

ASSOCIATION BETWEEN FIVE-MINUTE APGAR SCORES AND ADVERSE SHORT-TERM OUTCOMES IN NEONATES IN THE CLINICAL INFORMATION NETWORK HOSPITALS IN KENYA, 2018-2022: A RETROSPECTIVE COHORT STUDY

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A DISSERTATION SUBMITTED TO THE DEPARTMENT OF PUBLIC AND GLOBAL HEALTH IN PARTIAL FULFILMENT OF THE REQUIREMENTS FOR THE AWARD OF THE DEGREE OF MASTER OF PUBLIC HEALTH OF THE UNIVERSITY OF NAIROBI

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DECLARATION OF ORIGINALITY FORM

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Faculty.....Health Sciences

Department.....Public and Global Health

Course name.....Master of Public Health

Title of the work..... Association between five-minute Apgar scores and adverse short-term outcomes in neonates in the Clinical Information Network hospitals in Kenya, 2018-2022:
A retrospective cohort study

DECLARATION

I declare that this research proposal is my original work and has not been submitted elsewhere for examination, award of degree or publication. Where other peoples' work has been used, they have been duly acknowledged and referenced.

Signature.....


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SUPERVISORS' APPROVAL

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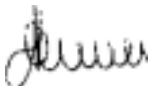
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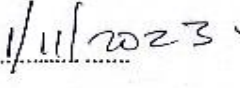
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DEDICATION

To Mugo, the wind beneath my wings and to Foi; you make it all worthwhile.

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LIST OF ABBREVIATIONS AND ACRONYMS

ANC- Ante-Natal Care

APH- Ante-Partum Hemorrhage

CEmONC- Comprehensive Emergency Obstetric and Newborn Care

CI- Confidence Interval

CIN- Clinical Information Network

CIN-N- Clinical Information Network for Neonates

CS - Caesarian Section

EmONC- Emergency Obstetric and Newborn Care

ERC- Ethics and Review Commission

HIE- Hypoxic-Ischaemic Encephalopathy

HIS- Health Information System

KASH- KEMRI Annual Scientific and Health

KEMRI- Kenya Medical Research Institute

KNH- Kenyatta National Hospital

KWTRP- KEMRI Wellcome Trust Research Programme

MoH- Ministry of Health

MSAF- Meconium-Stained Amniotic Fluid

NAR- Newborn Unit Admission Record

NBU- Newborn Unit

REDCap- Research Electronic Data Capture

SERU- Scientific and Ethical Review Unit

UoN-University of Nairobi

WHO- World Health Organisation

OPERATIONAL DEFINITIONS

Adverse neonatal outcomes-These referred to outcomes of either death, encephalopathy, or hospitalization to the newborn unit.

Apgar score- A score assigned to the newborn after assessment of various predetermined parameters at one minute and five minutes after delivery.

Asphyxia -Lack of oxygen in a newborn infant leading to injury mainly to the brain. Also called perinatal asphyxia or neonatal asphyxia or birth asphyxia.

Early neonatal death- A death between zero to six days of life.

Encephalopathy-A diagnosis of encephalopathy was considered in the presence of neurological symptoms such as convulsions abnormal tone and reduced level of consciousness at the time of admission.

Gestational age-Duration of pregnancy as recorded from the last normal menstrual period or obstetric ultrasound.

Hospital stay- Duration from admission to the newborn unit to time of discharge from the newborn unit or death

Inborn neonate-Neonate born in the CIN facility. This excluded referrals from other facilities or those born before arrival at a CIN facility

Late neonatal death- A death occurring from seven to twenty-eight days of life

Low birth weight-Neonate that weighed less than 2500g at birth

Macrosomia- Neonate weighing more than 4000g

Malposition of fetus- abnormal positions of the vertex of the fetal head relative to the maternal pelvis.

Neonatal mortality- Death within the first 28 days of life

Normal birth weight-Neonate with a weight between 2500g-4000g

Parity- Number of previous pregnancies carried beyond 28 completed weeks of gestation irrespective of the outcome

Post-term neonate-Neonates born at 42 or more completed weeks of pregnancy

Preterm neonate - Neonate born at a gestational age less than 37 completed weeks

Prolonged labour- regular rhythmic painful uterine contractions with accompanied cervical dilatation for longer than 20 hours in women who have not given birth before and 14 hours in women who have delivered before.

Short term outcomes-Outcomes that occurred within 0-28 days of life of the neonate

Term neonate-Neonates born after 37 completed weeks but before 41 completed weeks of pregnancy

The score- Refers to the Apgar score

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ABSTRACT

Background-The Apgar score is a good indicator of the quality of obstetric and newborn care. More than two-thirds of neonates with a low Apgar score die in the early neonatal period (0-7 days). There is therefore a need to look at the distribution of Apgar scores in primary referral centres in Kenya and to determine the prognosis of neonates in the neonatal period in relation to the Apgar score.

Methodology- This was a retrospective cohort study carried out in 22 neonatal units that are part of the CIN across 14 counties in Kenya. Singleton inborn neonates admitted to the neonatal unit on the first day of life between the years 2018-2022 were included. Those with major congenital defects, those born in twin/multiple pregnancy and those with a recorded score of less than zero or greater than ten were excluded. Data was abstracted from the Neonatal Admission Record and Newborn Unit Exit Form and captured into the REDCap tool. It was then exported to an excel file and analysed using R software version 4.1.2. Descriptive statistics were summarized as means, medians and proportions while inferential analysis was done using the Cox proportional hazards model, linear and logistic regression.

Results-The study found that 77%, 20% and 3% of neonates had normal, intermediate and low Apgar scores, respectively. The Apgar score was statistically significantly associated with mortality; an increase in the Apgar score by one led to a 37% reduction in the risk of death (HR 0.63 95% CI 0.61-0.64). The crude hazard ratio of death among those with a low and intermediate score were 12.44 (95% CI 11.6-13.35) and 4.02 (95% CI 3.83-4.22), respectively. The adjusted hazard ratios of death among those with low and intermediate Apgar scores were 10.97 (95% CI 9.45-12.73) and 3.6 (95% CI 3.26-3.97), respectively. When compared with the normal Apgar score, the odds of developing encephalopathy were 5.73 (95% CI 5.37-6.12) and 15.87 (95% CI 13.9-17.6) higher in intermediate and low Apgar score categories, respectively. With every unit increase in the Apgar score, the duration of stay was shortened by 0.34 days (95% CI -0.39 -0.30).

Conclusion- Most neonates had a normal Apgar score. The Apgar score was found to be an important determinant of neonatal mortality, encephalopathy and hospital stay.

Recommendation- There is need to continue monitoring the proportions of neonates with low and intermediate Apgar scores to inform targeted education and skills needs for the improvement of perinatal and neonatal care. Proper risk assessment and management of mothers in the antenatal period and planning for labour and delivery is important in order to mitigate against delivery of neonates with poor Apgar scores. Timely interventions for care of newborns scoring a less than normal Apgar score are necessary in order to reduce the occurrence of adverse outcomes.

CHAPTER ONE: INTRODUCTION

1.0: Introduction

This chapter provides an introduction to the Apgar score and explains the use of the score at five minutes and gives an introduction to the scope of the study.

1.1 Background

The Apgar score was developed by Dr. Virginia Apgar in the 1950s as an objective tool for the immediate assessment of newborn status. It contains an evaluation of five components namely the heart rate, respiratory rate, reflex irritability, muscle tone and colour. These components can quickly and easily be assessed by observation (except for the heart rate), without much interference with the newborn and without the need for special equipment (Apgar, 1953, Finster et al., 2005).

Each of these components is usually assigned a value of 0 for absent, 1, or a maximum value of 2, thereby totaling up to a maximum of 10 as shown in Table 1.1. They are assessed at the first, fifth, and tenth minute of life. The components are scored as follows:

Table 1.1: Apgar Scoring Chart with All Known Variations in Terminology

Component	Score		
	0	1	2
Heart rate	Absent	<100	>100
Respiratory rate	Absent	Weak cry; hypoventilation; shallow respirations; slow respirations; gasping	Good cry; strong cry; breathing well; good respiratory effort
Reflex irritability	Absent; no response	Grimace; some motion	Cough, sneeze, or cry; active withdrawal (pulls away from foot stimulation)
Muscle tone	Flaccid; limp	Some flexion	Flexion of extremities; the resistance of extension; active motion
Colour	Blue; pale	Body pink and extremities blue; acrocyanosis	Completely pink

Note: Reprinted from "The Apgar Score: Simple yet complex" by Rubarth, L.(2012) Neonatal Network: NN, 31(3), p.170.

Scores of 7-10 at the fifth minute are considered normal/reassuring, 4-6 intermediate, and 0-3 low (The Apgar Score, 2015). Scores less than seven are used as a predictor for perinatal asphyxia, mortality, and poor overall prognosis of the neonate (Rubarth, 2012). In addition to the initial assessment of the newborn, in the clinical setting, the Apgar score indicates the success of resuscitation efforts in the newborn, and this is indicated by a change in the score at 1 and 5 minutes (The Apgar Score, 2015).

In the 1960s, pediatricians Butterfield and Covey developed an epigram/mnemonic for the Apgar score to make it easier for clinicians to remember the components without altering its essence and elements as follows: A-appearance(to represent colour), P-pulse (heart rate), G-grimace (reflex irritability), A-activity (muscle tone), R-respiration (respiratory rate) (Butterfield & Covey, 1962).

1.2 One versus Five-minute Apgar score

The one-minute Apgar score usually is a result of a transient depression in the components assessed (Siddiqui et al., 2017). A score of 0-3 at one minute is not predictive of any individual neonate's outcome (The Apgar Score, 2015). The one-minute score is usually representative of the intrapartum process and indicative of the trauma the neonate has undergone in the delivery process (Thavarajah et al., 2018).

The five-minute Apgar score on the other hand has a greater predictive value for outcomes in large population studies in neonates. A score of 0-3 being predictive of neonatal mortality and long-term neurological outcomes irrespective of the birth weight and gestational age (Li et al., 2013, , Thavarajah et al., 2018). It is, therefore, useful as a marker of the neonate's ability to "survive and to thrive", thus called "vitality" of the infant (Jeganathan et al., 2017, Finster et al., 2005).

Globally, asphyxia and intrapartum related complications which lead to delivery of neonates with a low Apgar score are among the leading causes of neonatal mortality accounting for about two million newborn deaths with most occurring in the low and middle-income countries (Lee et al., 2013). An additional two million neonates develop hypoxic ischaemic encephalopathy (HIE) which refers to neurologic manifestations and among these, 1.2 million later on experience developmental delay (Sunny et al., 2021)

The neonatal mortality rate in sub-Saharan Africa is among the highest in the world at 27 per 1000 live births (Newborn Mortality, 2022). In Kenya, the rate is currently at 21 deaths per 1000 live births, which is comparable to the continent's statistics (Kenya Demographic and Health Survey, 2022: Key indicators report 2023). The leading cause of death has been found to be intrapartum-related events similar to the global picture (Newborn Mortality, 2022). This leads to babies developing asphyxia and manifests as a low Apgar score. Neonates with a low Apgar score have been shown to have a higher risk of mortality and encephalopathy as compared to those with an intermediate or normal score (Li et

al., 2013, Iliodromiti et al., 2014, Mu et al., 2021). Additionally, the Apgar score provides a useful precursor event in the prognostication of the duration of stay in hospital (Seaton et al., 2016). An increase in the one minute Apgar score was associated with a shorter predicted length of stay in hospital (Pepler et al., 2012).

The Apgar score is therefore a useful indicator of the quality of obstetric and newborn care (Dassah et al., 2014). It is also used as a predictor of outcomes in large population studies (The Apgar Score, 2015). Patient data management and storage in most low-income countries and in Kenya is a challenge and thus studies based on large data sets for the determination of outcomes are unavailable (Kihuba et al., 2014, Shah et al., 2012). The Clinical Information Network (CIN) was set up with an aim to solve the problem of data management and data availability. It is network of 22 high volume hospitals offering newborn care. It captures and stores data on the neonates that is abstracted from the neonatal admission records (NAR) and newborn unit exit forms. The data captured and stored electronically thus provided a unique opportunity to be able to assess and predict outcomes in our population setting using large data set.

This study aimed to look at the distribution of Apgar scores and the association of Apgar scores with death, encephalopathy and hospital stay in the neonatal period in hospitals captured in the CIN. The findings from this study were useful for feedback to healthcare workers on factors that affected the Apgar scores and provided an opportunity to assess their skills and training needs and also highlight gaps in care. This was important in order to optimise the provision of obstetric and newborn care and thus have good outcomes.

CHAPTER TWO: LITERATURE REVIEW

2.0 Introduction

This chapter summarises the literature on the prevalence of low Apgar scores, predictors of Apgar scores, Apgar scores and their association with adverse outcomes. It also describes the performance of the Apgar score as an assessment tool for immediate neonatal status. It also outlines gaps in literature that justify this study.

2.1 Prevalence of low Apgar score

The prevalence and trends in low Apgar score outcomes at five minutes are useful in the monitoring of newborn health outcomes in countries with a high birth rate. In countries with fewer births, it is useful for the evaluation of obstetric and newborn quality of care and resuscitation practices (Razaz, 2021).

In European countries, the prevalence of low Apgar score ranges from 0-2% (Siddiqui et al., 2017). A Danish study reported a <1% prevalence low score at five minutes (Ehrenstein et al., 2009). In Australia, the prevalence was found to be 1.4% (Thavarajah et al., 2018).

In Africa, Ethiopia, two separate studies had a low five minute Apgar score ranging from 13% to 35% (Gudayu, 2017, Yeshaneh et al., 2021). In Uganda, the prevalence was at 2.8% (Ondoa-Onama & Tumwine, 2003). In West Africa, the prevalence of low Apgar scores was found to range between 8% and 38% (Dassah et al., 2014).

