should be sampled for auditing; rather this depends on staffing and workload at the facility and considers the length of review meetings (World Health Organization, 2016b). Where the burden of stillbirths and neonatal deaths is high and it is infeasible to review all deaths, WHO recommends either selecting a subset of cases for detailed review or limiting review to cases that are most likely to be preventable such as stillbirths, early neonatal death or neonatal death among near-term babies (World Health Organization, 2016b). This appears relevant to our setting in that 50% of all stillbirths were intrapartum and 94.4% of all deaths and 87.9% of all audited deaths were early neonatal deaths. Our findings suggest a need for developing a sampling framework to guide the proportion of types of deaths reviewed to improve the feasibility and quality of audit and facilitate international comparisons.

5.6.3.3 Analysing information

We found that birth asphyxia was the leading cause of neonatal deaths in all hospitals, followed by prematurity. Almost all neonatal deaths (94.4%) and audited neonatal deaths (87.2%) occurred within seven days of life indicating the need to focus interventions during pregnancy, labour and birth. However, the identified modifiable factors and proposed solutions focused on caring for neonates in the nursery ward rather than the labour and birth ward, which would likely miss root causes. A focus on nursey ward factors was also noted during audit meeting observations and was evident from the document review. These

findings are contrary to WHO guideline which emphasise conducting a root-cause analysis to identify underlying causes and remaining open to all possible underlying problems and factors (World Health Organization, 2016b). We also noted that the focus on nursery ward factors affected the audit staff's assessment of the proportion of deaths that could have been prevented, with only one-third of deaths considered to have been avoidable. The hospitals with the lowest proportion of preventable deaths (hospitals 1 and 2) did not approach the system as a whole but mainly focused on nursery ward factors. The marked variation in the proportion of preventable deaths between hospitals is consistent with studies of audits in Tanzania, France, Solomon Island, and Uganda with proportions ranging from 20-80% (Kidanto *et al.*, 2009; Sauvegrain *et al.*, 2020; Sandakabatu *et al.*, 2018; Nakibuuka *et al.*, 2012; Kimambo, 2008).

The hospitals in our study followed the WHO guidance to identify modifiable factors at the family/patient, administrator and health provider levels (World Health Organization, 2016b). The most frequently identified modifiable factors were health provider-related, which agrees with other studies' findings (Nakibuuka *et al.*, 2012; Sandakabatu *et al.*, 2018; Kidanto *et al.*, 2009; Merali *et al.*, 2014).

Although WHO recommends the use of a globally recognised approach to the classification of stillbirths and neonatal death causes such as the International Classification of Disease 10 to share common language and allow comparisons across settings (World Health Organization, 2016b), this was not done in the hospitals in this study.

5.6.3.4 Recommending solutions

WHO recommends formulating solutions in action plans that are SMART (World Health Organization, 2016b), In this study, the proposed solutions and the feasibility of timeframes to implement solutions were limited. This agrees with a study done in Tanzania which found that most action plans were unsatisfactory (Kimambo, 2008).

5.6.3.5 Implementing solutions

Implementing actions to prevent deaths is the reason for conducting audit. Though staff reported witnessing improvements in care resulting from audit, this was difficult to verify objectively as there was no evidence of implementation of audit recommended solutions in

any of the facilities. The neonatal death audit data collection and reporting tools had no section to report or follow up recommendations made during previous audit meetings. The WHO guidelines for the action plan section includes a follow-up section, where audit recommendations are assessed as completed or not at the next meeting. This was lacking in the hospital audit forms which likely affected implementation of audit findings by staff. Similar challenges have been reported in a systematic review focusing on LMICs (Kerber *et al.*, 2015)

In contrast to WHO recommendations, review of previous minutes and follow-up records to see if previous recommendations had been implemented during audit meetings were not observed in any of the hospitals. This is likely due to the limitation of the audit form and reporting template. National level staff need to consider providing a reporting template that includes these elements to motivate staff to implement the solutions proposed during the audit process

5.6.3.6 Evaluating and refining

Furthermore, WHO stresses the importance of evaluating and refining the components of the audit cycle to identify what worked and what did not (World Health Organization, 2016b) but this was lacking in our study. Documenting change over time and having a system to provide real-time feedback linked to data showing long term trends motivates staff (World Health Organization, 2016b). WHO further recommends that audit committee members assess and reflect on progress at each implementation stage from creating awareness of audit to integration in the routine practice (World Health Organization, 2016b).

5.6.4 Strengths and Limitations

The strengths of this study are that it used a mixed-method approach to provide a comprehensive and detailed assessment of the gaps in the quality of stillbirth and neonatal death audit in an LMIC. We consider that this generated reliable evidence that can directly inform areas for improvement and provide credible recommendations for practice, policy and research in this and similar settings. The study was multisite, including seven hospitals in 7 districts of Malawi, thus increasing its applicability. Additionally, we assessed the quality

of stillbirth and neonatal death audits using internationally recognised WHO guidelines to allow comparison with other studies and similar settings.

Limitations result from the inclusion of one central hospital and six district hospitals in one region of Malawi. Hence, our findings might not reflect audit processes in the other hospitals in Malawi and other LMICs. We used convenience sampling for staff questionnaires that included staff from different cadres; however, our findings may not be generalisable to all staff. We could not collect complete patient information for all audits due to missing records in some hospitals. Despite this, we benefited from triangulation across different data collection methods to assess the quality of the audit.

5.6.5 Study implications and recommendations

The practical implication of our study is for national policymakers to ensure that developed stillbirth and neonatal death audit guidelines are used in hospitals and that the national or partner data collection or reporting templates are consistent with the audit cycle parameters in the WHO audit and review of stillbirth and neonatal death guidelines. Furthermore, to guide implementers and allow international comparisons a sampling framework needs to be developed to guide the proportion and types of deaths to be reviewed in settings where number of deaths are high. Quality audits need to be conducted regularly at the facility level, adhering to and completing the WHO death audit cycle(World Health Organization, 2016b). In addition, implementers need to be trained on all steps and supported by the management. Finally, few studies have reported the outcome of stillbirths and neonatal death audit on newborn outcomes (Pattinson *et al.*, 2009; Kirabira *et al.*, 2020). We propose that a multi-country trial is required to evaluate the effectiveness of audits on stillbirth rates and neonatal mortality.

5.7 Conclusions

The quality of stillbirth and neonatal death audit was poor due to challenges the hospitals faced in creating an enabling environment for audit and completing WHO audit cycle steps. This information is valuable for implementers, policymakers and researchers to improve the stillbirth and neonatal death audit process and, through this, the quality of care within maternity, postnatal, neonatal and nursery hospital wards. The implementation of regular audit cycles of a consistently high standard has the potential to reduce stillbirths and neonatal mortality.

CHAPTER 6: FACTORS IMPACTING ON STILLBIRTH AND NEONATAL DEATH AUDIT IN MALAWI: A QUALITATIVE STUDY (PAPER 4)

6.1 Chapter overview

Given that the quality of stillbirth and neonatal death audits conducted in the seven hospitals were of low standard due to challenges with guidelines, audit tools, data collection forms and action plans, it was necessary to explore factors that impact the quality of audits from the staff perspective. This chapter presents facilitators and barriers to stillbirth and neonatal death audits in the southern region of Malawi. Using a conceptual model (see Figure 6), this section reports factors at the individual, facility and national levels that impact staff engagement in audit activities and ability to implement suggested audit solutions. This section relates to objective number 3.

This chapter 6 was published in BMC Health Services Research Journal in September 2022. The publication can be found at the link below:
https://bmchealthservres.biomedcentral.com/articles/10.1186/s12913-022-08578-y

I led the conceptualization and conduct of this work (data collection and analysis) and was responsible for the original, revised and final manuscript preparation.

6.2 Abstract

Background

Over one million babies are stillborn or die within the first 28 days of life each year due to preventable causes and poor-quality care in resource-constrained countries. Death audit may be a valuable tool for improving the quality of care and decreasing mortality. However, challenges in implementing audit and their subsequent action plans have been reported, with few successfully implemented and sustained. This qualitative study aimed to identify factors that affect neonatal death audit at the facility level in seven hospitals in the southern region of Malawi.

Methods

Thirty-eight semi-structured interviews and seven focus group discussions with death audit committee members were conducted. Framework analysis was guided by a study

conceptual framework and applied inductive and deductive line-by-line coding to identify emerging themes.

Results

The factors that affected audit at the individual, facility and national level were related to training, staff motivation, power dynamics and autonomy, audit organisation and data support. We found that factors were linked because they informed each other. Inadequate staff training was caused by a lack of financial allocation at the facility level and donor-driven approaches to training at the national level, with training taking place only with support from funders. Staff motivation was affected by the institutional norms of reliance on monetary incentives during audit meetings, gazetted at the national level so that audits happened only if such incentives were available. This overshadowed other benefits and non-monetary incentives which were not promoted at the facility level. Inadequate resources to support audit were informed by limited facility-level autonomy and decision-making powers which remained controlled at the national level despite decentralisation. Action plan implementation challenges after audit meetings resulted from inadequate support at the facility level and inadequate audit policy and guidelines at the national level. Poor documentation affected audit processes informed by inadequate supervision and promotion of data usage at both facility and national levels.

Conclusion

Given that the factors that facilitate or inhibit audits are interconnected, implementers, policymakers and managers need to be aware that addressing barriers is likely to require a whole health systems approach targeting individual, facility and policy levels. This will require behavioural and complex intervention approaches.

6.3 Introduction

Preventable conditions cause approximately more than 1 million stillbirths and neonatal deaths each year, with low- and lower-middle-income countries (LMICs) contributing more than 80% of these deaths (UN IGME, 2020a; UN IGME, 2020b). Despite increased facility-based birth, babies still die or develop lifelong disabilities after reaching facilities due to poor quality care (Lawn *et al.*, 2016a; Fink, Ross and Hill, 2015; Souza *et al.*, 2013; World

Health Organization, 2020b). Evidence suggests that death audit may be a valuable tool for improving quality of care, but only if the audit and feedback loop link to action at the point of care (Pattinson *et al.*, 2009). Despite the adoption of World Health Organization (WHO) stillbirth and neonatal death audit guidelines (World Health Organization, 2016b) by most LMICs, and the publication of quality improvement (QI) models (Tuncalp *et al.*, 2015; Donabedian, 1980; WHO, 2007; Sally Fereday, 2015; Kaplan *et al.*, 2012), few countries have a fully functional stillbirth and neonatal death audit system. Furthermore, many audit action plans do not produce the desired change, with only a few being successfully implemented and sustained (Grimshaw, Eccles and Tetroe, 2004; Gould *et al.*, 2017; Miller, 2001).

The use of formal theories to inform strategies for implementing interventions to enhance benefits of death audits across settings has been advocated (Eccles *et al.*, 2005). We reviewed several quality improvement models (Tuncalp *et al.*, 2015; Donabedian, 1980; WHO, 2007; Sally Fereday, 2015; Kaplan *et al.*, 2012), to develop a conceptual framework to guide implementers, facility managers, policymakers and other stakeholders in understanding how structural factors are linked to the process of conducting stillbirth and neonatal death audit, which further link action plans to quality improvement initiatives (Figure 6).

Whilst structural facilitators and barriers have been described in the literature (Gondwe *et al.*, 2021; Lusambili *et al.*, 2019), addressing barriers to the success of the audit process in reducing mortality usually requires a change of the behaviour of multiple individuals and organizations. There has been little emphasis on the use of theories to identify behaviour change approaches to improve program implementation including death audit processes. Supporting staff to change their behaviour is key to successful intervention implementation (Grol and Grimshaw, 2003). This study explored factors that impacted staff participation in audit activities and the implementation of action plans with a view to developing a theoretically informed health system intervention.

6.4 Methods

6.4.1 Qualitative approach

This qualitative study was nested in a mixed methods research project evaluating stillbirth and neonatal death audit processes and neonatal outcomes in public hospitals in the southern region of Malawi. We used conceptually oriented investigation into the key factors impacting audit processes at the individual, social and structural levels.

6.4.2 Conceptual Framework

Given the lack of explanatory frameworks relevant to factors affecting the conduct of death audit and implementation of audit action plans, we reviewed the literature and from this, developed and used a conceptual framework to guide this study (Figure 6). The framework was developed from associations described in the literature between factors that affect the implementation of death audit at different levels (Tuncalp *et al.*, 2015; World Health Organization, 2016b; Kaplan *et al.*, 2012; Donabedian, 1980; Donabedian, 1988; WHO, 2007; Aragón and Giles Macedo, 2016). The conceptual framework informed the design and analysis of semi-structured interviews (SSIs) and focus group discussions (FGDs); guided the development of themes and helped align themes identified at individual (micro), facility (meso) or national (macro) level. Structure refers to characteristics of the setting in which audit is performed, process encompasses the components of the audit cycle and the interactions and outcome of audit (Donabedian, 1988).

6.4.3 Study setting

The study was conducted in seven public hospitals from seven districts in the southern region of Malawi. The hospitals were purposively selected to provide a broad representation of health care workers involved in stillbirth or neonatal death audits and populations with a wide variation in district level neonatal mortality rates (Appendix 37). Malawi's health system is organised at four levels (community, primary, secondary and tertiary) linked through an established referral system. Community, primary and secondary level care falls under district councils. The District Health Management Team (DHMT) is led by the Director of Health and Social Services (DHSS), who reports to the District Executive Committee locally and the central Ministry of Health (MoH). The selected hospitals included one tertiary

hospital (hospital 1) and six secondary hospitals (hospitals 2-7). The tertiary hospital provides specialised inpatient and outpatient care at a regional level and receives referrals from district hospitals within the region and health centres within the district. The secondary (district) hospitals provide outpatient and inpatient services and receive referrals from community hospitals and health centres. All hospitals had a high patient load, hospital 2 had the highest frequency of audit meetings, hospitals 4 and 6 had very few audit meetings, and only hospitals 1 and 2 had DHMT members present during audit meetings (chapter 5).

6.4.4 Researcher characteristics and reflexivity

MG, a female Malawian PhD research student and a registered nurse/midwife, conducted all SSIs and FGDs. With more than 14 years of experience as a nurse, MG's position as both a health professional and researcher balanced emic knowledge with an etic lens to deconstruct assumed knowledge and challenge where necessary (Li, 2020). Although MG was known to some respondents prior to undertaking the study, the purpose of the interviews and her role was made clear to the participants and MG was careful not to accept potentially common assumptions at face value. Furthermore, MG kept reflexive diaries which enabled her to explicitly map her role as researcher, record and acknowledge her experiences, thoughts, opinions and feelings during data analysis and interpretation (Vicary, Young and Hicks, 2016; Lincoln and Guba, 1986). The research team also had a field assistant (EJ) and a transcriber (HK), who were trained in qualitative research and assisted with notetaking during FGDs and transcription, respectively.

6.4.5 Sampling strategy

We used purposive and convenience sampling to select respondents involved in the audit process. Purposive sampling enabled us to capture different experiences by age, cadre, ward, roles and years of experience, while convenience sampling was used to approach those staff with required categories available during the time of interview (Appendix 38 and 39). We conducted SSIs and FGDs with nurses and clinicians involved in stillbirth and neonatal death audits and hospital/district management team members.

MG approached potential respondents face-to-face for SSIs, provided them with information about the study's aims and secured written informed consent prior to arranging

an interview for those who agreed to participate. Recruitment continued until the study team agreed to stop data collection due to data saturation when iterative analysis led to no further adjustments to the topic guides and no novel codes emerging (Glaser and Strauss, 2017). Before each session, respondents' socio-demographic data was collected, including cadre, department, age, gender, level of education and years of experience. Interviews were carried out face- to -face in the respondent's office or other private space. Only the participant and researcher (MG) were present in the room during SSIs which lasted between 30 to 45 minutes. Respondents were able to use either English or the local language, Chichewa, at any point during interviews.

For FGDs, MG provided information to audit committees and agreed on the discussion date and time. Only 1 FGD was conducted per hospital as the number of audit committee members ranged from five to 15 in each facility. FGDs lasted between 60 and 90 minutes.

Although there is a concern in the research that a group dynamic can undermine confidentiality and alter the depth of information provided (Morgan, 1993; Kitzinger, 1995; Theobald *et al.*, 2011), we incorporated pre-existing hierarchies (staff who already participate in death audit meetings) into the discussion. We also triangulated data collection methods by using both FGD and SSIs to mitigate the concerns.

6.4.6 Data collection

SSIs and FGDs were conducted between July and December 2020. SSIs and FGDs were guided by semi-structured topic guides developed by the research team based on existing literature and conceptual framework domains (Appendix 14 and 15). The topic guides explored experiences, facilitators and barriers in conducting stillbirth and neonatal death audit at the facilities and evolved following team discussions of emerging themes during the study period. FGDs also had an observer (EJ) who recorded non-verbal cues and kept time. MG and EJ were trained in human subjects' procedures, confidentiality and privacy protection. All data were audio-recorded and transcribed verbatim by a professional transcriber (HK). Interviews were anonymised through unique identifiers.

6.4.7 Data management and analysis

The respondent demographic and interview data were stored in secured databases and computers accessible only to research staff with approved access. Using a a framework analysis (Richie and Spencer, 1994), interview transcripts were analysed iteratively through a combined deductive and inductive approach using NVivo (V.12). The analysis was guided by five phases of framework analysis; familiarisation, identifying a themes (thematic framework), indexing, charting and mapping and interpretation (Richie and Spencer, 1994). MG independently undertook open coding on selected transcripts following familiarisation with the data by re-reading all the transcripts. After coding two interview transcripts, MG and ND met to discuss the initial codes. MG subsequently coded two more interview transcripts and an FGD transcript and built a coding tree inductively. After this initial coding round, MG and ND reviewed the detailed codes, and then arranged codes as they aligned to the conceptual framework (Figure 6) under staff, facility and national levels to understand the sub-themes within each category. This final framework (code book) was then used to code the remaining transcripts.

Initial themes were developed after coding all transcripts against structural factors in the conceptual framework. MG kept memos to mitigate her perspective and ensure her interpretation as a practising nurse was documented and accounted for and ran queries to identify patterns, similarities and differences in the identified themes across the facilities. These initial themes were then reviewed and refined according to the study's purpose and through the lens of the conceptual framework, which identified cross-cutting themes. Several team meeting discussions and reflections allowed continuous interaction with the data and a consensus to be reached where required.

6.4.8 Trustworthiness

Respondents were invited to review their transcripts, but only 20 respondents did. SSI and FGD data were triangulated to broaden the in-depth information from the interviews and compare across the facilities (Kirk *et al.*, 2016; Bergh *et al.*, 2013). Additionally, to provide data transparency, MG kept an audit trail by documenting all decisions made from conceptualisation through reporting (Bergh *et al.*, 2013; Kirk *et al.*, 2016).

Ethical approval was obtained from the research ethics boards of Malawi, Kamuzu University of Health Sciences formerly called College of Medicine (COMREC) (P.11/19/2869) and the Liverpool School of Tropical Medicine in the UK (19-076). This article follows the Standards for Reporting Qualitative Research Checklist (O'Brien *et al.*, 2014)

6.5 Results

6.5.1 Overview

We interviewed 38 audit committee members individually of whom 22 (58%) were women and 5 (13%) were DHMT members, 22 (58%) were nurses and 11 (29%) were clinicians. Median (IQR) age was 34.5 (39-30) years and level of clinical experience ranged between 3 months and 30 years. There were 6 (16%) respondents each from hospitals 1,2, and 7 and 5 each (13%) from hospitals 3 to 6. Two (5%) respondents had a master's degree, 21 (55%) a degree and 15 (39%) a diploma. For nurses, 12 (55%) worked in nursery wards, six (27%) in labour wards and two (9%) each from postnatal and antenatal wards. For clinicians, six (55%) were allocated to maternity wards and five (46%) to nursery/paediatric wards. Eighteen (47%) SSI respondents also held significant roles such as programme coordinator or ward in charge. See appendix 34 for a full description of each participant.

We also conducted 7 FGDs with a total of 49 respondents: 30 (61%) of whom were women, 9 (18%) were clinicians, and 40 (82%) were nurses working in nursery ward (20; 50%), labour ward (11; 27.5%), postnatal ward (5; 12.5%), nursery and paediatric wards (5; 13%), maternity ward (4; 10%) and two each (5%) from the antenatal and paediatric ward. Median (IQR) age was 32 (36-28) years and level of clinical experience ranged between 3 months and 27 years. Twenty-three (47%) had a degree while 26 (53%) had a diploma qualification. Similarly, to SSI respondents, 14 (29%) FGD respondents held other significant roles in their profession such as programme coordinator or ward in charge (Appendix 35).

We identified 5 themes, which either facilitated or hindered conduct of audit meetings and the implementation of action plans. The identified themes are interrelated as they impact at both individual (micro), facility (meso) and national (macro) health system levels. Anything happening at individual level necessarily influences facility level practice and in turn, national level or district level actions inform capacity to implement at facility level. Table 18

summarises how the main themes crosscut at each level. We present these results according to the main themes that arose with some illustrative quotes from respondents. The main themes were training, staff motivation, power dynamics and autonomy, audit organisation and data support. In the following section, we will present these themes and show how they were interrelated across different levels within the health system.

Table 17: Emerging themes

	Training	Staff motivation	Power dynamics and autonomy	Audit organisation	Data support
Individual level	Inadequate training	Incentive	Inadequate resources	Meeting attendance restriction	Poor documentation
Facility Level	Lack of budget allocation for audit training	Leaders' engagement	Lack of autonomy over procurement system	Attainment of a multidisciplinary team	Lack of data clerks
	Lack of peer-based training promotion		Lack of autonomy over recruitment system	Implementing action plans	Lack of data usage
National level	Donor support facility targeted training	Support from MoH	Decision making	Communication of audit findings	Mismatch of data indicators in the register
		Support from Donors			

6.5.2 Training

This theme discusses compulsory staff training for those staff participating in audits. We report how inadequate training, lack of budget allocation for audit training, lack of peer-based training promotion and donor support for facility targeted training impacted training access and engagement amongst staff. Trained staff with adequate skills and knowledge will likely be more effectively engaged in the audit process.

We found that where trainings were conducted, staff had adequate knowledge, understanding and acquired skills on audit. In contrast where it was not done, staff rarely engaged in audit activities. Trainings were done most frequently in hospital 2 as these were supported by an external donor, in contrast to hospitals 1 and 3 to 7 which had no external funding to promote audits. Staff from hospitals 1 and 3 -7 had only few staff trained as they waited for MoH initiated trainings on audit which was rarely conducted due to lack of funding. We also found that staff did not value in house training and peer-based training was not promoted at facility level due to the monetary incentive attached to externally funded training. DHMT rarely funded internal trainings due to inadequate funding and limited autonomy to make funding decisions and budgetary restrictions. Despite decentralisation, funding decisions are still taken at the national level. This led to dependency on external donors working in the district to fund trainings and resulted in inequity between hospitals.

> *'Attending training had helped me understand the importance of audit and I would more likely engage myself in audit' (SSI, SMC, Hospital Matron, Hospital 3)*
>
> *'Most staff are new from pre-service. They needed training in death audit to be equipped with the necessary skills. But when we asked for funds from DHMT, they said funding was inadequate and they have no control as decisions were made at national level' (FGD, SMC, Hospital 4)*
>
> *'Three of us were trained and planning to train each other. However, staff wanted to attend external training themselves due to the attached monetary incentive*' (SSI, In-charge, Neonatal focal person, Hospital 3).

*'Our partner (external donor) supports us with skills and training on how to conduct the death audits' (*SSI, Clinician, Nursery ward, Hospital 2)

Individuals believe they do not receive adequate training as a result of facility-level decision-making and a lack of budget allocation, which is informed by a lack of clear national guidance on training approaches that can be used at facilities other than externally funded trainings. Because of decentralized decision-making and cost constraints, facility training is mostly driven by donors resulting in inconsistent access to training by staff across different facilities.

6.5.3 Staff motivation

While adequate skills are needed for staff to perform audit, skilled and motivated staff are more likely to engage in audit activities. This theme explores the impact of staff motivation on implementing audit activities. Factors that affect staff motivation reported in this section include incentives, leaders' engagement, support from MoH and support from donors.

Similarly, to training, staff attendance at audit meetings relies on incentives such as lunch allowance and refreshments. As such, Hospital 2, where these are consistently provided by an external donor, reported the greatest regularity in audit meetings.

Despite DHMT being aware of sustainability issues with monetary incentives, they rarely offered non-monetary incentives like supportive supervision, participation in audit meetings and recognition. But in the few hospitals (hospitals 1 to 3) where DHMT supported audits, respondents felt motivated, and most action plans were implemented. In hospitals 1 and 2 where the majority of audit meetings were conducted and management team members attended audit meetings, staff recognised the benefit of audit and staff were more committed and accountable than in other hospitals. Another non-monetary incentive respondents appreciated was MoH support in terms of quarterly supportive supervisions although these were rarely conducted. The unavailability of national level stillbirth and neonatal audit guidelines was a demotivator to staff performing audits. As such audits were not prioritised, rarely conducted, or valued at all levels. Other respondents emphasised the importance of publicizing newborn deaths in the same way that maternal deaths are

publicized. This serves as a motivator for employees to undertake audits in order to ensure public accountability. In most hospitals frequency of audits was determined by the availability of external funding and internal funding from DHMT. Whilst donor support facilitated audits and staff motivation, DHMT was concerned with sustainability due to other funding priorities and an overall lack of resources.

