UNIVERSITY of RWANDA

COLLEGE OF MEDICINE & HEALTH SCIENCES

SCHOOL OF MEDICINE & PHARMACY

DEPARTMENT OF SURGERY

NEONATAL INTESTINAL OBSTRUCTION
Risk factors for Morbidity and Mortality at CHUK

Dissertation submitted in partial fulfillment of the requirements for the award of the Degree of Master of Medicine in General Surgery, University of Rwanda

By: Dr RUHOSHA Mathias

Supervisor: Dr NTAGANDA Edmond, MD, MMed, FCS

Kigali, May 2019

DECLARATION

Researcher:

I hereby declare that this thesis: "NEONATAL INTESTINAL OBSTRUCTION, Risk factors for Morbidity and Mortality at CHUK" is of my composition and that the research contained in it is my own unless stated otherwise. It has not been submitted to any university in Rwanda for the award of any degree or professional qualification.

Signed Date: 31st May 2019

Dr RUHOSHA Mathias

Supervisor:

I hereby declare that this dissertation has been submitted with my approval as the supervisor.

Signed Date: 31st May 2019

Dr NTAGANDA Edmond

ACKNOWLEDGEMENTS

My gratitude goes first to my supervisor, Dr NTAGANDA Edmond for his enthusiasm, continuous support and meticulous guidance. Without his knowledge and advices, this thesis would have never been completed.
My special thanks go to Dr NTIRENGANYA Faustin, the academic head of surgical department, who introduced me to General Surgery. His willingness to strengthen the University of Rwanda (UR) postgraduate program is bringing surgery to a higher level. His honest feedback during my training kept me on track making my dream a reality.

To you Prof. John TARPLEY for your encouragements, advices and push. Your professionalism and willingness to teach inspired me.

I take this opportunity to thank the whole team of Pediatric surgery unit at CHUK.

Special thanks to you members of my family; my wife, my children, my parents, brothers and sisters. We did this journey together.

For you all, cited or not cited herewith, find true recognition of your love and support.

Dr RUHOSHA Mathias

DEDICATION

To my wonderful wife Chantal BAHOZA, without your motivational, mental and spiritual support, I would never have completed this journey.

To my lovely children MUGISHA Brian and UWASE Zoe, for giving a meaning to my life.

To my dearest parents, thank you for your motivational support and trust.

To my siblings

To my brother and sister in law BAHOZA Claude and BAHOZA Natasha

I dedicate this work

ABSTRACT

Background: *Surgery in neonates is a challenging issue especially in developing countries.*

Obstruction in the newborn was almost always fatal in the past but significant advances in neonatal surgery have resulted in the improved survival of newborns with congenital malformation that were earlier considered lethal.

A clear understanding of the clinical profile, diagnosis and risk factors for morbidity and mortality would improve the quality of care provided in resource limited settings.

Objectives: *We aimed at determining the factors influencing morbidity and mortality in neonates with intestinal obstruction admitted to the pediatric surgical unit at CHUK in order to define strategies to improve care.*

Methods: *This was a prospective observatonal study including all neonates (0-28days) with intestinal obstruction who were admitted to the pediatric surgical unit at CHUK from April 2018 to March 2019.*

Results: *Of 60 patients, 36 were males and 24 were females. Majority of neonates were born at term (93,3%) and only 6,7% were born pre-term. The mean age at presentation was 6 days. Anorectal malformation and Intestinal atresia were the most common diagnoses both occurring at 36, 6%. Hirschsprung disease (13, 3%) was the third most common cause of obstruction in neonates in our study. Colostomy was the most common procedure done in our study.*
Risk factors for morbidity among neonates with IO were admission weight, age at admission and ICU admission. Risk factors for mortality were gestational age, associated anomalies, ICU admission and complications after operation.

Conclusion: *Anorectal malformation and small intestinal atresia were the commonest causes of neonatal intestinal obstruction followed by Hirschsprung's disease. Low number of associated anomalies has been reported. High rate of death were due to preventable causes such as sepsis.*

LIST OF ABREVIATIONS

CHUK: Centre Hospitalier Universitaire de Kigali
IO: Intestinal Obstruction
ICU: Intensive Care Unit
IRB: Institutional Review Board
UR: University of Rwanda
TEF: Tracheo-Esophageal Fistula
VACTERL: Vertebral, Anal, Cardiac, Tracheo-Esophageal, Renal, Limbs
ASD: Atrial Septal Defect
ETEA: End To End Anastomosis

LIST OF TABLES

LIST OF FIGURES

TABLE OF CONTENTS

I. INTRODUCTION

1. Background

Surgery in neonates is a challenging issue especially in developing countries.
Obstruction in the newborn was almost always fatal in the past.
Until 1950 there were only 125 successfully treated cases recorded in literature (1).
However, significant advances in neonatal surgery have resulted in the improved survival of newborns with congenital malformation that were earlier considered lethal.

Bilious vomiting, abdominal distension and Failure to pass meconium in neonates should raise a suspicion for neonatal intestinal obstruction.

The commonest reported causes of bowel obstruction in decreasing order includes anorectal malformations, small bowel atresia, Hirschsprung's disease, meconium ileus and meconium plug syndrome. (2)

There are no reports on the profiles of neonatal intestinal obstruction in Rwanda.

However, a number of studies have been done to show the pattern of neonatal intestinal obstruction in other parts of the world. (3)

University Teaching Hospital of Kigali (CHUK) is a tertiary, referral hospital that receives majority of referrals needing pediatric surgical care in Rwanda.

The mortality associated with neonatal intestinal obstruction is very high in developing countries when compared with results in developed countries. (4)

Late presentation of neonates with intestinal obstruction has been shown to be related with poor prognosis. (1)

The purpose of this study was to review the risk factors for morbidity and mortality in neonates with intestinal obstruction at CHUK.

2. Rationale of the study

Neonatal intestinal obstructions are commonly managed at CHUK but no study has yet been conducted on these conditions to establish the incidence and prevalence of neonatal intestinal obstruction or to define the patient outcome.

3. Research Questions

Do neonates with intestinal obstruction who present at CHUK beyond 48hours after birth have greater morbidity and mortality rates than neonates with intestinal obstruction who present within 48hours of life?

4. Hypothesis

The older the neonate with intestinal obstruction is at the time of presentation, the higher the risk of morbidity and mortality is.