Low Apgar scores are important indicators of the quality of newborn care. Studies have shown that more than two thirds of neonates with low Apgar scores may die in the perinatal period (Dassah et al., 2014). With such recorded high rates of low Apgar score in Africa, there is need to determine the proportion of neonates with low Apgar scores in Kenya and interrogate the contribution of low Apgar scores to neonatal mortality. This will provide a basis to address gaps in obstetric and immediate newborn care.

2.2 Predictors of low Apgar score

Various studies have described factors that influence the Apgar score. These factors are maternal, pregnancy, labour and delivery related as well as neonatal.

2.2.1 Maternal factors

A low or intermediate Apgar score has been noted in neonates of mothers who are younger than 20 years old, or older than 35 years (Mu et al., 2021). Women in these age categories are most likely to face complications related to pregnancy, labour and delivery which could include hypertensive diseases in pregnancy and preeclampsia, preterm birth, prolonged and obstructed labour, antepartum and post-partum haemorrhage (Ramaiya et al., 2014, Leader et al., 2018). Those women with a low number of ANC attendance were also noted to deliver babies who had a low score (Mu et al., 2021, Ondoa-Onama & Tumwine, 2003).

2.2.2 Labour and delivery

In two separate studies in Ethiopia, the factors that were statistically significantly associated with a low Apgar score included meconium-stained amniotic fluid (MSAF) and prolonged second stage of labor (Gudayu et al., 2017, Yeshaneh et al., 2021). Operative delivery whether emergency caesarean or instrumental delivery was associated with twice the risk of having a low Apgar score and three times likely to have an intermediate Apgar score as compared to those delivered via spontaneous vaginal delivery. (Thavarajah et al., 2018). Scores of 0-2 were also found to be more prevalent at 12% in caesarian deliveries and at 3% in vaginal vertex deliveries (Finster et al., 2005). Breech presentation was associated with two times higher odds whereas other non-cephalic presentations had ten times higher odds of low Apgar score compared to cephalic presentation (Lai et al., 2017). Scores of 0-2 were also found to be more prevalent (at 20%) in breech deliveries (Finster et al., 2005).

2.2.3 Gestational age at birth

Gestational age is the major determinant of neonatal death among preterm babies. Preterm births have been associated with the risk of low Apgar scores. The gestational age is inversely related to the Apgar score (Cnattingius et al., 2020). This score in preterm babies is mainly a reflection of biologic immaturity especially in the assessment of muscle tone, reflex irritability, color and respiratory activity (Catlin et al., 1986). Preterm babies with a gestational age between 28 and 31 weeks had eight times higher odds of a low Apgar score while those with a gestation of less than 28 weeks had 15 times odds higher of having a low score (Svenvik et al., 2015).

2.3 Apgar score and adverse outcomes

2.3.1 Neonatal mortality

The neonatal mortality rate in sub-Saharan Africa is among the highest in the world at 27 per 1000 live births (Newborn Mortality, 2022). In Kenya, the rate is currently at 21 per 1000 live births, which is comparable to the continent's statistics (Kenya Demographic and Health Survey, 2022: Key indicators report 2023). The leading cause of death has been found to be intrapartum-related events which lead to asphyxia. Intrapartum-related complications lead to babies being delivered with a low Apgar score thus developing asphyxia. This is an indicator that our health facilities and health care workers are inadequately prepared to handle the labour and delivery process and ensuing emergencies thereafter (Masaba & Mmusi-Phetoe, 2020).

The Apgar score can be used to predict neonatal mortality. Neonates with a low Apgar score have been shown to have a higher risk of mortality as compared to those with an intermediate or normal score. The mortality rates decrease in neonates with normal Apgar score from a neonatal mortality rate of 500/1000 live births in those with an Apgar score of 1 to 0.37/1000 live births in those with an Apgar of 10 in preterm, term and post term births (Li et al., 2013, Iliodromiti et al., 2014, Mu et al., 2021).

To achieve Sustainable Development Goal 2 of less than 12 neonatal deaths per 1000 live births, there is need to address the causes of infant and neonatal mortality and key among them is asphyxia (The 17 Goals | Sustainable Development, 2022). The availability of trained personnel, equipment and facilities influence the outcome of an asphyxiated neonate (Ekwochi et al., 2017). Obstetric emergencies account for up to 60% of early neonatal deaths (Yego et al., 2013). This therefore informs decisions on training programmes on emergency obstetric and neonatal care (EmONC) and their implementation. One such training programme is ‘The Helping Babies Breath’ initiative that aims to decrease neonatal mortality due to asphyxia. Training conducted in a rural hospital in Kenya saw the rates of asphyxia-related deaths reduce by half in the facility (Rule et al., 2017).

2.3.2 Factors predicting survival in low Apgar score

It is worthwhile to note that low Apgar scores cannot be used as a predictor of the individual neonatal mortality or neurologic outcomes (The Apgar Score, 2015). The reason is because individual neonatal characteristics influence the outcome. A higher birth weight of the neonate will ensure that the neonate is protected from hypothermia and cold stress, is able to maintain a stable blood glucose level, and is also associated with a higher immunity (Uleanya et al., 2019). Gestational age also influences mortality with preterm babies 11 times less likely to survive low Apgar scores as compared to the term babies. The category of Apgar score has been found to be a significant determinant of survival. Those with intermediate scores were three times more likely to survive than those with a low Apgar score (Uleanya et al., 2019).

Interventions at delivery are also important predictors of survival. Resuscitation at birth with bag and mask has been found to be a statistically significant predictor of survival (Padayachee & Ballot, 2013). Asphyxia and encephalopathy are also important predictor factors with development of birth asphyxia being associated with forty three times higher risk of mortality before discharge when compared to neonates who did not develop birth asphyxia (Sunny et al., 2021).

2.3.2 Neonatal encephalopathy

Neonatal encephalopathy refers to neurologic manifestations that range from irritability in the neonate to the end of the spectrum, which is seizures and coma. It therefore describes the clinical neurological manifestations of the neonate without regard for the cause of encephalopathy (Russ et al., 2021). Hypoxic-ischemic encephalopathy (HIE), also referred to as peri-natal asphyxia has been defined as the presence of metabolic acidemia-umbilical artery blood PH <7, persistence of an Apgar score of 0-3 for more than five minutes, neurologic manifestations such as seizures, coma, and multiple organ involvements (Use and Abuse of the Apgar Score, 1996). These factors if present prove that it is likely that neonatal encephalopathy is due to hypoxia and ischemia occurring in the intrapartum or peripartum period (Neonatal Encephalopathy and Neurologic Outcome, Second Edition, 2014).

As no bedside test is available for the diagnosis and confirmation of HIE, clinicians use the features of neurologic dysfunction (encephalopathy) to make a diagnosis of perinatal asphyxia (Douglas-Escobar & Weiss, 2015). In resource limited settings, the Apgar score has been shown to have a correlation with the diagnosis of HIE, with a low one-minute score being associated with severe forms of HIE while a moderate fifth minute score was correlated with mild form of HIE (Aliyu., 2018).

Globally, asphyxia and intrapartum related complications are among the leading causes of neonatal mortality accounting for about two million newborn deaths with most occurring in the low- and middle-income countries (Lee et al., 2013). An additional two million neonates develop HIE and among these, 1.2 million experience developmental delay (Sunny et al., 2021). In a systematic review of the burden of peri-natal asphyxia in East and Central Africa, the pooled prevalence was found to be 16% with individual studies having a range of 3% - 33% (Workineh et al., 2020).

Perinatal risk factors for asphyxia include mother's age (less than 20 years), maternal hypertension, instrumental delivery, prolonged second stage of labor, MSAF, male neonate, malposition of the baby, babies with low birth weight (<2500g), and those born post term Yeshaneh et al., 2021, Igboanugo et

al., 2020). Predictors of mortality among the neonates diagnosed to be having birth asphyxia include a maternal history of pregnancy induced hypertension, anaemia in the mother and a history of convulsions in the neonate (Dessu et al., 2021, Igboanugo et al., 2020). The risk factors for the development of encephalopathy can be anticipated during the antepartum period and emergency care provided intrapartum and subsequently to the neonate after delivery. Programmes that have incorporated training on neonatal care have seen a reduction in the number of neonates who did not undergo resuscitation, severity of encephalopathy, duration of hospitalization and an increase in the Apgar score at five minutes (Duran et al., 2008).

2.3.3 Apgar score and hospital stay

The Apgar score provides a useful precursor event in the prognostication of the duration of stay in hospital (Seaton et al., 2016). In Nigeria, the duration of stay was found to be one week among neonates with asphyxia who died, while for those that survived, the duration of stay was two weeks. Similar findings were demonstrated in South Africa (Uleanya et al., 2019, Padayachee & Ballot, 2013). Another study still in South Africa found that an increase in the one minute Apgar score was associated with a shorter predicted length of stay in hospital (Pepler et al., 2012). This information is useful in communicating to and counselling the parents on the expected length of stay. Length of stay is also important in resource planning-health workforce, supplies and other services required in the provision of neonatal care in the neonatal units (Seaton et al., 2019).

2.4 Performance of the Apgar score

Since the introduction of the Apgar scoring system, concerns have emerged on whether it is a valid method of assessment of the newborn. There have also been concerns on the association between the Apgar score and both short-term and long-term outcomes. Concerns have also emerged on whether a low five minutes Apgar score can be used in the prediction of perinatal asphyxia and death (Li et al., 2013).

With regards to the reliability of the Apgar score, various challenges exist. There exists great variability in the score assigned to each component of the score regardless of the maturity status of the neonate. The interobserver reliability is equally low (O'Donnell et al., 2006). The variability is higher in the evaluation of preterm and low birth weight infants due to their underdeveloped muscular function and reflexes (Bashambu et al., 2012, Rüdiger et al., 2009). It has also been demonstrated that labor ward staff are more likely to assign a higher score than independent observers. This is because of the belief that a higher score represents better obstetric care (Schmidt et al., 1988). Those caring for the newborns may also fear criticism from colleagues thus assign a higher score (Marlow, 1992).

Omission of Apgar score may occur where delivery happens in hectic situations. This leads to the assessment of the neonate being missed altogether or done incompletely or retrospectively to complete the patients' charts (Schmidt et al., 1988, Marlow, 1992).

To better describe the condition of the neonate, Rudiger came up with a few changes to the conventional score earlier described by Virginia Apgar. A specified Apgar score was developed which contained a more specific observation of chest movement and heart rate in addition to the other elements in the original score. These two elements were to be noted as they were, regardless of any ongoing interventions in place. The maximum score being 10 as in the conventional Apgar score. The expanded scoring system was developed to document any medical interventions. These are continuous positive airway pressure, oxygen, mask and bag ventilation, intubation chest compressions, surfactant, and drugs. These total up to seven. A score of seven indicating a neonate who has not needed any intervention at birth and zero for a neonate requiring all the medical interventions captured. The combined Apgar scoring system (combination of specified and expanded score) gives a total of 17 points (Appendix 1, M Rudiger, 2012).

A study conducted to compare the performance of these scoring systems in the prediction of asphyxia found the combined score to be the most sensitive and specific with values of 97% and 99%,

respectively. The conventional score scored 80% in both sensitivity and specificity. The combined score therefore giving a more precise assessment of the neonate (Dalili et al., 2015).

Despite the above limitations, the conventional Apgar score is still useful in our set up. This is because of the resource limitations and training gaps in the resuscitation of the neonate as would need to be captured in the expanded Apgar score. The conventional score still provides a standardized way of assessment of the newborn, assessment of neonates in need of resuscitation, assessing the success of resuscitation efforts and prediction of outcome in the neonate (Papile, 2001).

2.5 Gaps identified in literature

Looking at the literature available, there was a very wide range on the prevalence of low Apgar scores in Africa (3% to 38%) and the distribution of the intermediate and normal scores was not addressed by most studies which therefore led to the need to determine the distribution of Apgar scores in our country Kenya (Gudayu, 2017, Yeshaneh et al., 2021, Ondoa-Onama & Tumwine, 2003).

Maternal and neonatal factors were shown to be important predictors of Apgar scores and subsequently influenced the neonatal outcomes of death, encephalopathy and duration of stay in hospital (Mu et al., 2021, Cnattingius et al., 2020). Hence it was important to look at the contribution of these factors to adverse neonatal outcomes in our CIN-N facilities.

With the high rate of neonatal mortality in Kenya at 21 deaths per 1000 live births due to asphyxia and intrapartum related complications, there arose a need to look at the contribution of low and intermediate Apgar scores to mortality, encephalopathy and duration of hospital stay in our primary referral centres (Kenya Demographic and Health Survey, 2022: Key indicators report 2023). These centres are equipped with newborn units and the capacity; staff and equipment to care for small and sick newborns that may need hospitalization after delivery (Irimu et al., 2021). The study of other factors which predicted survival, development of encephalopathy and the duration of hospital stay in the neonates

was also a key area of study in the CIN-N facilities to determine if comparable to the literature available.

