ASSESSING THE EFFECT OF THE FACILITATED IMPLEMENTATION OF A CO-DESIGNED NEWBORN CLINICAL AUDIT TOOL ON OVERCOMING THE MODIFIABLE FACTORS IN THE FEEDING PRACTICES OF LOW BIRTH WEIGHT NEWBORNS: A MIXED METHODS STUDY

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A THESIS SUBMITTED IN PARTIAL FULFILMENT FOR THE AWARD OF DOCTOR OF PHILOSOPHY IN PAEDIATRICS AND CHILD HEALTH AT THE UNIVERSITY OF NAIROBI.

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Declaration

I declare that this dissertation is my own original work and has not been published elsewhere or presented for the award of a degree in any other institution. It has been prepared under the guidance of my supervisors.

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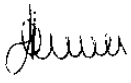
Signed  Date 29/11/2023.

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Dedication

I dedicate this PhD thesis to my loving and supportive parents; Prof and Mrs Ogola.

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Abbreviations and Acronyms

ARO	Assistant Research Officer
BPD	Bronchopulmonary dysplasia
CBA	Controlled Before and After
CCC	Comprehensive Care Clinic
CCM	Chronic Care Model
CIN-N	Clinical Information Network for Newborns
CKD	Chronic Kidney Disease
CME	Continuing Medical Education
CMR	Crude Mortality Rate
C.O.	Clinical Officer
CPAP	Continuous Positive Airway Pressure
CQI	Continuous Quality Improvement
cRCT	Cluster Randomised Controlled Trial
DB	Database
DQA	Data Quality Analysis
E tool	Electronic Tool
ELBW	Extremely Low Birth Weight
ESPGAN	European Society of Paediatric Gastroenterology and Nutrition
ETAT+	Emergency Triage Assessment and Treatment plus Admission
ET	Endotracheal Tube
FGD	Focus Group Discussion
GIC	Generic Instructor's Course

GI System	Gastrointestinal System
HCD	Human Centred Design
HIC	High-Income Countries
HIE	Hypoxic Ischaemic Encephalopathy
HIV	Human Immunodeficiency Virus
HMT	Hospital Management Team
HRIO	Health Records Information Officer
iPARIHS	Integrated Promoting Action on Research Implementation in Health Sciences
IQR	Interquartile Range
ISO	International Organisation for Standardisation.
IVF	Intravenous Fluid
KDHS	Kenya Demographic Health Survey
KEMRI	Kenya Medical Research Institute
KMC	Kangaroo Mother Care
KNH	Kenyatta National Hospital
KPA	Kenya Paediatric Association
KWTRP	KEMRI Wellcome Trust Research Programme
LBW	Low Birth Weight
LHS	Learning Health System
LONNS	Late Onset Neonatal Sepsis
LLINs	Long Lasting Insecticide Treated Nets
LMICs	Low-and-low-middle-income countries
MDT	Multidisciplinary Audit Team

MLKH	Mama Lucy Kibaki Hospital
MMED	Master of Medicine
M.O.	Medical Officer
MOH	Ministry of Health
MPDSR	Maternal and Perinatal Death Surveillance and Response
NAR	Neonatal Admission Record
NBU	Newborn unit
NDP	National Demonstration Project
NEC	Necrotising Enterocolitis
NEST Programme	Newborn Essential Solutions and Technologies
NG tube	Nasogastric Tube
NGT	Nominal Group Technique
NICU	Neonatal Intensive Care Unit
NMR	Neonatal mortality rate
PDSA cycle	Plan-Do-Study-Act cycle
PMRH	Pumwani Maternity Referral Hospital
PO	Participant Observation
QI	Quality Improvement
RAP	Reflective Adaptive Process
RBS	Random Blood Sugar
RCT	Randomised Controlled Trial
REDCap	Research Electronic Data Capture
SD	Self-Direction
SENSS score	Score for Essential Signs and Symptoms

SSNB	Small and Sick Newborn
UoN	University of Nairobi
VLBW	Very Low Birth Weight
WHO	World Health Organisation

Operational Definitions

Clinical audits	Improving the quality of newborn care and ensuring positive outcomes by reviewing the care rendered to both mortality and near-miss cases. These are compared against the set standards or criteria to implement changes where there are gaps in monitoring structures to confirm improvements in health care delivery.(1)
Complex health systems	A health system composed of many interrelated components which influence each other making it difficult to forecast the behaviour of the system based on its component parts.(2)
Complex interventions	Interventions with several interacting components and are characterised by interdependence among many factors, adapting and evolving factors, emergent outcomes created by the connections in the system and non-linearity between inputs and outputs.(3)
Continuing medical education	Educational fora attended by health workers involved in newborn care with the purpose of learning the methods of conducting the audit process.(4)
Extremely low birth weight	A birth weight of less than 1000 grams.(5)
Facilitation	Refers to a technique where an individual or 'change agent' provides support to others to help them change their ways of thinking and working and build their capacity to enable their own change process.(6)

Feed intolerance	Vomiting or abdominal distension that results in tolerance of ≤ 50 % of required enteral feeds for the postnatal day and weight or vomiting ≥ 3 times in 24 hours resulting in the temporary discontinuation of feeds.(7)
Full enteral feeds	*Unstable preterm newborns* - Attaining the required amount of fluid intake for the day of life as enteral feeds independent of intravenous fluids in unstable preterm neonates with a birthweight of 1000g-2500g OR *Stable preterm newborns* with a birthweight of 1000g-1500g - attaining enteral feeds at 150ml/kg/day.
Human Centred Design	An approach to the design and development of a quality improvement innovations that puts human needs, capabilities, and behaviour first, then designs to accommodate those needs, capabilities, and ways of behaving. (8)
iPARIHS framework	A framework that proposes that successful implementation of a quality improvement initiative is the function of four core constructs: The innovation, context, recipients and facilitation.(6)
Implementation guide	This will be the standard operating procedure for conducting the newborn clinical audits including: Composition of the multidisciplinary audit team, frequency of audit meetings, environment during the audit meetings, method of selection of cases for auditing use of a structured audit tool to guide in identifying and categorising modifiable factors, completion of audit cycle.(9)
Late onset neonatal sepsis	The onset of clinical signs and symptoms suggestive of sepsis with a positive septic screen occurring in neonates after 72 hours of life.(10)

Learning health system	A system that is designed to generate and apply the best evidence for the collaborative health care choices of each patient and provider; to drive the process of discovery as a natural outgrowth of patient care; and to ensure innovation, quality, safety, and value in health care.(11)
Life threatening condition	Severe illness that increases the likelihood of mortality. This includes one or more of: Preterm and low birth weight neonates, Apgar score < 7 at 5 minutes, diagnosis of neonatal sepsis, use of respiratory support – oxygen/ nasal continuous positive airway pressure/ mechanical ventilation, use of anticonvulsants, severe jaundice based on bilirubin levels, cardiopulmonary resuscitation, use of blood and blood products.(12)
Low birth weight	Newborns born with a birth weight of < 2500 grams.(5)
Modifiable factor	A care management problem that involves care that deviates from the safe limits of practice as laid down in guidelines, standards, protocols or normal practice and has the potential to lead, directly or indirectly, to an adverse outcome for the patient.'(13)
Mortality audit	The process of capturing information on the number and causes of neonatal deaths, and then identifying specific cases for systematic, critical analysis of the quality of care received, in a no-blame, interdisciplinary setting, with a view to improving the care provided to the neonates.(14)
Near miss cases	Newborns who suffer a life-threatening condition following birth and survive the first 28 days of life.(15)

Necrotising enterocolitis	A syndrome of acute intestinal necrosis characterised by clinical features such as; feed intolerance, abdominal distension, blood in stool and abdominal radiograph features of gaseous distension of bowel lumen, pneumatosis intestinalis, gas in the portal venous system or free air in the abdomen.(16)
Neonatal period	Period from birth to 28 completed days of life.(17)
Neonatal sepsis	Blood stream infection in newborns aged < 28 days presenting with all or some of: abnormal cardiovascular signs, abnormal respiratory signs, abnormal neurological signs, abnormal temperature, feed intolerance OR abnormal laboratory tests including: positive blood culture, elevated white blood cell counts and elevated immature: total neutrophil count.(10)
Newborn Essential Solutions and Technologies Programme	This is a programme whose goal is to provide newborn essential technologies to address the leading causes of newborn deaths with an aim to catalyse the achievement of Sustainable Development Goal 3 to reduce the neonatal mortality rate to ≤ 12/1000 live births.(18)
Perinatal period	Period from 22 weeks gestation to 7 completed days after birth.(19)
Rapid increment of feeds	Increasing enteral feeds by 30-40 ml/kg/day.(20)
Root cause analysis	"A process for identifying the basic or causal factor(s) underlying variation in performance. Variation in performance can (and often does) produce unexpected and undesired adverse outcomes, including the occurrence or risk of a sentinel event."(21)
Slow increment of feeds	Increasing enteral feeds by 15-20 ml/kg/day.(20)

Successful implementation	Successful implementation was defined as having regular audit meetings and completing documentation in the audit tool with the filling of the action plan summary form.
Systems thinking	"An approach that challenges simple cause and effect assumptions, and instead sees healthcare and other systems as a dynamic process. One where the interactions and relationships of different components simultaneously affect and are shaped by the system."(22)
Usability of an intervention	The extent to which a healthcare worker in newborn care can use the audit tool to improve the quality of newborn care with effectiveness, efficiency and satisfaction.(23)
Very low birth weight	Birth weight of 1000-1499 grams.(17)
Quality of care	Defined as the attributes of a health care service that are taken by the relevant stakeholders to be important enough to be measured and promoted within an organization.(24)

Abstract

Background

Prematurity and its complications account for the majority of the deaths during the newborn period in sub-Saharan Africa. The majority of these deaths are from preventable causes, indicating poor quality of in-hospital care. Clinical audits are proven to be an important quality improvement intervention that enable health workers to reflect on their practice and identify and act on modifiable gaps in the care provided to the small and sick newborns. The challenge however lies in the implementation strategy used that can be flexible enough to identify the requirements of an individual setting and adapt to them. Facilitation utilises such an approach and has proved to be effective for implementing complex interventions.

Study objective: To design and introduce the use of a newborn audit tool and its implementation guide to reduce the time to regain birth weight of LBW newborns through improved feeding practices in County Hospitals in Kenya.

Study methods

Study design: A quasi-experimental study design of the implementation science format that uses a mixed methods approach.

Study methods: The study was conducted in six hospitals that are part of a Clinical Information Network. These included Pumwani Maternity Referral Hospital (PMRH), Kenyatta National Hospital (KNH), Mama Lucy Kibaki Hospital, Kiambu County Referral Hospital, Thika Level 5 Hospital and Machakos Level 5 Hospital. The study population included two arms; the health workers who were involved in the audit meetings and the low birth weight and very low birth weight newborns who were used to evaluate the outcomes. The co-design of a newborn clinical audit tool and audit implementation guide using a three-step Human Centred Design (HCD) approach. The three steps included; (1) understanding the context,

the users and the available audit tools, (2) the cognitive walkthrough where the prototype audit tool was taken through several cycles of reviewing with users on real cases in KNH and PMRH newborn units and refining it based on their feedback, and (3) usability testing where the final prototype tool and the implementation guide were tested in two high volume newborn units to determine their usability.

The integrated Promoting Action on Research Implementation in Health Sciences (iPARIHS) framework was used as the conceptual framework to guide the implementation of the final audit tool and implementation guide in four hospitals using facilitation as a strategy with the intended recipients in their contextual setting. The four hospitals were randomly assigned to experimental and control arms and facilitation was used as an implementation strategy in the experiment arm. The secondary outcome of interest was the effect of facilitation on mortality of the LBW newborn. Evaluation of the effect of facilitation was done using a mixed methods approach. A controlled before and after (CBA) study was used to evaluate the effect of facilitation on improving newborn feeding practices and subsequently, reducing their time to regain birth weight. Participant observation was used to understand why and how facilitation worked or did not work.

Data analysis: Clinical characteristics were summarised descriptively. The inferential statistics used a competing risk survival analysis as the univariate analysis to estimate the probability of regaining birth weight with death as the competing risk. A Cox proportional cause-specific hazard regression analysis was used for the multivariable analysis. Qualitative data were managed on NVivo 12 software and thematic analysis was used for the qualitative analysis.

Results

Quantitative results: I included a total of 2956 low birth weight (LBW) (1500 – 2499g) and very low birth weight (VLBW) (1000 – 1499g) newborns from both study arms throughout the study period. The cumulative incidence function (CIF) curves showed that the probability of regaining birth weight compared to death was comparable between experimental (facilitation) and control study arms (non-

facilitated sites) and across the study periods. There was, however, a significant difference in overall mortality between the experiment and control hospitals in the post-intervention period with the probability of death peaking at 13% (95% CI 0.1 – 0.16) in the control arm compared to 6.6% (95% CI 0.04 – 0.09) in the experiment arm. The cause-specific hazard regression demonstrated no difference in the hazard of regaining birth weight in the experiment arm compared to the control arm (HR 0.95, p = 0.75) after adjusting for all the covariates. There was, however, a significant decrease in the hazard of death among the newborns in the experiment arm compared to the control arm (HR 0.64, p = 0.019).

Qualitative results: The factors supporting the implementation of the newborn clinical audit tool using facilitation included: Leadership with a dynamic mindset, ownership of the clinical audit, availability of infrastructure and the interrelatedness of the departments. The barriers included: Limited leadership support, resistance to change in how clinical audits were conducted, lack of a shared vision, power dynamics revealing team-based hierarchies, infrastructural constraints, hindrances to effective feed and fluid management and slow organizational adoption of digital technology.

Conclusion

Facilitation as an implementation strategy recognizes the complex, unpredictable and non-linear relationship between an innovation, the recipients and context making it an effect implementation strategy for the clinical audit. Facilitation was effective in enabling more use of audit processes. However, I observed no difference in the primary outcome but did observe a difference in mortality that likely requires further investigation.

Chapter 1: Introduction/Background

In the first chapter of this thesis, I will give a detailed introduction into; the preterm and low birth weight newborn survival gap in low and low-middle-income countries, the complexities of the interventions required to improve the quality of care, the use of clinical audits as a quality improvement intervention and the multifaceted implementation strategies required for successful implementation of the interventions into routine clinical practice.

The newborn survival gap between high-income countries (HICs) and low and low-middle-income countries (LMICs) has widened over the past few decades with 98% of all neonatal deaths occurring in LMICs.(25) In Kenya, the latest Kenya Demographic Health Survey (KDHS) conducted in 2022 illustrates a neonatal mortality rate (NMR) of 21/1000 live births compared to 22/1000 live births in the 2014 KDHS.(26) Mortalities due to prematurity and its complications account for the largest proportion of deaths during the neonatal period.(25) Irimu *et al, 2021* described neonatal mortality among inborn newborn unit (NBU) admissions in 16 Kenyan county hospitals. They demonstrated that the median mortality among the newborns with a birth weight < 1000g (extremely low birth weight (ELBW)) was 80%, 40% among the newborns with a birth weight between 1000-1499g (very low birth weight (VLBW)), 14% among the 1500 – 1999g (low birth weight (LBW)) and < 10% among each weight category above this.(27) The preterm and low birth weight newborns in LMICs die needlessly from conditions that can be prevented using basic and affordable interventions such as; optimising obstetric care, appropriate neonatal resuscitation, provision of warmth, feeding support, infection prevention practices and respiratory support which have the potential to reduce preterm deaths by 50%.(5, 28-31) Lessons can be borrowed from HICs which lowered their NMR from ≥ 40/1000 to < 15/1000 live births between 1900 and 1960s through optimising the basic neonatal care services. Only after this did the introduction of intensive care services result in a further decline in NMR.(5) This strengthens the evidence that preterm deaths in LMICs are not inevitable and that optimising the resources that are within reach can

accelerate the decline in NMR to attain the sustainable development goals (SDG 3) 2030 targets of a NMR of ≤ 12/1000 live births.(32, 33)

These interventions though described as basic are quite complex as they require an interaction between several stakeholders to ensure their success. Using feeding practices as an example, there are evidence-based guidelines for preterm and LBW feeding adapted from Cochrane reviews of randomised controlled trials that promote the early initiation and rapid progression of enteral feeds with clear evidence of the benefits of this to a preterm newborn.(20, 34, 35) There is evidence that poor enteral feeding practices in the preterm newborn are detrimental to their well-being in both the short and long term leading to complications such as; feed intolerance, post-natal growth restriction, prolonged hospital stay, increased risk of late onset neonatal sepsis and impaired neurodevelopmental outcomes.(36-38) Despite this, there is poor adherence to preterm feeding guidelines even in HICs.(39) Appropriate feeding is influenced by an interaction between; health workers and their inherent beliefs, fear of the development of necrotising enterocolitis (NEC) in the premature newborn, the extra care and support that is required while feeding a preterm newborn in an already demanding newborn unit (NBU) or neonatal intensive care unit (NICU) and parents with concerns about the ability of the fragile preterm to tolerate enteral feeds.(40) The Clinical Information Network for Neonatology (CIN-N) in Kenya is a collaborative effort between the Ministry of Health (MoH), Kenya Medical Research Institute (KEMRI)-Wellcome Trust Research Programme (KWTRP), the Kenya Paediatric Association (KPA) and 23 Kenyan county hospitals. The network was developed with a vision to become leaders in the use of information to improve paediatric hospital care in Kenya and the region.(41) Significant effort has been made by the CIN-N to use local data from county hospitals to improve the provision of neonatal inpatient care through promoting the adoption of evidence-based guidelines.(42) Before beginning this study, I looked at the 2019 data on feeding practices of the stable LBW newborns (1500 – 2499g) from four county hospital NBU's present in the CIN database. This showed that in three of the four hospitals < 5% of LBW

preterms in these NBUs receiving any enteral feeds on the first day of life. This is despite the national newborn care guidelines promoting the initiation of maximum enteral feeds on the first day of life for stable LBW newborns. This is evidence that the preterm feeding guidelines are not strictly adhered to in all facilities. The example of preterm and LBW feeding practices demonstrates how addressing newborn mortality requires a strategy that adapts a holistic approach. An effective strategy is one that understands the linkages, interactions and feedback between the different elements of the health system.

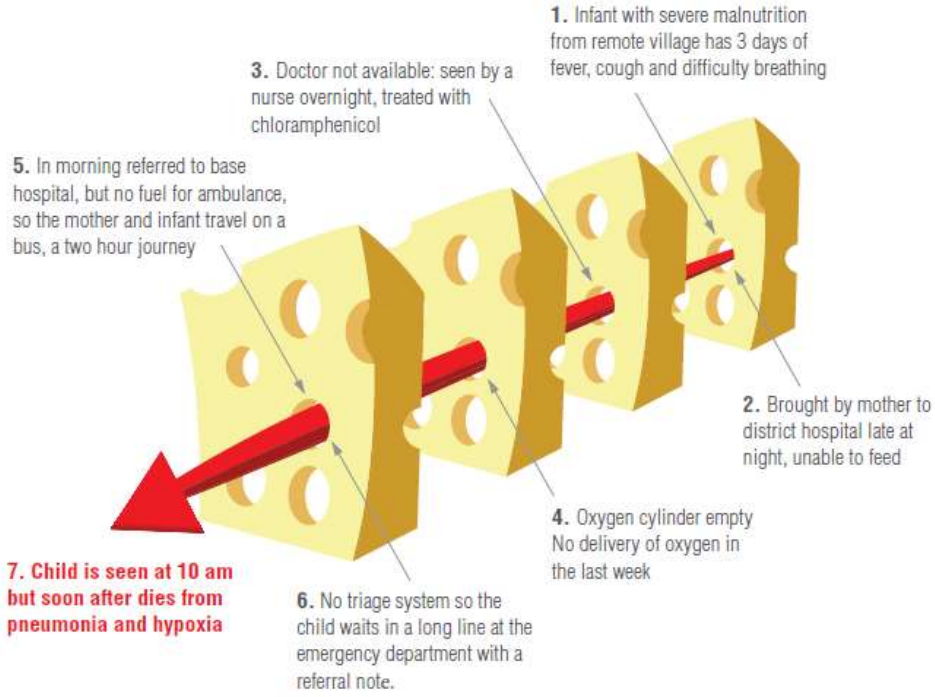


Figure 1: Swiss cheese model- Slices represent the barriers ensuring patient safety across the health system, the holes represent the modifiable system deficiencies. Source: "Improving the quality of paediatric care: an operational guide for facility-based audit and review of paediatric mortality."{World Health, 2018 #131}

Quality of care is defined as the attributes of a health care service that are taken by the relevant stakeholders to be important enough to be measured and promoted within an organization.(24) Newborn clinical audits are an effective way of measuring the quality of clinical care provided to the small and sick newborns (SSNBs) as they allow for a systematic assessment of patient management from

the point of initial contact which is the antenatal period to the point of death or occurrence of a near-miss event.(1, 14) Clinical audits examine three dimensions of health care; structure, process of care and outcome with the process of care being the most amenable to local change.(43) The process of care at each step in the continuum are compared against the accepted standards based on evidence based guidelines.(1) Clinical audits are based on the action learning theory which can be described as a team-based process of engagement, learning and reflection on one's own experiences and the outcomes of their actions. The health workers modify their behaviours, beliefs and attitudes on the basis of this reflection and this is summarised as the audit cycle in Figure 2 below.(44) Using a systems thinking approach, an understanding that adverse events in health care occur as a consequence of the accumulation of oversights and errors involving the entire health system.(45) This is known as the 'Swiss cheese model' and an example is provided in Figure 1 above. Through a team-based approach, the health workers document the care provided in a structured clinical audit tool and use this as a guide to reflect on the modifiable deficiencies that weaken the barriers that have been placed across the health system to ensure patient safety through a root cause analysis model.(21) A systems approach allows for targeted health system strengthening in order to provide solutions that prevent the re-occurrence of the problems rather than dealing with the symptoms.(46) The prerequisites for a successful clinical audit include the availability of evidence-based guidelines, good quality data and health workers trained on the use of the clinical audit tool, completion of the audit cycle and conducting the clinical audits under a favourable environment based on; a no-blame, non-judgemental environment, confidentiality and an environment that encourages learning.

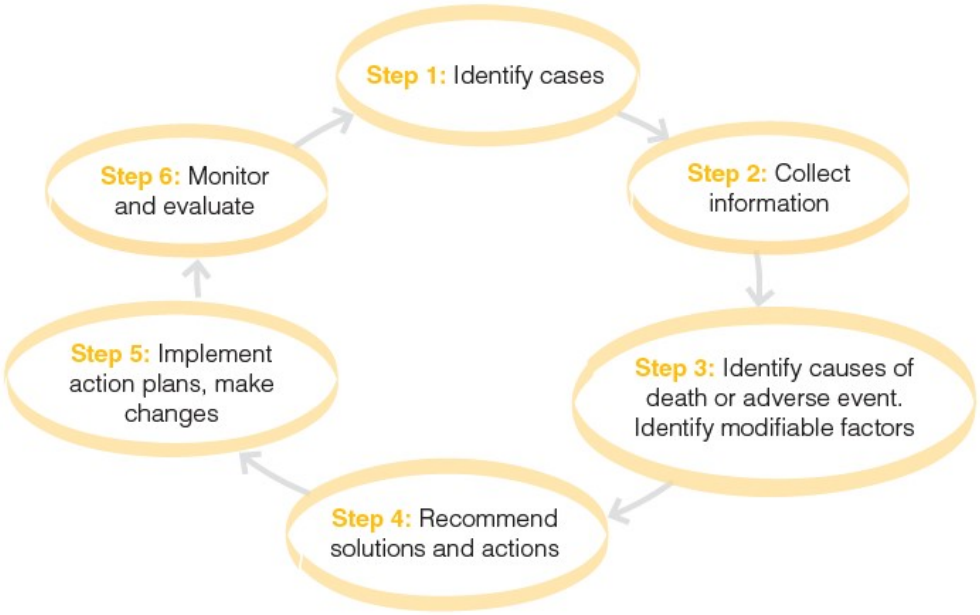


Figure 2: Recommended Facility-Based Clinical Audit Cycle as advised by WHO. Source: Improving the quality of paediatric care: an operational guide for facility-based audit and review of paediatric mortality. Geneva: WHO; 2018.

WHO has developed guidance for the continued care along the life course of the newborn by integrating maternal and newborn care through promoting the maternal and perinatal death surveillance and response tool (MPDSR).(28) The MPDSR has resulted in significant improvement in maternal and perinatal care in LMICs. The "P" is however silent with a focus on stillbirths and the immediate resuscitation provided after birth to the live newborn. (9-23) This resulted in a gap in the availability of a clinical audit tool that comprehensively covers the care provided to the newborn who survives the immediate resuscitation period. Figure 3 summarises the perinatal and neonatal periods and illustrates the gaps in the available perinatal and newborn clinical audit tools.

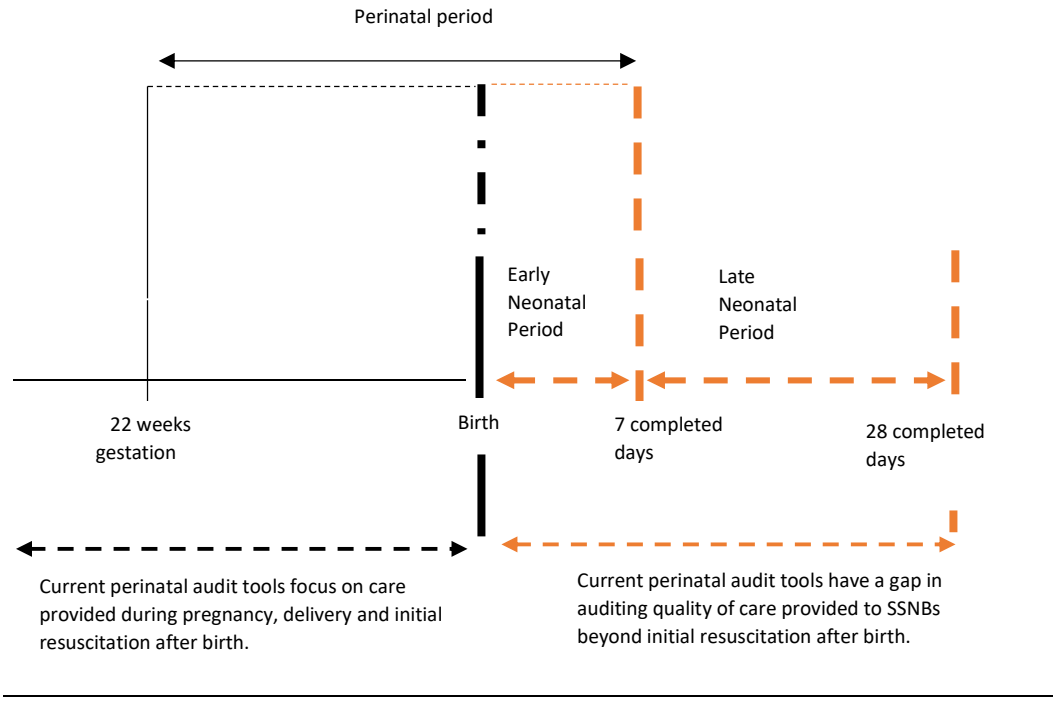


Figure 3: *Definition of perinatal and neonatal periods with focus on the gaps in newborn care auditing. Modified from; Indira et al. 'The Components of Essential Newborn Care,'2004.*

There was a need to design a tool that would complement the MPDSR by allowing for the review of SSNB care through the three periods of care. Quality design begins by understanding where the real gaps are in the current newborn audits. This allows for solving the right problem and doing so in a way that meets human needs and capabilities [13]. The use of a Human-Centred Design (HCD) approach considers the usability and human factor characteristics of the audit tool, and therefore, the experience it provides for the user [14, 15]. HCD "is a design approach that puts human needs, capabilities, and behaviour first, then designs to accommodate those needs, capabilities, and ways of behaving" [13]. This promotes the development of an audit tool that has a relative advantage over the available tools and is compatible to the setting by advocating for active user participation and allowing for several and subsequent modifications based on the users' requirements [16, 17].

The success of any quality improvement intervention is dependent on the implementation strategy used. Traditional methods such as the provision of training workshops with minimal to no supervision have not yielded positive results in integrating quality improvement interventions into routine practice.(49,50) There is evidence that the use of facilitation is a successful approach as an implementation strategy through the use of a facilitator who acts as a change agent by enabling the recipients to adopt the innovation by tailoring it appropriately for their context.(51) Facilitation as an implementation strategy is described in detail in section 5.5.

1.1 Study justification

Clinical audits have been proven to be an effective strategy for improving the quality of maternal, perinatal and newborn care based on the identification of modifiable gaps that lead to the morbidity or mortality of patients.(47-51) However, a scoping review conducted, identified that there was a dearth of perinatal and newborn care clinical audit tools that are specific to auditing the care of SSNBs beyond the initial resuscitation after birth.(52) Most audit tools, including the MPDSR tool and the WHO stillbirth and neonatal death case review form are perinatal audit tools are designed to audit stillbirths and the immediate newborn care after birth. This leaves a gap in auditing of care provided to the sick and small newborns who require extra care in the NBU. This is evident by the sections provided in both tools that focus on: antenatal care provided to the mother and obstetric care and complications during pregnancy, labour and delivery. There is no focus on the post-resuscitation care provided to the newborn. There is also no provision to summarise the care provided to the newborn in the NBU including; medication used, nutritional support, respiratory support, among others.(14, 53)

The successful implementation of the clinical audit tool required an implementation strategy designed to build on the facilitators and overcome the potential barriers as identified in the context.(54-56) The iPARIHS framework proposes that the successful implementation of quality improvement initiatives is the function of four constructs: Innovation, recipients, context and facilitation.(6) A HCD approach was

considered appropriate for the design of a context sensitive clinical audit tool and its implementation guide as it presumes that the users of an innovation understand its core challenges, and therefore hold the key to its solution. This approach would increase ownership of the innovation which is the audit tool by involving the healthcare workers who are the recipients and end-users in its design. Provision of multiple interactive training sessions would lead to an increase in knowledge, skills and motivation of the recipients, but would not translate to a change in practice by healthcare workers. Facilitation which is both a role (with a facilitator) and a process was believed to be the construct that would enable behaviour change as well as strengthen the context by enforcing supportive leadership and a healthy institutional culture. This is based on its dynamic nature that allows the strategy to adapt to individual settings and the team-based approach used to enable the development of reflective learning by helping to identify group needs, guide group processes, encourage critical thinking, and assess the achievement of expected QoC goals.(57)

Despite evidence on the benefits of early initiation and rapid progression of enteral feeding in preterm and LBW newborns, the literature demonstrates poor adherence to preterm feeding guidelines and consequently, poor preterm and LBW feeding practices in both LMICs and HICs.(39) This has both short and long-term detrimental effects on the preterm and LBW newborns. Preterm feeding is a complex intervention that is influenced by several interrelated factors such as the health workers, the environment and the guardians. It therefore requires a complex strategy to enable a change of behaviour among healthcare workers to adapt to preterm newborn feeding as recommended in the guidelines.

1.2 Research aims

The study had three main aims: (1) To co-design and test a small and sick newborn (SSNB) clinical audit tool and its implementation guide (June 2020 – April 2021), (2) to evaluate the effect of the intervention on measurable indicators of improved feeding practices of low birth weight newborns in newborn units

in Kenya (Jan 2021 – June 2022), and (3) to broaden the effect evaluation and explain the effect of the intervention using complementary qualitative approaches and integrating the findings with those of the quantitative section in a mixed methods approach.

1.2.1 Research question

Can external facilitation improve the effect of a co-designed SSNB clinical audit tool and its implementation guide focusing on the probability to regain birth weight based on feeding of the low birth weight newborn as an indicator?

Null hypothesis

A null hypothesis is presented linked to the second objective. The null hypothesis states that the use of facilitation as a strategy to implement a SSNB clinical audit tool and implementation guide does not result in a reduction in the time to regain birth weight and overall mortality in low-birth-weight neonates in the intervention compared to control hospitals.

1.2.2 Objectives

The SSNB clinical audit tool and implementation guide are complex interventions based on their interaction with multiple interrelated health system components. To promote successful implementation, I used facilitation as an implementation strategy. Facilitation uses a multifaceted approach that builds on the health system's strengths and mitigates the weaknesses. These strategies are described in my objectives below.

1.2.2.1 Main objective

To co-design and introduce the use of a SSNB clinical audit tool and implementation guide to improve feeding practices and subsequently time to regain birth weight of LBW newborns in County Hospitals in Kenya and assess the effect of facilitation as an implementation strategy.

1.2.2.2 Specific objectives

1. To co-design a comprehensive SSNB clinical audit tool and its implementation guide that takes into consideration the basic needs, capabilities and limitations of the health workers who will be the end-users while taking into account the key principles of HCD.
2. To assess the effect of facilitated implementation of a co-designed SSNB clinical audit tool and its implementation guide on mitigating modifiable factors that prevent adherence to recommended LBW newborn feeding guidelines using a controlled before and after study design.
3. To identify the role of external facilitation in building on the strengths and overcoming the implementation barriers to the SSNB clinical audit process – what works and what does not work.

In chapter 2, I will provide the current literature that demonstrates what is known about clinical audits, human centred design as an approach to designing QI initiatives, facilitation as an implementation strategy and preterm and LBW feeding practices. In chapters 3, I will describe the theory of change. In chapter 4, I will describe the methodology used for this PhD thesis and in chapters 5,6 and 7, I will present the results based on the objectives. I will discuss the results in chapter 8 and subsequently illustrate the strengths, limitations, conclusion and recommendations.

Chapter 2: Literature Review

In this chapter, I will begin by providing evidence of the current knowledge on modifiable factors in newborn care based on a scoping review. I will then discuss the facilitators and barriers to implementing a clinical audit and the implementation strategies to overcome these barriers. Finally, I will give evidence on the current feeding practices of the preterm and LBW newborns as recommended in the Kenyan guidelines.

2.1 Audit as a quality improvement strategy through identification of modifiable system gaps

I conducted a scoping review that aimed to: i) identify the modifiable factors related to the care of newborns in LMICs from individual hospital audits and, ii) assess the quality of the perinatal and newborn audits in health facilities in LMICs to allow for the identification of modifiable factors and the recommendation and implementation of solutions that lead to change.(52)

I conducted a narrative analysis of the six articles that met the inclusion criteria, and from this, one of the emerging themes was the three time periods in newborn care which refer to the transition of care of the small and sick newborn (SSNB) from delivery to the point of admission in the newborn unit (NBU). These periods included:

i. The period of immediate newborn care and resuscitation after birth (care provided to the newborn shortly after birth).
ii. Post-resuscitation care for the SSNB (continued care provided to the SSNB while still in the delivery room after the initial resuscitation as they await to be transported to the NBU).
iii. Period of care while in the newborn unit.

Recognizing the period of care in which the modifiable factors occur was considered important to ensure that safety measures were allocated to each of these periods and worked jointly to improve both the short and long-term outcomes of the SSNBs.

2.1.1 Categorisation of modifiable factors

A modifiable factor is defined as 'a care management problem that involves care that deviates from the safe limits of practice as laid down in guidelines, standards, protocols or normal practice and has the potential to lead, directly or indirectly, to an adverse outcome for the patient.'(13) Overall, 31 modifiable factors related to newborn care were identified across all periods of care from the individual audit studies. The modifiable factors were categorised to aid in uniformity of results both at a national and international level.(13)

We identified two methods of categorising modifiable factors in perinatal and neonatal clinical audits from the included studies. They may be classified as a three-phase delay model which are:

a. Delays in seeking appropriate care.
b. Delays in reaching a health facility.
c. Delays in receiving appropriate care at a health facility.

Mbaruku *et al,* 2009, Waiswa *et al,* 2010 and Musafili *et al,* 2017 identified the missed opportunities in neonatal deaths using the three-phase delay model. They identified that the phase one delays were mostly as a result of lack of recognition of danger signs and poor compliance to formal care.(48, 58) Phase two delays were as a result of lack of money, unreliable modes of transport, long distances to the health facilities and lack of health insurance.(48, 58, 59) The phase three delays reflect on the quality of care provided to both the mother during the antenatal period, labour and delivery; and to the sick and small newborn (SSNB) in the health facilities.(58, 60, 61) I acknowledge that a significant number of perinatal deaths occur due to the poor quality of care provided to the mother during pregnancy and delivery and this is extensively addressed in the MPDSR.(62) My study however focused on the

modifiable factors in the care provided to the SSNB after delivery. I therefore adapted the second method of categorisation based on the level of the health system in which they occurred.(13) This has been identified as a more comprehensive method as it shows the exact level within the health system in which action can be taken and includes:

1. Health worker related factors defined as those related to the errors, oversights and deviations from accepted standards of care by the health workers involved in patient management (63).
2. Administrative factors are those whose resolution fell within the scope of the top-level hospital managers such as the hospital administrators and the hospital chief executive officers. These include modifiable factors related to i) financial, physical and human resources, ii) availability of medication, medical equipment, technology and materials and, iii) the political, policy and learning environment (63).
3. Patient oriented factors reference those related to the interference by the caregivers in the clinical management of the newborns (63).

Health worker related factors were the most commonly identified categories across all time periods. The modifiable factors related to newborn care are presented in Table 1 below.

Table 1: Modifiable factors in newborn care in low resource settings categorised based on the period of care and the level of the health systems model in which they occur.

Period of immediate care and resuscitation after birth[1]	
Health worker factors	Unsatisfactory preparation of neonatal resuscitation equipment.(61) Unsatisfactory preparation of medication e.g. surfactant.(61) Poor newborn resuscitation skills.(60, 61) Delayed initiation of resuscitation.(58) Poor communication between obstetrics staff and NICU team.(61)
Period of post-resuscitation care of the newborn[2]	
Health worker factors	Insufficient prevention of hypothermia.(58, 61) Delay in transport to NICU.(61)
Period during care in the newborn unit	
Health worker factors	Failure to provide adequate warmth.(61) Poor management of neonatal jaundice.(58) No RBS done on neonates with convulsions or reduced level of consciousness.(64) Neonates requiring oxygen not indicated to have received.(64, 65) Neonates requiring IV fluids not documented to have received.(64) Poor preterm feeding practices.(58, 61) Poor neonatal resuscitation.(58, 61) Irregular monitoring of vital signs.(58, 65) Delay in life saving interventions e.g. ET intubation due to poorly skilled health workers, blood transfusions.(58) Delayed recognition or response to danger signs.(66) Sub-optimal infection prevention measures.(66) Sub-optimal management of sepsis e.g. less aggressive antibiotic treatment or incorrect antibiotic dosing.(64, 66)

[1] No administrative and patient-oriented modifiable factors in period of immediate care and resuscitation.
[2] No administrative and patient-oriented modifiable factors in post-resuscitation period.

	No action on abnormal lab investigations – neonates who were HIV exposed did not receive prophylaxis.(65) Incomplete diagnosis – No indication of prematurity as a diagnosis.(64) Improbable diagnosis e.g. gastroenteritis in neonates.(64) Poor documentation of Apgar score.(64) Poor documentation of birth weight.(64, 65) Poor communication among health workers.(61) Sub-optimal internal transfers.(66) Delayed decision to referral.(58)
Administrative related factors	Shortage of equipment e.g. monitors, airway devices & ventilators.(58, 61, 64, 66) Shortage of medication e.g. phenytoin.(58, 61) Shortage of staff.(64, 66) Inadequate laboratory capacity. Lack of capacity to perform bilirubin levels or blood cultures.(64)
Patient oriented factors	Family perception of prognosis.(66)

Abbreviations: ET, Endotracheal; HIV, Human Immunodeficiency Virus; IV, Intravenous; Lab, Laboratory; NICU, Neonatal intensive care unit; RBS, Random blood sugar.

The modifiable factors were observed to be broadly oriented and lacked the granularity required to get to the root cause of the problems leading to adverse events. For example, 'poor preterm feeding practices' as a modifiable factor does not specify if the poor practices are in the initiation of feeds, choice of feeds, volume of feeds, progression of feeds, route of feeding. It therefore becomes difficult to identify an actionable solution to mitigate the modifiable factor. Similar findings were observed in a systematic review that pooled together audit identified maternal and perinatal modifiable factors in low resource settings.(46) Broad categorisation of modifiable factors such as health worker related factors can be further refined into sub categories such as; lack of technical skills, lack of knowledge, presence and use of guidelines, poor communication, poor documentation. This has been attempted by the

Groningen system in the Netherlands that gives comprehensive and clearly defined modifiable factors.(13) This system groups modifiable factors into nine categories. Each category has three to seven sub-categories. The categories are based on the process of care and not on the levels of care e.g. medical practice is one of the categories and has two sub-categories; diagnosis and management plan. The sub-categories are categorised further into three sections: 1. use of guidelines 2. content of guidelines 3. common practice. A refined classification system allows for detailed investigations into the relation between the modifiable factors and the adverse events. This leads to proper allocation of modifiable factors into appropriate categories, allows for uniformity and enables comparison at national and international levels and helps to define more specific actions required to address the problem.(13, 46)

2.1.2 Quality of clinical audits

The clinical audit should observe certain standards as recommended by the World Health Organisation (WHO) for it to lead to meaningful change as a quality improvement strategy.(1, 14) The standards include; frequent and structured audit meetings, the use of a structured audit tool, presence of a multidisciplinary audit team (MDT), a favourable environment during the audit meetings and completion of the audit cycle.

Table 2 below summarises the factors of the clinical audit that should be adhered to as recommended by WHO and the publications that address these factors with an indication of what process they used.

Table 2: *Recommended audit process factors for a successful audit process addressed by different publications*

Author, Country, Year	Audit process factor	Description
• Demise et al, Ethiopia, 2015.(61) • Nakibuuka et al, Uganda, 2012.(60) • Wilmot et al, Rwanda, 2017.(67)	• Presence of a multidisciplinary audit team	• Consist of the different cadres involved in patient care. • Responsibilities: Organizing and steering regular meetings, liaison between health workers and

		administration, ensure implementation of recommendations.
• Kruse et al, Vietnam, 2013.(66) • Sandakabatu et al, Solomon Islands, 2018.(68) • Nakibuuka et al, Uganda, 2012.(60) • Duke et al, Papua New Guinea, 2002.(69)	• Frequent structured meetings	• Meetings should be held on a set day, date, time and location to ensure maximal attendance. • Facilities with high newborn mortality rates should have frequent meetings (1-2 weekly) to enable auditing of multiple deaths in a timely manner.
• Sandakabatu et al, Solomon Islands, 2018.(68) • Duke et al, Papua New Guinea, 2002.(69)	• Meeting participants	• Mortality meetings should be attended by all health workers involved in newborn care as they present a time to learn from deaths to prevent other deaths occurring from similar causes.
• Sandakabatu et al, Solomon Islands, 2018.(68) • Duke et al, Papua New Guinea, 2002.(69)	• Favourable environment	• No blame, non-judgmental environment, confidentiality, encourage learning.
• Demise et al, Ethiopia, 2015.(61) • Musafili et al, Rwanda, 2017.(58) • Wilmot et al, Rwanda, 2017.(67) • Nakibuuka et al, Uganda, 2012.(60)	• Structured audit tool	• Provides a structured method for conducting the audit process in a logical sequence.
• Demise et al, Ethiopia, 2015.(61) • Nakibuuka et al, Uganda, 2012.(60)	• Completion of audit cycle	• Documentation of all deaths occurring within 24 hours in death register • Selection of cases for auditing. • Summarising selected cases in structured audit tool. • Identification of causes of death and modifiable factors. • Generation of action points. • Recommendation of solutions.

		• Implementation of recommendations. • Monitoring and evaluation.

I developed a quality of audit score that was adapted from the WHO recommendations for a facility-based audit and this aimed to assess the quality of the clinical audits in LMICs. The score was based on seven factors drawn from the recommended methods for a successful audit process by WHO: Presence of a multidisciplinary audit committee (MDT) which usually includes the decision makers who are the heads of departments, including health workers involved in the care of the newborn who were not part of the committee in the audit meetings to promote learning, use of a structured audit tool, regular structured meetings and completion of the audit cycle by categorisation of modifiable factors, generating action points from the identified modifiable factors and implementing the recommendations. A traffic light coding system was used to give a visual representation of the quality of the audit process in the individual studies. Based on the scores assigned, it emerged that the newborn clinical audits in the included studies were not consistent with the WHO recommendations.(58, 60, 61, 64-66) Individual audit scores are attached in Appendix 1.

The studies that used a structured audit tool all used perinatal audit tools that exclude care in the NBU.(58, 60, 61, 66) None used an audit tool specifically designed for auditing care provided in the newborn units in LMICs. This is important because perinatal audit tools are designed to audit stillbirths and neonatal deaths occurring immediately after birth and would therefore not be a suitable guide to auditing the three periods of newborn care.(14, 53)

From this scoping review, I identified a need to design a newborn clinical audit tool that comprehensively covers the three periods of newborn care as there were none identified from the extensive literature. I also identified the need for the development of an implementation guide as the

standard operating procedure (SOP) for a high quality newborn clinical audit based on the quality of audit score.

Previous attempts at implementation of existing maternal and perinatal audit tools in LMICs have faced many challenges. For successful implementation of the newborn unit audit tool, I will begin by identifying the facilitators and barriers faced during the implementation of these tools in LMICs. This is because the implementation of the SSNB audit tool would most likely face similar challenges.

2.2 Facilitators and barriers to successful implementation and sustainability of facility-based clinical audits.

Successful implementation of a quality improvement innovation is defined as the achievement of set implementation goals and uptake and integration of the innovation into routine practice.(6)

A clinical audit is a complex intervention that interacts with multiple interrelated components of the health system for the desired quality improvement outcomes to be observed.(3) There are inherent strengths and weaknesses within the different components of the health system which have influenced the uptake of the clinical audits particularly in weak health systems such as in LMICs. Several studies have identified facilitators and barriers to the successful implementation of maternal and perinatal mortality and near miss audit processes.

A systematic review by Lazzerini *et al* (2018) synthesised the identified facilitators and barriers in the implementation of a maternal near miss review cycle in LMICs.(70) These were grouped into broad categories which included: Availability of national protocols, leadership, training, incentives, monitoring and supervision, resource availability, culture and practice of quality improvement, hierarchy and interpersonal relationships, attitude towards patients and conditions, outcomes and sustained support.

Lewis G *et al* (2014) identified the lessons learnt from maternal mortality audits in LMICs and the cultural environment required for a successful audit process.(71) These were summarised into three interdependent cultural factors; 'individual responsibility and ownership', 'a proactive institutional ethos

that supports learning as a crucial factor for improving quality of care' and, 'a supportive political and policy environment at both the local and national level.'

Kinney *et al* (2021) conducted a scoping review to examine the implementation factors related to adoption of the MPDSR using a theoretical framework. The framework considers four domains as a lens to understanding the facilitators and barriers; intervention (MPDSR characteristics, processes and components), individual (Characteristics of the individuals involved in the implementation), inner setting (factors internal to the organisation) and outer setting (external influences).(56)

Table 3 below has adapted the implementation framework applied in the study by Kinney *et al* to describe the determinants of successful implementation of maternal and perinatal clinical audits. The non-linearity and multiple causality features of these determinants lead to a feedback mechanism where a weakness in one component of the health system will interact with the other components and together, they can be a powerful influence on successful adoption of the audit process.

Table 3: Facilitator and barriers to implementation of maternal and perinatal facility-based clinical audits

Framework	Facilitators	Barriers
Intervention	• Positive results from audit process due to implementation of recommendations.(54, 72) • Documenting minutes to meetings with clear indications on who is responsible for follow up on action points.(51) • Compilation of regular reports.(51) • Skilled data entry clerks.(51) • User-friendly audit tool.(51) • Timely entry of data.(51) • Presence of death review forms.(73) • Independent chairperson for audit meetings.(50) strengthened the perception of patient safety in audit groups.(54) • Regular structured audit meetings.(50)	• Absence of senior staff e.g. specialists from meetings.(50, 74) • No audit committees.(75) • Audit committees that do not contain key decision makers.(75) • Poor or no implementation of recommendations.(76) • Poor dissemination of key decision points.(75) • Audits not standardised.(76) • Audit meetings held irregularly.(75, 77)
Individuals	• Presence of a change agent within the health facility.(51)	• Lack of accountability from staff – from top managers to care providers.(75) • Lack of knowledge on benefits of an audit.(75, 77) • Lack of knowledge and skills on audit conduction.(55, 74, 77) • Lack of time for audit process.(50, 54, 55) • Reduced motivation of caregivers.(54) • Staff with several competing interests making attendance of meetings difficult.(50, 74)

Inner context	• Cooperation between different cadres – no hierarchical differences.(54) • Team work.(51) • No name, no blame, confidential environment that encourages learning.(51, 76) • Communication system that ensures regular feedback and accountability.(51) • Commitment from senior management and clinicians.(51, 76) • Presence of quality of care guidelines.(74)	• Culture that does not promote confidentiality.(55, 72, 77) • Culture that promotes blame, naming and punishment for individuals thought to be responsible for deaths.(50, 55, 74-77) • High turnover of health workers.(55) • Staff shortage.(50, 74) • Inadequate documentation on patient records.(50, 74) • Lack of a health information system.(55) • Lack of computers to install software in regions where the data is entered digitally.(51) • Poor record keeping.(74) • Lack of funds for quality improvement activities.(54)
Outer context	• External supervisory support.(51, 54, 74) • Shared experiences of audit review process with staff from different hospitals.(51, 74)	• Lack of funds for quality improvement activities.(54) • Absence of policies or guidelines related to the clinical audits.(56)

Intervention; MPDSR characteristics, processes and components, individual; characteristics of the individuals involved in the implementation, inner setting; factors internal to the organisation and outer setting; external influences.

An understanding of the facilitators and barriers experienced in implementation of maternal and perinatal audit tools in similar contexts and environments is important. This will enable the development of implementation strategies that build on the strengths and aim to overcome the barriers to enable successful implementation.

2.3 Implementation strategies for successful integration of quality improvement initiatives into routine practice

Implementing evidence-based quality improvement strategies into practice is a complex, multifaceted process that requires a proactive effort to ensure successful implementation.(78) Based on the complexity of the process, a multifaceted implementation strategy that is designed to address these determinants of practice within the health system is recommended for successful implementation.(79) The integrated Promoting Action on Research Implementation in Health Sciences (iPARIHS) framework proposes that successful implementation of a quality improvement initiative is the function of four core constructs: The innovation, context, recipients and facilitation. The innovation is represented by the quality improvement initiative and the evidence supporting it. The recipients refer to the actors within the context who are 'affected by and influence implementation of the innovation'. The context is defined in terms of 'resources, culture, leadership, and orientation to evaluation and learning.' Facilitation is represented as 'the active ingredient assessing, aligning and integrating the other three components.'(6) Facilitation is the component that activates implementation by understanding and responding to the characteristics of the innovation and recipients within their context. This requires a facilitator and a set of strategies; the facilitation process that enables the recipients to adopt the innovation by tailoring it appropriately for their context. The key goal of the facilitator is to act as a change agent by driving and motivating change in practice and being a resource for making the change.(78, 80-82) Several studies have applied the iPARIHS framework for the design of implementation strategies by identifying the determinants that will influence the uptake of the innovation with the facilitation process being designed to overcome barriers within the context and recipients.(57, 83, 84)

The determinants influencing successful implementation of audit processes in LMICs have been summarised in Table 3 above. Based on these, the role of the facilitator will be to adopt a facilitation

strategy that is tailored to enhance ownership of the innovation, increase knowledge, attitude, skills and motivation of the recipients and strengthen the context by promoting supportive leadership and a healthy institutional culture.

2.3.1 The co-design of quality improvement initiatives using a human centred design approach.

The innovation was a structured clinical audit tool that comprehensively covers the three periods in care of the small and sick newborn based on the identified gap in the scoping review. A human-centred design approach was used to design the innovation.

Human Centred Design (HCD) is an approach to systems design and development that aims to make interactive systems more usable by focusing on the use of the system and applying human factors and usability knowledge and techniques.(8)

In health care, the culture has largely been to train health workers to adapt to poorly designed interventions that are not sensitive to the context, rather than designing interventions to suit people's needs.(85) HCD recognises that product end-users have basic needs, capabilities and limitations, and the designer should understand, predict and design interventions with these needs and limitations in mind.(8, 86) Involving important stakeholders in the design of an innovation is an important part of preparing for adoption by improving ownership and acceptance of the innovation.(87)

There are three principles of a human centred design approach recommended by International Organisation for Standardisation (ISO) – 9241-210 that must be followed, these include: 1. Identifying the end-user and describing the user needs or conducting a needs assessment, 2. Prototyping, which is the process of creating a series of low-fidelity and high-fidelity prototypes of the intervention and refining it several times through iterative processes of feedback from experts, users and stakeholders, 3. Testing the innovation with target-users while continuing to refine it based on user feedback.(88)

The ISO 9241-210 recommends that nine requirements must be fulfilled during the use of a HCD approach.(88) Harte *et al* (2017) summarised these requirements into a three-phase methodology which

was used for the design of a connected health system to continuously asses fall risk in the elderly by assessing gait and balance.(23) These included:

1. Establishing context of user and use case document (audit tool) which involves gaining an explicit understanding of users and their environment.
2. Expert inspection and walkthrough refers to the exposure of the prototype to a formative evaluation. This will consider its usability, human factors and overall user characteristics. Usability inspection involves an expert group that inspects the prototype and attempts to identify usability and human factor problems. During the cognitive walkthrough, the expert group test the intervention on real case scenarios while focusing on cognitive processes that the task requires. Any problems encountered with the use of the intervention are documented. This stage is a precursor to the formal piloting of the intervention. The outcome of this phase is an almost fully functional prototype with an accompanying manual that is ready for usability testing with end users.
3. Usability testing refers to the process of carrying out field testing of the advanced prototype with end-users.

Several studies have used a HCD approach for the design of quality improvement interventions. Different strategies used to accomplish each phase of the design process and the outcomes have been summarised in Table 4 below.

Table 4: Strategies used to accomplish each of the three phases of a human centred design approach

Author, year, Journal	**Methodology**	**Identifying users and user requirements**	**Expert inspection and walk through**	**Usability testing**	**Outcome**
Muinga et al, 2021, BMC Health Services Research. (89)	HCD approach through three design workshops with senior NBU nurses and paediatricians. Observation of chart completion to identify challenges with current charts and design requirements.	• Studying existing monitoring charts from NBUs. • User personas and user story mapping.	• Modified based on health worker inputs during workshops.	Two new charts were piloted in four hospitals over eight months and revised in a cyclical manner.	Comprehensive newborn monitoring chart.
Catalani et al, 2014, PLoS One(90)	HCD approach using a mixed methods approach- QUAL - observations and interviews QUANT – surveys To create an innovative system for improving TB prevention and treatment practices among HIV care providers.	• Site observations. • Key informant interviews. (Resulted in the development of 1st prototype of a clinical decision support system)	• Laboratory simulation which included dozens of cycles of prototype development until they reach zero errors.	Prototype tested at 3 clinical sites using 10 HIV clinicians to further refine the clinical decision support system.	The team created a system to integrate HIV and TB care through the clinical decision support system.

Neyens et al, 2013, Patient Preference and Adherence.(91)	User-centred approach that involved elderly during the design of a mobile interface of a monitoring and feedback system that assesses changes in their physical activity.	• Users identified as elderly population • Literature search. • Discussion meetings with geriatric health workers. • Workshops with geriatric population. (Resulted in the development of 1st prototype mobile phone interface for monitoring changes in physical activity)	• Elderly representatives and their advisors reviewed the 1st prototype and modified it. • 2nd prototype modified through heuristic evaluation by non-users. • 3rd prototype modified through think aloud usability by users. • Questionnaires.	• Population 70 years and older used the devices daily and provided feedback on their experience through questionnaires and semi-structured interviews	Developing of a mobile interface of a monitoring and feedback system that assesses changes in the physical activity of the elderly population.
Kim et al, 2019, Global Health Science and Practice.(92)	HCD approach using a mixed methods approach. QUAL – QUANT - to determine user preferences for the design of LLINs among the middle-class population in Ghana.	• Market analysis. • Literature review. • User interviews. • Stakeholder analysis. (Resulted in ideas for a prototype LLIN)	• Several focus group discussions that modified the prototype LLIN design through an iterative process.	-	Development of a design idea for a prototype LLIN based on the design solutions provided by the end-users.

Abbreviations: HIV; Human Immunodeficiency Virus , LLINs; Long Lasting Insecticide Treated Nets, QUAL; Qualitative studies, QUANT; Quantitative studies, TB; Tuberculosis.

In sections 2.3.2 and 2.3.3, I will discuss how the facilitation strategy can be designed to influence the recipients to adapt the innovation within their context. I will also discuss how an increase in knowledge and skills is important, but not enough to promote behaviour change among health workers.

2.3.2 Role of education and training workshops in behaviour change

The recipients of the innovation will be the NBU leadership, the frontline NBU health care workers and all health care workers who indirectly influence newborn care. An increase in health worker knowledge and skills is crucial in improving their attitudes and hence, improving translation of knowledge into practice. This is however dependent on the methods and frequency of education and training sessions used as discussed in this section.

Traditionally, the standard method for implementing quality improvement interventions in health care is through the use of one or two training workshops.(93, 94) The aim is often to effect changes in health worker performance and improve health-related outcomes through knowledge translation.(4) This has not always resulted in successful implementation as there has been minimal change in practice.(56)

A meta-analysis was conducted by Mansouri *et al* (2007) to assess the influence of continuous education on physician knowledge, performance and outcome.(95) The results showed that the use of education alone in the implementation of complex interventions has a moderate effect on improving health worker knowledge and skills and a minimal effect on improving health worker performance and outcomes. A before after study on the effect of interactive training sessions on blood pressure monitoring among nurses showed a significant improvement in quality of blood pressure recordings of cuff size, arm in which arm circumference was measured and patient position during recordings after the training.(96)

There are several methods for conducting education and training sessions as interventions for the purpose of improving health worker practice. These can be grouped into three categories: 1. Active interventions; workshops and individual trainings. 2. Passive interventions; conferences, didactic

education sessions, print out material. 3. Mixed interventions; combination of active, passive or both categories.(95)

Mansouri *et al* (2007) examined the three types of interventions and found that the mixed interventions had a larger effect size compared to the single interventions. The types of interventions that were most effective were: multi-faceted educational programmes, longitudinal workshops, interactive small groups and case discussion interventions. The correlation between multiple education sessions and general effect size was positive.(95)

A systematic review by Bloom *et al* (2005) demonstrated that the CME techniques most effective for improving physician behaviour are interactive workshops and mixed education programs. Didactic processes such as lectures and distribution of printed material have minimal effect in improving physician behaviour.(97)

P.S. Wu *et al*, 2009 used a pre-test post-test experimental design to assess the effect of interactive training workshops on clinician knowledge on TB treatment and patient stigmatisation and compared to a large workshop training. There was a statistically significant improvement in health worker knowledge after the interactive workshops and stigmatisation.(98)

The evidence presented in this section identifies the most effective education and training methods that will lead to translation of knowledge into practice and improve health worker behaviour. These methods are through using multiple education sessions, mixed education programmes and small interactive workshops.

Having knowledge alone is rarely enough to change behaviour. Mansouri *et al* (2007) showed that after the provision of education, the effect size of the intervention decreased with time meaning that new behaviours require re-enforcement to make them sustainable.(95)

2.3.3 External facilitation as a strategy for the implementation of complex interventions in complex systems.

External facilitation is a multipronged approach that involves experienced individuals who are external to the organisation who empower others, through a range of intervention approaches to address challenges in implementing quality of care improvement strategies into practice.(82) In addition to providing the re-enforcement to promote behaviour change among the recipients, this approach also establishes a context that supports quality improvement initiatives.

Baskerville *et al*. (2012) conducted a systematic review to estimate the effect size of using practice facilitation as a strategy to change evidence-based practice behaviour. The overall effect size point estimates show that practices that used external facilitation were 2.76 times more likely to translate evidence into practice.(99)

The role of the facilitator during external facilitation is to provide support to enable change to occur by improving health worker motivation and performance.(78) Cranley *et al* (2017) conducted a scoping review that identified the roles of different categories of facilitators; the role of external facilitators was described as; individuals external to the target organization who improve performance through a formal implementation process using educational visits or continuous quality improvement (CQI), provide feedback and support, provide audit and feedback, provide information/resources to promote uptake of best practice and build good working relationship between staff and facilitator.(78) Table 5 below describes the roles of external facilitators and outcome of using this method as an implementation strategy.

Table 5: Role of external facilitators in implementation of quality improvement interventions and outcomes of external facilitation as an implementation strategy.

Author, year, journal	**Methodology**	**Outreach facilitator role**	**Outcome**
Pirkle et al, 2013, BMC.(100)	Cluster RCT	Act as external opinion leaders - Educational outreach visits 3-monthly to support local opinion leaders. - Oversee audit meetings to ensure are being carried out appropriately. - Meetings with hospital professionals and administrators to promote evidence-based practice. - Clinical observations related to themes that were taught.	- 15% reduction in maternal mortality in intervention arm. - Significantly more women at intervention sites received good quality care compared to control sites (44.1% vs 29.7%, P = 0.00)
Dickinson et al, 2014, Ann Fam Med.(101)	Cluster RCT that assessed the effects of implementation of a Chronic Care Model for diabetes management using a) Facilitation through a CQI model b) Facilitation through the RAP model and c) SD method	1. CQI facilitator followed a prescribed strategy of implementing the CCM. - Assessment of practice communication change and work culture. - Assessing level of implementation - Provide feedback to practices. - Assist practices in developing implementation teams - Allow teams to set their own priorities, pace and targets of change. 2. RAP facilitator followed a more practice determined approach. - Initial practice assessment. - Provided feedback to the practices.	- Total care of process scores improved in all 3 groups ($p< 0.05$) and greater in the CQI groups compared with SD practices ($p<0.0001$) and RAD practices ($p<0.0001$). - CQI practices had the greatest improvement in practices. CQI vs RAP in checking HbA1c levels ($p<0.05$), CQI vs RAP in nephropathy screening ($p<0.05$), CQI vs SD practices in eye examination ($p<0.05$).

		- Assisted in forming practice improvement teams. - Provided a structure and process for quality improvement through PDSA cycles.	- RAP improved practice cultured.
Nutting et al, 2010, Ann Fam med.(102)	RCT in 31 practices over 2 years that compares the effect of outreach facilitation on the implementation of an NDP to improve practice outcomes in the family practice model compared to self-direction.	External facilitators visited the sites twice a year for 1-3 days. - Onsite education. - Formal and informal meetings with members of the practice. - Observation of workflow with suggestions for improvement. - Review of finances. - Problem solving and brainstorming on issues with members of the practice. When not on site, the outreach facilitators were in communication with members of the practice through telephone and email.	- Increased adaptive reserve in facilitated practices (group difference by time, P=0.005). - Facilitation significantly increased the number of adopted model components (group difference by time, P = 0.02)
Harvey et al, 2014, International Journal for Quality in Health Care.(103)	Improved diagnosis of CKD in primary care settings. 2 phases. Phase 1 – 19 practices recruited, formation of multidisciplinary practice improvement team, collaborative learning events,	2 eternal facilitators regularly visited the practices. Phase 1: - Assist with data searches. - Manage practice registers. - Develop process maps. - Advise on how to overcome barriers. Phase 2: Assisted practices to install IMPAKT tool and guided them on how to use it	- 1.2% increase in CKD prevalence due to improved screening. - Improved management of BP based on NICE guideline targets. - Phase 1 – From baseline of 34% to 74% reaching guideline targets. - Phase 2 – From baseline of 60% to 83% achieving guideline targets.

	outreach facilitation, Development of CKD improvement guide (IMPAKT tool) Phase 2 – Selection of 11 practices, installation of IMPAKT tool.		

Abbreviations: CCM; Chronic Care Model, CKD; Chronic Kidney Disease, CQI; Continuous Quality Improvement, NDP; National Demonstration Project, PDSA; Plan Do Study Act cycle, RAP; Reflective Adaptive Process, SD; Self Direction.

The facilitation strategy that will be used to lead to successful implementation of the intervention will use a HCD approach to promote ownership and acceptance of the intervention. An education approach through multiple education sessions and interactive workshops will aim to improve knowledge, attitude, skills and motivation of the health workers. Outreach facilitation will aim to promote a culture that encourages quality improvement and foster supportive leadership in the health facilities.

In the next section, I will discuss the tracer indicator of change that will evaluate the effect of the intervention as a quality improvement strategy. For this study, the tracer indicator has been selected as preterm feeding practices. This is because preterm feeding is a complex intervention, and despite available guidelines, there is minimal adherence to them by the health workers.(104)

2.4 Evidence informing the feeding guidelines of the preterm and low birth weight newborn and the factors influencing health worker adherence to the guidelines.