5. Goal and Objectives

a. Goal:

- To determine the factors influencing morbidity and mortality in neonates with intestinal obstruction admitted to the pediatric surgical unit at CHUK.

b. Objectives:

- To describe the clinical profile at presentation of neonates ultimately diagnosed with intestinal obstruction
- To describe the timing of presentation of neonates with intestinal obstruction at CHUK
- To describe the timing of operative intervention for neonates with intestinal obstruction relative to the time of initial presentation at CHUK.
- To identify risk factors for morbidity among neonates with IO at CHUK
- To identify risk factors for mortality among neonates with IO at CHUK
- To determine mortality rate among neonates with IO operated at CHUK

II. LITERATURE REVIEW

Bilious vomiting is the cardinal symptom of intestinal obstruction in the newborn.
Prompt recognition and treatment of neonatal intestinal obstruction is lifesaving.
The incidence of neonatal intestinal obstruction is 1 in 2000 live births. (5)

Neonatal intestinal obstruction often manifests itself with a number of cardinal signs including:

- Maternal polyhydramnios,
- Bilious emesis,
- Abdominal distention and
- Failure to pass meconium in the first 24 hours of life. (1)

In 51 cases of neonatal intestinal obstruction reviewed at a Tertiary Hospital in Ethiopia, Anorectal malformation was the commonest cause followed by small bowel atresia and Hirschsprung's disease. Death occurred in 20% of the cases. Neonatal sepsis and being unfit for anesthesia were determinants of mortality. (2)

In NIGERIA, 151 neonates were reviewed. Anorectal malformation was the commonest cause (68.9%), Hirschsprung's disease was the second cause representing 7.3%, Incarcerated or strangulated inguinal hernia and Intestinal atresia were 3rd and 4th causes respectively.Postoperative complications occurred in 16.8%. These were wound infection, anastomotic dehiscence and stoma complications. The overall mortality was 21.1%. (6)

In India, 298 newborns were reviewed at a Tertiary Care Hospital, Intestinal atresia was the commonest cause (49.6%) of neonatal intestinal obstruction. Other causes were Hirschsprung (13%), Malrotationand midgut volvulus (11.7%), meconium ileus (7.3%), duodenal obstruction (4%), obstructed hernia (2.7%) and others (2.7%). (1)

At Rajasthan Medical College in INDIA, 53 cases of neonatal intestinal obstruction were reviewed by the Department of Pediatric Surgery. Twenty seven patients had small bowel atresia, 3 patients had colonic atresia and 17 patients had HirschsprungDisease.
All patients were managed surgically. Overall mortality was 10/53 (18.8%). (7)

III. METHODOLOGY

III.1. Study design and period
This was prospective observational study carried out from April 2018 to March 2019.

III.2. Study setting
This study was conducted at University Teaching Hospital of Kigali (CHUK), a 395 beds tertiary level public hospital located in Nyarugenge District, Kigali City.

III.3. Study population
All neonates (0-28days) with intestinal obstruction admitted at CHUK pediatric emergency from April 2018 to March 2019.

III.3.1. Inclusion Criteria
- All neonates (0-28days) with intestinal obstruction who were admitted to the pediatric surgical unit at CHUK within the study period.

III.3.2. Exclusion Criteria
- Those who refused to consent to participate in the study.

III.4. Sampling and sample size calculation

A study done in Ethiopia (2) showed 0.58 prevalence of neonatal intestinal obstruction. Seventy neonates were operated on for intestinal obstruction in 2017 at CHUK. The sample size will be calculated using http://epitools.ausvet.com.au to estimate a single proportion.

$$n = \frac{Z^2 P(1-P)}{d^2}$$

Where:

n : sample size

Z : Statistic for a level of confidence

P : Expected prevalence or proportion

d : Precision

Therefore we enrolled fifty nine (59) patients.

III.5. Data collection and analysis

The diagnosis of neonatal intestinal obstruction was made by the pediatric surgical team; we then enrolled them after obtaining a signed consent to participate in our study.

Data were collected on sheets, recorded using EXCEL. Statistical analysis was done with SPSS software. Descriptive analysis of data was done at first, and then cross tabulation of variables with Fischer tests was done. P-value < 0.05 was considered significant for associations.

Morbidity and Mortality assessment was done as following:

- Surgical site infection
- Wound dehiscence
- Anastomotic leak
- Stoma complications
- Pneumonia
- Admission in Neonatal Intensive Care Unit
- Length of hospital stay
- Cause of Death

III.6. Ethical considerations

Informed consent was obtained from the patient's next of kin before enrollment into the study.

We applied for Ethical Approval to the Department of Research and Ethical committee at CHUK and to University of Rwanda institutional review board (IRB) before starting our research.

The study was designed so that there was no negative impact on the patient.

Patients' ID numbers will was used instead of their names.

The information obtained was confidential, and only used for the purpose of this study.

III.7. Limitations of the study

Quality of records that might have affected the quality of data collected

III.8. Benefits

There was no direct benefit to patients who were involved in this research

III.9. Conflict of interests

The principle investigator and supervisor of this study declare to have had no conflict of

interests and no proprietary interests.

IV. RESULTS

In total, 60 patients meeting the inclusion criteria were found during the study period.

IV.1. Demographic characteristic of respondent

Table 1: Demographic characteristic of respondent

Variable	Frequency N (%)
Age (In hours)	
0-48hours	34(56.7)
>48hours	26(43.3)
Gestational age	
Preterm	4(6.7)
Term	56(93.3)
Gender	
Male	36(60)
Female	24(40)
Province	
East	10(16.7)
Kigali	16(26.7)
North	10(16.7)
South	13(21.7)
West	11(18.3)

Majority of neonates were born at term (93,3%) and only 6,7% were born pre-term. Male sex was predominant at 60% among our respondents.