2.6 Conceptual framework

INDEPENDENT VARIABLE

INTERVENING VARIABLES

DEPENDENT VARIABLES

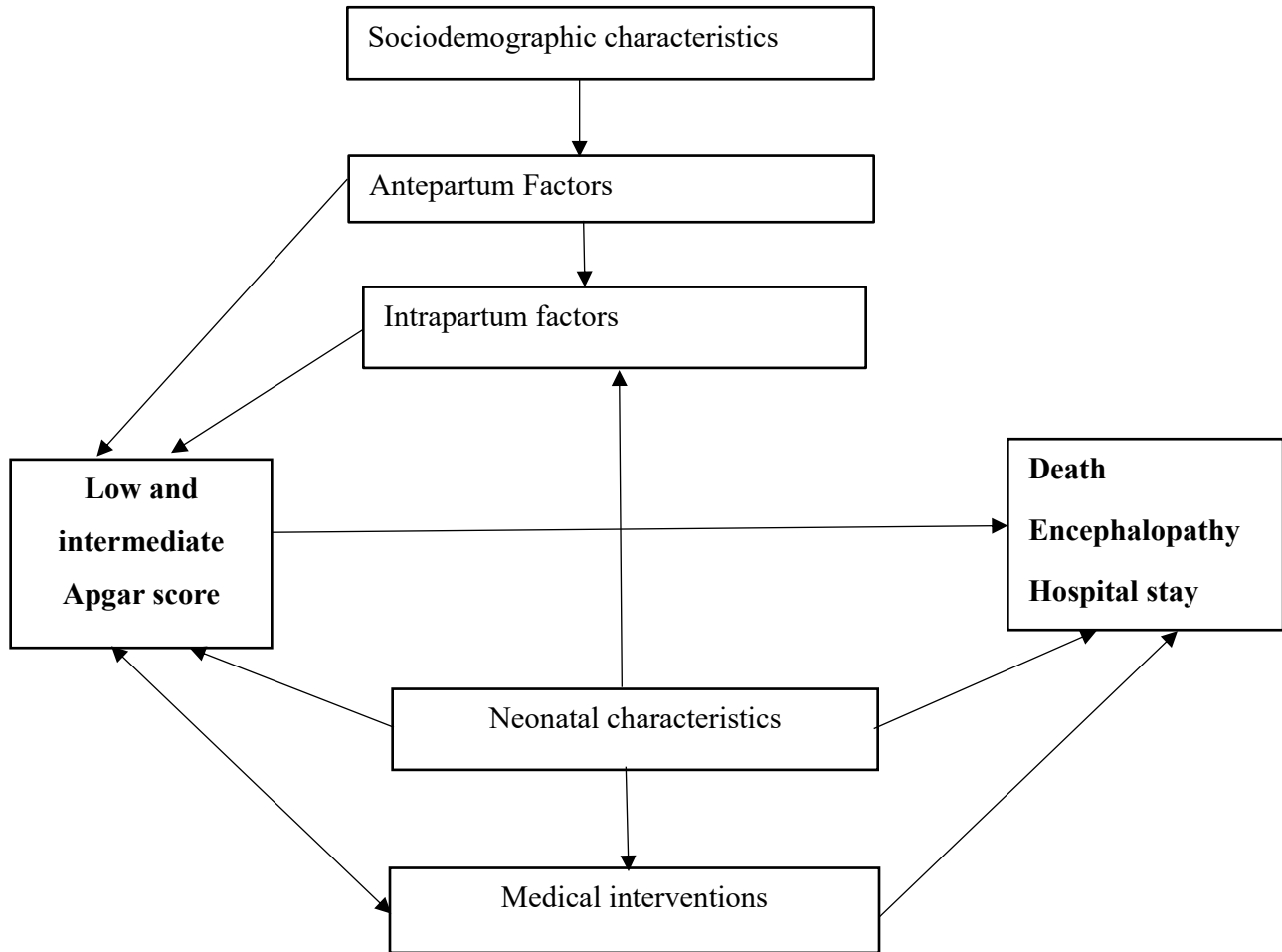


Figure 2.1: Causal diagram showing the interrelationship between Apgar score, maternal and neonatal factors and clinical outcomes.

2.6.1 Narration of the conceptual framework

A low and intermediate Apgar score at five minutes which is the independent variable is related to neonatal outcomes and this relationship is moderated by other variables. The sociodemographic characteristics of the mother determine the antepartum factors including illnesses and diseases in pregnancy and influence the intrapartum factors. Ante-partum factors also directly influence the Apgar score. Neonatal characteristics directly influence intrapartum factors- which are factors during the birth process which in turn influence the Apgar score. Neonatal characteristics affect both the score at five minutes and the three adverse outcomes. The Apgar score at five minutes determines the need for medical interventions and medical interventions could in-turn affect the Apgar score. These interventions also affect the neonatal outcomes. This interrelationship is shown in Figure 2.1 above.

2.7 Statement of research problem

The Apgar score is an indicator of the quality of obstetric and newborn care offered (Dassah et al., 2014). It has also been shown that the score is a good predictor of outcomes among them mortality and encephalopathy in population studies (The Apgar Score, 2015). In Kenya and most African countries however, there exists a challenge in patient data management and storage thus leading to poor quality data which may be incomplete or inaccurate (Kihuba et al., 2014). Studies available thus have depended on small numbers or on statistical modelling techniques in order to determine the prevalence of the Apgar score and subsequent outcomes (Shah et al., 2012). As such there has been a wide variation in the recorded prevalence of low Apgar scores and rates of encephalopathy in the African setting ranging from 3% -35% (Dassah et al., 2014, Gudayu, 2017) . The high neonatal mortality rate in Kenya of 21 deaths per 1000 live births also led to the need to determine the contribution of low Apgar scores and development of asphyxia to neonatal mortality in Kenyan facilities (Kenya Demographic and Health Survey, 2022: Key indicators report 2023). Without large data sets, it was difficult to determine the prevalence of low Apgar scores and validate the Apgar score as a good

predictor of adverse neonatal outcomes in Kenya as has been shown in literature carried out on large populations. There additionally arose a difficulty in assessing and identifying gaps in the provision of quality obstetric and newborn care. In this study, data captured from the Clinical Information Network (CIN) hospitals, which captures data from twenty-two high volume neonatal units was used. This provided a large pool of data and participants to determine the distribution of Apgar scores among neonates, assess the association between maternal and neonatal characteristics and the Apgar score at five minutes and determine the association of Apgar scores with adverse outcomes which are mortality, encephalopathy and hospital stay in the neonatal period.

2.8 Rationale/Study justification

Studies in high income countries demonstrated an increase in neonatal mortality where the Apgar score was low (Iliodromiti et al., 2014). There being differences in the practices of care, health resources capacity between Kenya and the high-income countries, there was uncertainty on whether the association would be the same. This study therefore aimed to look at the association of Apgar score and adverse outcomes in hospitals in Kenya captured in the network.

Studies focused on the predictor factors-both maternal and neonatal influencing the Apgar score (Gichogo et al., 2018). A study in Uganda focused on low Apgar score and the immediate neonatal outcomes- those occurring within the first 48 hours of birth (Ondoa-Onama & Tumwine, 2003). This study therefore looked at the Apgar score in totality and looked for associations with mortality, encephalopathy and hospital stay in the neonatal period spanning 0-28 days of life.

This was useful in enlightening health care workers involved in obstetric and neonatal care on the importance of correctly assigning the Apgar score as it may be predictive of outcomes. Additionally, the score which is used for the diagnosis of perinatal asphyxia and forms part of the admission criteria to the newborn unit would lead to more focused care of neonates categorized to have low or intermediate scores. Health care workers would be able to communicate and counsel parents on expected outcomes based on the score. At the hospital level, the results obtained could inform planning

for neonatal units such as resuscitation equipment, assess and plan for staff training needs with regards to resuscitation and continued neonatal care.

2.9 Research Question

What is the association between five-minute Apgar score and neonatal mortality, encephalopathy and hospital stay among neonates born and admitted to the new-born unit on day 1 of life in the CIN hospitals during the period 2018-2022?

2.10 Objectives

2.10.1 Broad objective

To determine the association between the five-minute Apgar scores and adverse neonatal outcomes among neonates born and admitted to the new-born unit, on day 1 of life, in the CIN hospitals, during the period 2018-2022.

2.10.2 Specific objectives

Among neonates inborn and admitted to the new-born unit on day one of life in the CIN hospitals during the period 2018-2022, to determine;

1. the distribution of Apgar scores at five minutes.
2. the association between the five-minute Apgar score and maternal and neonatal characteristics.
3. the association between five-minute Apgar scores and neonatal mortality, encephalopathy and hospital stay.

CHAPTER THREE: METHODOLOGY

3.0 Introduction

This chapter describes the materials and procedures used in the conduct of this study. It explains the study design, setting, participants, variables, statistical methods and ethical considerations in the conduct of the study.

3.1 Study design and data source

This was a retrospective cohort study. Inborn neonates admitted to the newborn unit on their first day of life formed the study population. The five-minute Apgar score and subsequent outcomes which are death, encephalopathy, and duration of stay in hospital were assessed during the neonatal period.

The exposed group was neonates with an Apgar score of less than 7 at five minutes. The unexposed/reference group was neonates with a normal Apgar score of between 7-10 at five minutes.

The study design was appropriate as it allowed us to examine multiple outcomes, the five-minute Apgar score being the exposure. A retrospective cohort study also allowed examination of the outcomes for the duration of 2018-2022 in a relatively short period of time.

Data captured in the CIN was used. Standardized Neonatal Admission Record (NAR) forms are used to capture the patient's biodata and clinical details during admission. Newborn unit exit forms capture the patient's discharge details which include diagnosis, and outcome: whether discharged alive or dead or if referred to another facility. The forms are filed together with laboratory investigation reports and other notes documented by the clinician. These forms part of patients' medical records. These forms have been adopted and are used by participating hospitals as part of their routine medical records. Data are collected soon after the patient is discharged by abstraction from the medical records into a database hosted in Research Electronic Data capture (REDCap), an open-source platform for capturing data (Harris et al., 2009).

3.2 Study area

This was a hospital-based study using data from 22 high volume neonatal units captured in the CIN. The CIN was established in 2013 as a collaboration between the Ministry of Health (MoH), Kenya Paediatric Association, KEMRI-Wellcome Trust Research Programme, University of Nairobi, and hospitals participating in the Network. One of the aims of the CIN was to improve the quality and use of data collected from patients (Irimu et al., 2021). The network also aimed to improve clinical care, clinical outcomes and service delivery (Tuti et al., 2016). It had initially started with the capture of general paediatric admissions (children aged 0-13 years), but from the year 2018 started including newborn units (NBU). It covers hospitals across 14 counties in Kenya. These include Vihiga, Kakamega, Nairobi, Machakos, Nyeri, Kisumu, Embu, Kirinyaga, Trans Nzoia, Busia, Kiambu, Nakuru, Kakamega and Bungoma. The participating hospitals represent a vast geography of the country (Tuti et al., 2015).

3.2.1 Selection of hospitals

The hospitals included in the CIN Neonatal (CIN-N) are those that offered first referral care to the surrounding communities (English et al., 2021). Twelve counties were identified purposefully by the MoH to represent two main groupings based on malaria prevalence-either high or low. Public hospitals within these counties estimated to have at least 1000 pediatric admissions per year were purposefully selected to ensure the feasibility of the project (Ayieko et al., 2016). By February 2014, thirteen county hospitals were part of the CIN. Over the years, the network has grown and had 22 hospitals by the end of the year 2020 (English et al., 2021).

The hospitals include Pumwani Maternity Hospital, Nakuru Level 5 Hospital, Thika Level 5 Hospital, Homabay County Referral Hospital, Jaramogi Oginga Odinga Teaching and Referral Hospital, Naivasha Level 5 Hospital, Kiambu Level 5 Hospital, Machakos Level 5 Hospital, Mama Lucy Kibaki Hospital, Mbagathi County Hospital, Kerugoya County Referral Hospital, Karatina District Hospital,

Nyeri County Referral Hospital, Kisumu County Hospital, Vihiga County Referral Hospital, Kakamega County General Teaching and Referral Hospital, Busia County Referral Hospital, Kitale County Referral Hospital, Embu Level 5 Teaching and Referral Hospital, Bungoma County Referral Hospital, World Friends/Ruaraka Neema Hospital and Migori County Hospital.

For purposes of this study, these hospitals were appropriate as they were centres that offered comprehensive emergency maternal and neonatal care (CEmONC facilities). They were therefore able to offer obstetric care and had neonatal units for the care of any neonate who needed admission and further management in a new born unit setting. These facilities also routinely used the standard Neonatal Admission Record (NAR), and this encouraged the accuracy and completeness of patient information captured. The health records department also had a records officer to capture the data into the REDCap database and provisions for a reliever in case the primary records officer was away ensuring continuity in data capture and easy data retrieval where necessary. They were therefore able to provide a good pool to assess the association between the Apgar score and adverse neonatal outcomes.

3.3 Study population

The study population included neonates admitted on the first day of life to the new-born unit in the CIN facilities meeting the eligibility criteria below:

3.4 Inclusion and exclusion criteria

Inclusion criteria

- a) Singleton birth
- b) Born between 2018-2022 (both years inclusive)
- c) Inborn neonates admitted to the newborn unit on day one of life

Exclusion criteria

- a) Neonates born with major congenital birth defects. This is because they have low Apgar score and a high mortality rate.

- b) Neonates born in multiple or twin gestation. This is because being born in a multi-fetal pregnancy has been documented to be associated with a low Apgar score due to pregnancy and delivery related complications such as preeclampsia, pre-term labour, malpresentation.
- c) Those with a recorded Apgar score <0 or >10 . This is an implausible value. The normal range is 0-10.

In this study, all the eligible participants captured in the CIN-N database were included. The purposive selection of the 22 neonatal facilities captured in the CIN-N introduced a selection bias in the study. All eligible neonates were included in order to reduce additional bias and random error that would be introduced by the determination and use of a sample from the participants whose data was included from the 22 neonatal units.

As a secondary data frame was available, only the neonates captured that did not meet the eligibility criteria were excluded. Data captured as 'minimum' or 'minimum record' was also excluded. This is data that is collected on a few variables usually required by the government health information system (HIS) (Tuti et al., 2016). As few variables were captured, this may have contributed to a great proportion of missingness of the data thus the reason for exclusion.

From these high-volume neonatal units, a large population study pool was available. This enhanced the generalizability of the results to other neonatal units and facilities that offer first referral care and may not be part of the CIN.