> *'If no monitory incentive, the members turn up would be poor, which left a lot of files unaudited thereby missing out some of the important action points'* (SSI, Clinician, Nursery, Hospital 2)
>
> *'We needed more motivation from DHMT like appreciation, their attendance in audit meeting, refreshments or a bottle of water*' (FGD, Clinician, Hospital 6)
>
> *'With improvements seen in care, we were motivated to keep on doing audit meetings'* (FGD, Nurse In-charge, Nursery ward, Hospital 2)
>
> *'The DNO and DMO helped us mobilise resources, identified partners and organised mentorship when they attended audit meetings. Solutions were achieved quick and fast; the team was motivated'* (SSI, Neonatal focal person, Hospital 2)
>
> *'…..to be honest on DHMT supervision, since I came here a year ago, we had never supervised the district hospital we usually went to the health centres'* (SSI, DMO, DHMT member, Hospital 7)
>
> *'The national level supervised us. Their feedback helped us improve the care and motivated us to continue doing audits as they asked for it during supervision'* (FGD, Paediatric Clinician, Hospital 3)
>
> *'The maternal death audit has well-stipulated guidelines on when to audit and report to MoH, unlike neonatal death audits, I had not come across any guidelines'* (SSI, DSMC, Labour Ward, Hospital 7)
>
> *'If a pregnant woman died, it became a public concern. Donors and management team would support it and staff attend it voluntarily'* (FGD, Clinician, Hospital 3)
>
> *'The team requested our support in terms of finance or refreshments, but we could not sustain it, that was why we said no to financial incentive*' (SSI, DNO, DHMT member, Hospital 2)

'….even sustaining audit meetings funding when partners pulled out it a challenge, we only fund occasionally' (SSI, DMO, Hospital 7)

The fact that individuals wait for availability of monetary incentives to convene or participate in audit activities is informed by facility level institutional norms of reliance on incentives and inadequate provision of non-monetary incentives, which in turn is informed by national level directives, policies and guidelines that allow donors to provide more monetary incentives than non-monetary and lack of national stillbirth and neonatal death audit policy and guidelines. The norm and culture of using monetary incentives to individuals when attending meetings or training dominate recognition of other audit benefits and provision of non-monetary incentives that have equal power to motivating staff. Nonetheless, facility managers' capacity to maintain monetary incentives is a concern.

6.5.4 Power dynamics and autonomy

Audit implementation and effectiveness within hospitals is influenced by and embedded within broader power dynamics within the system. This theme reports the impact of power dynamics at all system levels that affect resource management and audit implementation. The reported factors are lack of autonomy over procurement system, lack of autonomy over recruitment system and decision making.

Respondents were unable to implement audit activities in hospitals where resources were inadequate. The most inadequate resources included essential drugs, equipment and staffing. This was owing to centralized powers over resources, staffing and funding, which, notwithstanding decentralization, the facility level had no control over. With staff shortages and heavy clinical workloads, it was difficult to convene audit meetings or participate, which led to cancellations. Despite critical shortage of staff in wards, auditing all stillbirth and neonatal deaths was a requirement stipulated by the national-level authority. To fulfil the requirement, staff reported working in pairs to complete audits, as opposed to a multidisciplinary team approach and compromising the quality of audits. With more decision power at national level, DHMT members had limited autonomy and decision-making powers resulting in a disconnect between hospital needs and central level decisions. This led to competing priorities and inadequate or delayed funding which affected support

of audit meetings, resources to implement audit solutions and staff training as described in the previous section.

> *'We lacked supplies like oxygen, pulse oximeter, 50% dextrose, antibiotics and nasogastric tubes, which made us difficult to implement changes in care'* (SSI, NMT, Nursery ward, Hospital 7)

> *'We plan, we implement, but we do not decide how much money would get, how many staff we would employ and what training our staff would attend. The national level had all powers to decide'* (SSI, DMO, DHMT member, Hospital 7)

> *'We only have a sole medical supplier. We could not outsource, so the availability of drugs depended on those drugs at the central medical stores. We run out of options because of the policy and decision-makers sat at a national level*' (SSI, DMO, DHMT member, Hospital 7)

> *'Nurses and clinicians were few, but if we presented to DHMT, they said it was not in their capacity to decide but national-level' (*FGD, Paediatric Clinician, Hospital 3).

The situation that which staff (individuals) lacked resources to support stillbirth and neonatal death audit implementation is informed by limited facility-level autonomy and decision-making power created by national-level authorities, who are determinants for decision making at all system levels. Due to centralised decision-making powers, the facility level decisions are limited and mostly done at the national level which results in competing priorities and affects resource availability at facilities.

6.5.5 Audit organisation

Audit meeting is where staff meet to discuss deaths and identify gaps in care. It requires a multidisciplinary team and achievement of 6 steps of WHO death audit cycle for it to be effective. This theme reports gaps identified in areas of meeting attendance, attainment of a multidisciplinary team, implementing action plans and communicating audit findings.

Given that most audit meetings were done when there was funding, staff felt side-lined as most meetings were attended by invitation depending on budget restrictions as opposed to extended invitation in hospital 3. But even though the meeting invitation was open in hospital 3, it was difficult to get a full multidisciplinary team to attend audits due to busy

schedules or no incentive, which led to meeting cancellations. Hospitals 1-4 resorted to having departmental audits which excluded staff from other disciplines. It was difficult to implement suggested actions due to inactive quality improvement teams with no link with the stillbirth and neonatal death audit. However, despite some meetings being funded, completing the WHO 6 audit cycle steps as shown in Figure 5 was a challenge, with the last two steps rarely implemented as they were not included in the audit form template.

Even after the audit meetings, it was not clear where they report the audit findings as it was informed by the funding source rather than a well-defined line of authority. Although internal feedback was given in the wards, it lacked DHMT member representation. Since only two hospitals conducted stillbirth audits separately, the majority of respondents claimed that stillbirth audits were undertaken concurrently with maternal deaths audits. Stillbirths were not prioritized during the process.

> *'I did not participate in audit meetings always. It depends if you were invited or not'* (SSI, Nurse, Nursery ward, Hospital 4).
>
> *'We were supposed to have a hospital quality improvement team, but it is not active. There is a work improvement team available in the nursery, though inactive, and I did not even know who was in that committee'* (SSI, Paediatric Clinical Officer, Hospital 1).
>
> *'Mostly we met to do audits but not met to review previous action plans'* (SSI, DMO, DHMT Member, Hospital 7)
>
> *'…the form we used reports up to suggested solutions (action plan). No information on follow up of solutions or evaluation of process which limit staff in doing the steps'* (FGD, Paediatric Clinician, Hospital 1)
>
> *'We only report to a funder, who funded the audit meeting, not to the national level* (SSI, Neonatal focal person, Nursery ward, Hospital 5)
>
> *'After the audits, we make two reports one for the district management through the DNO and the second one we report to NEST 360 which is our partner helping us in neonatal care which we gave a report that goes to the Ministry of Health'* (SSI, Nursery Incharge, Hospital 3)

'When we give feedback to our junior colleagues, they do not take it seriously as we are on the same level. It would have been good if senior members were involved during ward or department feedback' (FGD, HBB Coordinator, NMT, Labour ward, Hospital 7)

'We have always started with maternal death audits, leaving no time for stillbirths, and we are mandated to report maternal deaths within 72 hours to Ministry of Health, which we do before stillbirths' (SSI, Deputy Safe motherhood Coordinator, Postnatal ward, Hospital 1)

The fact that the individuals were restricted to attend audit meetings, was attributed to an institution norm of reliance on monetary incentives, informed by national-level decisions on incentives as described in the previous section. It was also attributed to inadequate promotion of facilities to have active quality improvement teams due to inadequate enforcement at national level. It was also demoralising to individuals to see actions plans not implemented or reported, which was informed by inadequate support from DHMT as previously described, which in turn is informed by inadequate guidelines (audit form template) and lack of reporting system at national level. Well stipulated guidelines together with supportive supervision are more likely to motivate facility and staff in implementing audit activities.

6.5.6 Data support

Complete, accurate, consistent and valid data are necessary to identify gaps and solutions during audit. This theme reports data support challenges at all levels. The main challenges were poor documentation, lack of data clerks, lack of data usage and mismatch of data indicators in the register.

Incomplete patient information made analysis of death incomplete and affected audit outcomes across all facilities. Critical shortage of ward clerks in hospitals 2-7 made nurses responsible for entering data into the register. Timely data entry was difficult due to nurses' busy schedules or inadequate ward clerks. Poor filing systems resulted in unavailability of the mothers' clinical records which are key in analysing stillbirth and neonatal deaths. This was common in all hospitals, where most cases were referred from health centres, and where facilities waited a long time to audit deaths. Despite newborn data being collected, it

was rarely used by staff during audit. One of the respondents pointed to incompatibility of data indicators between the ward register and the HMIS platform, which made its usage difficult.

> *'Due to lack of adequate ward clerks, data entry was mostly incomplete. Sometimes nurses would help but because of their busy schedule, this was also impossible'* (FGD, Deputy Nurse Incharge, Nursery ward, Hospital 1).
>
> *'Mostly the patient records were incomplete, maternal files, feeding charts were not attached, making analysis incomplete'* (SSI, Clinician, Nursery ward, Hospital 4)
>
> *'We did not know how to use generated data. We waited for external assessors to use data for us, the same with audit data'* (FGD, Paediatric Clinician, hospital 3)
>
> *'The HMIS list of diagnoses is not compatible with the diagnosis we made in the wards. In HIMS it was just neonatal complications and some of the diagnoses were not so descriptive that you could analyse'* (SSI, DHOD, Paediatric ward, Hospital 1)

The fact that individuals did not complete patient information or attach appropriate forms, which affected audit process, was due to critical shortage of staff, inadequate guidelines and inappropriate guidance from facility level leaders, who rarely supervised staff. The decision-making powers at national level over staff recruitment contributed to ward clerk shortage in the facilities. Even though some data was collected, its usage by staff was not promoted at facility level and the newborn registers did not match with consolidated indicators in the HMIS platform which is controlled at the national level.

6.6 Discussion

6.6.1 Summary of the findings

We identified facilitators and barriers that affect staff engagement in audit activities including the implementation of action plans at all system levels. We found that the factors were interconnected, such that decisions made at national level informed decisions at facility level which in turn impacted staff behaviour at individual levels. Given that our original conceptual framework emphasised the role of different levels influencing the audit process, we have presented the results using this structure, highlighting the

interconnections between each level. We have found primarily that the different levels inform and are informed by each other. The identified factors are related to training, staff motivation, power dynamics and autonomy, audit organisation and data support.

The facilitators at Individual level were adequate training, availability of financial incentives, and recognition of audit benefits while barriers were inadequate training, over-reliance on financial incentives, inadequate resources, meeting attendance restrictions and poor documentation.

At facility level, facilitators were availability of DHMT during audit meetings and barriers were lack of budget allocation for audit training, lack of peer-based training promotion, fears of sustaining financial incentives, inadequate non-monetary incentive, unavailability of DHMT members during audit meetings, lack of supportive supervision, limited autonomy and decision-making powers, inability to attain multidisciplinary team, inactive quality improvement team, shortage of staff, inability to complete the WHO audit cycle steps and lack of data utilisation.

While at national level, facilitators were training support, donor coordination and availability of national-level supportive supervision while barriers were donor policy, donor support sustainability, decision-making powers, lack of national-level stillbirth and neonatal death audit policy and guidelines, unstructured reporting and feedback system. In this section, we will discuss strategies that may help to capitalize on facilitators and reduce barriers.

6.6.2 Facilitators

Staff skills in the neonatal death audit process and knowledge of its aims, objectives and values are key to ensuring effective implementation. One of the identified facilitators was a supported training programme that equipped and motivated staff in hospital 2 to engage in audit activities. Similar findings have been reported in an integrative review on the impact of education and training interventions for nurses and other health care staff involved in the delivery of stroke care, where interactive education and training delivered to multi-disciplinary stroke teams were associated with a positive impact on patient and quality of care outcomes (Jones *et al.*, 2018).

Given that donors and on a few occasions hospital management supported audit meetings with per diem or refreshments, staff were more willing to participate in audit meetings if such support were available as it motivated and supplemented their low wages. Similar findings have been reported in a study conducted in Malawi and Uganda that explored perceptions of per diems among government officers and non-governmental organization (NGO) officials, who reported that per diems provide benefits such as encouraging training, increasing staff motivation and supplementing salary (Vian *et al.*, 2013). Furthermore, another study done in Malawi also reported health workers scrambled for training if financial incentives were attached (Mueller *et al.*, 2011). More adequate means to improve health workers' knowledge and motivation through supervision, onsite training and non-financial incentives are needed.

Power dynamics and relationships play a part in intervention acceptability amongst staff, patients and management (Lawrence *et al.*, 2021). Participants identified management team members as key facilitators of audit implementation as they have the power of knowledge and decision making at the facility level. In hospitals where the management team supported audits through participation in audit meetings, staff were motivated. Furthermore, national-level supportive supervision in facilities facilitated staff engagement in audit activities. Similar findings have been reported in studies conducted in Pakistan and African countries, Ethiopia, Kenya, Malawi and Mozambique (Rabbani *et al.*, 2016; Kok *et al.*, 2018).

6.6.3 Barriers

In facilities where supported training programmes were missing (hospitals 4 and 6) staff rarely engaged in audit and failed to recognise audit benefits on the provision of care. This finding is consistent with a study in Australia, where misinterpretation of intention and meaning of an intervention impacted staff engagement in the baby-friendly initiative (Schmied *et al.*, 2011). Although these may clash with individual values, clearly stated values at the organisational-level influence staff's decisions about what you do and how you do it (Casali and Day, 2010).

Inadequate knowledge, skills and understanding of the value of audit can be resolved through training (Schmied *et al.*, 2011; Clark *et al.*, 2012). However, in this study, training was rarely conducted in hospitals 1 and 3-7 due to inadequate funding at facilities. In mitigation, there is a need for a structured plan on how knowledge or information should be transferred from trained staff to untrained staff. Furthermore, as staff expressed that they would like to attend external training due to the attached incentives, it was difficult for those already trained to transmit knowledge to untrained colleagues due to jealousy that they had received financial incentives while others covered their duties in the ward during the training period. But there was also inadequate promotion of peer-based training by management team members. Sensitisation of the value of implemented audit plans in improving health care is needed beyond personal benefits.

Although monetary incentives were a facilitator and motivator for some staff to participate in audit, staff commitment was often low due to over-reliance on monetary incentives. This finding agrees with studies conducted in LMICs, that found it challenging to implement interventions with no monetary incentive (Bulthuis *et al.*, 2021; Mueller *et al.*, 2011; Rowe *et al.*, 2005; Agaro *et al.*, 2016). While both monetary and non- monetary incentives determine staff motivation, managers in organisations spend less time and effort on non-monetary incentive measures (Silverman, 2004). This should be balanced in an organisation for staff to be motivated and be able to engage in activities.

Participants also mentioned barriers directly related to the hospital environment. These included resources, management support, inadequate staffing and busy ward schedules. Other studies have cited staff workload, shortages, staff turnover, changes in roster and lack of time for implementation as the most common barriers to audit (McAteer *et al.*, 2014; Nithianandan *et al.*, 2016; Kane *et al.*, 2016; Jones, 2000). System-level commitment and support from the management team are required to address barriers to audit (Kirk *et al.*, 2016; Bergh *et al.*, 2013). Facility readiness to change organisational culture depends on leadership style, management orientation, accountability and human and material resource policies (Mannion, Davies and Marshall, 2005).

We found that leadership was limited in terms of supervision, recognition and DHMT participation in audit meetings which were missed opportunities for staff motivation. Stronger transformational leadership has been associated with positive work attitudes and

high staff organisational commitment (De Hoogh *et al.*, 2005; Bass and Riggio, 2005).Transformational leadership is when leader's behaviours motivate and inspire people to perform beyond their perceived capabilities (Forester and Clegg, 1991). Transformational leadership also encourages followers to take moral responsibility for their actions, which is vital in auditing because the results of this study revealed a lack of staff and leadership accountability (Omar, 2017). This sort of leadership is perfect for the audit process because it enables employees to recognize that change at the hospital occurs with and because of them rather than to them (Omar, 2017). It also inspires followers to put their own interests aside for the good of the organisation (Omar, 2017). We suggest that hospital management invests time and effort to use non-monetary incentives to motivate staff as an example of transformational leadership. Drawing on the WHO Health Systems Framework (World Health Organization, 2010), which was incorporated in the study conceptual framework, it is also clear that the stillbirth and neonatal death audit programme should strive to reach a better balance between and among the six building blocks to achieve desired newborn health outcomes. We identified leadership and governance as a critical foundation, which could assist facilities in supporting other system blocks parameters during the implementation of audits.

Staff may complain of busy schedules as an excuse for not attending audit meetings (Kerber *et al.*, 2015). In this study, participants highlighted that using staff on duty to conduct audits created ward shortages. A study on stages of change for perinatal audit in South Africa suggested integration into a routine practice as one stage of change in audit, which could improve staff engagement to avoid perceiving audit as an external programme (Belizán *et al.*, 2011)

We observed donor dependency patterns in facilities where partners rather than the facilities themselves facilitated training, equipment supply and meeting allowances. Furthermore, donor dependency also encourages perception of audit as an external (externally funded and supported) initiative rather than a government driven requirement. According to the perspective of donors in a study conducted in Malawi, training was a quick fix to introduce new programmes or interventions. With number of trained staff as a key donor deliverable, they had no choice but to provide financial incentives for staff to attend training (Mueller *et al.*, 2011). Although DHMT has the mandate to oppose donor-imposed

training which is announced with short notice and limiting its inclusion in the district and MoH plans, it would be like standing in the way of their employers to receive financial incentives which supplement their low wages (Mueller *et al.*, 2011).

DHMT members also cited the difficulties resulting from the national level as the controllers of their human, material and funding resources. This finding agrees with a multi-country study where health system decision-making decentralisation is only on paper rather than in reality as the national level continues to control decision making for the district, in resources and staff hiring and dismissal (Bulthuis *et al.*, 2021). Due to this, DHMT is disempowered and fails to act on district issues due to limited decision-making power, leading to inadequate resources and staff that affect how audit meetings and the implementation of action plans can be supported. We suggest that national and DHMT support is paramount in audit activities; their presence in audit meetings and support will likely facilitate and motivate staff in attending the audit and to ensure implementation of its action plans.

Guidelines from the national level act as an external influencer for staff motivation and engagement if perceived that they will benefit patient outcomes (Schmied *et al.*, 2011). Despite WHO formulating and disseminating guidelines (World Health Organization, 2016b), implementation in LMICs is challenged by national-level factors. In an attempt to overcome these constraints, countries need to adapt the guidelines to suit the system and the context. Despite audit guidelines being adapted in Malawi, staff reported inability to complete the WHO audit cycle steps. Similar findings have been reported in a systematic review of LMICs (Kerber *et al.*, 2015). Interventions implemented as part of hospital policy and translated into standard practice facilitate long-term change (Rankin *et al.*, 2015). National guidelines for stillbirth and neonatal death audits, disseminated to facilities and training adequate staff would likely enhance staff capabilities to engage in neonatal death audit activities.

These factors drawn from participants' responses could best be addressed by a behaviour change approach. The use of behaviour models is of great importance in QI processes and can assist in achieving success in audit implementation which is greatly impacted by staff behaviours. Such models have been rarely used in QI approaches but are widely used for health systems interventions and feature widely within the Medical Research Council (MRC) complex interventions framework and guidelines (Skivington *et al.*, 2021). Several behaviour change models have been developed and used to understand behaviour, identify

mechanisms of change, describe why programmes succeed or fail and guide in building better programmes (Gielen and Sleet, 2003). But Michie, Atkins and West (2014) have merged them into a workable and adaptable framework- the COM-B. The COM-B model proposes that people need capability (C), opportunity (O) and motivation (M) to perform a behaviour (B), which needs to be considered when designing an intervention (Michie, Atkins and West, 2014).

Capability, opportunity and motivation interact to generate behaviour, which influences these components (Michie, van Stralen and West, 2011). Changing one or more components of the behaviour system can alter staff engagement in audit activities (Michie, van Stralen and West, 2011). Staff must have the appropriate knowledge and skills to perform audits and complete the audit cycle (capability), which can be acquired through mentorship and training. This skilled staff will require an opportunity to work in the environment in which he or she is employed, as well as the culture in which he or she is immersed. Audit policy and guidelines, resources, leadership involvement and data support are all possibilities. The staff's motivation to participate in audit activities might be influenced by both capabilities and opportunities. While this is a behaviour model, it also serves as a foundation for designing interventions to change behaviour (Michie, van Stralen and West, 2011). Applying this to intervention design, the objective would be to determine what the behavioural target for employees to be able to engage in audit activities would be, as well as what aspects of the behaviour system would need to be changed to facilitate staff engagement in audit activities (Michie, van Stralen and West, 2011).

6.6.4 Strengths and limitations

We used a conceptual framework developed from the quality improvement and health system strengthening models and applied it to describe barriers and facilitators to death audits. The framework has a solid theoretical base (Tuncalp *et al.*, 2015; World Health Organization, 2016b; Kaplan *et al.*, 2012; Donabedian, 1980; Donabedian, 1988; WHO, 2007; Aragón and Giles Macedo, 2016), meaning that our findings are more likely to be generalisable and can be compared to similar programmes implemented in a similar context. We also used both SSIs and FGDs to explore the experiences of staff on stillbirth and neonatal death audits. This helped in consolidating both individual and group

perspectives for comprehensive understanding of the concept. Furthermore, this is a multisite study that looks at the perspectives of workers from seven different locations and the data are compiled to present a full picture of the factors that influence audit implementation.

Our study had limitations because we only interviewed hospital workers and, due to time and financial constraints, we did not interview personnel from the Ministry of Health (national level) or external partners to get their perspective. Using purposive sampling to select sites and convenience sampling for study participants might have introduced sampling bias. However, triangulating data across the two collection methods ensured cadre level validation of key issues.

6.7 Conclusions

We have identified multiple, interconnected factors that impacted audit implementation at individual, facility and national levels. The interventions required to promote facilitators and reduce barriers need to be comprehensive to address issues at all system levels. This will necessitate a combination of behavioural and complex intervention methods. Our findings will inform implementers, policymakers and managers to identify facilitators and address barriers to positively impact stillbirth and neonatal death audits and thereby improve the quality of neonatal care and outcomes.

CHAPTER 7: GENERAL DISCUSSION

7.1 Chapter overview

The capacity to deliver neonatal care in the seven facilities engaged in this research was uniformly poor and the quality of stillbirth and neonatal death audits were of low standard due to barriers identified at all system levels. Here, I summarise the key findings and their impact on the future implementation of stillbirth and neonatal death audit.

I consider how the results from different chapters align to address the main aim of the study: to evaluate the quality, barriers and facilitators of stillbirth and neonatal death audit processes in seven public health facilities in the southern region of Malawi. I discuss in section 7.2 the resources available and barriers to delivering quality care for newborns in facilities, the quality of stillbirth and neonatal death audits and facilitators and barriers in implementing the audit process. I also present the conceptual study framework as a guide to help understand the steps to consider when implementing stillbirth and neonatal death audits to maximise their impact. This is followed by recommendations regarding the different strategies identified in this study. I discuss how this research has contributed to what is already published in the literature on stillbirth and neonatal audits and the Malawian context where this study was conducted in section 7.3. Section 7.4 presents methodological strengths and weaknesses, and section 7.5 presents general challenges. Section 7.6 presents recommendations and implications for policy and practice. Finally, section 7.7 describes the implications for research and section 7.8 concludes this chapter.

7.2 Summary of key findings

7.2.1 Overview

This study achieved its aim of evaluating quality, facilitators and barriers of stillbirth and neonatal death audit in the southern region of Malawi. In Malawi, the SBR decreased from an estimated 22.2 (uncertainty range 17.2-29.0) stillbirths per 1000 births in 2000 to 16.3 (uncertainty range 14.7-18.1) in 2019 (UN IGME, 2020b). Over the same period, NMR declined from an estimated 42 to 27 deaths per l000 live births (National Statistical Office (NSO) [Malawi] and ICF Macro, 2017). Despite these observed declines, SBR and NMR remain high and the continued loss of newborns due to preventable causes remains a major

public health concern.

The persisting high stillbirth and neonatal mortality levels are partly due to poor quality care. Implementing stillbirth and neonatal death audits could improve care quality and reduce mortality from preventable causes. Using quantitative and qualitative data collection methods, the study has contributed to the body of knowledge by presenting the current situation of stillbirth and neonatal death audit processes, identifying factors associated with the implementation of audits, and providing a conceptual framework to guide audit implementation. Understanding the current stillbirth and neonatal death audit situation is key to strengthening its implementation and informing the way forward to maximise its impact**.** Stillbirth and neonatal death audit processes have rarely been evaluated (Sandakabatu *et al.*, 2018; Nakibuuka *et al.*, 2012). In this study a logical progression of steps was followed using a comprehensive approach that included both qualitative and quantitative methods.

Firstly, I developed a conceptual framework by reviewing the literature on quality improvement and health systems strengthening. This identified factors that are key to the implementation of audit, illustrated how they are linked to the process of audit, emphasized the importance of completing the audit cycle and also the importance of the link to quality improvement initiatives which would improve quality of care and thereby, impact on stillbirth and neonatal mortality. Then, I evaluated the usefulness of the conceptual framework in practice, through 3 studies to understand the current situation in Malawi leading to the development of three papers. I reviewed the elements of conceptual framework (structure, processes, and outcomes) in my study. Although a few of the conceptual framework's components need to be adjusted, I found that most elements were relevant to stillbirths and neonatal death audits in Malawi which validated my framework. The conceptual framework will need adaptations to reflect the gap between stillbirth and neonatal death audits that exist in these facilities. The stillbirth audits were rarely done in the hospitals. This need to be considered when applying the framework in the future. Further adaptations to be considered will be relating to cross cutting issues such as decentralisation, transformational leadership and power dynamics and autonomy which

affect audit implementation. Finally, mothers' and family voices are not presented in this conceptual Framework.