Optimal nutritional support of preterm newborns is a fundamental part of their management. Preterms require an adequate caloric intake that enables a growth ratio that is compatible with that occurring in a normal foetus at the same post menstrual age.(105) However, preterm birth is complicated by immaturity of the motor and motility functions of the gastrointestinal (GI) system characterised by poor suck, swallow and breathing coordination and a predisposition to the development of necrotising

enterocolitis (NEC). This has led to a lot of controversy in the initiation and progression of enteral feeding in a large proportion of this cohort.(106) Despite clearly defined evidence-based preterm feeding guidelines that support the early initiation and rapid progression of enteral feeds, the perceived risk of the development of NEC leads to non-adherence to the guidelines and poor outcomes for the preterm newborns.(104, 107, 108) Due to the inability of some preterms to fully utilize the GI system for optimum nutritional intake, they receive parenteral nutrition through the intravenous route as an adjunct to enteral feeding. Intravenous nutrition presents a risk for the development of several complications and importantly, the development of late onset neonatal sepsis (LONNS).(7, 20, 36, 109) The benefits associated with early enteral feeding and the risks associated with intravenous nutrition emphasize the need to optimize enteral nutrition in preterm newborns.

2.4.1 Evidence informing the early initiation of enteral feeds.

Early enteral feeding aims to accelerate the functional adaptation of the immature GI system.(34) The milk feeds stimulate GI hormonal secretion and improve gut motility, therefore allowing for the rapid transition to full enteral feeds.(110) Early initiation of enteral feeds was initially described as the introduction of feeds within the 1st 96 hours of life.(34, 111) Further evidence then suggested that beginning enteral feeds within the 1st 48 hours of life in preterm and low birth weight newborns has more significant benefits than initiating within 72 or 96 hours of life.(37, 112, 113) Sallakh-Niknezhad *et al* (2012) followed two cohorts of 170 VLBW preterm infants; one cohort was enterally fed within 48 hours of life, while the 2nd cohort was enterally fed after 72 hours of life. There were significant reductions in the time to gain birth weight, duration of hospital stay and duration on parenteral nutrition for the cohort that began enteral feeding within 48 hours of life.(37) The evidence advocates for the initiation of enteral feeds as early as within the 1st 48 hours of life.

Unstable preterms including those requiring respiratory support, vasopressor support, neonates with severe birth asphyxia and extreme preterms may not be able to tolerate the maximum volume of fluids

for the day as enteral feeds on the first day of life. These newborns therefore receive the total fluid volume for the day as parenteral nutrition.(114) However, they require a minimal amount of enteral feeds to accelerate the gastrointestinal physiological, endocrine and metabolic maturity.(115) These are given as trophic feeds which are described as 'nutritionally insignificant volumes of enteral substrate to compromised newborns in order to stimulate and supply nutrients to the developing GI tract.'(116) The volume of trophic feeds given is between 10-24ml/kg/day.(34) A Cochrane review by Morgan *et al* (2013) compared the outcomes of VLBW preterm newborns who were initiated on trophic feeds within 96 hours of birth and those who were enterally fasted for a period of one week after birth. There were better outcomes among preterms who were initiated on trophic feeds within 96 hours.(34) However, further evidence shows improved benefits with even earlier initiation of feeds. Marinković *et al* (2016) conducted a prospective study to compare the benefits of early (<48 hours) versus late (>48 hours) initiation of trophic feeds among VLBW preterms. There was significantly better weight gain, more rapid achievement of birth weight and faster attainment of optimal enteral intake among the group that had early initiation of trophic feeds.(117) Trophic feeding is then followed by progressive feeding which has greater benefits than maintaining trophic feeds for a prolonged period.(117) A retrospective study by Salas *et al* (2017) assessed the benefits of a shorter duration of trophic feeds among extremely low birth weight preterms who progressed to increasing volume of feeds within an average of two days of life compared to prolonged trophic feeding. There was reduced time to full enteral feeds and no increase in incidence of NEC among the preterms who had a shorter duration of preterm feeds.(111) Recent evidence advocates for the early initiation of trophic feeds preferably within 24 hours and early progression of enteral feeds, however there are no controlled trials that would provide stronger evidence in this field.

An early total enteral feed regimen is however recommended for stable preterms with a birthweight of 1000g and above.(113, 118) This refers to initiating enteral feeds at a volume of 60-80ml/kg/day

depending on the birthweight. A randomised controlled trial by Arnon *et al* (2013) defined commencement of feeds by 24 hours of life as the early initiation of feeds and commencement of feeds after 24 hours of life as late initiation of feeds. The arm that began feeds at ≤ 24 hours of life had significant reduction in time to reach full enteral feeds and duration of hospital stay.(113) Alshaikh *et al* (2019) conducted a systematic review to assess the feasibility of initiating early total enteral feeds from birth onwards among stable preterm newborns with a birthweight above 1000g. These preterms had a lower rate of late onset neonatal sepsis, less time to reach full enteral feeds, reduced time to regain birthweight, reduced hospital stay and no difference in risk of NEC or feed intolerance compared to a control group with delayed initiation of enteral feeds.(118) Delayed initiation of enteral feeds in a setting that does not readily have access to parenteral nutrition may result in a catabolic state in the preterm newborn due to delayed protein intake, this then results in delayed time to regain birth weight.(7)

2.4.2 Evidence informing the rapid advancement of enteral feeds

Rapid advancement of enteral feeds refers to the increase of enteral feeds by 30-40ml/kg/day while gradually tapering off the intravenous feeds.(20) In recent years, there has been an increasing amount of literature supporting the rapid advancement of enteral feeds compared to slow advancement at 15-20ml/kg/day. A Cochrane review by Oddie *et al*. (2017) synthesised research evidence to assess if the slow advancement of feeds resulted in a decreased incidence of NEC among both stable and unstable VLBW and ELBW preterms.(20) The evidence suggests that rapid advancement of feeds in all groups presents no difference in risk for the development of NEC or feed intolerance or mortality. However, it significantly reduces time to reach full enteral feeds, provides a shorter duration of time on intravenous nutrition, reduces time to regain birth weight and reduces the risk of postnatal growth impairment and potentially neurodevelopmental challenges.(7, 36, 109) RCTs have been conducted among the different preterm and low birth weight categories to compare the effects of rapid versus slow advancement of

enteral feeds. The evidence supports the rapid advancement of enteral feeds and is summarised in Table 6 below. The time taken to reach enteral feeds among the VLBW preterms in the rapid advancement cohorts was a mean of seven days (5,96) and 19 days among the ELBW preterms in the rapid advancement cohort.(109)

Table 6: Benefits of rapid enteral feed advancement in preterm and low birth weight newborns

Author, country and year	**Methodology**	**Population**	**Rate of feed advancement**	**Time taken to regain birth weight**	**Outcome**
Karagol et al, 2017.(109)	RCT comparing outcomes of slow vs rapid feed advancement in preterms until attainment of full feeds – 180ml/kg/d	Preterms – 750g – 1250g. Sample size - 92	Slow advancement – 15 ml/kg/day. Rapid advancement – 30ml/kg/day.	Slow advancement – mean of 23 days. Rapid advancement – mean of 19.2 days.	Rapid advancement of feeds resulted in: • Reduced time to reach full feeds. • Shorter duration on intravenous nutrition. • No difference in NEC risk. • No difference in mortality risk.
Krishnamurthy et al, India, 2009.(7)	RCT comparing slow vs rapid feed advancement in preterm newborns until attainment of full enteral feeds – 180ml/kg/d	Stable VLBW preterms – 1000g – 1499g. Sample size - 100	Slow advancement – 20ml/kg/day. Rapid advancement – 30ml/kg/day.	• Slow advancement – mean of 22 days. • Rapid advancement – 16 days	Rapid advancement of feeds: • Reduced time to full enteral feeds ($p<0.001$). • Reduced duration of IV fluids ($p<0.001$). • Reduced time to regain birthweight ($p<0.001$). • No difference in risk of NEC ($P = 1$).

Caple et al, USA, 2004.(36)	RCT comparing slow vs rapid feed advancement in preterm newborns until attainment of full feeds – 150ml/kg/d	Sick and stable preterms – 1000g – 2000g. Sample size – 155	• Slow advancement – 20ml/kg/day. • Rapid advancement – 30ml/kg/day	• Slow advancement – mean of 13 days. • Rapid advancement – mean of 11 days	Rapid advancement of feeds: • Reduced time to full enteral feeds (p<0.01). • Reduced time on intravenous nutrition (p<0.01). • Reduced time to regain birthweight (p<0.01). • No difference in NEC risk (RR: 1.73; 95% confidence interval: 0.30–10.06; P = 0.66)

Abbreviations: NEC; Necrotising enterocolitis, RCT; Randomised controlled trials, USA; United States of America, VLBW; Very Low Birth Weight.

Full enteral feeds have been defined as either 150ml/kg/day or 180ml/kg/day. This is based on the fluid and caloric requirements of a growing preterm.(104) The European Society of Paediatric Gastroenterology and Nutrition (ESPGAN) regards a minimum volume of 135ml/kg/day and a maximum of 200ml/kg/day as adequate to provide the required caloric requirements. The required caloric requirements for a preterm newborn are 110-135kCal/kg/day and protein requirements of 3.5-4.5g/kg/day and this ensures a weight gain of 15g/kg/day which is a replica of intrauterine growth in the third trimester.(119) In 2000, Kuschel *et al* conducted an RCT to compare the growth of very preterm neonates fed on either 150ml/kg/day or 200ml/kg/day as the target feed volume. The feed volumes could be adjusted at the discretion of the physician if the newborns did not maintain a weight gain of 8g/kg/day or demonstrated signs and symptoms of fluid overload. Despite there being a trend towards those in the 150ml/kg/day group being less mature and of lower birthweight, there was no difference in

days to regain birthweight. Most (57%) of the preterms in the 150ml/kg/day group maintained the feeds at the same volume, while 54% of those in the 200ml/kg/day group deviated from the assigned feed volume to an average of 180ml/kg/day (150-200ml/kg/day).(120)

High volume enteral feeds have several disadvantages such as the added physiological and metabolic stress to the immature GIT that increases the risk of NEC, increased risk of gastroesophageal reflux which increases the risk of apnoea and fluid overload leading to peripheral or pulmonary oedema, patent ductus arteriosus (PDA) or bronchopulmonary dysplasia (BPD).(121) Feed volumes of 150ml/kg/day are safe with increase based on assessment from a paediatrician.

A retrospective study in India by Gupta *et al* (2017) on preterms with a birthweight of < 1500g or gestation of < 34 weeks demonstrated that; with optimum feeding, it is expected that preterms are expected to regain their birthweight between 14 and 17 days with an inverse relationship between gestation and time to regain birthweight. The average weight gain from birth should be approximately 9.5 – 10.8g/kg/day.(115)

Preterm feeding is a complex intervention because despite the availability of evidence-based feeding protocols, the degree to which they are adhered to is dependent on human and contextual factors.(104)

A survey published by Gregory *et al* (2012) in the United States of America (USA) and Canada assessed the level of adherence to preterm feeding protocols in NICUs. The survey showed that 61% of NICUs have preterm feeding protocols, but only 27% of respondents adhered to the protocols. The reasons given for non-adherence were grouped into three categories:

1. Individualized care of the preterms based on the clinical condition.
2. Practice patterns of the physicians where decisions on preterm feeding are made based on their clinical judgement and not based on the guidelines.
3. Practice patterns of nurses where some opt to use their own feeding preferences depending on the practices they are used to, this is especially common among the senior nurses.(104)

A survey of preterm feeding practices in Spain was conducted by Pipaón *et al* (2016) which showed the dissimilarities in the enteral feeding practices in preterm newborns across 53 NICUs in the country. Initiation of enteral feeds occurred within 48 hours for all NICUs at varying feed volumes, with 65% initiating enteral feeds within 24 hours. There was also variation in the progression of enteral feeds with 47% of units progressing at a volume of > 20ml/kg/day, 45% progressing at 10-20ml/kg/day and 7.5% progressing at 5-10ml/kg/day. Uniformity was however observed in the administration of parenteral nutrition across the 53 NICUs.(108)

The contextual determinants are based on the complexity of the newborn unit or NICU. This is a demanding environment with highly vulnerable patients and complex interactions between health workers and parents.(40) Johnson *et al* (2017) identified that the NBU context has a profound effect on the extent to which feeding practices can be implemented and implementation of feeding guidelines can only be successful if the implementation strategy accounts for contextual barriers.(40)

The Ministry of Health (MoH) Comprehensive Newborn Care protocols which are the newborn clinical practice guidelines advocate for the initiation of full volume enteral feeds on the first day of life for all stable preterm newborns with a birthweight of ≥ 1000g. Enteral feeds on the first day of life for VLBW (1000-1499g) begin at a volume of 80ml/kg/day with progressive increment of the feeds by 20ml/kg daily until attainment of maximum enteral feeds of 150ml/kg/day. Stable preterms with a birthweight of ≥ 1500g should breastfeed or feed by cup on demand. The unstable newborn is initiated on intravenous 10% dextrose on the first day of life and may receive trophic feeds at 2ml/kg every three hours. This results in a total volume of feeds of 16ml/day on the first day of life. This is consistent with the evidence-based recommendations that recommend trophic feeds between 12-24ml/kg/day. The total daily volume; intravenous fluids and enteral feeds should increase by 20ml/kg/day; however, the enteral feeds alone are increased by 30ml/kg/day from day two of life depending on stability of the newborn while gradually reducing the intravenous fluids to keep within the recommended total daily volume. The

intravenous fluid is stopped when the full 3-hourly feed volume achieved is appropriate for weight and postnatal age in days. These guidelines are modified from the WHO preterm feeding guidelines, 2017.(122) (see Appendices 2 and 3)

This chapter provides the evidence that: 1. Informs the decision to design a newborn unit audit tool 2. Identifies from literature the potential facilitators and barriers to implementation of the audit tool 3. Informs the strategy that will be used to successfully implement the newborn unit audit tool and process guide and, 4. Provides justification on the use of preterm feeding as the tracer indicator to assess the success of the intervention.

In the next sections, I will discuss the theory of change, describing how the four constructs of the iPARIHS framework were applied and are interlinked to influence the successful implementation of the newborn unit audit tool.

Theory of change

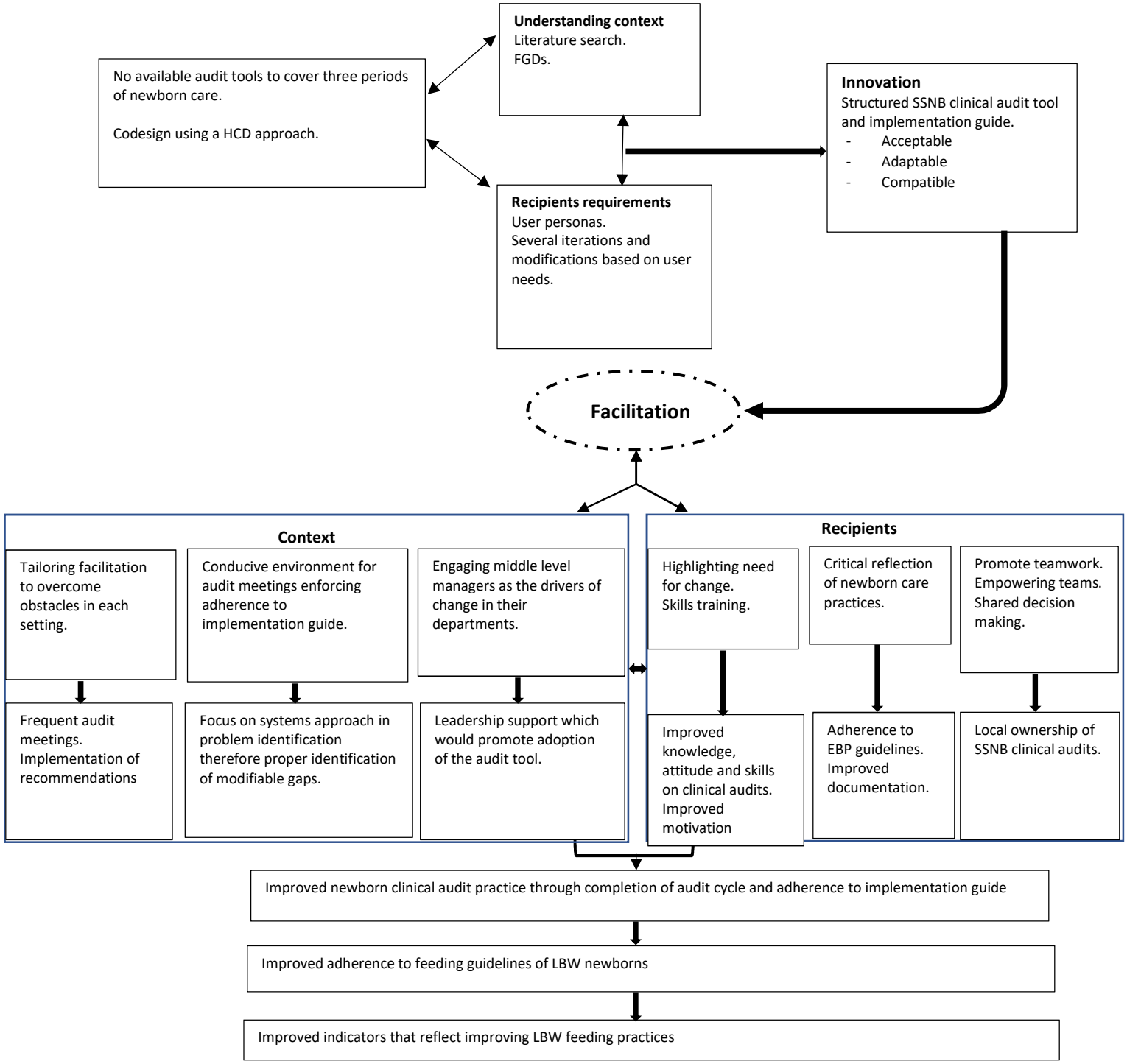


Figure 4: Theory of change diagram demonstrating the impact pathway and causal link assumptions influencing the implementation

The theory of change model is based on the iPARIHS framework that guided the design of this PhD thesis. The model begins by describing the direct outputs of the HCD process which were a SSNB clinical audit tool and implementation guide that were compatible to the study settings.

The activity utilised to enable implementation of the clinical audit tool was facilitation through the use of a facilitator who was familiar with the health workers in the study sites and had knowledge on newborn care, clinical audits and research methods. The facilitation activities were used to activate the other three constructs by understanding and responding to the characteristics of the innovation and recipients within their context.(6)

The recipients of the facilitation were the health workers involved in the audit meetings. The facilitation process was anticipated to provide capacity change among the recipients through the following inputs; highlighting the need for change in the way clinical audits are conducted, skills training on conducting clinical audits, skills on critical reflection of newborn care and promotion of teamwork. The expected outcomes were behavioural changes including; improved knowledge, attitude and skills on conducting clinical audits, adherence to the use of evidence based clinical guidelines and improved documentation and promoted local ownership of the audit tool.

The facilitation process had inputs on the context which included: tailoring the facilitation strategy to overcome obstacles within the settings, promoting a conducive environment for the audit meetings through enforcing adherence to the implementation guide and by directly engaging the middle level managers who are the drivers of change. The expected outcomes from these inputs included; holding frequent audit meetings with implementation of recommendations, proper identification of modifiable gaps using a root cause analysis and promoting leadership support of the clinical audits.

The interaction of the inputs and outcomes on the recipients and context would have an effect on how clinical audits were conducted, consequently resulting in improved adherence to feeding guidelines of

LBW newborns. These changes would result in an impact on the indicators of improving feeding practices in the newborns.

In the next chapter, I will provide an in-depth description of the methodology used to meet the objectives of this PhD thesis.

Chapter 3: Methodology

I will begin this chapter by describing in detail the Clinical Information Network which represents a unique platform of hospitals through which researchers implement key interventions to improve paediatric care delivery in Kenyan hospitals. (123) This provides an overview of the study sites involved in the development and implementation of a SSNB audit tool.

I will then describe the human-centred design (HCD) approach used for the innovation design, which was the small and sick newborn (SSNB) clinical audit tool and implementation guide.

This will be followed by a description of the methods used in the implementation where I'll begin by:

i. Describing the intervention which involved facilitated implementation of the clinical audit tool and implementation guide.

ii. Describing in detail the parallel mixed methods study used; a controlled before and after analysis of the quantitative data and participant observation of the SSNB clinical audit implementation. I will describe how the two research paradigms were integrated to produce stronger inferences and why a mixed-methods approach was appropriate to answer the research questions posed.

iii. Describing the study population, study outcomes, data collection methods, sample size calculation and data analysis for the quantitative and qualitative studies.

3.1 Introduction to the research methods

This was a two-phase, hospital-based mixed method, pragmatic study. Phase one was the development of the SSNB clinical audit tool and implementation guide using a Human Centred Design (HCD) approach. Phase two was the implementation of the SSNB clinical audit tool and specific use of facilitation to enhance adoption of the intervention using a mixed methods approach.

I will begin by describing the Clinical Information Network. Understanding the structure, purpose and functions of this network will enable better understanding of the assumptions made that resulted in the

selection of the methods used in the design of the audit tool, the implementation strategy and the quantitative and qualitative research methods.

3.1.1 Description of study setting

3.1.1.1 Introduction to the Clinical Information Network

The study involved six hospitals that are within a Clinical Information Network for newborns (CIN-Neonatal). The CIN-Neonatal is a collaborative effort between the Ministry of Health (MoH), Kenya Medical Research Institute (KEMRI)- Wellcome Trust Research Programme (KWTRP), the Kenya Paediatric Association (KPA) and the participating hospitals that aims to improve the quality and utilisation of patient level data.(41)

With the coming into effect of a new constitution in 2013, Kenya transitioned into a devolved government with a central government and 47 semi-autonomous county governments.(124) Under this new governance structure, healthcare functions such as allocation and management of healthcare resources and service provision were devolved to the county governments. The central government retained policy making and regulatory roles.(125) In the devolved health care services, the organisation of the public health care system is in six levels, which are categorized broadly into four tiers as illustrated in Figure 5 below.(124)

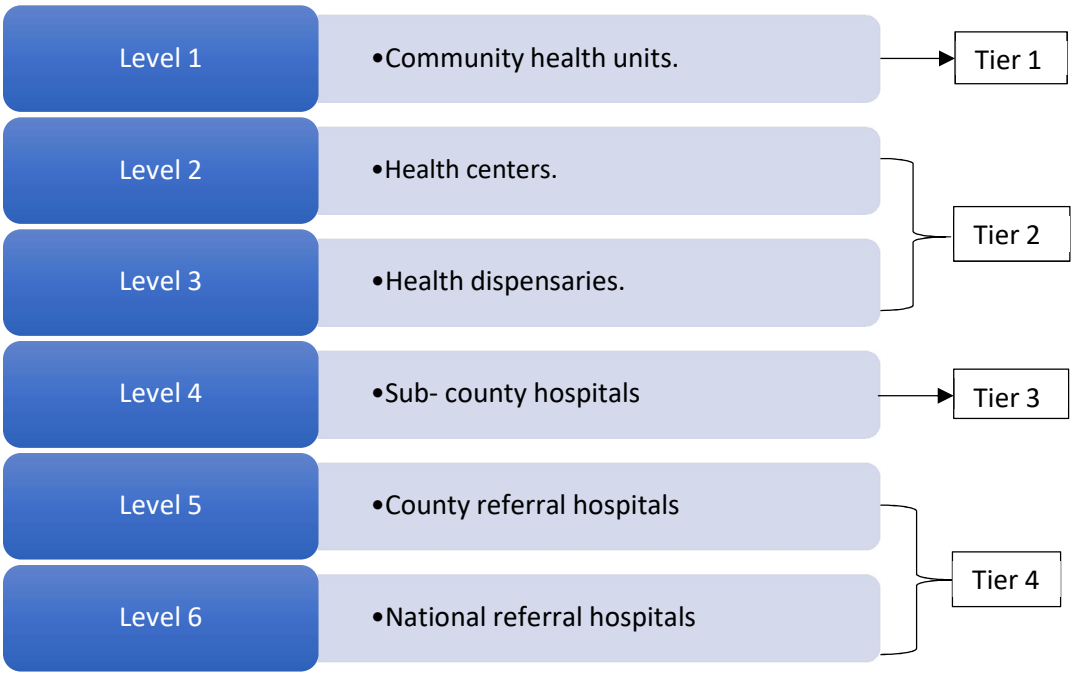


Figure 5: Organisation of the public health care system in Kenya

The CIN was initiated in 2013, shortly after the devolution of health services. The initial focus of the CIN was on the general paediatric wards with the selection of the participating hospitals done purposefully together with the MoH to select 14 County referral hospitals from 12 of the 47 counties.(126) The hospitals selected were based on a grouping of high or low/very low malaria prevalence and a workload of at least 1000 paediatric admissions per year.(126) The network has progressively expanded since 2013, and in 2018 it expanded into the hospitals' newborn units. This led to the establishment of two networks that are functionally and administratively linked; CIN-Paediatrics (CIN-Paeds) and CIN-Neonatal. CIN-Paeds generates data from the general paediatric wards for all paediatric admissions (0-13 years) and CIN-Neonatal generates data from the newborn unit admissions.(27) The participating hospitals in the CIN-Neonatal currently include 23 county referral hospitals, one faith based organisation and one tertiary level hospital from 16 out of the 47 Counties in Kenya.(27) The hospital care provided to newborns in all the hospitals under CIN-Neonatal is free. This is based on a government directive that all public health facilities in Kenya should provide free treatment to children below five years of age.(127) This is with the exception of Kenyatta National Hospital (KNH), the only parastatal institution

and tertiary level hospital in CIN-Neonatal which charged all patients user fees during the period of the study. The mortality and morbidity patterns in 16 of the CIN hospitals were previously described.(27) In brief, among the paediatric patients aged 0-13 years admitted during a two-year study period (April 2018 – March 2020), 46% were newborns aged 0-28 days. Among the admitted newborns in the NBU, low birth weight newborns with a birth weight < 2500g accounted for 30% of this newborn population. Newborn deaths contributed to two thirds of mortality among the patients aged 0-13 years with 91% of the deaths occurring among neonates aged 0-6 days of life. There were five preventable conditions that accounted for majority of newborn deaths; Intrapartum related conditions, respiratory distress syndrome, neonatal sepsis, neonatal jaundice and low birthweight.

The establishment of the Clinical Information Network drew on the key principles of learning health systems (LHS) (Box1).(11)

Box 1: Key Principles of learning health systems

i. Creating a network of engaged and motivated stakeholders.

ii. Enabling use of information emanating from routine clinical data for local improvements and wider health systems monitoring.

iii. Promoting rapid adoption of evidence into routine clinical care.

iv. Enabling researchers to use the same data to conduct rapid and efficient health research that supports strategic improvements in health.

The CIN-Neonatal focal persons in each participating hospital include the paediatrician/s, lead nurse in the NBU and the chief health records and information officer (HRIO).(126) The focal persons bring local authority and they understand the local contexts of hospital systems.(41) They participate in network meetings to co-design job-aides such as admission record forms and monitoring charts, share learning and review progress of their hospitals. (128) They also play a role in changing the behaviour of frontline

health workers in an effort to improve the quality of newborn care. The MoH asserts the needed authority, re-affirms policy and helps overcome challenges in implementation of evidence-based practices. The inclusion of KPA establishes professional endorsement, and the UoN helps raise funds and provides expertise in clinical and research knowledge.(41)

The CIN-Neonatal has a mission to generate hospital data that can be trusted by the partner representatives and the participant hospitals to inform their decisions and plans and monitor and evaluate their actions.(41) This has been achieved through the introduction of standardised structured forms that improve the collection and use of patient-level hospital data (neonatal admission record (NAR) forms, internal newborn unit transfer forms, treatment charts, comprehensive newborn monitoring charts, and exit forms) in the hospital NBUs.(89, 129, 130)

The standardised NAR forms are aligned to the MoH clinical practice guidelines; the Kenyan Basic Paediatric Protocols.(131) They capture information on the relevant maternal history, biodata and clinical history of newborns, examination findings and admission vital signs of newborns, the basic laboratory tests ordered and primary and secondary diagnoses on admission. The clinical variables included are based on the national guideline recommendations on the key signs and symptoms that should be assessed for all sick newborns. (Appendix 4a). The internal newborn unit transfer forms are filled by the midwives and postnatal ward nurses during the transfer of small and sick newborns from labour ward and the postnatal wards to NBU. They contain the mother's antenatal care (ANC) and labour and delivery details, the newborn's details and reason for referral to the NBU. (Appendix 4b) Treatment charts capture information on the medication prescriptions and other prescriptions such as feed and fluid prescriptions and blood transfusion prescriptions. The comprehensive newborn monitoring charts capture the vital signs, general assessment of the baby, and the feed and fluid prescription and monitoring (Appendix 4c). The exit forms contain information on the newborn's biodata, the discharge diagnoses, supportive and preventive care given, progress of patient and key

investigations, follow up and discharge instructions. These records promote good documentation practices that make the medical records an adequate source of accurate routine patient data.(129)

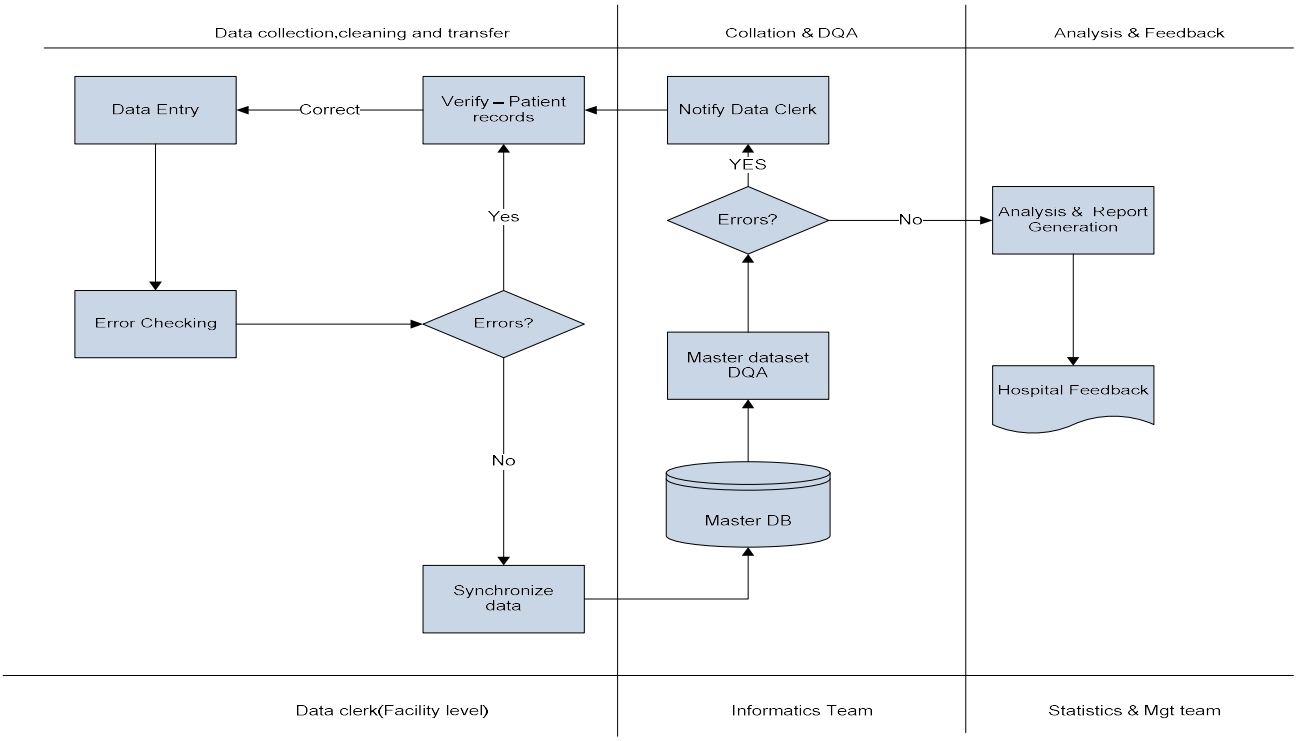
3.1.1.2 Clinical Information Network data collection and internal data quality assurance

Each facility has a trained data clerk with health records information experience who daily uploads data upon death or discharge of newborn patients.(42) The data collection is from the standard paper-based clinical documentation records as well as other additional source documents onto the data collection tool on Research Electronic Data Capture (REDCap).(123) REDCap is a data management tool used primarily for research and quality improvement strategies and has been set up on desktop computers provided to each site.(132) The information collected includes the biodata, admission and discharge diagnoses, supportive management and definitive management. The data collection across the sites is standardised using comprehensive written guidance in the form of standard operating procedures (SOPs) which have been refined during studies conducted over the years. These allow the data clerks to explicitly follow procedures in the abstraction of data from the paper records to the electronic form on REDCap.(123) The SOPs form the basis of the training of the data clerks (Appendix 5). Refresher trainings for the data clerks occur every three months during site visits and when there are updates of the SOPs with each new study.(123)

The first confirmed COVID-19 case in Kenya was reported on 12th March 2020. Subsequently, the Ministry of Health (MoH) put in various measures to curb the spread of the pandemic. These included; mandatory wearing of face masks, mandatory hand sanitizing or hand washing in public spaces, ban on large indoor gatherings, social distancing by individuals maintaining a 1.5-meter distance from each other in various spaces and travel restrictions within and outside the country. The data clerk trainings and updates were, therefore, done virtually at the height of the COVID-19 pandemic (2020 and 2021).

3.1.1.2.1 Clinical Information Network internal data quality assurance

For internal quality assurance; the site desktop computers have validation scripts which check for data entry errors in the uploaded data. The data clerk receives message alerts for any input that is outside the acceptable pre-set range for the different variables (subsequently described as errors), upon which the data clerk verifies the information from the patient records and uploads the corrected data onto REDCap. The data clerk runs the scripts again and if there are no errors, they synchronize the data with the main server at the KWTRP offices daily. The synchronized data is imported to the master data set, the scripts are run again remotely by the KWTRP data managers to check for errors. If any errors are detected, the data clerk at the site facility is notified and repeats the process of verification. If there are no errors, the data is cleaned, analysed and reports generated.



Abbreviations: DB; Database, DQA; Data Quality Analysis

Figure 6: Data management process in CIN-N hospitals from facility level to synchronisation with the master database and generation of feedback reports.(42)

3.1.1.2.2 Clinical Information Network external data quality assurance

External data quality assurance is conducted by the research team. The assistant research officers (AROs) visit the site hospitals every three months to support good data collection practices. The AROs randomly select 5% of files per hospital, go to the sites and conduct a verification of the data by independently re-entering the data from these selected files and compare and contrast these with the data entered by the data clerk. They then provide performance feedback to the hospital data clerk and HRIOs and provide training as required.(42)

The clinical coordinators and AROs regularly maintain phone and email contact with the hospital paediatricians and data clerks. Every Tuesday afternoon, the research team including the clinical coordinators and data management team review the data trends from all the hospitals under the CIN-Neonatal to track adherence in use of the NAR forms by the hospital teams. During this meeting, the AROs present any data entry errors flagged by REDCap arising from the different hospitals. These are discussed in detail by the clinical coordinators to determine if they are data entry errors or clinical errors. The clinical coordinators then immediately give feedback on identified clinical and managerial challenges to the hospital paediatricians and/or NBU nurse leaders from the affected facilities. The AROs give feedback to the data clerks, and HRIO for systemic challenges, on data entry issues arising from the affected facilities.

3.1.2 Generation of monthly and quarterly audit feedback reports from individual hospital data

Monthly and quarterly audit and feedback reports are generated from the quality data entered in REDCap and are used for the local improvement of healthcare provision to the in-patient newborns and to monitor the health systems performance. (41) These reports are presented to the focal persons in

each hospital who have been previously trained on interpreting them. The focal persons disseminate the reports to the rest of the hospital teams as feedback on their performance.

3.1.2.1 Nature of audit feedback reports and their utilisation

The hospitals get monthly feedback reports that provide a monthly summary of: (1) Admissions and discharges, (2) total deaths and crude mortality rate, (3) categorisation of mortalities, (4) referrals into and out of the NBU, summary of utilisation of CPAP and KMC, and (5) morbidity and mortality patterns by primary diagnosis and disease episodes.

A more detailed three-monthly quality of care feedback report that compares the hospital performance to other CIN-N hospitals. The quarterly reports provide: (1) A summary of number admissions and characteristics of admitted patients, (2) proportion of mortalities among the discharged patients and the details of mortality, (3) disease pattern trends, (4) quality of documentation on medical records including; signs and symptoms of severe illness and vital signs, and, (5) an assessment of adherence to the Kenyan Basic Paediatric Protocols and the Comprehensive Newborn Care Protocols in; antibiotic dosages (penicillin and gentamicin), type of feeds and fluids prescribed and incorrect feed and fluid prescriptions, and, prescription of continuous positive airway pressure (CPAP) and kangaroo mother care (KMC).(42)

The reports use 'traffic light coding' to identify problem areas, and any changes over the previous 12 months are then summarised. Each facility NBUs' focal persons are responsible for re-enforcing proper documentation in medical records that facilitates data collection.

3.1.3 Ethical Approval

I received ethical approval from Kenyatta National Hospital- University of Nairobi Ethics and Research Committee (KNH – UoN ERC P330/06/2020) see Appendix 6a. In addition, this PhD study has been covered under a broader project (A System Strategy to Optimise Neonatal Inpatient Care in Kenyan Hospitals - SONIC) that was granted approval; protocol no: KEMRI/SERU/CGMR-C/161/3852 and the

project (A Clinical Information Network – A Technical Collaboration with the Ministry of Health and County Hospitals to Support and Improve Strategies for Audit and Health Service Evaluation. This has been granted approval; protocol no: 3459. (see Appendix 6b and 6c)

3.1.4 Interaction between the research project and other research activities within the CIN-Neonatal

The SONIC project is a three phase project that included: (1) Phase of the co-design and testing of the comprehensive monitoring chart, the newborn clinical audit tool and communications training material with CIN-Neonatal focal persons, (2) phase of the implementation of the co-designed and tested material, and (3) phase of sustainability for continued reinforcement of good practices using the designed implementation strategies (phase two) with a focus on improving health outcomes while using the CIN-Neonatal data to track the processes and outcomes of the interventions. The co-design and implementation of the comprehensive monitoring chart was also conducted as part of a PhD project.(89, 133) The two studies influenced each other positively as the clinical audit process exposed the deficiencies in patient monitoring and documentation. This encouraged the uptake in use of the comprehensive monitoring chart for monitoring of vital signs, feed and fluid prescription and monitoring at the study sites.(9)

Thirteen of the CIN-Neonatal sites are enrolled in another newborn programme known as the Newborn Essential Solutions and Technologies 360^0 (NEST) programme. This is a programme whose goal is to provide newborn essential technologies to address the leading causes of newborn deaths with an aim to reduce the facility-based newborn mortality by half.(134) The NBU teams in the sites implementing the NEST programme use the MoH Comprehensive Newborn Care protocols as their newborn care management guidelines and have received training on the use of these protocols. In addition to the recommended newborn clinical management, these protocols contain guidelines on the use of the technologies that have been provided to each NEST site. The NEST 360 comprehensive newborn care

bundles at the time of the study include: Temperature stability (radiant warmers), prevention and treatment of hypoglycaemia (glucometers), breathing support (Continuous Positive Airway Pressure (CPAP), suction pumps, oxygen splitters, oxygen concentrators, pulse oximeters), management of jaundice (phototherapy lights and light meters). The NEST 360 model also includes enabling education ecosystems where clinicians, nurses and biomedical technicians are empowered to support SSNB care. This has been done through conducting regular continuous learning sessions with the clinical and biomedical teams as well as conducting newborn clinical audits which allow the teams to reflect on their own practice and learn from it. In an effort to ensure continuity of the quality initiative programs during the COVID-19 pandemic, the CME or conference rooms used for NBU learning activities for facilities in the NEST Programme had 55-inch smart TV screens installed. This facilitated communication between the Clinical Information Network, the NEST 360 Programme coordinators, and the hospital teams.

In summary, this study leverages an established Clinical Information Network for Newborns comprising 21 county hospitals in Kenya. The CIN-N provides a research database of patient level data from all neonatal admissions upon discharge with significant effort made to use local data to improve the provision of neonatal inpatient care through promoting the adoption of evidence-based guidelines. This study complements the aims of the CIN-N as the main objective of a clinical audit is to enforce adherence to evidence-based guidelines by identifying the modifiable gaps in the process of care that led to variation from best practices.

In the next section, I will describe the co-design phase of the study using a human centred design approach. I will describe the criteria used for the selection of study sites for the phase of development of the SSNB clinical audit tool and implementation guide, the study population and the methods used for the three step HCD process.

3.2 Methods used in the development of a SSNB clinical audit tool and implementation guide using a human centred design approach.

The development of the small and sick newborn (SSNB) clinical audit tool used a human-centred design (HCD) approach.(9) This co-design approach advances the development of usable systems by championing for active user participation and allowing for several iterations of the design and subsequent modifications based on the users' requirements.(135, 136) A HCD approach was selected as it would take into consideration the usability and human factor characteristics of the audit tool and implementation guide, and hence the experience it provides for the user.(23, 88) This would promote ownership of the innovation.

3.2.1 Description of the study sites used for the co-design of the SSNB audit tool and implementation guide.

All the selected study sites with the exception of KNH which was the only site that provided tertiary care provided services that placed their NBUs under the category; intermediate care hospital.(137) The services provided were similar and included:

a. Provision of warmth including incubator care for preterms and Kangaroo Mother Care (KMC).
b. Nutritional support including nasogastric tube (NG tube) insertion and intravenous fluids.
c. Respiratory support including oxygen by nasal prongs and CPAP.
d. Management of neonatal jaundice including standard and intensive phototherapy and exchange transfusion.
e. Management of convulsions including intramuscular phenobarbitone and intravenous phenytoin.
f. Management of sepsis with parenteral antibiotics.
g. Other services include transfusion of blood and blood products.

The staff dedicated to the NBUs differed across the study sites and will be described per individual site. There were, however, other departments that were not dedicated to the NBU but were still part of the

newborn care team and they were similar across the sites. These were; laboratory, pharmacy, radiology, occupational therapy, physiotherapy and biomedical engineering departments.

The county hospitals adhere to the national maternal perinatal death surveillance and response (MPDSR) guidelines while planning for and conducting their meetings.(62) They hold monthly MPDSR meetings where the maternal near misses are discussed in detail, and the NBU team is given an opportunity to briefly present a summary of the neonatal morbidity and mortality statistics for the month. The meeting is attended by the MPDSR committee that is composed of (i) senior most obstetrician who is the chair, (ii) midwife in charge of labour ward who is the deputy chair, (iii) administrators (medical superintendent, hospital administrator and hospital matron) (iv) anaesthesiologist, (v) nurse in charge of theatre, (vi) paediatrician, (vii) NBU nurse in charge, (viii) pharmacist, (ix) laboratory in charge, and (x) records officer. In the event of a maternal death, a meeting is held within 48 hours of the death and this is attended by members of the committee as well as the individuals involved in the care of the mother.

3.2.1.1 Study site description of hospitals used for the human centred design of the small and sick newborn clinical audit tool and audit implementation guide

The design and testing of the feasibility of the audit tool and implementation guide was majorly (15/18 audit meetings) conducted in Pumwani Maternity Referral Hospital (PMRH) which is a County referral hospital in Kenya that provides intermediate level care. PMRH is the largest referral maternity hospital in Kenya with approximately 100 deliveries a day. PMRH was selected because at the time of the study I had been a paediatrician in the newborn unit for one year. (see section 3.4) Kenyatta National Hospital (KNH) which is the largest teaching and referral hospital in Kenya that provides tertiary level care was included in the testing of the clinical audit tool and implementation guide. KNH expressed interest in improving its newborn clinical audit process and was incorporated into the study as a site to test the

feasibility and acceptability of the newborn clinical audit tool and implementation guide in January 2021.

A. Pumwani Maternity Referral Hospital

Pumwani Maternity Referral Hospital (PMRH) is located on the east side of Nairobi County where the lower income population are located. The NBU had approximately 350-400 newborn admissions per month with the highest number of daily admissions in April, May, July and September.(138) The bed capacity was 59 giving a cot occupancy of approximately 150%. The Kangaroo Mother Care (KMC) unit had 17 beds. PMRH has recently been upgraded to a County referral hospital. The hospital was previously under the management of the Municipal Council of Nairobi before devolution in 2013. Since devolution, the hospital has been under the jurisdiction of Nairobi City County (2013-2020) and Nairobi Metropolitan Services (NMS) (2020 – 2022). There was diversity in the hospital health workers as they were from three different employers and are all employed under different schemes of service. The NMS health workers were employed under contract (the initial group under a six-month contract, and the current group under a three-year contract).

The staff dedicated to the NBU included: 6 paediatricians, 10 medical officers, one clinical officer specialized in paediatrics, a nutritionist and a nurse: patient ratio of approximately 1:16 per day shift and 1:20 per night shift. Clinical in-patient work was provided by the medical officers and clinical officers who were supervised by the paediatricians. In addition to the services discussed in section 3.3.1, PMRH also provided human milk banking services.

The hospital had two main meeting rooms; a conference room and a boardroom where official hospital meetings were held. The NBU however had a Continuous Medical Education (CME) room where all NBU meetings and learning activities took place.

In addition to the MPDSR meetings which occurred monthly, at the time of the study, the NBU team held their own in-house meeting once a month to discuss the newborn morbidity and mortality statistics

for each month. The NBU meeting was attended by the NBU clinicians and nurses and was held in the CME room in the NBU.

B. Kenyatta National Hospital

This is the largest national referral hospital in Kenya with a total bed capacity of 1800. KNH also serves as the teaching hospital for the University of Nairobi (UoN) medical school. The hospital caters for the low-and-middle income population from Nairobi and its environs as well as referrals from other hospitals in the country and the greater Eastern Africa region.

The NBU of KNH had approximately 250 – 300 admissions per month from within the hospital and peripheral facilities across the country. The NBU had a bed capacity of 65 and a 10 bed KMC unit. The cot occupancy averaged 200%.(139) The staff solely dedicated to the NBU were: Approximately 15 paediatric residents doing a 12-week rotation at any given time, six neonatology fellows, one paediatrician, five neonatologists and a nurse: patient ratio of approximately 1:8 per shift. Majority of the newborn in-patient care was provided by the paediatric residents and the neonatology fellows. They were supervised by the neonatologists. The NBU provided intensive care services including invasive ventilation, inotropes, peritoneal dialysis, therapeutic hypothermia for management of hypoxic ischaemic encephalopathy (HIE) and surgical management for newborns when required. The NBU also had an in-house meeting room where learning activities took place. However, because of the COVID-19 pandemic, all quality improvement (QI) meetings and learning activities were held virtually at the time of the study.

The MPDSR meetings in KNH were not routine, they usually occurred within 48 hours of a maternal death. The NBU team were not included in the meetings.

In summary, the design and testing of the feasibility of the SSNB clinical audit tool and implementation guide majorly took place in PMRH which has the largest NBU in Kenya. PMRH provided intermediate level care and already had routine MPDSR meetings and newborn unit clinical audit meetings before the initiation of the study. KNH which is a tertiary level facility was incorporated into the study during the

testing phase. KNH NBU provided intensive care services as they provided services such as mechanical ventilation and therapeutic hypothermia. KNH did not conduct routine MPDSR meetings, and the NBU did not hold routine newborn clinical audit meetings before recruitment into the study.

In the next section, I will describe the study population involved in the co-design of the innovation as adopted from the iPARIHS framework.

3.2.2 Participants involved in the co-design of the SSNB clinical audit tool and implementation guide

The study population represented the 'recipient' construct of the iPARIHS framework. The study population in the co-design phase of this PhD thesis comprised of the following groups of participants.

A. The health care workers involved in the co-design of the audit tool.

B. The health care workers involved in the co-design of the implementation guide.

The study population involved in the cognitive walkthrough and the virtual design workshops included two groups:

A. Cognitive walkthrough in the co-design of the small and sick newborn audit tool and usability testing of the audit tool and implementation guide.

This study population represented those who attended the audit meetings in the hospitals. All the staff in the NBU were encouraged to attend the meetings.

1) Senior leadership from health facilities in the selected study sites. This included the medical superintendents, hospital administrators and matrons in charge of the facilities.

2) Frontline clinicians in the NBUs including:

- Neonatologists.
- Paediatricians.
- NBU nurses.

- Neonatology fellows (Paediatricians enrolled in a two-year fellowship programme to specialize in neonatology) from the University of Nairobi (UoN).
- Paediatric registrars (trainee paediatricians enrolled in a three-year postgraduate training programme in Paediatrics and Child Health) from the UoN.
- Junior clinicians (medical officer interns, medical officers, clinical officer interns and clinical officers) from the County hospital NBUs.

3) Other cadres in the health facilities involved in newborn care and attend the newborn unit audit meetings. These include; midwives, clinician representatives from maternity department, nutritionists, representatives from laboratory, radiology, pharmacy, occupational therapy, physiotherapy, records and biomedical engineering departments.

B. Co-design of audit implementation guide during a virtual design workshop

The design workshop participants included:

1) Stakeholders from the Ministry of Health, Division of Neonatal and child health.
2) Focal CIN paediatricians and nurses in charge of newborn units.
3) A neonatologist from the University of Nairobi.

3.2.3 Sample size estimation for steps in human centred design

In this section, I will describe the method used to calculate the sample size for the different steps in the co-design phase of the study.

I. Participants for structured de-brief during audit meetings

After the audit meeting, I had a structured de-brief session with 9 – 14 health care workers to get feedback on the usability of the audit tool. The sample included; 1-3 paediatricians, 2-3 M.Os, 3-4 NBU nurses, 1 midwife and 2-3 participants from other cadres attending the audit meeting (administration representative, nutritionist, laboratory representative, pharmacy representative or a representative from the biomedical team).

II. Respondents for focus group discussion during the design workshop

The group discussion consisted of the CIN-N focal paediatricians, nurses, a representative from the Ministry of Health involved in maternal and newborn health and one neonatologist from UoN. There was a total of 36 participants divided into four groups of nine in each group. The number selected for the FGDs was based on literature supporting the ideal group size for a successful group discussion. Literature supports a group size of five to ten participants with the ideal being six to eight participants. A group larger than 10 is thought to promote uneven participation and increase the potential for emergence of sub-groups. This makes it more difficult to manage group dynamics. A group smaller than five participants may lose some of the qualities of a group discussion particularly if the participants have different views.(140, 141)

III. Participants for design workshop

The design workshop was attended by the CIN focal paediatricians and nurse leaders from the County hospitals within the CIN network, one representative from the Ministry of Health involved in maternal and newborn health and one neonatologist from UoN. In total, there were 36 participants.

The MoH representatives and neonatologists were selected through purposive sampling to participate in the design workshop.

I will begin by outlining the HCD methods which were divided into three parts; part one describes the design of the SSNB audit tool, part two describes the design of the implementation guide, and part three describes the usability testing of the two.

3.2.4 Methods used in the co-design of a small and sick newborn clinical audit tool and implementation guide using a human-centred design approach

A three-step HCD methodology that spans the three parts of the co-design process was used as presented in Figure seven below.(23) The three-step methodology included:

i. Understanding the context of use, user requirements and the structure of the available audit tools. I did this through a review of the literature, a review of the structure of available audit tools, conducting focus group discussions (FGDs) and developing user personas. The outcome of this was the development of an implementation guide adapted from the WHO operational guide that was suited to the context and draft zero of the prototype of a SSNB audit tool. (1, 14, 53, 142).

ii. Cognitive walkthrough which refers to a structured approach towards evaluating the usability of the prototype audit tool. This involved the researcher walking the end users through several cycles of evaluating the prototype tool and the researchers modifying it accordingly. The outcome was a high-level prototype audit tool which was ready for testing with the end users.

iii. Usability testing which refers to the process of field testing the audit tool and implementation guide on their feasibility as the standard operating procedure (SOP) by which newborn audits would be conducted in the Kenyan public hospitals. The outcome of this was an audit tool and implementation guide that were scalable.

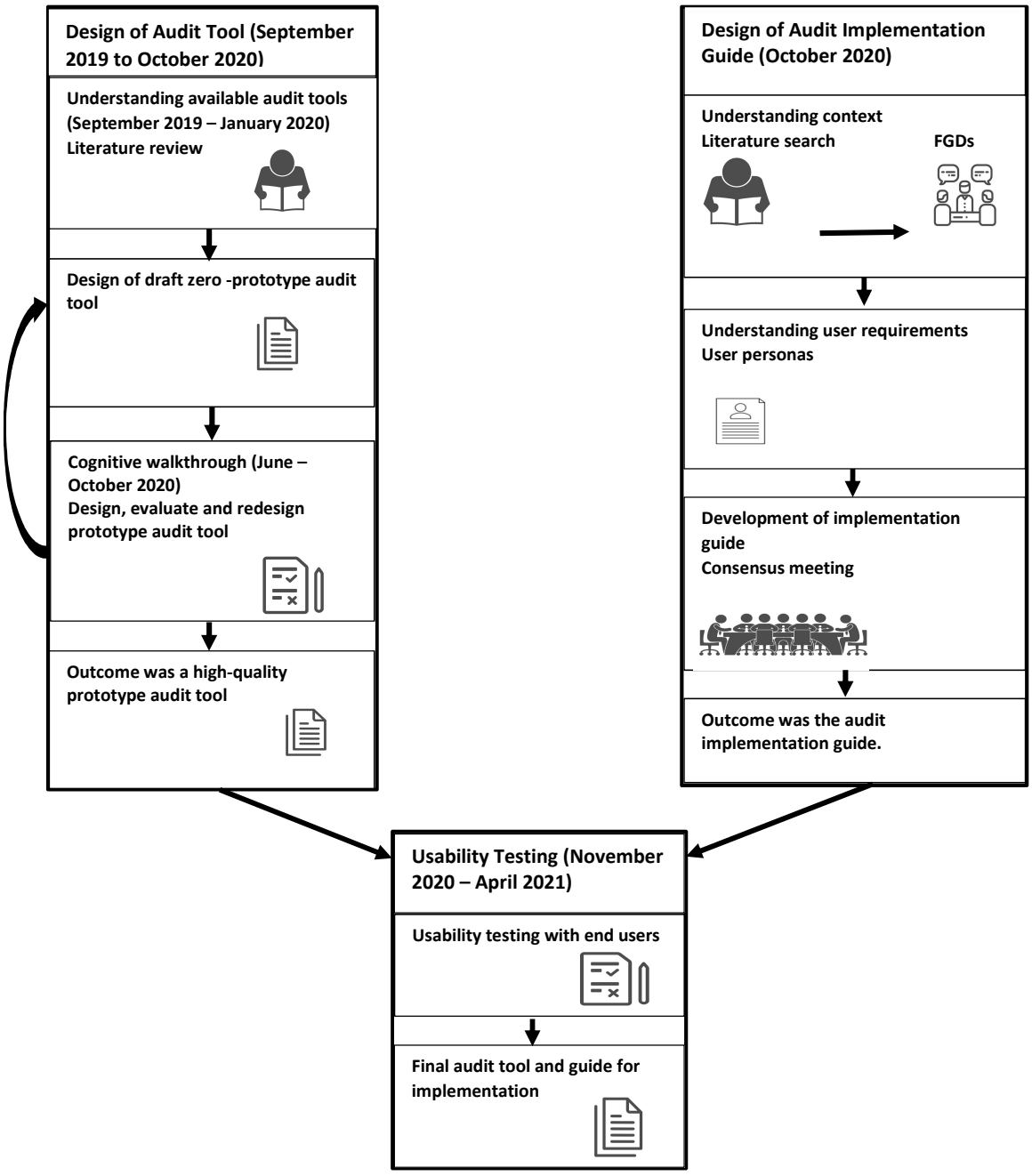


Figure 7: Summary of the three step HCD process and the components in each step

I will begin by describing the design of draft zero of the audit tool and its subsequent modifications using an iterative process that involved getting feedback from the end users of the tool.

3.2.4.1 Design of draft zero of the SSNB audit tool and subsequent modification through cognitive walkthrough with the end users

The design of draft zero of the prototype audit tool was based on an understanding of the literature and the available perinatal, neonatal and paediatric audit tools. This prototype was subsequently modified severally based on the needs and experiences of the end users who were the health workers attending the audit meetings.

a. *Understanding the modifiable factors in newborn care and the structure of available perinatal, newborn and child clinical audit tools*

I conducted a scoping review (described in section 2.1)(52) from which we identified the modifiable factors in hospital based newborn care from LMICs. These modifiable factors informed the content for each section of draft zero of the prototype audit tool. In addition, we were also guided by best practices as described in the Kenyan Basic Paediatric Protocol, Comprehensive Newborn Care Protocols and various WHO guidelines that outline standards of care for the SSNB.(122, 131, 143-145)

To inform the structure of draft zero of the SSNB prototype audit tool, we studied the existing audit tools. These audit tools included: Kenyan MOH MPDSR Tool(53), WHO Stillbirth and Neonatal Death Case Review Form(14) and WHO Child and Neonatal Death Review Form.(1) Draft zero was subjected to an iterative process of modification with the end users.

3.2.4.2 Cognitive walkthrough of the prototype audit tool

The modification of draft zero of the prototype newborn audit tool was through an iterative process where the end-users did a cognitive walkthrough by using the prototype newborn audit tool on real cases while focusing on the cognitive processes that the task required. This allowed for accurate identification of areas for improvement in the audit tool. The iteration involved the sequence of developing a prototype tool, evaluating it with the end users and modifying it based on their feedback.

The prototype newborn audit tool went through 15 cycles of evaluation and modification based on feedback from health workers in PMRH newborn unit between June and October 2020. The testing of the prototype audit tools was done both during the meeting preparation and during the audit meetings. In PMRH, newborn unit audit meetings were initially held once a month on the second Wednesday of the month as was the structure already in place. By the second month of the cognitive walkthrough, the NBU team opted to hold the audit meetings more frequently. The NBU team therefore settled on two-weekly audit meetings on the first and third Thursday of the month. To ensure that the meetings were held as scheduled, the audit meeting dates were documented in the NBU consultants' duty rota.

The cognitive walkthrough was conducted in five steps as described below:

Step 1: Selection of the team that would prepare the case summary

In PMRH, the newborn audit meetings were initially prepared for and presented by the junior clinicians with supervision from the Paediatricians. The junior clinicians had a rota that scheduled when each clinician would be responsible for the case summary preparation and presentation. Two months into the cognitive walkthrough phase, the NBU nurses were incorporated as an integral part of the audit process. I began by identifying the clinician and nurse who were responsible for preparing the case summary and presenting in the audit meeting and we would agree on a suitable date and time to meet at least three days before the audit meeting. The team would then move on to the meeting preparation.

Step 2: Evaluation of audit tool and feedback for modification during meeting preparation

I would initiate a discussion with the NBU paediatricians on their WhatsApp group on the criteria of interest in the selection of a case for discussion. This selection was based on an area that they felt needed to be highlighted. This resulted in consensus on the diagnosis of interest for each newborn audit. I would then discuss the selected criteria with the NBU nurse leader and determine if he agreed on the case selection criteria. Once all parties agreed, I communicated the diagnosis of interest to the junior clinician who would identify all the patient records that fit the criteria. We then both went

through the individual patient records and identified one case to audit. Once the case for audit was selected, the next step was to collect information on the care provided to the patient and summarise this onto the audit tool.

I would then walk the presenting clinician and nurse chosen in step one through the process of summarising the case on to the audit tool. The information on patient care was obtained from the patient's records such as the neonatal admission record form (NAR), newborn monitoring charts, feed and fluid monitoring charts, treatment charts, referral letters, patient continuation notes, nursing cardex and death summaries.

The information was summarised in a systematic way based on the structure of the audit tool, and during this process, the clinician and nurse would give feedback on emerging requirements of the audit tool based on their interactions with it. The feedback was based on (i) the ability of the structure of the audit tool to allow for the systematic flow of information, (ii) missing data from the audit tool that was important in newborn management, (iii) information that was not mandatory for the audit tool, and (iv) factors that limited the users' interaction with the audit tool.

Step 3: Implement modifications to audit tool based on feedback during meeting preparation

I discussed the proposed modifications to the audit tool with fellow researchers GI, ME and JA who would also weigh in on the feedback from the health workers. All the suggestions were taken into consideration and the changes implemented before the audit meeting. The collected information was summarised onto the modified audit tool which would be used during the audit meeting.

Step 4: Evaluation of audit tool during audit meetings

During the audit meeting, the clinician and nurse presented the case summary using the modified prototype audit tool as a guide. The audit meeting participants would then discuss the care provided in a systematic manner to identify the modifiable gaps in each section, determine the causes of death and recommend solutions.

The SSNB clinical audit tool was initially designed on Microsoft Word. I would print and distribute approximately 20 copies to the audit meeting participants and encourage them to fill in the tool as the case was presented. This ensured that a wider proportion of end users experienced using the audit tool and therefore giving diverse input into its design. At the end of the meeting, I would collect all copies of the audit tool for purposes of confidentiality. By the 9th version of the audit tool, we designed it as an electronic tool (E-tool) using PDF element and later Adobe Acrobat Pro 2020. This made it possible to fill the audit tool as a soft copy to allow for virtual attendance of the audit meetings. This was mainly due to MoH restrictions on large physical meetings due to the COVID-19 pandemic. The presenters would then project the audit tool onto the 55-inch smart screen TV for the purposes of the team attending the meeting physically and the rest of the team attended the meeting virtually through the Zoom platform. The clinician presented the sections on clinical management and the nurse presented the sections on patient monitoring and feed and fluid monitoring.

After the audit meeting, I recruited a few willing participants for a debrief session to give feedback on their thoughts of the audit tool and suggest areas that required modification. These would be the paediatricians in attendance, the clinicians and nurses in attendance and any other cadres present during the audit meeting.

Step 5: Revision of audit tool based on feedback from audit meeting participants

This step involved discussing the suggested changes to the audit tool based on comments from the audit meeting participants with fellow researchers. We also took into consideration our own observations and experiences of using the audit tool with focus on the flow of the story, missing information, extra information that was not considered relevant, sections that were not clear to the participants and time taken for each section. The audit tool would then be modified based on all this input before the next audit cycle. The outcome of this was a high-quality prototype audit tool that was ready for testing.

I will now describe the methods used for the development of the audit implementation guide.

3.2.4.3 Development of a context sensitive audit implementation guide by obtaining consensus opinion of the end users.

The implementation guide represented the context sensitive standard operating procedures (SOPs) for conducting the newborn clinical audit process that were adapted from the "Improving the quality of paediatric care: an operational guide for facility-based audit and review of paediatric mortality. Geneva: World Health Organization; 2018" manual.(1) Its development involved (i) understanding the context of use and user requirements through the review of literature which informed the content of the topic guide for focus group discussions, (ii) FGDs which enabled further understanding of the context, (iii) understanding the attributes of the users through creation of user personas and, (iv) arriving at consensus using the nominal group technique.

a. Understanding the context of use and user requirements

Initial work involved understanding the context of use for the audit tool and implementation guide and the requirements of the end users to facilitate the development of a context sensitive innovation.

b. Literature review

I reviewed literature describing the Kenyan health system context in terms of: (i)The organizational environment which included the organizational culture, values, leadership (27, 126, 146, 147), (ii) physical environment in terms of structures, accessibility of equipment, medicines and materials(148, 149), (iii) health workers behaviours, attitudes and work tasks(149-152), and (iv) literature describing the facilitators and barriers to the maternal and perinatal clinical audits in LMICs.(50, 51, 56, 70, 72, 74, 75, 77). This information was used to develop the topic guide for the focus group discussions.

c. Consensus design workshop

To gain further understanding of the context and the users, we conducted a virtual consensus design workshop using Zoom as a platform to engage the users in the design of the implementation guide. A total of 37 participants attended the virtual design workshop (two neonatologists, 17 paediatricians, 17

NBU nurse leaders and 1 representative from the Ministry of Health) each of whom received a copy of the “Improving the quality of paediatric care: an operational guide for facility-based audit and review of paediatric mortality. Geneva: World Health Organization; 2018” manual four days before the workshop.(1) The reason for this was to allow them to gain some knowledge on the recommended standards for conducting a clinical audit in order to enrich the discussions.

The purpose of the workshop was to (i) understand the strengths and barriers to the newborn clinical audit process within the Kenyan context through conducting focus group discussions (FGDs), and (ii) design an audit implementation guide based on the WHO guidelines that builds on the contextual strengths and overcomes its barriers.