3.5 Study variables

Table 3.1: Study variables, role of variables and method of measurement

Variable	Nature of variable	Role of the variable	Measurement of variable
Five-minute Apgar score	Categorical	Independent	Captured as numeric 1,2,3,4,5,6,7,8,9 or10.
Death	Binary	Dependent	Captured as yes or no
Encephalopathy	Binary	Dependent	Captured yes or no
Hospital stay	Continuous	Dependent	Captured in days
Gestational age	Continuous	Moderating	Captured in weeks
Birth weight	Continuous	Moderating	Recorded in grams
Sex	Binary	Moderating	Recorded as Male/female/indeterminate
Mode of delivery	Nominal	Moderating	Captured as spontaneous vaginal delivery, assisted vaginal delivery, breech, caesarian section
Maternal age	Continuous	Moderating	Captured in years
Maternal illness- fever, Diabetes, hypertension	Nominal	Moderating	Captured as yes or no
Medical intervention- resuscitation, oxygen, drugs	Nominal	Moderating	Captured as yes or no

3.6 Data collection procedures

In CIN hospitals, data are collected at the time of exit, either through discharge, referral, or death. Standard Neonatal Admission Records (NAR Appendix 2) and Newborn Unit Exit Forms (Appendix 3), approved by MoH have been adopted in the hospitals to improve documentation (Irimu et al., 2018). The data captured in the forms include patient’s biodata, clinical history and physical examination, diagnosis, treatment, and outcome. Data are captured in binary or categorical fields with checkboxes and yes or no options to reduce errors during entry. Trained data clerks abstract data from the NARs into REDCap tool (Harris et al., 2009, Tuti et al., 2016, Maina et al., 2018). As part of quality assurance protocols, at the end of every day, data quality checks (data completeness and any transcription errors)

are locally run using a script written in R programming language. In the event of any discrepancies, the data clerk corrects these after verification from the patient's records. The data clerk does not make alterations to any documentation errors made by the clinicians or nurses.

As data were entered into the REDCap tool from the NAR and the newborn unit exit form, a new identity was autogenerated for deidentification. Data quality was checked using validation rules that were preprogrammed and then synchronized to a central database at KTWRP daily.

For this study, data were abstracted from the REDCap interface, from the CIN-N project. The variables of interest (as listed in Table 3.1) were selected, and the data exported and saved to an Excel spreadsheet file. As this is deidentified secondary data, no consent was required. From Excel, the data was loaded onto R software for management and analysis.

3.7 Ethical consideration

Ethical approval: The national Scientific and Ethical Review Unit (SERU) of the Kenya Medical Research Institute (KEMRI) had granted CIN ethical approval for the conduct of this study (Appendix 5). Additional ethical approval was obtained from the Kenyatta National Hospital-University of Nairobi Ethics and Research Committee (KNH-UoN ERC Proposal no. P673/08/2022) (Appendix 4).

Consent: No consent was needed as this study used secondary data. No patients were directly involved in the conduct of this study.

Confidentiality: Data in the CIN was deidentified to ensure confidentiality. Data captured in Redcap was password protected and stored in secure KWTRP servers and only accessed by the CIN data clerk, CIN data manager and to the investigator on KEMRI-Wellcome Trust issued computers.

Beneficence- This study did not lead to any harm or risk towards the study participants as they were not directly involved. Beneficiaries of the study are healthcare workers working in the maternal and neonatal units as they will be more informed on factors that could affect the Apgar score and adequately prepare for labour and delivery to ensure good outcomes for neonates. Neonates also born in these facilities are also likely to have better outcomes as they are handled by staff who are able to recognize

dangers of a less than normal Apgar score and also optimize care for those who end up with a low or intermediate score

Justice- The study used secondary data collected among neonates. Because the neonates were not directly involved in the study, there was no infringement of their rights as a vulnerable population or effect on their welfare.

Dissemination of research findings: This was done at the 13th KEMRI Annual Scientific and Health (KASH) Conference and at a seminar presentation at the KEMRI-Wellcome Trust Research Programme Nairobi. The study will also be presented to liaison staff (nurses and clinicians) working with CIN-N and the county referral facilities. Additionally, publication of the research findings will be done in a journal of Public Health.

3.8 Data management and analysis

3.8.1 Data management

The data obtained from the REDCap interface for the CIN-N project was exported to R software for windows version 4.1.2. Data management involved coding of categorical variables and dealing with implausible values. Where missing patient data was encountered, the percentage of missingness was calculated. Multiple imputation was used under the assumption that data was missing at random. This allowed analysis of all eligible patients and thus maintained the validity of the inferences obtained.

3.8.2 Descriptive analysis.

The exposure, five-minute Apgar score distribution was presented in three categories (low, intermediate and normal) in a table over the years. Maternal and neonatal characteristics were tabulated and characterized in proportions. Outcomes which were mortality and encephalopathy were reported as proportions of total observations. The duration of hospital stay, which is a continuous variable, was summarized as a median with IQR.

3.8.3 Inferential analysis

The assess for association between Apgar score categories and maternal and neonatal characteristics, Chi-square was used as they were categorical variables.

To examine the association between the Apgar score and mortality, a Cox Proportional hazards model was used as it was a time to event assessment. Adjustments were made for covariates which were captured in the conceptual framework. These were gestational age, birth weight, gender, mode of delivery, maternal age, maternal illness, and medical interventions offered.

Encephalopathy was determined at the point of admission into the newborn unit and therefore was a binary outcome; either present or absent. A multivariable logistic regression analysis was performed to determine the association and strength of association between the Apgar score and encephalopathy.

A linear regression model was fitted to determine the association between the Apgar score and duration of hospital stay as it was a continuous outcome measured in days. Sensitivity analysis was then performed to compare the effect estimates of the models with the original dataset to the one with multiply imputed datasets.

CHAPTER FOUR: STUDY RESULTS

4.0 Introduction

This chapter describes the findings of this study in line with its objectives. The study participants and their demographic characteristics, documentation and trends in Apgar scores, and the association of Apgar score and other predictors with the outcomes - mortality, encephalopathy and hospital stay - are presented.

4.1 Study population

There were 108,182 neonatal admissions to CIN from 2018 to the year 2022. After excluding those who did not meet the inclusion criteria, 60,183 (42%) were available for analysis (Figure 4.1).

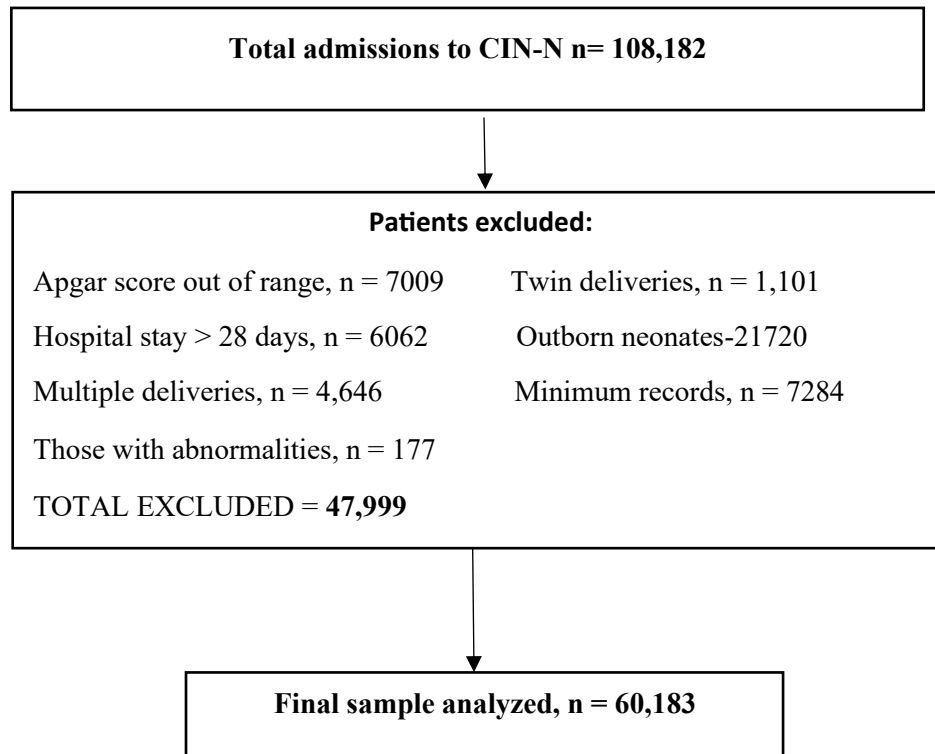


Figure 4.1: Participant inclusion criteria

4.2 Descriptive statistics of neonates admitted in the CIN-N facilities for period 2018-2022

60,183 participants were included in the analysis. 33,825 (56.56%) were male while 25,975 (43.44%) were female. The median number of days that all the neonates stayed in the hospital was three with an interquartile range (IQR) of 2 - 7 days. The crude mortality rate was 12%. Among those who died, their median duration of stay was two days (IQR = <1 - 2). The median duration of stay for those who were alive at discharge was four days (IQR = 2 -7). The proportion of babies who had encephalopathy was 8.8% (n = 5270), with 60% (n = 3166) being male and 40% (n = 2104) being female. There was full documentation of Apgar score at five minutes in all the hospitals included in this study. The documentation of Apgar scores at one and ten minutes were 99% and 97%, respectively. The 22 CIN-

N facilities contributed between 1% -12% of the total neonates for the period 2018-2022 as shown in Table 4.1.

Table 4.1: Descriptive statistics of the neonates admitted in the CIN-N facilities for the period 2018-2022

Variable	Value	Median (IQR)	Frequency (%)
Sex	Male	-	33825(56.56)
	female	-	25975(43.44)
Apgar score documentation	1 minute	-	59581(99)
	5 minutes	-	60183(100)
	10 minutes	-	58378(97)
Apgar score distribution	Low (0-3)		1637(2.7)
	Intermediate (4-6)		12035(19.9)
	Normal (7-10)		46511(77.3)
Outcomes	Mortality	-	
	Yes		7221(12)
	No	-	52962(88)
	Encephalopathy		
	Yes		5270(8.8)
	No		54913(91.2)
	Hospital stay		
	Duration of stay (All)	3(2-7)	-
	Duration of stay (Alive)	4(2-7)	-
Duration of stay (Dead)	2(<1-2)	-	
Neonate distribution in the CIN facilities	Hospital A	-	5756 (9.61)
	Hospital B	-	2380 (3.90)
	Hospital C	-	4166 (6.93)
	Hospital D	-	3886 (6.59)
	Hospital E	-	295 (0.53)
	Hospital F	-	1154 (1.97)
	Hospital G	-	2256 (3.76)
	Hospital H	-	5520 (9.12)
	Hospital I	-	6948 (11.57)
	Hospital J	-	6836 (11.48)
	Hospital K	-	2126 (3.85)
	Hospital L	-	2645 (4.48)
	Hospital M	-	2527 (4.25)
	Hospital N	-	1466 (2.44)
	Hospital O	-	2733 (4.5)
	Hospital P	-	918 (1.5)
	Hospital Q	-	563 (0.9)
	Hospital R	-	1312 (2.2)
	Hospital S	-	3936 (6.5)
	Hospital T	-	1273 (2.1)
Hospital U	-	679 (1.1)	
Hospital V	-	714 (1.2)	

4.3 Trends in Apgar score at five minutes

The proportion of babies with low Apgar score was about 3% for the study duration. Those with a normal Apgar score consisted of 77% of the total population while those with an intermediate score were about 20% (Table 4.1). Through the four-year period, there has been no change in the distribution of Apgar scores in the low, intermediate and normal score categories (Table 4.2).

	2018	2019	2020	2021	2022	Overall
Category	N%	N%	N%	N%	N%	N%
Low 0-3	216(2.8)	367(2.6)	389(2.7)	434(2.8)	231(2.6)	1637(2.7)
Intermediate 4-6	1623(21.0)	2692(19.0)	2820(20.3)	3266(20.8)	1634(18.9)	12035(19.9)
Normal 7-10	5905(76.2)	11074(78.4)	10652(77.0)	12067(76.5)	6813(78.6)	46511(77.3)

4.4 Distribution of sociodemographic characteristics and their association with the Apgar score at five minutes

The proportion of preterm babies with low Apgar score at five minutes was higher than those with intermediate and high scores (33% vs 29.1% and 28.1%, respectively; a p-value of <0.01). Those born at term had the highest proportion with normal scores at 58.1%. The distribution of Apgar scores for babies with normal birth weight, was 53%, 60% and 56% (p-value <0.01) respectively in the low, intermediate and normal Apgar score categories. Among babies who were resuscitated, 27% had low Apgar scores while 8.7% had normal Apgar scores at five minutes.

There were mixed results concerning maternal age and the Apgar score. Most mothers were in the age bracket of 20 to 34 years (72.1%). They additionally had the majority of the neonates in all Apgar score categories with 70% in the low, 70% at intermediate and 73% at the normal Apgar score. Mothers aged ≤19 years had 14.4% of their babies with intermediate Apgar score. About 34.9% of babies with low Apgar scores were born to mothers who had not previously had a live birth. Those born vaginally also had the majority (62.3%) being in the low Apgar score category.

Univariate chi-square test of associations between Apgar scores at five minutes categorized into low, intermediate and normal scores showed statistically significant associations with sex of the child (p-value <0.01), gestational age at birth (p-value <0.01), birth weight (p-value <0.01), baby's resuscitation status after birth (p-value <0.01), maternal age (p-value <0.01), parity (p-value <0.01), mode of delivery (p-value <0.01) and whether mother had diabetes (p-value <0.01) There was no statistically significant association between Apgar scores at five minutes and the mother being on tuberculosis treatment or having preeclampsia or eclampsia (p values 0.42, 0.17 and 0.41) (Table 4.3).