IV.2. Profile of enrolled neonates with intestinal obstruction

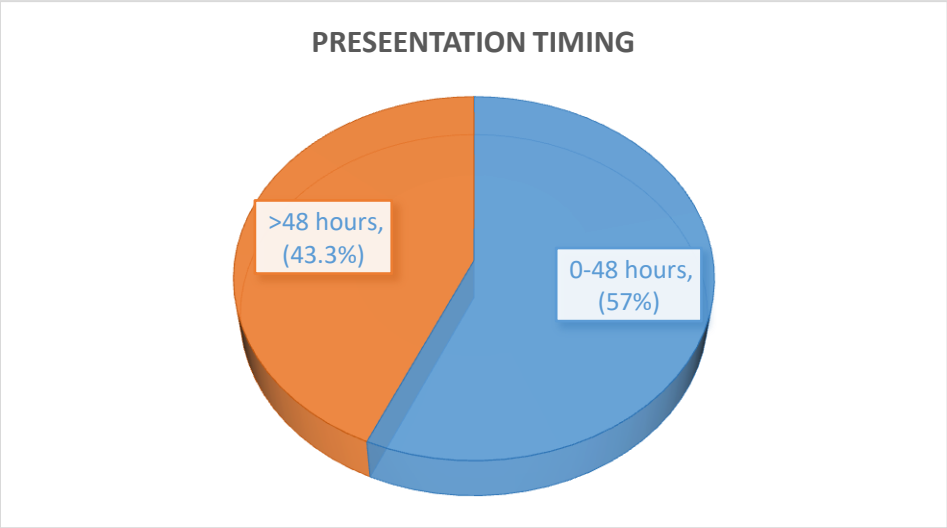
Table 2: Profile of enrolled neonates with intestinal obstruction

Variables	Frequency N (%)
Birth weight	
<2kg	3(5)
2-2.5kg	18(15)
>2.5kg	38(80)
Weight at presentation	
<2kg	4(6.7)
2-2.5 kg	18(30)
>2.5kg	38(63.3)
Symptoms	
Absent anus	23(38.3)
Abdominal distension	8(13.3)
Abdominal distension+ stool arrest	2(3.3)
Bilious vomiting	22(36.7)
Bilious vomiting+abdominal distension	5(8.3)

The commonest sign and/or symptom at presentation were absent anus (38.3%) and bilious vomiting (36.7%)

IV.3. Description of Diagnosis and Presentation time at CHUK for neonate with IO

Figure 1: Description of presentation time



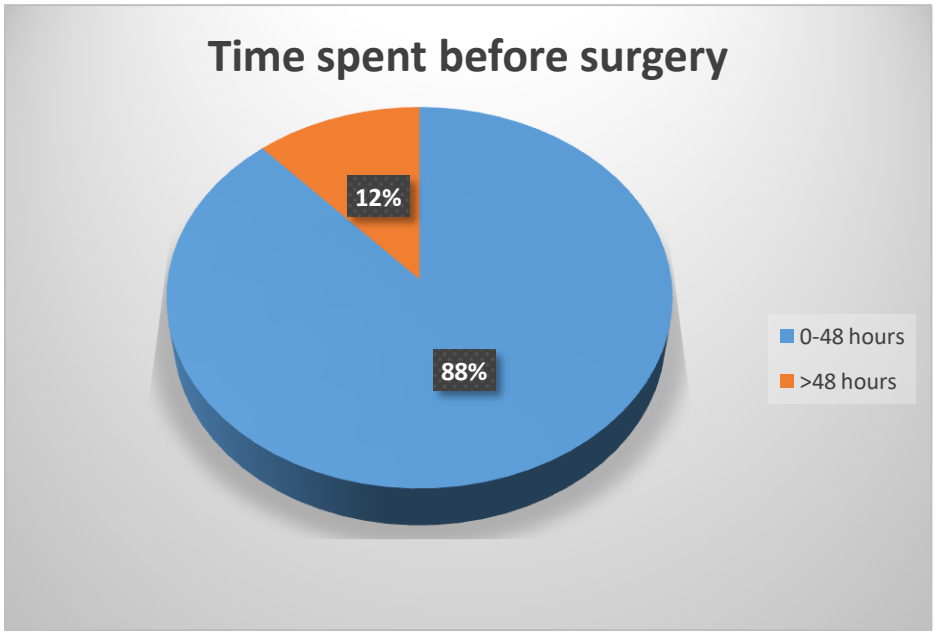
Majority of neonates presented at pediatric emergency within 48 hours of life (57%). Others (43%) presented after 48hours.

Table 3: Description of Diagnoses

Diagnosis	Frequency N (%)	Mean age in hours	Mean age in days
Annular pancreas	2(3.3)	420	17.5
ARM/imperforate anus	22(36.6)	51	2
Duodenal atresia	4(6.6)	102	4
Hirschsprung disease	8(13.3)	378	16
Ileal atresia	5(8.3)	77	3
Jejunal atresia	13(21.6)	90	4
Malrotation + midgut volvulus	4(6.6)	300	12.5
Mecomium ileus	1(1.6)	72	3
Obstructive cecal band	1(1.6)	168	7
Total	**60(100)**	**140**	**6**

IV.4. Description for timing of operative intervention for neonate with IO

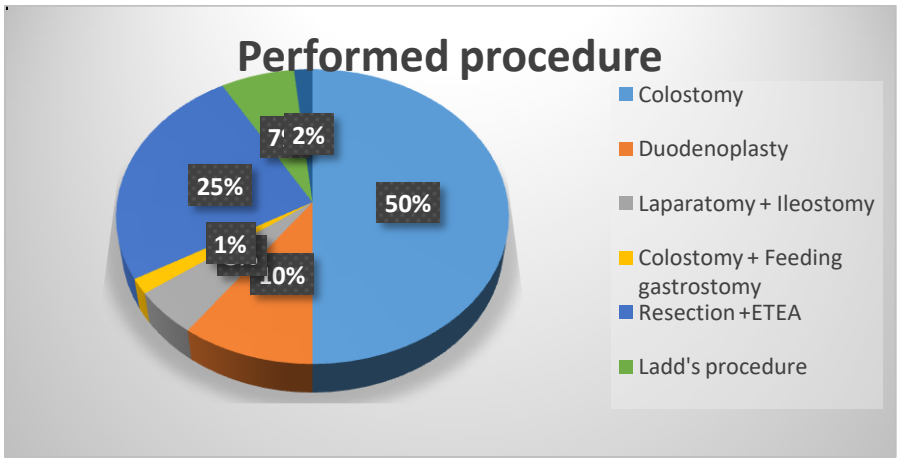
Figure 2: Description of timing of operative intervention



Majority of neonates (88%) with IO were operated on within 48 hours post admission.