7.2.2 Resources available and barriers to delivering quality care for newborns

Paper one captures resources available for newborn care, which is the first objective of this thesis: to assess the resources available to support appropriate care for newborns. As shown in the conceptual framework (Figure 6), facilities where audit is conducted must be well prepared to support the initiative. As the aim of stillbirth and neonatal audit is to improve care, resources needed to provide quality of care must be available to allow implementation of audit suggested solutions. The health facility assessment presents the contextual information of the reality of implementing quality improvement initiatives in limited resource settings. These are characterised by not only shortage of staff and inadequate in-service training, but also by poor working conditions due to poor infrastructure, lack of essential drugs, supplies, laboratory tests, treatment guidelines and inadequate professional support. Despite these challenges, staff often demonstrated resilience and continued to implement neonatal death audit activities but rarely implemented stillbirth audits since they were not prioritised.

7.2.3 Quality of stillbirth and neonatal death audit

Paper two assesses the quality of audit, which is the second objective of this thesis: to assess the quality of stillbirth and neonatal death audit processes. During the study period (15 months), only two hospitals occasionally conducted the stillbirth audit, and five hospitals never did any stillbirth audit. Assessment of the quality of neonatal death audits in this limited resource setting allowed a comprehensive understanding of the situation and how they adhered to international audit standards. As indicated in the conceptual framework, the audit process involves completing the 6 WHO audit cycles, having the necessary audit tools and guidelines. Paper 2 provided information on the quality of audits through reviewing audit documents and observing audit meetings to identify gaps in the process using mixed method research and data sources. The quality of stillbirth and neonatal death audits was of low standard not only because they were implemented in poor working conditions but due to several other factors. These included a lack of national audit guidelines and reporting templates, limited data collection, recommendations not followed,

poor documentation of patient information, challenges with action plans, irregular meetings, inadequate senior representation in audit and no documentation of implemented actions and follow-up which led to inability to comply with the 6 WHO audit cycle parameters. Neonatal health outcome assessment illustrated high patient load and mortality rates, suggesting the need for more evidence-based interventions to improve care and reduce mortality.

7.2.4 Factors impacting stillbirth and neonatal death audit

Paper 3 investigated the key factors impacting audit processes at the individual, facility and national levels in response to the evidence and key issues identified through mixed-method research and data sources. This addresses objective three of thesis: to identify facilitators and barriers in implementing stillbirth and neonatal death audit. Given that most facilitators and barriers that have been identified in the literature were mainly descriptive and lacked root cause analysis, I conducted this conceptually oriented investigation to identify the root cause of barriers and facilitators regarding audit in the Malawi setting. I found that factors were interconnected and informed by each other. The identified factors were primarily related to training, staff motivation, power dynamics and autonomy, audit organisation and data support.

By combining these three papers, I have demonstrated that better understanding of the audit process requires going beyond the numbers of deaths audited and modifiable factors identified. Listening to the stories of health care workers and facility managers about their perspective on and engagement with stillbirth and neonatal death audit provided a comprehensive picture and captured the reality of what was being done on the ground; key information in considering ways to improve stillbirth and neonatal death audit in the future. These stories identified the root cause of barriers and facilitators regarding stillbirth and neonatal audits. Through staff expressions, I have found that staff could disengage from audit activities if they did not perceive that there were benefits from attending audits which lacked promotion from the facility and national level. I also found that DHMT could fail to support the initiative because of their limited autonomy where decisions are made at a higher level (national).

In the course of this study, I have developed a conceptual framework to guide staff on how the audit process can be done to be effective. Testing this framework in Malawi proved its utility and it may apply to similar settings elsewhere. Going through the conceptual framework steps in the Malawian context revealed a lack of structural support in terms of resources, leadership, guidelines and training from national and facility levels, which impacted staff abilities and motivation to engage in audit and implement their findings. This leads to reduced morale of staff who are less likely to attend audit meetings unless they offer personal benefits such as financial incentives. The audit cycle was rarely completed which made linking audit findings to care improvement challenging. This was due to inadequate support from national and facility levels, causing quality improvement teams to be inactive in all facilities and rarely linked with stillbirth and neonatal audit teams. This is likely to have impacted the provision of care and care experience and contributed to high stillbirth and neonatal death rates, although this was not directly assessed in this analysis.

7.3 General discussion

7.3.1 Resources available for newborn care and outcomes

Although audit meetings do not require many resources, the implementation of audit solutions needs resources for providing enhanced newborn care. Despite facilities operating audits with poor infrastructure, limited resources, a high burden of disease and poor health outcomes, audit linked to quality improvement initiatives can still bring benefits in this setting. According to Leatherman *et al.* (2010), quality improvement can optimise the use of limited resources and reduce financial transaction costs (Leatherman *et al.*, 2010). Furthermore, adopting quality improvement could close the gap between actual and achievable practice in service delivery. Quality improvement initiatives can enhance individual performance, satisfaction and retention, thereby strengthening the health workforce.

Further potential benefits include enhancing the development and adoption of information systems, improving the appropriate evidence base and the use of limited resources and strengthening measurements, capacity, accountability and transparency (Leatherman *et al.*, 2010). What is required is developing a culture of quality in the wider health system from top to bottom levels to create awareness and commitment which leads to ownership of QI

initiatives introduced at the facility (Raven *et al.*, 2011). Nambiar *et al.* (2017) also suggested approaches to maximise the potential of QI in LMICs. These include system thinking, participatory approaches, accountability of the health system and use of innovative evaluations that have worked in a similar setting.

Despite inadequate resources, stillbirth and neonatal death audit is one innovation that has been widely used and been effective in other LMICs, which countries should learn from. In this study in Malawi, what was lacking was staff and managers and facilities failing to embrace the culture of quality to improve care rather than hiding behind limited resources. If facility managers take an active role in QI activities, better results are generated, and identified solutions are easier to implement (Raven *et al.*, 2011). Furthermore, Leatherman *et al.* (2010) proposed embedding QI within the existing health system structure rather than as a separate programme and proposed allocating a small percentage of future growth in health spending to the assessment and continual improvement of the quality of health care.

7.3.2 Quality of stillbirth and neonatal death audit

The underperformance of stillbirth audit at hospitals reflected the stigma that communities, policymakers, and healthcare professionals still attach to stillbirths, as documented in the literature (de Bernis *et al.*, 2016). In this study, staff in maternity wards also confirmed that their priority was to do maternal audits, leaving little or no time for stillbirths. Despite evidence of their impact on families, society, health care, and the economy, stillbirths were not routinely reported or tracked and have received less national and international attention than neonatal or child or maternal deaths (Cacciatore, 2013; Heazell *et al.*, 2016; Halbesleben and Rathert, 2008; Mills *et al.*, 2021). Although a stillbirth reduction target was included in ENAP (World Health Organization, 2014), challenges still exist in LMICs.

Unlike stillbirth and neonatal deaths audit, maternal death surveillance review is a well-established platform in Malawi with clear guidelines on how to conduct maternal audits at both community and facility level and a maternal death is a notifiable event that make everyone involved in the maternal care accountable for his or her actions (Government of Malawi, 2014). Similar to this, it is culturally believed that a community will not mourn the death of a stillbirth or neonatal death (Kiguli *et al.*, 2015). There is limited chance for public

mourning or expressions of sympathy when a stillborn baby is buried; it is done privately and mostly by women (Kiguli *et al.*, 2015). Women who had antepartum stillbirths in particular expressed the desire to "cry in silence" in order to protect themselves and their families from further social stigma (Kiguli *et al.*, 2015). This highlights the need for political will at all levels to advance its agenda.

Completing the six stages of the WHO stillbirth and neonatal death audit cycle can produce a good audit outcome. In order to achieve these steps, a sound data management system is essential to produce quality data that helps to identify deaths, collect adequate information from care records, analyse the causes and modifiable factors and plan recommendations for implementation. Quality data can support facility managers in prioritising actions; however, in LMICs, data is scarce, inadequate, incomplete, and there is a large disconnect between providers on the ground and the political bodies directing funds (Stevenson *et al.*, 2021). Data helps quantify the gap, understand the context and track the records. (Stevenson *et al.*, 2021). There is a need to invest in data management, storage and usage in facilities to provide quality of care.

The other critical issue that I identified in this study was the lack of leadership and governance at both facility and national levels regarding audit implementation. Both external leadership and facility leadership can influence audit implementation at the facility level. As shown in this study, the more leaders are not involved in the activity, the more staff would shun that activity. The implementation stage is critical and needs leadership guidance for it to be successful. Strong and committed leaders and managers are key drivers, champions and agents for successful QI (Belizán *et al.*, 2011; Kaplan *et al.*, 2012; Mathole *et al.*, 2018). National level leadership should be committed to providing policy and guidelines and technical assistance to successfully implement audits at the facility level (Kerber *et al.*, 2015). Additionally, committed national leadership should be demonstrated and influence facility leadership engagement in audit processes.

Despite WHO using a rigorous process to develop and disseminate evidence-based guidelines to improve quality of care, practical guidance on implementation is lacking (Wang, Norris and Bero, 2015). A study conducted in Myanmar, Uganda, Tanzania and Ethiopia found knowledge was not a barrier to implementing WHO guidelines but this was

due to practical issues like health workforce shortage, resources, distribution and management systems (Vogel *et al.*, 2015). In a similar study, participants suggested a need for local policies to support QI, mainly when outdated policies incongruent with current evidence guidelines were in use (Vogel *et al.*, 2015). This study has shown that Malawi still struggles in implementing international recommended guidelines despite adoption at the national level.

The other step in the WHO audit cycle which was not done at all was evaluating and refining the process. Monitoring and assessment of performance helps identify gaps in implementation and also guides the implementation process (Russell, Wallace and Ketley, 2011). Assessing the current situation of the facility before embarking on a QI initiative is important as it will both generate a benchmark that could be used to evaluate its impact and identifies other challenges that need to be addressed to achieve this. Stillbirth and neonatal death audit could also be used as a method of monitoring and assessing facility performance if facility trends are analysed during audit and benchmark setting. Communicating this data could also motivate staff as they can see the direct impacts of improvements in care.

7.3.3 Factors impacting stillbirth and neonatal death audit

Staff behaviour is critical in determining the success or failure of an intervention. What the conceptual framework in Figure 6 (page 25) captures is that a health worker with adequate skills, knowledge and understanding on audit is more likely to be engaged in audit activities if undertaken in the context of supervision, strong and committed leadership, active quality improvement and audit teams, adequate resources, clear audit processes and adequate data support from facility level. If these are complemented by availability of policy and guidelines, audit tools and national supportive supervision, a health worker will be accountable for audit intervention and motivated to implement audit. He/she is then more likely to implement a high-quality audit by completing the audit cycle and linking it to QI, which would improve the provision of care and health outcomes. Despite their importance in steering complex interventions by MRC, behavioural models have been rarely applied in QI programs (Skivington *et al.*, 2021). Interventions that employ a behavioural approach to address issues affecting audit implementation while considering interconnectedness of the

factors at all levels of the system are necessary. One such behavioural model is COM-B (Michie, Atkins and West, 2014). According to Silvester, Harriman and Downes (2016), the COM-B model was perfectly developed to describe and address unfavourable behaviour, provides a simple and practical approach for healthcare professionals to address their individual and organizational limits in order to accomplish the aim of continuous improvement. The COM-B model is useful in identifying what skills and capabilities the health providers require to improve their systems, what opportunity is required for them to do this in their daily work and the motivation to do it (Silvester, Harriman and Downes, 2016; Michie, Atkins and West, 2014). Staff must be able to work in an environment that provides them with opportunities and motivation. Many QI programmes, on the other hand, focus on front-line workers while ignoring management and senior levels who have the potential to motivate and create opportunities for continual improvement to employees (Silvester, Harriman and Downes, 2016). Individual self-awareness of the need for change, as well as organisational leadership, are required for successful audit implementation.

7.4 Strengths and limitations of the study

Using mixed methods where numerical data and voices are brought together was a key methodological strength of this study as it allowed triangulation of evidence from different perspectives. Establishing a solid theoretical base for the development of the conceptual framework to guide the stillbirth and neonatal death audit process was another key methodological strength in this study and means that our findings are likely relevant to similar settings and contexts. Using different data collection methods ensured a comprehensive understanding of the audit process. Listening to stories from healthcare workers and facility managers helped to frame understanding beyond the numbers and highlighted individual experiences, opportunities and challenges.

I consider that, overall, my positionality as an “insider researcher” was beneficial in this context. Through existing relationships with the participants, it was easy to engage with facilities during audit observations, SSIs and FGDs. I also have a good background understanding of the process and the context. The participants engaged actively and helped in generating rich data.

However, there were also limitations with being an insider where participants may have provided only information that they think I wanted to hear but not their own perceptions and feelings. However, I kept reminding participants of the study's aim and my position. In addition, I kept reflective diaries that allowed me to explicitly describe my role as a researcher, as well as record and acknowledge my experiences, ideas, opinions and feelings when analysing and interpreting data.

Another limitation in this study were using purposive and convenience sampling for study participants. This could introduce sampling bias and limit generalisation. However, the study sampling for the qualitative component followed the principle of saturation with interviews and discussion continued until no new data were generated. I also use SSIs and FGDs that enabled validation of key issues. Furthermore, the assessment was only conducted in seven hospitals in the southern region of Malawi, one central hospital and six district hospitals, which could limit generalisation. I could have also interviewed external donors and officials from Ministry of Health to capture their perspectives but, due to financial constraints, this was not possible.

The methods used to assess the availability of resources was primarily from self-reports; further studies could include direct observation of care to confirm data reliability and semi-structured interviews with staff and women to understand their experience of care as reported in chapter 4.

Finally, the methods used to assess the quality of audits depended on hospital records which were often incomplete and sometimes inaccurate as reported in chapter 5. Despite this, we were able to assess the audit's quality using triangulation across various data gathering methods. Because the majority of our findings were consistent across the seven facilities, we believe the study has generated reliable information that can help programmes, implementers, policymakers, and researchers enhance the quality of newborn care and outcomes.

7.5 Challenges of the study: Impact of the COVID 19 pandemic

As COVID-19 has reached many countries and paralysed the lives of many people forced to stay at home in confinement, my studies were significantly affected. I was doing my fieldwork in February 2020, when the pandemic hit hard on different countries. The critical

activity affected was a postponement of data collection/fieldwork for five months and an extension for field stay for 11 months longer than planned. Malawi Liverpool Welcome (MLW) Trust, a clinical research programme, hosted my fieldwork in Malawi. The MLW suspended all fieldwork on 7th April 2020, when I had only collected one-third of my data. The suspension was not lifted until 17th September 2020. As a result, I extended my data collection until the end of December 2020.

Due to the nature of the study, it was not possible to terminate early the data collection that remained during the suspension period. The study had phase one and phase two components, which both needed to be completed. Another crucial component was observation of audit meetings and interviews with health care workers. However, with my supervisors, we employed different ways of mitigating the impact; one of the ways was to change from face to face to phone/online interviews. The drawback was sending notification to the country Ethics committee for approval, which delayed and added extra cost to the project. After lifting the restrictions, I could resume fieldwork after a five-month break and finish in December 2020 and later than initially planned (August 2020). However, the five-month fieldwork break allowed me to complete other project activities like publishing a systematic review, data entry of the data collected to date and drafting other thesis chapters (Introduction, Background and Methodology chapters).

7.6 Recommendations and implications for stillbirth and neonatal death audit practice and policy in Malawi

Based on the findings of this study, I have produced recommendations to be provided to the relevant teams in the participating hospitals, external partners supporting participating hospitals and the Ministry of Health's quality improvement technical group so that they are aware of the concerns and how best to address them. Recommendations that require changes at policy or national level were categorised as National level services. Those related to facility level and nurses and clinicians were categorised under staff level. The following recommendations are suggested:

7.6.1 For national or regional level services

1. Improve hospital distribution of stillbirth and newborn death audit guidelines for facility and staff use.
2. Audit data collection and reporting templates to include all WHO death audit cycle parameters.
3. With the high numbers of stillbirths and neonatal deaths occurring in this setting, reduce the parameters collected on death audit forms to those that are most critical in informing improved health care.
4. Ensure that stillbirth and neonatal deaths are notifiable by national policy and enact a national mandate for stillbirth and neonatal death audits.
5. Decentralize decision making fully to give district staff the authority to decide on staff recruitment, training, procurement of drugs and equipment
6. Develop a clear structure for supportive supervision, reporting and feedback regarding audit implementation at all facilities.
7. Integrate audit in routine practice, whereby staff view audit as part of their job description and daily work.
8. Make audit activities mandatory for CPD for both nurses and clinicians and work together with training institutions and regulatory bodies to include audit in the pre-service curriculum.
9. Establish an electronic database at all facilities connected to the national level through HMIS for consolidating audit information, using its data for decision-making and feedback to facilities.
10. Implement criteria-based auditing, in which staff are given a set of standards to follow during the delivery of care and are audited against them to see how well they are complying to the standards.

7.6.2 For facility-level services

1. Ensure that stillbirth and neonatal death audits complete the WHO death audit cycle and that implementers are trained on audit steps. This can be accomplished by ensuring that all 6 WHO death audit cycle factors are represented in audit data collection forms and reporting templates.

2. Disseminate and apply the conceptual framework developed and evaluated in this study to guide steps in audit that could lead to improved care.
3. Consider providing a non-monetary incentive to staff engaged in audits to motivate them, such as recognition awards, acknowledging best staff or staff efforts in providing quality newborn care, leadership involvement in audit, implementing suggested solutions and using principles of transformational leadership.
4. Promote the use of audit solutions in conjunction with ward or facility-level quality improvement efforts. This can be accomplished by establishing an active quality improvement team at the facility level and an active work improvement team at the ward level, and these team members should attend audit meetings or be presented with audit results.
5. Review facility trends on mortality during audit meetings and use the data to make decisions. This can be performed by designating a team to compile newborn outcomes before audit meetings and present them during the meeting.
6. Document and share audit implementation success stories to motivate staff. This can be accomplished by keeping a record of what solutions were proposed, how they were implemented, and what improvements in care were noted and shared among the staff on quarterly basis.
7. Managers must show interest and participate in audit by ensuring that at least one DHMT member is present during audit sessions and respond in a timely fashion to actions assigned to them.
8. Provide newborn care protocols to labour and birth, postnatal and nursery wards and monitor their implementation at the quarterly DHMT and during MoH supporting supervision.
9. Ensure that enough supplies, medications, equipment and other resources are available to support optimal newborn care by conducting periodic supply requirements assessments prior to each monthly drug meeting.
10. Review and analyse the system as a whole when generating modifiable factors for preventable deaths by scrutinizing all points of patient contact with care, not merely the department where the death occurred.

7.6.3 For staff-level services

1. Establish in-house training of staff in conducting stillbirth and neonatal audits in addition to any external training that may be available.
2. Address modifiable factors affecting health workers by ensuring that they have the appropriate knowledge and skills while providing care and that senior employees supervise and mentor junior personnel.

7.7 Implications for future research

Few studies have reported the outcome of stillbirths and neonatal death audit on outcomes of care (Pattinson *et al.*, 2009; Kirabira *et al.*, 2020). We suggest that a multi-country study is needed to evaluate the effectiveness of audit on stillbirth rates and neonatal mortality. This could be a step-wedge design progressively assessing the impact of a programme supporting high-quality audit as it is rolled-out across facilities. Future studies could also test the conceptual framework developed and evaluated in this study (Figure 6) to explore its utility at the multicounty level.

Regarding recommendations on formulating a simple audit form, it should be tested in practice. While a paper-based system is less costly, it may result in loss of information, be difficult to aggregate or share data and requires time to manage (Kerber *et al.*, 2015). Although strategies to minimise paperwork such as cell phone-based audit and cloud storage systems have been piloted in LMICs, scale-up remains a challenge (Haskew *et al.*, 2015; Jagau, 2013). Future studies to explore scaling up such strategies are needed.

Based on factors identified in this study, it is clear that improving the audit process requires a behaviour change approach (Michie, Atkins and West, 2014). To date, there has been relatively little inclusion of behaviour change theory in QI initiatives. Future improvements will benefit from the inclusion of behaviour theories such as the application of the behaviour wheel and COM-B models (Michie, Atkins and West, 2014).

7.8 Conclusions

The results presented in this thesis contribute to the knowledge base of facility-based stillbirth and neonatal death audit in Malawi. The findings provide valuable up-to-date

information about resource availability and outcomes of newborns, quality of audits and factors that impact audit quality. These findings are of direct relevance to Malawi and likely to similar low-resource settings. Evaluating quality, facilitators and barriers of stillbirth and neonatal death audits is critical for ensuring that audits conducted in Malawi and similar settings maximise their impact on improving care.

In order to better support the stillbirth and neonatal death audit in resource-limited contexts like Malawi, I have argued that it is crucial to have adequate human and material resources to lead to better newborn care. But, in many LMICs, access to these resources is challenging due to facility and national level factors within the health system. That is why I have shown that good managerial and clinical leadership from national and facility-levels improves performance by guiding and creating an environment for support. Supportive supervision with the provision of resources improves health care, worker job satisfaction, motivation and performance. Good management of limited resources will also benefit the system.

I have also argued that stillbirth and neonatal death audit conducted in facilities should aim at improving practice rather than just serving as a data collection exercise. This could be done through implementing suggested actions and having time to evaluate the process. This has the potential to improve clinical outcomes and eventually reduce mortality. But this will only be possible if facility and national leadership offer full support to staff implementing this initiative in facilities.

I have shown that the factors that affect the implementation of stillbirth and neonatal death audits are at all system levels and are interconnected. Addressing challenges at only one level is unlikely to be adequate but a comprehensive approach informed by behavioural theory that addresses factors at all system levels, recognising the relationships between levels, is more likely to be successful. I have also provided and evaluated the application of a conceptual framework to guide implementers and policymakers to understand and optimise contextual factors affecting the success of stillbirth and neonatal audits.

Furthermore, given that there is little evidence outlining the process of implementing change or documenting the effect of death audit on newborn care, it is generally unclear

whether the data obtained is linked to enhanced perinatal and neonatal health. This research has provided a knowledge base on the barriers that prevent facilities from linking audit to care improvement. The study has also provided a conceptual framework to assist facility staff and managers as well as senior executives at the national level in facilitating the linkage that will likely lead to improvement in newborn care and outcomes.

In conclusion, I have undertaken a comprehensive study that utilised an evidence-based conceptual framework and triangulated quantitative and qualitative data to provide rich insights into the current conduct of stillbirth and neonatal death audits in the southern region of Malawi. The findings are of direct relevance to a range of stakeholders in Malawi and similar low resource settings aiming to maximise the impact of mortality audits on improving outcomes for highly vulnerable women and newborns.

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APPENDICES

Appendix 1: Standards of care and quality statements

Standard	Scope	Number of quality statements	
		Maternal and newborn Health	**small and sick newborn**
1	Evidence base practice	9	42
2	Actionable information system	2	3
3	Functional referral system	3	6
4	Effective communication and family participation	2	6
5	Respective women and newborn care	3	6
6	Emotional, Psychological and Developmental support	2	5
7	Competent, motivated, empathetic multidisciplinary human resources	4	4
8	Essential physical resources for small and sick newborns	6	6
	Total	**31**	**78**

Appendix 2: Search Terms and Boolean Operators Used in Final Searches of MEDLINE, CINAHL Complete, Academic Search Index, Science Citation Index, Complementary index, and Global health

1. "stillb*"
2. "neonat*"
3. "perinatal death"
4. "neonatal death"
5. audit OR review
6. These search terms were then combined to give a final search of 1 OR 2 OR 3 OR 4 AND 5, which was used to search abstracts in these databases.

Appendix 3: Questions used to assess quality of studies included by Hawker et al., 2002

Scoring Criteria
Good=4, Fair=3, Poor=2, Very poor=1
Lower scores =poor quality
Notes for appraising the quality of each paper
1. Abstract and title:

Did they provide a clear description of the study?

Good: Structured abstract with full information and clear title.

Fair: Abstract with most of the information.

Poor: Inadequate abstract.

Very Poor: No abstract.

2. Introduction and aims:

Was there a good background and clear statement of the aims of the research?

Good: Full but concise background to discussion/study containing up-to-date literature review and highlighting gaps in knowledge. A clear statement of aim AND objectives, including research questions.

Fair: Some background and literature review. Research questions outlined.

Poor: Some background but no aim/objectives/questions, OR aims/objectives but

Inadequate background.

Very Poor: No mention of aims/objectives. No background or literature review.

3. Method and data:

Is the method appropriate and clearly explained?

Good: Method is appropriate and described clearly (e.g., questionnaires included). Clear details of the data collection and recording.

Fair: Method appropriate, description could be better. Data described.

Poor: Questionable whether method is appropriate. Method described inadequately. Little description of data.

Very Poor: No mention of method, AND/OR Method inappropriate, AND/OR No details of data.

4. Sampling:

Was the sampling strategy appropriate to address the aims?

Good: Details (age/gender/race/context) of who was studied and how they were recruited. Why this group was targeted. The sample size was justified for the study. Response rates shown and explained.

Fair: Sample size justified. Most information given, but some missing.

Poor: Sampling mentioned but few descriptive details.
Very Poor: No details of sample.

5. Data analysis:

Was the description of the data analysis sufficiently rigorous?

Good: Clear description of how analysis was done. Qualitative studies: Description of how themes derived/ respondent validation or triangulation. Quantitative studies: Reasons for tests selected hypothesis driven/ numbers add up/statistical significance discussed.