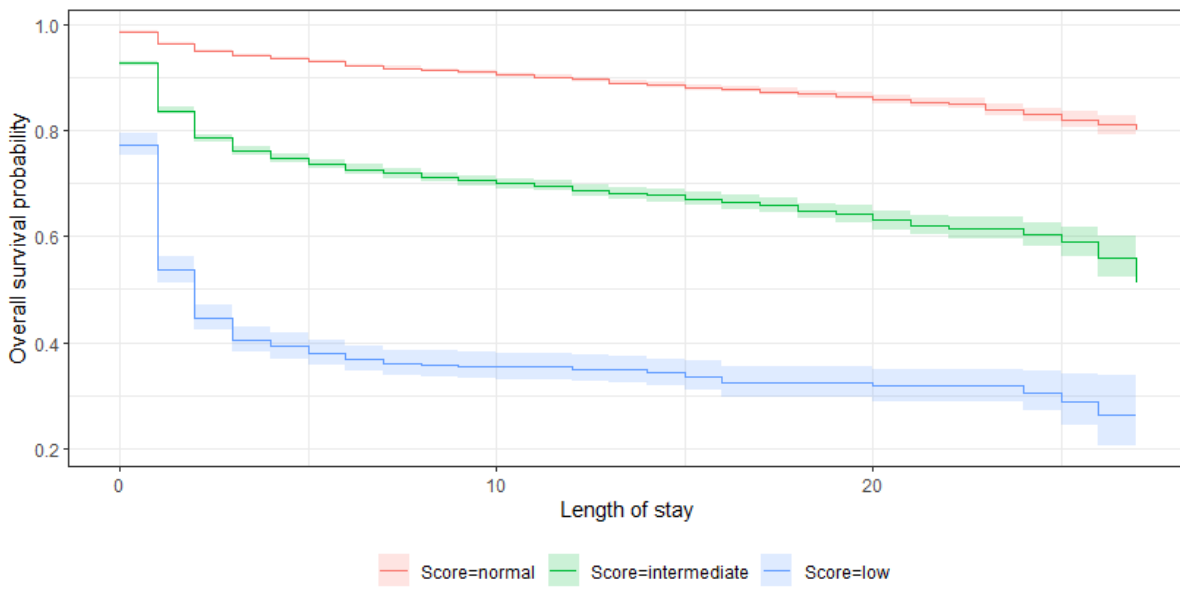
Table 4.3: Socio demographic characteristics and their association with the Apgar score at five minutes						
	Low (0-3) (N=1637)	Intermediate (4-6) (N=12035)	Normal (7-10) (N=46511)	Overall (N=60183)	Chi-square statistic (degrees of freedom)	p-value
Sex of the child					48.0 (4)	<0.01
Male	938 (57.3%)	7083 (58.9%)	25804 (55.5%)	33825 (56.2%)		
Female	690 (42.2%)	4856 (40.3%)	20429 (43.9%)	25975 (43.2%)		
Missing	9 (0.5%)	96 (0.8%)	278 (0.6%)	383 (0.6%)		
Gestational age					42.1 (4)	<0.01
Preterm	545 (33.3%)	3505 (29.1%)	13074 (28.1%)	17124 (28.5%)		
Term	850 (51.9%)	6764 (56.2%)	27038 (58.1%)	34652 (57.6%)		
Post term	60 (3.7%)	517 (4.3%)	1762 (3.8%)	2339 (3.9%)		
Missing	182 (11.1%)	1249 (10.4%)	4637 (10.0%)	6068 (10.1%)		
Birth weight					51.8 (4)	<0.01
Low birth weight	502 (30.7%)	3318 (27.6%)	12872 (27.7%)	16692 (27.7%)		
Normal birth weight	871 (53.2%)	7261 (60.3%)	26012 (55.9%)	34144 (56.7%)		
Macrosomia	37 (2.3%)	287 (2.4%)	3638 (7.8%)	3962 (6.6%)		
Missing	227 (13.9%)	1169 (9.7%)	3989 (8.6%)	5385 (8.9%)		
Baby resuscitated at birth					259.8 (2)	<0.01
Yes	437 (26.7%)	2780 (23.1%)	4054 (8.7%)	7271 (12.1%)		
No	239 (14.6%)	2157 (17.9%)	14507 (31.2%)	16903 (28.1%)		
Missing	961 (58.7%)	7098 (59.0%)	27950 (60.1%)	36009 (59.8%)		
Maternal age					139.4 (4)	<0.01
15-19 years	210 (12.8%)	1734 (14.4%)	5044 (10.8%)	6988 (11.6%)		
20-34 years	1137 (69.5%)	8392 (69.7%)	33863 (72.8%)	43392 (72.1%)		
35-49	131 (8.0%)	928 (7.7%)	4184 (9.0%)	5243 (8.7%)		
Missing	159 (9.7%)	981 (8.2%)	3420 (7.4%)	4560 (7.6%)		
Parity*					59.6 (4)	<0.01
0	572 (34.9%)	4307 (35.8%)	15298 (32.9%)	20177 (33.5%)		
1	430 (26.3%)	3491 (29.0%)	13637 (29.3%)	17558 (29.2%)		
>2	493 (30.1%)	3439 (28.6%)	14745 (31.7%)	18677 (31.0%)		
Missing	142 (8.7%)	798 (6.6%)	2831 (6.1%)	3771 (6.3%)		
Mode of delivery					102.4 (6)	<0.01
Vaginal	1020 (62.3%)	7540 (62.7%)	25036 (53.8%)	33596 (55.8%)		
Assisted vaginal	10 (0.6%)	77 (0.6%)	97 (0.2%)	184 (0.3%)		
Breech	103 (6.3%)	440 (3.7%)	609 (1.3%)	1152 (1.9%)		
Caesarean	491 (30.0%)	3914 (32.5%)	20578 (44.2%)	24983 (41.5%)		
Missing	13 (0.8%)	64 (0.5%)	191 (0.4%)	268 (0.4%)		
Mother with diabetes					21.38 (2)	<0.01
Yes	-	31 (0.3%)	237 (0.5%)	268 (0.4%)		
No	681 (41.6%)	5305 (44.1%)	20160 (43.3%)	26146 (43.4%)		
Missing	956 (58.4%)	6699 (55.7%)	26114 (56.1%)	33769 (56.1%)		
Mother with preeclampsia					3.5 (2)	0.17
Yes	22 (1.3%)	222 (1.8%)	876 (1.9%)	1120 (1.9%)		
No	622 (38.0%)	4925 (40.9%)	17723 (38.1%)	23270 (38.7%)		
Missing	993 (60.7%)	6888 (57.2%)	27912 (60.0%)	35793 (59.5%)		
Mother with eclampsia					1.74 (2)	0.41
Yes	5 (0.3%)	73 (0.6%)	244 (0.5%)	322 (0.5%)		
No	606 (37.0%)	4887 (40.6%)	17575 (37.8%)	23068 (38.3%)		
Missing	1026 (62.7%)	7075 (58.8%)	28692 (61.7%)	36793 (61.1%)		
Mother on TB treatment					1.66 (2)	0.42
Yes	2 (0.1%)	15 (0.1%)	72 (0.2%)	89 (0.1%)		
No	690 (42.2%)	5332 (44.3%)	20483 (44.0%)	26505 (44.0%)		
Missing	945 (57.7%)	6688 (55.6%)	25956 (55.8%)	33589 (55.8%)		

*Parity refers to number of previous pregnancies before the current delivery carried beyond 28 completed weeks of gestation irrespective of the outcome

4.5 Mortality and Apgar score

4.5.1 Probability of survival based on Apgar scores at 5 minutes

The probability of a baby surviving on day one of staying in the hospital with normal, intermediate, and low Apgar score were 96%, 83% and 54%, respectively (Figure 4.2). By the end of the 28 days, the probability of survival for babies with normal, intermediate, and low Apgar score at five minutes was 80%, 51% and 26% respectively.

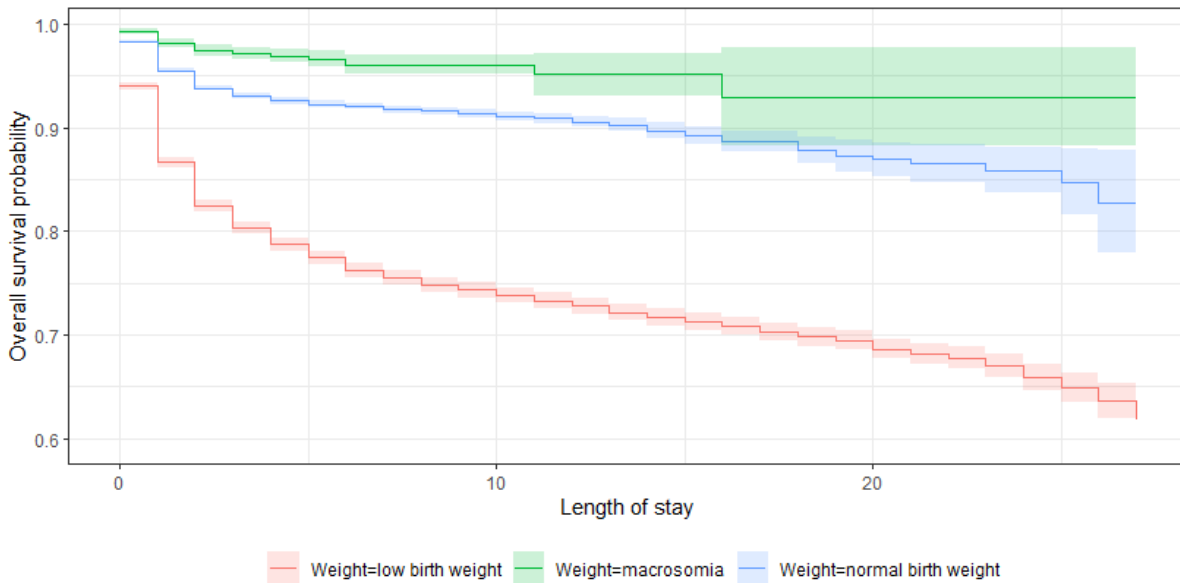


Score=normal			
At Risk	46471	6643	1645
Events	624	2999	3178
Score=intermediate			
At Risk	12029	1919	420
Events	884	3110	3197
Score=low			
At Risk	1636	227	56
Events	372	1018	1030

Figure 4.2: Kaplan Meir survival estimates by Apgar score at five minutes

4.5.2 Survival probability based on birth weight

Survival probabilities based on weight of the baby at birth showed that on day one of admission, those with macrosomia, normal and low birth weights had a 98%, 95% and 87% probability of survival, respectively (Figure 4.3). Babies with macrosomia were more likely to survive at the end of the study (93% probability of survival) when compared to those with normal birth weight at 83%, while those with a low birthweight had 62% probability of survival. A log rank test was performed which showed statistically significant differences between the curves (p-value less than 0.01).



Weight=low birth weight			
At Risk	16679	5379	1678
Events	1003	3877	4103
Weight=macrosomia			
At Risk	3960	142	19
Events	29	105	107
Weight=normal birth weight			
At Risk	34119	2588	255
Events	590	2373	2407

Figure 4.3: Kaplan Meir survival estimates given the birth weight

4.5.3 Hazard ratios of survival in relation to the five-minute Apgar score

Crude hazard ratios (HRs) of survival with Apgar scores at five minutes treated as a continuous variable showed that for every unit increase in the score, the risk of death was reduced by 37% (HR:0.63, 95% CI: 0.61-0.64). The adjusted HR was 0.63 (95% CI: 0.61-0.64). Covariates used to find the adjusted hazard ratio were the maternal and neonatal factors available for this study which are also factors similarly discussed in literature that influence the neonatal outcome given a specific Apgar score. These were neonates' sex, gestational age, birthweight, resuscitation, maternal age and maternal health conditions (diabetes, eclampsia, preeclampsia), mode of delivery and parity (Cnattingius et al., 2020, Thavarajah et al., 2018, Mu et al., 2021)

When the Apgar score categories were used, the crude hazard of death was 12.44 (95% CI 11.6-13.35) among those with a low Apgar score while the adjusted hazard ratio was 10.97 (95% CI 9.45-12.73) when compared with the normal Apgar score category. The hazard of death was four times higher (HR 4.02, 95% CI 3.83-4.22) in those with an intermediate Apgar score, while the adjusted hazard ratio was three times higher (HR 3.6 95% CI 3.26-3.97) when compared to those with a normal score (Table 4.4).

Babies born preterm and those with low birth weight, appeared to have 1.62 (95% CI 1.46 - 1.80) and 2.70 (95% CI 2.43 – 3.00) hazard of death compared to babies born at term and with normal birth weight, respectively. Babies with macrosomia had a 23% (HR 0.77 95% CI 0.5-1.05) lower risk of death compared to those with normal birth weight. This was, however, not statistically significant. Neonates that were resuscitated had 78% higher risk of death compared to those that were not resuscitated (HR: 1.78; 95% CI 1.71-1.86) (Table 4.4).