IV.5. Description of procedures performed

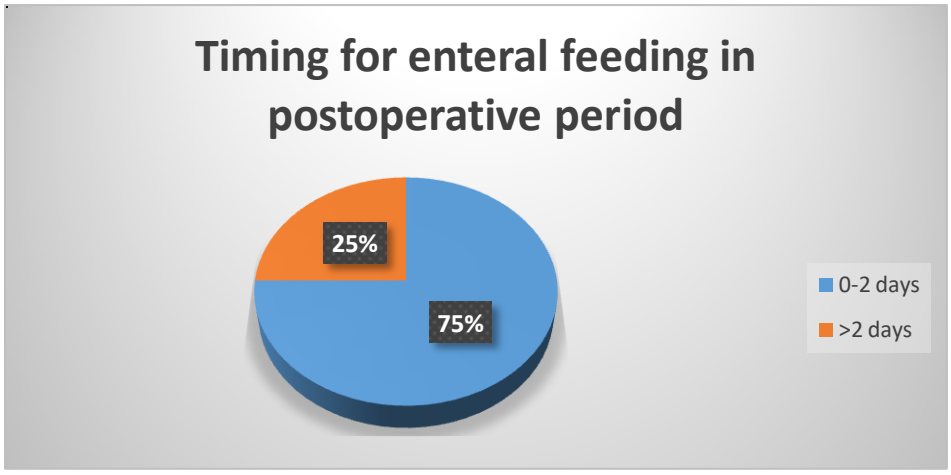
Figure 3: Description of procedures performed



The commonest performed procedure was colostomy with a percentage of 50% and Resection +ETEA was the second most performed procedure at percentage of 25%

IV.6. Description of timing for enteral feeding after surgery

Figure 4: Description of timing for enteral feeding

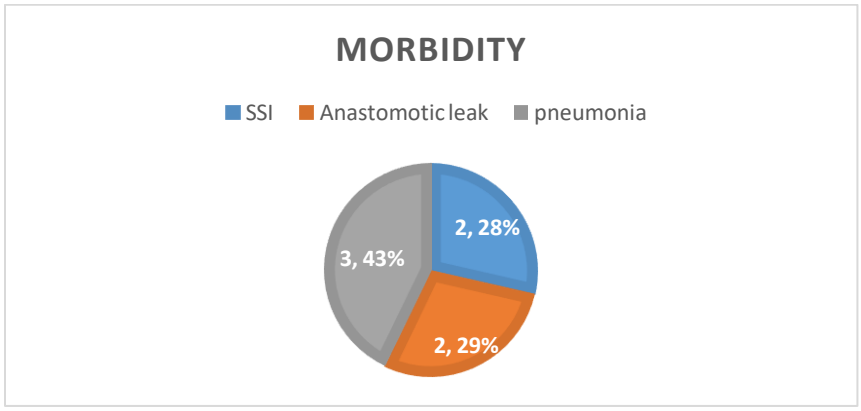


Majority of neonates received enteral feeding within 48 hours (75%)

IV.7. Description of cause of morbidity and mortality

IV.7.1. Morbidity causes frequency

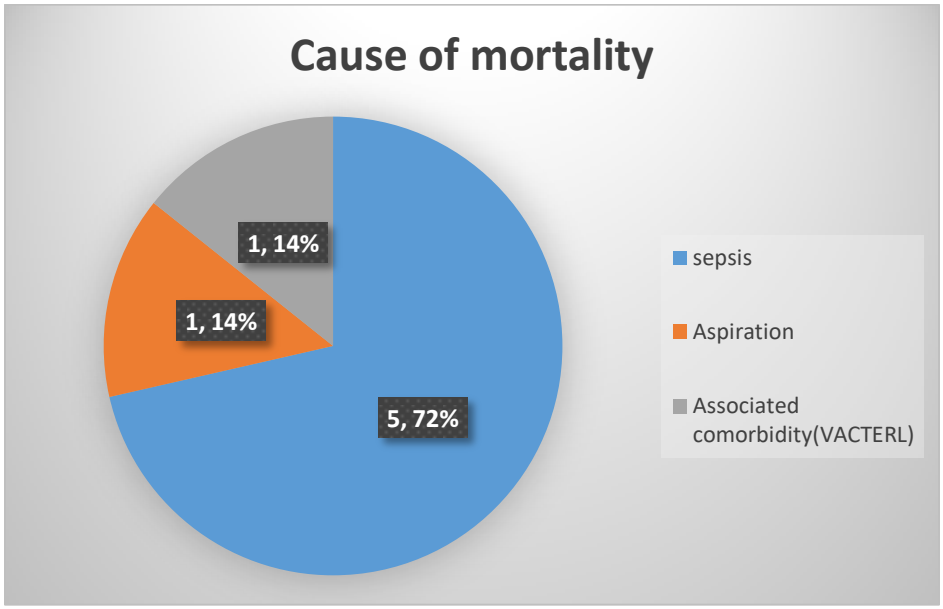
Figure 5: Morbidity causes frequency



The commonest cause of morbidity was pneumonia

IV.7.2. Mortality causes frequency

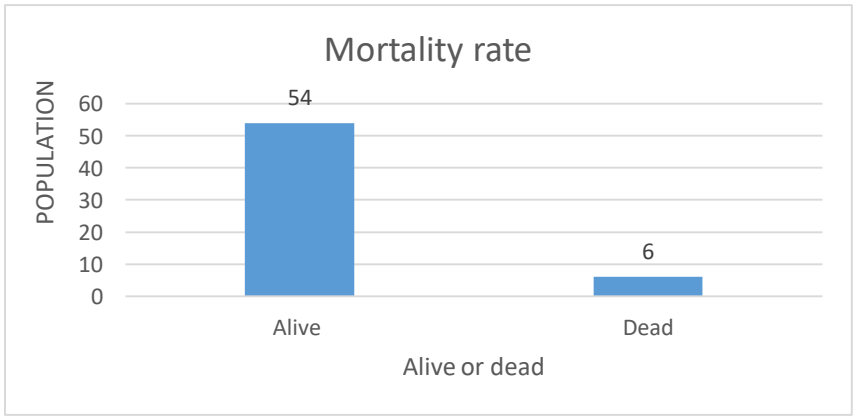
Figure 6: Mortality causes frequency



The commonest cause of death was sepsis**.**

IV.8. Mortality rate

Figure 7: Mortality rate



We observed a 10% mortality rate in operated neonates with IO at CHUK.