To achieve this, the consensus design workshop constituted the following three steps:

a. Focus Group Discussions with the study participants.
b. Plenary session to discuss audit implementation guidelines based on WHO recommendations.
c. Consensus on the standard operating procedure of conducting newborn audits in CIN-Neonatal hospitals using the nominal group technique.

3.2.4.3.1 Moderation of workshop

I was the main moderator and host of the workshop and had an assistant who acted as the overall rapporteur during the plenary sessions. The roles of the rapporteur included managing the group dynamics, responding to questions in the chat box and grouping participants into breakout rooms.

We used the Zoom breakout rooms feature for the smaller group sessions. The 37 participants were manually grouped into four heterogenous groups (groups one to four) consisting of paediatricians and nurses; each group had nine to ten participants. Each of the four breakout rooms had a moderator, a rapporteur and a note taker. As the host of the meeting, I oversaw all the groups and was able to move from one breakout room to another.

a. The group moderators were two nurses and two paediatricians who had previously been trained on group facilitation skills as they had gone through the UK Resuscitation's Council Generic Instructor's Course (GIC) in Kenya.(153)
b. The rapporteur in each group was a researcher from KWTRP who had experience in conducting qualitative research and moderating small groups.
c. The note taker in each group was a paediatric resident from UoN who was GIC trained and was proficient in using the Zoom platform and its different features. The paediatric resident was responsible for documenting highlights and contributions from the group discussions in the breakout rooms on the Zoom virtual whiteboard.

I held three rehearsals with the researchers before the virtual workshop. The rehearsals focused on ensuring that all the researchers were comfortable with the basic features of the Zoom platform (screen sharing, muting and unmuting participants, reading the chats, putting video on), teaching the moderators how to probe during the FGDs to ensure that topics arising were covered in depth and clarifying the different roles of the researchers as well as training them to follow the discussion guide. I oversaw these dry runs with assistance from GI and two qualitative researchers who have extensive experience with conducting FGDs.

The first part of the virtual implementation guide design workshop were the focus group discussions to understand the facilitators and barriers to the newborn clinical audit process in the hospitals within the CIN for newborns.

3.2.4.3.2 Understanding the facilitators and barriers to the perinatal and newborn audit process in LMICs

To design an implementation guide that was well suited to the Kenyan context, we set out to identify the circumstances within the health system that may act as facilitators and barriers to the audit process. This was important so that the tools and processes developed would build on the facilitators and try to mitigate the barriers. We did this through conducting virtual FGDs with the workshop participants to

gain further insight into what they perceived as the facilitators and barriers to the perinatal and newborn audit process within their environment.

A. Virtual focus group discussions

The participants were grouped into the four breakout rooms for the FGDs. Each group (one to four) had a different set of topics to discuss that were aligned to the topics that they later deliberated on during the group NGT sessions. The different discussion points for each group are summarised in Table 7 below.

i. Setting of ground rules

The moderators and the rapporteurs in each group began by welcoming the group participants and introducing themselves. They then gave some background information on the study, clearly explained the group's objectives and how the data from the FGD would be used. The moderators emphasized that the discussions held in the group were confidential and that they should not be repeated outside the session. The moderator encouraged active discussion and stressed that there were no right or wrong answers. They explained that the discussion would be recorded to allow the researchers capture all the information and, in an effort to improve interpersonal relations, the moderators asked the participants to keep their videos on during the session if bandwidth allowed. Once the participants understood their group's objectives and agreed to adhere to the regulations, they gave their informed consent to participate (Appendix 7).

ii. Obtaining informed consent

A two-part process was used to obtain informed consent. Four days before the audit meeting, I shared a consent form that detailed the workshop and FGD activities with each participant via WhatsApp and email. The consent form was an E-tool and I gave careful instructions to the participants on how they would fill in their names or signatures if they accepted to participate in the workshop. Each participant shared the filled consent form to my email or WhatsApp. The second part of the consent process

occurred at the beginning of the FGD process. Once the group moderator set the ground rules, they read out the detailed consent form and asked each participant to type "I agree" in the chat box if they agreed to participate in the FGD process.

Once all participants consented to participate, the moderators asked the participants to begin by introducing themselves.

iii. Participant introductions

The participants introduced themselves by saying their name and cadre. Each group also had an ice-breaking task as the participants introduced themselves (e.g. asking them to state their hobbies, their experiences with clinical audits, what they would like to do after the COVID-19 pandemic etc). Each participant was given an identifier (e.g. R1, R2) by the moderators which were used to address them during the session.

iv. Discussion

Each group moderator had a discussion guide to help structure the discussions and through probing, ensured that the relevant issues were covered in depth as summarised in Table 7 below and attached in Appendix 8. Data collection from each group was through video recording.

Table 7: Summary of group discussion topics during focus group discussions

Groups	Discussion topics
Group one	Determinants of who was invited to newborn audit meetings and factors influencing their attendance. Discussion on who managed the newborn audit meetings in the different hospitals.
Group two	Methods used to select cases for audit. Discussion on what was used as a guide during audit meetings (use of audit tools? If audit tools were used, which ones?).
Group three	Type of environment during audit meetings. (e.g. No name, no blame? Learning environment? Inclusive? Confidentiality?)
Group four	Measures put in place to ensure recommendations made during the audit are implemented.

With an understanding of the facilitators and barriers to the audit process from the FGDs, we set out to design an audit implementation guide that took into consideration what works and what does not work.

B. Discussion of audit implementation guidelines for LMICs based on WHO recommendations

The second session of the virtual design workshop was the plenary session where we held a discussion on the recommended methods of conducting a clinical audit based on the WHO manual which had previously been shared with the participants.

i. Virtual plenary session

I facilitated a 45-minute plenary session which focused on discussing the implementation of the audit tool as adapted from the WHO manual, "Improving the quality of paediatric care: an operational guide for facility-based audit and review of paediatric mortality. Geneva: World Health Organization; 2018".(1) The discussion was focused on (1) defining a desired quality of care audit, (2) describing the six steps of the audit cycle as per the WHO guidelines with emphasis on modifiable factors and the importance of completing the audit cycle, (3) describing factors that support a successful audit and (4) introducing the prototype newborn audit tool and explaining how the audit tool is intended for use during the audit meetings.

With an understanding of the WHO recommendations for implementing a clinical audit process, we used the nominal group technique for the third step which was to arrive at consensus on a context sensitive implementation guide for the audit process.

C. Consensus on a context sensitive implementation guide for the newborn clinical audit

The participants were grouped into the same four breakout rooms they were part of during the virtual FGD sessions. With an understanding of the WHO recommendations for the audit process, we began the process of ensuring the participants understood the attributes of the users that would influence the successful implementation of the audit tool and implementation guide. This was through the design of user personas which work to add a human touch to the design process.(154) The user personas were fictional characters that the group created to identify the different cadres who may participate in the audit process. They gave a general description of a typical participant in the audit process e.g. a nurse,

medical officer intern, nutritionist etc. This process aimed to help in recognising and understanding the needs, behaviours, experiences and goals of each of the different cadres. The design of user personas helped the participants understand who they were designing the audit process for and what factors would influence how they would implement the audit tool and therefore design the implementation guide with these in mind. The user personas are available in Appendix 9.

The group moderators encouraged the participants to reflect back on the roles, responsibilities, goals and experiences of their user personas as they engaged in the co-design of the implementation guide using the consensus group activity.

i. Arriving at consensus on the audit implementation guide using the nominal group technique

Each group was tasked with arriving at consensus on different components of the implementation guide using the nominal group technique. The selection of the components of the implementation guide was based on a quality of audit process score designed while conducting the scoping review.(52) The quality of audit process score was based on seven factors from the WHO recommendations that were considered crucial for an audit process to be successful. The different group roles are summarized on Table 8 below.

Table 8: Summary of group discussion topics for the nominal group technique

Groups	**Roles**
Group 1	Consensus on role of newborn multidisciplinary audit committee (MDT). Consensus on composition and size of newborn audit MDT.
Group 2	Consensus on the criteria for selection of cases for auditing and who selects cases for auditing. Consensus on number of cases to audit per meeting.
Group 3	Consensus on duration of audit meeting Consensus on frequency of audit meetings.
Group 4	Consensus on categorisation of modifiable factors.

ii. Description of the Nominal Group Technique

The Nominal Group Technique (NGT) was selected as the consensus focus group methodology because it allows for prioritisation of thoughts and ideas, encourages equal participation among members of the group and allows for quick problem solving. The methods used that align with the four-step process are described in Figure 8 below.

Throughout the group consensus process, participants were given space to think about the identified problem, make individual decisions and these were recorded through individual voting and tallying on the virtual whiteboard.

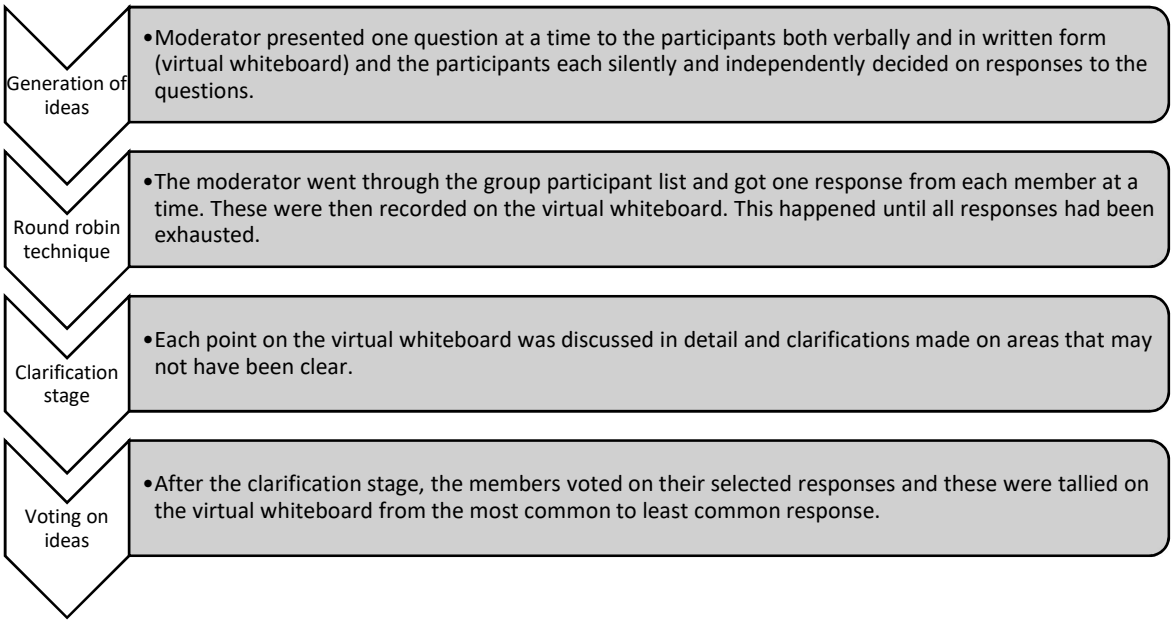


Figure 8: Four step process of the nominal group technique

The outcome of the design workshop was the development of a SSNB audit implementation guide based on the WHO manual and adapted to the context.

In order to transform the high-end prototype newborn audit tool and the implementation guide into a fully functional process, they were subjected to the 3rd part of the design process which was the usability testing to determine their scalability.

3.2.4.4 Usability Testing of the SSNB Audit Tool and Implementation Guide

The usability of the audit tool and implementation guide was tested in Pumwani Maternity Referral Hospital and Kenyatta National Hospital between November 2020 and April 2021.

At the beginning of the testing phase, the researcher communicated with the CIN-Neonatal focal persons involved in the design of the implementation guide via email and WhatsApp and informed them that she was happy to assist them in conducting newborn clinical audits in their hospitals. I shared the high-end prototype newborn audit tool on a common WhatsApp group to make it available to every hospital within the CIN-Neonatal. Seven hospitals expressed interest in getting assistance with the newborn audit process, this was however disrupted by a countrywide health worker strike between December 2020 and mid-February 2021. Many hospitals did not resume their newborn audit meetings for more than a month after hospital services resumed. I therefore did not get an opportunity to test the audit tool and implementation guide in any other facility.

The user testing phase involved monitoring how the end users interacted with the high-end prototype audit tool as they conducted the audit process based on the designed audit implementation guide. In addition to monitoring the use of the audit tool, I also monitored the feasibility of the implementation guide for the context. As the lead researcher, I therefore took a facilitative role while allowing the hospital teams to take over the management of the newborn audit process following the recommendations in the implementation guide.

I began by creating the audit committee that would be responsible for managing the audit process as per the guidelines.

a. Creating a multidisciplinary audit committee for the newborn audit process

In PMRH, I formed a newborn audit committee that was composed of eight members as agreed upon during the implementation guide design workshop (hospital administration, NBU nurse leader, NBU paediatrician, midwife in-charge, obstetrician, nutritionist, records representative, pharmacist). The

process began with the researcher holding a meeting with the head of clinical services (paediatrician who participated in the implementation guide design workshop) at the hospital and made a formal request to form a newborn audit committee. The head of clinical services then held a meeting with the in-charges of the eight cadres required to be part of the committee. They were informed of the need for a newborn audit committee and that they were identified as the key departments that required representation in the committee. Once established, I held a meeting with the audit committee where I described their roles as specified in the implementation guide and advised that they would be responsible for managing the audit process. Briefly, the implementation guide recommendations included: (i) Holding two weekly audit meetings on a set day and time lasting 1 – 1 hour 30 minutes, (ii) One to two cases audited during each meeting, (iii) criteria for selection of cases that would be audited in each meeting, (iv) promoting a conducive environment during the audit meeting, and (v) implementing recommendations arising from the audit meeting. I was available to provide guidance where needed, make observations as well as receive feedback from the members of the committee on components of the implementation guide that were difficult to implement. These were documented and modified accordingly. I formed a WhatsApp group composed of members of the committee to ease the communication between committee members. The senior most paediatrician in the NBU was made the chair of the audit committee as per the recommendations.

b. Selection of cases to be audited

Following the implementation guide, the audit meetings were held every two weeks and one case audited during each meeting. The chair of the newborn audit committee (paediatrician) together with the junior clinician would select the case to be audited using one of the criteria set in the implementation guide. Once the case for discussion was selected, the junior clinician and nurse would summarise the process of care onto the audit tool under the guidance of the paediatrician. The paediatrician or junior clinician shared the filled audit tool with me via email or WhatsApp to get

clarification on various issues as well as confirmation that the tool was properly filled. I would then schedule a phone call with the presenting team to address any arising issues as well as receive feedback on areas in the tool that required modification. Modifications were made to the tool based on feedback from the audit team before the meeting.

c. Audit meetings

The audit meetings were facilitated by the committee chair as I offered supportive supervision. At the end of the audit meeting, the research team would gather a small team to debrief and give feedback on the audit tool as well as the audit process just as was done during the cognitive walkthrough phase. Modifications were made to the audit tool before the next audit meeting.

In KNH, I did not test the implementation guide, I, however followed the steps in modification of the audit tool from feedback during meeting preparation and after the audit meeting. The meetings were fully virtual as this was preferred by the NBU team. They were prepared and led by the paediatric residents and NBU nurses. They were facilitated by the neonatology fellows and a neonatologist who was the team leader. They would engage with the researcher at each stage to seek clarification as well as provide feedback on the usability of the tool. All necessary modifications were made to the audit tool before each meeting.

After several iterations, modifications and testing, the final audit tool and implementation guide were ready for implementation. I will now describe the methods used for the implementation process. I will begin by describing the study site selection, I will then describe the intervention which was facilitation. Evaluation of the effect of facilitation was conducted using a mixed methods approach. I will describe the mixed methods approach used to evaluate the effect of the intervention; the quantitative methods used to evaluate the effect of the intervention on measurable indicators of improved feeding practices of low birth weight newborns in newborn units in Kenya and the qualitative methods to explain the effect of the intervention.

3.3 Methods used in the implementation of the clinical audit tool and implementation guide.

I will begin this section by describing the methods used in the selection of the study settings used in the implementation of the clinical audit tool.

3.3.1 Overall similarities between study sites involved in the implementation study.

All the selected study sites provided services that placed their NBUs under the category; intermediate care hospital.(137) The services provided were similar and included:

a. Provision of warmth including incubator care for preterms and KMC.
b. Nutritional support including NG tube insertion and intravenous fluids.
c. Respiratory support including oxygen by nasal prongs and CPAP.
d. Management of neonatal jaundice including standard and intensive phototherapy and exchange transfusion.
e. Management of convulsions including intramuscular phenobarbitone and intravenous phenytoin.
f. Management of sepsis with parenteral antibiotics.
g. Other services include transfusion of blood and blood products.

The staff dedicated to the NBUs differed across the study sites and will be described per individual site. There were, however, other departments that were not dedicated to the NBU but were still part of the newborn care team and they were similar across the sites. These were; laboratory, pharmacy, radiology, occupational therapy, physiotherapy and biomedical engineering departments.

The county hospitals adhere to the national maternal perinatal death surveillance and response (MPDSR) guidelines while planning for and conducting their meetings.(62) They hold monthly MPDSR meetings where the maternal near misses are discussed in detail, and the NBU team is given an opportunity to briefly present a summary of the neonatal morbidity and mortality statistics for the month. The meeting is attended by the MPDSR committee that is composed of (i) senior most

obstetrician who is the chair, (ii) midwife in charge of labour ward who is the deputy chair, (iii) administrators (medical superintendent, hospital administrator and hospital matron) (iv) anaesthesiologist, (v) nurse in charge of theatre, (vi) paediatrician, (vii) NBU nurse in charge, (viii) pharmacist, (ix) laboratory in charge, and (x) records officer. In the event of a maternal death, a meeting is held within 48 hours of the death and this is attended by members of the committee as well as the individuals involved in the care of the mother.

3.3.1.1 Study site selection and description of facilities that were used for implementation of the small and sick newborn clinical audit tool and implementation guide.

The implementation of the audit tool and implementation guide were conducted in four hospitals that are part of the CIN Neonatal. During the study site selection period, there were 21 hospitals under the CIN-Neonatal from 15 out of 47 counties in Kenya. These Counties are Nairobi, Kirinyaga, Kiambu, Nyeri, Machakos, Nakuru, Embu, Kisumu, Homabay, Kitale, Kakamega, Vihiga, Busia, Bungoma and Migori counties. All these are county hospitals and provide intermediate newborn care.(137)

The hospitals use the MoH Basic Paediatric Protocols while those implementing the NEST programme had dissemination of comprehensive newborn care guidelines. The low birth weight (LBW) feeding guidelines in both protocols were similar. They group the preterms into two populations depending on their stability; either to be initiated on enteral feeds or intravenous fluids (IVFs) on the day of birth (referred to as day one of life): (155)

1. The stable LBW newborns weighing ≥ 1000g should be initiated on full enteral feeds appropriate for weight and postnatal age on day 1 of life. The stable neonates weighing 1000-1500g should begin on 3-hourly enteral feeds via nasogastric/orogastric tube. While the stable low birth weight newborns weighing > 1500g should begin on cup feeds.
2. The unstable LBW newborns (severe respiratory distress evidenced by severe chest wall indrawing, convulsions, unconscious, absent bowel sounds) cannot be initiated on full enteral feeds on day 1 of life

and therefore recommended to be initiated on IVF's. Enteral feeds should then be gradually increased at 30ml/kg/day while IVF's are gradually reduced to keep within the total daily volume. When the neonate achieves the full 3-hourly feed appropriate for weight and postnatal age in days, the IVF's are stopped. (Appendix 3)

I selected four hospitals that were either in Nairobi or within a 2-hour driving distance from Nairobi that admit more than 50 low birth weight infants (1000-2500g) per month. This was because I regularly travelled to the facilities in the intervention arm of the study to facilitate the implementation of the audit tool and implementation guide. The selected hospitals had to be implementing the NEST program. This was due to the assumption that there would be baseline similarities in health worker knowledge and skills and NBU equipment. This would ensure that the control sites are a reasonable counterfactual for the intervention sites. The hospitals in Nairobi County that are part of CIN-Neonatal and the NEST program are Pumwani Maternity Referral Hospital (PMRH) and Mama Lucy Kibaki Hospital (MLKH). Of these, only MLKH was included as a study hospital. PMRH was excluded because it was used as the design and testing site for the audit tool and implementation guide. The remaining Counties that were within a two-hour drive from Nairobi were: Kiambu, Machakos, Kirinyaga and Nakuru Counties.

Kiambu County has two County Referral hospitals in the CIN-Neonatal; Thika Level 5 Hospital and Kiambu County Referral Hospital. Both were included in the study.

Machakos has one County Hospital, Machakos Level 5 Hospital and it was included in the study.

Nakuru County has one facility in the CIN-Neonatal that was within a two-hour drive from Nairobi; Naivasha County Referral hospital. However, the NBU in this facility admitted less than 50 preterms per month and was therefore excluded from the study.

Kerugoya County Referral Hospital had fewer than the required number of at least 50 preterm admissions per month to qualify for inclusion.

Thika Level 5 Hospital, Machakos Level 5 Hospital, Mama Lucy Kibaki Hospital and Kiambu County Referral Hospital were therefore included in the study. (Fig. 9 below).

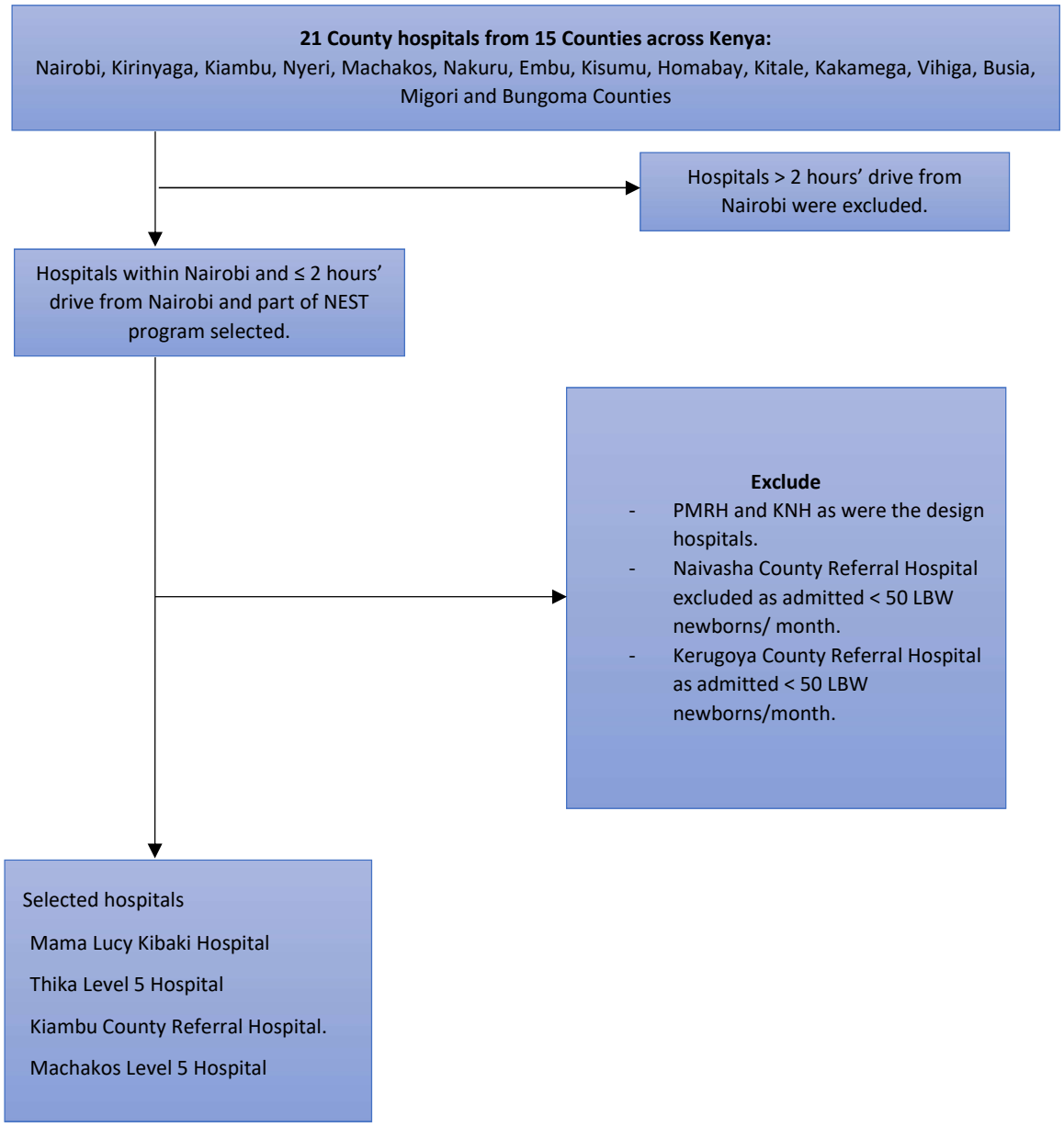


Figure 9: Study site selection process

3.3.1.1.1 Description of implementation study sites

1. **Mama Lucy Kibaki Hospital**

This is a level four hospital located in Embakasi west sub-county on the east side of Nairobi serving Nairobi's populous eastlands. It is one of three county referral hospitals in Nairobi county and has a bed capacity of 112. The facility also serves as a University teaching hospital for Jomo Kenyatta University of Agriculture and Technology (JKUAT).

The newborn unit in the facility had a bed capacity of 44 and a 10 bed KMC unit.(156) There were approximately 210 admissions per month, and of the total newborn admissions per month, approximately 70 (30%) were LBW admissions.(157)

The hospital had one neonatologist who returned from a neonatology fellowship program midway into the study and four general paediatricians (including one from JKUAT). The neonatologist was dedicated to the NBU, while the four general paediatricians rotated between the NBU and paediatric ward every three months (one in the NBU and three in the paediatric ward). There were four medical officers (M.Os.) stationed in the NBU and the nurse: patient ratio at any given day shift is approximately 1:16 and 1:20 for night shifts. MLKH is an internship centre, however there were no medical officer interns (M.O. Interns) or clinical officer interns (C.O. Interns) stationed in the NBU during the study period. The NBU provided intermediate care services (see above section 3.3.1).

MLKH had one conference room where all hospital meetings are held. The paediatric department had a scheduled date for a CME which may be monthly or two-monthly. Any other meetings occurring in the hospital must be scheduled ahead of time to avoid an overlap in the room occupancy.

2. Kiambu County Referral Hospital

This is a level five hospital located in Kiambu County. It is one of the three County referral hospitals in Kiambu County and has a bed capacity of 417.

The newborn unit in the facility had a bed capacity of 53.(158) There were 225 admissions per month, and of the total newborn admissions per month, approximately 60 (27%) were LBW admissions.(157)

At the time of the study, the hospital had three paediatricians; two of the paediatricians were dedicated to the NBU and one (head of department) was in the paediatric ward. There were three to four M.O. Interns rotating between the NBU and paediatric ward at any given time. There were no M.Os in the NBU and paediatric departments during the study period. The nurse: patient ratio at any given day shift was approximately 1:17 and the night shift ratio of approximately 1:33.

The hospital had one main boardroom that was used for meetings and learning activities by all departments including the NBU. Occupancy of the boardroom, therefore, had to be scheduled in advance. There was a smaller meeting room that is used when the main boardroom was occupied.

3. **Thika Level 5 Hospital**

This is a county referral hospital located in Kiambu County. It is one of the three County referral hospitals in Kiambu County and has a bed capacity of 467.

The newborn unit in the facility had a bed capacity of 51. There was a seven bed KMC unit. (159) The NBU had approximately 250 admissions per month, and of the total newborn admissions per month, approximately 80 (32%) were LBW admissions.(157)

The staff dedicated to the NBU were: Two paediatricians, one M.O. and two M.O. Interns rotating between the NBU and paediatric ward. The nurse: patient ratio at any given shift is approximately 1:18 both day and night.

4. **Machakos County Referral Hospital**

This is a county referral hospital located in Machakos town, Machakos County which is on the Eastern part of Kenya. It is the only County referral hospital in Machakos County and has a bed capacity of 375.

The newborn unit in the facility had a bed capacity of 60.with are four bed KMC unit. (160) There were approximately 200 admissions per month in the NBU and approximately 60 (30%) were preterm admissions.(157)

The staff dedicated to the NBU were: Two paediatricians, two M. Os and two M.O. Interns. The nurse: patient ratio at any given shift was approximately 1:13. Other departments that provided newborn care included: Nutrition, pharmacy, laboratory, radiology, biomedical engineering, occupational therapy, physiotherapy and records departments. A summary of the implementation hospitals is presented in Table 9 below.

Table 9: Characteristics of the implementation sites

Characteristics of implementation sites				
	MLKH	**Kiambu**	**Thika**	**Machakos**
Type of facility	County referral hospital	County referral hospital	County referral hospital	County referral hospital
CIN-Neonatal join date	June 2017	October 2018	October 2018	March 2018
Number of deliveries per year 2019	2384	2644	2964	2580
Level of care provided in the NBU	Intermediate level care	Intermediate level care	Intermediate level care	Intermediate level care
NEST programme implementing site	Yes	Yes	Yes	Yes
Number of NBU admissions per month	210	225	250	200
Number of LBW admissions on NBU per month (%)	72 (34%)	63 (28%)	77 (31%)	61 (31%)
Total NBU capacity (cots, incubators)	21	53	51	60
Number of KMC beds	10	0	7	4
Clinician staffing dedicated to NBU				
Paediatricians	2	2	1	2
Junior clinicians	4	1-2	2	4
NBU nurse staffing				
Day shift	1:16	1:17	1:18	1:13

Night shift	1:20	1:33	1:18	1:13
Frequency of MPDSR meetings	Monthly	Monthly	Monthly	Monthly

Abbreviations: **KMC; Kangaroo Mother Care, LBW; Low birth weight, MLKH; Mama Lucy Kibaki Hospital, MPDSR; Maternal and Perinatal Death Surveillance and Response, NBU; Newborn Unit.**

In the next section, I will describe the study population involved in the design and implementation of the innovation as adopted from the iPARIHS framework.

3.3.2 Study population participating in the implementation of the clinical audit tool

The study population represented the 'recipient' construct of the iPARIHS framework. The health care workers involved in the implementation of the audit tool and implementation guide by participating in the audit meetings included:

1) Senior leadership from health facilities in the selected study sites. This included the medical superintendents, hospital administrators and matrons in charge of the facilities.
2) Frontline practitioners in the NBUs including:

- Neonatologists.
- Paediatricians.
- NBU nurses.
- Junior clinicians (medical officer interns, medical officers, clinical officer interns and clinical officers) from the County hospital NBUs.

3) Other cadres in the health facilities involved in newborn care and attended the newborn unit audit meetings. These include; midwives, clinician representatives from maternity department, nutritionists, representatives from laboratory, radiology, pharmacy, occupational therapy, physiotherapy, records and biomedical engineering departments.

In section 3.4, I will describe the intervention; facilitation, justify its use as an implementation strategy and why I was best suited as the facilitator. I will describe my skills and experiences that made me suitable as the facilitator, the assumptions made during the design of the research project, and the methods used based on the theory of change.

3.4 Facilitation as the intervention enabling implementation of the clinical audit tool into practice.

Facilitation in the context of this PhD thesis is defined as the process of enabling the adoption and implementation of the SSNB clinical audit tool into practice.(82)

The clinical audit process was based on the theory of action learning as a catalyst for reflective practice.(161) Action learning is a cyclical approach of problem identification, taking action and learning from interpreting the consequences based on the principle that experiences generate knowledge.(162) Action learning takes a team-based approach where participants identify and discuss complex problems with the aim of generating innovative and creative solutions through a back and forth questioning process that elicits critical thinking. The process of action learning, therefore, encourages learners to reflect on and learn from their own experiences and those of their peers.(163)

Based on the principles of the action learning theory, facilitation was considered appropriate to guide the learning process in this PhD thesis. Berta *et al* argue that facilitation can be conceptualised as meta routines that are vital to support higher order organisational learning about new evidence-based knowledge.(82) In addition, facilitation takes a team-based approach to problem resolution and centres on driving a purposeful, progressive or iterative two-way process of change that focuses on building trusting relationships and sharing common goals between the facilitator and the participants.(80, 164) In this PhD thesis , the facilitation strategy demanded critical reflection by the health care workers as a means to make sense of and leverage their experiences. This would lead to critical questioning of work

processes which would then lead to transformation of perspective and improving the absorptive capacity of best practices in the NBU.(82)

3.4.1 My role as a facilitator and my background that influenced my facilitation.

As a facilitator, my goal was to (i) enable the health workers identify modifiable gaps in the quality of newborn care and in particular, feeding practices for LBW newborns, (ii) empower teams to develop appropriate solutions and that they are implemented with planned intent, (iii) introduce variation in ways of overcoming difficult challenges and empower the health workers to select and retain what they feel works for them, (iv) influence a change culture within the local environment by empowering health workers to view challenges in their work contexts as things that they can affect and modify, rather than being complacent (v) assist the teams in interpreting data on their monthly progress reports and reaching conclusions about action-outcome relationships, and (vi) identify important contextual factors that would influence the success of the implementation of the clinical audit tool and build on the strengths and overcome the contextual barriers. This has been described in table 10 below.

The expected outcome of this was to structure new ways of working and communicating which would result in improved clinical practices, ensuring that SSNB practices were consistent with the national guidelines.(78) I will now describe why I was suited for the role of the facilitator which aimed at facilitating skill development based on integration of knowledge gained from experience and knowledge gained by formal learning, underlined by critical reflection. This role also provided me, through my own process of reflective learning, with rich insight into the successes and challenges of implementation of the audit tools and the assumption I had in the facilitation to enhance their adoption.

3.4.1.1 My knowledge, skills and experiences that made me suitable as the facilitator

My role in this PhD research was that of a facilitator and therefore responsible for delivering the strategies that would promote uptake of the SSNB clinical audit tool.(165) I will therefore discuss my

personal experiences, beliefs, assumptions and perceptions that guided this PhD thesis while acknowledging how they might have affected the emergent construction of reality.

3.4.1.2 My training and experience that shaped my clinical knowledge and skills in newborn care

I underwent my Master of Medicine (MMED) in Paediatrics and Child Health (2014-2017) at the University of Nairobi (UoN) Medical School under sponsorship by the Nairobi County government which has been my employer from 2013 to date (I worked as a medical officer in the maternity unit of PMRH from 2013-2014). After completion of my training, I was posted back to PMRH as a paediatrician in the NBU in 2018 to date. During this period, I was a member of the hospital QI committee and coordinated regular CME sessions and clinical audit meetings for the NBU. I undertook a five-day training on Newborn Emergency Triage Assessment and Treatment plus admission (ETAT+), a programme for dissemination of the Comprehensive Newborn Care Protocols that were developed by MoH with the support of NEST 360^0 programme (see section 3.1.4). I also underwent a Generic Instructor's Course (GIC) training which aims to train future Newborn ETAT+ instructors in the principles of adult learning.(153)

3.4.1.3 Role of the Clinical Information Network in building my research skills

CIN was introduced to PMRH in 2014 as the initial CIN Neonatal site.(130) Shortly after my placement in the hospital as a paediatrician in 2018, I took over as the CIN focal paediatrician until 2019 when I began my PhD project. During this period, I attended several CIN activities that gave me leverage as I conducted my PhD work.

I. CIN activities attended before beginning the PhD project and their influence on the research methods selected for this PhD project

1. A consensus workshop on developing recommendations for neonatal inpatient care service categories (2018).(137)

2. A workshop to explore which tasks might be acceptable for nurses to share with a low-level, non-professional cadre known as neonatal health care assistants (2018).(166)
3. The annual meeting held with the CIN focal paediatricians and nurses from the participating hospitals (2018).
4. Three workshops that focused on the co-design of a comprehensive newborn monitoring chart (March - May 2019). (89)

Prior to this PhD, I had some experience in quantitative research from my Master of Medicine (MMED) dissertation which was titled "Prevalence of congenital cytomegalovirus infection among newborns admitted at the Kenyatta National Hospital." In addition, engagement with CIN activities exposed me to several research methods that I used for my PhD work such as group facilitation, the nominal group technique and other consensus group methods, problem and solution identification in service delivery and the co-design process. This was the first time I experienced being in a group of highly motivated nurses and paediatricians from different counties sitting together as equals to discuss strategies to improve the quality of paediatric care. I believed that these experiences exposed me to a broad idea of strategies that would otherwise have seemed alien to me while conducting the PhD work. Interacting with the county paediatricians and nurses also improved my familiarity with the team who would later on be involved in my research work. I felt that these initial interactions helped me be accepted by the CIN focal persons first as a colleague and a fellow county health worker then as a researcher.

3.4.1.4 My experience with clinical audits and measures taken to improve my knowledge and skills on how to effectively conduct clinical audits

I first participated in a clinical audit process as a paediatric resident at Kenyatta National Hospital (KNH) which is the teaching hospital for UoN. The meetings were referred to as 'monthly morbidity and mortality audit meetings' and they happened in each paediatric ward as well as in the NBU. My experience with these meetings was not pleasant as the sessions focused on naming and blaming of

individuals for perceived errors. The meetings had no proper structure and mostly entailed looking at the morbidity and mortality statistics and randomly selecting a few mortality files to identify the human errors. The meetings were only attended by the clinicians (medical officer interns, clinical officer interns, paediatric residents and the ward consultants) and the ward nurse in charge. The newborn clinical audit meetings and MPDSR meetings in PMRH were conducted in a similar manner. I, therefore, assumed that this was a practice that was being carried forward from the training institutions and I believed that the same practice was being replicated across the CIN hospitals. Having the audit meetings facilitated by an outsider, as in my study, would potentially aggravate the sensitivity of the clinical audits. Nevertheless, in the PhD thesis I assumed that the health workers would readily accept to implement the NBU clinical audit tool if they were collaborators involved from the stage of designing, implementation and evaluation of its uptake.

Besides the clinical practice engagement, I conducted a scoping review to identify the modifiable factors in newborn care and to assess the quality of perinatal and newborn clinical audits in LMICs based on a developed quality of audit process score. (52) This solidified my knowledge on how an effective clinical audit should be conducted based on the successes and failures documented in literature.

3.4.1.5 My positionality at the study sites that made it feasible to conduct the design of the innovation using a human-centred design (HCD) approach

While undertaking my PhD research, I continued to perform my clinical duties in PMRH NBU, though dedicating more time on issues related to continuous quality improvement. Thus, majority of the design and testing of the feasibility and acceptability of the clinical audit tool took place in PMRH.

3.4.1.6 My assumptions that shaped my role as facilitator during the implementation phase of the study

The assumptions I made as I planned for the implementation of the clinical audit tool were largely based on my experiences during the design phase. I counted on these prior experiences to strengthen the

facilitation process during implementation. I assumed that my previous interactions with the CIN Neonatal focal persons had helped us forge a camaraderie due to our shared experiences.

3.4.1.7 Linking my assumptions to the facilitator role using a theoretical framework

My PhD thesis was designed using the integrated Promoting Action on Research Implementation in Health Sciences (iPARIHS) framework (see section 2.3.3).(6) This framework proposes that the successful implementation of a quality improvement initiative is the function of four core constructs: The innovation, context, recipients and facilitation. This framework was adopted because it recognizes the dynamic nature of facilitation as an implementation strategy.(80) The study took place in different hospitals, therefore, requiring an implementation strategy that could adapt to the different contexts instead of a "one size fits all" strategy. Using the iPARIHS framework, I considered how the facilitation process would influence the three constructs namely the innovation, context, recipients.

Innovation: I conducted a scoping review that identified a gap in the availability of a clinical audit tool that covered the three periods in the care of the small and sick newborn (SSNB) which are: (i) immediate newborn care and resuscitation after birth, (ii) post resuscitation care, and (iii) care in the newborn unit.(52) The SSNB clinical audit tool acts as a structured guide to the newborn clinical audit process and together with its implementation guide, formed the innovation that would be designed and implemented in the study sites. I linked the design of the innovation to the core idea of the theory of design thinking which postulates that for an innovation to be successful it must satisfy human needs and capabilities.(8) Based on this theory, my role as the facilitator was to ensure that the co-design process adhered to the principles of human centred design (HCD) as described in section 3.2. The end product was a SSNB clinical audit tool and implementation guide that was tailored to meet the needs of the recipients within their contexts.

Recipients: The recipients of the innovation included all the health workers who provide newborn care at the study sites. The knowledge, attitude and skills of the health workers in conducting the clinical

audits would be paramount in determining the successful implementation of the clinical audit tool and implementation guide. My role as the facilitator was to employ strategies to build the skills of the health workers in (i) understanding how to use the SSNB clinical audit tool, (ii) empowering the health care workers to critically reflect on their practices and how they affected the newborn unit's outcomes. I would also enable them to identify areas that needed improvement to lead to quality care, identify feasible solutions to the performance gaps and act on the sustainable solutions. This contributed to each component of the metaprocess of variation-selection-retention that leads to adaptive learning (82), and, (iii) enforcing a multidisciplinary approach to the clinical audit process by promoting communication, team-work and equality during the audit meetings.

Context: Four hospitals that were part of the CIN-N were carefully selected as the study sites based on the similarities in their baseline characteristics. (see section 3.3) However, based on a priori knowledge on systems thinking, I linked my assumptions of the potential differences in organisational dynamics influencing successful implementation of the innovation to the theory of complex systems.(167-169) My role as the facilitator was to enable the recipients to interact with the innovation by identifying the root causes to modifiable gaps in LBW feeding practices in their hospitals using a systems lens. Based on this theory, this required understanding that despite the fact that the contexts appeared similar from the visible characteristics, the modifiable gaps affecting the quality of newborn care and, in particular, LBW feeding practices in each hospital were largely dependent on the invisible elements (organisational leadership, organisational culture, hierarchies, communication and feedback mechanisms, rules and regulations) in each individual hospital. The strategies I employed to engage with the different elements of each context, therefore, had to be dynamic meaning that I could change the way I interacted with them depending on the response to the innovation and learning in that particular context.

3.4.1.8 Embracing technologies to overcome challenges of the COVID-19 pandemic

The planning of this project was done before the COVID-19 pandemic and all activities were planned to be face-to-face. The first COVID-19 case in Kenya was confirmed on 12th March 2020, this was approximately one month before I had planned to begin the design process. The uncertainty of the pandemic and particularly in the context of a hospital meant that we had to delay the process. However, my PhD thesis had specified timelines, and as the facilitator, I had to be innovative and devise safe and acceptable methods of progressing the research work.

Conducting virtual clinical audit meetings required having an audit tool that was compatible with digital technologies. I, therefore, converted the clinical audit tool from a paper-based tool to an electronic tool (E-tool). This made it possible to project the audit tool to a virtual audience.

The design of the audit implementation guide required having focus group discussions and a consensus workshop with representatives from the other CIN-Neonatal hospitals. We, therefore had to adopt digital technologies which have been proven to be beneficial for anthropological research during the pandemic.(170) Digital conferencing tools such as the Zoom conferencing tool enabled us to have a full-day workshop with representatives from the CIN-Neonatal sites across the country. These tools also came in handy during the education and training sessions and in allowing us to hold clinical audit meetings with hospitals that were not comfortable with physical meetings. “Geographically limited but digitally supported research” became imperative during the COVID-19 pandemic.(171) The pandemic redefined “fieldwork” from being present in space to being present in time.(172)

3.4.1.9 Description of facilitation methods adopted at the intervention sites

The facilitation began during the preparation for the meetings. I would encourage the audit committee chair to hold the meetings two weekly as scheduled, preferably on a set date and time. I advised on modes of invitation of health workers to the audit meetings to encourage multidisciplinary attendance. These ranged from WhatsApp invitations, memos, face to face invitations; and were based on results

from the focus group discussions, experiences during the design phase of the study and modified based on what worked for each individual hospital. I created a WhatsApp group that included the paediatrician and NBU nurse in charge of NBU (chair and co-chair of audit committee) and allowed them to include all other members of the audit committee for ease of communication. I would also set up the Zoom link that would be used for virtual attendance before each meeting and shared it on the WhatsApp group and with the chair of the audit committee for distribution to the hospital teams. I was involved in the selection of the case to be audited for the initial two to three meetings in each intervention site. My role involved going through a summary of the mortality cases for the month with the paediatrician via phone call, and, guiding them in determining which cases were suitable for the audit based on the set criteria. I would then encourage them to get consensus from the NBU nurse leader and the presenting team before making a final decision on the case to be audited. The hospital teams fully took charge of the selection of cases once they were comfortable with prioritising the areas they needed to focus on. I was, however, available for consultation. I suggested to the teams in both sites that I could have a dry run with the presenting clinician and nurse before the meeting to ensure smooth progression of the meeting. This practice worked well in KNH during the design phase, however, this did not take off in the study sites.

I would begin the meetings by welcoming the participants, introducing myself and facilitating a round of introductions (name and cadre) from the physical and virtual participants. I would then briefly describe how the audit meeting would proceed and emphasized the group norms as per the implementation guide that included; a no name, no blame environment with a focus on gaps within the system, rather than on individuals, importance of maintaining confidentiality, encouraged equality and inclusivity during the meetings and emphasized the importance of using these sessions for learning purposes. The first part of the meeting was the case summary presentation where the case was presented as summarised on the audit tool.

The second part of the meeting was the case discussion to identify the cause of death, modifiable gaps and recommend solutions. I was the lead facilitator during the first one or two case discussions in each intervention site. The purpose was to demonstrate how to conduct a root cause analysis for problem identification and generation of appropriate recommendations. This role was then taken over by the chair of the committee in the subsequent meetings. During the case discussion stage, I guided the chair to create a conducive, non-punitive and inclusive environment that would ensure that the collective needs of the group were met. I did this by politely chiming in the discussion and reminding the participants of the meeting norms that do not advocate for naming or blaming whenever the need arose. I also encouraged the chair who was the local facilitator to engage with the silent participants to elicit contribution to the discussions. This ensured that all cadres and individuals got an opportunity to participate in the meetings. I collaborated with the chair to give brief teaching sessions based on knowledge gaps arising during the case discussions. I assisted the chair in conducting the "five-why technique" by helping them to probe the participants, therefore, stimulating them to brainstorm and get to the root cause of identified problems in the care of the newborn. I, however, used my position to shape the perceptions, cognitions and preferences of the teams towards appreciating the significance of appropriate feed and fluid prescription and monitoring in newborn care. This ensured that feed and fluid management was discussed during most meetings alongside other identified modifiable gaps. I did not make decisions or recommend solutions on behalf of the group, but instead focused on building capacity of the teams to generate appropriate and feasible action plans based on the analysis and reflection of the quality of care provided. (78, 81)

After the meeting, I routinely engaged the committee chair to discuss any challenges arising that were hindering the implementation of the audit tool and implementation guide. I would intervene where possible or offer solutions based on what has worked in other hospitals. I made attempts to engage the administration in both study sites but was not successful.

I followed up on the status of implementation of the action plans at least one week after each meeting, either through the audit committee WhatsApp group or by direct phone calls to the chair. I encouraged the team to ensure that the action plans were implemented.

Successful implementation was defined as having regular audit meetings and completing documentation in the audit tool with the filling of the action plan summary form. The categorisation of adoption was based on the period it took for the hospitals to begin holding regular meetings since the beginning of the five-month intervention period (less than two months from the beginning of the intervention period were considered early adopters, two to four months were late adopters and more than four months were laggards).

In section 3.5, I will now describe the rationale for using a mixed methods mixed methods approach to evaluate the effect of facilitation on improving feeding practices for the LBW newborn. I will outline the roles of the quantitative and qualitative studies and how they were integrated to make it a mixed methods study.

3.5 Rationale for the use of a mixed methods research design and description of the quantitative and qualitative methods used.

A mixed methods approach was best suited to evaluate the effect of the multifaceted intervention design of this study with a focus on processes and outcomes. The quantitative research was a controlled before and after (CBA) design with intervention and control hospitals. It was used to examine the hypothesis with a focus on evaluating the effect of facilitated implementation of the SSNB clinical audit tool on improving feeding practices for low birth weight newborns. The qualitative arm had an aim to understand the organisational dynamics at the intervention sites that would influence the success of the external facilitation as the implementation strategy for the uptake of the SSNB clinical audit tool and implementation guide.(173) In the qualitative study arm, I analysed data from participant observation

(PO) of the audit meetings and my own reflections on what was happening as recorded in my field notes.

Combining the quantitative and qualitative research methods was done for the purposes of contextual understanding and credibility of the study's conclusions.(174) The qualitative research helped identify reasons for implementation failure or success by describing the facilitation processes used during the audit process and why they worked or did not work.(175) The complementary strengths of each method would characterise complex phenomena more holistically than either approach used alone, therefore increasing yield of the study.(176)

I used a parallel mixed research methods strategy.(177) The qualitative and quantitative data were collected and analysed concurrently during a single phase of the study. The quantitative and qualitative results were used as a means to offset the weaknesses in one method with the strengths in the other. In summary, the use of a mixed methods approach ensured contextual understanding with an intention to improve the facilitation strategy which would reinforce good clinical audit practices with a focus on improving the quality of newborn care provided by the hospital teams while using the CIN-Neonatal data to track the effect of facilitation on improving feeding practices of the LBW newborn.

Integration of the two research methods began from the formulation of the research question where the quantitative study answered the what (what was the effect of the intervention) and the qualitative study answered the why and how of the same research question.(178) The two research methods remained integrated at the levels of data collection where continuous quality improvement from the facilitated audit processes were evaluated using quantitative methods. The emerging quantitative results available from CIN reports then influenced how I approached facilitation. They were also integrated at the interpretation of results.

Fig. 10 illustrates the integration of the QUAL and QUANT methods at the levels of the research question, data collection and at interpretation of results.

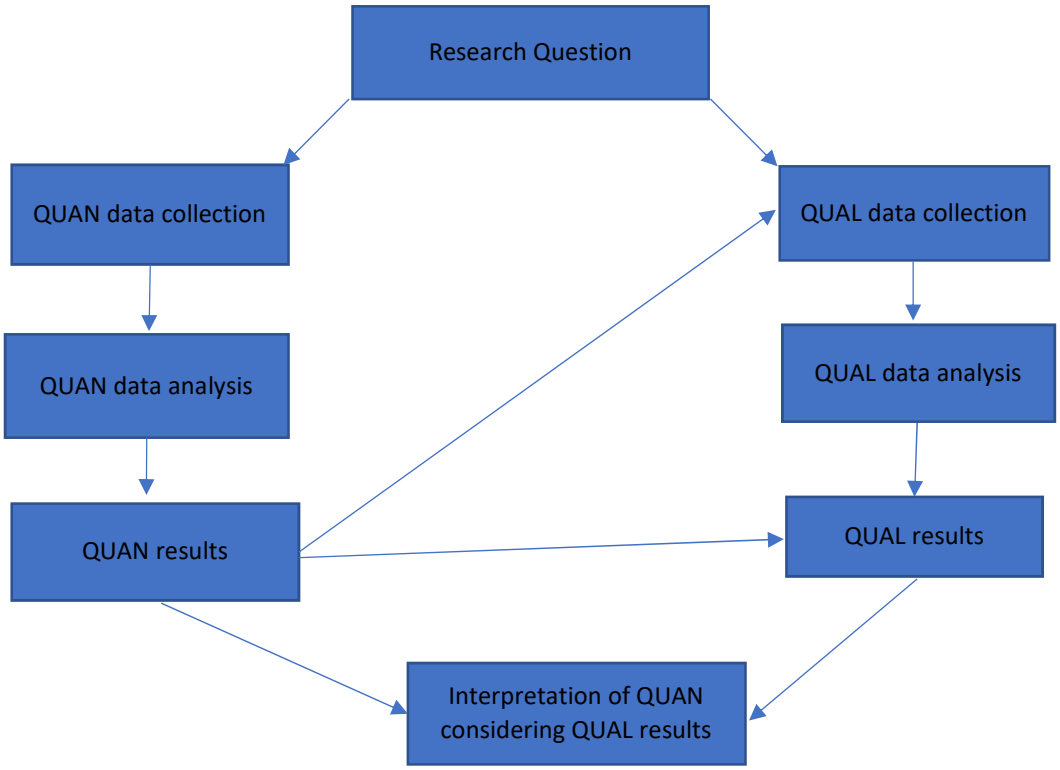


Figure 10: *Integration of QUAL and QUANT research methods at levels of research question, data collection and results*

In the next section, I will describe the quantitative research which aimed to evaluate the effect of facilitation on measurable indicators of improved feeding practices of low birth weight newborns in newborn units in Kenya.

Section 3.6 describes the controlled before and after study used to evaluate the effect of facilitation as an implementation strategy using feeding practices of the LBW newborn as the tracer indicator. I will begin by describing the study population, sample size calculation, study outcomes and the study period. I will then justify the use of a CBA study and describe the methods used. Finally, I will present the data collection used for the quantitative study and the quantitative data analysis used.

3.6 Quantitative study design

The design for the quantitative component was a controlled before and after (CBA). This quasi-experimental approach comprised intervention and control arms to answer the second objective; "to assess the effect of facilitated implementation of a co-designed SSNB clinical audit tool and its implementation guide on mitigating modifiable factors that prevent adherence to recommended LBW newborn feeding guidelines using a controlled before and after study design."

3.6.1 Study population for the quantitative arm

The reference population were the LBW newborns weighing 1000-2499g in the four study hospitals: Mama Lucy Kibaki Hospital, Thika Level 5 Hospital, Machakos County Referral Hospital and Kiambu County Referral Hospital.

3.6.1.1 Inclusion criteria

1. All low birth weight newborns (1000-2499g) admitted within the first 24 hours of life who had a quantified feed prescription (either as expressed breast milk or formula) or were breastfed.

3.6.1.2 Exclusion criteria

1. Low birth weight newborns (1000-2499g) who did not have any documented feed prescription (either a quantified feed prescription or a breastfeeding prescription) during the stay in the newborn unit.

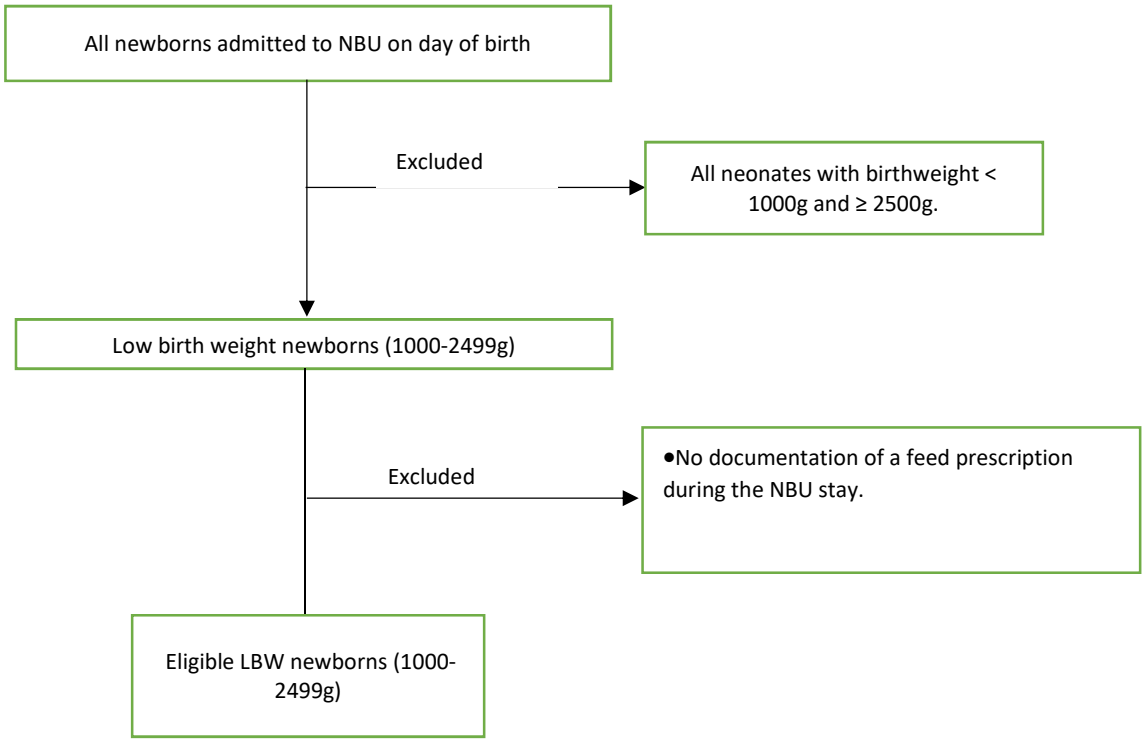


Figure 11: Flowchart describing the selection of study population for QUANT arm of the study

3.6.2 Sample size calculation

Power calculations were done under various sample size scenarios for a Cox regression model to detect a statistical difference in time taken to regain birthweight among the LBW and VLBW newborns in the experimental and control hospitals. I selected a Cox regression model to compare the survival function between two groups - Experimental (E) and Control (C) as it allows for variation in rate of change over time.

The Cox regression model was defined as:

$h(t|X1) = h0(t)exp(\beta 1X1)$

Power calculation approach

The power of detecting a hazard ratio of size (relative risk (RR) = exp ($\beta 1$)) can be computed as follows:

$$power = \Phi\ (\sqrt{k} * m * |RR - 1| / (k * RR + 1) - z1-\alpha/2)$$

$$m = nEpE + nCpC$$

$k = nE/nC$

where:

$z1-\alpha/2$ is the $100(1-\alpha/2)$ percentile of the standard normal distribution.

$\alpha = 0.05$

Φ is the cumulative distribution function (CDF) of $N(0, 1)$

n_E is children in experimental group and n_c is the number of children in the control group.

Censored – Outcome = Alive (0,1)

Length of stay (LOS) = (date of discharge - date of admission)

n_obs = 10 # estimated number of observations per hospital per month.

n_months in pre-intervention and post-intervention periods = 6 months

NC=NE= n_obs*6*2 *#number of observations in control and experimental hospitals over six months period when* HR=2

3.6.2.1 Power for different sample size and relative risk

HR= (1.5,2,2.5),

N= (5,10,15,25,50)

Based on the graph below, for a hazard ratio of 2 and power of 0.8, I required at least 10 eligible babies in each hospital per month so a total of 6 (months in each period) x 2 (hospitals) x 10 babies (per month). Therefore, in the control group; 120 babies in the before and 120 babies in the after period and then the same N = 120 in the before and after period in the intervention group.

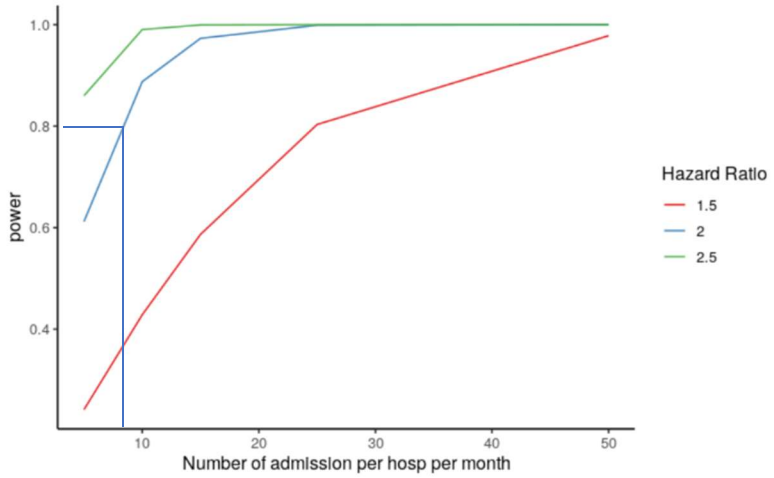


Figure 12: Power calculation based on hazard ratio and sample size

3.6.3 Definition of outcomes of interest

3.6.3.1 Primary outcome

Time to regain birth weight in low birth weight newborns 1000g-2499g. This was defined as the first date at which the post admission weight was equal to the birth weight or was higher than the birth weight.

Newborns with a birth weight ≤ 1500g take 14 – 17 days to regain their birth weight when optimally fed as recommended in the guidelines.(179) All the study hospitals weighed their newborns on alternate days.

3.6.3.2 Secondary outcome

Probability of in-patient mortality in low birth weight newborns 1000g-2499g who received an enteral feed.

3.6.4 Study Periods

Due to the length of the intervention period, I included it as a period of data collection. I, therefore, collected data over three periods; pre-intervention, intervention and post-intervention periods. There

was a one-month transition period between the intervention and post-intervention periods to allow the intervention to 'stabilise' before assessing its effects in the post-intervention phase.(180)

The pre-intervention and post-intervention data were each collected over a six-month period, and the intervention data was collected over a period of five months. Figure 13 below provides a graphical representation of the time in months for data collection during the pre-intervention, intervention, transition and post-intervention periods.

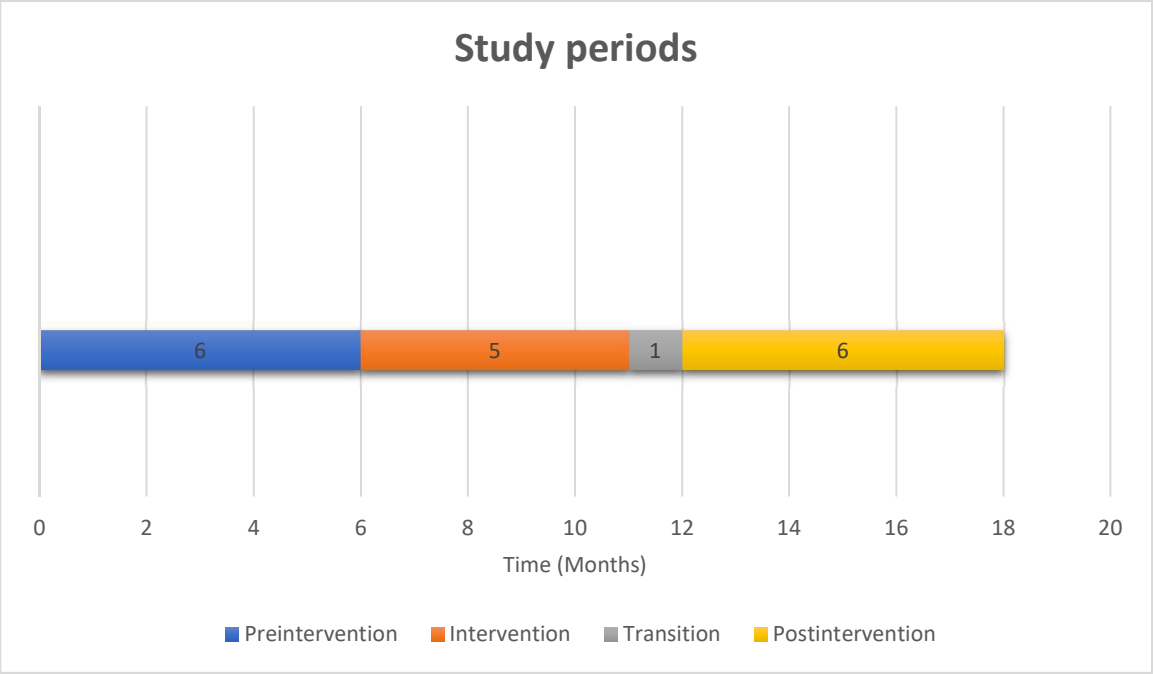


Figure 13: Duration of time in months for data collection during the pre-intervention, intervention, transition and post-intervention periods

3.6.5 Justification for a controlled before and after study design

A CBA study was selected as successfully assessing the effect of an implementation strategy in a complex system required an understanding of and working in real world conditions. An increased focus on external validity, while including elements of randomization to attempt to balance covariate distribution and, therefore, catering to internal validity would ensure that the implementation strategy is implementable in real life situations.(181) In addition to this, at least four clusters are required per

arm in a cluster randomised controlled trial (cRCT) to allow for a statistically meaningful comparison between the experimental and control arms. (182) A cRCT was not feasible due to the costs and the fact that as the only facilitator, it would be impractical to travel to and from more than two sites every two weeks to conduct the clinical audits.

The CBA study had a control group to reflect the counterfactual.(181) The counterfactual was approximated further using a difference-in-difference approach where I compared the size of change in the experimental and control arms.(183, 184) To ensure that the control groups were as similar as possible to the treatment groups in terms of observable baseline (pre-intervention) characteristics, I selected CIN-N hospitals that were implementing the NEST programme. Due to the complexity of the health system, these hospitals are different in their social, political and economic environs. The hospitals implementing the NEST programme had however received similar essential equipment for newborn care. The NBU health workers in these hospitals had received similar trainings in newborn care based on the Ministry of Health Comprehensive Newborn Care Protocols.(155) This training was integrated with guidance on use of NBU technologies and clinical procedures including expressing breastmilk, NG tube insertion and cup feeding to support feeding of the SSNB. In addition, the routine CIN components and activities for all the hospitals include giving monthly and quarterly feedback reports on the hospital performance assessed against the clinical practice guidelines.(section 3.1.2) Both intervention and control hospitals continued receiving the CIN-N reports during the study period. I also gave the prototype SSNB clinical audit tool and implementation guide to both the intervention and control hospitals. There is evidence of the effectiveness of clinical audits and it would be unethical to deny the control hospitals access to the audit tool for the purposes of the study.(51, 54, 185) The only intervention that was different from both sites was the external facilitation.