Fair: Qualitative: Descriptive discussion of analysis. Quantitative.

Poor: Minimal details about analysis.

Very Poor: No discussion of analysis.

6. Ethics and bias:

Have ethical issues been addressed, and what has necessary ethical approval gained? Has the relationship between researchers and participants been adequately considered?

Good: Ethics: Where necessary issues of confidentiality, sensitivity, and consent were addressed. Bias: Researcher was reflexive and/or aware of own bias.

Fair: Lip service was paid to above (i.e., these issues were acknowledged).

Poor: Brief mention of issues.

Very Poor: No mention of issues.

7. Results:

Is there a clear statement of the findings?

Good: Findings explicit, easy to understand, and in logical progression. Tables, if present, are explained in text. Results relate directly to aims. Sufficient data are presented to support findings.

Fair: Findings mentioned but more explanation could be given. Data presented relate directly to results.

Poor: Findings presented haphazardly, not explained, and do not progress logically from results.

Very Poor: Findings not mentioned or do not relate to aims.

8. Transferability or generalizability:

Are the findings of this study transferable (generalizable) to a wider population?

Good: Context and setting of the study is described sufficiently to allow comparison with other contexts and settings, plus high score in Question 4 (sampling).
Fair: Some context and setting described, but more needed to replicate or compare the study with others, PLUS fair score or higher in Question 4.

Poor: Minimal description of context/setting.

Very Poor: No description of context/setting.

9. Implications and usefulness:

How important are these findings to policy and practice?

Good: Contributes something new and/or different in terms of understanding/insight or perspective. Suggests ideas for further research. Suggests implications for policy and/or practice.

Fair: Two of the above (state what is missing in comments).

Poor: Only one of the above.

Very Poor: None of the above.

Appendix 4: Findings of the included studies

Authors and year	Number of cases audited	Interviews	Duration	Summary of findings	Quality score
Demise et al,2015	61 (30 stillbirths and 31 early neonatal deaths	No	6 months	• Avoidable factors in 70% of perinatal deaths • Health worker-related factors most common (84% • Patient-related factors (11%) • Administrative-related factors (5%)	31
Agaro et al, 2016	253 perinatal deaths	66 staff and 10 Key Informant interview	3 months	• Low participation of health workers in MPDR • Facilitators for MPDR -Existence of MPDR committees -Attendance of review meetings -Knowledge of MPDR objectives -Implementation of MPDR recommendations -Observed improvement in neonatal care -Provision of feedback • Barriers for MPDR -Health workers not aware of the MPDR process -Inadequate training of MPDR committee members -Inadequate support supervision -Lack of financial motivation to committee members. -Heavy workload to health workers -High number of perinatal deaths - Non-implementation of recommendations.	32

MPDR= Maternal Perinatal Death Review

Biswas et al,2015)	_	35 IDIs with facility staff and 1 FGD (5 doctors and 6 nurses)	11 months	• Senior staff nurses championed the facility death reviews • Doctors supported senior nurses. • Improved quality of care at facilities as a result of facility death audits	30
Stridulate et al, 2014	257 perinatal deaths	No	48 months	• Perinatal death audit improved maternity and newborn care • Reduced perinatal deaths at term by 1.5 per 1000; from 5.1 per 1000 in 2006 to 3.6 per 1000 in 2013 • Key activities included; -Trainings in audit -Setting up of audit committees -Implementation of the review of cases -Dissemination of information	23
Armstrong et al,2014	_	37 informants' interviews (IDIs) involved in MPDR	1 month	• Hospital reviews fail to identify appropriate challenges and solutions at the facility level. • Staff committed to the process of maternal death review, but action and response are insufficient	27
Nakibuuka et al, 2012	120 perinatal deaths (41 MSB, 38 FSB, 41 END)	No	9 months	• Avoidable factors included: -Poor neonatal resuscitation skills -Incorrect use of the partographs -Delay in performing caesarean sections • Activities implemented included: -Training on neonatal resuscitation -Introduction of CPAP for babies with respiratory distress -Staff updated on use of partographs	28

				• Perinatal mortality rate reduced by 0.9 per 1000 after introduction of the audits	
Nyamtema et al, 2010	_	29 IDIs and 30 semi-structured questionnaires with staff involved the audit	1month	• Maternal and perinatal audit systems poorly established in structure and process • Less effective to improve the quality of care • Key decision-makers did not take part in audit committees • Most care providers (60%) not aware of any action implemented as result of audit	29
Sandakabatu et al,2018	66 (48 neonatal deaths and 18 deaths older children)	No	6 months	• Proper use of systematic classification of causes of death • Included social risk factors and community problems in the modifiable factors • Followed-up implementation of action plans • Areas for improvement; -Communication -Clinical assessment and treatment -Availability of laboratory tests -Antenatal clinic attendance -Equipment for high dependency neonatal /paediatric care.	29
Kidanto et	133 deaths (MSB-18, FSB-78 and END-37)	No	5	• Suboptimal factors were identified in 80% of • Half of suboptimal factors caused adverse perinatal outcome and were preventable • Poor fetal heart monitoring during labour was indirectly associated with over 40% of perinatal death.	28

MSB=Macerated stillbirth, FSB=Fresh stillbirth, END=Early Neonatal death, CPAP=Continuous Positive Airway Pressure, IDIs In-depth Interviews

				• There was a poor to fair agreement between external and internal auditors	
Kasengele et al, 2017	146 (115, initial and 31 re-audit FSB)	No	3months	• Only 36 (33.3%) labouring women in the initial audit and 20 (65%) in the re-audit managed using a partograph • Obstructed labour was the main cause of intrapartum stillbirths • Antepartum haemorrhage caused 27 (23.5%) stillbirths in the baseline audit and 5 (16.1%) in the re-audit • Suboptimal care was observed in the initial audit but none in subsequent audit	28

MSB=Macerated stillbirth, FSB=Fresh stillbirth, END=Early Neonatal death

Appendix 5: Summary of studies included in the review

Author/ Year	Country	Hospital type/number	Methodology	Who performed audit	Audit meeting frequency	Who developed recommen dations	Who implemented recommend-ations	Type of death audited	Selection criteria
Demise et al.,2015	Ethiopia	1 National referral hospital	A prospective audit	Facility staff	monthly	Facility staff	NICU staff and Labour ward staff	Stillbirths and early neonatal deaths	All stillbirths and early neonatal deaths during the study period
Agaro et al., 2016	Uganda	1 district hospital, 1 Health Centre level IV, 5 Health Centre Level III	A cross-sectional mixed method study- a retrospective review of audited information	_	_	_	_	Stillbirths and early neonatal deaths	_
Biswas et al., 2015	Banglades h	2 District hospitals, 12 Sub-district facilities, 2 maternal and child welfare centres	Qualitative study-In-depth interviews, Focus group interviews and document review	_	_	_	_	Maternal, Neonatal deaths and stillbirths' audits	_

Author/ Year	Country	Hospital type/number	Methodology	Who performed audit	Audit meeting frequency	Who developed recommen dations	Who implemented recommend-ations	Type of death audited	Selection criteria
Stratulat et al., 2014	Moldova	Moldova country	Confidential Inquiry into perinatal deaths prospectively-project implementatio n	External panel	Monthly	External panel	Facility staff	Perinatal deaths (stillbirths and early neonatal deaths)	Reported stillbirths and neonatal deaths to national level
Armstrong et al., 2014	Tanzania	1 regional hospital,1 district hospitals and 1 faith-based hospital	Reviewed the national MPDR guidelines and conducted a qualitative study with key informants using semi structured interviews	_	_	_	_	Maternal and perinatal deaths audits	_
Nakibuuka et al., 2012	Uganda	1 Private not for profit hospital	Retrospective descriptive study - prospective audit	Hospital staff	Weekly	Hospital staff	Hospital staff	Perinatal deaths (stillbirths (FSB/MSB) and ENND)	All stillbirths and early neonatal deaths during the study period

Author/ Year	Country	Hospital type/number	Methodology	Who performed audit	Audit meeting frequency	Who developed recommen dations	Who implemented recommend-ations	Type of death audited	Selection criteria
Nyamtema et al., 2010	Tanzania	4 public hospitals (1 national hospital, 3 municipal hospitals) and 4 private hospitals	A cross-sectional mixed-method study	_	_	_	_	Maternal and perinatal deaths audits	_
Sandakabatu et al., 2018	Solomon Islands	1 national referral hospital (tertiary)	Reviewing Child death auditing process through systematic observations-prospective audit	Paediatric team monthly combined with the obstetric team	Weekly	Paediatric team and monthly combined with the obstetric team	Facility staff (doctors and nurses)	Child deaths (neonatal deaths and deaths on older children)	All neonatal and child deaths occurred during the study period
Kidanto et al., 2009	Tanzania	1 National Referral Hospital	Prospective death audit	3 auditors obstetrician (2 external and 1 internal auditors)	-	3 auditors obstetrician (2 external and 1 internal auditors)	Nurse and doctors from the labour ward and neonatal unit	Stillbirths, FSB/MSB and Early neonatal deaths	All perinatal deaths ≥1500g occurred during the study period

Dash (-) = Not reported, FSB= Fresh stillbirth, MSB= Macerated stillbirth

Author/ Year	Country	Hospital type/number	Methodology	Who performed audit	Audit meeting frequency	Who developed recommen dations	Who implemented recommend-ations	Type of death audited	Selection criteria
Kasengele et al., 2017	Zambia	1 District Hospital	Retrospective death audit	Clinical audit team members from the hospital	Weekly	Clinical audit team members from the hospital	Facility staff	FSB	FSB with fetal heart present, Apgar score of 0

Dash (-) = Not reported, FSB= Fresh stillbirth, MSB= Macerated stillbirth

Appendix 6: Summary of approaches

Author/year	Approach/Innovation	Type of intervention	Level of implementation		
			Macro Level	Meso Level	Micro Level
Demise et al, 2015	Review by hospital multidisciplinary audit team using a standardized data collection form	Prospective audit		Audit review meetings Implementing changes	
Stratulat et al, 2014	Confidential inquiry panel -External multidisciplinary panel	Prospective audit	National stakeholders developing methodology, standards, training tools, approval, endorsement of implementation and facilitate dissemination	Implementing changes; Implementing audit reviews at an institutional level using national confidential inquiry guidelines	Participated in audit sessions
Nakibuuka et al, 2012	Multidisciplinary team audit	Prospective audit	Ministry of Health developed perinatal death audit tools and guidelines	Adopted guidelines from MoH; Weekly audit meetings lead by senior obstetrician or paediatrician, trained medical officers, nurses and midwives on perinatal death audits	Participated in perinatal death audit, attending training on perinatal death audits

Dash (-) =Not reported

Author/year	Approach/Innovation	Type of intervention	Level of implementation		
			Macro Level	Meso Level	Micro Level
Sandakabatu et al., 2018	Multidisciplinary team audit	Prospective audit	_	Weekly audit meetings lead by senior paediatrician and monthly combined obstetric and paediatric team audit	_
Kidanto et al, 2009	Using external and internal auditors obstetrician (2 external and 1 internal auditors)	Prospective audit	Audits by international external auditors	Internal auditor from hospital, hospital nurses and doctors participated in protocol preparation and implementing changes. Training on audit	Participating in training
Kasengele et al, 2017	Obstetric team audit and external researchers	Retrospective (initial and re-audit)	External researchers	Clinical audit team members participated in the research: Hospital staff implementing changes	_

Dash (-) =Not reported, MoH=Ministry of

Appendix 7: Facility Assessment Checklist (Adapted from Colbourn, Nambiar and Costello, 2013)

HEALTH FACILITY SURVEY

Health facility name _____ Date_____

HUMAN RESOURCE

Labour ward (LW)	Total available	At least one available during day			Atleast one available during night		
		Always	Sometimes	Never	Always	Sometimes	Never
Medical officers							
Registered nurse/midwives							
Clinical officer							
Nurse/midwife techinicians							
Support staff							
Postnatal ward (PNW)	Total available	At least one available during day			Atleast one available during night		
		Always	Sometimes	Never	Always	Sometimes	Never
Medical officers							
Registered nurse/midwives							
Clinical officer							
Nurse/midwife techinicians							
Support staff							
Neonatal ward (NW)	Total available	At least one available during day			Atleast one available during night		
		Always	Sometimes	Never	Always	Sometimes	Never
Medical officers							
Registered nurse/midwives							
Clinical officer							
Nurse/midwife techinicians							
Support staff							

CLINICAL STAFF ATTENDED TRAINING IN PREVIOUS 12 MONTHS

	Number of participants from wards		
	LW	PN	NW
Integrated maternal and neonatal care in Malawi			
Helping Babies Breath (HBB)			
Care of the infant and newborn in Malawi (COIN)			
Perinatal and neonatal death audit			

INFRASTRACTURE

	Availability		
Electricity	Always	Sometimes	Never
Mains			
Solar			
Generator			
Water supply			

TRANSPORT

	Number		Availability				
	Total available	Total fuctional	Always	Sometimes	Never		
Ambulance							

COMMUNICATION

	Available(Y/N)	Availability					
		Always	Sometimes	Never			
Radio							
Telephone							
facility mobile phone							
Referral form							

ESSENTIAL SUPPLIES									
Availability	**Labour Ward**			**Postnatal ward**			**Neonatal ward**		
	Always	Sometimes	Never	Always	Sometimes	Never	Always	Sometimes	Never
Intravenous cannula									
Intravenous fluids									
Giving sets									
Sterile blade to cut cord									
Cord clamp									
NGT tubes									
Heaters									
Nasal prongs/catheters and masks									
Guedel airway									
Glucometer									
Glucometer test stripes									
Thermometers									
BP apparatus									
Foetal scope									
weiging scale									
urine dipstics									
ESSENTIAL DRUGS									
50% dextrose									
Diazepam									
Phenorbabitone									
Magnesium Sulphate									
Benzylpenicillin (first line)									
Gentamycin (first line)									
Ceftriaxone (second line									
Oxytocin									
Dexamethasone									
Vitamin K									
Metronidazole									
Intravenous Artesunate									
RESUSCITATION EQUIPMENT									
Bag and Mask									
Resuscitaire									
Suction machine									
Oxygen concentrator/cyrinder									
CPAP									
Phototherapy									
LABORATORY									
FBC									
Birirubin									
Blood Sugar									
Grouping and cross match									
CSF									
HB/PCV									
Arterial blood gases									
Urinalysis									
Blood culture									

TREATMENT GUIDELINES PASTED ON THE WALL				**GOVERNANCE/LEADERSHIP**		
	Availabily (tick YES/NO)			Availability yes/no	LW	PN/NW
	LW	PNW	NW	Quality Improvement (QI)team		
Neonatal resuscitation				QI team meet regularly (Quaterly)		
Infection prevention				Feedback mechannism in place		
Care of small and preterm babies				Facility performance dash board		
Care of sick neonate				Staff appraisal every year done		
Essential newborn care				Supervised by nataional level in last 3 months		
Management of complication of labour				Supervised by DHMT in last 3 months		
				Martenal/perinatal/neonatal death review team		
				Martenal/perinatal/neonatal death review team		
SERVICES				Mechanism in place to implement change		
	Availability (Yes/No)	**Number of beds**				
24 hours services for MNH		Labour ward				
Waiting area for mothers		Postnatal ward				
Partograph form available		neonatal ward				
Partograph form used		neonatal ward				
Critical care pathway(CCP) form available for neonates						
CCP form used						
Labour ward register						
Postnatal register						
Neonatal register						
KMC register						

Appendix 8: Surveillance data checklist (parameters adapted from WHO, 2016)

Fill one for each hospital every month

Date: _____ Name of facility: _____

Month_____

No	Parameter	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul
1	Total deliveries												
2	Total live births												
3	Antepartum stillbirths (macerated SB)												
4	Intrapartum stillbirths (fresh SB)												
5	Total stillbirths (3+4)												
6	Early neonatal deaths (1-7 days)												
7	Late neonatal deaths (8-28 days)												
8	Total neonatal deaths (6+7)												
9	Perinatal death (5+6)												
11	Preterm births (<28 weeks gestation)												
12	Preterm deaths												
13	Low birth weight births (<2500g)												

14	Low birth weight deaths												
15	Asphyxia cases												
16	Asphyxia deaths												
17	Neonatal sepsis cases												
18	Neonatal sepsis deaths												
19	Pneumonia cases												
20	Pneumonia deaths												
21	Respiratory Distress Syndrome (RDS) cases												
22	RDS deaths												
23	Congenital malformation cases												
24	Congenital malformation deaths												
25	Total admission for neonatal cases												
26	Change in modifiable factors												
27	Number of action plans planned												
28	Total action plans implemented												

Appendix 9: Newborn-perinatal death audit form used in Malawi

Note: The information in the highlighted space will be redacted before photocopying the form

NEWBORN PERINATAL DEATH AUDIT FORM

A copy of this form should be sent to the Ministry of Health
.
Date of Audit……

1. SECTION ONE: Identification

1.1 Mother's registration number: ……

1.1.2 New born's registration number……..

1.2 Name of the Health Facility: ……..

1.3 Type of Health Facility (tick)
(i) Health centre
(ii) Community hospital
(iii) District hospital
(iv) CHAM hospital
(v) Tertiary hospital
(vi) TBA
(vi) Others (specify)……

1.4 District……..

1.5 Mother's initials ……1.5.2 Age: ..... (yrs) 1.5.3 Address:……..

1.6 Was the baby referred?
(i) Yes
(ii) No
1.7 If Yes; from?
(i) Health centre
(ii) Community hospital
(iii) District hospital
(iv) CHAM hospital
(vi) TBA
(vi) Others (specify)……

1.8 If referred from health facility, name of the facility ……

2. SECTION TWO: Pregnancy progress and Care

2.1 Mother's Parity …….

2.1.2 No. of mother's living children

2.2 Type of pregnancy
(i) Singleton

(ii) Twin

2.3 Attendance of Antenatal care:
(i) Yes
(ii) No

2.4 If yes how many times……

2.5 Core ANC Interventions (tick appropriately)

2.5.1 Malaria prophylaxis:
(i) IPT1
(ii) IPT2
(iii) IPT3

2.5.2 Tetanus Toxoid:
(i) TTV 1
(ii) TTV 2 (iii)TTV 3

2.5.3 HIV test done
(i) Yes
(iii) No

2.5.4 HIV test results
(i) negative
(ii) positive

2.5.5 If HIV positive:
(i) On ARVs
(ii) Not on ARVs

2.5.6 Syphilis test done;
(i) Yes
(ii) No

2.5.7 Syphilis test results
(i) Negative
(ii) Positive

2.6 Conditions in present pregnancy (tick all applicable)

(i) Antepartum Haemorrhage (ii)Hypertension
(iii) Pre-labour rupture of membranes
(iv) Diabetes
(v) Anaemia
(vi) UTI
(vii) Malaria
(viii) Trauma-accidental
(ix) Trauma –gender based violence
(x) Multiple pregnancy
(xi) Others specify……

N.B. If multiple pregnancy, indicate birth order of the newborn . Fill separate form for each perinatal death.

3. SECTION THREE: Labour and Birth

3.1 Gestation at delivery ..... 3.1.2 Date of delivery …….

3.2 Place of delivery
(i) Health facility
(ii) Home (iii)TBA

3.2.1 If health facility specify name ……..

3.3 On admission, were there fetal sounds present?
(i) Yes
(ii) No
(iii) Not assessed

3.4 Was partograph used? (i)Yes
(i) No
(ii) Unknown
If 'Yes' was partograph used correctly?
(i) Yes
(ii) No, mention error……

3.5 Mode of Delivery:
(i) Normal Delivery
(ii) Caesarean Section
(iii) Vacuum or Forceps
(iv) Breech
(V) Others specify: .....

3.5.2 Indication for Instrumental /or Caesarean section:
……

3.6 Time between decisions for Cesarean section /instrumental and actual delivery of the baby:

(i) Less than 30 minutes
(ii) 30 minutes - 1 hour
(iii) Greater than 1 hour

3.6.1 Did vaginal delivery occur in spite of decision to do caesarean section?

(i) Yes
(ii) No

3.7 Condition of the Baby

3.7.1 Apgar score at 1 min ……..At 5min Don't know

3.7.2 Resuscitation done:

(i) Yes
(ii) No

3.7.3 Weight of the baby: gms……..

3.7.4 Sex:

(i) Male
(ii) Female

3.8 Type of Perinatal Death

(i) Fresh Still Birth
(ii) Macerated still Birth
(iii) Neonatal Death

3.8.1 If neonatal death, reason for admission/ diagnosis at admission (Tick all applicable)

(i) Difficult feeding
(ii) Bleeding
(iii) Jaundice
(iv) Anaemia
(v) Difficult breathing
(vi) Hypoglycaemia
(vii) Septicaemia
(ix) Hypothermia
(x) Other conditions specify: ……

3.9 Probable cause of death: Tick all applicable

(i) Tetanus
(ii) Septicaemia
(iii) Birth trauma
(iv) Birth Asphyxia
(v) Prematurity complications specify…….
(vi) Congenital Anomalies
(vii) Other- specify……
……
……

Premature: Born after 28 weeks but before 37 weeks of gestation

3.10 Avoidable factors/missed opportunities/substandard care. Which of the following factors were present (tick all appropriate)

(i) Delay to seeking health care
(ii) Delay to reach the health facility
(iii) Delay to provide care
(iv) Absence of critical human resources
(v) Lack of resuscitation equipment
(vi) Lack of supplies and drugs including blood
(vii) Poor monitoring and inadequate management plan
(viii) Inappropriate intervention
(ix) Poor documentation
(x) poor quality antenatal care
(x) Others specify…….

Comments on avoidable factors and missed opportunities:
……
……
Actions taken to address the avoidable problems
……
……

CONFIRMATION OF DETAILS

The form was completed by: Name: …… Tel: ……

Email: ……. Date: ……..;……Signature: ……

Appendix 10: Neonatal death audit form

District:_____ Hospital name_____ Birth Notification No. :_____

Confidential

Baby's name:		Residential address:	
Date of birth_____/_____/_____	Sex M / F	Birth wt_____grams	Wt on admission:_____grams
Place of birth: This facility / Other facility / Home / in-transit			
Date of admission_____/_____/_____	Time of admission:_____	Admission diagnosis_____ Outcome diagnosis_____	
Date of death_____/_____/_____	Time of death_____	When death occurred: Week day/ Public holiday/Week end, during day, at night	Dead on arrival /Brought in dead: Y/ N
Hours at death from admission	1. Less than 24 hours	2. more than 24hrs	
Type of death	Early neonatal death (<7 days of age)	Late Neonatal death (>7 days of age)	

Records

1. CCP used Y / N	2. Complete: Y / N	3. Admission Sheet Complete: Y / N	4. Feeding Chart Comment:	5. Other _____

Referred (Yes or No) if no, Go to next Section

Referred from:	Hospital / HC / Other HF:_____ Date:___/___/___ Time : _____	
Reason for referral: _____		
Pre-referral treatment given:_____ _____Time_____		Mode of transport: _____ Time of Arrival :_____

Antenatal care History

Mother's parity:_____ Mother's age :_____	**Type of pregnancy**	1. Singleton	2. Multiple	Did mother attend ANC? Yes/ No / Unknown
Tetanus toxoid: TTV1 / TTV2 / TTV3 / none / Unknown				
HIV test? **Y / N**	If yes when?:_____ Result: **NR / R**	If Reactive; Mother on HAART? **Y / N**	Baby given NVP **Y / N/ NA**	4. Unknown
VDRL done: **Y / N/ U**		If yes, when?_____ & result **treated:____**		**NR / R if R when was the mother**
Mother's problem during pregnancy	1.		2.	
	3.		4.	

Labour & delivery

Mode of delivery:	SVD		
	Breech		
	Caesarian Section	Why: _____	
	Forceps		
	Vacuum extraction		
Apgar Scores:	1 min:_____**/ 10**	5 min: _____**/ 10**	10 min:_____**/ 10**

Resuscitation measures: **(please circle)**	Stimulation/ Suctioning / Bag-Valve-Mask ventilation / Oxygen / CPR/ Iv fluids If BMV, how long? _____ minutes

Name officer filling the form:.....**TEL** .....**SIGNATURE**.....

Care offered in the nursery

Danger Signs on admission:_____	Triage: **E / P**	Initial Emergency Treatment given: Y / N / NA
Lowest Temperature_____ Highest Temperature_____	Lowest Blood sugar_____ Highest Sugar_____	Lowest Saturation:_____ Highest Saturation:_____
Lab investigations done Y/N/NA	If yes specify_____	
In your opinion, was the diagnosis correct? Y / N		
Was the treatment correct Y / N : Explain_____ _____ _____		
How often was the child's condition monitored? _____ by clinician _____ by nurses		

Cause of Death (insert cause of death and working diagnosis at death)

IMMEDIATE CAUSE (a)	Due to (b)	Due to (c)	Due to (d)

Modifiable Factors)

	Factor	Comment
1		
2		
3		
4		

In your opinion, had the process of caring been different, would this death have been avoidable?

1. Yes	2. Not sure	3. No

Action plan

Modifiable factor	**Proposed solution**	**By Whom**	**By when**
1.			
2.			
3.			

Name of team leader:.....**Phone** .....**Signature**.....