IV.9. Morbidity and mortality risk factors

Table 4: Risk factors for Morbidity

Variables	Morbidity		Chi-square	Fischer's test
	Yes	No		
Gender			0.970	0.422
Male	3(16.7)	20(83.3)		
Female	4(8.3)	33(91.7)		
Gestational age			6.111	0.063
Preterm	2(50)	2(50)		
Term	5(8.9)	51(91.1)		
Birth weight			6.833	0.052
<2	1(33.3)	2(66.7)		
2-2.5	3(33.3)	6(66.7)		
>2.5	3(6.3)	45(93.8)		
Admission weight			7.652	**0.028**
<2	2(50)	2(50)		
2-2.5	3(16.7)	15(83.3)		
>2.5	2(5.3)	36(94.7)		
Age			5.796	**0.022**
0-48 hours	1(2.9)	43(88.7)		
>48 hours	6(23.1)	6(85.7)		
Time before surgery			0.053	1
0-48 h	6(11.3)	43(88.7)		
>48 h	1(14.3)	6(85.7)		
Time of enteral feeding			9.111	**0.008**
0-2 days	2(4.4)	43(95.6)		
>2 days	5(33.3)	10(66.7)		
Province			2.251	0.762
East	0(0)	10(100)		
Kigali	2(12.5)	14(81.5)		
North	2(20)	8(80)		
South	2(15.4)	11(84.6)		
West	1(9.1)	10(90.9)		
Associated anomalies			7.802	0.227
None	6(10.3)	52(89.2)		
TEF	1(100)	0(0)		
TEF+ASD	1(100)	0(0)		

Risk factors for morbidity among neonates with IO were admission weight, age at admission, time before enteral feeding and ICU admission.

With regard to admission weight, findings revealed that weight below 2.5kg at admission was a significant factor for morbidity among neonates with IO as out of 7 neonates with postoperative complications, 5 neonates had weight below 2.5 kg(71%, P-value= 0.028)

With regard to age of newborn at admission, findings revealed that age of newborn at the time of admission was a significant factor for morbidity among neonates with IO as out of 7 neonates with postoperative complications, 6 neonates were above 3 days of age (86%, p-value=0.022). These findings show that early diagnosis and intervention reduce morbidity among neonates with IO**.**

With regards to timing for enteral feeding after intervention, findings revealed that neonates who were early fed had less risk for complications as out of 7 neonates with complications in postoperative period, 5 neonates were fed after 48 hours (71%, p-value 0.008). This suggests that early feeding can reduce morbidity while late feeding increase morbidity.

Table 5: Risk factors for mortality

Variables	Mortality		Chi-square	Fischer's test
	dead	alive		
Gender			0.278	0.675
Male	3(8.3)	33(91.7)		
Female	3(12.5)	21(87.5)		
Gestational age			7.619	**0.046**
Preterm	2(50)	2(50)		
Term	4(7.1)	52(92.9)		
Birth weight			6.833	0.052
<2	1(33.3)	2(66.7)		
2-2.5	2(22.2)	7(77.8)		
>2.5	3(6.3)	45(93.8)		
Admission weight			4.059	0.1
<2	2(50)	2(50)		
2-2.5	1(5.6)	17(94.4)		
>2.5	3(7.9)	35(92.1)		
Age			0.121	0.528
0-48hours	3(8.8)	31(91.2)		
>48hours	3(11.5)	23(88.5)		
Time before surgery			0.881	0.459
0-48 h	6(11.3)	47(88.7)		
>48 h	0(0)	7(100)		
Time before enteral feeding			0.249	0.634
0-2 days	4(8.9)	41(91.1)		
>2 days	2(13.3)	13(88.4)		
Province			9.130	**0.039**
East	0(0)	10(100)		
Kigali	0(0)	16(100)		
North	1(10)	9(90)		
South	4(30.8)	9(69.2)		

West	1(9.1)	10(90.9)		
Associated anomaly			18.621	**0.008**
None	4(6.9)	54(93.1)		
TEF	1(100)	0(0)		
TEF+ASD	1(100)	0(0)		
Morbidity			9.506	**0.017**
Yes	3(42.9)	4(57.1)		
No	3(5.7)	50(57.1)		

Risk factors for mortality were gestational age, associated anomalies, ICU admission and complications after operation.
With regard to gestational age, findings revealed that term neonates died more than preterm neonates did (66.6%, p-value=0.046). This may be because there were term neonates with associated anomalies.

Associated anomalies was found to be a significant factor for mortality as all of neonates with associated anomalies passed away (100%, p-value=0.008).
Presence of complications related to interventions was also found to be significant factors for mortality.

As shown in the table below, older neonates aged 48 hours and above had a high morbidity. Morbidity was significantly associated with mortality (p value=0.017).
These findings revealed that older neonates had a high morbidity (85%) than neonates aged less than 48 hours. Older neonates had the same mortality rate as neonate aged 48 hours and less.

Table 6: Age at presentation Vs morbidity and mortality

indicators	Morbidity	Mortality
Age at admission		
0-48 hours	1(14%)	3(50%)
>48 hours	6(86%	3(50%)

V. DISCUSSION

60 neonates who suffered from various types of intestinal obstructions and their associated congenital malformations were described in this study. Anorectal malformation and Intestinal atresia were the most common diagnoses both occurring at 36, 6%.
Hirschsprung disease (13, 3%) was the third most common cause of obstruction in neonates in our study.
The mean age at presentation was 6 days, similar to findings in India. (8)
Colostomy was the most common procedure done in our study whereas Resection and primary anastomosis was the commonest procedure done in other reports. (9)(10)
Male sex was reported more commonly than female sex, a finding consistently observed in many other reports too. (4)(11)(12)
High rate of death recorded mainly related to sepsis. Similar finding has been observed in other parts of the world too. (13)(14)
A study done in Ethiopia showed that anorectal malformations was the commonest cause of neonatal intestinal obstruction at 51% followed by Intestinal atresia at 13%. (2)
In developed countries, small intestinal atresia is a common cause of congenital intestinal obstruction, and it accounted for one-third of causes of neonatal intestinal obstructions according to one report. (15)
The same findings have been reported in two centers in India where the incidence of Atresia was 49, 6% and 22% respectively. (1)(7)
Researchers have suggested that patency of the entire gastrointestinal tract should be proven during repair of duodenal atresia as it can be associated with jejunoileal atresia. (16)

A very low prevalence of associated anomaly was observed in this study.
Tareen reported 80-100% associated congenital anomalies in their review, whereas C. Stoll et al reported 49% of their cases to have associated anomalies. (17)
In the latter studies, urogenital system (81.1%) and of the skeletal system (45.5%) were the most common organs involved.
Various authors suggested that a number of congenital anomalies may be missed on routine neonatal checkup. By the same token, F Tareen reported a case of previously undiagnosed ARM but also missed case of Tetralogy of fallot. (17)
C.Stole et al reported that half of their study cases of ARM had associated malformations and recommended routine screening for congenital malformations to be considered in patients with ARM. (18)

Vikal C. Shakya observed a 28,5% mortality in his report about neonates suffering from intestinal obstruction in Nepal. (4)
In the US, Nixon H. observed a 13,3% mortality in his report about small intestinal atresia. (19)
We observed 6 deaths (10%) a low rate compared to reports in Ethiopia and Nigeria. (2,3)
Associated anomalies was found to be a significant factor for mortality as all of neonates with associated anomalies passed away (100%, p-value=0.008).
Presence of complications related to interventions was also found to be significant factors for mortality.