To take account of any selection bias, I selected the observable confounding factors which were; study period, study arm and the severity of illness based on the score referred to as the Score for Essential

Signs and Symptoms (SENSS score which is a multivariable prediction model for severity of illness (male, difficulty feeding, convulsions, indrawing, central cyanosis, floppy, birth weight) and were accounted for in the analysis.(186, 187) These have been further described in section 3.6.8 below. As a result, the comparison of outcomes in the intervention and control groups limited bias on estimates of causal intervention effects.(188)

3.6.6 Description of the study methods used for the quantitative study

The quantitative study consisted of a 6-month pre-intervention period, a 5-month intervention period and a 6-month post intervention period with the tracer indicator being improved feeding practices for LBW newborns evidenced by reduction in time to regain birth weight in four County hospital NBUs. The hospitals in the experimental arm had facilitation as an implementation strategy as demonstrated in Figure 14 below. The hospitals in the control arm had the standard method of implementation of quality improvement interventions usually employed by the Ministry of Health, Kenya. This strategy was through holding education or training workshops and any follow ups were made in line with MoH procedures.(93)

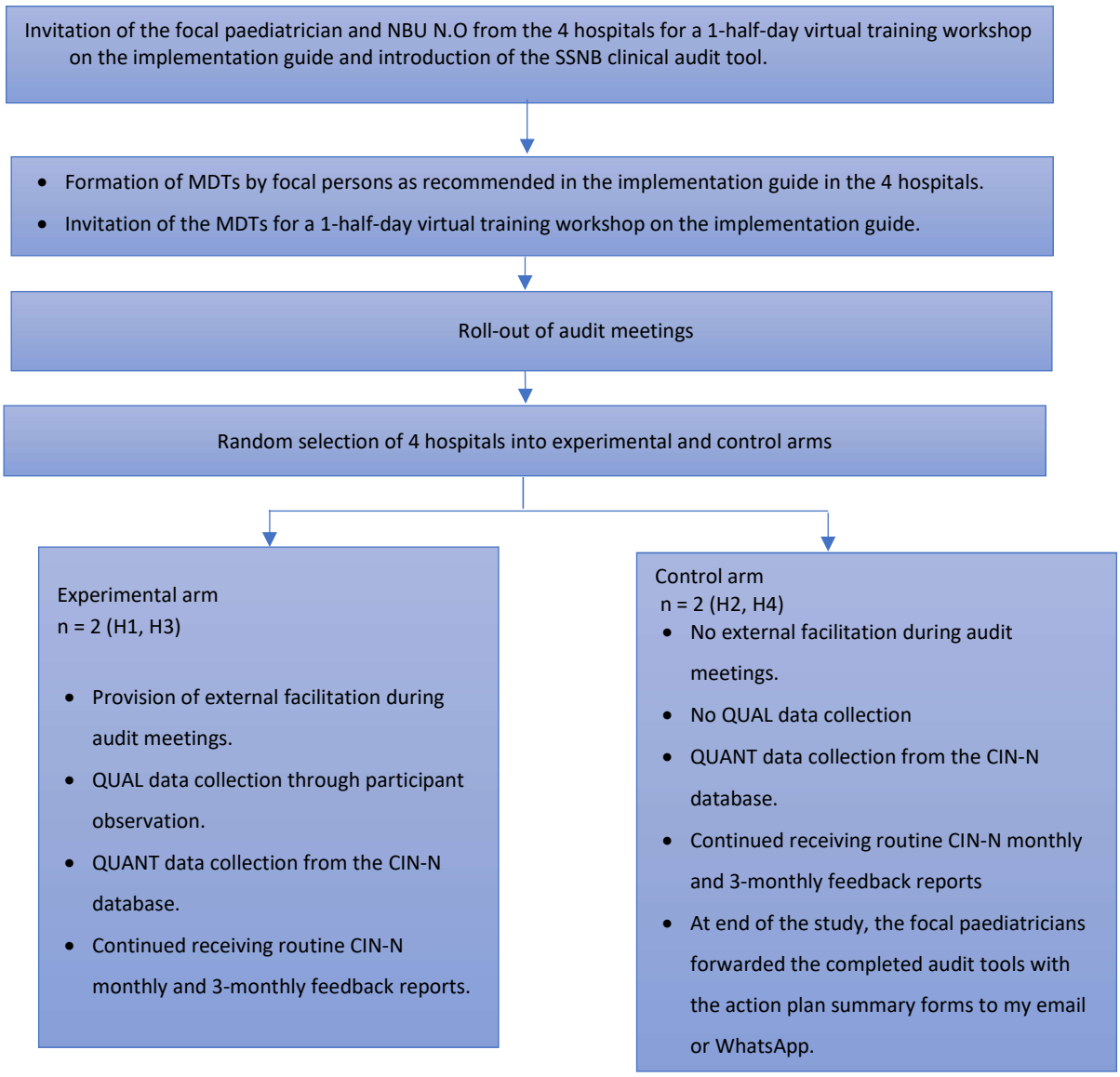


Figure 14: Implementation strategies used in the experimental and control hospitals

A. Training Workshops

I began the implementation strategy by holding two half day virtual training workshops for the four hospitals included in the study (H1, H2, H3, H4). The purpose of the training workshops was to ensure that the audit teams had the necessary skills required to successfully implement the newborn audit process by (i) ensuring that the audit teams were conversant with the use of the newborn audit tool, (ii)

highlighting the components of the audit implementation guide, and (iii) training the audit teams on conducting a root cause analysis using the “five why technique.”

The initial workshop was held in late April 2021 and involved the CIN focal paediatricians and NBU nurse leaders from the four hospitals. In preparation for the workshop, I began by making a phone call to each individual required to attend and informed them of the purpose of the training, as well as the date and time for the training. I then sent a formal invitation through the hospital medical superintendent via email one week before the training. This ensured that the participants were excused from hospital duties on the set date. In addition, I shared a copy of the SSNB clinical audit tool, implementation guide as well as a copy of the “Improving the quality of paediatric care: an operational guide for facility-based audit and review of paediatric mortality. Geneva: World Health Organization; 2018” manual with the paediatrician and NBU nurse attending the workshop. (1)

The half day training workshop was held virtually using the Zoom platform. I was the main facilitator of the plenary session and had a co-facilitator, GI who led some sections of the discussion. There were two moderators JW and NM who assisted both in maintaining the group dynamics and in moderating the smaller group sessions. The topics discussed in the plenary session included:

a. Description of the audit cycle.
b. Outlining the factors recommended for a successful clinical audit process based on the WHO recommendations.
c. Highlighting the audit process recommendations based on the implementation guide.
d. Describing complex health systems.
e. Overview on conducting a root cause analysis using the “five why” technique.
f. Outlining the use of the SSNB clinical audit tool.

I then held virtual group practice sessions where we randomly allocated the participants into two breakout rooms where they would get an opportunity to practice the “five why technique.” Each group

had a different case scenario and were required to brainstorm as a group to get to the root cause of the problem. The two workshop facilitators led each group and guided them through the "five why technique" until they got to the potential root cause of the problem.

At the end of the initial workshop, the focal persons were tasked with forming newborn audit committees (composed of the nursing officer in charge of the newborn unit, nursing officer in charge of labour ward, senior most clinician in the newborn unit, obstetrician/ medical officer from labour ward, representative from the records department, nutritionist, hospital administration, representatives from pharmacy and laboratory departments) in their hospitals and inviting them to the second workshop which was scheduled for two weeks after the first one. Three of the hospitals (one intervention (H2) and two control (H3 and H4)) were successful in creating audit committees in time for the second workshop which was held in mid-May 2021. We held a third workshop in early June 2021, two weeks after the second workshop for the benefit of the study site (H1) that was unable to attend the second workshop. I took this as an opportunity to include the other hospitals that were part of the NEST 360^0 programme for the training.

Once all the audit committee members were trained, the hospitals were encouraged to begin the newborn audit process in their hospitals. Hospitals were blind to allocation to experimental and control arms. I instead informed the hospital teams that I would help facilitate the audit meetings across the hospitals in phases and that they should go ahead with the meetings.

B. Randomisation of hospitals into experimental and control arms

The next step involved selecting the experimental and control sites. This was done by a fellow researcher who was involved in data management of the wider CIN group but not directly involved in the CIN-Neonatal sites. He did this by randomly sampling two hospitals out of the four using R version 4.2.2 and assigned them an arm (control) and the remaining two by default were assigned to the

experimental arm. Both study arms received the audit introduction and audit tool with facilitation being the intervention that was provided only to the experimental arm of the study.

C. External facilitation during the audit meetings

Once I was made aware of the allocation status of the four hospitals, I began communicating with the focal paediatricians and NBU nurse leaders from the experimental sites (H1 and H2) to encourage them to commence the audit meetings. I attended the first six meetings in H1 and five meetings in H2. The facilitation strategy was as described in section 3.4.1.9.

A summary of the implementation strategy used in the experimental and control hospitals is provided in Table 10 below.

Table 10: Components of implementation in experimental and control hospitals

Intervention	**Description**	**Treatment arm involved**
Audit process workshops	• Sensitisation of newborn care teams on WHO recommended process of conducting a clinical audit. • Two workshops. - 1st workshop involving newborn unit paediatricians and nurse leaders. - 2nd workshop involving newborn clinical audit committees. • Content of the workshops. a. Description of the audit cycle. b. Outline the factors recommended for a successful clinical audit process. c. Highlight the audit process recommendations based on the audit process guide. d. Training on conducting a root cause analysis using the "five why" technique. e. Description on use of the newborn clinical audit tool.	Experimental and control arms
Facilitation	• Attend the 1st six newborn audit meetings.	Experimental sites

	• Encouraging the teams to initiate the audit meetings. This was done through frequent reminders and follow up with the teams. • Guidance on selection of cases for audit. This was done through discussing the criteria of interest with the chair of the committee, scheming through the patient records that fit the criteria and agreeing on one case. • Provide support during audit meetings to ensure adherence to a conducive environment based on the implementation guide. This was through encouraging participation from all cadres; this included directing questions to certain individuals and discussing arising issues to exhaustion, reminders that the meeting was a no name and blame environment, providing teachings during the meeting on identified gaps. • Provide guidance to the hospital teams to use a systems approach in problem identification. This was done through using a root cause analysis ("five why" technique) in problem identification. • Empower the hospital teams to make appropriate and feasible recommendations based on identified modifiable factors. This was through ensuring that the teams focused on short and mid-term recommendations which were implementable. • Encourage the hospital teams to implement recommendations made during the audit meetings. This was through weekly reminders through phone calls or text messages to determine the progress of implementation. • Identification of clinical areas that require improvement based on indicators on CIN-Neonatal monthly and quarterly reports and monitoring for improvement every month. This was through reviewing the CIN audit reports with the team and identifying indicators that needed improvement. • Intervening where possible with challenges arising that would affect the successful implementation of the audit process. This was through brainstorming with the responsible persons on how to navigate the challenges, introducing variation in ways of overcoming difficult challenges through shared learning by providing	

	examples of how other hospitals may have navigated the same issues and acting as a mediator between the frontline workers and administration.	

3.6.7 Data collection for the controlled before and after study

Data for the descriptive and inferential analysis was collected through the abstraction of the routine data entered in the CIN Neonatal hospitals database as described in the sections below.

3.6.7.1 Data Collection to Determine Outcome

The data collection for this study was embedded to the description of the routine method of data collection in the CIN-Neonatal sites. This has been described in section 3.1.2. In brief, all newborn records are entered onto the data collection tools on REDCap by the data clerks upon death or discharge of the patients. The data then goes through a verification process where they are checked for errors. Once there are no errors detected, the data are synchronized onto the master database. The data is then remotely screened for errors by the data managers, and when no errors are detected, the data is analysed, and monthly and three-monthly reports are generated. These reports are then given to the healthcare workers as feedback on their performance.

I refined the section of the SOP manual that guides the data clerks on collection of the feed and fluid management and post admission weight monitoring data. To get an understanding of how to structure the SOPs for the feed and fluid data collection, I routinely entered data with the data clerks at Pumwani Maternity Referral Hospital (PMRH) where I practice as a paediatrician. During this period, the comprehensive newborn monitoring chart was being implemented at the CIN-Neonatal sites under a different study as described in section 3.1.4. The comprehensive newborn monitoring chart is a standardised and structured form for monitoring vital signs and prescribing and monitoring newborn feeds and fluids. The health workers in PMRH were gradually adapting to prescribing and monitoring feeds and fluids in the comprehensive monitoring charts. This was in addition to the doctors' continuation notes, nursing cardex and a different type of feed and fluid chart that was in use. This

experience helped me understand the complexity of sourcing for patient feed and fluid management data from the multiple types of patient records. I designed the feed and fluid data collection SOPs based on this experience.

While developing the proposal for this study, I intended to physically visit the study sites, train and interact with and routinely enter data with the data clerks. Further revision of the SOP manual and data collection tool on REDCap was expected to be based on our collective experience of sourcing for the data from the patient records and entering the data in the feed and fluid and post admission weight sections of the data collection tool. However, due to strict travel restrictions by MOH due to the COVID-19 pandemic, I was unable to visit the sites until July 2021 when the restrictions were cautiously lifted. I, therefore, trained the data clerks on the feed and fluid and post admission weight data collection using the SOP manual through a joint virtual session with other researchers from KWTRP who were also providing training on data entry for their fields of interest. I provided combined monthly virtual refresher trainings for three months with all the CIN Neonatal data clerks where I addressed any questions and concerns from the data clerks regarding feed and fluid and post admission weight data entry.

3.6.7.2 Sources of data

I enforced good documentation practices by building the capacity of the health workers to reflect on their current practices and their effects, and, therefore identifying areas for improvement. This enabled the health workers to appreciate the importance of feed and fluid prescription and monitoring and post admission weight documentation in the comprehensive newborn monitoring chart which was an adequate source of data when appropriately used.

In addition, we restricted the source of feed and fluid data as per the SOP manual to the structured forms; comprehensive newborn monitoring chart, treatment charts or other feed and fluid monitoring charts. The continuation notes and cardex were initially not included as a source of data meaning that

feeds and fluids documented in these forms would be considered as missing data. The sources of data for the post admission weight documentation were however not restricted and included the monitoring charts, doctor's continuation notes and nursing cardex. Restricting the sources of data collection for feed and fluid management was intended to encourage good documentation practices through the hospitals' feedback reports which depicted the proportion of records with the variables of interest documented. In spite of the efforts to achieve good documentation, the missingness of data was significant. I, therefore, had to re-enter the feed and fluid data at the four study sites allowing for use of the NAR, continuation notes and cardex as sources of data. Considering that this was an improvement intervention conducted under real life situations, the available retrospective feed and fluid data was based on the documentation practices in the hospitals. This re-entered data still could not produce valid, accurate results due to the level of missingness. The levels of missing data and data entry errors were higher in some hospitals compared to others which would potentially lead to biased findings as the errors were not random. It was not sensible to continue with the plan based on the PhD proposal to have time to reach full feeds as the primary outcome as this would call into question the validity of the quantitative results. I, therefore had to pivot to make the secondary outcome; time to regain birth weight the primary outcome.

3.6.7.3 Type of data collected

To determine the outcomes of interest from the four hospitals as documented above, I extracted the following variables from the routinely collected data in the CIN-Neonatal database. (Appendix 10)

1. Biodata – Survey ID, date of birth, date of admission, birth weight, newborn outcome, date of discharge or death, gender, Apgar score, mother's outcome.
2. Post admission weights.
3. Fluid management history - Fluids prescribed at admission using I.V. route. – Yes/No, fluids prescribed next day after admission using I.V. route – Yes/No.

4. Feed management history:
    i. If prescribed with enteral feeds at admission.
    ii. Type of enteral feeds prescribed.
    iii. Enteral feed volume at admission.
    iv. Frequency of administration of the enteral feeds as per the monitoring chart.
    v. Enteral feeds prescribed on the next day after admission.
    vi. Volume of feeds prescribed on the next day after admission.
    vii. Date enteral feeds first prescribed if not prescribed at admission or the next day after admission.
    viii. Date feeds only prescribed. (To represent the day of life IVFs were stopped).

3.6.7.3.1 Internal data quality assurance

After synchronization of the site data onto the master database, the scripts were run again remotely by the assistant research officers (AROs) to check for errors as described in section 3.1.2.

3.6.7.3.2 External data quality assurance

Due to the COVID-19 pandemic, I was unable to visit the study sites for data quality assurance. Together with the AROs, we held quarterly virtual data quality assurance (DQA) meetings with the data clerks from all the CIN-Neonatal sites. During these meetings, I explained each variable in the feed and fluid and post admission weight sections of the SOPs and made clarifications based on the questions and comments posed by the data clerks. This helped to enforce good data collection practices. The DQA focused on the entire SOP and not specifically the feed and fluid and post admission weight sections. (see section 3.1.2)

I worked closely with the ARO's and the clinicians to discuss feed and fluid management errors from the study sites during the weekly data review meetings. (see section 3.1.2) We would then provide feedback on data entry errors to the data clerks and clinical errors to the focal paediatricians from the four sites

(both experimental and control sites) through phone conversations or WhatsApp messages. We would provide clarification and guidance as needed to reduce both data entry and clinical errors

3.6.7.4 Data Security

There were multiple steps that were taken to ensure data security:1. All data clerks use desktops to enter data and not laptops which are vulnerable to theft, 2. All computers are encrypted, and password protected, 3. REDCap is password protected, 4. User rights are limited for different users e.g. access to some functions is dependent on the individual roles, 5. Use of Linux os, an operating system which is not prone to viruses, 6. Use of USB cables, flash discs or external hard drives to transfer data is inhibited, 7. Confidentiality is maintained through the de-identification of data, and 8. Data clerks work within the hospital compound and don't carry the files out of hospital.

3.6.8 Statistical analysis plan

Statistical analysis plan

Statistical analyses were conducted using R version 4.2.2. in a three parts description of the study population, survival analysis of the time to regain birth weight and in-patient mortality and a Cox proportional hazard of the association between the observable baseline covariates with the primary and secondary outcomes.

i. Descriptive analysis of population characteristics and implementation of audit meetings

The descriptive analyses were used to describe the characteristics of the population in the treatment arms and across the study periods. The included population were those with an enteral feed prescription as presented in Figure 15 below. The availability of a feed prescription was considered important as the study aimed to assess the effect of facilitation on improving the feeding practices of newborns. It was therefore important to describe the availability of feed prescriptions across the study periods and between the study arms.

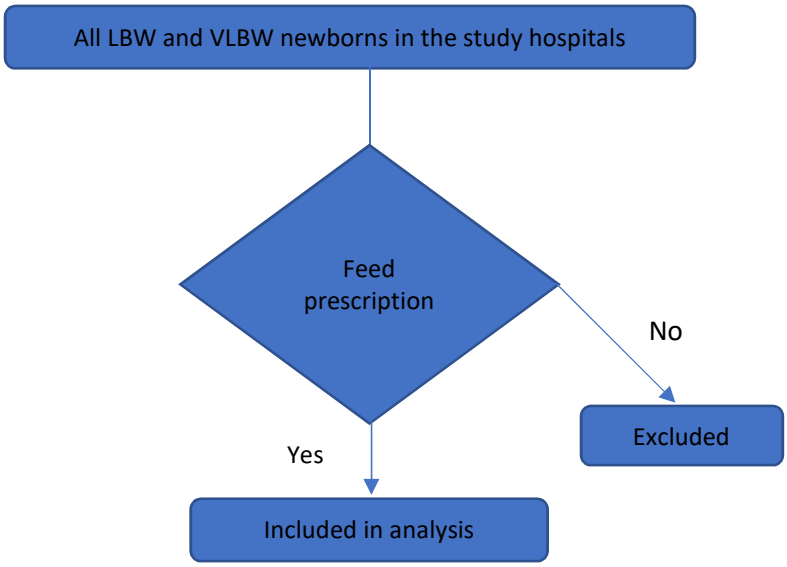


Figure 15: Inclusion criteria of the study population for the descriptive analysis

The description of the newborns with a prescribed feed was based on the documentation of the prescribed feeds and fluids. The newborns were considered to have a prescribed quantifiable feed if there was documentation of an enteral feed at admission, the next day after admission, or any other date when the feeds were first prescribed. A summary of the variables included in the analyses is presented in Table 11 below. The categorical variables are presented as percentages, while the continuous variables are presented as medians and interquartile ranges (IQR).

Table 11: Definition of descriptive variables

Variable type	**Descriptive variables**	**Definition**
Categorical	• Gender	• Male or female
	• Weight category	• VLBW – 1000 – 1499g • LBW 1 – 1500 – 1999g • LBW 2 – 2000 – 2499g
	• Difficulty breathing present	• Documented as a clinical symptom.
	• Convulsions present	• Documented as a clinical symptom.
	• Outcome	• The status of the newborn at the time of exit from the NBU – alive or dead.
	• Type of feed	• The neonates were considered breastfed and included in the study if:

		i. They were ≥ 1500g and did not have either a fluid prescription or a quantifiable feed on the day of admission. OR ii. If were ≥ 1500g and had IV fluids prescribed on the day of admission but neither IV fluids nor a calculated feed prescribed on the next day after admission, then date of breastfeeding was considered the day after admission. • EBM if only EBM prescribed throughout admission. • Formula if only formula prescribed throughout admission. • The type of feed prescribed was considered mixed feeds if there was documentation of expressed breast milk on one day and neonatal formula on the next day or vice versa or both types on the same day.
Continuous	• APGAR 5 min	• A scoring system used to assess how well the newborn is adapting to life outside the womb and response to resuscitation if was required.(189)
	• Length of stay	• Difference in days between the date of exit (death, discharge or referral) and date of admission
	• Time to start feeds	• Day of life when received the first feed.

Abbreviations: APGAR; Appearance, Pulse, Grimace, Activity, Respiration, EBM; Expressed breast milk, IV; intravenous, LBW; Low birth weight, NBU; Newborn unit, VLBW; Very low birth weight

I will also describe the implementation of the clinical audits in the intervention and control hospitals based on the frequency of the audit meetings.

iii. Descriptive analysis of the time to event

The entry point of the study population included in the time to event analysis were those included in the descriptive analysis as described in Figure 15 above. I then excluded the population with neither a documented post-admission weight nor a discharge weight. The discharge weight was analysed as a post-admission weight in this study. The exclusion of these newborns was based on the inability to assess the time to regain birth weight of the newborns without a documented post admission weight.

I used a competing risks survival analysis approach to describe the incidence of the occurrence of an event (regaining birth weight) while taking competing risks (death) into account. The primary outcome was time to regain birth weight, death before regaining birth weight was the competing risk, and loss to follow up was the censored event.

A competing risk is defined as "an event whose occurrence precludes the occurrence of the event of interest."(190) In this study, death 'competes' with regaining of birth weight (as described in Table 12) of the low birth weight (LBW) and very low birth weight (VLBW) newborns which is the outcome of interest. This differs from the standard survival analyses in which death would have been considered a censored event. Treating death before regaining birth weight as a censored event would violate the principles of non-informative censoring as the patients who died before regaining birth weight are not representative of those still on follow-up for the time to regaining birth weight.(191) Censoring the patients who died before regaining birth weight would induce bias and overestimate the risk of the outcome of interest by failing to account for the competing risk. The competing risks data were presented as cumulative incidence function (CIF) curves. The $CIF_k(t)$ denotes the probability of experiencing the kth event before time t and before the occurrence of a different type of event. The CIFs were computed by estimating the joint probability of regaining birth weight or death at a given time interval, given that the individual had not experienced either event in all prior intervals while comparing the experimental and control arms and the pre-intervention, intervention and post-intervention periods.(192)

I estimated the absolute risk of the occurrence of both event types (probability of regaining birth weight and probability of death, Table 12) in the study population up to the end of the study period

All the study hospital newborn units routinely weighed the neonates on alternate days and CIN-Neonatal routinely collects only the first 20 post-admission weights and the discharge weight. The survival time was defined as the date from admission to the date of occurrence of an event. The variables are summarised in Table 12 below.

Table 12: Description of the outcome variables used in the competing risk analysis

Variable type	**Outcome variables**	**Definitions**
Categorical variables	Dead before regaining birth weight	Outcome was death and newborn had not regained birth weight.
	Censored	• Discharged before regaining birth weight.

		• Documented as having regained birth weight within the first three days of life.
Continuous variables	Regained birth weight	• Documented post-admission weight that was more than or equal to the birth weight of the newborn if was documented after day four of life. This included newborns who died after regaining birth weight.
	Date regained birth weight	Considered as the first date in which the post-admission weight was more than or equal to the birth weight of the newborn if was documented after day four of life.
	Discharge date	Documented date of exit from NBU or the date at which the last post admission weight was taken.
	Discharge weight	The documented weight taken on the date of exit from the NBU or the last post-admission weight taken
	Post admission weight	Documented post-natal weight measurements of in-patient newborns.
	Time to regain birth weight	The time from the admission date to the date the baby regained birth weight.
	Time to death	The time from the date of admission to the date the baby died if died before regaining birth weight.

Abbreviations: NBU; Newborn Unit

The date the newborn regained birth weight was considered as the first date in which the post-admission weight was more than or equal to the birth weight of the newborn. Low birth weight newborns lose 10% of their birth weight and VLBW newborns lose 15-20% of their birth weight over the first five to seven days of life.(179, 193) Based on this, I took day four of life (two post admission weights as the hospitals weigh the newborns on alternate days) as the earliest possibility for the LBW and VLBW newborns to have regained birth weight. The newborns who were documented to have regained birth weight in less than four days were censored as it was considered improbable.

a. Regression model selection

As described in section 3.6.5, a controlled before and after study was selected to assess the effect of facilitation as the intervention in a complex system on the time to regain birth weight and overall mortality of LBW and VLBW newborns. A CBA study would provide an increased focus on external validity, while including elements of randomization to attempt to balance the distribution of the observable covariates, therefore, catering to internal validity. This would ensure that the implementation strategy is implementable in real life situations. I used a Cox-proportional hazards regression model to assess the association between the observable baseline covariates with the

outcome. The covariates were selected based on the observable factors that were considered to potentially be associated with the time taken to regain birth weight and mortality. These included; (i) the clinical factors which were the weight category and the severity of illness based on the score referred to as the Score for Essential Signs and Symptoms (SENSS score which is a multivariable prediction model for severity of illness (male, difficulty feeding, convulsions, indrawing, central cyanosis, floppy, birth weight))(186, 187) and (ii) the study period which accounted for the secular trend of the outcome variables due to the effect of the intervention.

The Cox-proportional hazards regression models the dependence of the cause-specific hazard (time to regain birth weight and death) on covariates. The Cox-proportional cause-specific hazards function was selected as it denotes the instantaneous rate of occurrence of the kth event in patients who are currently event free (i.e. have not experienced any of the events of interest).(192)

3.7 Qualitative Research

The qualitative study utilised an ethnographic approach in which participant observation of the health workers during the audit meetings and reflective note taking was carried out to understand the contextual factors that influenced implementation successes and failures.

3.7.1 Outcomes of Interest

In this section, I will discuss:

A. The qualitative outcomes of interest to explore the process of implementation of the audit tool and audit process guide.
B. The audit process outcomes of interest.

A. Qualitative Outcomes of Interest

1. Health care worker attitudes towards the audit process.
2. Motivation of health care workers.
3. Improved teamwork.

4. Improved accountability from top managers to frontline health care workers to improve newborn care.

A. Audit Process Outcomes of Interest

1. Proportion of mortality cases summarised per month.
2. Generation of actionable points during the audit process.
3. Proportion of action points implemented.
4. Proportion of audit meetings with evidence of recording of minutes.
5. Number and diversity of participants during each meeting.

3.7.2 Justification for utilising ethnography

Ethnography is defined as “the art and science of describing a group or culture” and is one of the oldest qualitative research methods, originating from cultural anthropology.(194) The fundamental aim of ethnography is to "describe individuals and groups within a holistic perspective and aim to uncover cultural beliefs and practices that generate observed behaviour."(195) This made it suitable for this mixed methods approach because of its dynamic nature that allowed the research design to evolve throughout the study.(196) The ability to adopt to a flexible strategy allowed for focus on the meanings of individuals’ actions and explanations. It also emphasized the importance of holistically understanding the context to better analyse phenomena, as well as using quantitative data to track the progress on improved feed and fluid practices for the LBW newborn.(196, 197)

Shah *et al* argue that it is not the data collection method that makes a study ethnographic, but rather, the intent of the study.(198) This has led to diversity in the field of ethnography for health research with division about important factors such as the length and depth of fieldwork, the epistemological framework, and data collection. I used focused ethnography for this PhD study.

3.7.2.1 Justification for focused ethnography

Focused ethnography is the study of shared experiences of a more confined, predetermined phenomenon.(195) This method was best suited for this study as it is used to examine experiences

within a culture or a subculture in particular settings, such as a NBU, as opposed to investigating an entire hospital culture. Furthermore, focused ethnography is pragmatic in nature and offers a proficient means of capturing specific contextual perspectives and making practical use of their understanding. Unlike traditional ethnographic methods, focused ethnography is also typified by focus on a specific research question, short-term field visits, intensive methods of data collection and a researcher with background knowledge of the cultural group which was suitable as I am a paediatrician in a NBU within the CIN Neonatal.(194, 195)

3.7.3 Participant observation

Participant observation is defined as "not merely a method of anthropology but is a form of production of knowledge through being and action."(198) Participant observation allows the researcher to live with and be a part of other people's lives as fully as possible, therefore, provoking us to question our fundamental assumptions and pre-existing theories about the world.(199) Through this close interaction, we are able to explore all aspects of the lives of the people we are working with and recognize their interconnections.(194)

Being the external facilitator allowed me to take on participatory roles in my capacities as a researcher and as a consultant paediatrician. My role as the PO not only entailed observing the health workers in their natural environment, but also playing a participant role in the study by providing guidance; together with my paediatrician colleagues on technical issues regarding patient care and in my capacity as a facilitator by enabling the completion of each audit cycle (case identification and collection of information, identifying the modifiable factors, recommending solutions, implementing the recommended solutions and monitoring and evaluation) to ensure the fidelity of the implementation process.

PO allowed for the analysis of activities such as the discussions and decision making processes during facilitation of the audit meetings, understanding the contexts and organisational dynamics, and

conversations with the health workers to understand challenges that may be hindering the implementation process with an intention to develop a strategy to overcome these challenges. This brought in an emic perspective and allowed me to see the world through the eyes of the health care workers and understand in detail how their behaviour regarding the implementation of the audit tool is embedded in their organisational culture.(141)

My involvement was overt.(200) I involved the CIN Neonatal focal paediatricians and nurses from the four study sites as co-researchers from the stage of proposal development where I introduced the planned study to the teams during a CIN Neonatal meeting (date and attendance). They were also involved during the development of the audit implementation guide where they participated in the FGDs that elaborated the facilitators and barriers to the clinical audit process. The CIN focal paediatricians and nurses participated in a group consensus discussion on the components of the audit implementation guide and I trained them on the use of the audit implementation guide as designed.

3.7.4 Justification for the use of participant observation

During the development of the implementation guide, I conducted focus group discussions to understand the facilitators and barriers to institutionalising newborn clinical audits within the hospitals in the CIN Neonatal context. (see section 3.2.4.3) This knowledge allowed me to design the initial facilitation methods based on these. There was however a possibility that the responses from the FGDs were orthodox based on the Geneva: World Health Organisation; 2018 manual that was shared before the FGD session.(1) This did not mean that the staff accounts would be dismissed as biased, however, it reflected the need for added depth in understanding the contextual factors, therefore, modifying the facilitation strategy based on what worked or did not work for each individual site.(196, 197)

PO recognises that knowledge itself is practical and that theoretical or abstract knowledge; that which is communicated in language must be situated in relation to practice.(201) Utilising an approach where I was not merely observing, but also participating in the audit preparations, meetings and follow up thus

enabled us to explore the disjuncture between what people say and what they do, therefore, understanding the complexities and dynamics of a complex system.(198)

The insights of participant observation were based not only on what was said but also on what was left unsaid and demonstrated only through action. This allowed me to holistically understand the context and organizational cultures by accessing the subconscious forms of knowledge expressed as behaviours that defy linguistic translation.(195) PO allowed for the facilitation strategy to rapidly evolve based on naturally occurring experiences, rather than relying on purely retrospective accounts.(196) It also allowed for timely intervention in areas requiring attention based on the quantitative results from the monthly CIN Neonatal reports.

3.7.5 Data collection methods adopted at the experimental sites.

Using a participant observation approach helped me get access into both what the participants said and what they did.(200) A semi-structured observation guide was used to direct the observations made during the audit meeting as presented in Appendix 10. As a participant observer during the audit meetings, I documented my observations of the interactions of health care workers during the audit meetings, process of conducting the audit meetings, observations and feedback on the facilitators and barriers to conducting the audit process. I carried a field diary as a repository for my observations during every meeting, reflections of my experiences and informal conversations held over the six months of facilitated implementation of the audit meetings at each experimental site. In addition, purposive sampling was applied to allow in-depth exploration of emerging issues through more focused observation and informal discussions.(202) I did not use formal, scheduled interviews preferring the continuous exploration possible during the six audit meetings. In this study, audiotaping was not applied for ethical reasons due to the sensitivity of the discussions during the audit meetings. The diary recordings were also not applied in real-time as I felt that this would hinder the staff expressing themselves. Thus, I made rapid field notes that were expanded into proper diary entries typed in MS

word every evening. Consequently, I do not have verbatim quotes; rather I present excerpts from the field diary that represent the observations and conversations during data collection.(203)

3.7.6 Qualitative data analysis

The field notes that were later typed in MS word were coded on NVivo 12. We adopted a thematic content analysis approach. This involved: familiarizing ourselves with the data through reading and re-reading the transcripts; generation of the initial codes; forming broader descriptive themes by grouping these codes to matching patterns and relating these to existing literature. The first phase of the analysis involved the independent coding of the data by the two authors, MO and GI. This was then followed by intensive discussions between the two authors who made comparisons between the individually identified codes to arrive at consensus on the coding framework. All data were then coded, guided by the coding framework using NVivo 12 through an iterative and flexible process, and the coding framework was updated as the data coding progressed allowing for emerging codes. An abstraction process then took place and the codes were grouped into themes and these were related to existing literature. The entire analytic process involved collaboration with MO and GI, and all discrepancies were discussed until consensus was reached.

In summary, a three step HCD approach was used to design a comprehensive SSNB clinical audit tool and its implementation guide. I used a controlled before and after (CBA) study to assess the effect of facilitation on reducing the time to regain birth weight through improving feeding practices of the LBW and VLBW newborns. The study involved four hospitals that are part of a Clinical Information Network for Newborns. The four hospitals were randomised into experiment (H1 and H3) and control (H2 and H4) hospitals, with the randomisation occurring at the hospital level. Facilitation of the clinical audit meetings was successfully provided to the two hospitals that had been randomly assigned to the experiment arm. Five months after the beginning of the intervention period, there were five facilitated audit meetings in H1 and six facilitated meetings in H3. The two hospitals that were randomly assigned

to the control arm (H2 and H4) conducted audit meetings with no external facilitation over the five-month period. None of the hospitals withdrew from the study. The data were collected through the abstraction of the routine data entered in the CIN Neonatal hospitals database. I used a competing risk analysis to estimate the effect of facilitation on the time to regain birthweight with time to death as the competing risk. I compared this between the experiment and control arms and between the pre-intervention, intervention and post-intervention periods.

I used a participant observation approach to collect the qualitative data. I documented my observations of the interactions of health care workers during the audit meetings, process of conducting the audit meetings, observations and feedback on the facilitators and barriers to conducting the audit process and reflections of my experiences and informal conversations. A thematic content analysis approach was adopted for the qualitative data analysis.

I will present the results of this PhD thesis in chapter 4. These show the outcome of the human centred design process, the results of the quantitative study and the results of the qualitative study.

Chapter 4: Results of the co-design of a small and sick newborn audit tool and implementation guide using a human-centred design approach

I will begin by describing the outcome from the co-design of the audit tool.

1. I will demonstrate the outcome of the steps taken that informed the design of draft zero of the prototype audit tool.
2. I will then present the structure of draft zero and the modifications made during the cognitive walkthrough phase.
3. I will present the structure of the final audit tool that was ready for testing.

I will then illustrate the results from the FGDs and virtual design workshop that informed the design of the implementation guide.

4.1 Outcome of the co-design of the small and sick newborn clinical audit tool

The iterative process in the design of the clinical audit tool began with a review of the available tools and subsequently, a cognitive walkthrough of the prototype audit tools which resulted in a high-level prototype tool for testing. The outcome of each of these steps are presented below.

4.1.1 Outcome of the review of the available maternal, perinatal and newborn audit tools to understand the gaps and inform the structure of draft zero of the SSNB audit tool

The three audit tools reviewed to inform draft zero of the prototype newborn audit tool were; Kenyan MPDSR tool, the WHO stillbirth and neonatal death case review form and the WHO child and neonatal death review form. The WHO stillbirth and neonatal death case review form focused on maternal and perinatal care. The WHO child and neonatal death review form had information on neonatal care but majorly focused on care beyond the neonatal period.(1, 14, 53)

As summarised in Table 13 below, the Kenyan MPDSR tool and the WHO stillbirth and neonatal death audit tool have a similar layout. The sequence of patient information to obtain data in a systematic manner was similar in both tools. The data began with hospital details, biodata of mother and newborn, mother's antenatal care, labour and delivery care, resuscitation of the newborn, cause of death, modifiable factors and action plans. The WHO child and neonatal death review form was not specifically designed to audit the perinatal and neonatal period. This tool gave provision to audit the care of children beyond the neonatal period. The structure of the audit tool however followed the same sequence of patient care details from admission to death with more allowance to discuss the care provided during the hospital stay. A summary of the structure and content of the three studied tools has been presented on Table 13 below.

Table 13: Summary of Structure and Content of Available Perinatal, Neonatal and Child Clinical Audit Tools

Basic design	**Kenyan MOH MPDSR Tool (53)**	**WHO Stillbirth and Neonatal Death Case Review Form (14)**	**WHO Child and Neonatal Death Review Form (1)**
1. Structure of input fields			
• Closed ended questions designed for single word and yes/no responses	✓	×	×
• Closed ended questions with free text.	×	✓	×
• Open ended questions with free text	×	×	✓
2. Details of facility where death occurred	✓	✓	✓
3. Biodata of patient	✓	✓	✓
4. Biodata of mother	✓	✓	×
5. If patient a referral in and if yes, details of facility referred from	×	✓	✓
6. ANC attendance	✓	✓	✓

7. Obstetric conditions during pregnancy, labour and delivery	✓	✓	✓
8. Management of labour and delivery	✓	✓	×
Newborn details			
9. Resuscitation of baby	✓	✓	×
10. Description of clinical illness and progression	×	×	✓
11. Investigations done and key results	×	×	✓
12. Primary and underlying diagnoses	×	×	✓
13. Treatment provided	×	×	✓
14. Cause of death	✓	✓	✓
15. Modifiable factors			
• A list with a checkbox for selection. Categorised as the three delays.	✓	×	×
• A list that is categorised as family, administrative and provider related modifiable factors.	×	✓	×
• Free text section to list down identified modifiable factors.	×	×	✓
16. Action plans			
• Free text section to list down action plans.	✓	✓	×
• Structured action plan summary form separate from audit tool	×	×	✓

Abbreviations: ANC, Antenatal care; MPDSR, Maternal and Perinatal Death Surveillance and Response; NBU, Newborn unit; WHO, World Health Organisation.

4.1.2 Structure of draft zero of the prototype newborn audit tool

Draft zero of the prototype newborn audit tool was designed as four sections (Appendix 11a):

1. Biodata of the newborn which included the inpatient number, gender, date of birth, birth weight, gestation at birth, age at death (mortality audits) or age at review (near miss audits), weight at death (mortality audits) or weight at review (near miss audits).
2. Mother's details which included
    i. ANC details: Mother's blood group, Human Immunodeficiency Virus (HIV) status, syphilis status, hypertension in pregnancy and diabetes in pregnancy.
    ii. Labour and delivery: Mode of delivery, complications during labour and delivery and if the newborn was resuscitated after delivery. These complications were coded at the bottom of the audit tool.
3. Review of the care provided during and after admission.

    This section began by reviewing the admission care. The structure allowed the audit participants to discuss the quality of care provided; what was well done, what could have been done differently and the recommendations made for each step in care during admission (timely admission, adequacy and appropriate assessment - history, physical examination, and investigations, primary and secondary diagnoses, supportive and definitive management).

    The next section reviewed the supportive and definitive management hinged on the progression of illness during the post admission period.
4. Details of death for mortality audits (primary and secondary cause of death) and the conditions leading to unfavourable outcomes for near miss audits.

4.1.3 Final outcome of the cognitive walkthrough of draft zero and the subsequent modified prototype audit tools

The feedback on the audit tool received from the end users during the cognitive walkthrough phase was categorised into one of the three groups; usability, human factors and user experience.

1. Usability – the degree to which the content of the audit tool enabled a comprehensive summary of the care provided to the small and sick newborns.
2. Human factors – the implementation of comments and responses to the structuring of the audit tool that facilitated or limited the users' interaction with the audit tool.
3. User experience - the perceptions and thoughts of the users based on their experience of using the audit tool.

The description of the user feedback and outcomes of the modifications made to the prototype audit tools during each audit cycle have been summarised in Table 14.

Table 14: Categorisation of identified changes to the prototype audit tool based on usability, human factors and user experience and the outcomes of the feedback

Audit tool number	Usability	Human Factors	User experience	Outcome
• Audit tool # 0		• To reduce the length of the audit tool while maintaining important information. • To get details on section one; newborn and mother's biodata and details of labour and delivery as a print-out from the CIN-Neonatal data clerks in the hospitals therefore reducing the workload of the clinicians filling the audit tool before the meeting.		• The 1st page on newborn and mother's details was separated from the audit tool. • Content of the audit tool remained the same, but the structure changed such that the left half of the page was for documenting the summary of the care provided before the audit meeting and the right half was for documenting modifiable gaps identified in each section during the audit meeting and the recommendations made. (Appendix 11a)
• Audit tool # 1		• To structure the section on newborn and mother's details as textboxes to make the tool easier to fill out. • To add more colour to the audit tool and make it neater.	• The audit tool seemed incomplete without the front page that had sections on newborn and mother's biodata. • An observation that it was cumbersome to look at the coded section on maternal complications which was at the end of the audit tool.	• Returned section one on newborn and mother's details. • Improvement on the aesthetics of the audit tool. • Format of the section on maternal complications was changed from selecting from a coded list to providing a free space for the clinicians to list any complications that may have been present. • The pages of the audit tool were divided into 3 sections. Section A as the summary filled before the audit meeting took 1/3rd of the page. Section B took 2/3rd of the page and had 2 parts – the 1st was to document the modifiable factors arising from the audit

				meeting and the 2nd was to document recommendations made during discussions. • The structure of the section on danger signs at admission was broken down to identify the specific abnormality in the vital signs e.g. if they were too high or too low as well as some specific danger signs that were considered critical.
• Audit tool # 2	• To borrow from the neonatal admission record (NAR) form on the structure of the admission details as it is comprehensive and has the relevant information required during the audit.	• To make as many sections with checkboxes to reduce the workload for the clinicians filling the audit tool.	• To include a section on the neonate's progress of illness after admission as there was a gap in the flow of information after admission details.	• Section on mother's antenatal history and labour and delivery complications were designed with checkboxes and textboxes borrowing from the neonatal admission record (NAR) form. • Section on labour and delivery complications; I included a checkbox on whether the newborn was resuscitated at birth. • Section on danger signs and symptoms at admission was reformatted to include those in the NAR form. • Separate the sections on supportive and definitive management at admission. I included a section for the clinician to document a summary of the progression of the child's illness post-admission.
• Audit tool # 3	•	•	• There was too much free text in the section on supportive management making it time-consuming to fill the audit tool.	• Section on investigations was structured further with each of the critical investigations listed and space provided to document the investigation results. • I included documentation of post-admission weights to the feed and fluid section.

			• The section on investigations was cumbersome and required to be structured in a way in which the important investigations are listed making it easier to fill.	• The section on supportive management was further refined to the management of specific conditions that were considered critical.
• Audit tool # 4	• No objective way of determining if the danger signs were recognized. • No provision to document the modifiable factors.	• Feedback to add more sections with checkboxes to reduce the workload for the clinicians filling the audit tool.	• The section required to determine if there was a delay in review at admission was too subjective and needed to be restructured. • To increase the writing space for sections with free text as the space provided was inadequate to provide relevant details.	• The structure of the audit tool was changed such that the pages were no longer divided into two parts, instead, the section for discussion came below the summary of care in each section. • In the section on review of care, I structured it to document time of birth, time of admission by NBU nurse and time of admission by the clinician in NBU. • I included a section on response to danger signs and symptoms at admission with checkboxes on the acceptable responses to danger signs based on the protocols. • The section on the critical basic laboratory and radiological investigations was formatted into a table that allowed for the documentation of each investigation result and the dates when the investigations were conducted. • The section on definitive management was further modified into a check box of the essential newborn medication based on the BPP. We also included columns to document the prescribed

				dosage, route and number of days the medication was prescribed. • I included a section at the end of the audit tool to document the modifiable factors identified from the discussion.
• Audit tool # 5	• I presented the audit tool to neonatologists from KNH who suggested that we include a section to audit the management provided at referring facilities as a significant percentage of the newborn population in the NBU was referred in from a different facility and it was important to know the quality of care that was provided at those facilities. • Suggestion that we should not only audit delays in conducting investigations but also delays in acting for abnormal results.		• Feedback that we should group the audit tool into two sections. . The first section to be the summary of the case being audited (section filled before the audit meeting) . The discussion section (section filled during the audit meeting). The experience was that discussing the quality of care after each section made the audit meeting take too long.	• The structure of the audit tool was changed to separate section A (summary of care provided) and section B (section for discussion of the quality of care during the audit meeting). We had section A as the 1st part of the audit tool and section B as the 2nd part. • Inclusion of details of referral for the patients referred into the newborn unit from different facilities. • Two columns were included in the Table of investigations – a column on the action taken and a column on the date the action was taken. • Section on supportive management was modified to include the possible management options for each sign and symptom based on the basic paediatric protocols.
• Audit tool # 6	• I included a section to document any medication that may have been used during the initial resuscitation after birth. This was in an attempt to highlight wrong practices during resuscitation.	•	•	• Section on newborn details – I increased the Apgar Score options to 20 minutes. • Section on newborn resuscitation after birth, we included options for any medication used during resuscitation and checkboxes for oxygen support post-resuscitation.

				• Section on investigations was restructured to the specific investigations and the dates the investigations were ordered, dates results were received, actions taken and the dates the actions were taken.
• Audit tool # 7	• The team made observations that the audit process seemed like it was only auditing the care provided by the clinicians and the nursing care was left out. • Poor participation by nurses in the audit meetings. *"I don't understand how you will find all cadres in the audit meeting; doctors, midwives, lab, pharmacy, you name it. But the nurses from the newborn unit never attend the meetings and when asked are always too busy."* (Audit meeting participant)	•	•	• I added a section on vital signs monitoring for each day of life for the newborn. • I included columns on feed and fluid monitoring to the section on feed and fluid management.
• Audit tool # 8	• The audit tool only allowed for the identification of the cases that were referred in and the reason given for referral. It however did not allow for details of the care provided at the referring facility. It was therefore not	•	• The section on response to danger signs at admission was repetitive.	• Audit tool was converted to an electronic tool using the application PDF element. • I deleted the section on response to danger signs at admission. • Included a section to summarise management at the referring facility if the case was a referral. • I planned to introduce the audit process to all the CIN-N sites and therefore transformed it into an electronic tool (E tool) as

	possible to identify gaps in care at the referring facilities.			this would make it possible for the hospitals to adhere to the MoH regulations that prevented large meetings due to the COVID-19 pandemic by conducting virtual audit meetings. This would also allow us to attend the meetings virtually due to travel restrictions across counties.
• Audit tool # 9	•	• To make it easier and faster to fill in the audit tool by adding drop-down calendars and checkboxes where possible.	• The end users had challenges in filling the section on modifiable factors as evidenced by the difficulty in filling the section during audit meetings.	• I changed the application used to design the audit tool from PDF Element to Adobe Acrobat Pro. • I included drop-down calendars to all the sections where a date was to be documented. • The modifiable factors were presented as a list as agreed upon during the consensus workshop.
• Audit tool # 10	•	• Section on modifiable factors could still be made easier to fill.	•	• The list of modifiable factors was converted to a drop-down list under the major categories and sub-categories.
• Audit tool # 11	•	• Feedback from the clinicians that a checkbox for the modifiable factors would be easier than the drop-down list.	•	• The format for the modifiable factors was changed from a drop-down list to a checkbox list.
• Audit tool # 12	• The section on the medication used during resuscitation was misleading as it gave the impression that this was the proper management. Suggestion that we should instead promote the correct practice by focusing on bag valve and mask (BVM) and	•	•	• I modified the section on newborn resuscitation after birth. I deleted the checkboxes on the medication used and included a checkbox on chest compressions.

	chest compressions. Any treatment beyond this should be put under others.			
• Audit tool # 13	•	•	• To include the action plan summary form as part of the audit tool as it was frequently forgotten.	• I included the action plan summary form as the last section of the audit tool.
• Audit tool # 14	• To include measurements of head circumference and length in the newborn admission examination details.	•	•	• I included the options of head circumference and length in the section on newborn details. • I modified section 3 on the review of the care provided. I included the date of admission by nurse and the date of admission by the clinician. (Appendix 11b)

The co-designed SSNB clinical audit tool was different in structure and content from the available aud

tools. A summary of these differences are summarised in box 2 below.

Box 2: Differences between the co-designed SSNB audit tool and the available audit tools		
Design details	**Structure of co-designed audit tool**	**Structure of available audit too**
Sections of the audit tools.	The audit tool has two sections. The first section is to provide a summary of the care provided. The second section is a guide for documenting the discussion on the quality of care in each section.	Only the WHO child and neonat review form has provision to do gaps identified during the audit discussion. The discussion howe after each section describing th care.
Structure of input fields.	The basic structure mostly includes check boxes, drop-down calendars and open-ended questions.	The MPDSR tool and the WHO s neonatal death case review forn structured as closed-ended que The WHO child and neonatal de form is structured as open-ende with free text. None of the tools have checkbo down calendars.
Resuscitation and post-resuscitation care.	The section on newborn resuscitation immediately after delivery specifies the type of resuscitation provided and includes the post-resuscitation care provided.	The available audit tools only do newborn was resuscitated but d details of the resuscitation. The provide details on post-resuscit
Details of admission.	The details of admission include details on delays in transfer from the delivery unit to the NBU and delays in the review of the newborn by the clinician while in the NBU.	The available audit tools do not on the delays in transfer of the NBU and the delays in review o during admission.
Description of clinical illness and progression.	A section to comprehensively describe the danger signs at admission and a different section to describe the progression of clinical illness post-admission.	The WHO child and neonatal de form include a section to summ child's illness and progression in
Nursing care audit.	A section to audit the nursing care provided during the hospital stay.	None of the available audit tool provisions to audit the nursing c to the newborns.
Treatment provided.	Detailed description of the supportive and definitive treatment provided to the newborn including the feed and fluid management.	The WHO child and neonatal de form include a section to descri treatment provided. This is how grouped into supportive and de treatment.
Action plans.	A structured action plan summary form that is part of the audit tool.	The WHO child and neonatal de form include a structured action form that is separate from the a The other audit tools have a fre to list down the action plans.
Audit meeting attendees.	A list with a check box to identify the members of the audit committee who attended the audit meeting.	None of the available audit tool section to document the audit m attendees.
Modifiable factors.	Structured list of modifiable factors categorised into administrative-related, health worker related and patient oriented factors. These have check boxes for selection instead of free text.	The MPDSR tool has a list with a selection. Categorised as the th The WHO child and neonatal de form has a list that is categorise administrative and provider rela factors.

		The WHO stillbirth and neonatal death case review form has a free text section to list down identified modifiable factors.

Abbreviations: MPDSR, Maternal and Perinatal Death Surveillance and Response; NBU, Newborn unit; WHO, World Health Organisation.

I will now present the results from the FGDs on the facilitators and barriers to the clinical audit process that describe what the practice was prior to the intervention. I will also illustrate the outcome of the consensus design workshop for the audit implementation guide which was the initial implementation guide. Finally, I will present the outcome of the usability testing which resulted in the final version of the audit tool and implementation guide for implementation.

4.2 Outcome of the development of an audit implementation guide adapted to the context

The user centred approach used for the design of the audit implementation guide ensured that it was compatible to the settings. The outcomes of the processes used in the design are presented below.

4.2.1 Characteristics of the context and users that were perceived as facilitators and barriers to using the newborn clinical audit process based on the focus group discussions

The FGDs described the facilitators and barriers to the clinical audits as experienced before the intervention. The themes arising include:

4.2.1.1 Perceived Facilitators of the newborn clinical audits

1. **Patient safety culture that focuses on minimizing patient harm**

Patient safety culture is defined as "an integrated pattern of individual and organizational behaviour based upon shared beliefs and values that continuously seek to minimize patient harm that may occur from the care delivery process."(204) The study participants elaborated on the ways in which their organisations prioritized patient safety by viewing patient care from a systems perspective and

therefore recognizing the value of multidisciplinary collaboration, creating an equal environment that supports open dialogue and an environment that encourages learning from preventable adverse events.

a. Collaborative approach to patient care

While some participants claimed that newborn audit meetings were only attended by the newborn unit health workers, others reported a different experience. The study participants expressed that the audit meetings provided an opportunity for different health worker cadres to work together and share responsibility for problem-solving and decision making. They pointed out that this team collaboration was important as a joint effort from a team with diversity in knowledge and skills would lead to solutions that best address the emerging avoidable gaps. The participants reported that the maternity/labour ward team were usually invited to the audit meetings, while the other cadres were invited based on the significance their input would add on a case to case basis.

….And then we also call upon the… the… nurses within the unit, like the newborn. Mostly we call all the nurses in the newborn unit and then the paediatrician usually is in the meeting. Among the other cadres we have the clinical officer interns, we have the medical officer interns and the medical officers rotating in the unit at that particular time. FGD 1 (R4)

"but if there is a need like our neonates, some of our neonates may need physiotherapy or occupational therapy. And probably if we are discussing a case that the occupational therapist's input might have improved the outcome, then we call the team from there. And that also occurs to…to… to… the other departments also." FGD 1 (R9)

"I like about the audits is the togetherness that it brings amongst us, the team, the team members within the department. The fact that we come together to discuss the… the… the… issues and see where the gaps are and be able to get solutions to improve the outcomes." FGD 1 (R2)

"Yes, at our facility, we don't have a structured newborn audit committee, but as a department led by the paediatrician and the head of the department, we have monthly… monthly audit meetings in which we have a variety of people from different departments. We always make sure there is somebody from the laboratory, pharmacy, public health and the maternity. Recently, we have also started.... in the newborn unit... on the third week we have an audit whereby we choose a case where we want to learn from, and the team from the newborn unit, including the doctors, the nurses, the clinical officers. And we invite somebody from the maternity whereby we discuss a case that is of concern." FGD 1 (R2)

"It's on the second Thursday of the month, in the afternoon, usually all cadres are invited. The meeting is chaired by the paediatrician in charge of the unit at that point in time." FGD 2 (R3)

"However, I still feel there are quick, quick wins, because it helps the team to be cohesive in management of patients. It brings the nurses like in our case, the medical officer, the interns together in taking care of the children. And that removes barriers between different cadres. And I think it's a good observation that normally with the newborn unit, we do not find the nurse refusing to do a blood sugar because the lab person is not there. You will not find a nurse refusing to fix a line because the medical officer has delayed to come. There is a bit of teamwork, because each one of us understands that just delaying to make that step may result into poor outcomes. So, I think that collaboration in the team, works" FGD 4 (R5)

"We're able to work as a multidisciplinary team with the labour ward team, the postnatal, maternity theatre, and, we come out with a positive reason as to why that death occurred, the neonatal death" FGD 4 (R7)

b. Equality during audit meetings

The study participants expressed that a non-hierarchical environment where every meeting participant was viewed as an equal and all contributions were respected facilitated a non-threatening environment. They explained how the creation of an environment that supports open dialogue and respects diverse perspectives allowed for exhaustive discussions which further strengthened confidentiality as they reported there was no continuation of the discussions outside the audit meeting.

"….You find that when you're in the audit meeting, usually it places everyone at par, so you're able to discuss and come to an agreement." FGD 1 (R4)

"And audit meetings actually brought this out. It doesn't matter who you are, whether you are a professor, whether you're a paediatrician, whether I'm a nurse. You know...So we're all given, from experience, we were all given an equal opportunity to speak out our mind." FGD 3 (R3)

"After the audit process is over, because everyone is given a chance during the audit. We don't encourage you to continue discussing the, you know, the cases afterwards. So that you don't start blaming... you know, blame game… So, after the audit, that is the end of the process." FGD 3 (R5)

c. Learning from errors

A strong patient safety culture encourages learning from modifiable factors. Modifiable factors are factors which may have prevented an adverse event from occurring if done differently.(1) The study

participants agreed that the reflective nature of the clinical audit enables practitioners to draw inferences from their own practice by analysing what was done and interpreting the relationship between their practice and patient outcomes. This reflective practice exposed the gaps in knowledge and skills and the participants therefore perceived it as a way to identify learning needs. We noted that study participants recognised that the lessons learned from each case would have a ripple effect on quality improvement. This was reflected in the way they selected cases to audit based on those that contributed to the highest mortality in the NBU.

"And normally, what we do is that we ask the interns to pick all the deaths like in a month, then we… we… categorize them according to the type of death. Let's say, if it is neonatal sepsis, then we normally give... If it's neonatal sepsis, then we'll discuss neonatal sepsis... a case of neonatal sepsis if it is if it is the most common cause of death in that month" FGD 2 (R6)

"What I like about audits is that it's usually a learning process. FGD1 (R4)

"But also, we pick an interesting case. In case we have one interesting case that we feel we should discuss we normally also discuss it." FGD 2 (R6)

"So, we discuss the case in terms of which one contributed for the highest morbidity and mortality for the month." FGD 2 (R2)

"…Because during the audit, we are here to learn, we are here to see how we can do better next time." FGD 3 (R5)

"In our case, in case we identify any mistake during our audit, we use it as a learning point. So, what we do we'll go over the condition the patient had and discuss it and help everyone to understand what we're supposed to do. It actually makes a topic for the next CME." FGD 3 (R5)

"Ok, it's basically what we've talked about, but sometimes like you realize that the problem is big, we even organize for CMEs. Like in our setting, I remember there is a time when we had issues with newborn resuscitation. When we realized there was a big gap, we had to organize for some resuscitation sessions for both the staff in newborn and labour ward." FGD 3 (R6)

"Like for example, let's say, we were doing an audit, and we realized, for example, this baby qualified for CPAP, and it was not initiated. The question will be, why was it not initiated? And maybe it will come up like maybe the person who was doing the shift that time, they didn't know how to set up the CPAP. So, at that time, we'll take it up and even discuss the advantages, how to do it, and the complications to anticipate. So that we can make sure it doesn't recur next time" FGD 3 (R5)

i. Mentorship provided to health workers from lower level facilities

The study participants acknowledged the connectedness between the County hospitals and the lower level referring facilities. They recognised that the quality of care provided to patients in the lower level facilities before referral to the County hospitals had a significant impact on the patient outcomes. Based on this, the FGD participants reported that as they learn lessons from preventable adverse events and modify practices that are perceived to be ineffective, they share this knowledge with health workers from the referring facilities to help them improve the quality of care they deliver. They reported that the knowledge transfer is usually done through inviting the health workers from referring facilities to the County hospitals for a period to work under supportive supervision until they acquired the necessary skills.

"Hallo everyone, the only thing I would like to add is that, when we do the auditing, we are able to identify the gaps, and, recently we've been able to mentor our referring facilities, especially the nurses from the referring facilities. So they have come in the newborn unit for at least a week, so that we mentor them on how to how to manage the newborn units...newborns, especially when they are delivered having birth asphyxias, and how they would be referring them to our facilities, including doing Kangaroo Mother Care during the referral, during when they are referring the babies." FGD 4 (R7)

So, they were called on board to come in the Obsgyn department, that is labour ward, newborn unit for mentorship for a whole month. So, in our newborn unit, they are coming for a week" FGD 4 (R7)

"We have some cases where, especially the periphery hospitals where they are fond of referring babies, especially babies with something like severe birth asphyxia with a score of maybe 4,5. So, during our audit meetings, we've been calling them to attend these meetings." FGD 3 (R4)

2. Completion of the audit cycle

An audit with no action will not lead to change. Poor implementation of recommendations arising from clinical audits has been identified as a major contributor to the limited confidence in the audit process.(50, 56) The study participants described the different strategies that they have put in place to ensure that recommendations are implemented. The strategies reported included; 1) direct task allocation, and 2) task-oriented minutes.

a. Direct task allocation for accountability in the implementation of recommendations

Some study participants reported that to ensure accountability, each action plan arising from the audit meetings is assigned to a specific person in the relevant department. This key person was responsible for ensuring that the action plan was implemented.

"So, we sat down as a department, everybody had an individual work plan. Because most of the recommendations we made are supposed to be implemented by the facility, and it's been taking long. So, we decided as a department, everybody will have an objective. So, we made an individual work plan, was it last month? Everybody is working on like... Everybody has an objective to reduce the number of deaths... like, all the nurses in the department, everybody has an objective. An example is somebody has an objective on resuscitation, another one on infection prevention" FGD 4 (R8)

"And get that the right person to deal with that gap. And after some time, we review to see if the gap has been sorted." FGD 3 (R2)

b. Task oriented minutes that were focused on identified problems and the recommended solutions

Study participants reported that one of the conditions that enforced implementation of recommendations from the audits was through taking minutes that focused on the identified modifiable gaps and the recommended solutions. The meetings are then interlinked by ensuring that one meeting is a continuation of the previous one through beginning the meeting by reading the minutes from the previous meeting and determining if the recommendations have been implemented.

"So that when you're coming in the next auditing day, we have now to look at the recommendations we have done, where have we reached? And, where are we?" FGD 4 (R7)

4.2.1.2 Perceived barriers to the newborn clinical audits

1. Unhealthy organisational culture that did not support quality improvement initiatives

This main theme reflects the perceptions of the FGD participants with regards to the impact their organizational culture had on the effectiveness of the audit process. The emerging categories were: Minimal leadership support, hierarchical relationships, name and blame culture and blame shifting.

a. Minimal support from the senior hospital leadership

The respondents perceived the leadership style as an important determinant of the success of the audit process. There was general agreement among the health care workers that the senior hospital leadership had a more laissez-faire approach towards the audit process. This was evidenced by their absence from most audit meetings; leaving them to be conducted and managed by the mid-level managers. The study participants recognised the importance of having the hospital leadership present at the audit meetings as it improved the chances of implementing audit recommendations. The hospital leadership however rarely voluntarily attend the audit meetings, the participants pointed out that they had to persuade the hospital leadership to attend when they required extra support to implement action plans beyond their control. Sometimes the only communication between the audit team and the hospital leadership was through the records officer who shared the meeting report with the leadership in the form of a report.

"Cause we find that when it comes to administrative representation, we would maybe just find the nursing officer in-charge in the meeting due to other commitments by the medical superintendent and the administrator." FGD 1 (R4)

"Yes, if there is a recurring problem that we have identified that involves a particular team or player, say, for example, administrative matters. That is when we go ahead, we also seek the audience for the participation of the hospital leadership mainly by either the hospital CEO, the administrator or the nursing officer." FGD 1 (R6)

"But we... we are encouraging collaboration at the county level because they have more resources than the facility level to ensure that we get the best outcomes, and we implement the actions we come up with." FGD 4 (R5)

"Once we do the audit process, all the forms and the data that we've collected and all the discussion that is emanating from the meeting, we usually task it to the records person to actually take it to the administration" FGD 1 (R4)

b. Hierarchical relationships between the health worker cadres

The study participants recognised that the relationships between the health worker cadres was hierarchical in nature. There was consensus that among the mid-level managers, the consultant was at the top of the hierarchical pyramid. The consultants independently determined if and when meetings would happen, who would be invited to the meetings as well as had the responsibility of chairing the meetings.