Appendix 11: Assessment criteria for quality of action plan and audit form

Section A: Description of Criteria for reviewing the quality of action plan for proposed solutions for modifiable factors (adapted from Kimambo, 2008)

Item	Grade	Criteria	Description
The score for an action plan			
	1	Unsatisfactory	No documentation, incorrect or inappropriate responses or key points missing
	2	Good	Correct, appropriate but incomplete responses
	3	Very good	Correct, appropriate and complete
Overall score total (5 parameters assessed)	15		
	≤7.5	Unsatisfactory	
	8-11	Good	
	12-15	Very good	

Section B: Grading action plan tool. Graded parameters adapted from (WHO,2016). Fill one form for each action plan after 2 independent scores have been discussed and if unresolved a third reviewer will be involved

No	Questions and filters	Coding Categories	Skip to
QAP 101	Date of audit?	Date |__|__| |__|__| |__|__||__|__| Unknown 99	
QAP 102	Month of audit?	August 1 September 2 October 3 November 4 December 5 January 6 February 7 March 8	

		April 9 May 10 June 11 July 12	
QAP 103	Initial of the baby on audit form reviewed for action plan?	Initial |__|__|	
QAP 104	Facility name?	Zomba Central Hospital 1 Thyolo District Hospital 2 Chiradzulu District Hospital 3 Chikwawa District Hospital 4 Machinga District Hospital 5 Mwanza District Hospital 6 Mulanje District Hospital 7	
QAP 105	Modifiable factor identified?	Unsatisfactory 1 Good 2 Very good 3 Unknown 99	
QAP 106	Specific action to address modifiable factor?	Unsatisfactory 1 Good 2 Very good 3 Unknown 99	
QAP 107	Responsible person assigned?	Unsatisfactory 1 Good 2 Very good 3 Unknown 99	
QAP 108	Feasibility of accomplishing the task within the planned timeframe?	Unsatisfactory 1 Good 2 Very good 3 Unknown 99	
QAP 109	Action taken and outcome (follow-up)?	Unsatisfactory 1 Good 2 Very good 3 Unknown 99	

Section C: Record of action plans and their outcomes

No	Actions planned			Outcome of action

		Actions implemented (Y/N)	Month	Record review (retrospective)	Direct Observation (prospective)

Section D: Criteria for grading quality of audit form. Fill separate form for each death audited. Parameters adapted from DAMA UK working group (2013)

Facility……. Month and Year……

Parameter	Grade	Criteria	Description
Score of parameters assessed			
1.Completeness			

	Less than 50%	Unsatisfactory	More than 5 data set, and items missing
	75%	Good	Less than 5 data set, and items missing
	100%	Excellent	All data set and items recorded
2. Accuracy			
	Less than 50%	Unsatisfactory	More than 5 data set not completed correctly
	75%	Good	Less than 5 data set not completed correctly
	100%	Excellent	All data set completed correctly
3.Consistency			
	Less than 50%	Unsatisfactory	More than 5 data set are inconsistent
	75%	Good	Less than 5 data set are inconsistent
	100%	Excellent	All dataset consistent
4.Validity			
	Less than 50%	Unsatisfactory	More than 5 data set are invalid
	75%	Good	Less than 5 data set are invalid
	100%	Excellent	Valid
1.Completeness			
2.Accuracy			
3. Consistency			
4.Validity			

Appendix 12: Observation checklist for audit process and cycle (adapted from WHO, 2016)

Note: If you want to take a photograph or photocopy of any document, make sure that any identifiable information is removed or obscured before taking a photograph or photocopying. Use separate form for each meeting.

Date: _____ Name of hospital: _____

Observation code: 0. No
1. Yes
2. Not observed
9. Not applicable

Parameter	0	1	2	9	Comments
General information					
1.Does the facility have a coordinator for maternal/perinatal/neonatal death audit?					
2.What cadre is the coordinator?					
1. Clinician					
2. Nurse					
3. Others specify in comment section					
3.Does the hospital have a separate audit team for maternal/perinatal/neonatal deaths? If yes, describe in the comment section					
4.Do the meetings have a chair?					
5.Who chairs the meeting?					
1. Focal person or coordinator 2. Senior nurse 3. Senior clinician 4. DHMT member 5. Others specify					
6.Does the meeting start with review of last					

meetings recommendations?					
7.The audit process approached with 'no name, no blame, no shame? If no (0) explain in the comment section.					
8.Any training and education opportunities during audit? If yes describe in comment section.					
Perinatal/neonatal death audit cycle-Step 1: Identifying stillbirths and neonatal deaths					
1.Which sources do they use to identify perinatal and neonatal deaths?					
1. Maternity register					
2. Neonatal care unit or nursery register					
3. Postnatal discharge records					
4. Patient notes					
5. Paediatric ward register					
6. Antenatal register					
7. Other; specify					
Perinatal/neonatal death audit cycle-Step 2: Collecting Information					
1.Does the hospital use a standardized tool for collecting information during an audit?					
1. Neonatal audit form					
2. Perinatal audit form					
3. Combined neonatal and perinatal audit form					
4. Other; specify					
2.What sections does the form have? Ask to take a copy of the form.					
1. Identification					

2. Pregnancy and antenatal care					
3. Labour and delivery					
4. Care offered in the nursery (neonates only)					
5. Causes of death					
6. Modifiable factors					
7. Action plan					
3.What documents are used to collect specific information about death?					
1. Patient records					
2. Registers					
3. Others; specify					
4.What system is used to classify causes of death?					
1. ICD-10					
2. Modified ICD-10					
3. None					
4. Other; specify					
5. Is there a system to classify modifiable factors or sub-standard care? Specify if yes					
1. Delays					
2. Root cause analysis					
3. Patient-Provider-Administrator					
4. Grading system					
5. None					
6. Others; specify					
6.Are there any statistics about stillbirths and neonatal deaths displayed somewhere?					
7.Does the team collect outcome data for that particular month before the audit to use when calculating mortality rates?					
Perinatal/neonatal death audit cycle-Step 3: Analysing Information					

1.Who is involved in the audit meeting? Confirm with the meeting register. Record the number of cadres present if more than 1 in the comment section					
1. DMO					
2. Clinical director					
3. Nursing director					
4. Hospital matron					
5. Unit matron					
6. HMIS officer					
7. Administrator					
8. Sister in-charge neonatal unit/paediatric					
9. Sister in-charge maternity unit					
10. Obstetrician specialist or clinician					
11. Paediatric specialist or clinician					
12. Environmental officer					
13. Neonatal/paediatric nurse					
14. Maternity unit nurse					
15. Partners in the district					
16. Others specify _____					
2.How often has a meeting been held in the last month?					
1. None					
2. once					
3. twice					
4. 3 times					
5. 4 times					
3.Numbers of deaths reviewed?					
1. All					

2. Sample					
4.If the sample used, what type?					
1. Random					
2. Systematic sampling. If yes, specify					
5. Are the meeting minutes or decisions documented during the meeting? If yes, ask to see it and comment.					
Perinatal/neonatal death audit cycle -Step 4: Recommending solutions					
1. Is the data on causes of death and modifiable factors used to recommend a solution?					
2. Is an action plan developed as part of the review process?					
Perinatal/neonatal death audit cycle-Step 5: implementing solutions					
1. Are individuals assigned to follow on the specific recommendations?					
2.Is there a process of feedbacking the team members on recommendations?					
3.Is there a written documentation system for tracking the follow-up on specific recommendations?					
Perinatal/neonatal death audit cycle-Step 6: Evaluating and Refining audit process					
Does the team examine the efficiency and effectiveness of processes and approaches used at a certain time during the meetings?					
If yes, which areas do they discuss? 1. How efficient is the system in					

identifying and reviewing deaths					
2. How can audit meetings be improved and used more effectively?					
3. What are the gaps in the dissemination of audit results?					
4. How can engagement in audit processes, use of findings, and application of recommendations be improved?					
5. How do staffing issues such as rotations/turnovers influence review meetings?					
6. How can feedback be improved?					
7. How can Committee leadership be improved?					
8. The implementation rate of the solutions?					
9. Any changes in modifiable factors?					
10. Are any issues concerning staff, equipment, drugs and supplies resolved?					
Further comments Use this section to document any comments noted during the observations which are not part of the checklist but are important					

Appendix 13: Questionnaire for interview of health workers working at maternity wards (Labour ward/postnatal ward) or neonatal ward, QIST and WIT members on maternal and perinatal/neonatal audit systems (adapted from Nyamtema et al,.2010)

Instructions: *Circle the appropriate code or fill the responses of the interviewee in the spaces provided after the question.*

Part I: Identification

Identification number _____ Hospital_____

1 Name of the Hospital

_____

2 Health worker's category 01 Doctor 02 Nurse 03 Other (specify)

_____

3 Section of the hospital 01 Maternity 02 Neonatal unit 03 Administration

Part II: Awareness

4 Are you aware of maternal and perinatal audit ? 01 YES 02 NO

5 If Yes, please mention the reasons for establishment of such audit?

i. _____

_____

ii.

_____

_____

6 Do you have an audit committee in this hospital? 01 YES 02 NO 03 DON'T KNOW

7 What type of committee among the two do you have?

01 Maternal audit 02 Perinatal and neonatal audit 03 both combined

8 Do you remember the reason why such committee was introduced in this hospital? 01 YES 02 NO

9 If yes in question 8, Explain

_____

_____

_____

_____

10 Do you know the main objective or vision of these committees? 01 YES 02 NO

11 If yes, what is it?

_____

_____

12 Are there core/constant members of these committees that you know? 01 YES 02 NO

13 If yes, mention few

1. _____ 3. _____

2_____ 4. _____

14 Have the objectives of these committees been communicated to all members of the staff working in maternity/neonatal wards? 01 YES 02 NO 03 DON'T KNOW

15 Are you aware of any QI team at this hospital?

01 YES 02 NO 03 DON'T KNOW

16.If Yes which QI committee do you know?

01 QIST 02 WIT 03 Both

17.Are you a member to any committee?

01Yes 02 No

18.Are you aware of any relationship between perinatal and neonatal death audit team and QI team at this hospital?

01 Yes 02 No

Part III: Attitude

19 Do you think audit committees can affect how people conduct maternal and newborn care anywhere? 01 YES 02 NO

20 Do you think audit committee can affect how you conduct maternal and newborn care in this hospital? 01 YES 02 NO

Part IV: Practices

21 Do you know any recommendation that has been provided by maternal/perinatal/neonatal death audit committee in this hospital? 01 YES 02 NO

22 If Yes, Mention them

1. _____

2. _____

23 Do you remember any action that was taken in this hospital because of maternal/perinatal/neonatal audit committee recommendation? 01 YES 02 NO

24 If Yes, Mention them

1. _____

2. _____

3. _____

25 Have you ever seen any effect on how maternal and neonatal care is been provided in this hospital because of audit committee recommendations? 01 YES 02 NO

26 How could functions of these committees be improved ? Explain

_____

_____

_____

_____

Appendix 14: Topic guide for the semi-structured interviews of the members of the maternal, perinatal and neonatal death audit committees

Start after self-introduction and getting the consent from the respondent.

1.Experience of conducting perinatal and neonatal mortality audit

(*Probe for more information on responsibilities, involvement in the perinatal/neonatal mortality audit committees in this hospital, for how long s/he has been involved in the committee*)

2. What do you think is working well in your facility regarding perinatal and neonatal death audit (*probe experience during audit process*)

3. What are/were the factors that facilitated implementation of perinatal and neonatal death audit in your facility?

4. What are/were some of the barriers/obstacles to the implementation of perinatal and neonatal death audit?

5. What changes would improve on the perinatal and neonatal death audit process in your facility?

6. What are your opinions on how audit is conducted and its impact on improving care (Probe on difference, if any, has it made to healthcare provider ability to provide or support care in maternity or neonatal unit?

7. Can you tell us about a time where the recommendations made during the mortality audit process resulted in a change in how care was provided?

8. Sometimes mortality audits can be a demoralising activity for staff. How is morale maintained in meetings?

9. In your view, how useful is perinatal and neonatal death audits for improving the quality of care and health outcomes for women and newborns in your facility?

Appendix 15: Topic guide for the focus group discussions of the members of the maternal, perinatal and neonatal death audit committees

Start after self-introduction and getting the consent from the respondent.

1. How is the audit process conducted?

(Probe for information on (who initiates the process of auditing? How soon after death is an audit conducted? How frequently are the audits conducted, who are involved in the typical case audit process (their professional and managerial positions), which cadre has the highest number? How the audit is done (map process using audit cycle) how are the deaths identified? Do you conduct audit on all deaths or only some? If only some, how is death selected for discussion? How is the information about perinatal/neonatal audit process collected and summarized? What materials are used for documenting the process, e.g., case notes, antenatal cards, partographs, birth records, etc ? what trend or statistics data are routinely presented at audit? How are the solutions identified? How do you use the data on cause of death and modifiable factors to support solution identification? How does the mortality review team identify and prioritize recommendations? How are recommendations documented (specify areas captured)? How do you reach a consensus on recommendation, how long does an audit take to complete? Who analyses the results of an audit? What is the process for reporting back to the review team and other stakeholders on the status of recommendations (feedback system, institutional administration, partners and Ministry of Health as well as the community)?

2. What kind of support did you get from management members and other stakeholders during the process of audit and implementing change (service delivery, staffing, training, supervision, resources, health information system, finances, leadership and governance, QI team) the following people?

Ministry of Health (National)

Zonal level

District Health and Social Services DHSS/ Hospital Director

District Medical officer

District Nursing Officer/ Principal nursing Officer/matron

HMIS officer

Health services administrator

Sister in charge (neonatal unit or maternity)

Obstetrics (specialist/GMO)

Paediatric (specialist/GMO)

Quality assurance officer

Partners

Others

3. In your opinion, do the medical records and registers capture the necessary information for assessment of cause of death and contributing factors for maternal and perinatal deaths?

4.In your opinion, what are some facilitators and barriers to ensuring recommendations are implemented following mortality audit?

5. Describe the link if present between mortality audit information and any other quality improvement activities in your facility?

6. How are the audit recommendations used by the hospital managers and health policymakers in planning and budgeting to implement changes in the hospital? (Probe for more information about the use of the recommendations in planning, budgeting in order to implement changes in the hospital, examples of the changes that have ever been implemented as a result of recommendation of the audit committee since its establishment, who was involved in this change, how was the change implemented, what was the result of the change in the maternity or neonatal unit, reasons for failures).

7. Let us discuss the sustainability of this initiative (Perinatal and neonatal death review process). Probes: What factors will facilitate the sustainability of this initiative in your facility? Why and how will these factors help to sustain the initiative? What do you think are obstacles to the sustainability of this initiative in your facility? Why and how these obstacles will hinder the sustainability of mortality reviews?

8. Do you have any other suggestions to improve the audit mechanism in order to bring changes in obstetric and neonatal care in the hospital?

Appendix 16: Recruitment log for interviews

Name of Facility: _____

Date of interview: _____

Initials	Cadre	Department	Age	Sex	Type of Interview	Level of education	Experience in years	Accepted (Y/N)	Comment Reason for refusals

Appendix 17: Participant information sheet

Evaluating the processes and outcomes of perinatal and neonatal death audit as a QI tool in the southern region of Malawi

My name is ..... You are being invited to take part in a research study. Before you decide whether to take participate, it is important for you to understand why the research is being done and what it will involve. I will read the information to you regarding the study. I will tell you about the purpose of the study and what will happen if you decide to take part.

What is the purpose of the study?
The purpose of the study is to help us understand the impact of implementing perinatal and neonatal death reviews in health facilities of Malawi. We aim to visit several hospitals in the southern region of Malawi. This information will be used to come up with strategies to improve quality of care and reduce stillbirths and neonatal deaths in our district and in Malawi.

Why have you been chosen?
You have been chosen because you are one/among the people who participate in or conduct perinatal and neonatal deaths reviews at this hospital, or you are in the QI Support Team or Work Improvement Team, or you work in maternity or neonatal wards where newborns or sick neonates are cared for. We want to discuss how best perinatal and neonatal deaths audits could be implemented to improve care and prevent avoidable deaths in the future.

Do you have to take part?
No. It is up to you to make a choice as to whether to take part in the study or not. If you choose to take part, you will be asked to give your consent by signing a consent form.

What will happen to you if you take part?
If you chose to participate in this study, you will be asked to answer a number of questions concerning perinatal and neonatal death audits. This will take place within your facility in a private area where other people will not be able to hear the discussion. You do not have to answer any questions that you do not feel comfortable talking about and you may stop the interview at any time. The discussion will last approximately 30 to 45 minutes. .

What are the possible benefits of taking part?
There might be some benefits to taking part in this study. If we identify barriers and other issues that impair audit, we will recommend measures to improve the process of conducting perinatal and neonatal audits which may prevent deaths in future. The results will be used to inform government programmes, policymakers, managers, healthcare providers and researchers in the field of QI to improve health services and ensure that women are treated properly when they are pregnant, and their babies are taken good care of as well.

What are the possible risks for you taking part?

There are minimal risks associated with this study. If you feel uncomfortable at any time during the discussion, the discussion will be stopped.

What if there is a question or problem?
If any time you have questions or problems related to this study, you may contact me, or the Principal Investigator, Mrs. Mtisunge Gondwe (see contact number at the end). I will try to resolve the problem in the first instance. If you remain unhappy and wish to complain formally, or if the problem relates directly to me, you can contact the secretariat for College of Medicine Research Ethics Committee (COMREC) or Liverpool School of Tropical Medicine Ethics Committee (LSTMREC) who approved this study (see contact number at the end).

Will my taking part in the study be kept confidential?
Yes. Only the researchers, Principal Investigator and study team will have access to the information that you have given us and all the documents containing your information will be kept under key and lock. All your personal information will be kept confidential. Consent forms will be stored in a locked cabinet and will only be accessible to the researcher. A study number will be used on the questionnaire instead of your name and this number will only be known to the researcher. Nobody from outside will be able to link the number to your identity. Data will be put onto a computer but only the researcher will know the password to access the computer. None of the data on the computer will have your name on it. All data collected in this study will be destroyed after the principal investigator has completed the higher degree. The higher degree may take 3 to 4 years to complete.

What will happen if you do not want to carry on with the study?
You are free to withdraw at any time during the study without giving reasons. A decision to withdraw at any time, or a decision not to take part, will not affect your job at the facility in any way.

What will happen to the results of the research study?
This study is being undertaken as a higher degree (Ph.D.) by Mrs. Mtisunge Gondwe, Liverpool School of Tropical Medicine in the UK. The results will be presented in a thesis. In addition, the results may be published and presented at conferences and published in the scientific literature. Results will be used to come up with strategies of reducing stillbirths and neonatal deaths.

Who is organizing and funding the research?
The Commonwealth Scholarship Commission (CSC) has paid for the principal Investigator to study in the UK. She is being supervised by Professor Stephen Allen, Department of Clinical Sciences, Liverpool School of Tropical Medicine, UK; Dr Mamuda Aminu, Centre for Maternal and Newborn Health, Liverpool School of Tropical Medicine, UK and Dr Nicola Desmond, Behaviour and Health group, Malawi Liverpool Wellcome Trust, Malawi and Liverpool School of Tropical Medicine, UK.

Who has reviewed the study?
This study has been reviewed and permission granted to conduct the research by the College of Medicine Research and Ethics Committee, Blantyre, Malawi and the Liverpool School of Tropical Medicine Research and Ethics committee, Liverpool, United Kingdom.

Please keep this information sheet and should you wish to take part, you will also be given a copy of the consent form.

If you have any questions about this study, please feel free to ask. If you think of any questions at a later stage, you can contact the following number and ask to speak to Mrs Mtisunge Gondwe Tel: 01874628/01876444

Alternatively, you can contact the chairperson of the College of Medicine which oversees the research, by telephone on 01871911 Ext 334, by email at comrec@medcol.mw or by postal address at Private bag 360, Chichiri, Blantyre 3.

You can also contact the chairperson of the Liverpool School of Tropical Medicine Research and Ethics committee, by email lstmrec@lstmed.ac.uk or by postal address at Liverpool School of Tropical Medicine, Pembroke Place, Liverpool L3 5QA, UK.

Thank you very much for taking time to read/listen to this information.

Appendix 18: Consent Form

Study Title: Evaluating the processes and outcomes of perinatal and neonatal death audit as a QI tool in the southern region of Malawi

I ……. have read information sheet which explains about perinatal and neonatal death audit study, what you are trying to find out, why should I participate, how the information given will be kept in confidential and its use

Please initial each box to show that you agree with the statement

1. I have read and understood the information sheet for the above study.
2. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐
3. I understand that participation in this study is voluntary, and I am free to withdraw consent at any time, without giving a reason, without any penalties. ☐
4. I understand the reasons for this interview, and I am willing and happy to participate in it. ☐
5. I understand that data collected during the study may be looked at by individuals from LSTM and from regulatory authorities. ☐
6. I hereby declare that I have not been subjected to any form of coercion in giving this consent. ☐
7. I consent to the processing of my personal information for the purposes of this research. I understand that such information will be treated as strictly confidential. ☐
8. I voluntary agree to take part in this study. ☐

Signing this declaration does not affect your right to decline to take part in any future study.

_____	_____	_____
Name of participant	Date	Signature
_____	_____	_____
Name of person taking consent	Date	Signature
_____	_____	_____
District	Cadre	Ward

Appendix 19: Approval from LSTM

Mtisunge Joshua Gondwe
Liverpool School of Tropical Medicine
Pembroke Place
Liverpool
L3 5QA

LSTM
LIVERPOOL SCHOOL OF TROPICAL MEDICINE
Pembroke Place,
Liverpool, L3 5QA, UK
Tel: +44(0)151 705 3100
Fax: +44(0)151 705 3370
www.lstmed.ac.uk

Friday, 14 February 2020

Dear Mrs Gondwe,

Research Protocol (19-076) **Evaluating the process and outcome of perinatal death reviews as a quality improvement tool in the southern region of Malawi**

Thank you for your letter of 13 December 2019 providing the necessary in-country approvals for this project. I can confirm that the protocol now has formal ethical approval from the LSTM Research Ethics Committee.

The approval is for a fixed period of three years and will therefore expire on 13 February 2023.

The Committee may suspend or withdraw ethical approval at any time if appropriate.

Approval is conditional upon:

- Continued adherence to all in-country ethical requirements.
- Notification of all amendments to the protocol for approval before implementation.
- Notification of when the project actually starts.
- Provision of an annual update to the Committee.
  Failure to do so could result in suspension of the study without further notice.
- Reporting of new information relevant to patient safety to the Committee
- Provision of Data Monitoring Committee reports (if applicable) to the Committee

Failure to comply with these requirements is a breach of the LSTM Research Code of Conduct and will result in withdrawal of approval and may lead to disciplinary action. The Committee would also like to receive copies of the final report once the study is completed. Please quote your Ethics Reference number with all correspondence.