Older neonates aged above 48 hours had a high morbidity. Morbidity was significantly associated with mortality (p value=0.017).
The rate of admission to the ICU was low in our study (10%) and 4 out of 6 neonates who were admitted to the ICU died. Other 2 neonates survived.

In a study done in Germany, low maternal education was found to be associated with a reduced uptake of prenatal screening, poorer neonatal outcomes, and a higher incidence of postoperative complications in newborns with congenital malformations. (20)
Though we did not assess the educational level of mothers of neonates with intestinal obstruction in our study, Rwanda might not be an exception to this finding.

VI. CONCLUSION AND RECOMMENDATIONS

Anorectal malformation and Intestinal atresia were the most common diagnoses in our study.
Low number of associated anomalies has been reported.
Jejunal atresia was the most common atresia in our study followed by Ileal and Duodenal.
High mortality was observed in neonates admited to the ICU as most of these cases had other associated congenital anomalies.
Antenatal diagnosis with early referral, adequate staff and post operative care can be made possible by collaborative efforts of pediatricians as well as pediatric surgeons.
Investment in pediatric surgery is required to reduce mortality and ensure better outcome in newborns with intestinal obstruction in developing countries and Rwanda in particular.
On top of promoting universal health coverage, we recommend to the government of Rwanda to put much emphasis on women's education as it has been associated with better prognosis of neonates with congenital malformations requiring surgery.
We also recommend future studies to focus on getting data on possible sources of neonatal sepsis as it was found to be the main killer in our study.

VII. REFERENCES

1. Verma A, Rattan KN, Yadav R. Neonatal intestinal obstruction: A 15 year experience in a tertiary care hospital. J Clin Diagnostic Res. 2016;10(2):SC10–3.
2. Mohammed M, Amezene T, Tamirat M. Intestinal Obstruction in Early Neonatal Period… Intestinal Obstruction in Early Neonatal Period: A 3-Year Review Of Admitted Cases from a Tertiary Hospital in Ethiopia Citation: Mustefa Mohammed, Tadesse Amezene, Moges Tamirat. Intestinal Obstruction in . J Heal Sci. 2017;27(4).
3. Osifo O, Okolo J. Neonatal intestinal obstruction in Benin, Nigeria. African J Paediatr Surg. 2009;
4. Shakya VC, Agrawal CS, Shrestha P, Poudel P, Khaniya S, Adhikary S. Management of jejunoileal atresias: An experience at eastern Nepal. BMC Surg [Internet]. 2010;10(1):35. Available from: http://www.biomedcentral.com/1471-2482/10/35
5. FROMM D. Principles of Surgery. Vol. 110, Archives of Surgery. 2011. 762 p.
6. Ameh EA, Chirdan LB. Neonatal intestinal obstruction in Zaria, Nigeria. East Afr Med J. 2000;77(9):510–3.
7. Singh V, Pathak M. Congenital Neonatal Intestinal Obstruction: Retrospective Analysis at Tertiary Care Hospital. J Neonatal Surg. 2016;5(4):49.
8. Gupta S, Gupta R, Ghosh S, Gupta AK, Shukla A, Chaturvedi V, et al. Intestinal Atresia: Experience at a Busy Center of North-West India. J Neonatal Surg. 2016;5(4):51.
9. GERRISH EW. Operative Management of Congenital Intestinal Atresia. Ann Surg. 1955;142(3):469–77.
10. Louw J. Congenital intestinal atresia and stenosis in the newborn. Observations on its pathogenesis and treatment. Ann R Coll Surg Engl [Internet]. 1959;25(1623):209–34. Available from: http://pubmedcentralcanada.ca/pmcc/articles/PMC2413911/pdf/annrcse00354-0003.pdf
11. Endo M, Hayashi A, Ishihara M, Maie M, Nagasaki A, Nishi T, et al. Analysis of 1,992 patients with anorectal malformations over the past two decades in Japan. J Pediatr Surg. 1999;
12. Murphy F, Puri P, Hutson JM, Holschneider AM. Incidence and frequency of different types, and classification of anorectal malformations. In: Anorectal Malformations in Children: Embryology, Diagnosis, Surgical Treatment, Follow-up. 2006.
13. Wyatt OS. Intestinal Obstruction in the Newborn and the Infant. J Am Med Assoc. 2011;146(3):236.
14. Mandiá N, Pérez-Muñuzuri A, López-Suárez O, López-Sanguos C, Bautista-Casanovas A, Couce ML. Congenital intestinal atresias with multiple episodes of sepsis: A case report and review of literature. Med (United States). 2018;97(23):4–7.

15. Neonatal Abdominal Emergencies. Group. 1971;64(April):372–4.

16. St. Peter SD, Little DC, Barsness KA, Copeland DR, Calkins CM, Yoder S, et al. Should We Be Concerned About Jejunoileal Atresia During Repair of Duodenal Atresia? J Laparoendosc Adv Surg Tech. 2010;20(9):773–5.

17. Tareen F, Coyle D, Aworanti OM, Gillick J. Delayed diagnosis of anorectal malformation - A persistent problem. Ir Med J. 2013;

18. Haider N, Fisher R. Mortality and morbidity associated with late diagnosis of anorectal malformations in children. Surgeon. 2007;

19. The essentials of paediatric surgery. By H. H. Nixon, M.A., F.R.C.S., Cinsultant Surgeon. The hospital for sick children, great ormond street, london and Barry O'Donnell, M.Ch., F.R.C.S., F.R.C.S.I., Consultant Surgeon, Our Lady'S Hospital for Sick Children, Dublin. Second edition. 81/2 × 51/2 in. Pp. 339+xii, with 74 illustrations. 1966. London: William Heinemann Medical Books Ltd. 50s. Br J Surg. 2007;

20. Dingemann C, Sonne M, Ure B, Bohnhorst B, Von Kaisenberg C, Pirr S. Impact of maternal education on the outcome of newborns requiring surgery for congenital malformations. PLoS One. 2019;14(4):1–15.