"most of the thing is the paediatrician who determines who comes into the meeting and also the date, the exact date when the meeting is on" FGD 1 (R6)

"So, the chairperson is the same. For the MPDSR it's automatic the chairperson is the obstetrician in charge, the… the… head of Department of obstetrics. So, when he's not there, then somebody else can take over." FGD 1 (R9)

The responses revealed skewed task shifting. When the consultant was not available, the responsibilities were automatically transferred to the junior doctor despite there being more senior representation from other cadres such as the nurses.

"That is not right. When the paediatrician is not there, we do delegate. Cause there are times when the paediatrician is out in other meetings... and... uh... usually like the paediatrician might have gone on leave. So, if there's a medical officer within that department, we usually like delegate that to the medical officer to run the audit meetings." FGD 1 (R4)

"Yes, so there's no stand-alone newborn audit committee per say. So, the... We have the… the… hospital MPDSR that holds the monthly meetings, but for the newborn unit now as the team in the newborn unit, led by either the paediatrician or the medical officer decide on when to hold the meetings. So that one involves just the clinical care team for the newborn unit. But it's not structured. It's just something that is routine that it has to be there every week. So, when the paediatrician is not there, then the medical officer will lead the team in the discussions in the audit." FGD 1 (R9)

The respondents also highlighted how the power differentials have been well accepted by the less powerful groups. This was portrayed by the fact that a key determinant of audit meeting attendance by the health care workers was the seniority of the person who called for the meeting.

"It is also the authority of the person calling the meeting that influences our turn out very greatly. For example, if it's the paediatrician or the hospital Med Sup calling the meeting, then you virtually almost get 100 percent attendance. But if the meeting is headed or called by a junior officer, usually the turn-out is quite poor" FGD 1 (R6)

c. Name and blame environment with punitive repercussions

Participants described how one of the most significant deterrents to the success of the clinical audits was a culture where the audits were not used as a quality improvement exercise, but rather as a 'witch hunt'. This instilled a fear of punishment and victimization among the health workers and therefore

reluctance to participate in audit meetings. The participants explained how the fear of punishment has fostered a culture of self-preservation whereby the health workers would get to the point of engaging in unethical practices to avoid punishment.

"Labour ward you were supposed to do this, and it was not done, no, newborn you were supposed to do this, and it was not done. So, what I've realized, ok that is me, what I've realised, when there's an audit, in fact, I've realised that some people do not like attending because of that blame." FGD 3 (R4)

"And what I don't like about audits is that at times it occurs that we may be pointing fingers at mistakes that people have been done so people feel like they are being probably pointed at or being seen as having failed." FGD 1 (R9)

"Or whether people get punished or whether they feel like they are being punished during the audit. I don't know how to put it, but I've seen especially from labour ward, when they have a patient who has a very bad score, or they get an FSB. They are made to, you know, to write a letter explaining what really happened. And that one makes people very scared. And you'll see they will do anything, even bring in a patient who is not even alive in the newborn unit. I don't know where we place that, because they feel already, they're already punished because of that." FGD 3 (R5)

"One of the measures again, that you know, if an individual keeps on making the same… same… repeating the same, same mistakes again, one of the… the… individual is you know, umm you know questioned, and one of the things that have come up, are you interested in newborn? Maybe this particular individual has never had an interest in newborn care, so there are times when changes have been done, maybe removed. He or she has been removed to an area where she can perform best.

Maybe in adults, maybe in paediatrics or you know, Obsgyn. Something like that, so that you do not, you know, keep on having this individual in an area that he or she has no interest." FGD 3 (R3)

The responses from the FGD participants suggested that the intention to victimize the health workers for 'mistakes' they made was evident from the methods used to select cases for audit. The selection of cases was based on perceived errors made by those who were lower most in the hierarchical structure who should ideally be working under supervision.

"Occasionally, what we do is that depending on maybe, if there was a laxity somewhere or if there was a problem that we had during the month, a case that we feel lacked by the interns" FGD 2 (R6)

d. Blame shifting by the hospitals attributing blame for their poor outcomes to the lower level hospitals

We noted that there was a general belief among the respondents that the lower level referring health facilities were the major contributors to the newborn morbidity and mortality burden in their hospitals. The attitude among the FGD participants was that the newborn outcomes would greatly improve if the referring facilities improved the care they provided. The FGD participants expressed that the health workers from referring facilities were routinely invited to audit meetings but they did not attend, and they strongly believed that this contributed to the failure to make changes based on findings from the audit meetings. This is despite data from the CIN for newborns showing that majority of the newborn deaths in the newborn units of these County hospitals were from babies born in their hospitals.

"Yes, yes daktari and I like audits. But what I what I don't like is when we are discussing, like, cases of mortality due to birth asphyxias from referral facilities, and they are not there. You know, we… we… we… discuss things that we can't change as in the newborn unit. And then, when… when… we send recommendations to them, they do nothing, it's like they don't feel it." FGD 4 (R6)

"Yeah, I think it would be more of repetitive, in that, when you try to welcome the referral facilities, it actually takes time for them to come or they don't come at all." FGD 4 (R3)

"In my facility, since most of the deaths, according to the numbers we have, are from the peripheries." FGD 4 (R8)

"one thing that we did with my paediatrician is that one-time last year, we went to a facility with the number of the… the… mortality cases that they had referred, and in a, in a year, they were 37. And we invited 37 staffs, and we...(laughs) we were able to give them the feedback and show them the multitude, you know, the magnitude of the mortality, how many babies we are losing. And then we are able to sit with their Med sup then, and we made recommendation, and actually it reduced by 30 percent." FGD 4 (R6)

2. Health workers' perceptions about the value of clinical audits

The FGD participants revealed that the health workers did not fully appreciate the benefits of the clinical audit process on quality improvement.

a. Poor ownership of the clinical audits

The MPDSR process has well established structures with clearly developed guidelines on how the process should be conducted at the hospital, Sub-County and County levels.(62) The MPDSR guidelines recommend that perinatal deaths are a notifiable event and that a proportion of the perinatal deaths should be reviewed at the facility level during monthly facility MPDSR meetings. Based on the responses from the participants, it emerged that in some Counties, the clinical audits were not held at the hospital level. The health workers instead waited for the three-monthly Sub-County meeting to be convened in

which every facility within the Sub-County only had a chance to present their morbidity and mortality statistics. We got the sense that the health workers did not own the MPDSR process as they did not appreciate the value conducting the audit at the hospital level had on identifying avoidable gaps.

"Ok, like for the MPDSR meetings, which are held at Sub-County level, not within the facility. The Sub-County MOH is the one that determines when these meetings are going to be held. So, we only get an invitation either through SMS, or we get a mail that there is a perinatal meeting that is going to occur on a given date." FGD 1 (R4)

"usually for our meetings, the MPDSR meetings involve the Sub-Counties, all the Sub-Counties within the County. So, they do a written memo to the records information officers in the various facilities or Sub-Counties through the secretary in the MPDSR." FGD 1 (R4)

b. Insufficient multidisciplinary collaboration in the review of the quality of newborn care

The contributions from the FGD participants revealed that health workers outside of the newborn unit did not appreciate the significant value of their participation in the newborn clinical audits. There was therefore poor multidisciplinary collaboration for the audit process with the audit meetings attended by only the newborn unit team with no participation from other departments involved in newborn care. The participants also expressed that in addition to poor collaboration from other departments, in some instances, the poor teamwork was also displayed among the newborn unit teams with the audit meetings attended by only doctors despite other cadres being invited.

"But otherwise, it's just limited to the immediate care team." FGD 1 (R6)

"Well, OK, most of the time it is done by the… the… the… the… medics, the doctors, but they invite us. So, they pick on cases, and then we discuss, we audit." FGD 2 (R4)

"And this usually involves only the newborn unit team." FGD 2 (R8)

We noted that the FGD participants were particularly displeased by the poor collaboration from the obstetrics departments in their facilities. There was agreement that the newborn outcomes would only improve if this was a shared goal between the obstetrics and newborn unit teams as majority of the poor outcomes could have been prevented with proper care during pregnancy, labour and delivery. The participants expressed their frustrations of how they routinely extended audit meeting invitations to the obstetrics team, but they did not honor the invitations.

"We've also been able to inform the maternity… um… team, but the turn out hasn't been that good." FGD 1 (R4)

"The challenges that we have, of course, is... especially us in Paediatrics section, is that most of these cases that we see, be it asphyxia, be it...umm... preterm births occur in the people in the obstetric department, and more often, they do not come in. And we do not discuss the issues together." FGD 4 (R5)

"We just need to focus and involve the team from maternity to try and show up. I know they do their own audit there, but they assume the outcome... the... what has come out of the maternal near misses is good." FGD 4 (R5)

"Ok...ummm...the audits...umm... what has improved is, initially we had... We started having some meetings with the maternity unit, they have not continued." FGD 4 (R4)

"We wish we could have more meetings with even our own maternity and not the outside facilities, because as many people have said, asphyxia is one of those things that we can actually manage if we

could only be able to cooperate with and work together with our obstetric team. But we are still working on that, I hope we'll be able to improve it." FGD 4 (R4)

c. Conducted out of obligation as a box-ticking exercise

The national MPDSR guidelines recommend that perinatal audit meetings should be held at the facility level at least once a month and a compilation of the report from the meeting should be submitted to the Sub-County MPDSR committee. Some study participants reported that they adhered to these guidelines and regularly held audit meetings at their hospitals. They however expressed their waning confidence in the audit meetings as there were no visible changes that emanated from them. According to the FGD participants, the audit meetings were a cycle that involved making the same recommendations ad infinitum. There were however no efforts made to implement these recommendations once the meeting was over. The health workers therefore developed a negative attitude towards the audit process and viewed it as an extra activity that would consume much of their already limited time.

"what I don't what I don't like about audits is um... when audit recommendations are not implemented and it's the same… same… things, you know, being reviewed over and over again."

"What I dislike, just like has been said is that we have these meetings, but most of the time we don't get to implement and when we get to the next audit meeting, we'll be discussing the same thing." FGD 1 (M2)

"when in some circumstances we tend to do audit, and we have recommendations and we know what we need to do, but we come back the next time and we are still seeing the same thing. So, identifying issues and not implementing solutions." FGD 1 (R8)

“But what I don't like is failure of, lack of recommendations that are never implemented most of the times, it's quite discouraging.” FGD 1 (R5)

“Why I hate it is because of the workload that I have, it adds to the burden of having so many meetings every now and then.” FGD 1 (R6)

“but what I don't like is actually when people don't act on it.” FGD 1 (R3)

“But what I dislike most about the audits is that they're really time consuming cause you find that some of us are the only paediatricians within the counties, so you're supposed to like commit your time to these audits, so it tends to be more of uh time consuming because you really have to come up with solutions.” FGD 1 (R4)

“What I don't like about the audits is the perennial system deficiencies, problems within the system that don't get improved, such as shortages that don't get addressed, such that every time we have an audit meeting, we are discussing the same problems within the system that are not changing.” FGD 1 (R2)

“the frequency, initially it used to be monthly, but I think people got fatigued of the monthly. So, we do it every three months.” FGD 1 (R9)

“Otherwise the audits are done together with the... using the MPDSR with the obstetricians and gynaecology teams. So, most of the time what we do is we just highlight a few of our concerns,

especially things like birth asphyxia and hypothermia, especially for the low birth weight babies from… So that we make the teams aware." FGD 2 (R5)

"I don't like when there's that part where we always write the recommendations at the end of the audit, we've been writing the recommendations for years and years, and yet nothing is done. There's nothing corrected" FGD 4 (R8)

"Nothing is put in place, it's like we keep on writing the same things, and nothing is being corrected or, things are just remaining the same." FGD 4 (R8)

"Then there are other recommendations within the county hospital that you can recommend, and it takes actually a long time for them to be implemented. So, you get it's like a… it's like a round song, a repetitive song. You recommend something, but it's not really put into… into… place." FGD 4 (R3)

"I don't like it when this ... especially neonatal deaths due to asphyxia. When babies die, we review the cases, we make recommendations, but the same things keep happening again and again, even within our own facility, and from the referring facility." FGD 4 (R1)

"I really... I've not I've not seen any, any serious thing been done at our facility, yuh, things are still the same." FGD 4 (R8)

"We use the MPDSR tool, and then and also, we fill it even at the same sitting at the end of the meeting we have to fill it and submit our report." FGD 2 (R2)

d. The silent "P" in MPDSR

Perinatal death review was added as a component to the national maternal death surveillance and response (MDSR) guidelines in 2016. The study participants however expressed that the perinatal aspect of the MPDSR was not given as much priority as the maternal component. The MPDSR meetings were scheduled based on the occurrence of a maternal death. In the event that there was none, no meetings were convened to discuss perinatal deaths. The study participants described how discussions on the maternal deaths occupied the bulk of the MPDSR meetings with just enough time at the tail end to discuss the perinatal mortality statistics. Contributions from the participants also revealed that there was a normative acceptance of perinatal deaths due to their high volume compared to maternal deaths. This lowered the perceived value placed on auditing individual perinatal deaths.

"For the one we do with the MPDSR, it's actually led by the secretary of the MPDSR team in the hospital. And this usually is erratic and the MPDSR meeting is only held when there is a maternal death" FGD 1 (R6)

"There is already a membership of the MPDSR, so we get invitations by SMS or WhatsApp. And as I said earlier, this meeting is very erratic because it only occurs when there's a maternal death, not neonatal death." FGD 1 (R6)

"Yes, I said that there's laxity in neonatal, perinatal audits, unlike the maternal audits. Why do I say so? When there's a maternal death, when there's a maternal death, within 24 hours, already there's an audit, unlike the perinatal death. So, there's that laxity." FGD 3 (R4)

"Probably the name, I think maternal mortality...umm... There's a lot of focus on maternal mortality more than the neonatal mortality, so for the neonates, we… we… we… have to be proactive. So that's how it has always been." FGD 1 (R9)

"The unfortunate bit being that most of the time, the Obs team takes the bulk of the time. So, you are just given to give a report. Yeah. So, we rarely do we do individualized cases." FGD 2 (R5)

"Ok, OK, when there's a maternal death, then there's an audit. You know, we need to have obstetricians around, we need to have paediatricians around, we need to have the nurses involved. But what I've realised, when there's a perinatal audit, what I've realised, it's only the paediatricians and the nurses mostly working in the newborn unit. But when there's a maternal audit, you see they'll need the paediatricians, they'll need the nurses even for the newborn unit. So, there's something, there's something." FGD 3 (R4)

"There's a structure, who's supposed to be the secretary, who is supposed to do ABCDE and it should, you know, this audit should occur within twenty-four hours of… of… of… the maternal death. However, the perinatal actually is disturbing. I think, globally, doctor, all of us will agree, even professor, that it is something we need to strengthen. The "P" aspect of audit, for example in the MPDSR. We need to come up with a structure, really. And I think, currently, I'm not so sure. But I here look at how often do these deaths occur? Maternal audits let's say they happen once. But it doesn't matter, even one maternal audit is a very... I mean death is of great concern. Perinatal audits, people say, from what I've heard from colleagues, in a day, for example for the high-volume hospitals, how many perinatal deaths do occur on a daily basis? So, you are not able, like, to constitute a team immediately, or after 24 hours and discuss. That's why they said... We need actually to be sampling

out, but actually, she's brought out it very well. We need to strengthen and come up. I don't know if the… the… team is looking at this, how we need to strengthen the perinatal audits in our facilities." FGD 3 (R3)

e. Meetings that are not regular or structured

Some dissonance was noted regarding the scheduling of meetings. Some participants expressed that the audit meetings were frequent and structured while many other participants expressed that audit meetings in their hospitals were not conducted on a regular schedule. The meetings were however dependent on factors such as the availability of the consultants and nurse leaders and the attitude of the NBU in-charges towards quality improvement activities

"In our place, the main determinant of these meetings, especially the one in the newborn unit, is the pediatrician, and that's myself. And it depends on my availability, and I usually am the one who has the onus to involve the others, the basic clinical care team that is in the unit" FGD 1 (R6)

"the team in NBU, that's the paediatrician, the nurse in charge, we are the ones who determine when we're ready to do the audit" FGD 1 (R5)

"For the one we do with the MPDSR, it's actually led by the secretary of the MPDSR team in the hospital. And this usually is erratic" FGD 1 (R6)

"For H2, we, we have mortality audits scheduled every month, but they don't occur at every month, depending on who is in charge of the unit at that point in time. However, we try as much as possible to get that every month something happens." FGD 2 (R3)

3. Knowledge to appropriately conduct clinical audits

The FGD participants brought out that there was a gap between what the health workers should be doing and what they have the knowledge to do. The emerging gaps included: Gaps in problem identification and problem solving skills, gaps in knowledge due to poor quality of pre-service training, conflicting guidelines and a poor reading culture.

a. Gaps in problem identification and problem solving skills

The study participants reported that despite formulating potential solutions to the identified gaps arising during the audit meetings, the same issues kept recurring with a focus on the things they do not have. The respondents suggested that some of the reasons the same problems kept recurring were; 1) lack of resources as the actions suggested required heavy investments that were beyond the scope of the newborn unit health care workers and sometimes beyond the scope of the hospital level management and 2) absence of certain medication and materials which were considered essential for newborn care. We noted that the health workers did not have the knowledge to get to the root cause of the problems evidenced by how simple problems were not seen as an issue with focus predominantly on what they did not have. This therefore resulted in the same discussions occurring during every meeting with no change.

Because we realized we we've been discussing the causes and the mortality for many years. But we are not seeing any change simply because in most cases you are not the cause, the cause is coming from another facility or due to many other shortages, like the delay of the ambulance, the shortage of the nurses, the whatever...And we realize as much as the neonatal and the maternity team we keep on sitting and discussing these issues, we're not making any impact. We're getting the same… same… results. FGD 4 (R6)

"at the newborn unit, of course there are things that we…we call those that are beyond us that at times are commonly contributing factors to neonatal deaths that takes a while, they require investment. And some of them it's heavy investments. And, because of constrained resources, we end up not implementing." FGD 4 (R5)

"Thank you, I think for… for… H4, we do our recommendations in two phases. One is there are those that we capture in our annual work plan, and depending on the resources and currently, the County has released funds to the hospital under what we call Implementation Facility Improvement Act at County level. So, beginning this financial year, I think the facility will have a bit of resources to implement most of the action points that are required. Previously, what we have been doing is a collaboration with the County and through the support of GHS, and we put up requests that are captured in the annual work plan. We have had EMOC trainings, several in the Counties that were purely focusing on obstetrics. But at present, we… we… have encouraged them to include the paediatric group, especially those in nursery, to have them training." FGD 4 (R5)

"Initially it has been difficult. We have been making calls to the coordinator of paediatric and child health and the RH coordinator because they are the ones that implement those action points. So, more often we find lobbying and advocacy to those officers who represent the disciplines. So, more of it is just lobbying and enquiring. Do we have resources for this? Are we able to move and implement this action point? And, I think it works... it works that way. At times, when we wait for information it doesn't come up... So, most of it we have to enquire." FGD 4 (R5)

"Sometimes, like we have, we have had issues with the preterm babies. In our facility, we don't have surfactant factor, we don't have caffeine citrate. So, you realize that it's like the audit, the whole year

when we come, it is still caffeine citrate, we don't have, it's still surfactant factor. So, at times, the reason may just recur and recur and recur and recur because of the system, because of the of… of… of… issues to do with the with the procurement." FGD 3 (R9)

"That is procurement and pharmacy. But pharmacy say they… they… they… also order, KEMSA don't bring the especially the 2, the 2 drugs. So, it's… it's… just a big challenge. They order, and KEMSA does not, does not supply when they bring other supplies. So, it's quite tricky. So, it has been over and over discussing the same thing in every audit." FGD 3 (R9)

"But we... we are encouraging collaboration at the county level because they have more resources than the facility level to ensure that we get the best outcomes, and we implement the actions we come up with." FGD 4 (R5)

"So, we started involving the RH representative and all the sub county representatives, the management of the hospital from the nursing officer in charge to the manager, the director. And I'm believing this will bring a change, because majority of what is causing these deaths is what we can't do in newborn, or we can't change." FGD 4 (R6)

b. Quality of pre-service training influencing clinical care

There was an opinion that with every new group of health care workers reporting to the hospitals, there was a decline in the newborn quality of care and an increase in mortality. The group participants expressed that having a new group of trainee clinicians and nurses placed an extra burden on the supervisors as the onus was on them to bring their knowledge up to an acceptable level.

"I like audits because... umm, always at the beginning of every rotation with the new interns…ummm... I think because of learning processes we tend to have at least higher mortalities, but with continuous doing of the audit reports, we get improvements and things get better all the time." FGD 4 (R4)

"What was done is that the reproductive health department in the County, in my County, they went all round the facilities. They were able to identify the gaps the nurses are having, especially the newly employed." FGD 4 (R7)

"I think sometimes in the department, we'll find people keep on changing like the clinical officers and medical officer interns will keep on coming and we get new ones every other time. So, you may find when they come, they have the same issues. If it's resuscitation, for example, if it's use of CPAP. So, for me, you'll find them recurring, but you see it as a way of knowing where the gaps are and, uh, continuing to teach and, you know, to improve every other time when they come." FGD 3 (R5)

c. Variation in performance due to conflicting guidelines

Participants suggested that a significant barrier to providing quality newborn care was the availability of multiple guidelines for the management of the same condition. There were regular updates on patient management guidelines from different groups with no feedback to the frontline health workers on which guidelines should be adapted for patient management. This led to lack of clarity on the management approach they should follow for different conditions and therefore resulting in variation in care for the same conditions.

"Now, the problem of the system working, not working. It's also bringing a problem when it comes to the protocol you have introduced. We have the protocol we are all using. We have a new protocol,

which is in the internet, and then we have the old protocol. So, there is usually a problem between the dosage and the management, because now the ones who have the new, especially the birth asphyxias. Yes. We have a new management of fluids. So, when you tell them of the protocol, we have, the one of... I think is... the recent one, 2016. So, you see them arguing on the management there. So, we need to have one universal protocol for all of us so that we can be sharing the same information now." FGD (R7)

4. Knowledge on meaning of clinical audits

Some contributions in the FGDS revealed that while some participants understood clinical audits as a reflective exercise on the quality of care that was provided to selected patients, some participants believed that simply reviewing the monthly morbidity and mortality statistics constituted a clinical audit. This was reflected in how the participants responded that they would mostly look at the newborn statistics that describe the disease and death patterns and not go further into reviewing selected cases to identify avoidable gaps in care. We also noted the frequent use of the term 'morbidity and mortality meetings' which further reflects that the health workers use these meetings to describe the disease and death patterns in the NBU over a given period.

"most of the time we'll look at the… the… the… general statistics, so, for example, what are the morbidity patterns, what is, and then after that, we look at specific… specific… cases that we sample from… from… the different files" FGD 1 (R8)

"Yuh, In H4 usually we do combined morbidity, mortality audits together with the Obsgyn and the newborn unit… yuh... Every first Friday of the month. Usually we just look at the statistics." FGD 2 (R5)

"So, all of them (obstetrics departments from referring facilities) present their MPDSR reports and then usually... OK, no, no individualized discussion is done. We (newborn unit team) just do an overall comment." FGD 2 (R5)

4.2.2 Outcome of the consensus meeting to design the implementation guide

With an understanding of the user requirements through the creation of user personas (Appendix 9), the team arrived at consensus on the standard operating procedure for conducting the SSNB clinical audit in Kenyan public hospitals using the nominal group technique. Table 15 below describes the seven components of the audit implementation guide and the proposed procedures by which they would be carried out to ensure the completion of each audit cycle.

Table 15: Components of the audit implementation guide

Component of the newborn audit implementation guide	**Standard Operating Procedure**
Size and composition of the audit committee.	Include all who can influence change. Nursing officer-in-charge of NBU and NO in charge of labour ward. Senior clinician in NBU (neonatologist/ paediatrician) and Obstetrician/ medical officer from labour ward. Hospital administrator – (medical superintendent/hospital administrator/matron in charge of facility). Representatives from service departments (Nutrition, pharmacy, laboratory and health records).
Roles of the audit committee	Conformity with WHO audit guidelines Identifying cases for discussion during the audit meeting. Ensuring that records are kept safely and confidentially. Providing feedback on audit recommendations to the clinical team and administration. Following up on action plans and ensuring they are implemented.
Frequency of audit meetings	Audit meetings to be held two-weekly on a set day and time. Audit meetings should take 1 hour to 1 hour 30 minutes.
How many cases should be audited per session.	Based on the time allocated to the audit meetings, only one or two cases should be audited per meeting.

Criteria for selection of cases for auditing	Prevalence (a most common cause of death, increased mortality due to a particular diagnosis). Indications that the death is preventable (glaring gaps in the management of a case, preventable diseases or conditions). For learning purposes (cases that were difficult to deal with, unexpected deaths, rare cases).
Environment during audit meetings	Predictable, all-inclusive and blame-free Regular and structured meetings. To be held in a spacious room large enough to accommodate all participants. Meetings should be all-inclusive. Chair of the audit committee should chair the meetings. Meetings should be attended by audit participants who can influence change. Equality with all participants allowed to express themselves freely. Blame-free and non-judgemental environment. Environment that maintains confidentiality. Should have a strong educational aspect.
To ensure the audit cycle is completed.	To ensure action plans are implemented. Key decision-makers in relevant departments should be made aware of the action plans. Direct task allocation and clear role clarification. Specific timeframe for implementing what was discussed. Taking clear minutes during each meeting and beginning each meeting by reviewing the minutes from the previous meeting. Audit team to give regular feedback to hospital administration and hospital management teams on arising recommendations and their implementation status. Audit team to follow up on implementation progress with the people tasked to implement them. A maximum of three action plans for implementation arising from each audit meeting.
Abbreviations: NBU; Newborn Unit, NO; Nursing Officer	

4.2.3 The outcome of usability testing of the audit tool and implementation guide

The seven components of the implementation guide were tested in the county hospital to determine their feasibility for the Kenyan context. Some of the components were modified as they were difficult to implement.

The four roles of the committee were retained. There was, however, an amendment to the mandatory members of the audit committee to the six listed below with other members to attend as required:

a. Nursing officer in charge of the newborn unit.
b. Nursing officer in charge of labour ward.
c. Senior most clinician in newborn unit – Neonatologist/paediatrician/medical officer in charge.
d. Obstetrician/ medical officer from labour ward.
e. Nutritionist
f. Hospital administration – medical superintendent/hospital administrator/matron in charge of the facility.

The teams were successful in holding two-weekly audit meetings majority of the time. A recommendation was made that only one case should be audited per meeting as each case took between one and two hours on average.

To enforce implementation of the action plans, the chair of the audit committee used direct task allocation and giving specific timeframes for implementation. It was agreed that the chair was responsible for follow up on the implementation of the action plans either directly or through delegation. The modified implementation guide after the testing period is attached in Appendix 12b.

There were few adjustments to the audit tool during the testing phase and these were mostly based on recommendations from the KNH team. The adjustments focused on the content, ensuring that the audit tool was detailed enough for use in the teaching and referral level hospitals. O incorporate the feedback, I restructured the sections on newborn resuscitation, adding important parameters to the first section on newborn details and widening the scope of options for respiratory support. The final newborn audit tool and implementation guide are attached in Appendices 11b and 12b.

In this chapter, I have described the outcome of the co-design of the audit tool and implementation guide. In chapter 4, I will present the results from the controlled before and after study that used a

competing risk analysis to assess the effect of facilitation on the feeding practices of the low birth weight newborns.

Quantitative results

The quantitative methods used in this PhD thesis are presented in section 3.6 In this section, I will describe the effect of the intervention on the primary outcome; time to regain birth weight of low birth weight (LBW) (1500 -2499g) and very low birth weight (VLBW) (1000 – 1499g) newborns through improving feeding practices and the secondary outcome; overall mortality of the same population.

4.3 Characteristics of the study population that were included in the study

There were 11092 newborns admitted within the first 24 hours of life in the four study hospitals (H1, H3 (experiment arm) and H2 and H4 (control arm)) between January 2021 and June 2022. Of the 11092 newborns; 3399 were in the pre-intervention period with 1666 (49%) in the experiment arm (H1 – 920 (27.1%) and H3 – 746 (21.9%)) and 1733 (51%) in the control arm (H2 (942 (27.7%)) and H4 (791 – 23.3%)), 3322 were in the intervention period with 1819 (54.8%) in the experiment arm (H1 – 1053 (31.7%) and H3 – 766 (23.1%)) and 1503 (45.2%) in the control arm (H2 – 774 (23.3%) and H4 – 729 (21.9%)) and 4371 were in the post-intervention period with 2221 (50.8%) in the experiment arm (H1 – 1315 (30.1%) and H3 – 906 (20.7%)) and 2150 (49.2%) in the control arm (H2 – 1116 (25.5%) and H4 – 1034 (23.7%)).

Included in the study were only the LBW and VLBW newborns who accounted for 3247/11092 (29%) of admitted newborns during the study period. A total of 291/3247 (9%) of the study population were excluded from all data analyses as they had no documented feed prescription. Out of the 291 excluded newborns, 167/3247 (5.1%) (25 (15%) LBW and 142 (85%) VLBW) did not have any documentation on the feed management as they died before receiving any feed and 124 had missing information on prescribed feeds. Therefore, we included 2956 of the 3247 newborns; 2453 LBW and 503 VLBW newborns with information on the prescribed feeds. The study hospitals in the experiment arm of the study accounted for 1283 newborns (43.4%) and the hospitals in the control arm of the study accounted

for 1673 newborns (56.6%) throughout the study period. A summary of the distribution of the LBW and VLBW newborns included in the study across the three study periods and the experiment and control arms is presented in Figure 17 below.

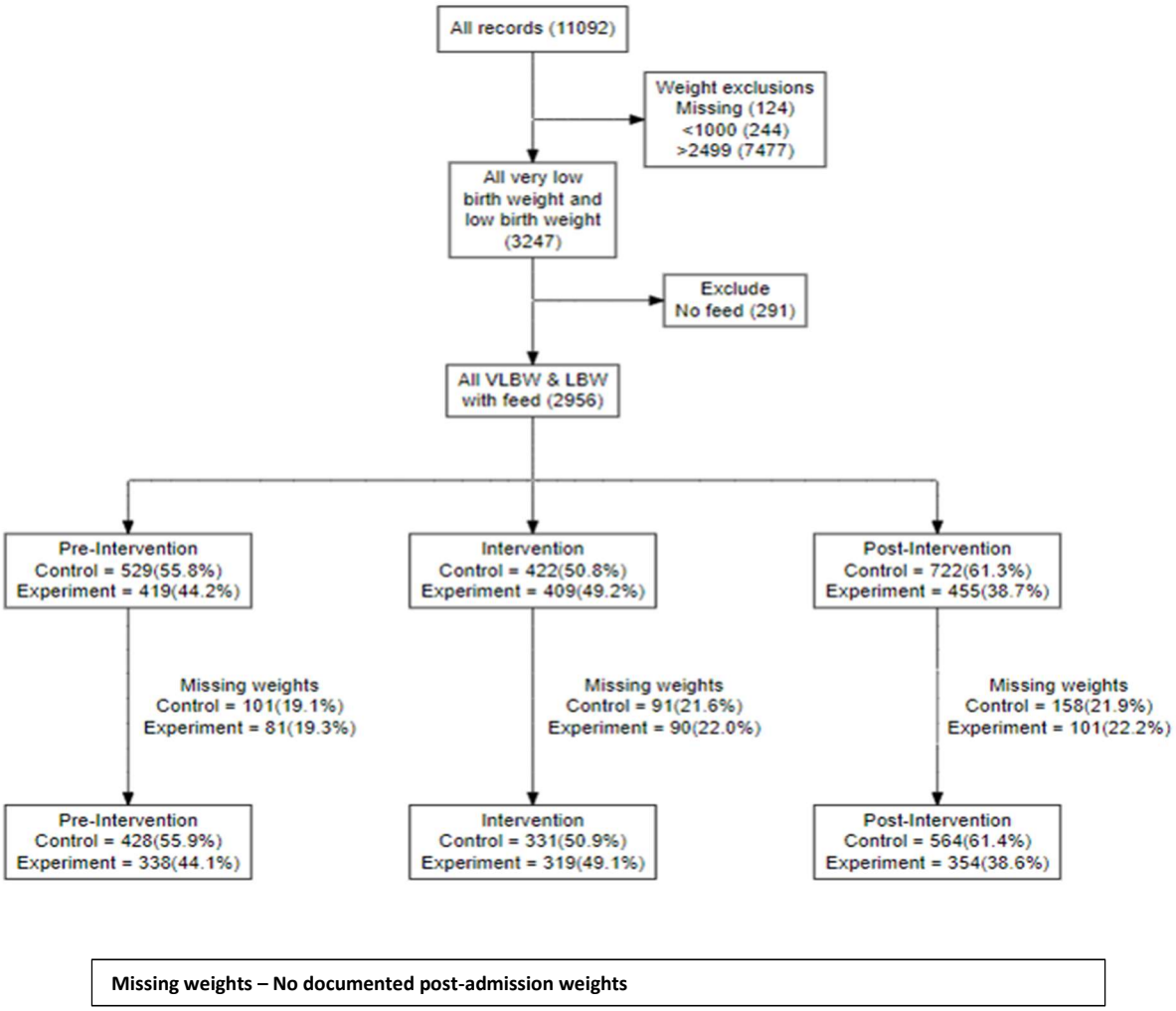


Figure 16: Flow diagram of inclusion criteria and selection of newborns into the study periods and study arms.

4.4 Demographic and clinical characteristics of study population

Table 16: Demographic and clinical characteristics of the newborns at admission based on the study period and study arm.

Indicator	Levels	Pre-intervention		Intervention		Post-intervention	
		Experiment (419)	Control (529)	Experiment (409)	Control (422)	Experiment (455)	Control (722)
Gender	Male n (%)	214 (51%)	279 (53%)	190 (46%)	208 (50%)	238 (52%)	345 (48%)
Weight category	1000 – 1499 g	62 (15%)	92 (17%)	64 (16%)	71 (17%)	64 (14%)	150 (21%)
	1500 - 1999 g	174 (42%)	205 (39%)	170 (42%)	182 (43%)	194 (43%)	296 (41%)
	2000 - 2499 g	183 (44%)	232 (44%)	175 (43%)	169 (40%)	197 (43%)	276 (38%)
APGAR 5 min	Median (IQR)	8.0 (7.0-9.0)	8.0 (7.0-9.0)	8.0 (7.0-9.0)	8.0 (7.0-9.0)	8.0 (7.0-9.0)	8.0 (7.0-9.0)
Convulsions	Yes n (%)	5 (1%)	7 (1%)	4 (1%)	0 (0%)	2 (0%)	2 (0%)
Difficulty breathing	Yes n (%)	152(38%)	223(43%)	146(37%)	168(42%)	108(24%)	278(41%)

Abbreviations: APGAR, Appearance Pulse Grimace Activity Respiration; IQR, Interquartile range

The male: female ratio was comparable in the pre-intervention, intervention and post-intervention periods. During the pre-intervention period, the LBW newborns accounted for the majority of the population in the experiment arm, 357/419 (85%) and the control arm, 437/529 (83%). The proportion of LBW newborns was five to six times that of VLBW newborns across the study periods in both arms. The LBW newborns were further categorised based on birth weight (1500 – 1999 g) and (2000 – 2499 g). During the pre-intervention period, the 2000-2499g birth weight category accounted for the highest proportion at 44% in both the experiment and control arms. The proportion remained comparable during the intervention and post-intervention periods in the experiment arm but declined in the control arm to 276/722 (38%). The proportion of VLBW newborns in the experiment and control arms was comparable between the experimental and control arms during the pre-intervention and intervention periods. There was, however, an increase in the proportion of VLBW newborns in the control arm during the post-intervention period, from 92/529 (17%) in the pre-intervention period to 150/722 (21%) in the post-intervention period. Table 16.

The Comprehensive Newborn Care Protocols recommend that unstable low birth weight newborns (presence of convulsions, unconscious, severe respiratory distress evidenced by severe chest wall indrawing or absent bowel sounds) should not be given enteral feeds other than the trophic feeds within the first 24 hours of life.(122) The characteristics of the study population for the three study

periods based on the symptoms and signs that influence the feeding of the newborn were similar in both the experiment and control arm except for difficulty in breathing. Difficulty in breathing was lower in the experiment arm compared to the control arm and declined from 38% during the pre-intervention period to 24% during the post-intervention period as presented. The baseline median APGAR score at five minutes was eight (IQR 7-9), which did not change during the intervention and post-intervention periods. The newborns presenting with convulsions were negligible (0-1%) in both study arms and across the study periods. There was a higher proportion of newborns with difficulty breathing in the control arm at baseline, 223/529 (43%) compared to those in the experiment arm, 152/419 (38%). This remained constant during the intervention period with a decrease in the proportion of newborns admitted with difficulty breathing in the experiment arm during the post-intervention period, 108/455 (24%).

4.4.1 Description of length of stay and mortality across the study periods

The median length of stay remained higher in the experiment arm in all weight categories across the study periods. The VLBW newborns had a longer length of stay with the 2000- 2499g weight category having a shorter length of stay as demonstrated in Table 17 below.

Table 17: The length of stay based on weight categories in the three study periods and two study arms

		Pre-intervention						Intervention						Post-intervention					
		Experiment (N= 419)			Control (N= 529)			Experiment (N = 409)			Control (N = 422)			Experiment (N = 455)			Control (N = 722)		
	Levels	VLBW N= 62	LBW1 N = 174	LBW2 N = 183	VLBW N = 92	LBW1 N = 205	LBW2 N = 232	VLBW N = 64	LBW1 N = 170	LBW2 N = 175	VLBW N = 71	LBW1 N = 182	LBW2 N = 169	VLBW N = 64	LBW1 N = 194	LBW2 N = 197	VLBW N = 150	LBW1 N = 296	LBW2 N = 276
Length of stay	**Median (IQR)**	35.0 (20.0-40.8)	14.0 (6.0-22.0)	6.0 (3.0-8.0)	27.0 (12.8-37.2)	11.0 (5.0-20.0)	4.0 (2.0-7.0)	32.0 (25.0-44.2)	14.0 (6.0-20.0)	5.0 (3.0-8.0)	26.0 (12.0-34.0)	13.0 (6.0-19.0)	4.0 (2.0-8.0)	34.0 (25.0-42.0)	15.0 (7.0-21.8)	5.0 (4.0-7.0)	27.0 (18.2-37.8)	10.0 (4.0-18.0)	4.0 (2.0-8.0)
Outcome	**Dead n (%)**	9 (15%)	21 (12%)	9 (5%)	18 (20%)	26 (13%)	11 (5%)	10 (16%)	19 (11%)	14 (8%)	18 (25%)	23 (13%)	12 (7%)	10 (16%)	18 (9%)	10 (5%)	26 (17%)	31 (10%)	20 (7%)

Abbreviations: IQR, Interquartile range; LBW, low birth weight - LBW1 (1500 – 1999 g); LBW2 (2000 – 2499 g); VLBW, very low birth weight (1000 – 1499 g).

The proportion of deaths among the study population remained higher in the control arm across all weight categories and in the three study periods. There was higher mortality among the VLBW category in both study arms and across the study periods as demonstrated in Table 17.

4.4.2 Baseline characteristics for feeding practices

I will describe the distribution of documented types of feeds within the first 48 hours of life. The newborns in the study hospitals were either only breastfed, or fed on expressed breast milk (EBM), formula, mixed feeds (EBM and formula). Of the 2956 newborns included in the study, 363/2956 (12.2%) had missing information on the type of feed prescribed as shown in Table 18. The total number of newborns that were included for this analysis was, therefore, 2593. The majority of the newborns were on EBM in both experiment and control hospitals and across the study periods. Almost three-quarters (72%) of the newborns in the control arm during the pre-intervention period were fed on EBM compared to 224/367 (61%) in the experiment arm. The proportions changed only slightly in each study arm in the intervention and post-intervention periods. Approximately one-quarter of the admitted newborns in the experiment hospitals were breastfed from admission during the three time periods with the proportions decreasing from 94/367 (26%) during the pre-intervention period to 89/389 (23%) during the post-intervention period. There were more newborns who were breastfed in the experiment arm compared to the control arm.

Table 18: Description of feeding practices in the study population comparing the three time periods and the two study arms

Indicator	Levels	Pre-intervention N= 869		Intervention N = 711		Post-intervention N = 1013	
		Experiment N= 367	Control N = 502	Experiment N = 338	Control N = 373	Experiment N = 389	Control N = 624
Type of feed	**Breastfed**	94/367 (26%)	56/502 (11%)	85/338 (25%)	60/373 (16%)	89/389 (23%)	94/624 (15%)
	EBM	224/367 (61%)	363/502 (72%)	213/338 (63%)	275/373 (74%)	235/389 (60%)	463/624 (74%)
	Formula	19/367 (5%)	36/502 (7%)	11/338 (3%)	22/373 (6%)	22/389 (6%)	31/624 (5%)
	Mixed feeds	9/367 (2%)	33/502 (7%)	5/338 (1%)	11/373 (3%)	10/389 (3%)	20/624 (3%)
Time to start feeds	**Median (IQR)**	1.0 (0.0-1.0)	0.0 (0.0-1.0)	1.0 (0.0-1.0)	0.0 (0.0-1.0)	1.0 (0.0-1.0)	1.0 (0.0-1.0)

Abbreviations: EBM, Expressed Breast Milk; Mixed feeds, Expressed Breast Milk and formula; IQR, Interquartile range.

4.5 Implementation of the intervention

I will report the frequency and distribution of audit meetings in the hospitals in the experiment and control arms of the study (Figure 18). My role as the facilitator as described in section 3.4 was not to prepare the cases but to chair or co-chair the meetings, prompt discussion on modifiable factors and action points, follow up on the implementation of recommendations and review these in the next meeting.

4.5.1 Frequency and distribution audit meetings in the hospitals in the experiment arm during the period of facilitation

H1 had a total of five meetings throughout the study period. There was a one-month gap between the second training and the first audit meeting. There was another two-month gap between the first audit

meeting and the second audit meeting. The subsequent meetings took place two-weekly as recommended in the audit implementation guide. I participated as a facilitator in all five meetings.

H3 had a total of six meetings throughout the study period. The second training for H3 took place three weeks after the other study hospitals. There was a two-month gap between the second training and the first audit meeting. The audit meetings were held on average monthly throughout the study period. I participated as a facilitator in all six meetings.

4.5.2 Frequency and distribution of audit meetings in the hospitals in the control arm

H2 had six meetings during the study period. The first meeting was held approximately one month after the second training with the subsequent meetings held on average monthly.

H4 had two audit meetings during the study period. The first meeting was held five months after the second training. The second meeting took place one week after the first meeting.

Training and audit meeting timeframes in the four study hospitals

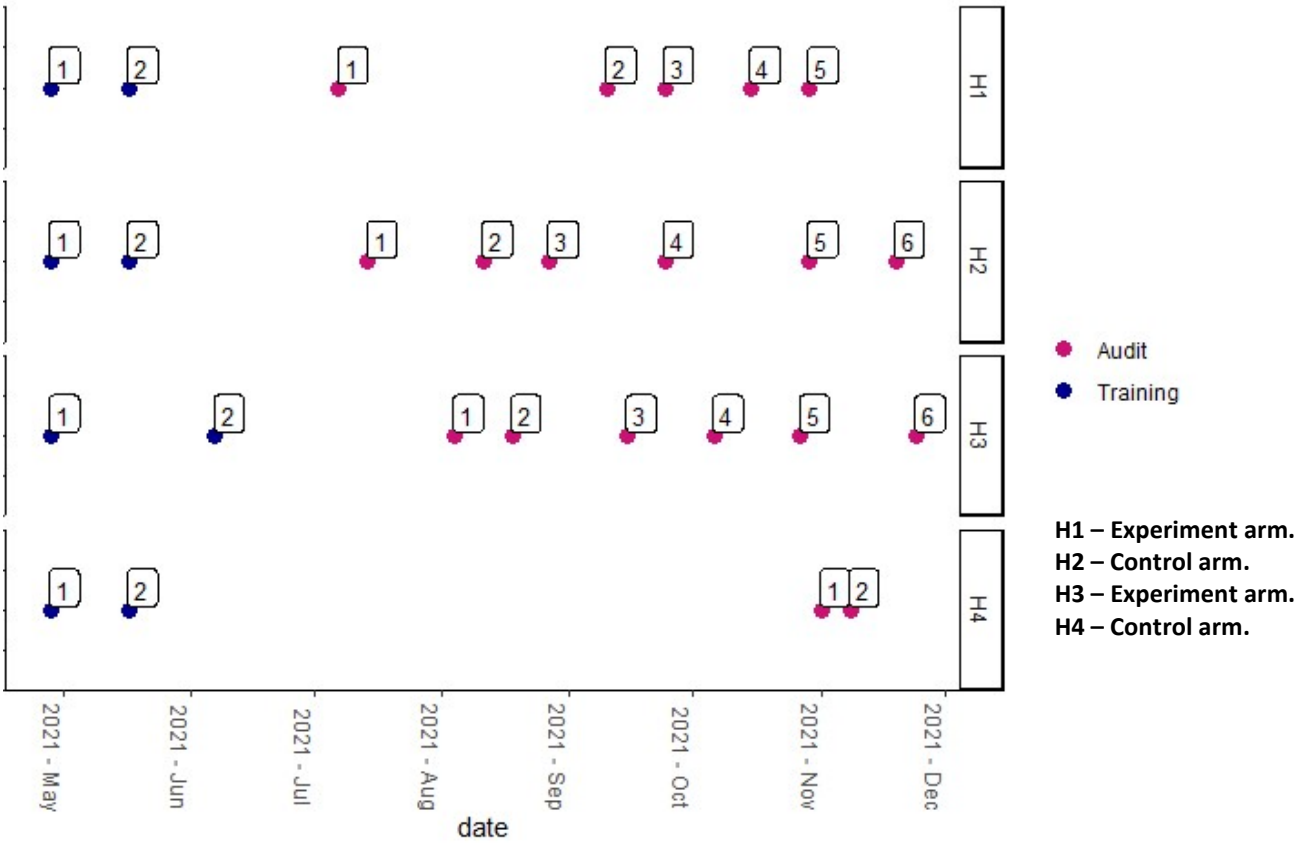


Figure 17: Frequency and distribution of audit meetings in the experiment and control hospitals

4.6 Primary outcome – time to regain birth weight and secondary outcome – time to death

The primary outcome was the effect of facilitation on reducing the time to regain birth weight through improving newborn feeding practices among the LBW and VLBW newborns in the study hospitals. Out of the 2956 newborns eligible for the study, 622/2956 (21%) were excluded from the final analysis due to missing data on post-admission weights. The flowchart (Figure 18) above demonstrates the distribution of the 2334 newborns included in the competing risk analysis based on the study period and study arm. During the pre-intervention period, of the 419 LBW and VLBW newborns in the risk set (population that

had not yet experienced either of the events of interest), 338 (80.7%) had post-admission weights in the experiment arm and 428/529 (80.9%) in the control arm. During the intervention period, 319/409 (78%) in the experiment arm and 331/422 (78.4%) in the control arm had post-admission weights. During the post-intervention period, 354/455 (77.8%) in the experiment arm and 564/722 (78.1%%) in the control arm had post-admission weights.

Figure 19 compares the probability of regaining birth weight before death which was the competing risk between the experiment and control arms. The probabilities are then compared between the pre-intervention period and the intervention and post-intervention periods.

4.6.1 Primary outcome: Time to regain birth weight in the experiment arm compared to the control arm

The descriptive results for the competing risk survival analysis were presented as cumulative incidence function (CIF) curves. The CIF curves represent the incidence of occurrence of the event (regaining birth weight) over time taking the competing risk (death) into account. The results of the regression model which was a Cox proportional cause-specific hazards regression model for time to death are also presented below.

4.6.1.1 Cumulative incidence function curves for the time to regain birth weight

The x-axis in the CIF curves represents the time in days and the y-axis represents the cumulative incidences for occurrence of the event type. The probability of regaining birth weight before death rapidly rises and remains higher than the probability of death before regaining birth weight during all periods.

Pre-intervention period: During the pre-intervention period, the risk set was 338 newborns in the experiment arm and 428 newborns in the control arm. During this period, the probability of regaining birth weight conditional on not having died was slightly earlier in the control arm. The probability of regaining birth weight conditional on not having died by day 10 was 56% (95% CI 50% – 62%) in the

control arm and 55% (95% CI 49% – 61%) in the experiment arm. This changed with the probability of regaining birth weight conditional on not having died at day 20 of life being 82% (95% CI 77% – 86%) in the control arm and 87% (95% CI 82% – 90%) in the experiment arm. The last event occurred on day 47 in the experiment arm and day 35 in the control arm as described in Figure 19a below.

Intervention period : During the intervention period, the probability of regaining birth weight conditional on not having died was slightly higher in the experiment arm compared to the control arm. The probability of the newborns regaining their birth weight before death by day 10 was 58.4% (95% CI 52% – 64%) in the experiment arm compared to 54% (95% CI 48% – 60%) in the control arm. By day 30, the probability of regaining birth weight conditional on not having died was at 89% (95% CI 85% – 92%) in the experiment arm compared to 83% (95% CI 78% – 87%) in the control arm as described in Figure 19b below.

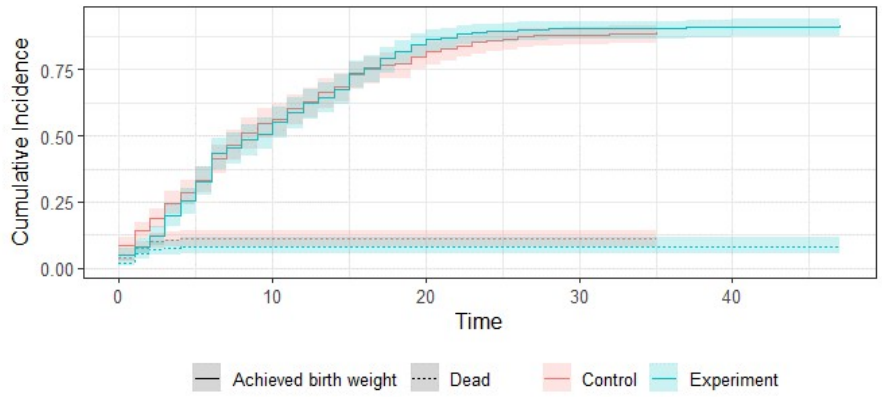


Figure 19a: Probability of regaining birth weight or death during pre-intervention period

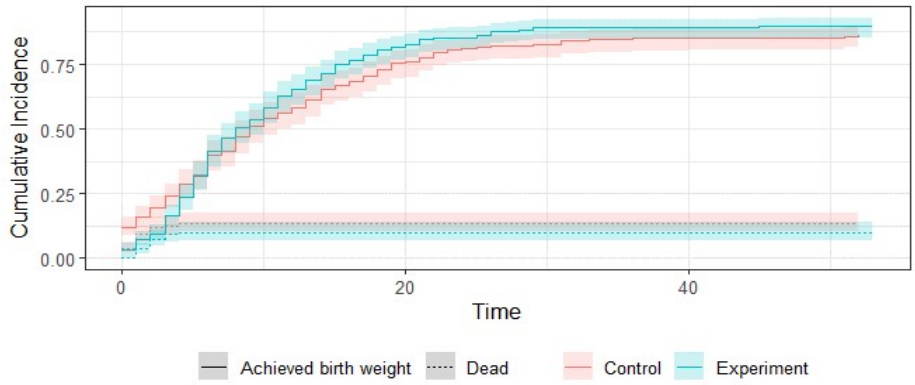


Figure 19b: Probability of regaining birth weight or death during intervention period

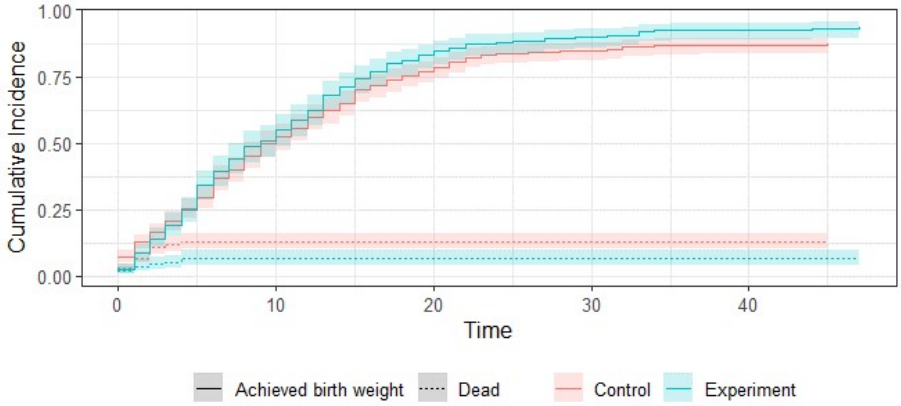


Figure 19c: Probability of regaining birth weight or death during post-intervention

Figure 18: Cumulative incidence curves comparing the probability of the time to regain birth weight or time to death among LBW newborns in the experiment and control hospitals and the pre-intervention, intervention and post-intervention periods.

Post intervention period – The cumulative incidence of regaining birth weight before death was higher in the experiment arm than in the control arm during the post-intervention period. The probability of regaining birth weight conditional on not having died by day 10 of life was 55% (95% CI 49% – 61%) in the experiment arm and 52% (95% CI 47% – 57%) in the control arm. The probability rapidly rises in the experiment arm until day 20 of life where the probability of regaining birth weight was 85% (95% CI 80% – 88%) compared to a probability of 78% (95% CI 74% – 82%) in the control arm on day 20 of life. There were fewer events after day 20 of life, however, the cumulative incidence curve peaked higher for the experiment arm with the last event occurring on day 47 of life in the experiment arm and day 45 of life for the control arm. This is described in Figure 19c above.

4.6.1.2 Cox proportional hazard regression model of the cause-specific hazards for regaining birth weight

The multivariable regression model assessed the effect of the covariates (study period, weight category and the severity of illness based on the score referred to as the Score for Essential Signs and Symptoms (SENSS score which is a multivariable prediction model for severity of illness (male, difficulty feeding, convulsions, indrawing, central cyanosis, floppy, birth weight) on the cause-specific hazard of regaining birth weight and death.(186, 187) The robust standard error accounts for clustering. As presented in Table 19, the Cox proportional hazard regression model demonstrates no difference in the hazard of regaining birth weight in the experiment arm compared to the control arm (HR 0.95, p = 0.75) after adjusting for all the covariates. With each unit increase in severity of illness score on the SENSS scale there was a decrease in the likelihood of regaining birthweight earlier in the admission represented by the hazard ratio of 11% after adjusting for all covariates.

Table 19: Regression model for time to regain birth weight comparing with the control arm for the experiment arm and with the pre-intervention period for the intervention and post-intervention periods

Term	Hazard ratio	Standard error	Robust standard error	p value
Experiment arm	0.95	0.05	0.16	0.75
Intervention period	0.92	0.07	0.09	0.33
Post-intervention period	0.90	0.06	0.08	0.23
SENSS score	0.89	0.02	0.05	0.02

Abbreviations: SENSS score – Score for Essential Signs and Symptoms that includes - Male, difficulty feeding, convulsions, indrawing, central cyanosis, floppy, birth weight)

4.6.2 Secondary outcome: Time to death

The incidence of occurrence of death before regaining birth weight is presented as cumulative incidence curves. The results of the regression model which was a Cox proportional cause-specific hazards regression model for time to death are also presented below.

4.6.2.1 Cumulative incidence function curves for the time to death

The probability of death before regaining birth weight is compared between the two study arms and the three time periods.

Pre-intervention period: There was a steep rise in the probability of death before regaining birth weight within the first 72 hours at baseline in both the experiment and control hospitals. During this period, the probability of in-hospital death conditional on not having regained birth weight was higher in the control arm peaking at 11% (95% CI 8% – 14%) in the control arm and 8.3% (95% CI 6% – 12%) in the experiment arm within the first 72 hours of life as demonstrated in Figure 19a above.

Intervention period: The probability of death before regaining birth weight was highest in the control arm during the intervention period, peaking at 14% (95% CI 10% – 18%) within the first 72 hours of life.

The probability of death before regaining birth weight increased in the experiment arm, peaking at 10% (95% CI 7% – 14%) within the first 72 hours of life as demonstrated in Figure 19b above.

Post-intervention period: The cumulative incidence of in-hospital death conditional on not having regained birth weight was significantly lower in the experiment arm compared to the control arm. Similar to the other periods, the cumulative incidence of death before regaining birth weight remained highest within the first five days of life in both the experiment and control arms. The probability of death peaked at 13% (95% CI 10% – 16%) in the control arm compared to 6.6% (95% CI 4% – 9%) in the experiment arm as described in Figure 19c above.

4.6.2.2 Cox proportional hazard regression model of the cause-specific hazards for death

As presented in Table 20 below, there was a 36% decrease in the hazard of death among the newborns in the experiment arm compared to the control arm (HR 0.64, p = 0.019) after adjusting for all the covariates. The intervention period had a 34% higher hazard of death compared to the pre-intervention period (HR 1.34, p = 0.011). With each unit increase in severity of illness score on the SENSS scale there was a 76% higher hazard of death represented by the hazard ratio (HR 1.76, p = <0.01) after adjusting for all covariates.

Table 20: Regression model for the competing risk time to death comparing with the control arm for the experiment arm and with the pre-intervention period for the intervention and post-intervention periods

Term	HR	Std. error	Robust.se	P value
Experiment arm	0.64	0.14	0.19	0.019
Intervention period	1.34	0.17	0.12	0.011
Post-intervention period	1.09	0.16	0.09	0.31
SENSS score	1.76	0.05	0.03	< 0.01

Abbreviations: SENSS score – Score for Essential Signs and Symptoms that includes - Male, difficulty feeding, convulsions, indrawing, central cyanosis, floppy, birth weight)

In summary, the results of the primary outcome demonstrated no significant difference in the time to regain birth weight between the experiment and control hospitals. There was, however, a significant decrease in time to death in the experiment compared to the control arm with an increase in the hazard for death during the intervention period.

I will now present the results on the facilitators and barriers to the facilitated implementation of the clinical audit tool.

Facilitators and barriers to the implementation of the clinical audit tool and implementation guide and the facilitation strategies used to build on the strengths and overcome the barriers

I will begin by illustrating the themes arising as facilitators to the implementation process. I will then describe the arising barriers and highlight the facilitation strategies used based on the facilitators and barriers. I did not have verbatim quotes; rather I have (and present as illustrative data) excerpts from the field diary representing a recollection of observations and conversations.(203)

4.7 Facilitators to the implementation of the clinical audit tool and implementation guide

The following themes emerged as facilitators to the implementation of the clinical audit tool and its implementation guide using facilitation as a strategy.

1. **Progressive thinking leadership that facilitates the adoption of quality improvement innovations**

The availability of leaders who were willing to accept and advocate for the integration of the audit tool and its implementation guide into their routine practice played a significant role in influencing the success of the newborn clinical audits. I observed that the paediatricians and nurses who were trained on the implementation guide were able to change their mindset about how clinical audits should be conducted, and advocate for this in their hospitals. These NBU leaders ensured that the audit meetings happened as scheduled. They understood the importance of having the hospital leadership in the audit meetings and strived to invite them to all meetings without giving up even when there was no response. They recognised the resources they had at their disposal such as the nursing students and how they could better utilise them to meet their objectives. Further, they encouraged their team members to

participate in the audit meetings and appreciated the changes that could emanate from proper problem identification and implementation of recommendations.

"I absolutely understand why we need to have the meetings every two weeks, or even more frequently if possible, just thinking how many deaths we have, and it makes sense…. I just wish we could implement all the recommendations that we come up with, it's annoying talking about the same thing. What are other hospitals doing that we're not doing? I know we can do better. There's the constant excuse of staff shortage, but, I mean, there are students who can take up some of these tasks so if we really wanted to change, we'd do it." Paediatrician 1, H3

"...I think it's the matron who attended... yes, it's her, but now she always says that she's busy, I even feel like I'm bothering her, at what point do you give up? ... laughs." Paediatrician 1, H1.

2. Ownership of the audit tool and implementation guide

One of the main themes that emerged as a facilitator to the implementation of the audit tool and implementation guide is that the healthcare workers gradually took ownership as they appreciated that the newborn clinical audits were relevant to them even beyond the research period. I observed the ownership of the audit tool and its implementation guide based on the positive changes that progressively took place throughout the study period. The changes included: Change in attitude towards the audit meetings, audit meetings beginning at the scheduled time, newborn unit (NBU) teams taking over the selection of cases and chairing of the meetings, and nurses joining in the preparation and presentation of the audit meetings.

"I really enjoy the audit meetings, and I truly believe that they can make a difference.... daktari, I'll convince the nurses to attend." Nurse 1, H1

"Remember how the 1st meeting was... laughs... I'm so proud of how people are now committed to beginning on time and everything is prepared… It has now become part of us... laughs..."

Paediatrician 1, H1

3. **Availability of infrastructure in the hospitals that is suitable to support hybrid meetings**

With the emergence of the COVID-19 pandemic, the scientific community faced restrictions on in-person interpersonal interactions which are important for the sharing of scientific knowledge. This led to the adoption of digital technology as a new norm to encourage the continuity of these interactions. In keeping with this, the clinical audit tool was designed as an electronic tool to facilitate virtual meetings. I observed that the study hospitals had the advantage of having the infrastructure in place for hybrid meetings such as smart TVs and internet connectivity. This played a significant role in ensuring that the audit meetings took place.

4. **Acknowledging the interrelatedness of departments and teamwork in a hospital setting**

I observed that the healthcare workers recognised the importance of having interdepartmental audit meetings that included the different departments that were involved in newborn care. The paediatric ward nurse and the biomedical engineer in H1 were very grateful that they were invited to the audit meeting and requested to be invited to subsequent meetings. The laboratory technician in H3 also expressed interest in the laboratory department being included in subsequent NBU meetings.

"Thank you for inviting us and we would appreciate it if you included us in other meetings. The only way we could change some of these problems is if we worked together." Biomedical engineer, H1.

"Thanks for inviting me to this meeting. I'm kindly requesting that you include us in other meetings that you have. This will help us know how to improve what we do. Laboratory technician, H3.

" We appreciate you inviting us to this meeting, the paediatric ward should always be involved in these meetings, I mean... we also take care of a huge number of newborns and we need to learn."

Nurse 2, H1.

There was also a recognition of the positive effect of teamwork on improving feed and fluid documentation and management. The NBU team recognised that both the nurses and the clinicians had a role to play in improving feed and fluid management. This is demonstrated in the excerpts below:

"If the doctors prescribe in the chart it would enforce monitoring done on the charts." Paediatrician 2, H1

"I think if the doctors prescribe in the chart then the monitoring will also be done in the chart... let's agree to do that." Paediatrician 2, H3

"... sometimes we understand the situation, one M.O. (medical officer) being called left, right and centre, it's tough for them. So, what we do as nurses sometimes is, we just adjust the feeds ourselves, we've attended the NEST training so we just increase based on the guidelines. Nurse 1, H3

"I can (ensure that feeds and fluids are prescribed in the monitoring charts) ... we can check the files during ward rounds to ensure that prescription and monitoring of feeds and fluids is being done in the monitoring charts, doc (Medical officer) tell your colleagues and sister (NBU nurse) please enforce it with the nurses... " Paediatrician 2, H3

4.8 Barriers to the implementation of the clinical audit tool and implementation guide

The following themes emerged as barriers to the successful implementation of the audit tool and implementation guide using facilitation as a strategy.

1. **Limited leadership support**

One of the major themes emerging from this study was limited leadership support. Visible leadership supporting patient safety improvement efforts is key to enforcing its success and sustainability. We observed a gap in leadership support in both H1 and H3. This included both the leadership from the mid-level managers (departmental heads) and the hospital administration. There was poor to no attendance of the audit meetings by the leadership despite several attempts to engage them leaving the healthcare

workers frustrated. This was also expressed by the healthcare workers as demonstrated:

"I feel like I've hit a dead end with getting them (hospital leadership) to attend. I've tried everything but it's all in vain. I don't think this is that important to them." Paediatrician 1, H1.

"...I think it's the matron who attended (training)... yes, it's her, but now she always says that she's busy, I even feel like I'm bothering her, at what point do you give up? ... laughs." Paediatrician 1, H1.