Table 4.4 Cox proportional hazard model fitted to evaluate the association between Apgar score, neonatal and maternal factors and death								
	Outcome		Crude hazard ratio			Adjusted Hazard ratio		
	Alive n (%)	Died n (%)	HR	95% Confidence Interval	P-value	HR	95% Confidence Interval	P-value
Apgar score at 5 minutes								
Normal	43250 (71.92)	3221 (5.36)	Reference					
Low	603 (1.00)	1033 (1.72)	12.44	11.6 – 13.35	<0.01	10.97	9.45 – 12.73	<0.01
Intermediate	8810 (14.65)	3219 (5.35)	4.02	3.83 – 4.22	<0.01	3.6	3.26 - 3.97	<0.01
Child sex								
Male	29687 (49.68)	4114 (6.88)	Reference					
Female	22654 (37.91%)	3299 (5.52)	1.04	0.99-1.09	0.07	1.03	0.94-1.12	0.78
Gestational age								
Term	32167 (53.49)	2456 (4.08)	Reference					
Pre-term	2154 (3.58)	185 (0.31)	1.13	0.97-1.32	0.09	1.62	1.46 - 1.80	<0.01
Post-term	18342 (30.50)	4832 (8.40)	2.67	2.54-2.81	<0.05	1.17	0.90 – 1.53	0.23
Birth Weight								
Normal	31708 (57.91)	2411 (4.40)	Reference					
Macrosomia	12516 (22.86)	4163 (7.60)	3.12	2.96-3.26	<0.05	0.77	0.56 – 1.05	0.05
Low	3853 (7.04)	107 (0.20)	0.42	0.34-0.52	<0.05	2.70	2.43 – 3.00	<0.01
Resuscitation at birth								
No	5749 (23.80)	1517 (6.28)	Reference					
Yes	15280 (63.25)	1612 (6.67)	0.43	0.40-0.47	<0.05	0.78	0.71-0.86	<0.01
Maternal age in years								
20-35	38138 (68.61)	5224 (9.40)	Reference					
15-19	6066 (10.91)	915 (1.65)	1.07	0.99-1.14	0.07	1.08	0.74 – 1.64	0.39
35-49	4623 (8.32)	618 (1.11)	0.96	0.88-1.04	0.34	1.13	0.95 – 1.33	0.88
Mother with diabetes								
No	243 (0.92)	25 (0.09)	Reference					
Yes	22871 (86.63)	3261 (12.35)	1.37	0.92-2.03	0.11	1.01	0.62 -1.65	0.60
Mother with pre-eclampsia								
No	896 (3.68)	220 (0.90)	Reference					
Yes	20367 (83.55)	2893 (11.89)	0.72	0.62-0.95	<0.05	0.98	0.82 – 1.17	0.50
Mother with eclampsia								
No	254 (1.09)	68 (0.29)	Reference					
Yes	20189 (83.36)	2867 (12.26)	0.65	0.51-0.83	<0.01	0.91	0.66 – 1.26	0.41
Mode of delivery								
Vaginal delivery	28887 (48.25)	4690 (7.83)	Reference					
Assisted vaginal delivery	158 (0.26)	25 (0.04)	0.93	0.62-1.38	0.73	1	0.5 - 2	0.89
Breech	846 (1.41)	306 (0.51)	1.90	1.69-2.15	<0.05	0.92	0.73 - 1.16	0.80
Caesarian section	22550 (37.66)	2408 (4.02)	0.69	0.65-0.72	<0.05	0.88	0.8 - 0.97	<0.01
Parity live birth								
0	17946 (31.84)	2218 (3.93)	Reference					
1	15421 (27.36)	2120 (3.76)	1.11	1.04-1.17	>0.05	0.94	0.84 - 1.05	0.30
>2	16141 (28.63)	2525 (4.48)	1.23	1.18-1.31	>0.05	1.1	0.98-1.24	0.21
Note: sex, gestational age, birthweight, resuscitation, maternal age and maternal health conditions (diabetes, eclampsia, preeclampsia), mode of delivery and parity were used to adjust the crude hazard ratio								

4.6 Encephalopathy and Apgar score

The odds of developing encephalopathy when a baby had an intermediate and low Apgar score at five minutes were 5.73 (95% CI 5.37-6.12) and 15.87(95% CI 13.9-17.6) times higher respectively compared to the normal Apgar score.

Babies resuscitated at birth had one third higher odds of developing encephalopathy (OR: 1.28; 95% CI 1.23-1.35) compared to those who were not resuscitated. Those born via caesarian section had 30% lower odds (OR 0.7; 95% CI 0.56-0.88) of developing encephalopathy when compared with those delivered vaginally. A prior parity of one was associated with 36% lower odds (OR 0.64; 95% CI 0.49-0.84) of the risk of developing encephalopathy when compared with those that had not had a previous delivery and this was statistically significant (Table 4.5).

Being female, macrosomia, assisted vaginal delivery and parity of more than two (OR 0.99; 95% CI 0.8-1.21, OR 0.62; 95% CI 0.32-1.09, OR 0.01; 95% CI -0.23-0.04, and OR 0.91; 95% CI 0.69-1.19, respectively) were found to be protective against encephalopathy. However, these associations were not statistically significant.

Compared to term neonates, preterm (OR; 1.13 95% CI 0.86-1.47) and post-term (OR 1.12; 95% CI 0.62-1.87) neonates had higher odds of developing encephalopathy. Similarly, those with low birth weight (OR 1.06; 95% CI 0.8-1.39) had higher odds of developing encephalopathy compared to those with normal birth weight. Neonates born to mothers on the extreme age categories (15-19 years and 36-49 years) had about 10% higher odds (OR 1.1; 95% CI 0.8-1.47 and OR 1.13; 95% CI 0.77-1.6, respectively) of developing encephalopathy when compared to those born to mothers in the 20-35 years age category. These factors though associated with a higher risk of developing encephalopathy had no statistically significant association demonstrated. Those born to mothers who had eclampsia showed no added risk (OR 1; 95% CI 0.41-3.43) of developing encephalopathy when compared to those whose mothers did not have eclampsia (Table 4.5).

Table 4.5: Binomial logistic regression of neonatal and maternal factors and the risk of developing encephalopathy					
Predictors	Number without encephalopathy (%)	Number with encephalopathy (%)	Odds ratio	95% Confidence interval	P value
Apgar score at 5 minutes					
Normal (7-10)	46511 (79.41)	532 (7.00)	Ref.		
Intermediate (4-6)	12035 (20.63)	2035 (38.64)	5.73	5.37 - 6.12	<0.01
Low (0-3)	0 (0.00)	2729 (55.36)	15.87	13.9 - 17.6	<0.01
Sex					
Male	32887 (56.23)	788 (56.60)	Ref.		
Female	25285 (43.28)	596 (42.84)	0.99	0.8 -1.21	0.89
Baby resuscitated at birth					
No	6834 (11.75)	371 (26.79)	Ref.		
Yes	16664 (28.50)	205 (14.77)	1.28	1.23 – 1.35	<0.01
Gestational age					
Term	33802 (57.75)	721 (51.87)	Ref.		
Pre-term	22465 (38.42)	620 (44.59)	1.13	0.86 – 1.47	0.37
Post-term	2279 (3.93)	51 (3.72)	1.12	0.62 – 1.87	0.68
Birth weight					
Normal	33273 (56.82)	731 (52.51)	Ref.		
Low	16190 (27.74)	437 (31.43)	1.06	0.8 – 1.39	0.7
Macrosomia	3925 (6.76)	30 (2.25)	0.62	0.32 – 1.09	0.13
Maternal age in years					
20-35	42255 (72.29)	959 (68.90)	Ref.		
15-19	6778 (11.62)	187 (13.47)	1.1	0.8 – 1.47	0.56
36-49	5112 (8.74)	112 (8.00)	1.13	0.77 – 1.6	0.52
Mode of delivery					
vaginal delivery	32576 (55.61)	859 (61.70)	Ref.		
Assisted vaginal	174 (0.31)	4 (0.38)	0.01	-0.23 –0.04	0.95
Breech	1049 (1.80)	85 (6.11)	2.28	1.38 – 3.57	<0.01
Caesarean section	24492 (41.80)	437 (31.40)	0.7	0.56 -0.88	<0.01
Mother with preeclampsia					
No	1098 (1.91)	19 (1.42)	Ref.		
Yes	22648 (38.70)	533 (38.30)	0.94	0.56 – 1.69	0.83
Mother with eclampsia					
No	317 (0.51)	5 (0.41)	Ref.		
Yes	22462 (38.40)	521 (37.43)	1	0.41 – 3.43	0.99
Parity live birth					
0	19605 (33.51)	491 (35.30)	Ref.		
1	17128 (29.32)	361 (25.90)	0.64	0.49 -0.84	<0.01
>2	18184 (31.10)	426 (30.60)	0.91	0.69 -1.19	0.49

4.7 Apgar score and hospital stay

Table 4.6: Linear regression model fitted to determine relationship between Apgar score and Neonatal and maternal factors with length of hospital stay			
Predictors	Regression Coefficients	95% Confidence Interval	P value
Intercept	-0.34	-0.39 – -0.30	<0.001
Apgar score at 5 minutes			
Normal	Ref.		
Intermediate	0.98	0.82 – 1.15	<0.001
Low	1.66	1.25 – 2.07	<0.001
Gestational age			
Term	Ref.		
Pre-term	1.25	1.07 – 1.43	<0.001
Post-term	-0.05	-0.40 – 0.31	0.800
Birth weight			
Normal	Ref.		
Low	3.59	3.40 – 3.78	<0.001
Macrosomia	0.92	0.63 – 1.21	<0.001
Baby resuscitated at birth			
No	Ref.		
Yes	0.01	-0.17 – 0.16	0.971
Child sex			
Male	Ref.		
Female	-0.11	-0.25 – 0.03	0.127
Mode of delivery			
Vaginal delivery	Ref.		0.468
Assisted vaginal delivery	-0.19	-0.71 – 0.33	0.479
Breech	0.07	-0.08 – 0.21	0.362
Outcome of neonate			
Alive	Ref.		
Dead	-5.66	-5.87 – -5.45	<0.001
Maternal age in years			
20-35	Ref.		
15-19	0.17	-0.05 – 0.39	0.123
36-49	0.28	0.03 – 0.52	0.027
Parity live birth			
0	Ref.		
1	-0.19	-0.37 – -0.02	0.026
>2	-0.15	-0.33 – 0.04	0.122
Mother with pre-eclampsia			
No	Ref.		
Yes	1.15	1.02 – 1.52	<0.001
Mother with eclampsia			
No	Ref.		
Yes	-0.33	-1.00 – 0.34	0.336

The linear regression intercept was -0.34 (95% CI -0.39 – -0.30) indicating that a unit increase in the Apgar score was associated with a decrease in the duration of hospital stay by approximately one day. With reference to those babies with normal Apgar scores, those with intermediate Apgar scores stayed one day more ($\beta=0.98$; 95% CI 0.82-1.15) and those with low Apgar scores stayed approximately two days longer ($\beta=1.66$; 95% CI 1.25-2.07) and this was statistically significant. Babies born preterm stayed approximately two days longer ($\beta=1.25$; 95% CI 1.07-1.43) than those born at term. In addition, those who were born with low birthweight stayed four days longer ($\beta=3.59$; 95% CI 3.40-3.78) and those born with macrosomia a day less ($\beta=-0.92$; 95% CI -1.21 – -0.63) than those born with normal weight. Babies who were resuscitated at birth, stayed a day more ($\beta=0.01$; 95% CI -0.17– 0.16) than those who were not resuscitated. Neonates that died had six days less duration of stay ($\beta=-5.66$; 95% CI -5.87 – -5.45) compared to those that were alive at the end of the neonatal period. For neonates born to mothers who had pre-eclampsia, they had a two day longer stay ($\beta=1.15$; 95% CI 1.02-1.52) in hospital than those born to mothers who did not have pre-eclampsia (Table 4.6)

CHAPTER FIVE: DISCUSSION

5.0 Introduction

This chapter aims to discuss the study findings and compares the results with other authors' work to identify similarities or differences.

5.1 Descriptive statistics discussion

The neonatal mortality rate in this study was found to be 12%. This is similar to other studies done on the CIN-N on the same population, which found a mortality rate of 10-12% (Irimu et al., 2021). Studies looking at neonates admitted to the newborn units in Kenya have found mortality rates ranging from 3-60% (Aluvaala et al., 2019). The wide range could reflect the quality of care and resource availability as a low mortality rate was seen in a private facility while rates up to 60% were seen in district facilities in the rural areas of Kenya.

The median duration of stay was three days with an interquartile range of 2-7 days. Those who died had a shorter duration of stay (two days) compared to those who were discharged alive (four days). Similar findings were reported in Johannesburg and Nigeria where those who died had a shorter stay than those discharged alive, Uleanya et al., 2019). This could be an indicator that those who died had severe conditions at admission (Padayachee & Ballot, 2013).

The proportion of babies that had encephalopathy in our study was 8.8%. This is consistent with the findings in a Nigerian teaching hospital that had a prevalence of 7.1% and Eritrea at 6% (Ezenwa et al., 2021, Shah et al., 2012). The reason could be due to the uniformity in the definition of encephalopathy used in the studies. The definition used was the presence of neurologic signs and symptoms. These included altered level of consciousness, convulsions, abnormal tone and history of delayed cry or prolonged duration of resuscitation at birth. This is, however, lower than the pooled prevalence noted in Central and East African countries at 16% (Workineh et al., 2020). The wide

disparity can be explained by the different definitions used for perinatal asphyxia and encephalopathy across the different studies, including the inclusion of the Apgar score at one minute or five minutes and the cut-off point of the score (some used a score of 6 while others used a score of 7) in defining asphyxia. Additionally, these studies with a high prevalence were conducted in large teaching and referral hospitals, which tend to admit larger numbers of neonates in more critical condition while our study was set in primary referral centres (Uleanya et al., 2019, Ezenwa et al., 2021, Ilah et al., 2015, Ondoa-Onama & Tumwine, 2003).

5.2: Distribution of Apgar scores at five minutes

This study found that 77% of neonates inborn in the CIN-N facilities had normal Apgar scores at five minutes. This is consistent with most studies looking at the Apgar score at five minutes indicating that a majority of newborns have a normal score (Thavarajah et al., 2018).

The highest proportion of neonates had an Apgar score of nine this being 28% of the population studied. Those with low Apgar score constituted about 3% of the total neonates. This is consistent with a study done in Uganda that found the prevalence of low scores to be at 2.8% (Ondoa-Onama & Tumwine, 2003). This is also similar to studies in European countries, which found a low Apgar score prevalence of 0-2% (Ehrenstein et al., 2009, Siddiqui et al., 2017, Thavarajah et al., 2018). It differs from studies in Africa which have recorded a prevalence of up to 38% (Dassah et al., 2014, Gudayu, 2017, Yeshaneh et al., 2021). This could be explained by the differences in coverage, quality and access to maternal care in the different regions (Workineh et al., 2020)

5.3: Maternal and neonatal characteristics and their association with the five-minute Apgar score

The results indicated that male neonates were the majority in all Apgar score categories. This was similarly demonstrated in a study in Israel (Wainstock & Sheiner, 2022). This could be due to the sex-ratio at birth being in favour of the male (Kenya National Bureau of Statistics et al., 2015).