VIII. APPENDICES

VIII.1. Consent

CONSENT FORM IN ENGLISH

We are doing a research study on "**Neonatal Intestinal Obstruction, Risk factors for Morbidity and Mortality at CHUK**"

The aim of this study is to determine the relationship between age at presentation and mortality rates among neonates with intestinal obstruction admitted to the pediatric surgical unit at CHUK. If you decide that you want to be part of this study, you will be asked by a clinician to answer questions related to the study.

You can ask questions any time, now or later. You can talk to the doctors, your family or someone else. You do not have to be in this study, no one will be mad at you if you don't want to do this.

I, …… agree to participate in the study

"NEONATAL INTESTINAL OBSTRUCTION, Risk factors for Morbidity and Mortality at CHUK **".**

I am aware that participation in the study is voluntary and I will not be paid for the participation. In addition, all information provided will be treated with confidentiality and that my anonymity will be maintained.
I am aware that the result of this study may be published but I will not be identified as an individual. I reserve the right to withdraw from the study at any time if I so wish.

…….. …… ……..
Name of participant Signature of participant Date

…… …….. ……
Name of researcher Signature of researcher Date

Principal researcher contacts: Dr RUHOSHA Mathias
E-mail: ruhoshamathias@gmail.com, Tel: 0783477641

CONSENT FORM IN KINYARWANDA

AMASEZERANO YO KWEMERA KUJYA MU BUSHAKASHATSI
UBUSHAKASHATSI: **‘‘Neonatal Intestinal Obstruction**, **Risk factors for Morbidity and Mortality at CHUK”**

Umushakashatsi: Dr Mathias RUHOSHA Telefoni: 0783477641
Turakora ubushakashatsi kuri “**Neonatal intestinal obstruction, Risk factors for morbidity and mortality at CHUK”**
Impamvu nyamukuru yo gukora ubu bushakashatsi ni ukugerageza kwerekana isano ryaba riri hagati y’igihe umurwayi atugereyeho n’ibyago byo kuba yatakaza ubuzima cangwa ibindi bibazo agirira mubitaro bishobora gusinzikaza ubuzima bwe.
Niwemera kwitabira ubu bushakashatsi, umuganga azagira ibibazo akubaza bijanye no kuvura ububabare ku barwayi bagize ubushye..
Ushobora kubaza abaganga cyangwa umuryango wawe, cyangwa undi muntu uwo ariwe wese.
Ushobora kubaza ikibazo igihe icyo ari cyo cyose. Ntabwo ari itegeko kwitabira ubu bushakashatsi. Ntawe uzakurakarira nuba utabyitabiriye

Jyewe, …….. nemeye kujya mu ubushakashatsi
bwitwa “**Neonatal Intestinal Obstruction**, **Risk factors for Morbidity and Mortality at CHUK**”
Nasobanuriwe ko kujya muri ubu bushakashatsi ari ubushake bwanjye, ko ntagihembo ntegereje guhabwa, kandi ko nzagirirwa ibanga kugiti cyanjye ndetse n’amakuru yose nzatanga.
Nasobanuriwe ko ibizava muri ubu bushakashatsi bizatangazwa ariko ko ntazerekanwa nk’umuntu ku giti cye.
Mfite uburenganzira bwo kuva muri ubu bushakashatsi igihe cyose nabishakira.

…… …… …… Amazina
n’umukono by’uwasobanuriwe Italiki
…… ……
Amazina n’umukono by’umushakashatsi Italiki

VIII.2. Questionnaire

- Patient's ID……
- Age at presentation…….
- What was theGestation age at birth:
- Sex: ……..
- Date and time of admission at CHUK……..
- Address: …… (district of origin)
- Birth weight…….
- Weight at presentation…….
- Main presenting symptom:……..
- Pre-operative Diagnosis……..
- What is the patient's associated congenital anomaly? (if any)……
- Date and time of surgery…….
- Type of procedure done…….
- Post-operative Diagnosis…….
- When the neonate did start enteral feeding post-operatively?.....
- Has the neonate been admitted to NICU?.....
- In-hospital complication(s)
  - Surgical site infection……..
  - Anastomotic leak…….
  - Pneumonia…….
- Probable cause of death…….....

VIII.3. IRB Ethical Approval

UNIVERSITY OF RWANDA

COLLEGE OF MEDICINE AND HEALTH SCIENCES

CMHS INSTITUTIONAL REVIEW BOARD (IRB)

Kigali, 23rd /07/2018

Dr RUHOSHA Mathias
School of Medicine and Pharmacy, CMHS, UR

Approval Notice: No 265/CMHS IRB/2018

Your Project Title *"NEONATAL INTESTINAL OBSTRUCTION: Risk factors for Morbidity and Mortality at CHUK)"* has been evaluated by CMHS Institutional Review Board.

		Involved in the decision		
			No (Reason)	
Name of Members	**Institute**	Yes	**Absent**	**Withdrawn from the proceeding**
Prof Kato J. Njunwa	UR-CMHS		X	
Prof Jean Bosco Gahutu	UR-CMHS	X		
Dr Brenda Asiimwe-Kateera	UR-CMHS	X		
Prof Ntaganira Joseph	UR-CMHS	X		
Dr Tumusiime K. David	UR-CMHS	X		
Dr Kayonga N. Egide	UR-CMHS	X		
Mr Kanyoni Maurice	UR-CMHS	X		
Prof Munyanshongore Cyprien	UR-CMHS	X		
Mrs Ruzindana Landrine	Kicukiro district		X	
Dr Gishoma Darius	UR-CMHS	X		
Dr Donatilla Mukamana	UR-CMHS	X		
Prof Kyamanywa Patrick	UR-CMHS		X	
Prof Condo Umutesi Jeannine	UR-CMHS		X	
Dr Nyirazinyoye Laetitia	UR-CMHS	X		
Dr Nkeramihigo Emmanuel	UR-CMHS		X	
Sr Maliboli Marie Josee	CHUK	X		
Dr Mudenge Charles	Centre Psycho-Social	X		

After reviewing your protocol during the IRB meeting of where quorum was met and revisions made on the advice of the CMHS IRB submitted on 20th May 2018, **Approval has been granted to your study.**

Please note that approval of the protocol and consent form is valid for **12 months**.