2. Factors influencing the resistance of health workers to change how they conduct clinical audits

Resistance of health workers to change has been described as a phenomenon that either delays or slows down the beginning of a change process or hinders its implementation.(205) This theme reflected the reasons the healthcare workers may have been unwilling to buy into the newborn clinical audits with three categories emerging from this which were: Unfavourable past experiences with audit and feedback that led to a pessimistic perception of the newborn clinical audit, reactive mindset among healthcare workers that encourages complacency and the perception of the relative advantage of the clinical audit tool and implementation guide over the existing maternal and perinatal clinical audit.

i. ***Unfavourable past experiences with audit and feedback led to a pessimistic perception of the newborn clinical audit.***

The mortality meetings have frequently been used as a fault-finding mission. Despite the training and emphasis on the audit meetings being a no-name, no-blame process, the past experiences of the health workers appeared to influence their attitude towards the audit process. There appeared to be apprehension in having a “friendly outsider” closely participate in this sensitive process due to fear of exposure of human errors. This was evidenced by the teams in both hospitals being laggards in engaging in the audit process.(206) This scepticism resulted in the initial delays in initiating the audit process for example:

The initial attempts by the facilitator to communicate with the paediatrician in H1 to commence the audit meetings were mostly disregarded. In addition, the team then went ahead and planned a meeting

without including the facilitator. On further inquiry, the paediatrician confessed that she was nervous about how the audit meeting would turn out based on her previous experiences. She was relieved that there was no fault finding during the audit meeting.

"I'm really sorry, I was so… so… nervous... I thought this meeting would just be about looking for issues and blaming each other. I'm so relieved by how it went, I'll definitely involve you going forward." Paediatrician 1, H1.

There were also remarks made, particularly by nurses and other cadres from both hospitals, that what they liked about how we conducted the audit meetings was that there was no victimization and that the audits were effective. This implied that their experience of the audit meetings was that they were used to victimize the healthcare workers, were poorly organised and did not lead to change.

"I like that no one is blamed for the deaths during the meetings and everyone is given a chance to speak. For once the focus is on the newborn not like the MPDSR." NBU nurse (deputy), H1.

"Doc, I really liked the meeting, kwanza (especially because) there was no victimization, how wonderful... and the way the doctors and nurses are working together…" Nurse 1, H1

"I'm really passionate about quality improvement, and since I attended the training you held, I knew these audit meetings would be different... in a good way... laughs and I'm ready to offer assistance from the pharmacy aspect." Pharmacist, H1.

"…this audit is so detailed and organised unlike what I've previously attended in other departments." Intern 1, H1

ii. Reactive mindset among healthcare workers that encouraged complacency

A reactive mindset is defined as "a resignation or tendency to believe that obstacles are inevitable." (207) Some responses from the healthcare workers implied that they had resigned to the idea that they did not have the capability to break the practice cycles that had been embedded into their culture

despite being aware that the practices were sub-standard. This mindset encouraged complacency by accepting that “that’s just the way things were done.”

This was portrayed in H1 where a paediatrician remarked that the laboratory did not always have the capability to conduct biochemistry tests which were crucial for appropriate diagnosis and management of the newborns. During interactive discussions on the ways in which the laboratory could be engaged to provide efficient services to ensure timely and appropriate diagnosis, she was hesitant and responded that; ***" ...these lab issues are too complicated. I don't think they'll lead anywhere." Paediatrician 2, H1***

The reactive mindset of the long-serving staff was portrayed during a conversation with a paediatrician in H3. We were brainstorming on why paediatricians were not attending the audit meetings and how to encourage them to attend. The paediatrician commented that the longer-serving paediatricians seemed to be frustrated by the system and had no hope of things changing and that there would be more successful in roping in the newer paediatricians.

"I think the guys who've been here longer are just tired, the system is frustrating, and people just do what they can and leave because things just don't seem to be changing. The only hope is to rope in Dr. Z…, maybe she'll have more enthusiasm." Paediatrician 3, H3

The health care workers also demonstrated how their reactive mindset was based on having severally attempted to make positive change with no success.

It's not for a lack of trying, we've really tried, and things are not changing. It's so exhausting asking and begging for things that never come." Paediatrician 4, H3

"... these heaters we're talking about, we started asking for them in March, we even wrote memos and still... nothing... sometimes you feel so helpless and frustrated wondering what else to do." Nurse 1, H3

The healthcare workers believed their environment did not allow them to improve the quality of care. This was demonstrated during the discussions on the monthly morbidity and mortality statistics that we

held once a month before beginning the audit meeting. During interactive discussions on the reports, we observed that the crude mortality rate (CMR) per month in H3 remained high. There was the belief that the opportunity to reduce neonatal mortality was hindered by the unavailability of high-cost interventions despite the clinical audits constantly revealing modifiable gaps that could be prevented using the available resources.

"... there's only so much we can do without NICU (neonatal intensive care unit) services. I don't expect the mortality rate to change significantly until we get there..." Paediatrician 4, H3

"It's impossible to reduce our mortality rate without NICU services... we should be realistic…" Paediatrician 4, H3

iii. Perception of the relative advantage of the clinical audit tool and implementation guide over the existing maternal and perinatal clinical audit

As the PO, I got the perception that the healthcare workers required convincing that the structured newborn clinical audit was different from the existing clinical audits. The maternal and perinatal death surveillance and response (MPDSR) was a requirement by the Ministry of Health as a quality improvement initiative for maternal and perinatal care.(62) The healthcare workers, however, did not consider it as beneficial for the newborn population based on their experiences as depicted below:

"...kweli (it's true), the newborn unit is not given much time during the MPDSR..." Midwife, H3

"no wonder the Paediatricians don't bother to attend the MPDSR meetings... "Those meetings just feel like a waste of time, no one really talks about the newborn." Nurse 1, H3

"... It's true... I understand where you're coming from... we don't pay much attention to the newborns in the MPDSR..." Obstetrician, H3

I observed that the challenge came in understanding the value of another meeting in addition to the MPDSR which they were already required to attend based on Ministry of Health (MoH) policy.(62) This lengthened the decision-making process to take up the innovation as it was viewed as a burden even before they had a chance to experience it. This was depicted by the postponement of the training in H3, multiple postponements of the initial meeting in both intervention hospitals, various complaints about the audit tool and the implementation guide before they had a chance to use it. These encounters are demonstrated below:

After the first training on the implementation guide, the team that attended the training which was composed of the paediatricians and NBU nurse managers in the four study sites arrived at consensus on a suitable date for the next training. H3 was unable to attend the second training as scheduled as they had not managed to form an audit committee as presented below:

"....Monday is such a busy day for us, I know we agreed to have the training on Monday, but it looks like it won't be possible. We're not even ready with an audit committee yet... gosh, I know it's so last minute...we're so disorganised, I'm so embarrassed... but please can we have the training on another day. Paediatrician 3, H3

On inquiry from the NBU nurse manager in H3 about commencing the meetings, she mentioned the poor acceptance of the audit tool by the paediatricians. This is described below:

"They (paediatricians) all know about the clinical audit process, but they keep complaining that the tool is too long and it's going to increase their workload." Nurse 1, H3

During a meeting with the NBU team in H3 to brief them on how the audit meetings will be conducted, the NBU nurse manager remarked that the newborn audit meeting was adding onto their already heavy workload.

"… daktari, you're giving us a lot of work...this (audit meeting) just sounds like adding onto our heavy workload... laughs... I know we already do audits, but we haven't had one in a long time since COVID and anyway we don't have the time." Nurse 1, H3

One of the paediatricians in H3 commented that the clinical audit as designed was tedious to plan and execute despite not having previously participated in preparing for the meetings or implementing the action plans. There was more interest in reviewing the morbidity and mortality statistics than actually auditing the care provided as it took less time. This is illustrated below:

" These 2 weekly meetings are just too much, having to look for people to attend every two weeks, having to implement recommendations from the meeting, no wonder they are not being implemented. People will get burn out from attending these meetings, we already have enough on our plates. I prefer just sitting as the NBU team and looking at the statistics like we used to do, that's quick and efficient instead of having to do all this work." Paediatrician 4, H3

3. Lack of a shared vision despite the high degree of connectivity of the teams

The very definition of a team is that individual goals must be aligned.(208) When there is diversity in goal orientation, it induces disagreement which, in turn, might have negative consequences on team processes and performance.(209) It emerged that there was diversity among the team members in what their vision and goals were, and this was demonstrated by a silo mentality and vertical leadership.

i. Silo mentality of the healthcare workers resulting in poor interdepartmental collaboration

The silo mentality is a consequence of the organizational structure in which the different departments in the hospital are divided functionally, and with insufficient communication channels between them.(210) The silo mentality was demonstrated by the manner in which the different departments work as autonomous units leading to the development of disjointed work processes and ultimately leading to poor service delivery.

In H1, it was apparent that the paediatric ward and the newborn unit worked as two separate entities despite the fact that newborns were admitted in both units. The nurse from the paediatric ward protested at how the newborns in the paediatric ward were treated differently from those in the NBU. She revealed how the paediatric ward had only two phototherapy machines to cater to all (on average 5-8) the newborns admitted to the ward with jaundice resulting in them having to request the NBU for assistance as they had more phototherapy machines.

The paediatric ward nurse from H1 emphasized the need for both the nurses in the NBU and those in the paediatric ward to get similar trainings as they were all caring for newborns as illustrated in this excerpt:

"We take care of newborns in the Paeds (paediatric) unit but do not get the same training, equipment and support as the NBU team." Nurse 2, H1.

The silos were not only between departments but also within the same department. This was observed in H3 where the paediatric ward was divided into different sections based on the diagnosis of the patient. One paediatrician was assigned to each room and they rotated every three months. Each paediatrician focused on their room and attended activities that were seen as relevant to their current station. Therefore, it was only the paediatricians who were in the newborn unit who were expected to attend the newborn clinical audits leading to division of the department into four different units.

The silo mentality also divided the departments into professional classes where the different cadres worked independently affecting their attitude and commitment to patient care. During an audit meeting discussion in H3, it was noted that there was poor documentation of the admission weight in the neonatal admission record (NAR) form due to disagreement on who should fill the section.

"The M.Os are the ones who are supposed to fill in the NAR, so it's their responsibility to fill in the admission weight, the nurse takes the weight and documents it in the cardex, so the M.Os should get the admission weight from there and fill in the NAR." Nurse 1, H3

The silo mentality is also demonstrated by the poor multidisciplinary attendance of audit meetings as shown in Table 22. I observed that often, the audit meetings were attended by only the newborn unit health workers. This gave the impression that there was poor collaboration between the different departments that were involved in newborn care, with poor recognition of the interlinkage between them. During a conversation with an obstetrician in H3, on bringing up the conversation on attending the audit meetings, he remarked to the paediatrician: ***"… laughs…you're not going to give up on this?"***

Obstetrician, H3

ii. Vertical leadership undermined teamwork

This refers to the convention in which leadership is viewed as solely an individual phenomenon that is focused on a single designated leader rather than being distributed among team members.(211) This is in contrast to shared leadership where the leadership influence is distributed across several team members with mutual influence embedded in their interactions.(212) This improves team performance. Assigning all responsibilities to one individual resulted in poor support from other team members. This was observed in the way the NBU nurses seemed to perceive the audit meetings as a preserve of the nurse managers, and when they were away, there was nobody else to attend or participate. On inquiry on whether the nurses attend other departmental activities such as CMEs, the response was that they are encouraged to but usually do not. This is illustrated in the following excerpt:

"…there is a bit of resistance from the nurses and I suspect that it's because the nurse in charge is on leave." Nurse 1, H1.

"…we're (NBU nurses) all usually expected to attend these things (departmental activities) but honestly we don't…" Nurse 2, H1.

This same response was given by the paediatrician when she was requested to ensure that the nurses were also involved in the preparation of the audit meeting.

"the NBU nurse i/c is currently away and that's why it's been difficult to get the nurses to cooperate, but I'll keep trying." Paediatrician 1, H1.

Vertical leadership was also demonstrated among the paediatricians. It was observed that one paediatrician was given the responsibility to manage the clinical audits. This responsibility would solely belong to one person who would barely receive any support from their colleagues. We observed that the other paediatricians rarely attended meetings despite several requests to do so, and in the event that the paediatrician managing the audits was not able to attend the meeting (conflicting meetings, leave, sickness, etc.), it would not take place.

"Doc, you're seeing how I'm already struggling to even get them (paediatricians) to respond to messages." Paediatrician 1, H1.

"I feel bad that the seniors have left me to do all these activities. Even just responding on the WhatsApp group is a problem. If I had their full support we'd be so far." Paediatrician 1, H1.

"Hey, doc, I started my one-month leave yesterday, can we take a one-month break from the newborn audit?" Paediatrician 1, H1.

"County management had called for a meeting with the HODs (heads of departments) and this is scheduled for the same morning as the audit meeting. The NBU nurse I/C is also attending a different meeting on the same morning. Could we move the meeting to next week?" Paediatrician 3, H3.

"I feel like I need support from the other paediatricians as I won't always be available." Paediatrician 3, H3.

4. Power dynamics revealing team-based inequalities

One of the emerging themes was that there were power dynamics within the teams. This was portrayed by the hierarchical relationships and the authoritarian leadership demonstrated in the study sites.

i. Hierarchical relationships influencing the success of the newborn clinical audit

It emerged that the relationships among the health workers were hierarchical in nature, even among

the consultants who were at the top of the pyramid. It was observed that the paediatricians who were relatively junior compared to their colleagues in terms of years of experience were routinely put in charge of the newborn clinical audits. Despite this, they did not have the autonomy to drive the meetings as it seemed that the senior paediatrician still had the deciding power on whether the meetings would happen. This resulted in delays in the initiation of the audit meetings and poor attendance by authority figures who would be influential in enforcing the implementation of action plans and the sustainability of the audit meetings beyond the research period.

"I believe that for the administrators to attend the meetings, the initiative to invite them has to come from Dr. Y (HOD)." Paediatrician 1, H1.

"You know that for this thing to work, it has to come from the HOD (head of department), if they don't support it there's very little I can do." Nurse 1, H3

I hit a dead end in one of the study sites as the head of the Paediatrics department did not give the green light for the newborn clinical audits to proceed as designed in the implementation guide, she preferred the former method where the group reviewed the monthly morbidity and mortality statistics. The paediatrician was at her wit's end, and after several weeks of delay, she was pleased at the request by the researchers to intervene on her behalf as illustrated in her response:

"I think this can help. Yes, she (researcher G.I) can speak to her please." Paediatrician 1, H1.

The hierarchies in the hospitals were not only among cadres, but also interdepartmental, with some departments considered more "critical" than others. This influenced the distribution of healthcare workers in the various departments. It emerged that the NBU was commonly not considered a high priority department as depicted below:

You know we don't have M.Os so all this is literally between me and the interns... the few M.Os are taken to the 'critical' departments, surgery and obstetrics and us who are not considered critical are left with no M.Os it's really difficult. Paediatrician 1, H1

"…Can you imagine with this shortage, one M.O was removed from NBU and taken to maternity. We're not considered a priority. It's really frustrating…" Paediatrician 3, H3

ii. Authoritarian leadership hindering effective interpersonal communication

Authoritarian leadership "stresses personal dominance, strong centralised authority and control over subordinates and unquestioning obedience."(213) This was observed during an audit meeting where the paediatrician dominated the discussion and used some rigid responses regarding knowledge of use of the CPAP machines. This is illustrated below:

"Yes, everyone rotating in the NBU knows how to use the CPAP machines. If there's anyone who doesn't know my opinion is that they're not interested, and I don't know what to do about that." Paediatrician 2, H3.

When the paediatrician was asked why they felt this way. The response given was as illustrated:

"...because there's no one who's new to the NBU, so I expect that everyone should be familiar with this by now." Paediatrician 2, H3.

In H3, the team kept rescheduling the audit meetings. It appeared that the junior clinicians were not fully conversant with their role in the audit meetings but did not communicate this to their supervisors.

"Kindly could we meet on Wednesday for orientation then we can do the audit next week... Maybe then you can meet all the M. Os and explain to us what is required... Yes Dr. M (paediatrician) suggested that we can meet for orientation so that we know what you expect if that's ok." M.O. 2 H3.

On consultation with the paediatrician, she informed me that she had no such conversation with the junior clinician as illustrated below:

"I think she (M.O) is running away from the task, from 2 weeks ago I had told her (M.O) just as I had told you (facilitator) to work with you and prepare the mortality. Looks like she's (M.O) still not ready. I will get you (facilitator) someone else tomorrow." Paediatrician 2, H3

5. Structure as a constraint to quality improvement initiatives

This theme reflects the impact the organisational and physical structures as depicted in the Donabedian model had on countering the success of the audit meetings.(43)

Each of the two intervention hospitals had one main boardroom where all hospital meetings and learning activities took place. This had an effect on the scheduling of audit meetings which had a set date and time that had been appropriately communicated as they were frequently postponed or cancelled due to the unavailability of the boardrooms. There were instances where the team had to rush through the meeting or find a space to relocate to halfway into the meeting as there was another group waiting to occupy the boardroom.

In addition to the physical structures, human resource constraints were often reported to affect the attendance of audit and feedback meetings and the subsequent implementation of action plans.

"... it's because of staff shortage! We're too few to have more than one person attending, but I'll relay the message." Nurse 1, H1

"It's difficult for the nurses to find time to prepare the case with the interns because of staffing, but we'll try..." Nurse 1, H1

"You know we don't have M.Os so all this is literally between me and the interns..." Paediatrician 1, H1.

"… we want to do our best but we can't because of staff shortage..." Paediatrician 3, H3

6. Hindrances to effective feed and fluid management

There were challenges that emerged as hindrances to effective feed and fluid prescription, monitoring and data collection. These mainly included the documentation practices and the knowledge gaps.

i. Documentation practices as a constraint to effective auditing of feed and fluid management

The hospitals that are part of the Clinical Information Network (CIN) aim to improve the collection and use of patient-level hospital data through the introduction of standardised structured forms. The structured forms include a comprehensive newborn monitoring chart that is used to prescribe and

monitor feed and fluid management as well as for vital signs monitoring. The teams highlighted how most of the feed and fluid documentation still happened in the clinical notes and nursing cardex as demonstrated below:

" ... we usually just prescribe in our notes..." M.O 3, H3

"... to be honest, we still mostly prescribe the feeds and fluids in our notes..." Intern 2, H1

“... no, unfortunately most of the time it won't be documented but we just tell the mother how much to feed." Nurse 1, H3

"I know that we should monitor in the chart, but to be honest, we still just monitor in the cardex...” Nurse 1, H3

The team appreciated that documenting feed and fluid management in a structured chart facilitates team communication as it provides critical information for timely intervention. The poor documentation of the feed and fluid management in the clinical notes frequently led to difficulties in obtaining adequate information both to adequately manage the patient as well as to comprehensively audit the feed and fluid practices. This was highlighted in the following comments:

"It's so difficult getting this information (feed and fluid and vital signs monitoring) from the file that's why it's incomplete on the tool, but I'll look through the file again and see if I can fill in." Intern 3, H1

"I'm glad that this has come up, it is such a big problem, it's not even possible to follow what was prescribed and what was given by looking through the file. We need to find a way forward... you can't monitor fluids on a cardex the monitoring charts must be used. We need to reinforce this during ward rounds." Paediatrician 2, H1

“…It's truly very difficult to follow feed and fluid management in our patients…” Paediatrician 2, H3

"... I just filled the information that was available. There seemed to be some days with no prescription or I just couldn't find it in the file." M.O 4, H3

The health workers agreed that the comprehensive monitoring chart was usually available:

"...the monitoring charts are always in the cupboard and available for anyone who needs them." Nurse 1, H1

"…no, the charts are available, Infact we attach them to the file and do our vitals monitoring very well because we're part of the other study for vital signs monitoring, but the feeds and fluid section is usually left blank... laughs... Nurse 1, H3

Considering that the monitoring charts were available, some of the reasons given for the poor documentation of the feed and fluid management included; the absence of the monitoring chart from the file. This brought in the fear of charts getting misplaced or getting attached in different parts of the file which affects continuity of care, the documentation of the feeds and fluids in the continuation notes or cardex was also sometimes out of habit. The health workers also felt that staff shortage affected the daily assessment of patients.

"... Ideally, we should prescribe the feeds and fluids in the monitoring chart, but the problem is that it's usually not in the file so it's easier to just prescribe in the notes instead of looking for a monitoring chart." Intern 4, H1

"...sometimes you're just afraid that the chart will fall off when attached to the file, that's the biggest problem." Intern 4, H1

"...that's another challenge, they're stapled at different places and it becomes difficult to follow the feed and fluid prescriptions in order..." Intern 5, H1

"...if the clinician doesn't even know what the baby is currently getting how will they even know how much to prescribe? If two days are missing then you don't know if to give the fluids for that day of life or to continue from the last documented... it's tough." Nurse 1, H3

"…I think people find it difficult to do that section in the chart or are just too used to the cardex." Nurse 1, H3

ii. Knowledge gaps on newborn feed and fluid management

Another sub-theme that emerged as a barrier to the optimum feed and fluid management of the newborn was the knowledge gaps. This was highlighted in the intervention hospitals with solutions arising such as putting up the management protocols in the NBU, supportive supervision and holding CMEs. This is highlighted below:

"We have not had the CME yet, however, I've been paying closer attention to the feed and fluid prescriptions during ward rounds and even printed the SOPs from the protocol and put them in the NBU." Paediatrician 1, H1

"Yes, I can do that (hanging the feed and fluid management protocols in NBU) this week and also make sure to be keen on the management during the ward rounds." Paediatrician 2, H3

7. **Slow organisational adoption of digital technology influencing multidisciplinary attendance of audit meetings**

The availability of infrastructure for virtual meetings provided a convenient option for healthcare workers who could not physically attend meetings, and, therefore, had the benefit of a wider and more diverse audience. I supported the hospitals to provide hybrid meetings (partly in person and partly online) by providing the online platform for each meeting which was shared with the teams in advance. Despite this, there were instances where this was taken up well, however, the majority of the time, we observed that there was no online attendance which affected the diversity of the audit meeting participants. The nurses often reported that they were too short-staffed to attend the meetings, yet there was an online option and they could attend even when not on duty. The slow adoption of digital technology also affected the use of the audit tool which was an electronic tool as the healthcare workers some of whom had attended the trainings initially believed that special software was required to fill the audit tool as illustrated in this excerpt:

"The intern says that she was not aware that this tool should be filled on the laptop, I mean, it is a PDF document... by the way, I don't think we have the software to fill this tool as a soft copy, we just have normal laptops." Paediatrician 1, H1.

es used to build on the strengths and overcome the barriers in the implementation of the clinical audit tool and implementation guide

	Nature of facilitation strategy to overcome barriers	**Was the strategy successful?**	**Facilitators and barriers to facilitation strategy**
nces d to a ne	Helping overcome resistance to change how the health workers conduct the clinical audits by calling a meeting to re-introduce the clinical audit tool and implementation guide to health workers and understanding the challenges they're experiencing in establishing meetings (H3). Monitor and evaluate practice change by encouraging the teams to routinely go through their monthly performance statistics. This was done by beginning the 2nd audit of each month by going through the statistics.	Yes – There audit meetings picked up in H3 after this meeting. Yes – the teams took up the practice well and the improvement observed in the process of care encouraged them to have a better perception of the clinical audits. An interesting observation was that many paediatricians were not aware that they receive monthly and quarterly performance reports.	Poor attendance of meeting by NBU leadership. Increased time is taken for the audit meeting when the morbidity and mortality statistics were reviewed before beginning the meeting. A solution was to have a set day every month for a departmental meeting where the report would be read. This was not actualised in any of the hospitals.
	Build a good working relationship between health workers by encouraging teamwork in preparing and presenting in audit meetings.	Partially successful in H3 – The NBU nurses were occasionally involved in the preparation of the audit meetings.	Staff shortage leading to poor attendance and participation by the NBU nurses. Competing for staff time.

		Facilitator not only interacted with paediatricians but also with the NBU nurse leaders in the planning of audit meetings. Creating WhatsApp groups with NBU teams to involve them all as a team in the preparation of audit meetings and to enhance communication between researchers and hospital teams. (H3) Engaging all the cadres in the case discussions during audit meetings to ensure equal participation and divergent views. Encouraging selection of cases for discussion from the paediatric ward to overcome the poor integration of the two units. Having the paediatric ward attend the audit meetings and have their challenges addressed. Mediating between the senior and junior health workers to allow for equal participation.	Partially yes -the nurse felt that the paediatrician had the final say when it comes to scheduling audit meetings. Partially – minimal engagement on WhatsApp group. Yes – actively encouraging participation from all the cadres represented in the meetings enabled diversity in problem identification. Yes – H1 managed to include the paediatric ward in the NBU clinical audit. Yes – mediating between the junior and senior clinicians encouraged the junior clinicians to contribute to the audit meeting discussions in H3. Obstetrician in H1 attended one meeting. H3 obstetricians advised that we incorporate the discussion into the MPDSR meeting as that was the only way they could attend.	Poor participation in the WhatsApp groups where the facilitator would engage in discussion with minimal response.

		Engaging obstetricians to gain their support in meeting attendance. Understanding how the nurses and clinicians in NBU conduct their duties to understand how to improve teamwork.		
H1 and H3	Cynical attitude towards research which is viewed as being for the benefit of the researcher rather than a patient safety initiative.	The facilitator would follow up with NBU teams to determine progress on action plans. Peer support/ shared learning across study sites.	Partially – this was not always successful as majority of the action plans remained partially implemented in both study hospitals. Yes – whenever the teams found a recurring problem, they would seek my opinion on how other hospitals that have faced similar challenges overcame them.	Teams were willing to learn from others' experiences.
H1 and H3	Ownership of the audit process.	Further encouraging local ownership by encouraging the teams to facilitate their meetings. The facilitator would oversee the meetings to ensure that they were conducted as required. Allowing teams to set their priorities.	Yes – the chair of the audit committee from both hospitals effectively took over the facilitation of the audit meetings. This allowed them to be more conscious about scheduling meetings and encourage other cadres to attend for purposes of a fruitful discussion that would ultimately lead to improved QoC and following up on action plans.	The audit committee chairs were trained on the implementation guide and had previously observed the facilitator facilitating at least two audit meetings. The facilitator was available to provide guidance where needed.

H1 and H3	Limited leadership support.	Engaging hospital leadership to gain support for the newborn audit process. Attempts to improve buy-in from NBU leadership through invitations to meetings aimed at clarifying the audit process and addressing any rising concerns.	Partially - Hospital leadership attended one meeting – H3. Senior most paediatricians attended at least one meeting in H1 and two in H3.	Resistance from NBU leaders to organise meetings with hospital leadership. Poor or no attendance of NBU leadership.
H1 and H3	Structure as a constraint to quality improvement initiatives	Encouraged a set day, date and time for audit meetings which were well known to the health worker in charge of scheduling meetings. This would ensure that they were recognised as formal hospital meetings	Yes	Occasionally had other hospital meetings occurring at the same time and would therefore have the meeting at a different venue.
H1 and H3	Reactive mindset	Encouragement, providing constructive feedback, acknowledging success and recognising achievements.	Yes – the slow gains encouraged the teams to believe that change was possible.	Low morale among team leaders.
	Slow adoption of digital technology. Silo mentality	Hybrid meetings whereby the facilitator would create a Zoom link using her Zoom account and share it with the teams a few days before the audit meeting to allow for virtual attendance which would encourage diversity.	Partially – There was occasional virtual attendance.	

Table 22 below represents a summary of the audit process trainings and the audit meeting dates, attendance, modifiable factors, action plans and their implementation status in the two experimental study hospitals.

Table 22: Summary of audit process training dates, audit meeting dates, attendance, modifiable factors, action plans and implementation status in the study hospitals

Hospital	Workshop 1 dates	Workshop attendees	Workshop 2 dates	Workshop attendees2	Audit meeting dates	Audit meeting participants	Modifiable factors	Action plans	Implemented Y/N	Audit meeting dates3	Audit meeting participants4
H1	28th April 2021	NBU paediatrician NBU nurse i/c	17th May 2021	NBU paediatrician NBU nurse i/c Midwife HRIO Nutritionist Hospital matron Pharmacist. M.O Obs/gynae.	7th July 2021	3 paediatricians NBU nurse i/c Paediatric ward nurse i/c 1 M.O. 3 MOIs HRIO Nutritionist	1. Improved documentation in monitoring charts. 2. Knowledge gaps in vital signs. 3. Timely initiation of CPAP. 4. Improved methods of NGT insertion. 5. Use of CPAP hats.	1. Supportive supervision on students and qualified nurses to enforce monitoring of patients. 2. CMEs to improve knowledge and skills. 3. Acquisition of litmus paper and permanent markers acquired. 4. CPAP hats acquired from the NEST team.	10th September 2021	1. 1 paediatrician. 2. 1 Obstetrician. 3. NBU deputy nurse i/c. 4. 4 MO interns. 5. Nutritionist. 6. Pharmacist. 7. HRIO.	
H3	28th April 2021	NBU paediatrician NBU nurse i/c	7th June 2021	NBU paediatrician NBU nurse i/c Midwife HRIO Nutritionist M.O Obs/gynae.	4th August 2021	2 paediatricians Nurse i/c NBU 1 midwife 1 nutritionist 1 HRIO 1 M.O from NBU	Delayed review of patient by clinician due to lack of existing hospital guidelines. Prevention and mangement of hypothermia. Timely initiation of CPAP Monitoring and action on abnormal vital signs and feed and fluid mangement.	Formulate a policy to guide on duration that should be taken to admit a newborn to the NBU. CME on prevention and management of hypothermia. CME on RDS management	Yes and ongoing OJT.	18th August 2021	1 paediatrician Nurse i/c NBU Nurse NBU 1 midwife 1 M.O. NBU 1 nutritionist 1 HRIO (virtual attendance)

Modifiable factors5	Action plans6	Implemented Y/N7	Audit meeting dates8	Audit meeting participants9	Modifiable factors10	Action plans11	Implemented Y/N12	Audit meeting dates13	Audit meeting participants14	Modifiable factors15	Action plans16
1. Standardizing the referral process. 2. Improved vitals and fee/fluid monitoring.	1. Meeting between administration and paeds department to standardize the referral form. 2. Standardize the position of attachment of the monitoring chart on the file.	1. Yes - initial meeting held. 2. Monitoring chart attached before the treatment sheet to make it standard in every file.	24th September 2021	1. 2 paediatricians (one attended virtually) 2. NBU deputy nurse i/c 3. 2 family medicine registrars. 4. 4 MO interns 5. 1 midwife.	1. Improved monitoring of category A babies. 2. Lab investigations for babies with SBA. 3. Improve knowledge on newborn feed and fluid management. 4. Continue process of standardizing referral form.	1. Mini audit of a few files to ensure 6 hourly monitoring of patients has been done. 2. SOPs on lab investigations for SBA. 3. CME and OJT on feed/fluid management. 4. Follow up design of referrral form.	1. Mini audit pushed forward to the next week as NBU nurse i/c tasked with this was not on duty. 2. OJT for feed/fluid management has been ongoing, however CME was slotted for the following week. 3. Discussions on lab investigations began, however not all parties were agreeable that it was necessary to do lab investigations for neonates with SBA. 4. Suggestions to adopt the NAR as the standardized referral form.	15th October 2021	1. 4 M.O.Is (2 NBU, 2 paeds) 2. Paediatrician (HOD) 3. Paediatrician (chair audit committee) 4. 2 family medicine registrars. 5. Nutritionist. 6. Pharmacist. 7. C.O.I	1. Serial monitoring of vitals, feed/fluids and RBS. 2. Timely initiation of CPAP. 3. Prevention and management of hypothermia.	1. IVF and feeds discussion in MWR. 2. Schedule CPAP and hypothermia as CME topics and continue discussions during major ward rounds.
Modifiable factors5	Action plans6	Implemented Y/N7	Audit meeting dates8	Audit meeting participants9	Modifiable factors10	Action plans11	Implemented Y/N12	Audit meeting dates13	Audit meeting participants14	Modifiable factors15	Action plans16
RBS monitoring for all babies during admission. Daily review of all babies in NBU by clinicians. Knowledge gaps in several areas	Reminder to all nurses and clinicians on the WhatsApp groups as well as constant reminders during handovers. Clinicians meeting to discuss working arrangements and organisation. Meeting with administration tighlight gaps in staff numbers. Regular CMEs atleast twice a month on a set date.	1. Yes 2. Yes 3. Yes 4. No	15th September 2021	1. Neonatologist. 2. Paediatrician. 3. 1 Medical officer. 4. NBU nurse i/c 5. NBU nurse. 6. Midwife. 7. Nutritionist	1. Poor knowledge and skills on newborn resuscitation 2. Knowledge gaps in several areas of newborn care. 3. Investigations not ordered. 4. Poor documentation of patient's sero status	1. Regular (monthly) skills refresher sessions. 2. Set a regular CME date to keep health workers regularly updated. 3. Baseline investigations must be done for each admitted newborn. 4. Ensure completion of internal transfer form from I/ward	1. 1st refresher session had in NBU. 2. No regular date set for NBU CMEs. 3. Issues with capacity to conduct investigations that required input from the lab and administration. 4. Done.	6th October 2021	Physical attendance 1. Paediatrician - chair of committee. 2. NBU nurse i/c. 3. Nutritionist. Virtual attendance 1. Deputy med sup. 2. Paediatrician who newly joined the NBU. 3. M.O. presenting. 4. Lab i/c.	1. Timely transfer of critical babies from OPD to paeds department despite staff shortage. 2. Improved documentation (monitoring of patients). 3. Laboratory challenges - inability to do biochemistry at certain times and on certain days	1. Meting with OPD i/c, administration and paeds department. 2. Adopt neonatal monitoring chart in the neonatal room. 3. Meeting between laboratory and paediatrics department.

Implemented Y/N17	Audit meeting dates18	Audit meeting participants19	Modifiable factors20	Action plans21	Implemented Y/N22	Audit meeting dates23	Audit meeting participants24	Modifiable factors25	Action plans26
1. Yes. The feed and fluid discussions were happening during MWRs. 2. The topics were scheduled for CMEs and OJT was ongoing in the NBU.	29th October 2021	1. 2 M.O.Is 2. C.O.I 3. 2 family medicine registrars. 4. 2 biomedical engineers. 5. paediatric ward nurse. 6. Paediatrician. 7. Pharmacist	1. Lack of phototherapy machines in the paediatric ward. 2. Poor monitoring of random blood sugar.	1. Presentation of urgency of the need for the phototherapy machines in the HMT. 2. Refresher on importance of routine RBS monitoring.					
1. Meeting was held between the departments, however the issue not yet resolved as more oxygen ports were required in the admission room which required more time. 2. Adoption of monitoring chart in neonatal room of paeds department remained a challenge due to the staff shortage and would not be possible due to this. 3. Initial meeting between the lab and paeds departments held and 2nd meeting scheduled	27th October 2021	1. Neonatologist. 2. Paediatrician from NBU. 3. NBU nurse i/c. 4. 2 nurses from Othaya involved in NEST QI activities. 5. M.O. presenting. 6. Nutritionist. 7. Lab i/c who initially attended virtually then later joined physically. 8. 2 paediatricians also attended virtually - HOD and 1 paediatrician from paeds department.	1. Improved monitoring of neonates in the NBU. 2. RBS monitoring for all newborns at admission. 3. Reduce time taken for the clinician to review and admit neonates.	1. 3- hourly vital signs monitoring for all in-patient neonates. 2. Enforce RBS monitoring within 2 hours of admission for all neonates and 6-hourly therefater for category A babies. 3. Meeting to be held between consultants and the MOs to discuss the coverage of NBU and paeds units that lead to delay in review of the patients.	None implemented with reason given as staff shortage.	24th November 2021	1. Neonatologist. 2. NBU nurse i/c. 3. NBU nurse. 4. M.O. presenting	1. Prevention of hypothermia. 2. Appropriate and timely lab works. 3. Shortage on clinical coverage. 4. Regular training of staff and students.	1. Installation of heaters in the NBU. 2. Outsourcing of lab works when they are not working in the facility. 3. Increase number of staff and coverage. 4. Regular CMEs, optimize on grand rounds.

In chapter 4, I have described the results from the co-design of the audit tool and implementation guide, the controlled before and after study and the facilitators and barriers to the implementation process based on participant observation. In the next section, I will discuss the PhD thesis results based on my objectives.

Chapter 5: Discussion

This PhD thesis had three main aims: (1) To co-design and test a small and sick newborn (SSNB) clinical audit tool and its implementation guide, (2) to evaluate the effect of the intervention on measurable indicators of improved feeding practices and overall mortality of low birth weight newborns in newborn units in Kenya, and (3) to broaden the effect evaluation and explain the effect of the intervention using complementary qualitative approaches and integrating the findings with those of the quantitative section in a mixed methods approach. This research was motivated by the identification of a gap in the availability of a clinical audit tool that comprehensively covers the three periods in the continuum of newborn care which were; i) the period of immediate newborn care and resuscitation after birth, ii) the post-resuscitation care for the small and sick newborns and, iii) the period of care while in the newborn unit. There was also an identified need for an implementation strategy that would consider the complex individual, organizational, and health system relations that would influence the adoption of the audit tool in real-world settings.(214)

To address this, I co-designed a comprehensive SSNB clinical audit tool and its implementation guide with HCWs participating in a Clinical Information Network using a HCD approach. These were implemented in four study hospitals using facilitation of the audit meetings as a strategy. Successful implementation was defined as having regular audit meetings and completing documentation in the audit tool with the filling of the action plan summary form.

In the controlled before and after study, the four study hospitals were assigned to either experiment or control arms and were assessed over three periods; pre-intervention (six months), intervention (five months) and post-intervention periods (six months). A competing risk analysis was used to demonstrate the probability of occurrence of each event type; regaining birth weight (primary outcome) or death (competing risk and secondary outcome) during the study period. The study did not demonstrate a

significant effect on the primary outcome. The multivariable analysis argues against a positive effect of the intervention on the probability of regaining birth weight. It demonstrated a 5% decrease in the hazard of regaining birth weight in the experimental arm compared to the control arm (HR 0.95, p = 0.75) after adjusting for all the covariates. The Cox proportional hazard was in favour of a positive effect of the intervention on the hazard of death. The regression model demonstrated a 36% decrease in the probability of death among the newborns in the experimental arm compared to the control arm (HR 0.64, p = 0.019) after adjusting for all the covariates. This translated into a difference in cumulative survival probability. However, there was an imbalance at baseline making it difficult to interpret absolute values. It is also important to be cautious with the interpretation as the hazard of death was the secondary outcome. Being a pragmatic study, the qualitative methods identified the complex interacting factors that influenced the implementation of the audit tool. I will therefore apply the findings from the qualitative study to explain the effects of the intervention.

A. Co-design of a comprehensive SSNB clinical audit tool and its implementation guide by considering the key principles of human-centred design.

The co-design process used real cases in busy, high-volume newborn units that admitted newborns with a diverse range of conditions. This allowed the users to identify a wide range of modifiable factors perennial to their setting at each care process step and revise the tool to consider all these possibilities. The result was the development of a context-sensitive audit tool. While the cognitive walkthrough phase has been carried out in controlled settings in some HCD studies, other studies have demonstrated the use of real cases and real scenarios.(89, 91) As expressed by Vermeulen *et al*, "the use of real cases provides more accurate and detailed information into the experiences and problems that can occur."(91) The relative advantage of the SSNB clinical audit tool over the existing tools was that it was designed by the end-users and this ensured that it provided inclusivity. As demonstrated in other

studies, clinical audits are typically centred around the clinician's practice. There's usually limited room to audit the care provided by nurses even though the nursing aspect of newborn care has been identified as very crucial to the survival of newborns.(150, 151) This gap in the prototype audit tools was identified and rectified with the intention of improving diversity in the participation of the audit meetings by having other cadres who participate in newborn care (representatives from the obstetrics team, pharmacy, laboratory, nutrition, health records office, biomedicine departments, hospital administration, etc) attend the audit meetings. Previous studies have reported poor audit meeting attendance by nurses and other cadres and minimal involvement in discussions when they attend.(72, 77) We, therefore, developed an audit tool that adopted a systemic approach and that recognizes that the care of SSNBs is multifaceted and multidisciplinary. The design process took on a delicate balance of ensuring that the audit tool was detailed while at the same time being conscious of the human factors, therefore, ensuring effective human-audit tool interaction. Ensuring ease of use and, hence, promoting adherence to the audit tool by developing it as an electronic tool, incorporating checkboxes, textboxes and drop-down calendars and leaving free text-only where necessary. Muinga *et al* identified similar findings in the design of a comprehensive newborn monitoring chart where the users recommended the design of sections of the chart as fixed options to reduce time spent filling it.(89)

B. Effect of facilitated implementation of a co-designed SSNB clinical audit tool and its implementation guide on mitigating modifiable factors that prevent adherence to LBW newborn feeding guidelines.

The assumption was that improved feeding practices would be pegged on adherence to the audit tool and implementation guide. The implementation guide contained the guidelines that would encourage completion of the audit cycle. This included; holding frequent meetings, appropriate problem

identification and implementation of recommendations and monitoring and evaluation of the effect of the indicators of improved newborn care and planning based on this. The implementation guide as presented in Appendix 13b recommends that the audit meetings should be held two-weekly. The distribution of the audit meetings, however, varied in the four hospitals and the NBU focal leaders played a significant role in determining how and when the audit meetings occurred. The two hospitals (H1 and H3) in the experiment arm were late adopters (took two or more months to begin holding frequent meetings). They had a slow start in initiating the audit meetings and required some 'friendly nudging' to hold them regularly with complete filling of the audit tool. H2 which was in the control arm took less than two months after training to begin holding frequent meetings. It was the first hospital to initiate and institutionalise the audit meetings evidenced by holding the meetings consistently throughout the study period despite not receiving facilitation. They, however, did not implement the complete documentation in the audit tool. On the other hand, H4 held only two audit meetings throughout the study period with the first meeting held five months after the beginning of the intervention period. They did not document in the audit tool for either of the audit meetings. The adoption of the audit meetings was linked to the top-down leadership phenomenon observed in most of the study hospitals. I will focus on the NBU leadership as I believe that they were the most influential factor in shaping the organisational adoption of the clinical audit tool and implementation guide. Middle-level managers are positioned as key strategic actors in the improvement of QI initiatives with literature arguing that the performance of an organisation is heavily influenced by this leadership level.(215) There is a consistent association between effective middle-level leadership (the paediatricians and NBU nurse managers), their role as opinion leaders and champions of change and the adoption of a quality improvement innovation into practice as demonstrated in this study. In the study hospitals, the paediatrician in-charge of the NBU solely made decisions on behalf of the team. The challenge posed by this leadership style is that the inspiration and vision of a single person would be the

driving force behind the performance of the clinical audits.(211) Nzinga *et al* examined middle level leadership in Kenyan county hospitals using distributive leadership as the unit of analysis and the findings reflected those of this study that the leadership practices are more hierarchical and authoritarian.(216) The power dynamic was observed to affect the clinical audits as the paediatricians who were trained had the knowledge and skills, however, they were junior to their peers and, therefore, did not have the influence to effect change. Meanwhile, the senior paediatricians with the influence did not actively engage in the implementation.(217) The effect of power dynamics on the implementation of interventions has been reflected in other studies.(218) In addition to the disconnect between the paediatricians, was the decision-making authority of the NBU nurse managers. Nurse managers play an important role in the leadership of the NBU; however, they often perceive their role as more of a supporting rather than a complementary role to the paediatricians. This has been demonstrated in studies conducted in both LMICs and HICs.(219, 220) The nurse managers have a different set of skills from paediatricians and action to merge the strengths of the two leaders, working jointly on implementing the clinical audit would help to regularize the audit meetings. The NBU leadership in control hospital H2 portrayed collectivistic values by having aligned goals that promoted team productivity and the successful integration of the audit meetings into their routine practice. In H2, this collaboration influenced the success despite not receiving facilitation. This further demonstrates the influence of middle level management style in the implementation of the audit tool. Prior studies that have focused on leadership style as a determinant for the success of QI initiatives have promoted a distributed or shared leadership style compared to the traditional vertical leadership style.(212, 221, 222) This leadership style is more successful as it is viewed as a dynamic process in which the behavioural roles that often fall under the leadership umbrella may be taken up by multiple individuals and distributed based on their skills and expertise.(223)

In addition, the conduct of the perinatal and newborn clinical audits in the implementation settings are governed by the MPDSR guidelines as enshrined in the MoH policies.(85) The MPDSR has made significant strides in improving the quality of maternal care, however, as reflected in several studies, there is a general feeling of silence towards the post-resuscitation care of the newborn. (9, 224, 225) Nevertheless, the MPDSR being a policy from the MoH with a requirement for the hospitals to produce a monthly report of the meetings, the health workers abide to these requirements as a 'ritual observance'.(62) The introduction of an NBU care clinical audit that complements the MPDSR by strengthening the newborn care aspects was accepted. However, some of the SOPs were conflicting with those of the MPDSR such as the focus on the quality by conducting in-depth audits of one case per meeting rather than auditing all the newborn deaths over a period. The implementation guide also recommended at least two-weekly meetings rather than monthly meetings.(9, 62) The delay in adoption of the clinical audit tool may therefore have been due to the deviation from the guidelines as set in the policy.(226)

Linking the clinical audits to improving indicators of newborn feeding practices

The lack of difference in findings on time to regain birth weight are in contrast to studies on the outcomes of improved feeding practices for the LBW newborn.(7, 109, 227) These studies were however controlled trials that only included stable LBW newborns. A possible explanation for the results of this study is that the burden of newborn morbidity and mortality in these hospitals is high and mainly from preventable causes as demonstrated by Irimu *et al*.(27) Based on this, the audit tool was designed to cover all the aspects of newborn care rather than being specific to newborn feeding practices.(9) During the audit meetings, I used my position to steer the discussions towards feed and fluid management, however, the health workers focused on the gaps that they perceived to be a priority for them as demonstrated in the audit meeting summaries in table 20. The limited focus on feed and fluid

management of the newborn was therefore not likely to result in a significant decrease in the hazard to regain birthweight. Other aspects of care may have however improved resulting in the reduced hazard for death in the experiment arms. This argument is also supported by the emerging modifiable factors on feed and fluid management which were predominantly on the documentation practices rather than the knowledge and skills to appropriately prescribe and administer the newborn feeds. In their work to implement a comprehensive newborn monitoring chart, Muinga *et al* made similar observations on the challenges of structured documentation of feed and fluid management in monitoring charts with a preference for continuation notes and the nurses cardex.(133) From the results, some challenges that were attributed to the slow implementation of recommendations for improved documentation practices were hospitals that were crippled by gross shortages in health workers. Human resources have been described as the "heart of the health system."(228) The recommendations for intermediate care NBUs include a nurse: patient ratio of 1:3, one paediatrician on call in the NBU and 24-hour cover by one or more medical officers dedicated to the NBU.(137) The study hospitals however fall short of these recommendations by a huge margin as demonstrated in previous work conducted in the Kenyan context.(133, 150, 229) With a depleted workforce, there is increased strain on the existing workers. This makes it difficult for the clinical audit to result in any meaningful change as they are the executers of all recommendations made to improve the process of care. Short-term recommendations that could be implemented within available resources such as improving knowledge and skills on feeding practices of the low birth weight newborns were implemented. However, the poor documentation practices provided poor quality data to assess if the knowledge was translated into actual practice. Another challenge affecting documentation practices was the rapidly changing clinical workforce demonstrated by the variation of participants at the audit meetings over the six-month study period. Hospitals such as H1 had no medical officers in the paediatric department with only medical officer interns on a three-month rotation in the paediatric unit and who were stationed in the newborn unit for less than a month.

The M. O interns are usually responsible for documenting the daily patient care based on decisions made during the ward rounds with the paediatricians. Documentation practices acquired from other departments influence their behaviours requiring prolonged periods of supportive supervision to observe a change in behaviour which may be at the tail end of their rotation.(230) Similar findings on the rapidity of staff turnover were identified by English *et al* resulting in rotation of those who have acquired the knowledge and skills. In addition, the reallocation of staff away from paediatric and newborn areas that were considered low priority was also observed in the study sites in this thesis.(148) There is a requirement for an adequate number of clinicians and nurses to ensure thorough daily assessment of all the newborns with proper documentation of the daily feed and fluid management. There would be better health system performance with the availability of well trained and motivated health workers.(231)

Another possible explanation for the reduction in mortality was the improving quality of care observed particularly in H1 based on the declining mortality rates from the CIN-N monthly feedback reports as well as the perceptions of the health workers. It can be argued that improving the quality of care improved the survival of critically ill newborns who would otherwise have died. These surviving newborns would therefore have increased time to regain birth weight. These explanations may be supported by the probability of mortality remaining constant in the control hospitals but declining in the experiment hospitals. Aluvaala *et al* produced a similar argument when they proposed that improving the quality of care for the low birth weight newborn would increase the length of hospital stay for these newborns.(232)

The peak in mortality for this population in both the experiment and control arms and across the three study periods was within the first 72 hours of life. This is comparable to neonatal mortality studies conducted in both HICs and LMICs which demonstrated a higher probability of death within the first week of life among all newborn weight group categories.(27, 232-234) This underscores the importance

of strengthening the continuum of care provided to newborns who survive the initial resuscitation and immediate care after birth. The descriptive characteristics of the study population demonstrated a population that remained comparable across the study periods. The study population at highest risk for mortality were the (1000-1499g) and (1500-1999g) weight categories. The proportion of newborns in these weight categories in the post-intervention period remained comparable with the proportions during the pre-intervention and intervention periods. Based on this, it is unlikely to attribute the declining probability of mortality in the experiment arm during the post-intervention period to a difference in the characteristics of the study population. These results match those observed in other studies where facilitation as an intervention has resulted in reduced neonatal mortality rates, though the studies have mostly been randomised controlled trials where the researchers ensured readiness of the sites. In these studies, there was no effect on mortality demonstrated in less than two years.(235, 236) However, for a pragmatic study, several contextual factors influencing the readiness for implementation could potentially influence the success of the implementation.

C. Role of external facilitation in building on the strengths and overcoming the implementation barriers to the SSNB clinical audits

The facilitation process aimed at overcoming the challenges and strengthening support for newborn clinical audit by understanding and responding to the interaction between the innovation, recipients and context.(82) This made it an appropriate strategy for implementing a complex intervention in a complex adaptive system composed of components that interact and connect with each other in unpredictable and unplanned ways.(22) The behaviour of a complex adaptive system is determined by its internal structure rather than by external influence.(2) Similar to findings from previous research, this study demonstrated that the organizational environment in the study hospitals is marred with a myriad of challenges. These challenges include; inadequate financial, infrastructural and human resources, limited

support from organizational leadership with poor response to recommendations for improvement from QI initiatives and a name and blame culture where there are punitive repercussions against the health workers perceived to have committed 'errors' during the care of the patient.(148-150, 203, 237, 238)

A general pattern of inertia and apathy was observed in the study hospitals. Health workers place significant importance on the satisfaction they derive from providing good quality care and this includes implementing initiatives that would improve QoC. However, operating in an "environment of scarcity" with inadequate resources to implement recommendations needed to improve QoC leads to burnout, a condition characterized by frustrations, depersonalization and decreased intrinsic motivation.(239) The clinical audit requires complex and deep-rooted changes in staff practice and professional culture. It also requires time commitment and an effort to prepare for, conduct audit meetings and implement the recommendations. This is difficult to achieve when the workforce have low morale based on previous experiences of limited organisational commitment to implementing recommendations generated from patient safety initiatives as expressed in H3. Jepkosgei *et al* have previously demonstrated these shortcomings as contributors to the negative attitude towards newborn clinical audits in Kenya.(76) These challenges have also mirrored other studies in resource limited settings (70, 75, 77). This affected the success of implementation of the audit tool and implementation guide as despite identifying the modifiable factors that would improve newborn care and in particular newborn feeding practices, there were challenges in implementation of the recommendations. A high performing organisation that provides institutional support promotes best practice initiatives and their implementation by ensuring the availability of adequate resources to support the implementation of action plans arising from the meetings. This requires commitment from senior level managers at the hospital, county and national levels. The presence of an external facilitator who had experienced that the newborn clinical audit improved newborn care including feeding practices played a role in the diffusion of the innovation. As a facilitator, I directed the conversations to place more emphasis on short term and mid-term

recommendations that were not capital intensive. The external facilitator sought to minimize the scepticism towards the clinical audit by supporting the teams to implement the audit tool and implementation guide as recommended. Through frequent reminders, positive reinforcement, supportive supervision, peer support through shared learning, there was progress in implementation of recommended action plans which eventually resulted in favourable outcomes. This changed the attitude of the health workers and promoted improving ownership of the clinical audits as evidenced by the positive changes in attitude and conduct of the audits observed as the study progressed. Previous studies that have used facilitation as a strategy have documented these roles as effective for implementation.(78, 164, 165)

The study demonstrated a fragmented culture by the way in which the different departments and cadres are disconnected from each other and work in silos.(240) Recognition of this culture as a barrier to improving newborn care is important because the complex interdepartmental interactions demand that appropriate changes in all parts of the system are needed to support change in the NBU. Several studies have demonstrated how the audit meetings are routinely attended by only doctors and occasionally a few nurses with no representation from other departments.(50, 76, 225) However, the presence of an external facilitator who was a senior paediatrician and researcher affiliated to the CIN provided access to the opinion leaders in the various departments enabling the health workers to appreciate how interlinked the departments were. This supported Rogers theory of successful diffusion where the change agent should be homophilous to the opinion leaders in aspects such as status, rank, education level etc, but heterophilous in knowledge on the innovation.(241) This helped to create clear communication lines among the stakeholders and therefore creating an equitable environment for productive discussions during audit meetings. This application of the theory has been proven to be successful in various fields such as the mental health field as well as in the education field.(242, 243) Compared to other studies on clinical audits, this study has illustrated better intercadre interactions

through a more divergent attendance of the audit meetings and this can be linked to the effect of facilitation.

Despite H2 holding frequent audit meetings early in the study without the intervention of a facilitator, it was observed that the adoption of the clinical audits was selective. This was based on the fact that they continued old practices of poor documentation in the clinical audit tool. There was incomplete filling of the audit tool with no documentation of the modifiable factors and the action plans recommended and implemented. In keeping with systems thinking, individuals will not change their modes of thinking or behaviour until their existing modes are proved beyond doubt, through direct experience to not be working.(244) This shows that even in highly performing organisations, a facilitator is required to enforce behaviour change.

Strengths and Limitations

The main strength in the co-design were the several iterations involving the end-users. Using real cases during the cognitive walkthrough enabled the design of an audit tool that comprehensively captured the modifiable factors within the context. In addition, there were senior representatives in the field of newborn medicine actively participating in the design process and this contributed to the development of a context relevant and comprehensive small and sick newborn clinical audit.

The pragmatic approach applied in this thesis allowed for demonstration of the efficacy of interventions in real-life settings.

The use of a mixed methods approach allowed for comprehensiveness by understanding the difficulties of implementing complex innovations in a complex system. A range of methodologies are required to understand and evaluate these complexities.

The study sites had participated in network activities over several years in projects that had successful outcomes which helped build trust in this research work.(130, 137, 216, 226) In addition, the positionality of the facilitator as a fellow paediatrician practicing in a newborn unit that is part of the CIN-N provided familiarity with the health workers in the study sites. This permitted candid discussions during the audit meetings enabling proper problem identification.

The restrictions resulting from the COVID-19 pandemic stimulated out of the box innovativeness to improve audit meeting attendance. This was supported by the availability of technologies such as smart screen TVs in the hospitals and smart phones that promoted easy communication.

A limitation was that the study was not conducted in a random sample of hospitals. The findings are most directly generalizable to county hospitals that provide primary referral inpatient care and that receive support in form of; continuous medical education, mentorship and routine performance feedback in the form of audit reports as provided in the CIN hospitals.(41)

The limitations of the design study were that the “Improving the quality of paediatric care: an operational guide for facility-based audit and review of paediatric mortality. Geneva: World Health Organization; 2018” manual was shared with the participants before the focus group discussions.(1) I speculated that this would broaden their knowledge on the recommended standards for conducting a clinical audit to enrich the discussions. This, however, had the effect of contaminating the FGDs as the participant responses seemed to be premeditated. Another limitation was the use of only two in the design and testing phase. This was necessitated by the COVID-19 pandemic and a nationwide strike that involved most of the hospitals within the CIN-N except for the two that were included.

Feed and fluid data collection was happening under real life conditions. The lack of structure in how the feed and fluid prescriptions were documented and also where the documentation was done resulted in poor quality of data. The levels of missing data and entry errors were higher in some hospitals compared

to others which would potentially lead to biased findings as the errors were not random. There was therefore a need to change the primary outcome from time to reach full feeds to avoid calling into question the validity of the quantitative results. My interest in this PhD thesis was on the effect of facilitation on the indicators of improved newborn feeding practices. Because weight was better documented, this became the primary outcome as it is a consequence of feeding and in one sense is a step further along the cause-and-effect pathway than prescribing (which does not capture what actually happens). So, in one way or another, this shift in primary outcome might have been beneficial as it captures a broader effect of facilitation and team behaviour beyond prescribing. In addition, the study settings have multiple preventable gaps affecting newborn care. The broad focus of the tool may therefore have distracted the staff from gaps affecting newborn feeding practices with them choosing to focus on issues that they considered more pressing to their hospitals. Nevertheless, this resulted in the improved quality of other aspects of newborn care not specific to newborn feeding practices.

A limitation of the CBA study was that there were only a few hospitals which was linked to the availability of resources (one facilitator attending two-weekly meetings). I, however tried to use the most rigorous design that was feasible. The few hospitals made it difficult to separate the effect of the hospitals from those of the interventions. Being a pragmatic study, there were other research activities in the study hospitals that may have had an effect on the outcome. Determining the effect of each categorical variable for a given intervention (for example the effect of the NEST programme) would be possible if there were a number of hospitals receiving the research activities and others that were not. There were other confounding factors such as newborns with severe congenital anomalies with increased risk of mortality. These were however not excluded as this information is not routinely collected as part of CIN-N data.

The short intervention duration may omit the effect of facilitation on improving newborn feeding practices (245) In addition, despite the meetings having more diverse participation than what has been

previously documented (50, 76), the study provided insufficient time for buy in from all the disciplines required to attend the audit meetings.

Conclusion

This PhD thesis demonstrated the need for a clinical audit tool that comprehensively covers the three periods in newborn care. The study illustrates that the use of a Human-Centred Design process enabled the researchers and the users to design a high-quality audit tool and implementation guide that can achieve its intended goals with efficiency, effectiveness and satisfaction while considering the capabilities and limitations of the end-users within their context.

The thesis illustrates the complexity of translating into practice an intervention that requires a change in behaviour from the existing policy. It demonstrates the need for facilitation which is a multifaceted implementation strategy that takes a team-based approach and that focuses on building trusting relationships and sharing common goals between the researcher and the health workers. Facilitation as an implementation strategy is flexible and can be modified to adapt to the contextual challenges that would influence the successful implementation of a complex intervention in different settings.

The thesis highlights the challenges in the documentation of newborn feed and fluid management which was a recurring gap in the study sites and in the wider CIN-N. This demonstrates that feed and fluid documentation challenges are complex with the solution being far from the problem and whose resolution may not have been satisfactorily identified. These challenges are however likely related to workforce gaps.

Based on these results, I believe that the facilitated implementation of the audit meetings contributed to the improving quality of newborn care. Despite there being no effect on the primary outcome, there was an effect on mortality that warrants further study as it could be important.

Recommendations

The scalability of the newborn clinical audit tool requires the creation of an enabling environment for change. To encourage behaviour change, the support of the newborn clinical audit by the MoH, training institutions and the professionals themselves is required. This would be through the development of a clear supportive policy that adopts the implementation guide as the SOP for the conduct of the newborn clinical audit must be in place. There is also the need to put in place measures to enforce implementation of action plans at the facility, county and national levels.

The facilitator interacts with multiple components of the implementation setting and thus requires intricate knowledge on the organisational characteristics that shape their behaviour. The success of the facilitation was also dependent on the access the facilitator had to the multiple actors who directly or indirectly influence newborn outcomes.(9) An external facilitator would require extensive periods of engagement to gain this level of trust and acceptance if not already part of the system. For sustainability, it would be prudent to train local facilitators from within the implementation settings who have bought into the innovation. Local facilitators would have a major impact on implementation outcomes, including the sustainability of practices once external support is removed. Research that has looked at the roles of both external and local facilitators has demonstrated that a collaboration between external facilitators and local facilitators is critical. It provides nuanced understanding of the factors influencing implementation of an innovation in a given context, and what processes need to change in order to increase its uptake.(164)

Further research work should be done to understand if and how newborn clinical audits are conducted in other public, private and faith-based organisations in Kenya that are involved in the in-hospital care of newborns and the need to scale up the newborn clinical audit using facilitation as a strategy.

The importance of quality improvement should be emphasized from the pre-service training of clinicians, nurses and health records officers. During this period, there should be significant weight placed on the importance of the use of data for quality improvement and hence strengthening proper documentation practices. QI initiatives such as the newborn clinical audit should be introduced during the pre-service training. In addition, the data generators (frontline workers) and data collectors (HRIOs) should be aware of the data to be collected as quality of care indicators. There is also need to emphasize the use of the MoH guidelines in the prescription of feeds and fluids. The guidelines have calculated the feed and fluid volumes for the newborns based on the weight and day of life (Appendices 2 and 3). This negates the need for the health workers to manually calculate the feed and fluid volumes and therefore reducing errors and enabling easy comprehension of the prescriptions. The required feed and fluid volumes based on the weight and day of life should be printed and strategically placed in the NBUs for easy reference by the health workers.

Additionally, there is a need for process mapping to identify where the gaps in newborn feeding practices are and act on them to prevent them from recurring.

There is a need for political will on adequate health staffing that has a significant impact on newborn quality of care. Adequate staffing will in addition enable the NBUs to have long-term staffing rather than relying on interns who are constantly rotating. Additionally, strengthening the leadership capacity of the NBU nursing team will allow for breaking the hierarchical barriers in the care teams.

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Appendices

Appendix 1: Quality of audit process score based on WHO recommendations on conduct of a facility-based audit process

Quality Process	Score 0	Score 1	Score 2
Presence of MDT	No MDT	Only clinicians	Other cadres
Presence of health workers in audit meetings	Only MDT	MDT and clinicians	MDT and other health workers
Frequent structured audit meetings	No meetings	Not structured. Held > 2-weekly.	Held at most 2-weekly.
Use of a structured audit tool.	No tool	Perinatal audit tool	Neonatal audit tool
Categorised modifiable factors	Not categorised	Phase delays	Level of health system in which it occurs.
Recommendation of solutions	None	Not based on modifiable factors.	Based on modifiable factors.
Implementation of recommendations	None	Not based on recommendations	Based on recommendations.

0-4 (Poorly conducted audit process)

5-9 (Moderately well conducted audit process)

10-14 (Well conducted audit process)

Appendix 2: Comprehensive newborn care protocols

1.5 Feeds and Fluids

Is the baby unstable? Characteristics of an unstable newborn include; Convulsions, Unconscious, severe respiratory distress, Distress evidenced by severe chest wall indrawing, absent bowel sounds.

Can the baby breastfeed? From weight 1500grams breastfeed, if not able to breastfeed, feed by cup. Health workers must have the skill of cup feeding and must teach the same to the mothers (section 3.5). If using EBM, show mother how to express breastmilk (section 3.5).

The Aim

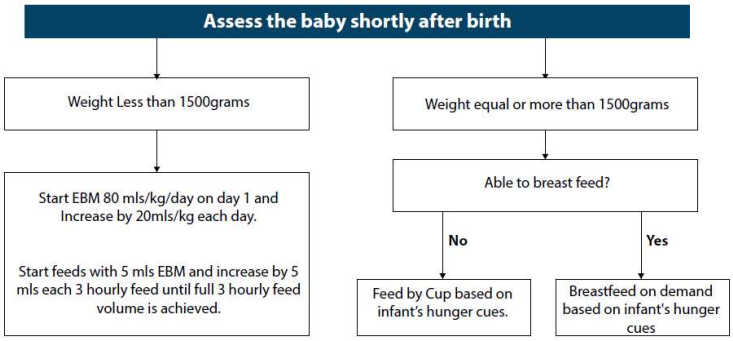
1. Weight gain – 15grams/kg/day
2. Appropriate time taken to reach full enteral feeds - Neonates <1000grams at birth – 2 weeks & neonates with birthweight 1000-1500grams – 1 week

a) **Feeding STABLE AND WELL babies birth weight less than 1.5 kg and equal or over 1.5kg**
Stable babies are well, without respiratory distress and do not have a congenital malformation as a contraindication to enteral feeding.

Stable babies' birthweight less than 1.5kg: Start with EBM 80mls/kg/day on day 1 and increase by 20mls/kg each day to max 180mls/kg/day. It may be possible to increase volumes further to as much as 200mls/kg/day but seek expert advice.

Stable babies' birthweight equal to or over 1.5kg: Assess ability to breastfeed.