Yours sincerely

Graham Devereux

Professor Graham Devereux
Chair
LSTM Research Ethics Committee

Appendix 20: Approval from COMREC

UNIVERSITY OF MALAWI

CERTIFICATE OF ETHICS APPROVAL

This is to certify that the College of Medicine Research and Ethics Committee (COMREC) has reviewed and approved a study entitled:

P.11/19/2869 - Evaluating the processes and outcomes of perinatal and neonatal death audit as a quality improvement tool in the sourthern region of Malawi by Mtisunge Joshua Gondwe

On 13-Dec-19

As you proceed with the implementation of your study, we would like you to adhere to international ethical guidelines, national guidelines and all requirements by COMREC some of which are indicated on the next page for your study

Dr. YB. Mlombe - Chairperson (COMREC)

13-Dec-19

Date

Approved by College of Medicine
13-Dec-2019
(COMREC)
Research and Ethics Committee

Appendix 21: Total ambulances by facility

Hospital	Available ambulance	Functional ambulance	% of functional ambulance	District[11] Population	Functional ambulance to population ratio
[12]Hospital 1	6	3	50.0%	851,737	-
Hospital 2	9	5	55.6%	721, 456	1 :144,291
Hospital 3	8	6	75.0%	356,875	1:59,479
Hospital 4	8	5	62.5%	564,684	1:112,937
Hospital 5	18	13	72.2%	735,438	1:56,572
Hospital 6	6	4	66.7%	130,949	1:32,737
Hospital 7	7	6	85.7%	684, 107	1:114,017
Total	**62**	**42**	**67.7%**	**4,045,246**	**1:81,885[13]**

[11] Source: 2018 Malawi Population and Housing Census Report

[12] Ration was not calculated as it's a tertiary level facility and its population covers both city and rural. The district has district health office that manages transportation of referrals to tertiary hospital (hospital 1)

[13] The total ambulance to population ratio excludes hospital 1

Appendix 22: Training of Clinicians and Nurses

Staff Training	Hospital 1			Hospital 2			Hospital 3			Hospital 4			Hospital 5			Hospital 6			Hospital 7			Total
	LW	PNW	NW	LW	PNW	NW	LW	PNW	NW	LW	PNW	NW	LW	PNW	NW	LW	PNW	NW	LW	PNW	NW	
Total clinicians and nurses	**21**	**16**	**16**	**8**	**7**	**7**	**17**	**6**	**6**	**15**	**8**	**6**	**15**	**13**	**10**	**11**	**0**	**4**	**20**	**13**	**6**	**225**
Integrated Maternal and Neonatal care (IMNC)	20	9	0	0	4	0	14	1	3	0	0	0	0	0	0	0	NA	0	0	0	0	51
Proportion trained in IMNC	**54.7%**			**18.2%**			**62.1%**			**0.0%**			**0.0%**			**0.0%**			**0.0%**			**22.7%**
Helping Babies Breath (HBB)	20	0	1	0	4	0	14	1	1	0	0	0	11	0	0	0	NA	0	0	0	0	52
Proportion Trained in HBB	**39.6%**			**18.2%**			**55.2%**			**0.0%**			**28.9%**			**0.0%**			**0.0%**			**23.1%**
Care of the Infant and Newborn (COIN)	4	3	10	2	3	1	0	2	5	0	0	0	0	0	1	0	NA	0	0	0	4	35
Proportion trained in COIN	**32.1%**			**27.3%**			**24.1%**			**0.0%**			**2.6%**			**0.0%**			**10.3%**			**15.6%**
Maternal and neonatal death audit	20	3	10	0	3	5	0	1	6	0	0	2	0	0	0	0	NA	1	0	0	6	57
Proportion trained in death audit	**62.3%**			**36.4%**			**24.1%**			**6.9%**			**0.0%**			**6.7%**			**15.4%**			**25.3%**

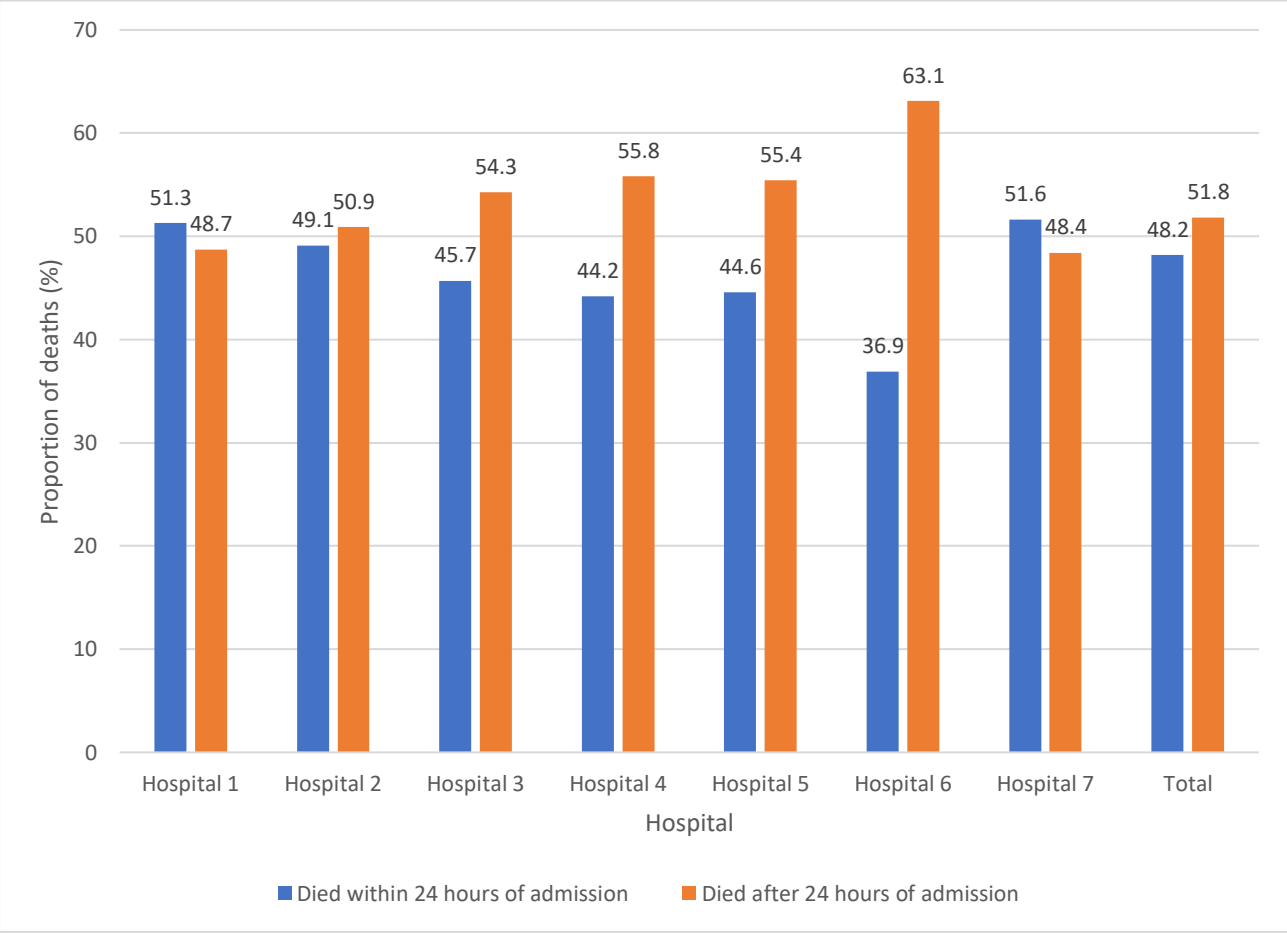
Appendix 23: Number of stockout days in the preceding month of essential supplies and drugs in pharmacy

	Hospital 1	Hospital 2	Hospital 3	Hospital 4	Hospital 5	Hospital 6	Hospital 7
Month	**Jan-20**	**Jan-20**	**Jan-20**	**Feb-20**	**Feb-20**	**Feb-20**	**Jan-20**
Essential supplies							
Intravenous cannula size 24	0	0	0	0	0	0	0
Given sets (60 drop factor)	0	0	0	0	0	0	0
Surgical blade for cutting cord	0	0	0	0	0	0	0
Cord clamp	23	31	0	14	17	11	26
Nasogastric tube size FG6/8	0	31	0	0	0	20	0
Nasal prongs	0	31	0	23	0	0	30
Thermometers	0	31	0	0	0	0	0
Blood Pressure calf	0	31	0	0	0	0	0
Essential drugs							
50% dextrose	0	24	0	28	0	0	0
Diazepam Intravenous	0	0	0	25	0	0	0
Phenobarbitone Intravenous	0	0	0	0	0	0	0
Magnesium Sulphate Intravenous	0	0	7	10	0	0	23
Benzylpenicillin	0	0	0	28	1	10	0
Gentamycin	0	12	0	0	0	0	0
Ceftriaxone	0	2	0	0	0	0	30
Oxytocin	0	0	0	5	0	0	0
Dexamethasone Intravenous	0	0	28	0	0	0	0
Vitamin K Intravenous	0	30	0	0	0	0	0
Metronidazole Intravenous	0	0	1	0	0	0	0
Artesunate Intravenous	0	0	0	0	0	0	0
Aminophylline oral	0	0	0	0	10	24	0
Total number of essential supplies and drugs affected by stockouts	**1/21**	**8/21**	**3/21**	**7/21**	**3/21**	**4/21**	**4/21**

Appendix 24: Causes of neonatal admissions to nursery wards for the 15 months study period by study site

	Admissions(n)			Causes of neonatal admission (%)											
				Prematurity		RDS		Sepsis		Birth Asphyxia		Pneumonia		Others	
	Total	0-7 days	8-28 days	0-7 days	8-28 days	0-7 days	8-28 days	0-7 days	8-28 days	0-7 days	8-28 days	0-7 days	8-28 days	0-7 days	8-28 days
Hospital 1	3418	3093	325	17.0	0.3	11.0	0.2	9.7	3.2	26.7	0.1	1.0	2.1	22.8	3.6
Hospital 2	2223	1947	276	9.7	0.1	7.5	0.2	25.0	5.3	30.1	0.0	2.1	3.1	17.1	3.7
Hospital 3	1604	1506	98	14.6	0.1	12.1	0.1	20.6	2.2	29.8	0.0	2.4	1.7	13.8	1.7
Hospital 4	930	780	150	10.0	0.1	5.1	0.1	20.1	7.3	29.1	0.9	2.4	4.1	14.0	3.9
Hospital 5	2219	2075	144	27.5	0.1	7.3	0.0	9.2	2.5	27.2	0.2	0.9	1.5	20.5	2.2
Hospital 6	1012	885	127	20.8	0.5	5.2	0.0	13.9	5.5	27.9	0.5	3.7	4.0	18.3	3.0
Hospital 7	1707	1584	123	23.1	0.7	11.0	0.2	21.4	2.8	25.8	0.1	1.2	1.9	9.5	1.9
Total	**13113**	**11870**	**1243**	**17.8**	**0.3**	**9.0**	**0.1**	**16.1**	**3.7**	**29.4**	**0.1**	**1.7**	**2.4**	**17.6**	**2.9**
Total/case	**13113**	**13113**		**18.1**		**9.2**		**19.9**		**29.6**		**4.0**		**20.6**	

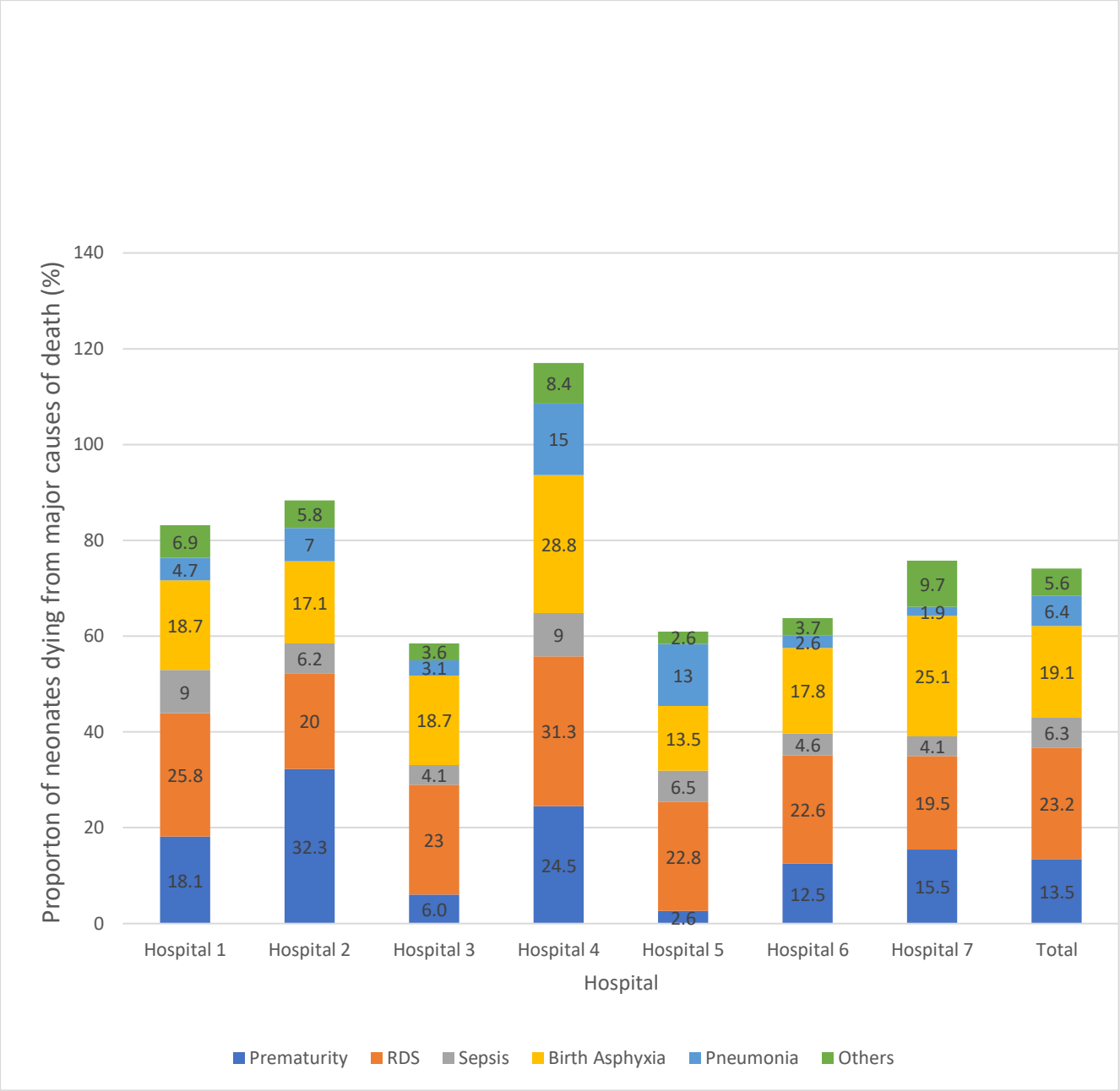
Appendix 25: Time of deaths by facility



Appendix 26: Proportion of facility causes of death by age

	Deaths (n)			Causes of neonatal deaths (%)											
				Prematurity		RDS		Sepsis		Birth Asphyxia		Pneumonia		Others	
	Total	0-7 days	8-28 days	0-7 days	8-28 days	0-7 days	8-28 days	0-7 days	8-28 days	0-7 days	8-28 days	0-7 days	8-28 days	0-7 days	8-28 days
Hospital 1	499	464	35	18.6	2.8	19.8	0.0	5.8	2.2	37.1	0.2	0.0	1.0	9.6	2.8
Hospital 2	293	278	15	23.9	0.0	11.6	0.0	11.6	2.7	39.9	0.0	1.7	1.0	7.5	1.7
Hospital 3	173	171	2	8.1	0.0	26.0	0.0	7.5	1.2	55.4	0.0	1.2	0.0	4.6	0.6
Hospital 4	172	150	22	13.4	0.0	8.7	0.0	6.4	7.0	52.3	0.0	1.7	3.5	6.4	1.7
Hospital 5	186	177	9	8.6	0.0	19.4	0.5	8.1	1.1	47.8	0.0	1.6	2.2	5.9	1.1
Hospital 6	103	101	2	20.8	0.0	11.7	0.0	7.8	1.0	43.7	0.0	1.0	1.0	7.7	0.0
Hospital 7	306	295	11	20.6	0.0	12.1	0.0	4.9	0.7	40.8	0.0	0.0	0.3	3.9	2.3
Total	**1732**	**1636**	**96**	**17.7**	**0.8**	**16.1**	**0.1**	**7.2**	**2.2**	**42.7**	**0.1**	**0.8**	**1.2**	**6.9**	**1.8**
Overall total	**1732**	**1732**		**18.5**		**16.1**		**9.4**		**42.8**		**2.0**		**8.7**	

Appendix 27: Proportion of neonates dying from each major cause of death by hospital



Appendix 28: Ministry of Health provided list of modifiable factors

Modifiable factor	
1. Clinical factors	
A/W01	Insufficient notes on clinical care on admission (assess, manage, monitor)
A/W02	Inadequate history taken on admission
A/W03	Inadequate physical examination on admission
A/W04	Inadequate investigations on admission
A/W05	Investigation results not used
A/W06	Results of investigations inadequately documented (including x-rays) in ward
A/W07	Inadequate daily nursing 'Care Plan' in ward
A/W08	New danger signs inadequately identified while in ward
A/W09	Inadequate response to new danger signs
A/W10	Danger signs missed due to inadequate monitoring in ward
A/W11	No oxygen given due to Inadequate sources in ward
A/W12	Delay in changing treatment despite observing non response to treatment.0
A/W13	Inadequate monitoring vital signs in ward
A/W14	Inadequate review of neonate with severe illness
A/W15	Convulsions not managed according to standardized protocol in ward
A/W16	Delayed referral to higher level of care for very sick neonate
A/W17	Inadequate monitoring of blood glucose in ward
A/W18	Coma score and/or AVPU not done in ward
A/W19	Incorrect type of IV fluids given in ward
A/W20	Too much/too little fluids prescribed for IV fluids in ward
A/W21	NGT feedings not prescribed when indicated in ward
A/W22	Prescribed NGT feeds not given in ward
A/W23	Prescribed feeds not given in ward
A/W24	Inadequate monitoring of IV fluids
A/W25	Inadequate intake-output charting in ward
A/W26	Incorrect antibiotics prescribed in ward
A/W27	Immunizations not up to date
A/W28	Clinician not called for critically ill neonate in ward
A/W29	Clinician called, but did not come
A/W30	Ward staff inadequately communicated with caregiver
A/W31	Critically ill neonate not reviewed by clinician during weekend/public holiday in ward
A/W32	Essential prescribed treatment not given in ward
A/W33	Essential treatment not prescribed
A/W34	Inadequate dose of prescribed oxygen
2. Administrative factors	
A/W35	Inadequate record keeping system for neonates in ward
A/W36	Lack of blood
A/W37	No functioning pulse oximeter in ward
A/W38	Inadequate oxygen supply to ward
A/W39	No suction in ward
A/W40	No emergency tray or emergency tray not updated

Modifiable factor	
1. Clinical factors	
A/W41	Lack of High Dependency Unity (HDU)
A/W42	Inadequate antibiotic supply to ward
A/W43	Inadequate number of clinicians assigned to neonatal ward
A/W44	Clinicians in neonatal ward inadequately supervised
A/W45	Inadequate number of nurses assigned to neonatal ward
A/W46	Inadequate supervision of nurses in neonatal ward
A/W47	Lack of professional nurse in neonatal ward 24 hours a day
A/W48	Lack of experienced clinician for neonatal ward
A/W49	Lack of hospital beds and/or ward overcrowded
A/W50	Lack of standardized case management protocols in ward
3. Caregiver factors	
A/W51	Health passport information not present in child's passport book
A/W52	Caregiver declined consent for life-saving intervention in ward
A/W53	Caregiver declined HIV test in ward

Referring Facility Care (RFC)

Modifiable factor	
1. Clinical factors	
RC01	Inadequate referral notes from referring facility
RC02	Severity of neonate's condition incorrectly assessed at referring facility
RC03	Neonate not re-assessed at time of departure from referring facility
RC04	Emergency or priority care not provided at referring hospital
RC05	No or delayed referral to higher level
RC06	Neonate with life-threatening condition not monitored at referring facility while awaiting ambulance
RC07	Inadequate monitoring and critical care equipment (e.g. oxygen concentrator) in referring facility
2. Administrative factors	
RA01	No observation room in referring facility for pre-transfer care of critically ill neonate
RA02	No ambulance available for transfer from referring to receiving hospital
RA03	Delayed arrival of ambulance at referring facility
RA04	No lifesaving equipment in the ambulance
RA05	Inadequate in-transit consumables (e.g. volume expanders, dextrose, anticonvulsant) in ambulance
RA06	Lack/inadequate critical care equipment in ambulance
3. Caregiver factors	
RCG01	Traditional remedy given
RCG02	Caregiver delayed seeking care
RCG03	Caregiver declined HIV test for the neonate
RCG18	Caregiver did not take neonate to clinic for vaccines as scheduled
RCG19	Neonate accessed poison/drug
RCG20	Caregiver refused oxygen therapy

Appendix 29: Maternal demographic and clinical characteristics of audited neonatal deaths(n=438)

Characteristics		Hosp 1 n=96 (%)	Hosp 2 n=223 (%)	Hosp 3 n=8 (%)	Hosp 4 n=3 (%)	Hosp 5 n=74 (%)	Hosp 6 n=3 (%)	Hosp 7 n=31 (%)	Total n=438 (%)
Maternal age	<15	1(1.0)	4 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	**5 (1.1)**
	15-19	27 (28.1)	67 (30.0)	3 (37.5)	1 (33.3)	13 (17.6)	3 (100.0)	9 (29.0)	**123 (28.1)**
	20-24	29 (30.2)	52 (23.3)	2 (25.0)	0 (0.0)	13 (17.6)	0 (0.0)	5 (16.1)	**101 (23.1)**
	25-29	12 (12.5)	26 (11.7)	1 (12.5)	1 (33.3)	4 (5.4)	0 (0.0)	4 (12.9)	**48 (11.0)**
	30-34	5 (5.2)	21 (9.4)	0 (0.0)	0 (0.0)	3 (4.1)	0 (0.0)	4 (12.9)	**33 (7.5)**
	35-39	7 (7.3)	13 (5.8)	2 (25.0)	0 (0.0)	2 (2.7)	0 (0.0)	6 (19.4)	**30 (6.8)**
	>=40	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	4 (5.4)	0 (0.0)	3 (9.7)	**8 (1.8)**
	No Information	15 (15.6)	39 (17.5)	0 (0.0)	1 (33.3)	35 (47.3)	0 (0.0)	0 (0.0)	**90 (20.5)**
	Mean (SD)	22.9 (5.9)	23.2 (6.5)	24.3(8.4)	21.5(5.0)	24.7(8.6)	18.7 (0.6)	26.9(8.7)	**23.6(7.0)**
Parity	Para 1	31 (32.3)	131 (58.7)	4 (50.0)	2 (66.7)	20 (27.0)	2 (66.7)	13 (41.9)	**203 (46.3)**
	Para2-4	32 (33.3)	53 (23.8)	2 (25.0)	0 (0.0)	8 (10.8)	1 (33.3)	13 (41.9)	**109 (24.9)**
	Para 5 or more	3 (3.1)	9 (4.0)	2 (25.00	0 (0.0)	3 (4.1)	0 (0.0)	5 (16.1)	**22 (5.0)**
	No Information	30 (31.3)	30 (13.5)	0 (0.0)	1 (33.3)	43 (58.1)	0 (0.0)	0 (0.0)	**104 (23.7)**
Antenatal visit	Attended	69 (71.9)	124 (55.6)	8 (100.0)	2 (67.7)	26 (35.1)	1 (33.3)	24 (77.4)	**254 (58.0)**
	Not attended	4 (4.2)	4 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	**8 (1.8)**
	Unknown	22 (22.9)	75 (33.6)	0 (0.0)	1 (33.3)	41(55.4)	2 (66.7)	7 (22.6)	**148 (33.8)**
	No information	1 (1.0)	20 (9.0)	0 (0.0)	0 (0.0)	7 (9.5)	0 (0.0)	0 (0.0)	**28 (6.4)**
Type of Pregnancy	Singleton	83(86.5)	179 (80.3)	6 (75.0)	2 (66.7)	57 (77.0)	1 (33.3)	27 987.1)	**355 (81.1)**
	Multiple	10 (10.4)	15 (6.7)	2 (25.0)	1 (33.3)	6 (8.1)	0 (0.0)	4 (12.9)	**38 (8.7)**
	No Information	3 (3.1)	29 (13.0)	0 (0.0)	0 (0.0)	11 (14.9)	2 (66.7)	0 (0.0)	**45 (10.3)**
Mother HIV status	Reactive	10 (10.4)	30 (13.5)	0 (0.0)	0 (0.0)	7 (9.5)	0 (0.0)	4 (12.9)	**51 (11.6)**
	Non-Reactive	74 (77.1)	160 (71.7)	8 (100.0)	2 (66.7)	44 (59.5)	0 (0.0)	24 (77.4)	**312 (71.2)**
	No Information	12 (12.5)	33 (14.8)	0 (0.0)	1 (33.3)	23 (31.0)	3 (100.0)	3 (9.7)	**75 (17.1)**
Syphilis test results	Positive	3 (3.1)	8 (3.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.2)	**12 (2.7)**
	Negative	53 (55.2)	132 (59.2)	5 (62.5)	2 (66.7)	28 (37.8)	3 (100.0)	20 (64.5)	**243 (55.5)**

Characteristics		Hosp 1 n=96 (%)	Hosp 2 n=223 (%)	Hosp 3 n=8 (%)	Hosp 4 n=3 (%)	Hosp 5 n=74 (%)	Hosp 6 n=3 (%)	Hosp 7 n=31 (%)	Total n=438 (%)
	Unknown	18 (18.8)	4 (1.8)	1 (12.5)	1 (33.3)	28 (37.8)	0 (0.0)	3 (9.7)	**55 (12.6)**
	No information	22 (22.9)	79 (35.4)	2 (25.0)	0 (0.0)	18 (24.3)	0 (0.0)	7 (22.6)	**128 (29.2)**
Pregnancy complication	Anaemia	1 (1.0)	0 (0.0)	0 (0.0)	1 (33.3	0 (0.0)	0 (0.0)	0 (0.0)	**2 (0.5)**
	APH	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.2)	**2 (0.5)**
	Asthma	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	**1 (0.2)**
	Abnormal Vaginal discharge	0 (0.0)	2 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	**2 (0.5)**
	Draining liquor	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	1 (3.2)	**2 (0.5)**
	Hypertensive disorders	2 (2.1)	4 (1.8)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	2 (6.5)	**9 (2.1)**
	Malaria	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	**1 (0.2)**
	None	91 (94.8)	216 (96.9)	8 (100.0)	2 (66.7)	72 (97.3)	3 (100.0)	27 (87.1)	**419 (95.7)**

Appendix 30: Demographic and clinical characteristics of audited neonatal deaths (n=438)