Preterm neonates were most likely to have low Apgar scores while most of the term neonates had higher Apgar scores. This could be explained by the expected immature neurologic system and the difficult respiratory and cardiac transition seen in preterm babies (Cnattingius et al., 2020, Mu et al., 2021, Catlin et al., 1986, Wainstock & Sheiner, 2022).

Those in the low-birth-weight category similarly had more neonates with low Apgar scores. This is similar to a study done in Ethiopia (Gudayu, 2017). Low birth weight babies were more likely to experience difficulties in cardiac and respiratory transition from the uterine environment and additionally have reduced muscle tone and thus record a low Apgar score (Yeshaneh et al., 2021). For the neonates with macrosomia, most had a normal score. They additionally had the least proportion of neonates with low scores similar to a study in China (Mu et al., 2021).

For the babies noted to have been resuscitated at birth, a large proportion still had a low Apgar score at five minutes. This is despite the essential resuscitation equipment as listed by WHO - bag and mask, suction, source of warmth for the baby and a clock - being available. This could be a pointer to health care workers being untrained and not competent in proper resuscitation techniques and pointing to the need for refresher training (Kinoti, 1993, Gichogo et al., 2018, Rule et al., 2017).

Primiparous women constituted the majority in our study and were more likely to have neonates with a low Apgar score. Studies in Nigeria, East, Central and Southern Africa have reported similar findings. This could be because they may have been unaware of the risks in pregnancy and the need for antenatal care attendance and timely plan for skilled delivery (Kinoti, 1993, Ilah et al., 2015).

Most deliveries occurred vaginally. The highest proportion of those with low and intermediate Apgar scores was in the neonates born vaginally. This is consistent with studies in Africa and in China (Mu et al., 2021, Gudayu, 2017, Shah et al., 2012). About 30% of neonates delivered via caesarian section had a low Apgar score. This could be an indicator of unavailability of skilled health personnel for

vaginal or caesarian deliveries. It could also indicate lack of timely caesarian deliveries in the health facilities more often being done once labour has become prolonged and the foetus is in distress (Ondoa-Onama & Tumwine, 2003). Given that the hospitals under study are primary referral centres in the particular counties, delays occasioned by distance to the health facilities, or lack of transportation and funds to reach the health facilities could be responsible for the low number of deliveries via caesarian section and therefore poor Apgar scores among neonates who are inevitably delivered vaginally (Irani & Deering, 2015).

Breech deliveries also had most neonates scoring low Apgar scores. This could be due to the complex maneuvers and increased manipulation to deliver the foetus, difficulty in delivery and trauma endured by neonates not presenting in the vertex position (West & Opara, 2013, Gudayu, 2017).

For maternal conditions in pregnancy, only diabetes was found to have a statistically significant association with the Apgar score category. Most neonates born to mothers with diabetes were in the intermediate Apgar score category, similar to studies in Australia and Israel (Lai et al., 2017, Wainstock & Sheiner, 2022). Pre-eclampsia, eclampsia and being on treatment for tuberculosis was not found to have statistically significant association with the Apgar score category similar to a study in Australia (Thavarajah et al., 2018). Other studies have found hypertensive diseases in pregnancy to be associated with a low Apgar score (Lai et al., 2017, Odd et al., 2008, Wainstock & Sheiner, 2022). We, however, note a huge percentage of missing data on medical conditions, which could have influenced any association.

5.4: Association between five-minute Apgar scores and neonatal mortality, encephalopathy and hospital stay.

5.4.1 Apgar score and neonatal mortality.

On the first day of life, survival probability was highest in the neonates with normal Apgar score than in those with intermediate and low scores in the neonatal period. At the end of the neonatal period

survival probability was highest in the normal Apgar score category at 80% and lowest in the low Apgar score category at 26%. Similar findings were reported in a study conducted in America (Li et al., 2013). This further cements the usefulness of the Apgar score at five minutes as an indicator of the neonates ability to “survive” and “thrive” (Jeganathan et al., 2017, Finster et al., 2005).

A unit increase in the Apgar score at five minutes was associated with a 37% reduction in the hazard of death (HR 0.63; 95% CI 0.61-0.64). This is comparable to a study in South Africa where increase in the Apgar score led to a decline in the odds of death (Pepler et al., 2012). The crude hazard of death was 12 times higher among those in the low Apgar score category while among those with an intermediate score, the crude hazard was four times higher. Similar findings have been demonstrated in various studies indicating that the Apgar score category is a useful predictor of neonatal mortality (Cnattingius et al., 2020, Li et al., 2013, Mu et al., 2021).

Those with low birth weight had the lowest chance of survival within the neonatal period. Preterm birth and low birthweight were found to have statistically significant associations with the risk of death. This is comparable with studies that have found the risk of neonatal death to increase as the gestational age decreases. The highest mortality being in babies with a lower gestational age, those with low birth weight and a low score at five minutes (Cnattingius et al., 2020, Mu et al., 2021, Lee et al., 2010, Shah et al., 2012, Pepler et al., 2012). This can be attributed to difficulties in delivery, difficulty in regulation of body temperature and glucose levels, hypoxia and metabolic acidosis in the preterm neonate thus leading to lower survival rates (Uleanya et al., 2019, Shah et al., 2012). Looking at survival categorizing by birthweight, those with macrosomia had higher survival rates than those with normal birth weight indicating that a higher birth weight was protective.

Babies that were resuscitated at birth had an increased hazard of death. This could indicate that those who were resuscitated were sicker and in worse condition compared to those who did not need resuscitation and therefore at a higher risk of death. It could also be a pointer to the quality of

resuscitation. A study on resuscitation in low-income settings found that there was increased mortality among neonates resuscitated due to lack of required skills and equipment in the facilities (Shukla et al., 2022).

There was no statistically significant relationship between maternal age and maternal conditions and the hazard of death. Maternal age was also not found to be associated with the risk of neonatal death in Eritrea (Shah et al., 2012). We, however, note a huge degree of missingness in our data on maternal conditions and this could have influenced the relationship with neonatal mortality.

No statistically significant association was noted between mode of delivery and parity and the hazard of death in our study. However, studies have been able to demonstrate increased risk of neonatal mortality among caesarian section deliveries in Africa. This is due to the fact that there is low access to operative delivery facilities and therefore mothers present late and at higher risk for surgery thus leading to increased risk of maternal and neonatal mortality (Bishop et al., 2019).

5.4.2 Apgar score and encephalopathy

Female sex was found to be protective against encephalopathy. Similar findings have been reported in India (Sunny et al., 2021). This could be due to the protective benefit conferred by an additional X chromosome in females which offers protection against both infectious and non-infectious diseases (Pongou, 2013). Being male was found to be a risk factor for encephalopathy (Futrakul et al., 2006). Additionally, sex differences in the immune response following hypoxia and ischemia have been reported leading to a worse manifestation in the male neonates (Mirza et al., 2015).

Neonates born both preterm and post term had more than one-fold odds of encephalopathy. However, this was not found to be statistically significant in our study. Studies in Ethiopia and Thailand have found a statistically significant association (Futrakul et al., 2006). The reason could be due to complications arising from prematurity and an ageing and insufficient placenta (Sunny et al., 2021).

Macrosomia was found to be protective against encephalopathy; however, the association was not statistically significant. Low birth weight neonates had added risk of developing encephalopathy. This differs from studies which have demonstrated that both low birth weight and macrosomia are associated with increased risk of encephalopathy (Zhang et al., 2008). Pregnant women that had macrosomic babies were at an increased risk of delivery via caesarian section (Olorok et al., 2015). This could explain macrosomia being protective as outcomes in the neonate are optimized through a timely caesarian delivery. Proper preparation for the anticipated delivery, for example, a delivery through a caesarian section as opposed to a vaginal delivery could significantly reduce the risk of encephalopathy (Osaikhuwuomwan et al., 2016).

5.4.3 Apgar score and hospital stay

A low Apgar score was associated with two days longer duration of stay while an intermediate Apgar score was associated with a day longer duration of stay when compared to the normal Apgar category. Similar findings were reported in South Africa (Pepler et al., 2012).

Mothers with pre-eclampsia had a two day longer duration of hospital stay. Pre-eclampsia is associated with a higher incidence of adverse outcomes in the neonate. These include prematurity, low birth weight and low five minute Apgar scores in the neonate which could explain a longer duration of stay (Schimmel et al., 2015).

On neonatal factors, babies born preterm had an approximately two days longer duration of stay as compared to the term infants. Low birth weight was associated with a four day longer duration of stay. Similar findings were reported in Ethiopia. This could be explained by the fact that babies born premature and with low birth weight have more health problems such as respiratory distress and may require more care to survive (Biru et al., 2021). Macrosomia was associated with a day longer length of stay when compared to those with a normal birth weight. A study in Ethiopia found that a higher birth weight was associated with a longer hospital stay owing to complications that may arise including

asphyxia owing to cephalo-pelvic disproportion, prolonged and obstructed labour and hypoglycemia in the macrosomic neonate (Biru et al., 2021 Ilah et al., 2015).

Resuscitated infants had a longer duration of stay as compared to those who were not resuscitated. However, this association was not statistically significant. Neonates needing resuscitation for proper transition to extrauterine life could be having, among other conditions, prematurity and asphyxia for which resuscitation improves survival. Resuscitation hence prolongs their hospital stay with continued interventions including oxygen supplementation and positive pressure ventilation (Cho et al., 2015). Additionally, this could be a pointer to the delay in initiation of resuscitation which requires a series of time sensitive steps or the quality of resuscitation by health care workers. A study conducted in Tanzania found that with every thirty seconds delay in initiating resuscitation, the risk of prolonged duration of admission in the neonatal unit increased by 16% (Ersdal et al., 2012 , Shukla et al., 2022).

Neonates who died had a six-day less duration of stay compared to those who were alive at the time of discharge. This could indicate that the neonates who died had been admitted with conditions that were more severe than those who remained alive. Similar findings were reported in South Africa (Padayachee & Ballot, 2013).

5.5 Study strengths and limitations

This study was able to answer the research question and meet the objectives on the distribution of Apgar scores among neonates, assess the association between maternal and neonatal characteristics and the Apgar score at five minutes and determine the association of Apgar scores with adverse outcomes.

This study was the first of its kind to look at Apgar score and adverse outcomes in neonates in 22 neonatal units in the country. This large number of observations means that the results can be

extrapolated to other primary referral centres. This allowed the validation of the Apgar scoring system which has proven utility in large populations.

However, this study was not able to assess the accuracy of the assigned Apgar scores which could have ultimately influenced the relationships explored between the Apgar scores and outcomes.

Individual hospital factors that affect the length of stay were not assessed. Length of hospital stay is affected by among other factors the hospital resources. These include the staff and their cadres, health care equipment and technologies available which may be different in the 22 units assessed though they all are primary referral centres.

CHAPTER SIX: CONCLUSION AND RECOMMENDATIONS

6.0 Introduction

This chapter outlines the major findings of this study in line with the specific objectives and provides recommendations from the study.

6.1 Conclusion

This study found that 77% of neonates had a normal Apgar score while 3% had a low Apgar score in the CIN facilities from the year 2018-2022.

Neonatal factors including sex, gestational age, birth weight and resuscitation status at birth had a statistically significant association with the Apgar score category. Maternal factors influencing the Apgar score included maternal age, parity, mode of delivery and a mother who had diabetes.

Survival probability of neonates was higher at the end of the neonatal period in those with a normal Apgar score and a unit increase in the Apgar score led to a 37% reduction in risk of death in the neonatal period. Low and intermediate Apgar score categories were associated with 11 times and four times higher hazard of death respectively when compared to the normal Apgar score.

Resuscitation at birth and breech delivery increased the odds of developing encephalopathy while caesarian section delivery and mother having had a prior delivery was protective against encephalopathy.

Hospital stay decreased with a unit increase in the Apgar score. Preterm neonates and those with a low birth weight had an increased duration of stay in hospital.

6.2 Recommendations

In view of the above findings, the following recommendations are made in order to improve the utility of the Apgar score in our setting:

1. There is a need to continue monitoring the proportions of neonates with low and intermediate Apgar scores as this may inform targeted educational and skills needs for the improvement of perinatal and neonatal care.
2. Proper risk assessment and management of mothers in the antenatal period and planning for labour and delivery is important in order to mitigate against delivery of neonates with poor Apgar scores as there are both maternal and neonatal factors that influence the Apgar score.
3. Timely interventions for care of newborns scoring a less than normal Apgar score are necessary in order to reduce the occurrence of adverse outcomes.

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APPENDICES

APPENDIX 1: The Combined Apgar Score

PARAMETER		MINUTES		
C	Continuous Positive Airway Pressure	1	5	10
O	Oxygen			
M-B	Mask and Bag Ventilation			
I	Intubation and Ventilation			
N	Neonatal Chest Compression			
E	Exogenous Surfactant			
D	Drugs			
	Sum of Expanded Apgar			
	Scoring 0=Intervention performed; 1=No intervention performed			
A	Appearance (skin color) 2=Completely pink 1= centrally pink with acrocyanosis 0=centrally blue/ pale			
P	Pulse 2=>100 beats per minute 1=<100 beats per minute 0=No heartbeat			
G	Grimace 2=Appropriate for gestational age 1= Reduced for gestational age 0=No reflex			
A	Activity 2=Appropriate for gestational age 1= Reduced for gestational age 0=No activity			
R	Respiration 2=Regular chest movement 1=Small/irregular chest movement 0=No chest movement			
	Sum of specified Apgar			
Total (Sum of Expanded +Specified)				

Reprinted from “Newborn assessment in the delivery room” by Rüdiger, M., & Aguar, M. (2012)

Neoreviews, 13(6), e336-e342.