1.5 a) Feeding Stable and Well Babies - birth weight less than 1.5 kg vs equal to or more than 1.5kg



Example: 1000gm baby
Day 1: 80mls/kg/day → 1kg X 80 = 80ml ÷ 8 feeds/day = 10mls 3hrly feeds. First feed 5mls, then 10mls 3hrly
Day 2: 100ml/kg/day
Day 3: 120ml/kg/day
Day 4: 140ml/kg/day
Day 5: 160ml/kg/day
Day 6: 180ml/kg/day

Three hourly NGT EBM feed volumes in milliliters (mls) for stable newborns with birth weight 1000 - 1499grams (Table includes NGT feed volumes for birthweight less than 1000grams if unsafe to give IVF)

Age	0.6kg	0.7kg	0.8kg	0.9kg	1.0kg	1.1kg	1.2kg	1.3kg	1.4kg	1.5kg
Day 1	6	7	8	9	10	11	12	13	14	15
Day 2	8	9	10	11	13	14	15	16	18	19
Day 3	9	11	12	14	15	17	18	20	21	23
Day 4	11	12	14	16	18	20	21	23	25	26
Day 5	12	14	16	18	20	22	24	26	28	30
Day 6	14	16	18	20	23	25	27	29	32	34

1.5 b) Feeding Unstable Babies - birth weight Less than 1.5 kg and equal to or more than 1.5kg

Three hourly NGT EBM feeds and ONE hourly IVF for UNSTABLE NEWBORNS with birth weight less than 1500grams

Age	0.6kg		0.7kg		0.8kg		0.9kg		1.0kg		1.1kg		1.2kg - 1.3kg		1.4kg - 1.5kg		Total daily fluid/ milk volume
	EBM 3hrly	IVF mls/hr	EBM 3hrly	IVF mls/hr	EBM 3hrly	IVF mls/hr	EBM 3hrly	IVF mls/hr	EBM 3hrly	IVF mls/hr	EBM 3hrly	IVF mls/hr	EBM 3hrly	IVF mls/hr	EBM 3hrly	IVF mls/hr	
Day 1		2		2		3		3		4		4		4		5	80ml/kg/day
Day 2	2	2	3	2	3	2	3	3	4	3	4	3	5	4	5	4	100ml/kg/day
Day 3	5	2	5	2	6	2	7	2	8	3	8	3	9	3	11	4	120ml/kg/day
Day 4	7	1	8	1	9	2	10	2	12	2	12	2	14	3	16	3	140ml/kg/day
Day 5	9	1	11	1	12	1	14	1	16	1	16	1	19	2	22	2	160ml/kg/day
Day 6	11	0	13	0	15	0	17	0	20	0	20	0	23	0	27	0	180ml/kg/day
Day 7	14	0	16	0	18	0	20	0	24	0	24	0	28	0	33	0	180ml/kg/day

Day 1– Give 2mls/kg of colostrum every 3 hours as trophic feeds on Day 1 after A, B and C are stabilized – DO NOT SUBTRACT THIS FROM THE IVF, THUS IVF REMAINS AS SHOWN IN THE CHART 80mls/kg/day

Newborn ≥ 1.5kg: Feeding / Fluid requirements

- **Well baby** - Immediate milk feeding **-Table A.** For first feed give 7.5mls and each feed increase by this amount until full daily volume reached
- **Day 1 - Unstable baby** start with IV 10% Dextrose for the first 24 hours. To stimulate the gut give 2mls/kg of colostrum via NGT every 3hrs once ABC are stabilized - **do not deduct this from IVF. Table B**
- **From Day 2,** start feeding with EBM via NGT (unless baby is still unstable) at 30ml/kg/day EBM. Increase the EBM feeds by 30m/kg day and reduce IV fluids to keep within the total daily volume until IVF stopped ie until full 3 hourly feed volume achieved appropriate for weight and postnatal age in days. Increase total feeds (IVF + EBM) by 20ml/kg/day to max of 150ml/kg/day. Once no longer on IVF increase EBM to max of 180ml/kg/day, but it may be possible to increase volumes further to as much as 200mls/kg/day but seek expert advice.**Table C**
- For IV fluids from Day 2, add Na+ 2-3mmol/kg/day (19mls/kg of normal saline) and K+ 1-2mmol/kg/day (0.5 - 1ml/kg/day of 15% KCl) to 10% dextrose solution.
- Always feed with EBM unless contra-indicated
- Maximum fluid that can be given intravenously is 150ml/kg/d.
- If signs of poor perfusion or fluid overload please ask for senior opinion on whether to give a bolus, step-up or step-down daily fluids.

Age	Total Daily Fluid / Milk Vol.
Day 1	60 mls/kg/day
Day 2	80 mls/kg/day
Day 3	100 mls/kg/day
Day 4	120 mls/kg/day
Day 5	140 mls/kg/day
Day 6	160 mls/kg/day
Day 7	180 mls/kg/day

A. Nasogastric 3hrly feed amounts for well babies on full volume feeds on day 1 and afterwards

Weight (kg)	1.5 to 1.6	1.7 to 1.8	1.9 to 2.0	2.1 to 2.2	2.3 to 2.4	2.5 to 2.6	2.7 to 2.8	2.9 to 3.0	3.1 to 3.2	3.3 to 3.4	3.5 to 3.6	3.7 to 3.8	3.9 to 4.0
Day 1	12	14	15	17	18	20	21	23	24	26	27	29	30
Day 2	15	18	20	22	24	26	28	30	32	34	36	38	40
Day 3	19	23	25	28	30	33	35	38	40	43	45	48	50
Day 4	24	27	30	33	36	39	42	45	48	51	54	57	60
Day 5	28	32	35	39	42	46	49	53	56	60	63	67	70
Day 6	32	36	40	44	48	52	56	60	64	68	72	76	80
Day 7	36	41	45	50	54	59	63	68	72	77	81	86	90

B. IV fluid rates in mls/hr for unstable newborns > 1.5kg who cannot be fed

Weight (kg)	1.5 to 1.59kg	1.6 to 1.7kg	1.8 to 1.9kg	2.0 to 2.1kg	2.2 to 2.3kg	2.4 to 2.5kg	2.6 to 2.7kg	2.8 to 2.9kg	3.0 to 3.1kg	3.2 to 3.3kg	3.4 to 3.5kg	3.6 to 3.7kg	3.8 to 3.9kg
Day 1	4	4	5	5	6	6	7	7	8	8	9	9	10
Day 2	5	6	6	7	8	8	9	10	10	11	12	12	13
Day 3	6	7	8	9	10	10	11	12	13	14	15	15	16
Day 4	8	9	10	11	12	13	14	15	16	17	18	19	20
Day 5+	9	10	11	12	13	15	16	17	18	19	20	22	23

C. Standard regimen for introducing NGT feeds in an unstable newborn ≥ 1.5kg after 24 hrs IV fluids

Weight (kg)	1.5 - 1.6kg		1.7 - 1.8kg		1.9 - 2.0kg		2.1 - 2.2kg		2.3 - 2.4kg		2.5 - 2.6kg		2.7 - 2.8kg		2.9 - 3.0kg	
	EBM 3hrly	IVF mls/hr	EBM 3hrly	IVF mls/hr	EBM 3hrly	IVF mls/hr	EBM 3hrly	IVF mls/hr	EBM 3hrly	IVF mls/hr	EBM 3hrly	IVF mls/hr	EBM 3hrly	IVF mls/hr	EBM 3hrly	IVF mls/hr
D-1	3	4	4	4	4	5	4	5	5	6	5	6	6	7	6	7
D-2	6	3	7	4	7	4	8	4	9	5	10	5	10	6	11	6
D-3	12	3	13	3	15	3	16	4	18	4	19	4	21	5	22	5
D-4	17	2	20	2	22	2	24	3	26	3	29	3	31	3	33	4
D-5	23	1	26	2	29	2	32	2	35	2	38	2	41	2	44	2
D-6	29	1	33	1	37	1	40	1	44	1	48	1	52	1	55	1
D-7	35	0	39	0	44	0	48	0	53	0	57	0	62	0	66	0

*Give 2mls/kg of colostrum every 3hours as trophic feeds on Day 1 after A, B and C are stabilized – **DO NOT SUBTRACT THIS FROM THE IVF.***

Newborn < 1.5kg: Feeding requirements (well newborns)

All babies <1.5 kg and well (without respiratory distress, who have not required BVM resuscitation, and do not have a congenital malformation as a contraindication to feeding) start feeds with EBM of 5 mls and increase by 5 mls **each 3 hourly** feed until full 3 hourly feed volume achieved (80 mls/kg/day on day 1 and increasing by 20mls/kg each day)

Always use EBM for NGT feeds unless contra-indicated

Causes of failure to gain weight should be carefully investigated; if underlying causes have been excluded case by case decisions should be made on how best to support nutritional intakes to enable growth

Fortifiers are not routinely required. For babies with poor weight gain, start EBM feeds with hind milk.

All preterms and low birth weight neonates should routinely receive recommended vitamin and mineral supplements at appropriate post-gestational ages.

It may be possible to increase volumes further to as much as 200mls/kg/day but seek expert advice.

Age	0.6kg	0.7kg	0.8kg	0.9kg	1.0kg	1.1kg	1.2kg	1.3kg	1.4kg	1.5kg
D-1	6	7	8	9	10	11	12	13	14	15
D-2	8	9	10	11	13	14	15	16	18	19
D-3	9	11	12	14	15	17	18	20	21	23
D-4	11	12	14	16	18	20	21	23	25	26
D-5	12	14	16	18	20	22	24	26	28	30
D-6	14	16	18	20	23	25	27	29	32	34

Newborn < 1.5kg: Feeding / Fluid requirements (Unstable newborns)

- **Day 1 - unstable newborn** (convulsions, unconscious, severe respiratory distress evidenced by severe chest wall indrawing, absent bowel sounds) start IV 10% Dextrose for 24hrs. To stimulate the gut, give 2mls/kg of colostrum via NGT every 3hrs to be started when A,B,C are stabilized - **do not deduct this from IVF!**
- **Day 2:** Start feeding with EBM via NGT (unless baby is still unstable) at 30ml/kg/day EBM. Increase the EBM feeds by 30ml/kg/day and reduce IV fluids to keep within the total daily volume until IVF stopped i.e. until full 3 hourly feed volume is achieved appropriate for weight and postnatal age in days. Increase total feeds (IVF + EBM) by 20ml/kg/day to max of 150ml/kg/day. Once no longer on IVF increase to max of 180ml/kg/day, but it may be possible to increase enteral feeds further to as much as 200mls/kg/day but seek expert advice.
- For IV fluids from Day 2, add Na+ 2-3mmol/kg/day (19mls/kg of normal saline) and K+ 1-2mmol/kg/day (0.5 - 1ml/kg/day of 15% KCl) to 10% dextrose solution.
- Always feed with EBM unless contra-indicated.
- Maximum fluid that can be given intravenously is 150ml/kg/d.

Age	Total Daily Fluid/Milk Vol.
Day 1	80 mls/kg/day
Day 2	100 mls/kg/day
Day 3	120 mls/kg/day
Day 4	140 mls/kg/day
Day 5	160 mls/kg/day
Day 6+	180 mls/kg/day

Hourly IV Fluid rates for unstable Newboms <1.5kg:
Using a burette / soluset with 60 drops = 1ml
then drip rate = mls/hr

Weight (kg)	8.0 to 0.9	0.9 to 1.0	1.1 to 1.2	1.3 to 1.4	1.4 to 1.5
Day 1	3	3	4	4	5
Day 2	4	4	5	5	6
Day 3	5	5	6	7	8
Day 4	5	6	6	8	9
Day 5+	6	7	7	9	10

Standard regimen for introducing NGT feeds for unstable newboms <1.5kg

	0.6kg		0.7kg		0.8kg		0.9kg		1.0-1.1kg		1.2-1.3kg		1.4-1.5kg	
	EBM 3 hrly	IVF mls/ hr	EBM 3 hrly	IVF mls/ hr	EBM 3 hrly	IVF mls/ hr	EBM 3 hrly	IVF mls/ hr	EBM 3 hrly	IVF mls/ hr	EBM 3 hrly	IVF mls/ hr	EBM 3 hrly	IVF mls/ hr
D-1		2		2		3		3		4		4		5
D-2	2	2	3	2	3	2	3	3	4	3	5	4	5	4
D-3	5	2	5	2	6	2	7	2	8	3	9	3	11	4
D-4	7	1	8	1	9	2	10	2	12	2	14	3	16	3
D-5	9	1	11	1	12	1	14	1	16	1	19	2	22	2
D-6	11	0	13	0	15	0	17	0	20	0	23	0	27	0
D-7	14	0	16	0	18	0	20	0	24	0	28	0	33	0

*Give 2mls/kg of colostrum every 3hours as trophic feeds on Day 1 after A, B and C are stabilized – **DO NOT SUBTRACT THIS FROM THE IVF.***

Appendix 4: Standard forms used in newborn units in CIN-N

Appendix 4a: Newborn unit admission record form

Newborn Unit Admission Record

Infant's details									
Name				**Date of Admission**	dd/mm/yyyy		**IP No.**		
DOB		**Age**	days	hrs	**Sex**	**F**☐ **M**☐ **Indeterminate**☐	**Gestation**	wks	
ROM	<18h☐ >=18h☐ unkn.☐	**Delivery**	SVD ☐ CS☐ Breech☐ Forceps☐ Vacuum☐		***If CS, type***	Elective☐ Emergency☐			
Multiple Delivery	**Y**☐ **N**☐	***If YES number?***	=		**BVM Resus at birth?**	**Y**☐ **N**☐			
APGAR	1m 5m 10m	**Born outside this facility?**	**Y**☐ **N**☐	***if Yes, born where?***	Home/Roadside☐	Other facility☐			
Mother's details									
Name		**IP No.**		**Age**		**Parity**	+		
Blood Grp	A☐ B☐ AB☐ O☐ unkn.☐	**Rhesus**	Pos☐ Neg☐ unkn.☐	**VDRL**	Pos☐ Neg☐ unkn.☐				
PMTCT Status	Pos☐ Neg☐ unkn.☐	**Mother ARVs**	**Y**☐ **N**☐	**Diabetes**	**Y**☐ **N**☐ unkn.☐				
Hypertension in Pregnancy	**Y**☐ **N**☐ unkn.☐	**APH**	**Y**☐ **N**☐	**Prolonged 2nd Stage**	**Y**☐ **N**☐ unkn.☐				

Mother's problems during pregnancy / labour & relevant maternal treatment

Any maternal illness / fever? Any maternal treatment for TB or antibiotics in labour? (***Describe***)

Mother's problems during pregnancy / labour & relevant maternal treatment

Any maternal illness / fever? Any maternal treatment for TB or antibiotics in labour? (***Describe***)

Infant's Presenting Problems & any treatment given

When did problems start, how did they progress and what are problems now?

History & Examination

Vital Signs	**Temp(⁰c)**		**Resp Rate**	bpm	**Pulse**	/min	**0_2 Sat**	%
Anthropometry	**Birth wt**	grams	**Weight now**	grams				
	Head circumference	cm	**Length**	cm				

Time baby seen	am/pm		**Any other important history and family / social history?**
Fever	**Y**☐	**N**☐	
Difficulty breathing	**Y**☐	**N**☐	
Difficulty feeding	**Y**☐	**N**☐	
Convulsions	**Y**☐	**N**☐	

C	Pallor/Anaemia	None☐	+☐	+++☐
	Murmur		Y☐	N☐
	If murmur is YES, describe in free text			
D	Can breastfeed?		Y☐	N☐
	Bulging fontanelle		Y☐	N☐
	Irritable		Y☐	N☐
	Tone	Normal☐ Increased☐ Reduced☐		
Abd.	Distension		Y☐	N☐
	Umbilicus	Clean☐ Local pus☐ Pus+red skin☐ Others ☐		

Birth defects? Y☐ N☐ ***if YES tick and describe***

Major GI Abnormality	☐	Neurotube defects/spina bifida	☐
Hydrocephalus	☐	Limb abnormalities	☐
Cleft lip/palate	☐	Birth Injury/abnormalities	☐
Microcephaly	☐		

Summary of Presentation and problems

List problems (most important **first**).

Investigations ordered-(record subsequent tests and all results in medical record)

Glucose	Y☐ N☐ =_____ mmol/l	**Bilirubin**	Y☐ N☐ =_____ µmol/l☐ / mg/dl☐

List other Investigations ordered

Apnoea	Y☐	N☐
Reduced/Absent movement	Y☐	N☐
Bloody stool	Y☐	N☐
Bilious Vomiting	Y☐	N☐

General Examination				
Skin	Bruising☐ Rash☐ Pustules☐ Mottling☐ Normal☐			
Jaundice	None☐	+☐	+++☐	
A & B	Cry	Normal☐ Weak/Absent☐ High pitched☐		
	Central Cyanosis		Y☐	N☐
	Indrawing	None/mild☐ Severe☐		
	Grunting		Y☐	N☐
	Good bilateral air entry		Y☐	N☐
	Crackles		Y☐	N☐
	Cap Refill (Sternal)	secs		

Further Examination

Neuro'- Describe any abnormal posture / movement and check reflexes (Sucking; Rooting; Grasp; Moro)

Further examination of Resp / CVS / GIT / GU / Skin / Birth Trauma?(Specify any abnormality**)**

Admission Diagnoses-Select ONE primary diagnosis (tick box indicating "1") and ANY secondary diagnoses (tick box indicating "2")

Birth asphyxia Severe/Encephalopathy☐ Mild/Moderate ☐	1☐	2☐	***Multiple Delivery***	1☐	2☐	***Other diagnoses (name below and indicate if primary diagnosis or secondary)***	
Preterm	1☐	2☐	***Newborn RDS***	1☐	2☐		1☐ 2☐
Neonatal sepsis	1☐	2☐	***Jaundice***	1☐	2☐		1☐ 2☐
Meconium aspiration	1☐	2☐	***Meningitis***	1☐	2☐		1☐ 2☐
			Birth Wt <2kg	1☐	2☐		1☐ 2☐

Clinician Name & Sign	**Time** am / pm	**Date** dd/mm/yyyy

Appendix 4b: Internal newborn unit transfer form

Mother's details													
Name				**Age**			**IP No.**						
Parity	**+**		**Gestation**	wks	**LMP**	dd/mm/yyyy	**EDD**	dd/mm/yyyy					
ANC attendance	**Y☐ N☐**		**Blood Grp**	A☐ B☐ AB☐ O☐ unkn☐			**Rhesus**	Pos☐ Neg☐ unkn☐					
VDRL	Pos☐ Neg☐ unkn.☐		**PMTCT Status**	Pos☐ Neg☐ unkn.☐			**Mother ARVs**	**Y☐ N☐**					
Diabetes	Pos☐ Neg☐ unkn.☐		**Current TB treatment**	**Y☐ N☐** unkn.☐			**Antibiotics**	**Y☐ N☐**					
Fever	**Y☐ N☐**		**APH**	**Y☐ N☐**			**Multiple PG**	**Y☐ N☐**	***if YES number? =***				
HTN in Pregnancy	**Y☐ N☐** unkn.☐		**Pre-eclampsia**	**Y☐ N☐**			**Eclampsia**	**Y☐ N☐**					
Any other maternal condition													
Current Maternal Drugs													
Delivery													
Labour	**1st Stg**	hr	**2nd Stg**	min	**Time of Delivery**	am/pm	**ROM**	<18h☐ >=18h☐ unkn.☐					
Fetal Distress	**Y☐ N☐**		**Thick Meconium**	**Y☐ N☐**	**If yes, Meconium grade? 1☐ 2☐ 3☐**								
Delivery	SVD☐ CS☐ Breech☐ Vacuum☐ Forceps☐		***If CS, type?***	Elective☐ Emergency☐									
Reason for Emergency CS													
BVM Resuscitation?	**Y☐ N☐**		**Placenta Complete?**	**Y☐ N☐**	**Abnormal Placenta?**	**Y☐ N☐**							
Specify Placenta Abnormalities													
Preventive care given	**OPV**	**Y☐ N☐**	**BCG**	**Y☐ N☐**	**TEO**	**Y☐ N☐**	**Vit K**	**Y☐ N☐**	**CHX**	**Y☐ N☐**			
Infant's Details													
Date of Birth	(dd/mm/yyyy)		**Sex**	**F☐ M ☐ Indeterminate☐**			**IP. No**						
Apgar	1m	5m	10m	**Birth Wt.**	grams		**Weight now**	grams					
Baby from postnatal ward?	**Y☐ N☐** ***if Yes Fill in Age and* BBA**						**Age**	days	hrs.				
Born outside this facility?	**Y☐ N☐** ***if Yes, born where?*** Home/Roadside☐ Other facility☐												
Reasons for referral to NBU													
Completed by(Name):					**Signature**								
Baby received on NBU by: **Time……am/pm**													

Appendix 4c: Comprehensive newborn monitoring chart

[HOSPITAL NAME]

COMPREHENSIVE NEWBORN MONITORING CHART

Version 2.7

Name		**IP NO**			**Sex M □ F □**				**D.O.A**				**D.O.B**		
Date today		**Diagnosis**													
Birth Wt	**gm**	***Interventions:***	***CPAP □***	***Oxygen □***	***Phototherapy □***				***Blood tranfusion □***				***Exchange transfusion □***		***KMC □***	
Daily Clinician Feed and Fluid prescription			Monitoring Freq___hrs | Time													
Day of Life	**Current Wt =** **gm**	**Vitals**	Temp (^{0}C)													
Total input(feed and fluid) 24hrs = **ml**			Pulse (b/min)													
Feed: BF □ EBM □ Term Formula □ Pre-Term Formula □			Resp Rate (b/min)													
Route: Cup□ NGT□ OGT□			Oxy Sat (%) or Cy^0 Cy$^+$													
Volume & Frequency = _____ml 3hrly □ 2hrly □			Resp Distress 0,+,+++													
Total 24hr Volume = _____ml			CPAP Pressure (cm H_2O)													
IV Fluid & Additives	**Vol (ml)** **Duration**	**Assessment**	FiO_2 (%)													
			Jaundice 0,+,+++													
			Apnoea Y/N													
			Blood Sugar (mmol/l)													
			Completed by (name)													
Other prescribing instructions		**Feed**	Breastfeeding sufficient Y/N													
			EBM vol given (ml)													
			Formula vol given (ml)													
		Fluid	IV volume given (ml)													
Clinician's name Time:			IV Line working Y/N													
Daily IV Fluid Nursing plan		**Output**	Vomit Y/N													
Start time:			Urine Y/N													
Hourly rate= _____ ml (____ drops/min)			Stool Y/N													
Planned vol = _____ ml in_____ hrs			Completed by (name)													

Morning shift notes — Total feed+fluid in this shift_____ ml — Completed by (name)
Category: A□ B□ C□ — Deficit_____ ml

Afternoon shift notes — Total feed+fluid in this shift_____ ml — Completed by (name)
Category: A□ B□ C□ — Deficit_____ ml

Night shift notes — Total feed+fluid in this shift_____ ml — Completed by (name)
Category: A□ B□ C□ — Total feed+fluid in 24hrs_____ ml — Deficit_____ ml

Jaundice 0 none, +mild(face),+++severe(feet) — Tick the category of baby after assessment — Alerts : circle readings outside normal range with red pen and action

Appendix 5: REDCap standard operating procedure

KEMRI Wellcome Trust Research Programme Nairobi
Health Services Unit

CIN - Standard Neonatal Tool PID 331

Codebook

Data Dictionary Codebook 12/14/2022 1:26pm

Collapse all instruments

#	Variable / Field Name	Field Label *Field Note*	Field Attributes (Field Type, Validation, Choices, Calculations, etc.)
Instrument: **Biodata** (biodata)			Collapse
1	id	Unique ID *Use format [hosp id][record id]*	text, Required Custom alignment: RH
2	random Show the field ONLY if: [age_recorded] = '1' and [age_recorded] = '0'	Randomized?	yesno 1, Yes 0, No Custom alignment: RH

3	hosp_id	Hospital ID	dropdown, Required 1, Pumwani Maternity Hospital 40, Nakuru Level 5 Hospital 41, Thika Level 5 Hospital 43, Homabay County Referral Hospital 44, Jaramogi Oginga Odinga Teaching and Referral Hospital 45, Naivasha Level 5 Hospital 51, Kiambu Level 5 Hospital 52, Machakos Level 5 Hospital 53, Mama Lucy Kibaki Hospital 54, Mbagathi County Hospital 55, Kerugoya County Referral Hospital 57, Karatina District Hospital 58, Nyeri County Referral Hospital 62, Kisumu County Hospital 64, Vihiga County Referral Hospital 63, Kakamega County General Teaching and Referral Hospital 66, Busia County Referral Hospital 68, Kitale County Referral Hospital 71, Embu Level 5 Teaching and Referral Hospital 76, Bungoma County Referral Hospital 80, World Friends/Ruaraka Neema Hospital 81, Migori County Hospital 17, Kenyatta National Hospital 88, Malindi Sub County Hospital Custom alignment: RH
4	ipno	Patients IPNO *(Input -1 for empty)*	text (integer), Required Custom alignment: RH
5	nar_used	Document Source	radio, Required 1, NAR 2, Free Text 3, PAR Custom alignment: RH
6	twin_delivery Show the field ONLY if: [is_minimum] = '0' and [is_minimum] = '1'	Twin delivery?	yesno 1, Yes 0, No Custom alignment: RH
7	multiple_delivery	Multiple Delivery	radio 1, Yes 2, No Custom alignment: RH

8	number_delivered Show the field ONLY if: [multiple_delivery] = '1'	Number	dropdown 2 | 2 3 | 3 4 | 4 5 | 5 6 | >5 -1 | Empty Custom alignment: RH
9	birth_wt	Birth Weight *Input -1 for empty*	text (number), Required Custom alignment: RH
10	birth_wt_units Show the field ONLY if: [birth_wt] > 0	Birth weight units	radio -1 | Empty 1 | Grams 2 | Kilograms Custom alignment: RH
11	date_of_birth	Date of birth *(for empty date type 1914-01-01))*	text (date_ymd), Required Custom alignment: RH
12	t_birth	Time of birth *((if empty leave blank))*	text Custom alignment: RH
13	date_adm	Admission Date *(for empty date type 1914-01-01)*	text (date_ymd), Required Custom alignment: RH
14	t_adm	Time of admission *((if empty leave blank))*	text Custom alignment: RH
15	t_seen	Time baby seen *((if empty enter -1))*	text Custom alignment: RH
16	date_discharge	Date of discharge/death *(for empty date type 1914-01-01))*	text (date_ymd), Required Custom alignment: RH
17	t_discharge	Time of discharge *((if empty leave blank))*	text Custom alignment: RH
18	leave_period	Is leave period?	yesno 1 | Yes 0 | No Custom alignment: RH
19	is_minimum	Is record minimum	text Custom alignment: RH
20	date_today	Today's date *Select 'Today'*	text (date_ymd), Required Custom alignment: RH
21	timestamp	Timestamp	text Custom alignment: RH
22	age_recorded	Age Recorded?	yesno, Required 1 | Yes 0 | No Custom alignment: RH
23	age_less_than_24hrs Show the field ONLY if: [age_recorded] = '1'	Age less than 24hrs	radio 1 | Yes 2 | No Custom alignment: RH Question number: NA

Instrument: **Weight Monitoring** (weight_monitoring) [Collapse]

40	weight_doc Show the field ONLY if: (([birth_wt] < 2.5 and [birth_wt] > 0 and [birth_wt_units]='2') or ([birth_wt] < 2500 and [birth_wt] > 0 and [birth_wt_units]='1')) and datediff([date_discharge] ,[date_adm],"d") >=7 and [birth_wt] >0	Is weight documented after admission?	yesno 1 Yes 0 No Custom alignment: RH
41	weight_1_units Show the field ONLY if: [weight_doc] = '1'	weight units	radio, Required -1 Empty 1 Grams 2 Kilograms Custom alignment: RH
42	weight_1 Show the field ONLY if: [weight_doc] = '1'	Weight One	text (number) Custom alignment: RH
43	date_1 Show the field ONLY if: [weight_doc] = '1'	Date Weight One was recorded.	text Custom alignment: RH
44	other_weight Show the field ONLY if: [weight_doc] = '1'	Other weight documented?	yesno 1 Yes 0 No Custom alignment: RH
45	weight_2_units Show the field ONLY if: [other_weight] = '1'	weight units	radio, Required -1 Empty 1 Grams 2 Kilograms Custom alignment: RH

46	weight_2 Show the field ONLY if: [other_weight] = '1'	Weight Two	text (number) Custom alignment: RH
47	date_2 Show the field ONLY if: [other_weight] = '1'	Date Weight Two was recorded.	text Custom alignment: RH
48	other_weight_2 Show the field ONLY if: [other_weight] = '1'	Other weight documented?	yesno 1 Yes 0 No Custom alignment: RH
49	weight_3_units Show the field ONLY if: [other_weight_2] = '1'	weight units	radio, Required -1 Empty 1 Grams 2 Kilograms Custom alignment: RH
50	weight_3 Show the field ONLY if: [other_weight_2] = '1'	Weight Three	text (number) Custom alignment: RH
51	date_3 Show the field ONLY if: [other_weight_2] = '1'	Date Weight Three was recorded.	text Custom alignment: RH
52	other_weight_3 Show the field ONLY if: [other_weight_2] = '1'	Other weight documented?	yesno 1 Yes 0 No Custom alignment: RH
53	weight_4_units Show the field ONLY if: [other_weight_3] = '1'	weight units	radio, Required -1 Empty 1 Grams 2 Kilograms Custom alignment: RH
54	weight_4 Show the field ONLY if: [other_weight_3] = '1'	Weight Four	text (number) Custom alignment: RH
55	date_4 Show the field ONLY if: [other_weight_3] = '1'	Date Weight Four was recorded.	text Custom alignment: RH
56	other_weight_4 Show the field ONLY if: [other_weight_3] = '1'	Other weight documented?	yesno 1 Yes 0 No Custom alignment: RH
57	weight_5_units Show the field ONLY if: [other_weight_4] = '1'	weight units	radio, Required -1 Empty 1 Grams 2 Kilograms Custom alignment: RH
58	weight_5 Show the field ONLY if: [other_weight_4] = '1'	Weight Five	text (number) Custom alignment: RH

59	date_5 Show the field ONLY if: [other_weight_4] = '1'	Date Weight Five was recorded.	text Custom alignment: RH
60	other_weight_5 Show the field ONLY if: [other_weight_4] = '1'	Other weight documented?	yesno 1 Yes 0 No Custom alignment: RH
61	weight_6_units Show the field ONLY if: [other_weight_5] = '1'	weight units	radio, Required -1 Empty 1 Grams 2 Kilograms Custom alignment: RH
62	weight_6 Show the field ONLY if: [other_weight_5] = '1'	Weight Six	text (number) Custom alignment: RH
63	date_6 Show the field ONLY if: [other_weight_5] = '1'	Date Weight Six was recorded.	text Custom alignment: RH
64	other_weight_6 Show the field ONLY if: [other_weight_5] = '1'	Other weight documented?	yesno 1 Yes 0 No Custom alignment: RH
65	weight_7_units Show the field ONLY if: [other_weight_6] = '1'	weight units	radio, Required -1 Empty 1 Grams 2 Kilograms Custom alignment: RH
66	weight_7 Show the field ONLY if: [other_weight_6] = '1'	Weight Seven	text (number) Custom alignment: RH
67	date_7 Show the field ONLY if: [other_weight_6] = '1'	Date Weight Seven was recorded.	text Custom alignment: RH
68	other_weight_7 Show the field ONLY if: [other_weight_6] = '1'	Other weight documented?	yesno 1 Yes 0 No Custom alignment: RH
69	weight_8_units Show the field ONLY if: [other_weight_7] = '1'	weight units	radio, Required -1 Empty 1 Grams 2 Kilograms Custom alignment: RH
70	weight_8 Show the field ONLY if: [other_weight_7] = '1'	Weight Eight	text (number) Custom alignment: RH
71	date_8 Show the field ONLY if: [other_weight_7] = '1'	Date Weight Eight was recorded.	text Custom alignment: RH

72	other_weight_8 Show the field ONLY if: [other_weight_7] = '1'	Other weight documented?	yesno 1 Yes 0 No Custom alignment: RH
73	weight_9_units Show the field ONLY if: [other_weight_8] = '1'	weight units	radio, Required -1 Empty 1 Grams 2 Kilograms Custom alignment: RH
74	weight_9 Show the field ONLY if: [other_weight_8] = '1'	Weight Nine	text (number) Custom alignment: RH
75	date_9 Show the field ONLY if: [other_weight_8] = '1'	Date Weight Nine was recorded.	text Custom alignment: RH
76	other_weight_9 Show the field ONLY if: [other_weight_8] = '1'	Other weight documented?	yesno 1 Yes 0 No Custom alignment: RH
77	weight_10_units Show the field ONLY if: [other_weight_9] = '1'	weight units	radio, Required -1 Empty 1 Grams 2 Kilograms Custom alignment: RH
78	weight_10 Show the field ONLY if: [other_weight_9] = '1'	Weight Ten	text (number) Custom alignment: RH
79	date_10 Show the field ONLY if: [other_weight_9] = '1'	Date Weight Ten was recorded.	text Custom alignment: RH
80	other_weight_10 Show the field ONLY if: [other_weight_9] = '1'	Other weight documented?	yesno 1 Yes 0 No Custom alignment: RH
81	weight_11_units Show the field ONLY if: [other_weight_10] = '1'	weight units	radio, Required -1 Empty 1 Grams 2 Kilograms Custom alignment: RH
82	weight_11 Show the field ONLY if: [other_weight_10] = '1'	Weight Eleven	text (number) Custom alignment: RH
83	date_11 Show the field ONLY if: [other_weight_10] = '1'	Date Weight Eleven was recorded.	text Custom alignment: RH

84	other_weight_11 Show the field ONLY if: [other_weight_10] = '1'	Other weight documented?	yesno 1 Yes 0 No Custom alignment: RH
85	weight_12_units Show the field ONLY if: [other_weight_11] = '1'	weight units	radio, Required -1 Empty 1 Grams 2 Kilograms Custom alignment: RH
86	weight_12 Show the field ONLY if: [other_weight_11] = '1'	Weight Twelve	text (number) Custom alignment: RH
87	date_12 Show the field ONLY if: [other_weight_11] = '1'	Date Weight Twelve was recorded.	text Custom alignment: RH
88	other_weight_12 Show the field ONLY if: [other_weight_11] = '1'	Other weight documented?	yesno 1 Yes 0 No Custom alignment: RH
89	weight_13_units Show the field ONLY if: [other_weight_12] = '1'	weight units	radio, Required -1 Empty 1 Grams 2 Kilograms Custom alignment: RH
90	weight_13 Show the field ONLY if: [other_weight_12] = '1'	Weight Thirteen	text (number) Custom alignment: RH
91	date_13 Show the field ONLY if: [other_weight_12] = '1'	Date Weight Thirteen was recorded.	text Custom alignment: RH
92	other_weight_13 Show the field ONLY if: [other_weight_12] = '1'	Other weight documented?	yesno 1 Yes 0 No Custom alignment: RH
93	weight_14_units Show the field ONLY if: [other_weight_13] = '1'	weight units	radio, Required -1 Empty 1 Grams 2 Kilograms Custom alignment: RH
94	weight_14 Show the field ONLY if: [other_weight_13] = '1'	Weight Fourteen	text (number) Custom alignment: RH
95	date_14 Show the field ONLY if: [other_weight_13] = '1'	Date Weight Fourteen was recorded.	text Custom alignment: RH

96	other_weight_14 Show the field ONLY if: [other_weight_13] = '1'	Other weight documented?	yesno 1 Yes 0 No Custom alignment: RH
97	weight_15_units Show the field ONLY if: [other_weight_14] = '1'	weight units	radio, Required -1 Empty 1 Grams 2 Kilograms Custom alignment: RH
98	weight_15 Show the field ONLY if: [other_weight_14] = '1'	Weight Fifteen	text (number) Custom alignment: RH
99	date_15 Show the field ONLY if: [other_weight_14] = '1'	Date Weight Fifteen was recorded.	text Custom alignment: RH
100	other_weight_15 Show the field ONLY if: [other_weight_14] = '1'	Other weight documented?	yesno 1 Yes 0 No Custom alignment: RH
101	weight_16_units Show the field ONLY if: [other_weight_15] = '1'	weight units	radio, Required -1 Empty 1 Grams 2 Kilograms Custom alignment: RH
102	weight_16 Show the field ONLY if: [other_weight_15] = '1'	Weight Sixteen	text (number) Custom alignment: RH
103	date_16 Show the field ONLY if: [other_weight_15] = '1'	Date Weight Sixteen was recorded.	text Custom alignment: RH
104	other_weight_16 Show the field ONLY if: [other_weight_15] = '1'	Other weight documented?	yesno 1 Yes 0 No Custom alignment: RH
105	weight_17_units Show the field ONLY if: [other_weight_16] = '1'	weight units	radio, Required -1 Empty 1 Grams 2 Kilograms Custom alignment: RH
106	weight_17 Show the field ONLY if: [other_weight_16] = '1'	Weight Seventeen	text (number) Custom alignment: RH
107	date_17 Show the field ONLY if: [other_weight_16] = '1'	Date Weight Seventeen was recorded.	text Custom alignment: RH

108	other_weight_17 Show the field ONLY if: [other_weight_16] = '1'	Other weight documented?	yesno 1 Yes 0 No Custom alignment: RH
109	weight_18_units Show the field ONLY if: [other_weight_17] = '1'	weight units	radio, Required -1 Empty 1 Grams 2 Kilograms Custom alignment: RH
110	weight_18 Show the field ONLY if: [other_weight_17] = '1'	Weight Eighteen	text (number) Custom alignment: RH
111	date_18 Show the field ONLY if: [other_weight_17] = '1'	Date Weight Eighteen was recorded.	text Custom alignment: RH
112	other_weight_18 Show the field ONLY if: [other_weight_17] = '1'	Other weight documented?	yesno 1 Yes 0 No Custom alignment: RH
113	weight_19_units Show the field ONLY if: [other_weight_18] = '1'	weight units	radio, Required -1 Empty 1 Grams 2 Kilograms Custom alignment: RH
114	weight_19 Show the field ONLY if: [other_weight_18] = '1'	Weight Nineteen	text (number) Custom alignment: RH
115	date_19 Show the field ONLY if: [other_weight_18] = '1'	Date Weight Nineteen was recorded.	text Custom alignment: RH
116	other_weight_19 Show the field ONLY if: [other_weight_18] = '1'	Other weight documented?	yesno 1 Yes 0 No Custom alignment: RH
117	weight_20_units Show the field ONLY if: [other_weight_19] = '1'	weight units	radio, Required -1 Empty 1 Grams 2 Kilograms Custom alignment: RH
118	weight_20 Show the field ONLY if: [other_weight_19] = '1'	Weight Twenty	text (number) Custom alignment: RH
119	date_20 Show the field ONLY if: [other_weight_19] = '1'	Date Weight Twenty was recorded.	text Custom alignment: RH

147	apgar_1min Show the field ONLY if: [apg_doc] = '1'	Apgar 1 minute *(select -1 if unrecorded)*	dropdown 0, 0 1, 1 2, 2 3, 3 4, 4 5, 5 6, 6 7, 7 8, 8 9, 9 10, 10 -1, Empty Custom alignment: RH Question number: NA
148	apgar_5min Show the field ONLY if: [apg_doc] = '1'	Apgar 5 minute *(select -1 if unrecorded)*	dropdown 0, 0 1, 1 2, 2 3, 3 4, 4 5, 5 6, 6 7, 7 8, 8 9, 9 10, 10 -1, Empty Custom alignment: RH Question number: NA
149	apgar_10min Show the field ONLY if: [apg_doc] = '1'	Apgar 10 minute *(select -1 if unrecorded)*	dropdown 0, 0 1, 1 2, 2 3, 3 4, 4 5, 5 6, 6 7, 7 8, 8 9, 9 10, 10 -1, Empty Custom alignment: RH Question number: NA
150	wt_now	Weight at admission (now) *kgs (enter -1 if not recorded)*	text (number), Required, Identifier Custom alignment: RH

159	time_of_admission_document Show the field ONLY if: [is_minimum] = '0' and [is_minimum] = '1'	Time of Admission Documented	yesno 1 Yes 0 No Custom alignment: RH
160	time_baby_seen Show the field ONLY if: [is_minimum] = '0' and [is_minimum] = '1'	Time baby seen	text (time) Custom alignment: RH Question number: NA
161	fever Show the field ONLY if: [is_minimum] = '0'	Fever	radio, Required 1 Yes 2 No -1 Empty Custom alignment: RH Question number: NA
162	fever_duration Show the field ONLY if: [fever] = '1'	Fever Duration (Less Than a day?)	radio 1 Yes 2 No -1 Empty Custom alignment: RH Field Annotation: @HIDDEN
163	fever_duration_in_days Show the field ONLY if: [fever] = '1' and [fever_duration] = '0'	Fever Duration (More Than a day?) *(Indicate in days)*	text Custom alignment: RH Field Annotation: @HIDDEN
164	difficulty_breathing	Difficulty breathing (DIB)	radio, Required 1 Yes 2 No -1 Empty Custom alignment: RH Question number: NA
165	diarrhoea Show the field ONLY if: [age_days] >= 3 and [age_days] < 3	Diarrhoea *(Indicate Yes, for age >= 3 days)*	radio 1 Yes 2 No -1 Empty Custom alignment: RH Field Annotation: @HIDDEN
166	severe_vomiting Show the field ONLY if: [is_minimum] = '0' and [is_minimum] = '1'	Severe vomiting(vomits everything)	radio 1 Yes 2 No -1 Empty Custom alignment: RH Field Annotation: @HIDDEN
167	difficulty_feeding	Difficulty feeding/breastfeeding	radio, Required 1 Yes 2 No -1 Empty Custom alignment: RH Question number: NA

168	convulsions Show the field ONLY if: [is_minimum] = '0'	Convulsions	radio, Required 1 Yes 2 No -1 Empty Custom alignment: RH Question number: NA
169	partial_focal_fits Show the field ONLY if: [is_minimum] = '0' and [is_minimum] = '1'	Partial / focal fits	radio 1 Yes 2 No -1 Empty Custom alignment: RH Field Annotation: @HIDDEN
170	level_of_activity Show the field ONLY if: [apg_doc] = '1'	Reduced/Absent movement	radio, Required 1 Yes 2 No -1 Empty Custom alignment: RH
171	apnoea Show the field ONLY if: [is_minimum] = '0'	Apnoea	radio, Required 1 Yes 2 No -1 Empty Custom alignment: RH Question number: NA
172	high_pitched_cry Show the field ONLY if: [is_minimum] = '0' and [apg_doc] = '1' and [apg_doc] = '0'	High pitched cry	radio 1 Yes 2 No -1 Empty Custom alignment: RH Field Annotation: @HIDDEN
173	infant_drugs Show the field ONLY if: [infant_drugs] = '1'	Infant drugs	sql (autocomplete) select value from redcap_data where project_id = 188 and field_name = 'drug' Custom alignment: RH
174	babys_history_complete	Section Header: *Form Status* Complete?	dropdown 0 Incomplete 1 Unverified 2 Complete
Instrument: **Baby's Examination** (examination)			Collapse
175	temperature_degrees_celciu	Temperature(degrees Celsius) *in degrees celsius to one decimal place (enter -1 if empty)*	text (number, Min: -1, Max: 42), Required Custom alignment: RH Question number: NA
176	respiratory_rate_rr_per_mi Show the field ONLY if: [is_minimum] = '0'	Respiratory rate- RR (per minute) *(input -1 for empty)*	text (number, Min: 20, Max: 110), Required Custom alignment: RH
177	heart_rate_hr_min Show the field ONLY if: [is_minimum] = '0'	Enter pulse value/Heart rate/HR(per minute) *indicate per min(input -1 for empty)*	text (number, Min: 60, Max: 200), Required Custom alignment: RH

178	oxygen_saturation_measured Show the field ONLY if: [is_minimum] = '0'	Oxygen saturation documented	radio, Required 1 Yes 0 No Custom alignment: RH Question number: NA
179	oxygen_saturation Show the field ONLY if: [oxygen_saturation_measured] = '1' and [is_minimum] = '0'	Oxygen saturation(%) *(Input -1 for empty)*	text (number) Custom alignment: RH Question number: NA
180	stirdor Show the field ONLY if: [is_minimum] = '0' and [is_minimum] = '1'	Section Header: *Airway and Breathing* Stridor	radio 1 Yes 0 No -1 Empty Custom alignment: RH Field Annotation: @HIDDEN
181	cry Show the field ONLY if: [is_minimum] = '0'	Cry	radio 1 Normal 2 Weak 3 Hoarse 4 High pitched -1 Empty Custom alignment: RH
182	central_cyanosis	Central cyanosis	dropdown, Required 1 Yes 2 No 3 Not specified -1 Empty Custom alignment: RH Question number: NA
183	indrawing	Indrawing	radio, Required 1 none/mild 2 severe 3 sternum -1 Empty Custom alignment: RH Question number: NA
184	grunting Show the field ONLY if: [is_minimum] = '0'	Grunting	radio, Required 1 Yes 0 No -1 Empty Custom alignment: RH Question number: NA
185	air_entry_bilateral Show the field ONLY if: [is_minimum] = '0'	Air entry bilateral	radio 1 Yes 0 No -1 Empty Custom alignment: RH Question number: NA

186	crackles Show the field ONLY if: [is_minimum] = '0'	Crackles/Crepitations	radio, Required 1 Yes 0 No -1 Empty Custom alignment: RH Question number: NA
187	cap_refill Show the field ONLY if: [is_minimum] = '0'	Section Header: *Circulation* Capillary Refill Time (CRT)	dropdown, Required 1 X-Indeterminate 6 1 second 2 2 seconds 3 3 seconds 4 More than 3 secs 5 2-3 seconds -1 Empty Custom alignment: RH
188	pallor_anaemia Show the field ONLY if: [is_minimum] = '0'	Pallor/Anaemia	dropdown, Required 1 none 2 +(mild/moderate) 3 +++(Severe) 4 Not classified -1 Empty Custom alignment: RH Question number: NA
189	suck_breastfeed	Section Header: *Disability* Can suck/breastfeed?	radio, Required 1 Yes 0 No -1 Empty Custom alignment: RH
190	bulging_fontanelle Show the field ONLY if: [is_minimum] = '0'	Bulging fontanelle	radio, Required 1 Yes 2 No/flat -1 Empty Custom alignment: RH Question number: NA
191	irritable Show the field ONLY if: [is_minimum] = '0'	Irritable	radio 1 Yes 0 No -1 Empty Custom alignment: RH Question number: NA
192	eye_pus Show the field ONLY if: [is_minimum] = '0' and [is_minimum] = '1'	Eyes Pus	radio 1 Yes 0 No -1 Empty Custom alignment: RH

193	tone	Tone	radio 1 Normal 2 Increased 3 Reduced -1 Empty Custom alignment: RH
194	redced_movement_floppy Show the field ONLY if: [is_minimum] = '0' and [is_minimum] = '1'	Reduced movement/floppy	radio 1 Yes 0 No -1 Empty Custom alignment: RH Question number: NA
195	umbilicus Show the field ONLY if: [is_minimum] = '0'	Umbilicus	dropdown 1 Clean 2 Local pus 3 Pus+red skin -1 Empty 4 Other Custom alignment: RH Question number: NA
196	skin Show the field ONLY if: [is_minimum] = '0' and [is_minimum] = '1'	Section Header: *General Examination* Skin	radio 1 Bruising 2 Rash 3 Pustules 4 None / Normal -1 Empty Custom alignment: RH Question number: NA
197	jaundice Show the field ONLY if: [is_minimum] = '0'	Jaundice(Yellowness of eyes)	dropdown, Required 1 none(0) 2 +(mild/moderate) 3 +++(severe) 4 Not classified -1 Empty Custom alignment: RH Question number: NA
198	gest_size Show the field ONLY if: [is_minimum] = '0' and [is_minimum] = '1'	Gest/Size	radio 1 Normal 2 Prem 3 SGA/wasted -1 Empty Custom alignment: RH Field Annotation: @HIDDEN

353	fluid_feed_monitoring_chart Show the field ONLY if: [date_of_birth] >= [date_adm]	Section Header: *Fluids Prescription* Fluids prescribed at admission using intravenous(I.V) route.	radio, Required 1 Yes 2 No Custom alignment: RH
354	date_fluid_presc Show the field ONLY if: [fluid_feed_monitoring_chart] = '1' and [is_minimum] = '0'	Date Fluid Prescribed	text Custom alignment: RH
355	intravenous_fluids_presc Show the field ONLY if: [fluid_feed_monitoring_chart] = '1' and [is_minimum] = '0'	IV fluids prescribed	dropdown 1 Half strength darrows(HSD) 2 Half strength darrows with 5% DW 3 10% DW(D10W) 4 Normal Saline(NS) 5 Ringers Lactate/Hartmanns(RL) 6 Other 7 5% DW(D5W) Custom alignment: RH
356	total_volume_of_iv_fluids Show the field ONLY if: [fluid_feed_monitoring_chart] = '1' and [is_minimum] = '0'	Total volume of IV fluids	text (number) Custom alignment: RH

357	duration_of_iv_fluid_presc Show the field ONLY if: [fluid_feed_monitoring_chart] = '1' and [is_minimum] = '0'	Duration of IV fluid prescribed *in hours*	text Custom alignment: RH Question number: NA
358	other_fluid Show the field ONLY if: [is_minimum] = '0' and [fluid_feed_monitoring_chart] = '1'	Other fluid	radio, Required 1 Yes 2 No Custom alignment: RH Question number: NA
359	other_fluid_prescribed Show the field ONLY if: [other_fluid] = '1' and [is_minimum] = '0'	Specify other fluid prescribed	dropdown 1 Half strength darrows(HSD) 2 Half strength darrows with 5% DW 3 10% DW(D10W) 4 Normal Saline(NS) 5 Ringers Lactate/Hartmanns(RL) 6 Other 7 5% DW(D5W) Custom alignment: RH Question number: NA
360	total_vol_of_other_fluid Show the field ONLY if: [other_fluid] = '1' and [is_minimum] = '0'	Total volume of other fluid prescribed *(total vol in mls)*	text (number) Custom alignment: RH
361	duration_prescribed Show the field ONLY if: [other_fluid] = '1' and [is_minimum] = '0'	Duration of flow prescribed *(time in hrs,if unrecorded fill -1)*	text (number) Custom alignment: RH Question number: NA
362	other_fluid_2 Show the field ONLY if: [is_minimum] = '0' and [other_fluid] = '1'	Other fluid 2	yesno 1 Yes 0 No Custom alignment: RH Question number: NA
363	specify_other_fluid_2_pres Show the field ONLY if: [other_fluid_2] = '1'	Specify other fluid 2 prescribed	dropdown 1 Half strength darrows(HSD) 2 Half strength darrows with 5% DW 3 10% DW(D10W) 4 Normal Saline(NS) 5 Ringers Lactate/Hartmanns(RL) 6 Other 7 5% DW(D5W) Custom alignment: RH Question number: NA
364	total_volume_of_fluid_2 Show the field ONLY if: [other_fluid_2] = '1'	Total volume of fluid 2 *total vol in mls*	text (number) Custom alignment: RH Question number: NA
365	duration_of_flow_2 Show the field ONLY if: [other_fluid_2] = '1'	Duration of flow_2 *in hours*	text Custom alignment: RH Question number: NA

366	fluids_presc_next_day Show the field ONLY if: [is_minimum] = '0'	Fluids prescribed next day after admission?	radio 1 Yes 2 No Custom alignment: RH
367	total_fluids_next_day Show the field ONLY if: [is_minimum] = '0' and [fluids_presc_next_day] = '1'	Total volume of IV fluids next day after admission	text (number)
368	child_prescribed_with_feed	Section Header: *Feeds* Child prescribed with feeds at admission	yesno, Required 1 Yes 0 No Custom alignment: RH Question number: NA
369	date_feeds_prescribed Show the field ONLY if: [child_prescribed_with_feed] = '1' and [is_minimum] = '0'	Date feeds prescribed	text Custom alignment: RH
370	type_of_feeds Show the field ONLY if: [child_prescribed_with_feed] = '1' and [is_minimum] = '0'	Type of feeds prescribed	dropdown 0 Test feed 1 Expressed Breast Milk (EBM) 2 Neonatal formula 3 Cow's milk 4 Mixed feeding 5 Other Custom alignment: RH Question number: NA
371	other_feeds Show the field ONLY if: [type_of_feeds] = '5' and [child_prescribed_with_feed] = '1' and [is_minimum] = '0'	Other feed	notes Custom alignment: RH
372	time_to_start_feeds_after Show the field ONLY if: [child_prescribed_with_feed] = '1' and [is_minimum] = '0' and [is_minimum] = '1'	Time to start feeds(after admission)	dropdown 1 < 1 hr 2 1-2 hrs 3 >2hrs -1 Empty Custom alignment: RH Question number: NA
373	feeding_route_prescribed Show the field ONLY if: [child_prescribed_with_feed] = '1' and [is_minimum] = '0'	Feeding route prescribed *'if feeding route indicated as OGT, select NG Tube'*	dropdown 1 NG Tube 2 Cup and spoon 3 Cup -1 Empty Custom alignment: RH
374	feed_volume Show the field ONLY if: [child_prescribed_with_feed] = '1' and [is_minimum] = '0'	Feed Volume *total vol in mls per feed*	text (number) Custom alignment: RH Question number: NA

375	freq_of_administration Show the field ONLY if: [child_prescribed_with_feed] = '1' and [is_minimum] = '0'	Frequency of administration	dropdown 1, hrly 2, 2hrly 3, 3hrly 4, 4hrly 5, 5hrly 6, 6hrly 7, Test Feed -1, Empty Custom alignment: RH
376	date_feeds_only_presc Show the field ONLY if: [child_prescribed_with_feed] = '1' or [fluid_feed_monitoring_chart] = '1' and [is_minimum] = '0'	Date feeds only prescribed *(for empty date 1914-01-01)*	text Custom alignment: RH
377	feeds_presc_next_day Show the field ONLY if: [child_prescribed_with_feed] = '1' or [child_prescribed_with_feed] = '0'	Feeds prescribed next day after admission?	yesno 1, Yes 0, No Custom alignment: RH
378	date_feeds_first_presc Show the field ONLY if: [child_prescribed_with_feed] = '0' and [feeds_presc_next_day] = '0'	Date when feeds first prescribed *(capture date when feeds first prescribed if not prescribed during admission or next day after admission)*	text, Required Custom alignment: RH
379	type_feed_presc_next_day Show the field ONLY if: [feeds_presc_next_day]= '1'	Type of feed prescribed next day after admission.	dropdown 0, Test feed 1, Expressed Breast Milk (EBM) 2, Neonatal formula 3, Cow's milk 4, Mixed feeding 5, Other Custom alignment: RH
380	nxtday_feed_rt_presc Show the field ONLY if: [feeds_presc_next_day]= '1'	Feeding route prescribed *'If feeding route indicated as OGT, select NG Tube'*	dropdown 1, NG Tube 2, Cup and spoon 3, Cup -1, Empty
381	freq_of_administration_2 Show the field ONLY if: [feeds_presc_next_day] = '1' and [is_minimum] = '0' and ([hosp_id] = '17' or [hosp_id] = '53' or [hosp_id] = '54' or [hosp_id] = '72')	Frequency of administration	dropdown 1, hrly 2, 2hrly 3, 3hrly 4, 4hrly 5, 5hrly 6, 6hrly 7, Test Feed -1, Empty Custom alignment: RH

382	total_feeds_presc_next_day Show the field ONLY if: [feeds_presc_next_day]= '1'	Total volume of feeds prescribed next day after admission.	text (number) Custom alignment: RH
383	total_input Show the field ONLY if: [fluid_feed_monitoring_chart] ='1' or [fluids_presc_next_day] ='1' or [child_prescribed_with_feed]='1' or [feeds_presc_next_day]='1'	Total Input (feeds + fluids)	text (number)
384	baby_breastfeeding	Is the baby breastfeeding?	yesno, Required 1 Yes 0 No Custom alignment: RH
385	phototherapy	Section Header: *Phototherapy* Phototherapy ordered/given on the day of admission?	radio, Required 1 Yes 2 No Custom alignment: RH Question number: NA
386	photo_therapy_on_any_other Show the field ONLY if: [phototherapy] = '2'	Phototherapy ordered/given on any other day during hospitalization?	radio, Required 1 Yes 2 No Custom alignment: RH
387	start_date_phototherapy Show the field ONLY if: [photo_therapy_on_any_other]='1'	Start date of photo-therapy *If unrecorded enter 1914-01-01*	text, Required Custom alignment: RH
388	stop_date_phototherapy Show the field ONLY if: [photo_therapy_on_any_other]='1' or [phototherapy] ='1'	Stop date of phototherapy *If unrecorded enter 1914-01-01*	text, Required Custom alignment: RH
389	k_mother_care	Section Header: *Kangaroo Mother Care* Was Kangaroo Mother Care(KMC) given?	yesno, Required 1 Yes 0 No Custom alignment: RH
390	supportive_care_complete	Section Header: *Form Status* Complete?	dropdown 0 Incomplete 1 Unverified 2 Complete

Appendix 6: Ethical approval

Appendix 6a: KNH-UoN ethical approval

UNIVERSITY OF NAIROBI
COLLEGE OF HEALTH SCIENCES
P O BOX 19676 Code 00202
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KNH-UON ERC
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Facebook: https://www.facebook.com/uonknh.erc
Twitter: @UONKNH_ERC https://twitter.com/UONKNH_ERC

KENYATTA NATIONAL HOSPITAL
P O BOX 20723 Code 00202
Tel: 726300-9
Fax: 725272
Telegrams: MEDSUP, Nairobi

Ref: KNH-ERC/A/14

17th January 2021

KENYATTA NATIONAL HOSPITAL * APPROVED 17 JAN 2021 KNH/UoN-ERC * P.O. BOX 20723 - 00202 NAIROBI *

Dr. Esther Muthoni Ogola
PhD Candidate
Dept. of Paediatrics and Child Health
School of Medicine
College of Health Sciences
University of Nairobi

Dear Dr. Ogola

RESEARCH PROPOSAL – DEVELOPING A NEWBORN UNIT AUDIT PROCESS AND ASSESSING THE IMPACT OF FACILITATED IMPLEMENTATION OF THE PROCESS ON OVERCOMING MODIFIABLE FACTORS IN PRETERM FEEDING PRACTICES (P330/06/2020)

This is to inform you that the KNH- UoN Ethics & Research Committee (KNH- UoN ERC) has reviewed and **approved** your above research proposal. The approval period is 17th January 2021 – 16th January 2022.

This approval is subject to compliance with the following requirements:

a. Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
b. All changes (amendments, deviations, violations etc.) are submitted for review and approval by KNH-UoN ERC before implementation.
c. Death and life threatening problems and serious adverse events (SAEs) or unexpected adverse events whether related or unrelated to the study must be reported to the KNH-UoN ERC within 72 hours of notification.
d. Any changes, anticipated or otherwise that may increase the risks or affect safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH- UoN ERC within 72 hours.
e. Clearance for export of biological specimens must be obtained from KNH- UoN ERC for each batch of shipment.
f. Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. (*Attach a comprehensive progress report to support the renewal*).
g. Submission of an *executive summary* report within 90 days upon completion of the study. This information will form part of the data base that will be consulted in future when processing related research studies so as to minimize chances of study duplication and/ or plagiarism.

Protect to discover

For more details consult the KNH- UoN ERC website**http://www.erc.uonbi.ac.ke**

Yours sincerely,

PROF. M. L. CHINDIA
SECRETARY, KNH-UoN ERC

c.c. The Principal, College of Health Sciences, UoN
The Senior Director, CS, KNH
The Chairperson, KNH- UoN ERC
The Assistant Director, Health Information Dept, KNH
The Dean, School of Medicine, UoN
The Chair, Dept. of Paediatrics and Child Health, UoN
Supervisors: Prof. Grace Irimu, Dept.of Paediatrics and Child Health, UoN
Prof. Mike English, Dept.of Tropical Medicine and Global Health, Medicine and Paediatrics, Oxford University
Dr. Jalemba Aluvaala, Dept.of Paediatrics and Child Health, UoN

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Twitter: @UONKNH_ERC https://twitter.com/UONKNH_ERC

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Ref. No.KNH/ERC/R/128

31st July 2023

Dr. Esther Muthoni Ogola
PhD Candidate
Dept. of Paediatrics & Child Health
School of Medicine
Faculty of Health Sciences
University of Nairobi

Dear Dr. Ogola,

Re: Approval of Annual Renewal – Developing a newborn unit audit process and assessing the impact of facilitated implementation of the process on overcoming modifiable factors in preterm feeding practices (P330/06/2020)

Your communication dated 24th July 2023 refers.

This is to acknowledge receipt of the study progress report and hereby grant annual extension of approval for ethics research protocol P330/06/2020.

The approval dates are 17th January 2023 – 16th January 2024.

This approval is subject to compliance with the following requirements:

a) Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
b) All changes (amendments, deviations, violations etc.) are submitted for review and approval by KNH- UoN ERC before implementation.
c) Death and life threatening problems and severe adverse events (SAEs) or unexpected adverse events whether related or unrelated to the study must be reported to the KNH- UoN ERC within 72 hours of notification.
d) Any changes, anticipated or otherwise that may increase the risks or affect safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH- UoN ERC within 72 hours.
e) Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. (*Attach a comprehensive progress report to support the renewal*).

f) Clearance for export of biological specimens must be obtained from KNH- UoN-Ethics & Research Committee for each batch of shipment.

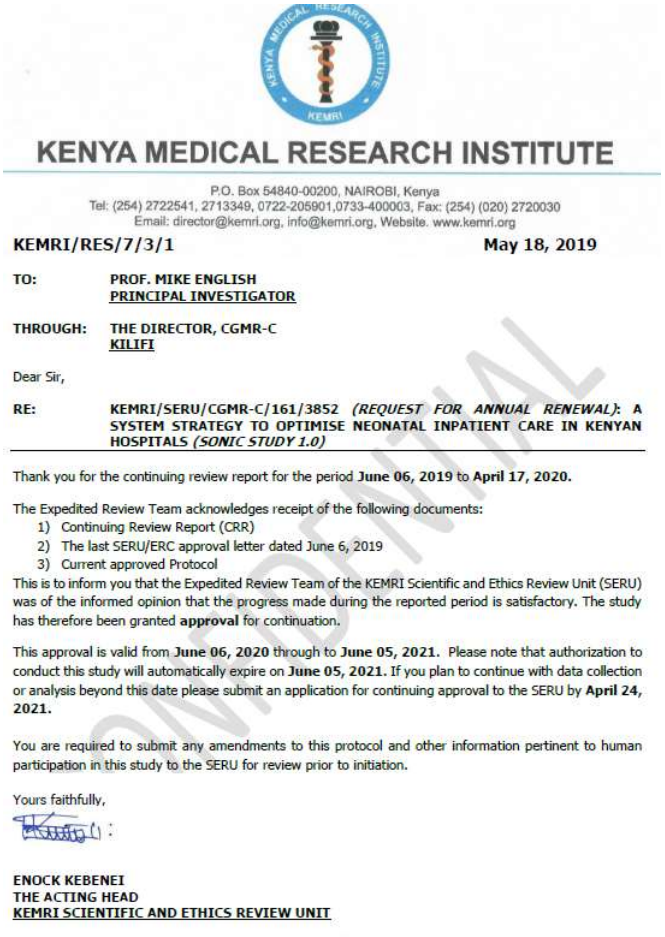
g) Submission of an *executive summary* report within 90 days upon completion of the study. This information will form part of the data base that will be consulted in future when processing related research studies so as to minimize chances of study duplication and/or plagiarism.