Characteristics		Hosp 1 n=96 (%)	Hosp 2 n=223 (%)	Hosp 3 n=8 (%)	Hosp 4 n=3 (%)	Hosp 5 n=74 (%)	Hosp 6 n=3 (%)	Hosp 7 n=31 (%)	Total n=438 (%)
Mode of delivery	Spontaneous vaginal delivery	68 (70.8)	166 (74.4)	7 (87.5)	2 (66.7)	48 (64.9)	3 (100.0)	24 (77.4)	**318 (72.6)**
	Caesarean section	14 (15.6)	29 (13.0)	1 (12.5)	0 (0.0)	14 (18.9)	0 (0.0)	4 (12.9)	**62 (14.2)**
	Assisted delivery (Vacuum)	5 (5.2)	1 (0.4)	0 (0.0)	0 (0.0)	2 (2.7)	0 (0.0)	1 (3.2)	**9 (2.1)**
	Breech	9 (9.4)	11 (4.9)	0 (0.0)	1 (33.3)	2 (2.7)	0 (0.0)	1 (3.2)	**24 (5.5)**
	No Information	0 (0.0)	16 (7.2)	0 (0.0)	0 (0.0)	8 (10.8)	0 (0.0)	1 (3.2)	**25 (5.7)**
Place of birth	This facility	55 (57.3)	139 (62.3)	4 (50.0)	1 (33.3)	58 (78.4)	2 (67.7)	22 (71.0)	**281 (64.2)**
	Other facility	38 (39.6)	63 (28.3)	4 (50.0)	1 (33.3)	11 (14.9)	0 (0.0)	8 (25.8)	**125 (28.5)**
	Home	1 (1.0)	11 (4.9)	0 (0.0)	0 (0.0)	2 (2.7)	1 (33.3)	1 (3.2)	**16 (3.7)**
	In-transit	2 (2.1)	4 (1.8)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	**7 (1.6)**
	No Information	0 (0.0)	6 (2.7)	0 (0.0)	1 (33.3)	2 (2.7)	0 (0.0)	0 (0.0)	**9 (2.1)**
Referral status	Referred	37 (38.5)	60 (26.9)	4 (50.0)	2 (67.7)	14 (18.9)	0 (0.0)	8 (25.8)	**125 (28.5)**
	Not referred	59 (61.5)	163 (73.1)	4 (50.0)	1 (33.3)	60 (81.1)	3 (100.0)	23(74.2)	**313 (71.5)**
Referring facility type	CHAM hospital	2 (5.4)	1 (1.7)	0 (0.0)	0 (0.0)	1 (7.1)	0 (0.0)	1 (12.5)	**5 (4.0)**
	Health Centre	30 (81.1)	50 (83.3)	4 (100.0)	1 (50.0)	8 (57.1)	0 (0.0)	7 (87.5)	**100 (80.0)**
	Private	0 (0.0)	2 (3.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	**2 (1.6)**
	Others	0 (0.0)	0 (0.0)	0 (0.0)	1 (50.0)	0 (0.0)	0 (0.0)	0 (0.0)	**1 (0.8)**
	No information	5 (13.5)	7 (11.7)	0 (0.0)	0 (0.0)	5 (35.7)	0 (0.0)	0 (0.0)	**17 (13.6)**
Dead on arrival	Yes	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.2)	**1 (0.2)**
	No	96 (100.0)	223 (100.0)	8 (100.0)	3 (100.0)	74 (100.0)	3 (100.0)	30 (96.8)	**437 (99.8)**
Brought in Dead	Yes	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.2)	**1 (0.2)**
	No	96 (100.0)	223 (100.0)	8 (100.0)	3 (100.0)	74 (100.0)	3 (100.0)	30 (96.8)	**437 (99.8)**

Characteristics		Hosp 1 n=96 (%)	Hosp 2 n=223 (%)	Hosp 3 n=8 (%)	Hosp 4 n=3 (%)	Hosp 5 n=74 (%)	Hosp 6 n=3 (%)	Hosp 7 n=31 (%)	Total n=438 (%)
Admission hours death occurred	<24hours	36 (37.5)	104 (46.6)	1 (12.5)	2 (66.7)	27 (36.5)	1 (33.3))	15 (48.4)	**186 (42.5)**
	>24hours	60 (62.5)	113 (50.7)	7 (87.5)	1 (33.3)	46 (62.2)	2 (66.7)	15 (48.4)	**244 (55.7)**
	No information	0 (0.0)	6 (2.7)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	1 (3.2)	**8 (1.8)**
When death occurred	Weekday-day	28 (29.2)	58 (26.0)	0 (0.0)	2 (67.7)	14 (18.9)	1 (33.3)	10 (32.3)	**113 (25.8)**
	Weekday-Public Holiday	1 (1.0)	1 (0.4)	1 (12.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	**3 (0.7)**
	Weekend-Day	11 (11.5)	24 (10.8)	0 (0.0)	0 (0.0	10 (13.5)	0 (0.0)	5 (16.1)	**50 (11.4)**
	Weekday-Night	38 (39.6)	86 (38.6)	5 (62.5)	0 (0.0)	33 (44.6)	2 (67.7)	9 (29.0)	**173 (39.5)**
	Weekday-Night public Holiday	1 (1.0)	2 (0.9)	0 (0.0)	0 (0.0)	0(0.0)	0 (0.0)	0 (0.0)	**3 (0.7)**
	Weekend-Night	17 (17.7)	49 (22.0)	2 (25.0)	1 (33.3)	16 (21.6)	0 (0.0)	5 (16.1)	**90 (20.5)**
	No information	0 (0.0)	3 (1.3)	0 (0.0)	0 (0.0)	1 (1.4)	0(0.0)	2 (6.5)	**6 (1.4)**
At 1 minute Apgar Score	1/10 to 3/10	26 (27.1)	61 (27.4)	2 (25.0)	0 (0.0)	25 (33.8)	1 (33.3)	7 (22.6)	**122 (27.9)**
	4/10 to 7/10	22 (22.9)	55 (24.7)	5 (62.5)	0 (0.0)	20 (27.0)	0 (0.0)	14 (45.2)	**116 (26.5)**
	7/10-10/10	28 (29.2)	42 (18.8)	0 (0.0)	0 (0.0)	12 (16.2)	0 (0.0)	4 (12.9)	**86 (19.6)**
	No information	18 (18.8)	68 (30.5)	1 (12.5)	2 (67.7)	17 (23.0)	2 (67.7)	6 (19.4)	**114 (26.0)**
At 5 minutes Apgar Score	1/10 to 3/10	12 (12.5)	24 (10.8)	1 (12.5)	0 (0.0)	11 (14.9)	1 (33.3)	2 (6.5)	**51 (11.6)**
	4/10 to 7/10	26 (27.1)	56 (25.1)	1 (12.5)	0 (0.0)	24 (32.4)	0 (0.0)	7 (22.6)	**114 (26.0)**
	7/10-10/10	38 (39.6)	70 (31.4)	4 (50.0)	0 (0.0)	23 (31.1)	0 (0.0)	14 (45.2)	**149(34.0)**
	No information	18 (18.8)	76 (34.1)	2 (25.0)	2 (67.7)	16 (21.6)	2 (67.7)	8 (25.4)	**124 (28.3)**
Age of baby at death (days)	0 to 3 days	75 (78.1)	164 (73.5)	6 (75.0)	2 (66.7)	57 (77.0)	2 (66.7)	27 (87.1)	**333 (76.0)**
	4 to 7 days	6 (6.3)	38 (17.0)	1 (12.5)	1 (33.3)	11 (14.9)	0 (0.0)	3 (9.7)	**60 (13.7)**
	8-11 days	4 (4.2)	4 (1.8)	0 (0.0)	0 (0.0)	4 (5.4)	1 (33.3)	0 (0.0)	**13 (3.0)**
	12-15 days	5 (5.2)	7 (3.1)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	1 (3.2)	**14 (3.2)**
	16-19 days	3 (3.1)	5 (2.2)	1 (12.5)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	**10 (2.3)**
	20-24 days	2 (2.1)	3 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	**5 (1.1)**

Characteristics		Hosp 1 n=96 (%)	Hosp 2 n=223 (%)	Hosp 3 n=8 (%)	Hosp 4 n=3 (%)	Hosp 5 n=74 (%)	Hosp 6 n=3 (%)	Hosp 7 n=31 (%)	Total n=438 (%)
	25-28 days	1 (1.0)	2 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	**3 (0.7)**
	Mean (SD)	3.6 (5.5)	3.1 (5.0)	3.4 (5.7)	2.0 (3.5)	2.5 (3.1)	3.7 (4.0)	1.8 (2.5)	**3.0 (4.7)**
Sex of baby	Male	53 (55.2)	124 (55.6)	4 (50.0)	1 (33.3)	35 (47.3)	2 (66.7)	15 (48.4)	**234 (53.4)**
	Female	39 (40.6)	89 (39.1)	4 (50.0)	0 (0.0)	36 (48.6)	1 (33.3)	15 (48.4)	**184 (42.0)**
	No information	4 (4.2)	10 (4.5)	0 (0.0)	2 (67.7)	3 (4.1)	0 (0.0)	1 (3.2)	**20 (4.6)**
Admission weight	>1000g	7 (7.3)	5 (2.2)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	1 (3.2)	**14 (3.2)**
	1000-1400g	23 (24.0)	40 (17.9)	2 (25.0)	2 (67.7)	10 (13.5)	1 (33.3)	5 (16.1)	**83 (18.9)**
	1500-1900g	14 (14.6)	33 (14.8)	1 (12.5)	0 (0.0)	10 (13.5)	0 (0.0)	5 (16.1)	**63 (14.4)**
	2000-2400g	11 (11.5)	32 (14.3)	0 (0.0)	0 (0.0)	9 (12.2)	1 (33.3)	4 (12.9)	**57 (13.0)**
	2500-2900g	21 (21.9)	44 (19.7)	1 (12.5)	0 (0.0)	22 (29.7)	0 (0.0)	7 (22.6)	**95 (21.7)**
	3000-3400g	14 (14.6)	25 (11.2)	3 (37.5)	0 (0.0)	14 (18.9)	0 (0.0)	7 (22.6)	**63 (14.4)**
	3500-3900g	3 (3.1)	13 (5.8)	1 (12.5)	0 (0.0)	2 (2.7)	0 (0.0)	0 (0.0)	**19 (4.3)**
	4000-4400g	0 (0.0)	3 (1.3)	0 (0.0)	0 (0.0)	2 (2.7)	0 (0.0)	1 (3.2)	**6 (1.4)**
	>4500g	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	**1 (0.2)**
	No information	2 (2.1)	28 (12.6)	0 (0.0)	1 (33.3)	4 (5.4)	1 (33.3)	1 (3.2)	**37 (8.4)**
	Mean (SD)	2152.3 (874.5)	2258.4 (827.6)	2395.6 (964.8)	1200.0 (0.0)	2430.6 (771.8)	1700.0 (848.5)	2302.8 (842.5)	**2261.6 (835.3)**
HIV status	Exposed	10 (10.4)	30 (13.5)	0 (0.0)	0 (0.0)	7 (9.5)	0 (0.0)	4 (12.9)	**51 (11.6)**
	Non exposed	74 (77.1)	160 (71.7)	8 (100.0)	2 (67.7)	44 (59.5)	0 (0.0)	24 (77.4)	**312 (71.2)**
	Unknown	12 (12.5)	33 (14.8)	0 (0.0)	1 (33.3)	23 (31.1)	3 (100.0)	3 (9.7)	**75 (17.1)**
Type of neonatal death	Early neonatal death (0-7 days)	79 (82.3)	194 (87.0)	7 (87.5)	3 (100.0)	67 (90.5)	2 (67.7)	30 (96.8)	**382 (87.2)**
	Late Neonatal Death (8-28 days)	17 (17.7)	23 (10.3)	1 (12.5)	0 (0.0)	6 (8.1)	1 (33.3)	1 (3.2)	**49 (11.2)**
	No information	0 (0.0)	6 (2.7)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	**7 (1.6)**

Appendix 31: Characteristics of care provided (n=438)

Characteristics		Hosp 1 n=96 (%)	Hosp 2 n=223 (%)	Hosp 3 n=8 (%)	Hosp 4 n=3 (%)	Hosp 5 n=74 (%)	Hosp 6 n=3 (%)	Hosp 7 n=31 (%)	Total n=438 (%)
Resuscitation in the labour ward	Done	72 (75.0)	105 (47.1)	5 (62.5)	2 (66.7)	42 (56.8)	1 (33.3)	19 (61.3)	**246 (56.2)**
	Not applicable	6(6.3)	28 9 (12.6)	0 (0.0)	1 (33.3)	8 (10.8)	2 (66.7)	7 (22.6)	**52 (11.9)**
	Unknown	18 (18.8)	61 (27.4)	3 (37.5)	0 (0.0)	14 (18.9)	0 (0.0)	1 (3.2)	**97 (22.1)**
	No information	0 (0.0)	29 (13.0)	0 (0.0)	0 (0.0)	10 (13.5)	0 (0.0)	4 (12.9)	**43 (9.8)**
Resuscitation measures used frequency(n=345)	Stimulation	50 (27.0)	24 (19.0)	0(0.0)	0 (0.0)	0 (0.0)	1 (25.0)	0 (0.0)	**75 (21.7)**
	Suctioning	44 (23.8)	18 (14.3)	1 (20.0)	0(0.0)	0 (0.0)	1 (25.0)	0 (0.0)	**64 (18.6)**
	BVM Ventilation	40 (21.6)	68 (53.9)	3 (60.0)	0(0.0)	15 (78.9)	1 (25.0)	6 (100.0)	**133 (38.6)**
	Oxygen	49 (26.5)	12 (9.5)	1 (20.0)	0(0.0)	3 (15.8)	1 (25.0)	0(0.0	**66 (19.1)**
	CPR	2 (1.1)	4 (3.2)	0(0.0)	0(0.0)	1 (5.3)	0(0.0)	0(0.0)	**7 (2.0)**
Period of BVM if used (n=133)	1-10 minutes	13(32.5)	8 (11.8)	0(0.0)	0(0.0)	3 (20.0)	0(0.0)	0(0.0)	**24 (18.0)**
	11-20 minutes	7 (17.5)	11 (16.2)	1 (33.3)	0(0.0)	1 (6.7)	0(0.0)	0(0.0)	**20 (15.0)**
	21-30 minutes	4 (10.0)	8 (11.8)	0(0.0)	0(0.0)	3 (20.0)	0(0.0)	0(0.0)	**15 (11.3)**
	31-40 minutes	1 (2.5)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	**1 (0.8)**
	41-50 minutes	1 (2.5)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	**1 (0.8)**
	51-60 minutes	1 (2.5)	2 (2.9)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	**3 (2.3)**
	> 60 minutes	1 (2.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	**1 (0.8)**
	No information	12 (14.5)	39 (57.4)	2 (66.7)	0 (0.0)	8 (53.3)	1 (100.0)	6 (100.0)	**68 (51.1)**
	Mean (SD)	19.0(17.5)	21.0 (14.2)	20	_	19.1(11.2)	_	_	**19.9 (15.2)**
Triage category	Emergency	77 (80.2)	172 (77.1)	7 (87.5)	2 (66.7)	68 (91.9)	2 (66.7)	25 (80.6)	**353 (80.6)**
	Priority	8 (8.3)	13 (5.8)	1 (12.5)	0 (0.0)	4 (5.4)	1 (33.3)	3 (9.7)	**30 (6.8)**
	No information	11 (11.5)	38 (17.0)	0 (0.0)	1 (33.3)	2 (2.7)	0 (0.0)	3 (9.7)	**55 (12.6)**
Initial treatment	Given	87 (90.6)	163 (73.1)	8 (100.0)	2 (66.7)	68 (91.9)	0 (0.0)	24 (77.4)	**355 (81.1)**
	Not given	4 (4.2)	5 (2.2)	0 (0.0)	0 (0.0)	2 (2.7)	0 (0.0)	2 (6.5)	**13 (3.0)**
	Not applicable	2 (2.1)	2 (0.9)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	**5 (1.1)**

Characteristics		Hosp 1 n=96 (%)	Hosp 2 n=223 (%)	Hosp 3 n=8 (%)	Hosp 4 n=3 (%)	Hosp 5 n=74 (%)	Hosp 6 n=3 (%)	Hosp 7 n=31 (%)	Total n=438 (%)
	No information	3 (3.1)	53 (23.8)	0 (0.0)	1 (33.3)	3 (4.1)	0 (0.0)	5 (16.1)	**65 (14.8)**
Perinatal ARV for exposed babies (n=51)	Given	8 (80.0)	19 (63.3)	0 (0.0)	0 (0.0)	7 (100.0)	0 (0.0)	2 (50.0)	**36 (70.6)**
	Not given	2 (20.0)	3 (10.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (25.0)	**6 (11.8)**
	No information	0 (0.0)	8 (26.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (25.)0)	**9 (17.6)**
Critical Care Pathway form	Used	96 (100.0)	196 (87.9)	7 (87.5)	3 (100.0)	56 (75.7)	3 (100.0)	23 (74.2)	**384 (87.7)**
	Not used	0 (0.0)	27 (12.1)	1 (12.5)	0 (0.0)	18 (24.3)	0 (0.0)	8 (25.8)	**54 (12.3)**
Completeness of CCP form (n=384)	Complete	63 (65.6)	194 (99.0)	6 (85.7)	3 (100.0)	37 (66.1)	1 (33.3)	14 (60.9)	**318 (82.8)**
	Not complete	33 (34.4)	2 (1.0)	1 (14.3)	0 (0.0)	19 (33.9)	2 (66.7)	9 (39.1)	**66 (17.2)**
Completeness of admission form	Complete	46 (47.9)	199 (89.2)	7 (87.5)	2 (66.7)	34 (45.9)	1 (33.3)	22 (71.0)	**311 (71.0)**
	Not complete	50 (52.1)	24 (10.8)	1 (12.5)	1 (33.3)	40 (54.1)	2 (66.7)	9 (29.0)	**127 (29.0)**
Feeding charts used	Used	14 (14.6)	12 (5.4)	3 (37.5)	0 (0.0)	6 (8.1)	0 (0.0)	7 (22.6)	**42 (9.6)**
	Not used	77 (80.2)	97 (43.5)	4 (50.0)	1 (33.3)	30 (40.5)	2 (66.7)	22 (71.0)	**233 (53.2)**
	Not applicable	0 (0.0)	3 (1.3)	0 (0.0)	0 (0.0)	10 (13.5)	0 (0.0)	0 (0.0)	**13 (3.0)**
	No information	5 (5.2)	111 (49.7)	1 (12.5)	2 (66.7)	28 (37.8)	1 (33.3)	2 (6.5)	**150 (34.2)**
Maternal records	Attached	2 (2.1)	60 (26.9)	6 (75.0)	0 (0.0)	12 (16.2)	1 (33.3)	29 (93.5)	**110 (25.1)**
	Not attached	94 (97.9)	163 (73.1)	2 (25.0)	3 (100.0)	62 (83.8)	2 (66.7)	2 (6.5)	**328 (74.9)**
Monitoring by clinician frequency	0-2 times	69 (71.8)	159 (71.3)	7 (87.5)	3 (100.0)	66 (89.2)	3 (100.0)	30 (96.8)	**337 (76.9)**
	3-4 times	17 (17.7)	28 (12.6)	0 (0.0)	0 (0.0)	3 (4.1)	0 (0.0)	1 (3.2)	**49 (11.2)**
	> 4 times	10 (10.4)	14 (6.3)	1 (12.5)	0 (0.0)	2 (2.7)	0 (0.0)	0 (0.0)	**27 (6.2)**
	No information	0 (0.0)	22 (9.9)	0 (0.0)	0 (0.0)	3 (4.1)	0 (0.0)	0 (0.0)	**25 (5.7)**
	Mean (SD)	1.9 (1.8)	1.8 (2.7)	1.5 (2.3)	1.0 (0.0)	0.9 (1.4)	0.3 (0.6)	0.5 (0.8)	**1.5 (2.2)**
Monitoring by nurses frequency	0-2 times	25 (26.0)	66 (29.6)	1 (12.5)	0 (0.0)	17 (23.0)	2 (66.7)	10 (32.3)	**121 (27.6)**
	3-4 times	27 (28.1)	54 (24.2)	6 (75.0)	0 (0.0)	27 (36.5)	1 (33.3)	9 (29.0)	**124 (28.3)**
	> 4 times	44 (45.8)	78 (35.0)	1 (12.5)	3 (100.0)	27 (36.5)	0 (0.0)	12 (38.7)	**165 (37.7)**
	No information	0 (0.0)	25 (11.2)	0 (0.0)	0 (0.0)	3 (4.1)	0 (0.0)	0 (0.0)	**28 (6.4)**
	Mean (SD)	6.0 (5.6)	6.9 (9.8)	5.8 (5.8)	7.0 (1.7)	5.5 (4.9)	2.7 (1.2)	4.8 (3.8)	**6.2 (7.8)**

Appendix 32: Vital signs recorded during provision of care

Characteristics		Hosp 1 n=96 (%)	Hosp 2 n=223 (%)	Hosp 3 n=8 (%)	Hosp 4 n=3 (%)	Hosp 5 n=74 (%)	Hosp 6 n=3 (%)	Hosp 7 n=31 (%)	Total n=438 (%)
Lowest temperature (n=186)	<32.0 °C	4 (4.5)	3 (5.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	**7 (3.8)**
	32.0-35.9 °C	63 (71.6)	44 (80.0)	0 (0.0)	0 (0.0)	24 (64.9)	0 (0.0)	6 (100.0)	**137 (73.7)**
	36.0-36.4°C	11 (12.5)	5 (9.1)	0 (0.0)	0 (0.0)	8 (21.6)	0 (0.0)	0 (0.0)	**24 (12.9)**
	36.5-37.4°C	7 (8.0)	2 (3.6)	0 (0.0)	0 (0.0)	3 (8.1)	0 (0.0)	0 (0.0)	**12 (6.5)**
	>=37.5°C	3 (3.4)	1 (1.8)	0 (0.0)	0 (0.0)	2 (5.4)	0 (0.0)	0 (0.0)	**6 (3.2)**
	Total	**88 (91.7)**	**55 (24.7)**	**0 (0.0)**	**0 (0.0)**	**37 (50.0)**	**0 (0.0)**	**6 (19.4)**	**186 (42.5)**
	No information	8 (8.3)	168 (75.3)	8 (100.0)	3 (100.0)	37 (50.0)	3 (100.0)	25 (80.6)	**252 (57.5)**
	Mean (SD)	34.7 (1.7)	34.2 (1.6)	_	_	35.0(1.5)		33.8 (1.3)	**34.6(1.6)**
Highest temperature (n=175)	32.0-35.9 °C	9 (10.2)	5 (10.4)	0 (0.0)	0 (0.0)	5 (13.5)	0 (0.0)	0 (0.0)	**19 (10.9)**
	36.0-36.4°C	10 (11.4)	3 (6.3)	0 (0.0)	0 (0.0)	1 (2.7)	0 (0.0)	0 (0.0)	**14 (8.0)**
	36.5-37.4°C	23 (26.1)	15 (31.3)	0 (0.0)	0 (0.0)	5 (13.5)	0 (0.0)	0 (0.0)	**43 (24.6)**
	37.5-38.4°C	22 (25.0)	16 (33.3)	1 (100.0)	0 (0.0)	11 (29.7)	0 (0.0)	1 (100.0)	**51 (29.1)**
	38.5-39.4°C	16 (18.2)	5 (10.4)	0 (0.0)	0 (0.0)	11 (29.7)	0 (0.0)	0 (0.0)	**32 (18.3)**
	39.5-40.4°C	7 (8.0)	2 (4.2)	0 (0.0)	0 (0.0)	1 (2.7)	0 (0.0)	0 (0.0)	**10 (0.6)**
	>=40.5	1 (1.0)	2 (4.2)	0 (0.0)	0 (0.0)	3 (8.1)	0 (0.0)	0 (0.0)	**6 (3.4)**
	Total	**88 (91.7)**	**48 (21.5)**	**1 (12.5)**	**0 (0.0)**	**37 (50.0)**	**0 (0.0)**	**1 (3.2)**	**175 (40.0)**
	No information	8 (8.3)	175 (78.5)	7 (87.5)	3 (100.0)	37 (50.0)	3 (100.0)	30 (96.8)	**263 (60.0)**
	Mean (SD)	37.6 (1.4)	37.5 (1.6)	38.0	_	38.1 (1.6)	_	38.0	**37.7 (1.5)**
Lowest Blood sugar (n=116)	<25mg/dl	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	**0 (0.0)**
	25-44mg/dl	1 (1.4)	4 (10.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (50.0)	**6 (5.2)**
	45-124mg/dl	63 (87.5)	32 (82.1)	0 (0.0)	0 (0.0)	3 (100.0)	0 (0.0)	1 (50.0)	**99 (85.3)**
	125-149mg/dl	5 (6.9)	1 (2.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	**6 (5.2)**
	>=150mg/dl	3 (4.2)	2 (5.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	**5 (4.3)**
	Total	**72 (75.0)**	**39 (17.5)**	**0 (0.0)**	**0 (0.0)**	**3 (4.1)**	**0 (0.0)**	**2 (6.5)**	**116 (26.5)**

Characteristics		Hosp 1 n=96 (%)	Hosp 2 n=223 (%)	Hosp 3 n=8 (%)	Hosp 4 n=3 (%)	Hosp 5 n=74 (%)	Hosp 6 n=3 (%)	Hosp 7 n=31 (%)	Total n=438 (%)
	No information	24 (25.0)	184 (82.5)	8 (100.0)	3 (100.0)	71 (95.9)	3 (100.0)	29 (93.5)	**322 (73.5)**
	Mean (SD)	89.5 (38.2)	83.9 (32.1)	_	_	70.3 (31.2)		52.0 (25.5)	**86.5 (36.0)**
Highest blood sugar (n=101)	<25mg/dl	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	**0 (0.0)**
	25-44mg/dl	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	**0 (0.0)**
	45-124mg/dl	38 (61.3)	20 (58.8)	0 (0.0)	0 (0.0)	2 (50.0)	0 (0.0)	1 (100.0)	**61 (60.4)**
	125-149mg/dl	9 (14.5)	5 (14.7)	0 (0.0)	0 (0.0)	2 (50.0)	0 (0.0)	0 (0.0)	**16 (15.8)**
	>=150mg/dl	15 (24.2)	9 (26.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	**24 (23.8)**
	Total	**62 (64.6)**	**34 (15.2)**	**0 (0.0)**	**0 (0.0)**	**4 (5.4)**	**0 (0.0)**	**1 (3.2)**	**101 (23.1)**
	No information	34 (35.4)	189 (84.8)	8 (100.0)	3 (100.0)	70 (94.6)	3 (100.0)	30 (96.8)	**337 (76.9)**
	Mean (SD)	141.1 (110.6)	143.7 (88.6)	_	_	120.5 (34.0)		98.0	**140.8 (100.6)**
Lowest saturation (n-172)	<90%	54 (58.1)	24 (49.0)	0 (0.0)	0 (0.0)	26 (89.7)	0 (0.0)	1 (100.0)	**105 (61.0)**
	91-94%	21 (22.6)	13 (26.5)	0 (0.0)	0 (0.0)	2 (6.9)	0 (0.0)	0 (0.0)	**36 (20.9)**
	95-100%	18 (19.4)	12 (24.5)	0 (0.0)	0 (0.0)	1 (3.4)	0 (0.0)	0 (0.0)	**31 (18.0)**
	Total	**93 (96.9)**	**49 (22.0)**	**0 (0.0)**	**0 (0.0)**	**29 (39.2)**	**0 (0.0)**	**1 (3.2)**	**172 (39.3)**
	No information	3 (3.1)	174 (78.0)	8 (100.0)	3 (100.0)	45 (60.8)	3 (100.0)	30 (96.8)	**266 (60.7)**
	Mean (SD)	79.8 (17.7)	77.5 (22.3)	_	_	64.3 (20.6)		65.0	**76.5 (20.3)**
Highest saturation (n=170)	<90%	10 (11.4)	1 (2.1)	0 (0.0)	0 (0.0)	3 (9.1)	0 (0.0)	0 (0.0)	**14 (8.2)**
	91-94%	6 (6.8)	1 (2.1)	0 (0.0)	0 (0.0)	3 (9.1)	0 (0.0)	0 (0.0)	**10 (5.9)**
	95-100%	72 (81.8)	45 (95.7)	0 (0.0)	0 (0.0)	27 (81.8)	0 (0.0)	2 (100.0)	**146 (85.9)**
	Total	**88 (91.7)**	**47 (21.1)**	**0 (0.0)**	**0 (0.0)**	**33 (44.6)**	**0 (0.0)**	**2 (6.5)**	**170 (38.8)**
	No information	8 (8.3)	176 (78.9)	8 (100.0)	3 (100.0)	41 (55.4)	3 (100.0)	29 (93.5)	**268 (61.2)**
	Mean (SD)	95.3 (10.2)	95.3 (14.3)	_	_	94.6 (12.1)	_	96.5 (0.7)	**95.2 (11.7)**