APPENDIX 2: Newborn Unit Admission Record

Infant's details										
Random ID No.					Date of Admission dd/mm/yyyy					
DOB		Age	days	hrs	Sex	F <input type="checkbox"/> M <input type="checkbox"/> Indeterminate <input type="checkbox"/>	Gestation		wks	
ROM	<18h <input type="checkbox"/> >=18h <input type="checkbox"/> unkn. <input type="checkbox"/>		Delivery		SVD <input type="checkbox"/> CS <input type="checkbox"/> Breech <input type="checkbox"/>	If CS, type		Elective <input type="checkbox"/> Emergency <input type="checkbox"/>		
			Forceps <input type="checkbox"/> Vacuum <input type="checkbox"/>							
Multiple Delivery		Y <input type="checkbox"/> N <input type="checkbox"/> <i>If YES number? =</i>			BVM Resus at birth?		Y <input type="checkbox"/> N <input type="checkbox"/>			
APGAR	1m	5m	10m	Born outside this facility?		Y <input type="checkbox"/> N <input type="checkbox"/> <i>if Yes, born where?</i>		Home/Roadside <input type="checkbox"/> Other facility <input type="checkbox"/>		
Mother's details										
Age		Parity	+							
Blood Grp	A <input type="checkbox"/> B <input type="checkbox"/> AB <input type="checkbox"/> O <input type="checkbox"/> unkn. <input type="checkbox"/>			Rhesus	Pos <input type="checkbox"/> Neg <input type="checkbox"/> unkn. <input type="checkbox"/>		VDRL	Pos <input type="checkbox"/> Neg <input type="checkbox"/> unkn. <input type="checkbox"/>		
PMTCT Status	Pos <input type="checkbox"/> Neg <input type="checkbox"/> unkn. <input type="checkbox"/>			Mother ARVs		Y <input type="checkbox"/> N <input type="checkbox"/>		Diabetes	Y <input type="checkbox"/> N <input type="checkbox"/> unkn. <input type="checkbox"/>	
Hypertension in Pregnancy	Y <input type="checkbox"/> N <input type="checkbox"/> unkn. <input type="checkbox"/>			APH	Y <input type="checkbox"/> N <input type="checkbox"/>		Prolonged 2nd Stage		Y <input type="checkbox"/> N <input type="checkbox"/> unkn. <input type="checkbox"/>	
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(⁰ c)		Resp Rate	bpm	Pulse	/min	O 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 <input type="checkbox"/>	N <input type="checkbox"/>						
Difficulty breathing	Y <input type="checkbox"/>	N <input type="checkbox"/>						
Difficulty feeding	Y <input type="checkbox"/>	N <input type="checkbox"/>						

Convulsions	Y <input type="checkbox"/>	N <input type="checkbox"/>
Apnoea	Y <input type="checkbox"/>	N <input type="checkbox"/>
Reduced/Absent movement	Y <input type="checkbox"/>	N <input type="checkbox"/>
Bloody stool	Y <input type="checkbox"/>	N <input type="checkbox"/>
Bilious Vomiting	Y <input type="checkbox"/>	N <input type="checkbox"/>

General Examination			Further Examination			
Skin		Bruising <input type="checkbox"/> Rash <input type="checkbox"/> Pustules <input type="checkbox"/> Mottling <input type="checkbox"/> Normal <input type="checkbox"/>				
Jaundice		None <input type="checkbox"/>	+ <input type="checkbox"/>	+++ <input type="checkbox"/>		
A	Cry	Normal <input type="checkbox"/> Weak/Absent <input type="checkbox"/> High pitched <input type="checkbox"/>				
	Central Cyanosis		Y <input type="checkbox"/>	N <input type="checkbox"/>		
	Indrawing		None/mild <input type="checkbox"/> Severe <input type="checkbox"/>			
	Grunting		Y <input type="checkbox"/>	N <input type="checkbox"/>		
Neuro - Describe any abnormal posture / movement and check reflexes (Sucking; Rooting; Grasp; Moro)						

&	Good bilateral air entry		Y <input type="checkbox"/>	N <input type="checkbox"/>
	B	Crackles		Y <input type="checkbox"/>
C		Cap Refill (Sternal)	secs	
	Pallor/Anaemia	None <input type="checkbox"/>	+ <input type="checkbox"/>	+++ <input type="checkbox"/>
	Murmur		Y <input type="checkbox"/>	N <input type="checkbox"/>
	<i>If murmur is YES, describe in free text</i>			
D	Can breastfeed?		Y <input type="checkbox"/>	N <input type="checkbox"/>
	Bulging fontanelle		Y <input type="checkbox"/>	N <input type="checkbox"/>
	Irritable		Y <input type="checkbox"/>	N <input type="checkbox"/>
	Tone	Normal <input type="checkbox"/>	Increased <input type="checkbox"/>	Reduced <input type="checkbox"/>
Abd.	Distension		Y <input type="checkbox"/>	N <input type="checkbox"/>
	Umbilicus	Clean <input type="checkbox"/>	Local pus <input type="checkbox"/>	
		Pus+red skin <input type="checkbox"/>	Others <input type="checkbox"/>	

Further examination of Resp / CVS / GIT / GU / Skin /

Birth Trauma?(Specify any abnormality)

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 <input type="checkbox"/> N <input type="checkbox"/> = _____ mmol/l	Bilirubin	Y <input type="checkbox"/> N <input type="checkbox"/> = _____ μmol/l / mg/dl <input type="checkbox"/>
----------------	--	------------------	---

List other Investigations ordered

Admission Diagnoses-Select ONE primary diagnosis (tick box indicating “1”) and ANY secondary diagnoses (tick box indicating “2”)

Birth asphyxia						<i>Other diagnoses (name below and indicate if primary diagnosis or secondary)</i>		
Severe/Encephalopathy <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	Multiple Delivery	1 <input type="checkbox"/>	2 <input type="checkbox"/>			
Mild/Moderate <input type="checkbox"/>			Newborn RDS	1 <input type="checkbox"/>	2 <input type="checkbox"/>		1 <input type="checkbox"/>	2 <input type="checkbox"/>
Preterm	1 <input type="checkbox"/>	2 <input type="checkbox"/>	Jaundice	1 <input type="checkbox"/>	2 <input type="checkbox"/>		1 <input type="checkbox"/>	2 <input type="checkbox"/>

Neonatal sepsis	1 <input type="checkbox"/>	2 <input type="checkbox"/>	Meningitis	1 <input type="checkbox"/>	2 <input type="checkbox"/>		1 <input type="checkbox"/>	2 <input type="checkbox"/>
Meconium aspiration	1 <input type="checkbox"/>	2 <input type="checkbox"/>	Birth Wt <2kg	1 <input type="checkbox"/>	2 <input type="checkbox"/>		1 <input type="checkbox"/>	2 <input type="checkbox"/>
<u>Clinician Name & Sign</u>						Time am / pm	Date dd/mm/yyyy	

APPENDIX 3: Newborn Unit Exit Form

Random ID.									
Age	days	Sex	F <input type="checkbox"/>	M <input type="checkbox"/>	Indeterminate <input type="checkbox"/>	Birth wt	grams	Exit wt	grams
Mode of delivery		SVD <input type="checkbox"/> CS <input type="checkbox"/> Breech <input type="checkbox"/> Vacuum <input type="checkbox"/> Forceps <input type="checkbox"/>			Date of Admission		dd/mm/yyyy		
Infant HIV sero-exposed?		Y <input type="checkbox"/> N <input type="checkbox"/>		If yes ARVs given?		Y <input type="checkbox"/> N <input type="checkbox"/>		Date of Discharge/Referral / Death	
								dd/mm/yyyy	
Outcome		Died <input type="checkbox"/> Alive <input type="checkbox"/>		If alive		Discharged <input type="checkbox"/> Absconded <input type="checkbox"/>		Referred <input type="checkbox"/>	
Referred to				Reason					
Neonatal Diagnoses: Select ONE primary diagnosis (tick 1) and for secondary diagnoses (tick 2)									
Birth asphyxia				Neonatal sepsis		1 <input type="checkbox"/> 2 <input type="checkbox"/>		Jaundice	
Severe/Encephalopathy <input type="checkbox"/>								1 <input type="checkbox"/> 2 <input type="checkbox"/> Highest bilirubin = ____	
Mild/Moderate <input type="checkbox"/>		1 <input type="checkbox"/> 2 <input type="checkbox"/>		Meningitis		1 <input type="checkbox"/> 2 <input type="checkbox"/>		Anaemia	
								1 <input type="checkbox"/> 2 <input type="checkbox"/> Discharge HB = ____	
				Multiple Delivery		1 <input type="checkbox"/> 2 <input type="checkbox"/>			
Preterm		1 <input type="checkbox"/> 2 <input type="checkbox"/>		Other diagnoses-name and indicate if primary(1) or secondary(2)					
Newborn RDS		1 <input type="checkbox"/> 2 <input type="checkbox"/>				1 <input type="checkbox"/> 2 <input type="checkbox"/>		1 <input type="checkbox"/> 2 <input type="checkbox"/>	
Meconium aspiration		1 <input type="checkbox"/> 2 <input type="checkbox"/>				1 <input type="checkbox"/> 2 <input type="checkbox"/>		1 <input type="checkbox"/> 2 <input type="checkbox"/>	
Supportive Care given									
KMC	Y <input type="checkbox"/> N <input type="checkbox"/>	CPAP	Y <input type="checkbox"/> N <input type="checkbox"/>	Phototherapy		Y <input type="checkbox"/> N <input type="checkbox"/>	Transfusion	Y <input type="checkbox"/> N <input type="checkbox"/>	
Preventive Care given									
OPV	Y <input type="checkbox"/> N <input type="checkbox"/>	BCG	Y <input type="checkbox"/> N <input type="checkbox"/>	TEO	Y <input type="checkbox"/> N <input type="checkbox"/>	Vit K	Y <input type="checkbox"/> N <input type="checkbox"/>	Chlorhexidine	Y <input type="checkbox"/> N <input type="checkbox"/>
Feeding at Discharge		Breast Milk only <input type="checkbox"/> Formula only <input type="checkbox"/> Formula&Breastmilk <input type="checkbox"/> Fortified breastmilk <input type="checkbox"/>							
Summary of Key Investigations, Interventions, Progress & Needs at Discharge									
<p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p>									
Condition on D/C		Normal <input type="checkbox"/> Neuro Sequelae <input type="checkbox"/> Other Complication <input type="checkbox"/> =							
Follow up		None <input type="checkbox"/> POPC/NOPC <input type="checkbox"/> KMC Clinic <input type="checkbox"/> Physio/OT <input type="checkbox"/> PMTCT <input type="checkbox"/> Other facility <input type="checkbox"/>							
		Weeks after discharge =		Date:		Time:			

Discharge Drugs:	
Name of Clinician Discharging:	
Signature:	
Consultant in-charge :	

Complete form up to and including summary of clinical care of the deaths and retain in medical file

APPENDIX 4: KNH-UON ERC Approval



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Dr. Pauline Njeri Karing'u
Reg. No.H57/37855/2020
Dept. of Public & Global Health
Faculty of Health Sciences
University of Nairobi



23rd November, 2022

Dear Dr. Karing'u,

RESEARCH PROPOSAL: ASSOCIATION BETWEEN FIVE-MINUTE APGAR SCORES AND ADVERSE SHORT-TERM OUTCOMES IN NEONATES IN THE CLINICAL INFORMATION NETWORK HOSPITALS IN KENYA, 2018-2022: A RETROSPECTIVE COHORT STUDY (P673/08/2022)

This is to inform you that KNH-UoN ERC has reviewed and approved your above research proposal. Your application approval number is **P673/08/2022**. The approval period is 23rd November 2022 – 22nd November 2023.

This approval is subject to compliance with the following requirements;

- i. Only approved documents including (informed consents, study instruments, MTA) will be used.
- ii. All changes including (amendments, deviations, and violations) are submitted for review and approval by KNH-UoN ERC.
- iii. Death and life threatening problems and serious adverse events or unexpected adverse events whether related or unrelated to the study must be reported to KNH-UoN ERC 72 hours of notification.
- iv. Any changes, anticipated or otherwise that may increase the risks or affected 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.
- v. Clearance for export of biological specimens must be obtained from relevant institutions.
- vi. 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.
- vii. Submission of an executive summary report within 90 days upon completion of the study to KNH-UoN ERC.

Protect to discover

APPENDIX 5: SERU Approval



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.**

In Search of Better Health



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KEMRI/RES/7/3/1

May 12, 2017

TO: **PROF. MIKE ENGLISH**
PRINCIPAL INVESTIGATOR

THRO' **THE DIRECTOR, CGMR-C**
KILIFI

Handwritten signature and date: 12/5/17

Dear Sir,

RE: **KEMRI/SERU/CGMR-C/081/3459 (RESUBMISSION OF INITIAL): 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**

Reference is made to your letter dated April 25, 2017. The KEMRI/Scientific and Ethics Review Unit (SERU) acknowledges receipt of the revised study documents on April 27, 2017.

This is to inform you that the Committee notes that the issues raised during the 262nd meeting of the KEMRI/Scientific and Ethics Review Unit (SERU) Committee A held on April 11, 2017 have been adequately addressed.

Consequently, the study is granted approval for implementation effective this day, **May 11, 2017** for a period of one year. Please note that authorization to conduct this study will automatically expire on **May 10, 2018**. If you plan to continue data collection or analysis beyond this date, please submit an application for continuation approval to SERU by **March 29, 2018**.

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 the SERU when the study is completed or discontinued.

You may embark on the study.

Yours faithfully,

for 
DR. EVANS AMUKOYE,
ACTING HEAD,
KEMRI/SCIENTIFIC AND ETHICS REVIEW UNIT



In Search of Better Health

APPENDIX 6: Plagiarism Report

NAME: KARINGU PAULINE NJERI
REGISTRATION NO: H57937855/2020
STUDY TITLE: ASSOCIATION BETWEEN FIVE-MINUTE APGAR SCORES AND ADVERSE SHORT-TERM OUTCOMES IN NEONATES IN THE CLINICAL INFORMATION NETWORK HOSPITALS IN KENYA, 2018-2022: A RETROSPECTIVE COHORT STUDY

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