Yours sincerely,

PROF. BEATRICE K.M. AMUGUNE
SECRETARY, KNH- UoN ERC

cc. The Principal, college of Health Sciences, UoN
The Senior Director, Clinical Services, KNH
The Chair, KNH-UoN ERC

Appendix 6b: Ethical approval SONIC study



KENYA MEDICAL RESEARCH INSTITUTE

P.O. Box 54840-00200, NAIROBI, Kenya
Tel: (254) 2722541, 2713349, 0722-205901,0733-400003, Fax: (254) (020) 2720030
Email: director@kemri.org, info@kemri.org, Website. www.kemri.org

KEMRI/RES/7/3/1 **May 18, 2019**

TO: **PROF. MIKE ENGLISH**
PRINCIPAL INVESTIGATOR

THROUGH: **THE DIRECTOR, CGMR-C**
KILIFI

Dear Sir,

RE: **KEMRI/SERU/CGMR-C/161/3852 *(REQUEST FOR ANNUAL RENEWAL)*: A SYSTEM STRATEGY TO OPTIMISE NEONATAL INPATIENT CARE IN KENYAN HOSPITALS *(SONIC STUDY 1.0)***

Thank you for the continuing review report for the period **June 06, 2019** to **April 17, 2020.**

The Expedited Review Team acknowledges receipt of the following documents:

1) Continuing Review Report (CRR)
2) The last SERU/ERC approval letter dated June 6, 2019
3) Current approved Protocol

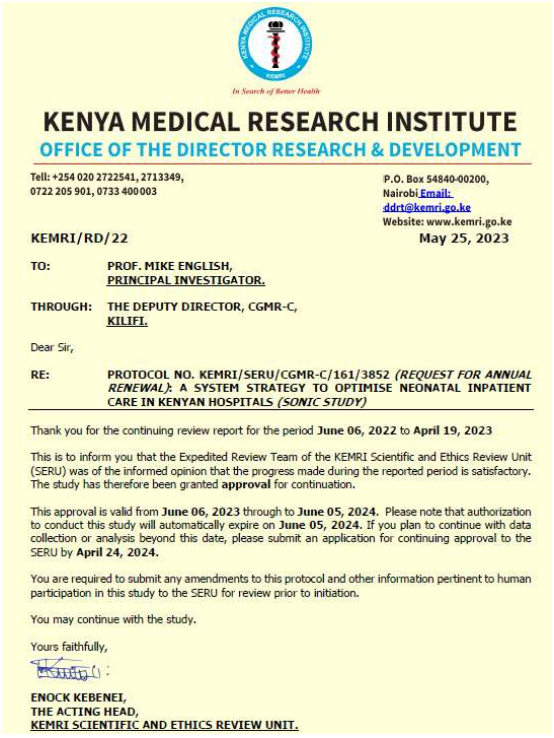
This is to inform you that the Expedited Review Team of the KEMRI Scientific and Ethics Review Unit (SERU) was of the informed opinion that the progress made during the reported period is satisfactory. The study has therefore been granted **approval** for continuation.

This approval is valid from **June 06, 2020** through to **June 05, 2021.** Please note that authorization to conduct this study will automatically expire on **June 05, 2021.** If you plan to continue with data collection or analysis beyond this date please submit an application for continuing approval to the SERU by **April 24, 2021.**

You are required to submit any amendments to this protocol and other information pertinent to human participation in this study to the SERU for review prior to initiation.

Yours faithfully,

ENOCK KEBENEI
THE ACTING HEAD
KEMRI SCIENTIFIC AND ETHICS REVIEW UNIT



In Search of Better Health

KENYA MEDICAL RESEARCH INSTITUTE
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Tell: +254 020 2722541, 2713349,
0722 205 901, 0733 400 003

P.O. Box 54840-00200,
Nairobi Email:
ddrt@kemri.go.ke
Website: www.kemri.go.ke

KEMRI/RD/22 **May 25, 2023**

TO: **PROF. MIKE ENGLISH,**
PRINCIPAL INVESTIGATOR.

THROUGH: **THE DEPUTY DIRECTOR, CGMR-C,**
KILIFI.

Dear Sir,

RE: **PROTOCOL NO. KEMRI/SERU/CGMR-C/161/3852 *(REQUEST FOR ANNUAL RENEWAL)*: A SYSTEM STRATEGY TO OPTIMISE NEONATAL INPATIENT CARE IN KENYAN HOSPITALS *(SONIC STUDY)***

Thank you for the continuing review report for the period **June 06, 2022** to **April 19, 2023**

This is to inform you that the Expedited Review Team of the KEMRI Scientific and Ethics Review Unit (SERU) was of the informed opinion that the progress made during the reported period is satisfactory. The study has therefore been granted **approval** for continuation.

This approval is valid from **June 06, 2023** through to **June 05, 2024.** Please note that authorization to conduct this study will automatically expire on **June 05, 2024.** If you plan to continue with data collection or analysis beyond this date, please submit an application for continuing approval to the SERU by **April 24, 2024.**

You are required to submit any amendments to this protocol and other information pertinent to human participation in this study to the SERU for review prior to initiation.

You may continue with the study.

Yours faithfully,

ENOCK KEBENEI,
THE ACTING HEAD,
KEMRI SCIENTIFIC AND ETHICS REVIEW UNIT.

Appendix 6c: Ethical approval CIN-N study

KENYA MEDICAL RESEARCH INSTITUTE

P.O. Box 54840-00200, NAIROBI, Kenya
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KEMRI/RES/7/3/1 **May 07, 2020**

TO: **PROF. MIKE ENGLISH**
PRINCIPAL INVESTIGATOR.

THROUGH: **THE DIRECTOR, CGMR-C**
KILIFI

Dear Sir,

RE: **SERU PROTOCOL NO. 3459 (*REQUEST FOR ANNUAL RENEWAL*): A CLINICAL INFORMATION NETWORK- A TECHNICAL COLLABORATION WITH THE MINISTRY OF HEALTH AND COUNTY HOSPITALS TO SUPPORT AND IMPROVE STRATEGIES FOR AUDIT AND HEALTH SERVICE EVALUATION**

Thank you for the continuing review report for the period **May 11, 2019** to **March 23, 2020**.

This is to inform you that the Expedited Review Team of the KEMRI Scientific and Ethics Review Unit (SERU) was of the informed opinion that the progress made during the reported period is satisfactory. The study has therefore been **granted approval.**

This approval is valid from **May 11, 2020** through to **May 10, 2021**. Please note that authorization to conduct this study will automatically expire on **May 10, 2021**. If you plan to continue with data collection or analysis beyond this date please submit an application for continuing approval to the SERU by **March 29, 2021.**

You are required to submit any proposed changes to this study to the SERU for review and the changes should not be initiated until written approval from the SERU is received. Please note that any unanticipated problems resulting from the implementation of this study should be brought to the attention of the SERU and you should advise them when the study is completed or discontinued.

You may continue with the study.

Yours faithfully,

ENOCK KEBENEI,
THE ACTING HEAD,
KEMRI SCIENTIFIC AND ETHICS REVIEW UNIT.

Appendix 7: Informed consent form for focus group discussions

This informed consent form is for health workers participating in a group discussion on the facilitators and barriers of the newborn unit audit process.
Principal investigator: Dr. Muthoni Ogola
Organisation: University of Nairobi
Sponsor: Initiative to Develop African Research Leaders (IDEAL)
Study Title: "Developing a newborn unit audit process and assessing the effect of facilitated implementation of the process to overcome modifiable factors in preterm feeding practices."
This Informed Consent Form has two parts:
• Information Sheet
• Certificate of Consent

You will be given a copy of the full Informed Consent Form to keep.
PART I: Information Sheet
Introduction
My name is Dr. Muthoni Ogola and I am currently studying for a research fellowship degree at the University of Nairobi. We are conducting a research study on the impact of the newborn unit audit process in identifying modifiable factors in preterm feeding practices. I am going to give you information on the study and then invite you to be part of this research. Before you decide, you can talk to anyone you feel comfortable with about the research.
There may be some words that you do not understand. Please ask me to stop as we go through the information and I will take time to explain. If you have any questions later.
A well conducted audit process is a quality improvement initiative that aims to identify the modifiable factors in patient care by determining if the care provided was consistent with evidence-based guidelines. My work focuses on designing and implementing a standardised newborn audit process in County Hospitals in Kenya.
Type of research intervention
I will conduct a group discussion with health care workers who have participated in the audit process to identify the facilitators and barriers in conducting audits in the facility.
Your participation in this research is entirely voluntary. It is your choice whether to participate or not.
Study procedure and duration
If you agree to participate in the study, I will invite you for a group discussion session with 5-7 other participants from your hospital who have attended the newborn unit audit meetings. During the group discussion sessions, I will note responses from the group in a field diary. I will not indicate any participant's name or details.
Risks
There are no risks to participating in this study as no identification information will be used and everything discussed will be confidential. We will strictly discuss facilitators and barriers within the system and not individual people.

Benefits
There are no individual benefits to participating in the study, however, this will enable the research team advice the Ministry of Health on strategies to improve the implementation process nation-wide.
Re-imbursement
There will be no re-imbursement for participating in this group discussion.
Confidentiality

The information that we obtain from this research project will be kept confidential. Information about you will be coded and no names will be used. I am the only person who will know who the codes belong to.

Sharing of results

The knowledge that we get from conducting this research will be shared with the Hospital Management Team of your hospital before it is made widely available to the public. Confidential information will not be shared. We will conduct a feedback forum for all newborn unit health workers at the end of the study to provide feedback on our study results. At the end of the study, we will also publish the results so that other interested people may learn from our research. The information that will be provided to the hospital team and published will not have any identifiers that can be linked back to you.

Right to Refuse or Withdraw

You do not have to take part in this research if you do not wish to do so and refusing to participate will not affect you or your hospital in any way.

Who to Contact?

If you have any questions you may ask them now or later, even after the study has started. If you wish to ask questions later, you may contact me using this address or telephone number.

Muthoni Ogola
MOgola@kemri-wellcome.org
Telephone No: 0722435015

You may also contact my supervisors using these contacts:

Prof. Grace Irimu,
Email: GIrimu@kemri-wellcome.org
Telephone number: 0722564600

Prof. Mike English
Email: MEnglish@kemri-wellcome.org

Dr. Jalemba Aluvaala
Email: JAluvaala@kemri-wellcome.org
Telephone number: 0722217034

This proposal has been reviewed and approved by the Kenyatta National Hospital-University of Nairobi Ethics and Research Committee, which is a committee whose task it is to make sure that research participants are protected from harm.

You may contact the ethics committee using this address or telephone number:

Kenyatta National Hospital/University of Nairobi Ethics and Research Committee,
College of Health Sciences,
P.O. Box 19676, Code 00202, Nairobi.
Telephone number: 0729 406939, email address: uonknh_erc@uonbi.ac.ke

You can ask me any questions about any part of the research study, if you wish to. Do you have any questions?

PART II: Certificate of Consent

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked, have been answered to my satisfaction. I consent voluntarily to participate in this research.

Print Name of Participant_____ Witness _____
Signature of Participant _____ Signature _____
Name of investigator _____
Signature of investigator _____

Appendix 8: Focus group discussion guides

Group one facilitation guide

Group One Facilitation	
9.15 – 10.00 am	Participants settle down into the groups. Group facilitator and moderator introduce themselves and facilitator requests participants to turn on videos for the group session. They explain that this will improve interpersonal relations. Group facilitator asks participants to introduce themselves. Group facilitator sets ground rules for the session. Participants encouraged to remain on mute until asked to speak. Participants asked to raise hand or type questions, comments or clarifications in chat box. The discussion regarding the issues raised will be led by the group moderator. Group facilitator will explain the group objective which is to determine how audits are conducted in the different County hospitals and the facilitators and barriers to this process. The facilitator will encourage open discussion by assuring participants that there are no wrong answers only differing points of view and participants are encouraged to share their points of view even if they differ from others. The facilitator will let participants know that the session is being recorded for consumption by the researchers after the workshop and will not be shared with anyone else. The facilitator will use a guide to probe the participants into having an in-depth discussion. The moderator will document responses on the white board in verbatim. These will then be compiled after the session. After the session, participants are asked to take a 15-minute tea break.
11.15 – 11.25 am (10 mins)	Participants settle down into the groups. Group facilitator requests participants to turn on videos for the group session. They explain that this will improve interpersonal relations. Group facilitator sets ground rules for the session. Participants encouraged to remain on mute until asked to speak. Participants asked to raise hand or type questions, comments or clarifications in chat box. The discussion regarding the issues raised will be led by the group moderator. Group facilitator explains group objectives and role of group participants. Group objectives will be: To arrive at consensus on the role of the audit team/committee. To arrive at consensus on the size and composition of the audit team/committee. Participant roles – To arrive at consensus on these two aspects of the audit process taking into consideration the strengths and weaknesses within our setting. Emphasize that the group's work will contribute to the audit process guide.
11.25 – 11.45 am (20 mins)	**Creating user personas.** Group facilitator to explain the concept of creating user personas to the group. To represent the different types of users that may be involved in the audit process. To consider the facilitators and barriers that these users may experience during the audit process. (These will be compiled before the session and shared with the group facilitators. Facilitator will project these onto the screen) Explain that this will help with understanding the user's needs, experiences, behaviours and goals and design with these in mind. The participants will suggest a cadre to work with, they will give a name, gender, age and daily tasks of this user.

	The group facilitator will ask participants to contribute by raising their hands and will speak when chosen to speak. They will encourage participation from the entire group and avoid dominance of some participants. The group facilitator will get consensus on each character of the user persona before moving on. The moderator of the group will document all these on the whiteboard (may draw a character to represent the persona). After all characteristics are included, the facilitator will conclude this session and move on to the group consensus process. (see below)
11.45 – 12.30 pm (45 minutes)	The group facilitator will explain the group process to the participants. The 4 steps will be explained and any questions arising addressed. Step 1 – In this step, the facilitator presents one question at a time to the participants both verbally and in written form and the participants will each silently and independently write down their key ideas in response to the questions. The ideas should be listed in order of their considered priority. Step 2 – In this step, the facilitator will go through the group participant list and get one key idea from each member at a time. These will then be recorded on the Zoom whiteboard. This will happen until all responses have been exhausted. Step 3 - Each point on the whiteboard will be discussed in detail and clarifications made on areas that may not be clear – discussion will be moderated by the group moderator. Step 4 - Voting on ideas will be using the polling function on zoom. After the clarification stage, the members will be asked to rank their ideas from most important to least important through a poll. The poll responses will be made visible to the group members at the end of the polling phase. **1st consensus activity – Role of audit team/committee** **Step 1 (10 minutes)** Facilitator presents 1st question to the participants both verbally and in written form. (The moderator will write this question on the virtual whiteboard) **The 1st question will be what should the role of the audit team/committee be?** The participants will each silently and independently write down their key ideas in response to the questions. They will do this on their own writing material. There will be no discussions going on at this stage. Participants will be encouraged to type in the chat box if they have any questions to avoid disrupting the group. These will be addressed by the moderator. **Step 2 (10 minutes)** The facilitator will use the participant list and get one response from each member at a time. This will happen until all the responses from all participants have been exhausted. The moderator will record these responses verbatim on the virtual whiteboard as they are read out. **Step 3 (10 minutes)** The facilitator will go through each response on the whiteboard and ask the participants to raise their hands if there are any points that are not clear. The facilitator will then seek clarification on these points from the participants who raised them.

	Step 4 (10 minutes) The moderator will create a poll using the responses raised by the participants. The poll will request the participants to vote on the ideas, ranking them from most important to least important. e.g. the moderator can create a poll asking Which of these do you agree should be included in the roles of the audit committee? (Participants vote in the chat using the numbers, all roles that have more than 50% votes will be selected. Those that have less than 50% will be subjected to another round of voting and only chosen if get more than 50% agreement)
12.30 – 1.30 pm – Lunch break (1 hour)	
1.30 -2.10 pm (40 minutes)	**2nd consensus activity – Size and composition of audit team/committee** The steps will be followed as in the 1st activity. **Question – What should be the size of audit team/committee and which cadres should be represented?** Step 1: 5 minutes Step 2: 10 minutes Step 3: 10 minutes Step 4 voting (8 minutes each): **Voting Qn 1: What should be the committee size be? (Participants to vote on one response only in the chat. (8 minutes)** If several responses, the response with the lowest number of votes to be removed from the vote and participants to vote between the responses with the highest number of votes until there is more than 50% consensus on one response. **Voting Qn 2: Which cadres should be represented in the audit committee? (8 minutes)** Ask the participants to select the cadres in the chat box. The number to be selected is based on the agreement for the size of the committee. Vote until more than 50% consensus on each role. The results will be compiled and presented to the wider group.

Group two facilitation guide

Group Two Facilitation	
9.15 – 10.00 am	Participants settle down into the groups. Group facilitator and moderator introduce themselves and facilitator requests participants to turn on videos for the group session. They explain that this will improve interpersonal relations. Participants introduce themselves. Group facilitator sets ground rules for the session. Participants encouraged to remain on mute until asked to speak. Participants asked to raise hand or type questions, comments or clarifications in chat box. The discussion regarding the issues raised will be led by the group moderator. Group facilitator will explain the group objective which is to determine how audits are conducted in the different County hospitals and the facilitators and barriers to this process. The facilitator will use a guide to probe the participants into having an in-depth discussion. The moderator will document responses on the white board. These will then be compiled after the session. After the session, participants are asked to take a 15-minute tea break.

11.15 – 11.25 am (10 minutes)	Participants settle down into the groups. Group facilitator requests participants to turn on videos for the group session. They explain that this will improve interpersonal relations. Group facilitator sets ground rules for the session. Participants encouraged to remain on mute until asked to speak. Participants asked to raise hand or type questions, comments or clarifications in chat box. The discussion regarding the issues raised will be led by the group moderator. Group facilitator explains group objectives and role of group participants. Group objectives will be: To arrive at consensus on the criteria for selection of cases for auditing and who selects cases for auditing. To arrive at consensus on number of cases to audit per session. Participant roles – To arrive at consensus on these two aspects of the audit process taking into consideration the strengths and weaknesses within our setting. Emphasize that the group's work will contribute to the audit process guide.
11.25 – 11.45 am (20 mins)	**Creating user personas.** Group facilitator to explain the concept of creating user personas to the group. To represent the different types of users that may be involved in the audit process. To consider the facilitators and barriers that these users may experience during the audit process. (These will be compiled before the session and shared with the group facilitators. Facilitator will project these onto the screen) Explain that this will help with understanding the user's needs, experiences, behaviours and goals and design with these in mind. The participants will suggest a cadre to work with, they will give a name, gender, age and daily tasks of this user. The group facilitator will ask participants to contribute by raising their hands and will speak when chosen to speak. They will encourage participation from the entire group and avoid dominance of some participants. The group facilitator will get consensus on each character of the user persona before moving on. The moderator of the group will document all these on the whiteboard (may draw a character to represent the persona). After all characteristics are included, the facilitator will conclude this session and move on to the nominal group technique (see below)
11.45 – 12.30 pm (45 minutes)	The group facilitator will explain the group process to the participants. The 4 steps will be explained and any questions arising addressed. (5 minutes) Step 1 – In this step, the facilitator presents one question at a time to the participants both verbally and in written form and the participants will each silently and independently write down their key ideas in response to the questions. The ideas should be listed in order of their considered priority. Step 2 – In this step, the facilitator will go through the group participant list and get one key idea from each member at a time. These will then be recorded on the Zoom whiteboard. This will happen until all responses have been exhausted. Step 3 - Each point on the whiteboard will be discussed in detail and clarifications made on areas that may not be clear – discussion will be moderated by the group moderator. Step 2 - Voting on ideas will be using the polling function on Zoom. After the clarification stage, the members will be asked to rank their ideas from most important to least important through a poll. The poll responses will be made visible to the group members at the end of the polling phase. **1st consensus activity – Criteria for selection of cases for auditing** **Step 1 (10 minutes)**

	Facilitator presents 1st question to the participants both verbally and in written form. (The moderator will write this question on the virtual whiteboard) **What methods should be used to select cases for auditing?** The participants will each silently and independently write down their key ideas in response to the questions. They will do this on their own writing material. There will be no discussions going on at this stage. Participants will be encouraged to engage the moderator privately using the chat box if they have any questions to avoid disrupting the group. These will be addressed by the moderator. **Step 2 (10 minutes)** The facilitator will use the participant list and get one response from each member at a time. This will happen until all the responses from all participants have been exhausted. The moderator will record these responses verbatim on the virtual whiteboard as they are read out. **Step 3 (10 minutes)** The facilitator will go through each response on the whiteboard and ask the participants to raise their hands if there are any points that are not clear. The facilitator will then seek clarification on these points from the participants who raised them. **Step 4 (10 minutes)** The moderator will create a poll using the responses raised by the participants. The poll will request the participants to vote on the ideas, ranking them from most important to least important. e.g. the moderator can create a poll asking What 5 criteria rank highest in enabling identification of modifiable factors? The response that is selected by the greatest number of participants will be the selected method. Polling can be done more than once if there is a tie in the responses. The option that will be selected by more than 50% of participants will be dropped from subsequent poll. The results will be compiled and presented to the wider group.
12.30 – 1.30 pm – Lunch break (1 hour)	
1.30pm -2.10 pm (40 minutes)	**2nd consensus activity – Number of cases to audit per one audit session.** The steps will be followed as in the 1st activity. At end of session, participants will move to main group. **Question – How many cases should be audited during each audit meeting?**

Group three facilitation guide

Group One Facilitation	
9.15 – 10.00 am	Participants settle down into the groups. Group facilitator and moderator introduce themselves and facilitator requests participants to turn on videos for the group session. They explain that this will improve interpersonal relations. Participants introduce themselves. Group facilitator sets ground rules for the session.

	Participants encouraged to remain on mute until asked to speak. Participants asked to raise hand or type questions, comments or clarifications in chat box. The discussion regarding the issues raised will be led by the group moderator. Group facilitator will explain the group objective which is to determine how audits are conducted in the different County hospitals and the facilitators and barriers to this process. The facilitator will encourage open discussion by assuring participants that there are no wrong answers only differing points of view and participants are encouraged to share their points of view even if they differ from others. The facilitator will let participants know that the session is being recorded for consumption by the researchers after the workshop and will not be shared with anyone else. The facilitator will use a guide to probe the participants into having an in-depth discussion. The moderator will document responses on the white board in verbatim. These will then be compiled after the session. After the session, participants are asked to take a 15-minute tea break.
11.15 – 11.25 am (10 mins)	Participants settle down into the groups for the 2nd group session. Group facilitator requests participants to turn on videos for the group session. They explain that this will improve interpersonal relations. Group facilitator sets ground rules for the session. Participants encouraged to remain on mute until asked to speak. Participants asked to raise hand or type questions, comments or clarifications in chat box. These will be addressed by group moderator. Group facilitator explains group objectives and role of group participants. Group objectives will be: To arrive at consensus on the health care worker cadres who should be present during the audit meetings. To arrive at consensus on frequency of audit meetings. Participant roles – To arrive at consensus on these two aspects of the audit process taking into consideration the strengths and weaknesses within our setting. Emphasize that the group's work will contribute to the audit process guide. Ask the participants to have writing material with them.
11.25 – 11.45 am (20 mins)	**Creating user personas.** Group facilitator to explain the concept of creating user personas to the group. To represent the different types of users that may be involved in the audit process. To consider the facilitators and barriers that these users may experience during the audit process. (These will be compiled before the session and shared with the group facilitators. Facilitator will project these onto the screen) Explain that this will help with understanding the user's needs, experiences, behaviours and goals and design with these in mind. The participants will suggest a cadre to work with, they will give a name, gender, age and daily tasks of this user. The group facilitator will ask participants to contribute by raising their hands and will speak when chosen to speak. They will encourage participation from the entire group and avoid dominance of some participants. The group facilitator will get consensus on each character of the user persona before moving on. The moderator of the group will document all these on the whiteboard (may draw a character to represent the persona).

	After all characteristics are included, the facilitator will conclude this session and move on to the nominal group technique.
11.45 – 12.30 pm (45 minutes)	The group facilitator will explain the nominal group technique to the participants. The 4 steps will be explained and any questions arising addressed. (5 minutes) Generation of ideas – In this step, the facilitator presents one question at a time to the participants both verbally and in written form and the participants will each silently and independently write down their key ideas in response to the questions. Round robin technique – In this step, the facilitator will go through the group participant list and get one key idea from each member at a time. These will then be recorded on the whiteboard. This will happen until all responses have been exhausted. Clarification stage - Each point on the whiteboard will be discussed in detail and clarifications made on areas that may not be clear. Voting on ideas - Voting on ideas will be using the polling function on zoom. After the clarification stage, the members will be asked to rank their ideas from most important to least important through a poll. This will be made visible to the group members at the end of the polling phase. **1st consensus activity – Health worker cadres present during audit meetings** **Generation of ideas (10 minutes)** Facilitator presents 1st question to the participants both verbally and in written form. (The moderator will write this question on the virtual whiteboard) **What health worker cadres should be present during the audit meetings as a bare minimum?** The participants will each silently and independently write down their key ideas in response to the questions. They will do this on their own writing material. There will be no discussions going on at this stage. Participants will be encouraged to type in the chat box if they have any questions to avoid disrupting the group. These will be addressed by the moderator. **Round robin technique (10 minutes)** The facilitator will use the participant list and get one response from each member at a time. This will happen until all the responses from all participants have been exhausted. The moderator will record these responses verbatim on the virtual whiteboard as they are read out. **Clarification stage (10 minutes)** The facilitator will go through each response on the whiteboard and ask the participants to raise their hands if there are any points that are not clear. The facilitator will then seek clarification on these points from the participants who raised them. **Voting on ideas (10 minutes)** The moderator will create a poll using the responses raised by the participants. The poll will request the participants to vote on the ideas, ranking them from most important to least important. e.g. the moderator can create a poll asking What 5 cadres are the bare minimum for an effective newborn audit meeting?

	The results will be compiled and presented to the wider group.
12.30 – 1.15 pm – Lunch break (45 mins)	
1.15 -1.55 pm (40 minutes)	**2nd consensus activity – Frequency of audit meetings** The steps will be followed as in the 1st activity. At end of session, **Question – How many cases should be audited during each audit meeting?**

Group four facilitation guide

Group One Facilitation	
9.15 – 10.00 am	Participants settle down into the groups. Group facilitator and moderator introduce themselves and facilitator requests participants to turn on videos for the group session. They explain that this will improve interpersonal relations. Participants introduce themselves. Group facilitator sets ground rules for the session. Participants encouraged to remain on mute until asked to speak. Participants asked to raise hand or type questions, comments or clarifications in chat box. These will be addressed by group moderator. Group facilitator will explain the group objective which is to determine how audits are conducted in the different County hospitals and the facilitators and barriers to this process. The facilitator will use a guide to probe the participants into having an in-depth discussion. The moderator will document responses on the white board in verbatim. These will then be compiled after the session. After the session, participants are asked to take a 15-minute tea break.
11.15 – 11.25 am (10 mins)	Participants settle down into the groups. Group facilitator requests participants to turn on videos for the group session. They explain that this will improve interpersonal relations. Group facilitator sets ground rules for the session. Participants encouraged to remain on mute until asked to speak. Participants asked to raise hand or type questions, comments or clarifications in chat box. These will be addressed by group moderator. Group facilitator explains group objectives and role of group participants. Group objectives will be: To arrive at consensus on the categorisation of modifiable factors. Participant roles – To arrive at consensus on these two aspects of the audit process taking into consideration the strengths and weaknesses within our setting. Emphasize that the group's work will contribute to the audit process guide. Ask the participants to have writing material with them.
11.25 – 11.45 am (20 mins)	**Creating user personas.** Group facilitator to explain the concept of creating user personas to the group. To represent the different types of users that may be involved in the audit process. To consider the facilitators and barriers that these users may experience during the audit process. (These will be compiled before the session and shared with the group facilitators. Facilitator will project these onto the screen) Explain that this will help with understanding the user's needs, experiences, behaviours and goals and design with these in mind. The participants will suggest a cadre to work with, they will give a name, gender, age and daily tasks of this user.

	The group facilitator will ask participants to contribute by raising their hands and will speak when chosen to speak. They will encourage participation from the entire group and avoid dominance of some participants. The group facilitator will get consensus on each character of the user persona before moving on. The moderator of the group will document all these on the whiteboard (may draw a character to represent the persona). After all characteristics are included, the facilitator will conclude this session and move on to the nominal group technique.
11.45 – 12.30 pm (45 minutes)	The group facilitator will explain the nominal group technique to the participants. The 4 steps will be explained and any questions arising addressed. (5 minutes) Generation of ideas – In this step, the facilitator presents one question at a time to the participants both verbally and in written form and the participants will each silently and independently write down their key ideas in response to the questions. Round robin technique – In this step, the facilitator will go through the group participant list and get one key idea from each member at a time. These will then be recorded on the whiteboard. This will happen until all responses have been exhausted. Clarification stage - Each point on the whiteboard will be discussed in detail and clarifications made on areas that may not be clear. Voting on ideas - Voting on ideas will be using the polling function on zoom. After the clarification stage, the members will be asked to rank their ideas from most important to least important through a poll. This will be made visible to the group members at the end of the polling phase. **1st consensus activity – Categorisation of health worker related modifiable factors** **Generation of ideas (10 minutes)** Facilitator presents 1st question to the participants both verbally and in written form. (The moderator will write this question on the virtual whiteboard) **How should health worker related factors be categorised?** The participants will each silently and independently reflect on the health worker related modifiable factors. They will indicate yes or no on the provided categories and write down any other key ideas they may have in each category. They will do this on their own writing material. There will be no discussions going on at this stage. Participants will be encouraged to type in the chat box if they have any questions to avoid disrupting the group. These will be addressed by the moderator. **Round robin technique (10 minutes)** The facilitator will use the participant list and get one response from each member at a time. This will happen until all the responses from all participants have been exhausted. The moderator will record these responses verbatim on the virtual whiteboard as they are read out. **Clarification stage (10 minutes)** The facilitator will go through each response on the whiteboard and ask the participants to raise their hands if there are any points that are not clear. The facilitator will then seek clarification on these points from the participants who raised them. **Voting on ideas (10 minutes)**

	The moderator will create a poll using the responses raised by the participants. The poll will request the participants to vote on the ideas, ranking them from most important to least important. e.g. the moderator can create a poll asking The response that is selected by the greatest number of participants will be the selected method. Polling can be done more than once if there is a tie in the responses. The results will be compiled and presented to the wider group.
12.30 – 1.15pm – Lunch break	
1.15 -1. 55pm (40 minutes)	**2nd consensus activity – Administrative related and patient related factors** The steps will be followed as in the 1st activity. **Question – How many cases should be audited during each audit meeting?**

Appendix 9: User personas

User Personas

Group one

Nurse, Female, Immaculate, 30 years, Married, has 1 child

Neonatal nurse, Diploma holder, 5 Years experience in NBU

Goals: Upgrade to a degree holder in nursing

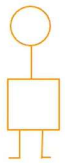
Roles/responsibilities in NBU:
-Drug administration
-Monitoring babies- temperature, respiration rate etc
-Feeding babies
-Performing neonatal procedures eg photo therapy, CPAP
-Top tailing (cleaning babies)
-Looking after mother of baby
-Giving information on progress and plans for babies to parents
-Record keeping/ documentation
-Supervising other staff
-On night duty covering in hospital
-Assisting students in care of newborns in NBU

Group two

User identifier

Name: Dr. Mary
Sex: Female
Cadre: General paediatrician
Age: 50years
Duties in NBU: Conducting major ward rounds, chairing the audits, teaching the interns(MOI), NBU incharge of daily running of the unit, managing the staff(eg nurses), member of HMT involved in various processes including budgeting, member of other committees- e.g. infrustructure committee, teaches students (medical stuents and clinical officer students, lecturer at the MTC, works in private hospitals(private practice)
Goals/needs of Dr. Mary: subspecialize in neurology, maintain a work life balance, reduce mortality in the NBU, participate in research in the hospital, increase survival rate in the unit

Group three



NUTRITIONIST

Name: Marion
Sex: Female
Age: 22years old,
Marital status: Single

Responsibilities

- ensure proper attachement and positioning
- monitor growth of the neonate
- ensure required amont of feeds (R1)
- help mother expressed breast milk(R3)
- consel mothers on importance of breast feeding
- ensure mothers are feeding well to provide for the baby(R7)
- to be a team player; find solutions to identified problems and share with other team members, suggesting possible solutions as well(R6)

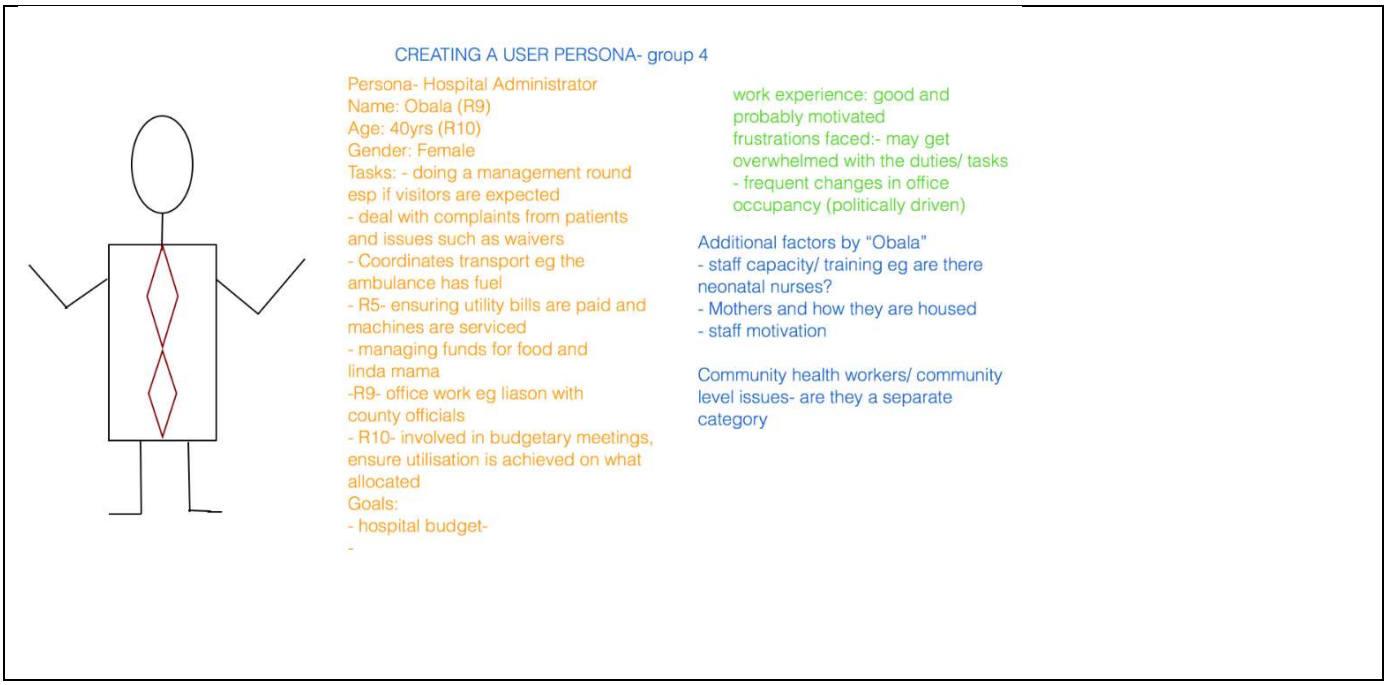
Goals

- as a fresh graduate: she wants to gather experiencies
- looking for a better job(R5)
- to do well and impress her supervisor
- to get a family (R9)
- she wants to do well and get promoted(R7)
- wants to put the knowledge into practice(R1)

experiences

- experience challenges in delivering care (R7)
- being blamed for wrong actions she is scared(R3)
- she finds it strange that what she was taught is not what is in practice
- blamed for being online or having distraction with her phone(R4)
- confused because of working with more grown up people and she is still young with low experience(R5)
- very impatient with mothers and wondering why breat feeding is hard for then
- withholding her ideas
- she feels nutriionist should not be working over weekends(R6)
- she feels she is not being respected being young
- she doesnt know how breast milk is expressed or pumped

Group four



Appendix 10 : Semi structured participant observation guide

Participant Observation Guide for Intervention Hospitals

The researcher will observe the following:

1. Audit meeting preparations
    - Who determines when the audit meeting will be held? (Is there a set date? Hierarchical approach or team consensus?)
    - Who determines the selection of the case to be presented? (Are nurses involved in the selection of the case? Are paediatricians (chair of audit committee) involved in the selection of the case?)
    - Approach taken for the summary of the case on the audit tool (Do the clinicians and nurses summarise the case on the audit tool together as a team or individually? Do the junior clinicians prepare on their own? Are paediatricians involved in the preparation?)

- Invitation to the audit meetings (Who determines who is invited? What modes are used for the invitation? How soon before the audit meeting are the invitations distributed?)
    - *Explore more on the audit preparation during discussions with audit team members as may not be able to observe the preparation process.*

2. Team composition during audit meetings
    - Who attends the audit meetings? (Do all audit committee members attend the meetings? Diversity in terms of cadre and hierarchy)
        - *Explore more on members of the audit committee who do not attend meetings. What are the possible reasons for non-attendance? Is it a pattern?*

3. Participation from hospital and NBU leadership

- *Is there representation from the hospital leadership during audit meetings? (which members attend the meetings?*

4. Facilitation of audit meetings
    - Observe the interactions between the facilitator and audit meeting participants.
        - Was there follow-up on the action plans arising from the previous meeting?
            - What was the action on recommendations that were not implemented?
        - Did the facilitator ensure equality and inclusivity in the discussions? How?
            - Who talked? What is their cadre and role?
            - Which cadres are more dominant in the discussions? Are all cadres actively participating or are they encouraged to participate by the facilitator?
        - Was there a punitive tone to the discussions? How did the facilitator navigate this?
        - Was there learning taking place during the audit meetings?

- How was learning/teaching taking place?

- Were the issues raised related to quality of care and patient safety?
  - What are the modifiable factors relating to newborn feeding practices?
  - What other issues of interest are arising other than newborn feeding practices?
  - How were the action plans generated? Was it a group discussion?
    - Was the action plan summary form used?
- Were the action plans implemented?
  - How many action plans were implemented?
  - What circumstances resulted in poor implementation of action plans?

Appendix 11: Small and sick newborn clinical audit tool

Appendix 11a: Draft zero clinical audit tool

Newborn Unit Clinical and Mortality Audit Tool

Name of health facility: _____

Type of health facility: Sub-County Hospital ☐ County Referral Hospital ☐

National Teaching and Referral Hospital ☐

Date of audit __ /__ /_____

Section 1: Newborn details

1.1 I.P. Number Newborn _____

1.2 Sex M ☐ F ☐

1.3 Date of birth ___/____/ _____

1.4 Birth weight (grams)

1.5 Gestation at birth

1.6 Apgar score: 1 min 5 mins 10 mins

1.7 Age (in days) at review/death

1.8 Weight at review/death

Section 2: Mother's details

2.1 Antenatal care details

2.1.1 Mother's blood group _____

2.1.2 HIV status **+ve** □ **-ve** □ **not done** □

If positive, on HAART? **Yes** □ **No** □

When was HAART initiated? **Before pregnancy** □ **during pregnancy** □ **during labour** □ **after delivery** □

2.1.3 Syphilis testing **positive** □ **negative** □ **not done** □

2.1.4 Hypertensive disease **Yes** □ **No** □

2.1.5 Diabetes in pregnancy **Yes** □ **No** □

2.2 Labour and delivery

2.2.1 Mode of delivery **SVD** □ **CS (Emergency** □ **Elective** □**)** **Breech** □ **Assisted vaginal delivery (vacuum/forceps extraction)** □

2.2.2 Complications during labour and delivery (coded) _____

2.2.3 Resuscitation of newborn after delivery? **Yes** □ **No** □

1. **Initial clinician review on admission**
   What was done right? _____

   Was there a delay in clinician review? _____
   If yes, why? _____

   Recommendations _____

2. **Recognition of danger signs during admission assessment – History and physical examination**

   What danger signs were appropriately recognised? _____

   What danger signs were missed? _____

   Why? _____

Recommendations

3. **Appropriate investigations based on clinical assessment**
   What laboratory and radiological investigations were appropriately ordered?

What significant investigations were not done?

Why?

Recommendations

4. Initial Diagnosis
   - Primary diagnosis
   - Secondary diagnoses

Timely and appropriate action taken based on the investigation results

What appropriate action was taken based on the results?

What delays in recognition and action on the critical investigation results were experienced?

Why?

Recommendations

Management at Admission

Supportive care

A. Nutritional Care

Fluid management

What IV fluids were prescribed and at what volume in ml/kg/day? _____

_____

What was done correctly in the fluid prescription? _____

_____

What was not appropriately done in the fluid prescription? _____

_____

Why? _____

_____

Were intravenous fluids given as prescribed? _____

If no, why? _____

_____

Recommendations _____

_____

_____

Enteral feed management

What enteral feeds were prescribed, at what volume in ml/kg/day and via what route?

_____

_____

What was done correctly in the prescription of the feeds? _____

_____

What was not appropriately done during prescription of feeds? _____

_____

Why? _____

Were feeds given as prescribed? _____

If no, why? _____

Recommendations _____

B. Respiratory Support

What was appropriate about the mode of respiratory support selected? _____

If the selection of respiratory support was not appropriate, what could have been done differently?

Recommendations _____

C. Other Supportive Management

Based on the danger signs, what other supportive management was required? _____

Was it appropriately given? _____

What was not appropriately done? _____

Why? _____

Recommendations _____

Definitive Management

Based on the danger signs, what was appropriately done in the selection and dosage of prescribed medication?

Was medication given as prescribed? _____

If no, why not? _____

_____

What was not appropriately done in the selection and dosage of prescribed medication?

_____

Why? _____

_____

_____

Recommendations _____

_____

_____

Post Admission Management

Diagnosis

New or additional diagnoses

_____

_____

Supportive care

A. Nutritional Care

Fluid management

What was done correctly in the continued fluid management?

_____

What was not appropriately done in the continued fluid management? _____

_____

Why? _____

_____

Were intravenous fluids given as prescribed? _____

_____

If no, why? _____

_____

Recommendations

Enteral feed management

If enteral feeds were not initiated at admission, when were they initiated? at what volume in ml/kg/day and via what route?

What was done correctly during progression of enteral feeds? Was it at the recommended volume?

Were enteral feeds stopped at any point after they were initiated? If yes, why? for how long?

What was not appropriately done during enteral feed management of the child?

Why?

Were feeds given as prescribed?

If no, why?

Recommendations

B. Respiratory Support

What was appropriate about the mode of respiratory support selected?

If the selection of respiratory support was not appropriate, what could have been done differently?

Recommendations

C. Other Supportive Management

Based on the danger signs, what other supportive management was required?

Was it appropriately given?

What was not appropriately done?

Why?

Recommendations

Definitive Management

Based on the danger signs, what was appropriately done in the selection and dosage of prescribed medication?

Was medication given as prescribed?

If no, why not?

What was not appropriately done in the selection and dosage of prescribed medication?

Why?

Recommendations

Section 4: Details of death (mortality audit) or cause of unfavourable outcomes (clinical audit)

Mortality audit

Date of death ___/___/_____
Time of death _____
Primary diagnosis that led to death

_____

Underlying conditions or associated diagnoses

_____

_____

Clinical audit

Conditions that led to unfavourable outcomes

_____

_____

_____

Codes for complications during labour and delivery

Chapter 9: M1: Antepartum haemorrhage

Chapter 10: M2: Prolonged/obstructed labour

Chapter 11: M3: Prolonged rupture of membranes

Chapter 12: M4: Chorioamnionitis

M5: Meconium stained liquor

Appendix 11b: Final draft of the clinical audit tool

Newborn Clinical and Mortality Audit Tool

Name of health facility:

Type of health facility: Sub-County Hospital ☐ County Referral Hospital ☐

National Teaching and Referral Hospital ☐

Date of audit

Section 1: Newborn Details

I.P. number newborn

Date of birth

Date of admission

Referral Y ☐ N ☐

Referring facility

Reason for referral

Age at review/death days Birth weight grams

Weight at review/death grams

Gestation at birth weeks

Sex M ☐ F ☐ Indeterminate ☐

Apgar Score: 1 min 5 mins 10 mins 20 mins

Not documented ☐

HC cm Not done ☐ Length cm Not done ☐

Section 2: Mother's Details

Antenatal History

ANC attendance	Y ☐	N ☐	Blood Group		VDRL status	pos ☐	neg ☐	unkn. ☐
PMTCT status	pos ☐	neg ☐	unkn. ☐	If positive, on HAART?	Y ☐	N ☐	unkn. ☐	
HTN in pregnancy	Y ☐	N ☐	unkn. ☐	Diabetes in pregnancy	Y ☐	N ☐	unkn. ☐	

Any other conditions in pregnancy

Labour and Delivery

Delivery SVD ☐ CS ☐ Breech ☐ Vacuum ☐ If CS, type? Elective ☐ Emergency ☐

ROM < 18h ☐ ≥ 18h ☐ unkn. ☐ Any other complications

BVM resuscitation at birth? Y ☐ N ☐ Not documented ☐

Chest compressions at birth? Y ☐ N ☐ Not documented ☐

Medication used during resuscitation? If yes,

Oxygen administered post resuscitation Y ☐ N ☐ If yes, method of delivery and flow rate

Nasal prongs/short nasal catheter ☐ flow rate Nasopharyngeal catheter ☐ flow rate

Face mask with reservoir bag ☐ flow rate Other

Section 3: Review of Care Provided

Time of birth

Time of admission by nurse

Date of admission by nurse

Time of admission by clinician

Date of admission by clinician

Time to referral (if applies)

1. Danger signs & symptoms at admission:

Temp °C Not done ☐ Sp02 % Not done ☐

RR /min Not done ☐ Jaundice Y

HR /min Not done ☐ Pallor

RBS mmol/l Not done ☐ Cap refill time secs

a. Difficulty in breathing Y ☐ N ☐ Not documented ☐ if yes,

- Chest indrawing Y ☐ N ☐ Not documented ☐
- Grunting Y ☐ N ☐ Not documented ☐
- Central cyanosis Y ☐ N ☐ Not documented ☐

b. Inability to breastfeed Y ☐ N ☐ Not documented ☐

c. Convulsions Y ☐ N ☐ Not documented ☐

d. Apnoea Y ☐ N ☐ Not documented ☐

e. Reduced/absent movement Y ☐ N ☐ Not documented ☐

f. Bilious vomiting Y ☐ N ☐ Not documented ☐

2. Management provided at referring facility (if applies)

3. Initial diagnosis

Primary diagnosis

Secondary diagnoses

4. Describe how the child's illness progressed since admission (document new or worsening clinical signs or diagnoses and day of life identified)

5. Describe the daily vital signs monitoring of the newborn (Nursing section)

Day of life	Frequency of monitoring	Temperature	Respiratory Rate	Heart Rate	Oxygen saturations
		Highest temp °c Lowest temp °c	Highest RR /min Lowest RR /min	Highest HR /min Lowest HR /min	Highest Spo2 Lowest Spo2
Intervention					
		Highest temp °c Lowest temp °c	Highest RR /min Lowest RR /min	Highest HR /min Lowest HR /min	Highest Spo2 Lowest Spo2
Intervention					
		Highest temp °c Lowest temp °c	Highest RR /min Lowest RR /min	Highest HR /min Lowest HR /min	Highest Spo2 Lowest Spo2
Intervention					
		Highest temp °c Lowest temp °c	Highest RR /min Lowest RR /min	Highest HR /min Lowest HR /min	Highest Spo2 Lowest Spo2
Intervention					
		Highest temp °c Lowest temp °c	Highest RR /min Lowest RR /min	Highest HR /min Lowest HR /min	Highest Spo2 Lowest Spo2
Intervention					
		Highest temp °c Lowest temp °c	Highest RR /min Lowest RR /min	Highest HR /min Lowest HR /min	Highest Spo2 Lowest Spo2
Intervention					
		Highest temp °c Lowest temp °c	Highest RR /min Lowest RR /min	Highest HR /min Lowest HR /min	Highest Spo2 Lowest Spo2
Intervention					

6. What critical basic laboratory and radiological investigations were done since admission considering the progression of illness and what were the key results.

Investigations		Date ordered	Date results received	Action taken	Date action taken	Highest and lowest daily RBS	Action taken
Highest Hb							
Lowest Hb							
Highest T. bilirubin							
Lowest T. bilirubin							
Highest	Lowest						
Na^+							
K^+							
Ca^{2+}							
Mg^{2+}							
Urea							
Creat							
Others							

Supportive Management

Airway and Breathing, Circulation, Disability and Others

7. Respiratory support Y ☐ N ☐	Oxygen therapy ☐ Start date Stop date	CPAP ☐ Start date Stop date	Mechanical ventilation ☐ Start date Stop date
8. Management of dehydration Y ☐ N ☐			
9. Transfusion of blood and blood products Y ☐ N ☐	PRBC transfusion ☐ No. of transfusions Volumes	Whole blood transfusion ☐ No. of transfusions Volumes	Other blood products ☐ FFP ☐ Platelets ☐ No. of transfusions Volumes
10. Management of hypoglycaemia Y ☐ N ☐	IV 10% dextrose ☐ Volumes	Buccal 50% dextrose ☐ Volumes	Others Volumes
11. Management of jaundice Y ☐ N ☐	Standard phototherapy ☐ Start date Stop date	Intensive phototherapy ☐ Start date Stop date	Exchange transfusion ☐ Date

Enteral Feed and Fluid Management

12. How was the progressive maintenance fluid and enteral feed management since admission? (Document day of life, type of fluid prescribed, volume of feed and fluid prescribed and total volume)

Day of life	IV fluid type & vol. prescribed	IV fluid vol. given	Enteral feed type, vol., freq. & route prescribed	Enteral feed vol. given	Total daily volume	Documented weights
					Prescribed Given	
					Prescribed Given	
					Prescribed Given	
					Prescribed Given	
					Prescribed Given	
					Prescribed Given	
					Prescribed Given	
					Prescribed Given	
					Prescribed Given	
					Prescribed Given	

Section B – To be filled during audit meeting

Care at Admission

1. Was the mother appropriately monitored during labour and delivery? If given another opportunity, what can be done differently?

Was the mode of delivery appropriate? Yes

If CS, were there any delays? If yes, why?

2. Was the baby appropriately resuscitated if required, and was the baby appropriately put on oxygen post resuscitation? If no, why?

3. Was there a delay in transfer of baby to NBU based on guidelines set by the hospital? If yes, what factors could have contributed to this?

4. Was there a delay in initial clinician review based on hospital guidelines?

If yes, what factors could have contributed to this?

5. If baby was referred in, comment on the quality of care provided at the referring facility. What could be done differently?

6. Was the response to danger signs at admission timely and as recommended in the newborn care guidelines? If not, what may have contributed to this?

7. Comment on diagnoses

Progression of Illness

8. Comment on the monitoring of the newborn to enable early recognition of danger signs including frequency of monitoring of vital signs.

Definitive Management

13. What medication was progressively prescribed since admission and at what dosages and routes?

Medication	Route	Dose & frequency	Days
Xpen			
Gentamicin			
Ceftazidime			
Ceftriaxone			
Amikacin			
Phenobarbitone			
• Loading dose			
• Maintenance dose			
Aminophylline			
• Loading dose			
• Maintenance dose			
Caffeine citrate			
• Loading dose			
• Maintenance dose			
Others			

Laboratory and Radiological Investigations

9. Comment on any critical investigations that were not done and what factors may have contributed to this?

10. Was timely and appropriate action taken on the key results?

If no, what was not appropriately acted on? What may have contributed to this?

Management

Supportive care

Fluid and Enteral Feed Management

11. Comment on the fluid and enteral feed prescription and management since admission. Was it consistent with the accepted guidelines? Were fluids and feeds given as prescribed?

a. Was the selection of enteral feed and IV fluid types, volumes and frequencies appropriate? If no, what may have contributed to this?

b. Were enteral feeds and fluids given as prescribed? Is this clearly documented in the feed and fluid chart? If no, what may have contributed to this?

c. Comment on weight monitoring and progressive weight gain (Check the % weight loss/day in the 1st 5-7 days & weight gain in g/kg/d if > 7 days)

Other Supportive Management After Admission

12. Comment on the modes of supportive management selected. What was done well? What could be done differently?

Definitive Management

13. Was the selection of medication, dosage and route of administration appropriate as per the management guidelines? If no, what factors may have contributed to this?

14. Was the medication given as prescribed and clearly documented? If no, what factors may have contributed to this?

Section 4: Details of death (mortality audit) or cause of near miss (clinical audit)

Mortality audit

Date of death

Time of death

Primary diagnosis that led to death

Underlying conditions or associated diagnoses

Clinical audit

Diagnoses in case audited

Section 5: Action Plan Summary Form

Name of hospital					Review action at follow-up
Date of mortality audit meeting					
Practice to be improved	**Action to be taken**	**Level at which action is required**	**Person responsible for making change**	**Deadline**	**Action taken and outcome**

Members of Newborn Audit Committee Present

1. Paediatrician (Chair of audit committee)
2. Nursing officer in-charge of newborn unit
3. Nursing officer in-charge of labour ward
4. Obstetrician/ Medical officer from labour ward
5. Representative from records department
6. Nutritionist
7. Hospital administration (medical superintendent/hospital administrator/matron in-charge of facility)
8. Representative from pharmacy
9. Others

Appendix 12: Audit implementation guide

Appendix 12a: Initial audit implementation guide

This standard operating procedure (SOP) aims to provide guidance to the hospitals as they prepare and conduct newborn audits. The SOPs are based on consensus from paediatricians and nurses from the Clinical Information Network – Neonatal hospitals on what is practical for the Kenyan context based on World Health Organisation (WHO) recommendations.

1. **Audit Team or Committee**

WHO recommends that an audit team or committee is necessary to ensure quality improvement. The committee will comprise of at least 8 representatives from the cadres presented below. Hospitals may choose to add more members; however, these eight cadres should be present.

a. Nursing officer in charge of the newborn unit.
b. Nursing officer in charge of labour ward.
c. Senior most clinician in newborn unit – Neonatologist/paediatrician/medical officer in charge.
d. Obstetrician/ medical officer from labour ward.
e. Representative from the records department.
f. Nutritionist
g. Hospital administration – medical superintendent/hospital administrator/matron in charge of facility.
h. Representative from pharmacy.

The roles of the audit committee will be:

a. Identifying cases for discussion during the audit meeting – This means that the audit committee will be responsible for selecting the cases that will be discussed during the audit meeting based on the agreed upon criteria for selection of cases.

b. Ensuring that records are kept safely and confidentially – There should be a file to keep all documentation from the audit secure and confidential. These include the filled audit tool and the meeting minutes. This file should be kept at a specific and secure location.

c. Providing feedback of audit recommendations to the clinical team and administration - Audit team to give feedback to hospital administration, hospital management team and key departmental heads on action plans that arise during the audit meetings and the key persons responsible for implementing them. They should also give feedback on whether the action plans have been implemented or not.

d. Following up on action plans and ensuring that they are implemented - Audit team to follow up on progress of implementation of action plans by the responsible people.

2. **Frequency of audit meetings**

WHO recommends that hospitals with high newborn mortalities should have more frequent audit meetings to allow for more cases to be discussed. The duration of time from an event to its discussion should be as short as possible. The meetings should be held on a set day, date, time and venue.

Newborn audit meetings should therefore be held every two weeks and should take a maximum of 1 hour – 1 hour 30 minutes.

3. **Cases for auditing during audit meetings**

a. **How many cases should be audited**

An audit meeting should entail the systematic review of care provided in particular morbidity or mortality cases and not only the review of progress reports and statistics. It is more beneficial to audit a few cases in depth, than several cases superficially.

- Morbidity cases are defined as cases in which there was a serious or severe case or in which the patient deteriorated but survived.
- Mortality cases are defined as cases in which the patient died.

Based on the time allocated for the audit meetings, the participants should audit 1 – 2 morbidity or mortality cases per session.

b. **Criteria for selection of cases for auditing**

Cases for auditing should be selected from individual patient records, admission, discharge or death registers, referral notes etc.

Cases that are audited should be those in which adverse events were preventable and in which lessons could be learned.

Cases for auditing should be selected based on any of the following criteria:

i. **Most common cause of death –** This means that majority of deaths in the newborn unit are occurring due to the particular diagnosis.

ii. **Increased mortality due to a particular diagnosis –** This means that there is an increasing number of newborns in the newborn unit dying due to a particular diagnosis unlike what was previously occurring.

iii. **Glaring gaps in the management of a case –** This means that the management of the newborn was not consistent with evidence-based guidelines.

iv. **Preventable diseases or conditions –** This refers to newborn conditions that could have been avoided through available and affordable interventions.

v. **Cases that were difficult to deal with –** This refers to cases in which the diagnosis was difficult to establish or in which the newborn continued deteriorating despite best efforts in management.

vi. **Unexpected deaths –** This refers to newborns who were relatively stable or had mild disease and suddenly deteriorated and died.

vii. **Interesting cases for learning purposes.**

4. Environment during audit meetings

A favourable environment is important for a successful morbidity or mortality audit meeting.
These are the criteria that should be observed to ensure a favourable environment.

a. **Regular and structured meetings with invitations done in good time -** This means that the meeting will be held every 2 weeks on a set day, date and time.

b. Should be held in a spacious room, preferably a boardroom that is large enough to accommodate all the participants. The room should be in a quiet environment to avoid distractions.

c. **The meeting should be all inclusive –** This means that the audit meeting should be multidisciplinary involving the clinical team and other health care cadres who are involved in newborn care.

d. **There should be a chair to the meeting -** This will be the chair of the audit committee. The chair of the meeting should facilitate the discussions and encourage openness and allow equal participation among members.

e. **Attendance by audit participants who can influence change –** This means that the key decision makers (heads of department) from each department should ideally be those invited to the audit meeting.

f. **Should allow participants to express themselves freely and their opinions should be respected –** This means that the meeting will encourage active participation and open discussion from all members. The discussions during the audit meeting should take a team approach to allow for different viewpoints and opinions. This enables identification of modifiable factors.

g. **Blame-free and non- judgemental environment -** This means that the environment should be friendly and not name, blame or punish individuals or cadres thought to be responsible for mistakes. The meeting should instead focus on identifying modifiable gaps within the system.

h. **An environment that maintains confidentiality –** This means that discussions during audit meeting should be open, but no discussion about the audit cases should happen outside the audit meeting.

i. **Should have a strong educational aspect –** This means that there should be a focus on learning by all participants. The meeting room should be equipped with the necessary educational items and stationery to ensure that learning occurs. These include; whiteboard/blackboard/flipcharts/TV screen/ projector/other audio-visual equipment.

5. How to ensure action plans are implemented

a. The most influential people or key decision makers in each department should be made aware of the action plans and the timelines by which they should be implemented.

b. Direct task allocation – This means that the implementation of an action plan is allocated to a specific person.

c. Give a timeframe for implementing what was discussed – This means that the person responsible for implementing the action plan should be given a timeframe by which the action plan should be implemented. The time frame given should be feasible.

d. Taking clear minutes during each meeting. At the beginning of each audit meeting, the minutes from the previous meeting should be discussed to determine if action plans were implemented.

e. Audit team to give feedback to hospital administration, hospital management team and key departmental heads on action plans that arise during the audit meetings and the key persons responsible for implementing them.

f. Audit team to follow up on progress of implementation of action plans by the people responsible and give feedback to the administration, HMT and key departmental heads on whether it was implemented or not.

g. There should be a maximum of 3 action plans for implementation arising from each audit meeting.

Appendix 12b: Modified audit implementation guide

NEWBORN AUDIT PROCESS

STANDARD OPERATING PROCEDURE

This standard operating procedure (SOP) aims to provide guidance to the hospitals as they prepare and conduct newborn audits. The SOPs are based on consensus from paediatricians and nurses from the Clinical Information Network – Neonatal hospitals on what is practical for the Kenyan context based on World Health Organisation (WHO) recommendations.

6. Audit Team or Committee

WHO recommends that an audit team or committee is necessary to ensure quality improvement. The committee will comprise of at least 8 representatives from the cadres presented below. Hospitals may choose to add more members; however, these eight cadres should be present.

i. Nursing officer in charge of the newborn unit.

j. Nursing officer in charge of labour ward.

k. Senior most clinician in newborn unit – Neonatologist/paediatrician/medical officer in charge.
l. Obstetrician/ medical officer from labour ward.
m. Representative from the records department.
n. Nutritionist
o. Hospital administration – medical superintendent/hospital administrator/matron in charge of facility.
p. Representative from pharmacy.
q. Laboratory representative.

The roles of the audit committee will be:

The chair of the audit committee has the responsibility of ensuring that the roles are carried through, either individually or through delegation to other members of the audit committee.

e. Identifying cases for discussion during the audit meeting – This means that the audit committee will be responsible for selecting the cases that will be discussed during the audit meeting based on the agreed upon criteria for selection of cases.

f. Ensuring that records are kept safely and confidentially – There should be a file to keep all documentation from the audit secure and confidential. These include the filled audit tool and the meeting minutes. This file should be kept at a specific and secure location.

g. Providing feedback of audit recommendations to the clinical team and administration - Audit team to give feedback to hospital administration, hospital management team and key departmental heads on action plans that arise during the audit meetings and the key persons responsible for implementing them. They should also give feedback on whether the action plans have been implemented or not.

h. Following up on action plans and ensuring that they are implemented - Audit team to follow up on progress of implementation of action plans by the responsible people.

7. Frequency of audit meetings

WHO recommends that hospitals with high newborn mortalities should have more frequent audit meetings to allow for more cases to be discussed. The duration of time from an event to its discussion should be as short as possible. The meetings should be held on a set day, date, time and venue.

Newborn audit meetings should therefore be held every two weeks and should take a maximum of 1 hour – 1 hour 30 minutes.

8. Cases for auditing during audit meetings

a. How many cases should be audited

An audit meeting should entail the systematic review of care provided in particular morbidity or mortality cases and not only the review of progress reports and statistics. It is more beneficial to audit a few cases in depth, than several cases superficially.

- Morbidity cases are defined as cases in which there was a serious or severe case or in which the patient deteriorated but survived.
- Mortality cases are defined as cases in which the patient died.

Based on the time allocated for the audit meetings, the participants should audit 1 morbidity or mortality cases per session.

b. Criteria for selection of cases for auditing

Cases for auditing should be selected from individual patient records, admission, discharge or death registers, referral notes etc.

Cases that are audited should be those in which adverse events were preventable and in which lessons could be learned.

Cases for auditing should be selected based on any of the following criteria:

viii. **Most common cause of death –** This means that majority of deaths in the newborn unit are occurring due to the particular diagnosis.

ix. **Increased mortality due to a particular diagnosis –** This means that there is an increasing number of newborns in the newborn unit dying due to a particular diagnosis unlike what was previously occurring.

x. **Glaring gaps in the management of a case –** This means that the management of the newborn was not consistent with evidence-based guidelines.

xi. **Preventable diseases or conditions –** This refers to newborn conditions that could have been avoided through available and affordable interventions.

xii. **Cases that were difficult to deal with –** This refers to cases in which the diagnosis was difficult to establish or in which the newborn continued deteriorating despite best efforts in management.

xiii. **Unexpected deaths –** This refers to newborns who were relatively stable or had mild disease and suddenly deteriorated and died.

xiv. **Interesting cases for learning purposes.**

9. Environment during audit meetings

A favourable environment is important for a successful morbidity or mortality audit meeting.

These are the criteria that should be observed to ensure a favourable environment.

j. **Regular and structured meetings with invitations done in good time -** This means that the meeting will be held every 2 weeks on a set day, date and time.

k. Should be held in a spacious room, preferably a boardroom that is large enough to accommodate all the participants. The room should be in a quiet environment to avoid distractions.

l. The meeting should be all inclusive – This means that the audit meeting should be multidisciplinary involving the clinical team and other health care cadres who are involved in newborn care.

m. There should be a chair to the meeting - This will be the chair of the audit committee. The chair of the meeting should facilitate the discussions and encourage openness and allow equal participation among members.

n. Attendance by audit participants who can influence change – This means that the key decision makers (heads of department) from each department should ideally be those invited to the audit meeting.

o. Should allow participants to express themselves freely and their opinions should be respected – This means that the meeting will encourage active participation and open discussion from all members. The discussions during the audit meeting should take a team approach to allow for different viewpoints and opinions. This enables identification of modifiable factors.

p. Blame-free and non- judgemental environment - This means that the environment should be friendly and not name, blame or punish individuals or cadres thought to be responsible for mistakes. The meeting should instead focus on identifying modifiable gaps within the system.

q. An environment that maintains confidentiality – This means that discussions during audit meeting should be open, but no discussion about the audit cases should happen outside the audit meeting.

r. Should have a strong educational aspect – This means that there should be a focus on learning by all participants. The meeting room should be equipped with the necessary educational items and stationery to ensure that learning occurs. These include; whiteboard/blackboard/flipcharts/TV screen/ projector/other audio-visual equipment.

10. How to ensure action plans are implemented

h. The most influential people or key decision makers in each department should be made aware of the action plans and the timelines by which they should be implemented.

i. Direct task allocation – This means that the implementation of an action plan is allocated to a specific person.

j. Give a timeframe for implementing what was discussed – This means that the person responsible for implementing the action plan should be given a timeframe by which the action plan should be implemented. The time frame given should be feasible.

k. Taking clear minutes during each meeting. At the beginning of each audit meeting, the minutes from the previous meeting should be discussed to determine if action plans were implemented.

l. Audit team to give feedback to hospital administration, hospital management team and key departmental heads on action plans that arise during the audit meetings and the key persons responsible for implementing them.

m. Audit team to follow up on progress of implementation of action plans by the people responsible and give feedback to the administration, HMT and key departmental heads on whether it was implemented or not.

n. There should be a maximum of 3 action plans for implementation arising from each audit meeting.