EMAIL: researchcenter@ur.ac.rw P.O. Box: 3286, Kigali, Rwanda WEBSITE: http://cmhs.ur.ac.rw/ www.ur.ac.rw

You are responsible for fulfilling the following requirements:

1. Changes, amendments, and addenda to the protocol or consent form must be submitted to the committee for review and approval, prior to activation of the changes.
2. Only approved consent forms are to be used in the enrolment of participants.
3. All consent forms signed by subjects should be retained on file. The IRB may conduct audits of all study records, and consent documentation may be part of such audits.
4. A continuing review application must be submitted to the IRB in a timely fashion and before expiry of this approval
5. Failure to submit a continuing review application will result in termination of the study
6. Notify the IRB committee once the study is finished

Sincerely,

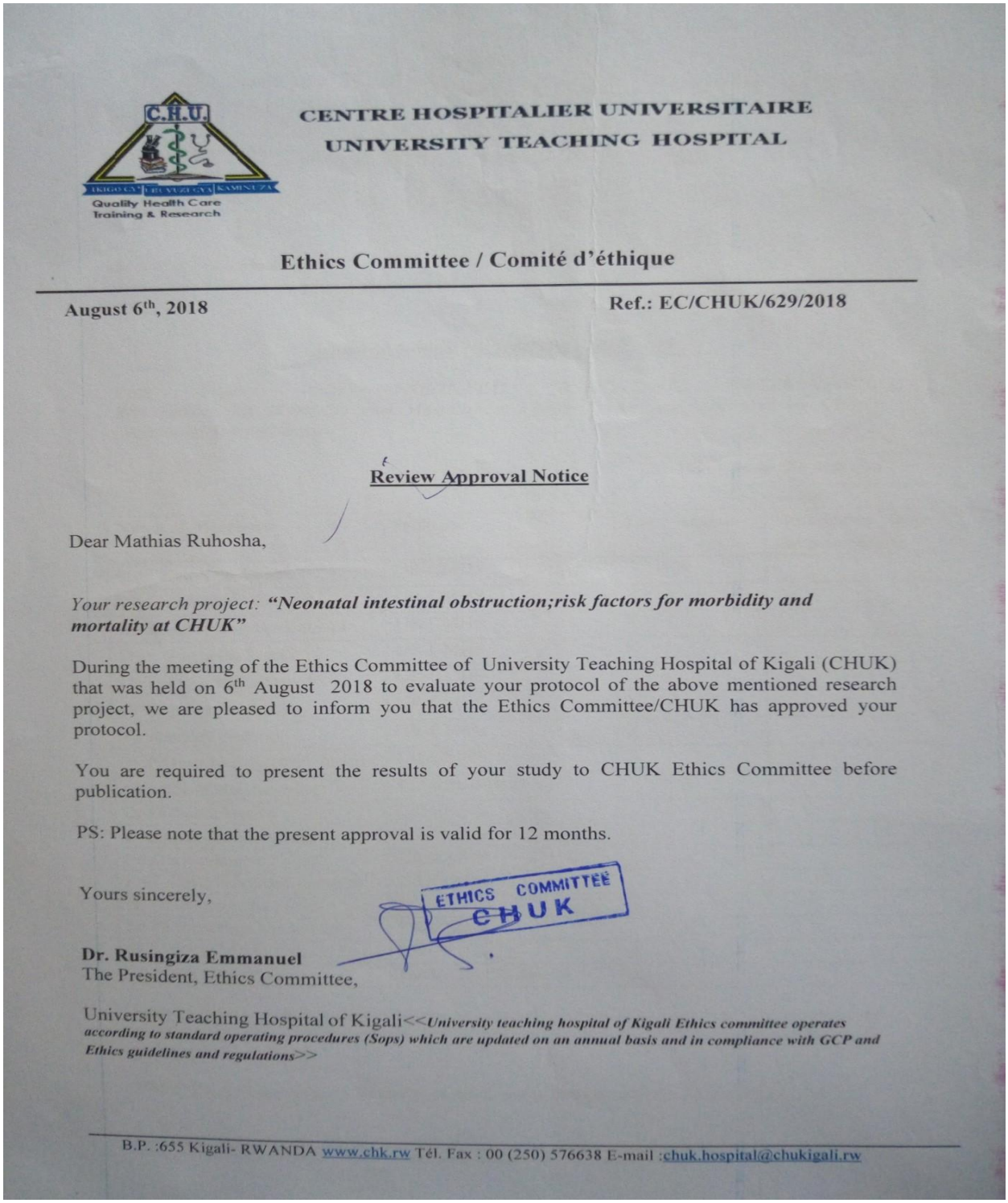
Date of Approval: The 23rd July 2018

Expiration date: The 23rd July 2019

For Professor Kato J. NJUNWA
Chairperson Institutional Review Board,
College of Medicine and Health Sciences, UR

Cc:
- Principal College of Medicine and Health Sciences, UR
- University Director of Research and Postgraduate Studies, UR

VIII.4. CHUK Ethical Committee Approval



CENTRE HOSPITALIER UNIVERSITAIRE
UNIVERSITY TEACHING HOSPITAL

Quality Health Care
Training & Research

Ethics Committee / Comité d'éthique

August 6th, 2018 **Ref.: EC/CHUK/629/2018**

Review Approval Notice

Dear Mathias Ruhosha,

Your research project: ***"Neonatal intestinal obstruction;risk factors for morbidity and mortality at CHUK"***

During the meeting of the Ethics Committee of University Teaching Hospital of Kigali (CHUK) that was held on 6th August 2018 to evaluate your protocol of the above mentioned research project, we are pleased to inform you that the Ethics Committee/CHUK has approved your protocol.

You are required to present the results of your study to CHUK Ethics Committee before publication.

PS: Please note that the present approval is valid for 12 months.

Yours sincerely,

ETHICS COMMITTEE
CHUK

Dr. Rusingiza Emmanuel
The President, Ethics Committee,

University Teaching Hospital of Kigali<<*University teaching hospital of Kigali Ethics committee operates according to standard operating procedures (Sops) which are updated on an annual basis and in compliance with GCP and Ethics guidelines and regulations*>>

B.P. :655 Kigali- RWANDA www.chk.rw Tél. Fax : 00 (250) 576638 E-mail :chuk.hospital@chukigali.rw