Appendix 33: Presumed causes of neonatal deaths

Cause of death	Immediate cause n=433	Secondary cause1 n=376	Secondary cause 2 n=161	Secondary cause 3 n=34	Total n=1004
Hypoxia	218 (50.3)	2 (0.5)	1 (0.6)	0 (0.0)	221 (22.0)
Birth Asphyxia	39 (9.0)	152 (40.4)	11 (6.8)	0 (0.0)	202 (20.1)
Prematurity	5 (1.2)	59 (15.7)	37 (23.0)	4 (11.8)	105 (10.5)
Respiratory Distress Syndrome	55 (12.7)	40 (10.6)	4 (2.5)	1 (2.9)	100 (10.0)
Infection/ neonatal sepsis	37 (8.5)	13 (3.5)	4 (2.5)	1 (2.9)	55 (5.5)
Prolonged labour	0 (0.0)	8 (2.1)	33 (20.5)	4 (11.8)	45 (4.5)
Feeds Aspiration	20 (4.6)	14 (3.7)	4 (2.5)	0 (0.0)	38 (3.8)
Meconium Aspiration	11 (2.5)	16 (4.2)	10 (6.2)	0 (0.0)	37 (3.7)
Hypothermia	16 (3.7)	13 (3.6)	5 (3.1)	1 (2.9)	35 (3.5)
Congenital abnormality	5 (1.2)	10 (2.6)	6 (3.7)	1 (2.9)	22 (2.2)
Poor feeding	0 (0.0)	8 (2.1)	2 (1.2)	2 (5.9)	12 (1.2)
Hypoglycaemia	6 (1.4)	3 (0.8)	1 (0.6)	0 (0.0)	10 (1.0)
Brain damage	0 (0.0)	3 (0.8)	7 (4.3)	0 (0.0)	10 (1.0)
Shock	6 (1.4)	1 (0.3)	0 (0.0)	0 (0.0)	7 (0.7)
Delayed decision	0 (0.0)	0 (0.0)	3 (1.9)	4 (11.8)	7 (0.7)
Pneumonia	2 (0.5)	4 (1.1)	0 (0.0)	0 (0.0)	6 (0.6)
Bleeding	1 (0.2)	2 (0.5)	2 (1.2)	0 (0.0)	5 (0.5)
Anaemia	4 (0.9)	1 (0.3)	0 (0.0)	0 (0.0)	5 (0.5)
CPD	0 (0.0)	1 (0.3)	2 (1.2)	2 (5.9)	5 (0.5)
Jaundice	0 (0.0)	4 (1.1)	1 (0.6)	0 (0.0)	5 (0.5)
Difficulty breech delivery	0 (0.0)	1 (0.3)	1 (0.6)	3 (8.9)	5 (0.5)
Other conditions	8 (1.8)	21 (5.6)	27 (16.8)	11 (32.4)	67 (6.7)

Appendix 34: Modifiable factors and proposed action

Avoidable factors/Actions	Hospital 1	Hospital 2	Hospital 3	Hospital 4	Hospital 5	Hospital 6	Hospital 7	Total
Number of deaths reviewed	96	223	8	3	74	3	31	438
Health Provider factors								
Poor monitoring of sick neonates	109 (38.7)	43 (11.7)	6 (21.4)	5 (35.7)	62 (39.2)	0 (0.0)	24 (25.3)	249 (26.1)
Inadequate documentation	45 (16.0)	54 (14.7)	2 (7.1)	0 (0.0)	3 (1.9)	2 (18.2)	13 (13.7)	119 (12.5)
Inadequate clinical and nursing review for critically ill neonate	59 (20.9)	25 (14.1)	5 (17.9)	1 (7.1)	15 (9.5)	1 (9.1)	4 (4.2)	110 (11.5)
Poor management and treatment procedures	18 (6.4)	57 (15.5)	9 (32.1)	2 (14.3)	21 (13.3)	0 (0.0)	2 (2.1)	109 (11.4)
Inadequate feeding	32 (11.3)	28 (7.6)	2 (7.1)	4 (28.6)	11 (7.0)	0 (0.0)	6 (6.3)	83 (8.7)
Delayed decision to refer, deliver, review, and manage	1 (0.4)	42 (11.4)	0 (0.0)	0 (0.0)	7 (4.4)	0 (0.0)	18 (18.9)	68 (7.1)
Poor monitoring of labour progress	0 (0.0)	27 (7.3)	0 (0.0)	0 (0.0)	7 (4.4)	0 (0.0)	10 (10.5)	44 (4.6)
Inadequate investigation	12 (4.3)	13 (3.5)	1 (3.6)	0 (0.0)	4 (2.5)	1 (9.1)	1 (1.1)	32 (3.4)
Inadequate skills among health workers	0 (0.0)	19 (5.2)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	8 (8.4)	28 (2.9)
Inadequate education to mothers	0 (0.0)	3 (0.80	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.3)
Total health provider factors	276	311	25	12	131	4	86	845 (88.5)
Mean number of factors identified per death	2.9	1.4	3.1	4	1.8	1.3	2.8	1.9
Administrative factors								
Lack of facilities, equipment, drugs and supplies	0 (0.0)	21 (5.7)	1 (3.6)	0 (0.0)	15 (9.5)	1 (9.1)	3 (3.2)	40 (4.2)
Inadequate number of staff	1 (0.4)	1 (0.3)	2 (7.1)	0 (0.0)	1 (0.6)	2 (18.2)	0 (0.0)	7 (0.7)
Inadequate ambulance	0 (0.0)	8 (2.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	8 (0.8)

Avoidable factors/Actions	Hospital 1	Hospital 2	Hospital 3	Hospital 4	Hospital 5	Hospital 6	Hospital 7	Total
Number of deaths reviewed	96	223	8	3	74	3	31	438
lack of standardised case management protocols	2 (0.7)	4 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	6 (0.6)
Total administrative factors	3	34	3	0	16	3	3	**61 (6.4)**
Mean number of factors identified per death	0.0	0.2	0.4	0	0.2	1	0.1	**0.1**
Caregiver factors								
Delay seeking care	3 (1.1)	22 (6.0)	0 (0.0)	2 (14.3)	11 (7.0)	4 (36.4)	6 (6.3)	48 (5.0)
Treatment refusal	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.1)
Total caregivers' factors	3	23	0	2	11	4	6	**49 (5.1)**
Mean number of factors identified per death	0.0	0.1	0	0.6	0.1	1.3	0.2	**0.1**
Overall total	**282 (29.5)**	**368 (38.5)**	**28 (2.9)**	**14 (1.7)**	**158 (16.5)**	**11 (1.2)**	**95 (9.9)**	**955**
Mean number of factors identified per death (total)	**2.9**	**1.7**	**3.5**	**4.7**	**2.1**	**3.7**	**3.1**	**2.1**
Proposed solutions								
Improve quality of management of sick neonates	227 (78.0)	211 (49.4)	14 (51.8)	2 (50.0)	59 (34.3)	2 (22.2)	54 (58.7)	**569 (55.7)**
Lobby and provides equipment, facilities, drugs and supplies	3 (1.0)	31 (7.3)	1 (3.7)	0 (0.0)	56 (32.6)	4 (44.4)	5 (5.4)	**100 (9.8)**
Capacity building of staff	4 (1.4)	44 (10.3)	3 (11.1)	1 (25.0)	18 (10.5)	2 (22.2)	15 (16.3)	**87 (8.5)**
Improve documentation	49 (16.8)	27 (6.3)	1 (3.7)	1 (25.0)	3 (1.7)	0 (0.0)	3 (3.2)	**84 (8.2)**
Improve referral system	6 (2.1)	38 (8.9)	7 (25.9)	0 (0.0)	17 (9.9)	0 (0.0)	10 (10.9)	**78 (7.6)**
Health education and community sensitisation	2 (0.7)	40 (9.4)	0 (0.0)	0 (0.0)	16 (9.3)	1 (11.1)	5 (5.4)	**64 (6.3)**

Avoidable factors/Actions	Hospital 1	Hospital 2	Hospital 3	Hospital 4	Hospital 5	Hospital 6	Hospital 7	Total
Number of deaths reviewed	96	223	8	3	74	3	31	438
Improve quality management of labour and postnatal care	0 (0.0)	36 (8.4)	1 (3.7)	0 (0.0)	3 (1.7)	0 (0.0)	0 (0.0)	**40 (3.9)**
Total	**291 (28.5)**	**427 (41.8)**	**27 (2.6)**	**4 (0.4)**	**172 (16.8)**	**9 (0.9)**	**92 (9.0)**	**1022**
Mean number of solutions per death	**3.0**	**1.9**	**3.4**	**1.3**	**2.3**	**3**	**3.0**	**2.3**

Appendix 35: Frequency of neonatal death audit meetings by facility

	Hospital 1	Hospital 2	Hospital 3	Hospital 4	Hospital 5	Hospital 6	Hospital 7
Aug-19	1	3	0	0	0	0	1
Sep-19	0	3	0	0	0	1	1
Oct-19	0	1	1	0	0	0	2
Nov-19	0	3	0	0	0	0	0
Dec-19	0	0	0	0	0	0	0
Jan-20	1	0	1	0	0	0	0
Feb-20	1	0	0	0	0	0	1
Mar-20	1	1	0	0	0	0	0
Apr-20	1	0	0	0	0	1	0
May-20	1	3	0	0	0	0	0
Jun-20	4	0	0	0	0	0	0
Jul-20	4	3	0	0	0	0	0
Aug-20	2	4	0	0	1	0	0
Sep-20	0	6	0	1	2	1	0
Oct-20	0	10	1	0	1	0	0
Nov-20	2	2	1	0	0	0	2
Total meetings	**18**	**39**	**4**	**1**	**4**	**3**	**7**

Appendix 36: Health workers views about neonatal death audit process

Variable	Hosp1 n=6	Hosp2 n=6	Hosp3 n=4	Hosp4 n=5	Hosp5 n=5	Hosp6 n=4	Hosp7 n=5	Total n=35 (%)
Cadre of health worker								
Doctor/Clinician	2	2	1	1	1	1	1	9 (25.7)
Nurse	4	4	3	3	4	3	4	25(71.4)
Others	0	0	0	1	0	0	0	1 (2.9)
Section where the staff works at the hospital								
Maternity wards	2	2	1	2	2	2	4	15 (42.9)
Nursery ward	4	3	3	2	2	1	1	16 (45.7)
Administration	0	1	0	1	1	1	0	4 (11.4)
Knowledge								
Aware of maternal and neonatal death audits	6	6	4	5	5	4	5	35 (100.0)
Mentioned at least one reason for establishing such audits	5	6	4	5	5	4	5	34 (97.1)
Aware of presence of audit committee in their facility	6	6	4	5	5	4	5	35 (100.0)
Knew the main objective or vision of audit committee	5	6	2	3	4	4	5	29 (82.9)
Reported that the objective of audit has been communicated to all	4	6	2	1	1	2	4	20 (67.0)
Knew at least one core/constant member of audit committee	6	6	4	5	5	4	4	34 (97.1)
Aware of presence of quality improvement committee at the facility	5	6	4	5	5	1	5	31 (88.6)
Reported to be a member of quality improvement committee	4	3	3	3	5	2	2	22 (71.0)

Variable	Hosp1 n=6	Hosp2 n=6	Hosp3 n=4	Hosp4 n=5	Hosp5 n=5	Hosp6 n=4	Hosp7 n=5	Total n=35 (%)
Mentioned at least one relationship between death audit and quality improvement at the facility	3	5	3	4	5	2	3	25 (71.4)
View								
Believed that death audit can affect how people conduct maternal and newborn care anywhere	6	6	4	5	5	4	5	35 (100.0)
Believed that death audit can affect how people conduct maternal and newborn care at this facility	6	6	4	5	5	4	5	35 (100.0)
Impact								
Knew at least one recommendation provided by neonatal death audit committee	6	6	4	3	4	4	3	30 (85.7)
Remembered at least one action implemented due to audit recommendations	5	6	3	4	5	4	3	30 (85.7)
Mentioned at least one action implemented in their ward or facility due to audit	5	6	3	5	4	2	3	28 (80.0)
Ever seen any effect on maternal and newborn care in the hospital due to audit	5	6	4	5	5	3	4	32 (91.4)
Mentioned at least one recommendation to improve functions of audit committee	5	3	2	3	3	1	2	19 (54.3)

Appendix 37: Purposive criteria for hospital selection

1. A government public hospital
2. Either central or district hospital
3. Located in southern region of Malawi
4. Hospitals that conduct regular stillbirth or neonatal death audit
5. Wide range of neonatal mortality rates by including lowest, medium and highest district neonatal mortality rates (15-30 per 1000 births)

Appendix 38: Characteristics of participants participated in semi-structured interviews (n=38)

participant ID	Facility name	Department	Cadre	Other roles	Age (years)	Gender	Level of education	Professional experience
1	Hospital 1	Nursery ward	Nursing Officer	Neonatal focal person	29	F	Degree	4 years
2	Hospital 1	Nursery ward	Nurse/Midwife Technician		36	F	College Diploma	10years
3	Hospital 1	Nursery ward	Nursing Officer	Nursery ward in-charge	38	F	Degree	15years
4	Hospital 1	Nursery/Paediatric wards	Clinical technician		36	M	College Diploma	10years
5	Hospital 1	Postnatal ward	Nursing Officer	Safe Motherhood Coordinator	30	F	Degree	5years
6	Hospital 1	Management team member	Chief Clinical Officer	Deputy Head of Department	51	M	College Diploma	29 years
7	Hospital 2	Labour ward	Senior Nursing Officer	Safe Motherhood Coordinator/ hospital Matron	30	F	Degree	5years
8	Hospital 2	Maternity wards	Senior Medical Officer		32	M	Honours Degree	3 months
9	Hospital 2	paediatric/Nursery wards	Clinical technician		41	M	College Diploma	6 years
10	Hospital 2	Nursery ward	Nurse/Midwife Technician		55	F	College Diploma	27years
11	Hospital 2	Nursery ward	Nurse/Midwife Technician	Neonatal focal person	39	F	College Diploma	17 years

participant ID	Facility name	Department	Cadre	Other roles	Age (years)	Gender	Level of education	Professional experience
12	Hospital 2	Management team member	District Nursing Officer		55	F	Degree	30years
13	Hospital 3	Maternity wards	Senior Nursing Officer	Safe Motherhood Coordinator	37	M	Master's Degree	12 years
14	Hospital 3	Paediatric/Nursery wards	Paediatric Clinical Officer		35	M	Degree	8 years
15	Hospital 3	Nursery ward	Nursing Officer		26	F	Degree	2 years
16	Hospital 3	Maternity and general wards	Chief Clinical Officer		50	M	Degree	30 years
17	Hospital 3	Nursery ward	Nursing Officer	Neonatal focal person/ In charge	33	F	Degree	10 years
18	Hospital 4	Management team member	Acting Administrator	Transport Officer	58	M	Diploma	30 years
19	Hospital 4	Nursery ward	Nurse/Midwife Technician		57	F	College Diploma	27 years
20	Hospital 4	Labour ward	Nursing Officer	Safe Motherhood Coordinator	32	F	Degree	8 years
21	Hospital 4	Nursery ward	Nursing Officer	Neonatal Focal Person/Nursery in charge	30	F	Degree	6 years
22	Hospital 4	Maternity and general wards	Senior Medical Officer		25	M	Honours Degree	5 months
23	Hospital 5	Labour ward	Nursing Officer	Labour ward in charge	32	F	Degree	8 years
24	Hospital 5	Postnatal ward	Nurse/Midwife Technician		26	M	College Diploma	4 years

participant ID	Facility name	Department	Cadre	Other roles	Age (years)	Gender	Level of education	Professional experience
25	Hospital 5	Nursery ward	Nursing Officer	Neonatal focal person/ in charge	30	F	Degree	6 years
26	Hospital 5	Paediatric/Nursery wards	Clinical Officer		30	M	Degree	6years
27	Hospital 5	Management team member	District Nursing Officer		53	F	Degree	32 years
28	Hospital 6	Management team member	Hospital Matron		38	F	Master's Degree	8 years
29	Hospital 6	Maternity ward	Clinical technician		28	M	Diploma	3 years
30	Hospital 6	Nursery ward	Nursing Officer	Nursery ward in charge	23	F	Degree	1 year
31	Hospital 6	Antenatal ward	Nurse/Midwife Technician	Safe Motherhood Coordinator	28	M	College Diploma	4 years
32	Hospital 6	Labour ward	Nursing Officer	Labour ward in charge	30	F	Degree	3 years
33	Hospital 7	Labour ward	Nursing Officer	Safe Motherhood Coordinator	34	M	Degree	11 years
34	Hospital 7	Antenatal ward	Registered Nurse/Midwife		35	F	University Diploma	10 years
35	Hospital 7	Maternity wards	Clinical technician		37	M	Diploma	2 years
36	Hospital 7	Nursery ward	Nurse/Midwife Technician		38	F	College Diploma	8 years
37	Hospital 7	Labour ward	Nurse/Midwife Technician	Helping Baby Breathe (HBB) coordinator	40	F	College Diploma	15 years
38	Hospital 7	Management team member	District Medical Officer		30	M	Honours Degree	3 years

Appendix 39: Characteristics of participants participated in 7 focus group discussions (n=49)

FGD Number	Facility name	Department	Cadre	Other roles	Age (years)	Gender	Level of education	Professional experience
Focus Group Discussion 1								
FGD 1.1	Hospital 1	Nursery/Paediatric	Clinical Officer	Neonatal Focal Person	33	M	Degree	10 years
FGD 1.2	Hospital 1	Nursery ward	Nurse/Midwife Technician		36	F	College Diploma	10years
FGD 1.3	Hospital 1	Nursery ward	Nurse/Midwife Technician		26	F	College Diploma	1 year
FGD 1.4	Hospital 1	Nursery ward	Nursing Officer	Nursery ward in charge	38	F	Degree	15years
FGD 1.5	Hospital 1	Nursery/Paediatric wards	Clinical technician		36	M	College Diploma	10years
FGD 1.6	Hospital 1	Nursery ward	Nursing Officer	Deputy ward in charge	32	M	Degree	9 years
FGD 1.7	Hospital 1	Nursery ward	Registered Nurse/Midwife		42	M	University Diploma	10 years
Focus Group Discussion 2								
FGD 2.1	Hospital 2	Nursery ward	Nurse/Midwife Technician		55	F	College Diploma	27years
FGD 2.2	Hospital 2	Maternity wards	Senior Medical Officer		32	M	Honours Degree	3 months
FGD 2.3	Hospital 2	Nursery ward	Nursing Officer	Ward in charge	35	F	Degree	12 years
FGD 2.4	Hospital 2	Nursery ward	Nurse/Midwife Technician		28	M	College Diploma	3 years

FGD Number	Facility name	Department	Cadre	Other roles	Age (years)	Gender	Level of education	Professional experience
FGD 2.5	Hospital 2	Nursery ward	Nurse/Midwife Technician		38	F	College Diploma	10 years
FGD 2.6	Hospital 2	Nursery ward	Nurse/Midwife Technician		50	F	College Diploma	26 years
FGD 2.7	Hospital 2	Labour ward	Registered Nurse/Midwife		30	F	University Diploma	3 years
FGD 2.8	Hospital 2	Labour ward	Registered Nurse/Midwife		26	F	University Diploma	1 year
Focus Group Discussion 3								
FGD 3.1	Hospital 3	Paediatric/Nursery ward	Clinical Officer		40	F	Degree	14 years
FGD 3.2	Hospital 3	Nursery ward	Nursing Officer		26	F	Degree	2 years
FGD 3.3	Hospital 3	Nursery ward	Nurse/Midwife Technician		34	F	College Diploma	10 years
FGD 3.4	Hospital 3	Postnatal ward	Nurse/Midwife Technician		23	M	College Diploma	2 years
FGD 3.5	Hospital 3	Paediatric ward	Nursing Officer	Paediatric ward in charge	32	F	Degree	8 years
FGD 3.6	Hospital 3	Labour ward	Nursing Officer	Labour ward in charge	38	M	Degree	16 years
FGD 3.7	Hospital 3	Paediatric/Nursery wards	Paediatric Clinical Officer		35	M	Degree	8 years
Focus Group Discussion 4								
FGD 4.1	Hospital 4	Labour ward	Nursing Officer		29	F	Degree	4 years
FGD 4.2	Hospital 4	Nursery ward	Nursing Officer		28	F	Degree	2 years
FGD 4.3	Hospital 4	Postnatal ward	Nursing Officer		27	M	Degree	2 years

FGD Number	Facility name	Department	Cadre	Other roles	Age (years)	Gender	Level of education	Professional experience
FGD 4.4	Hospital 4	Paediatric ward	Nursing Officer		28	M	Degree	2 years
FGD 4.5	Hospital 4	Labour ward	Nursing Officer	Safe Motherhood Coordinator	32	F	Degree	8 years
Focus Group Discussion 5								
FGD 5.1	Hospital 5	Labour ward	Nursing Officer	Labour ward in charge	32	F	Degree	8 years
FGD 5.2	Hospital 5	Nursery ward	Nursing Officer	Neonatal focal person/Nursery in charge	30	F	Degree	6 years
FGD 5.3	Hospital 5	Nursery ward	Nurse/Midwife Technician		29	M	College Diploma	5 years
FGD 5.4	Hospital 5	Postnatal ward	Nursing Officer		22	F	Degree	3 months
FGD 5.5	Hospital 5	Maternity wards	Clinical technician		26	F	Diploma	3 years
FGD 5.6	Hospital 5	Postnatal ward	Nurse/Midwife Technician		40	F	Diploma	1 year
FGD 5.7	Hospital 5	Paediatric/Nursery wards	Clinical Officer		30	M	Degree	6years
FGD 5.8	Hospital 5	Nursery ward	Nursing Officer		23	F	Degree	1 year
FGD 5.9	Hospital 5	Postnatal ward	Nurse/Midwife Technician		26	F	College Diploma	2 years
FGD 5.10	Hospital 5	Labour ward	Nurse/Midwife Technician		34	F	College Diploma	5 years
Focus Group Discussion 6								
FGD 6.1	Hospital 6	Nursery ward	Nurse/Midwife Technician		28	F	College Diploma	6 years

FGD Number	Facility name	Department	Cadre	Other roles	Age (years)	Gender	Level of education	Professional experience
FGD 6.2	Hospital 6	Antenatal ward	Nurse/Midwife Technician	Safe Motherhood Coordinator	28	M	College Diploma	4 years
FGD 6.3	Hospital 6	Labour ward	Nursing Officer	Labour ward in charge	30	F	Degree	3 years
FGD 6.4	Hospital 6	Nursery ward	Nursing Officer	Nursery ward in charge	23	F	Degree	1 year
FGD 6.5	Hospital 6	Labour ward	Nurse/Midwife Technician		26	M	College Diploma	4 years
FGD 6.6	Hospital 6	Maternity ward	Clinical technician		28	M	Diploma	3 years
Focus Group Discussion 7								
FGD 7.1	Hospital 7	Antenatal ward	Registered Nurse/Midwife		35	F	University Diploma	10 years
FGD 7.2	Hospital 7	Nursery ward	Nurse/Midwife Technician		38	F	College Diploma	8 years
FGD 7.3	Hospital 7	Labour ward	Nurse/Midwife Technician	Helping Baby Breathe (HBB) coordinator	40	F	College Diploma	15 years
FGD 7.4	Hospital 7	Labour ward	Nursing Officer	Deputy Safe Motherhood Coordinator	34	M	Degree	11 years
FGD 7.5	Hospital 7	Maternity wards	Clinical technician		37	M	Diploma	2 years
FGD 7.6	Hospital 7	Nursery ward	Nurse/Midwife Technician		30	M	College Diploma	6 years