Functional outcomes and clinical characteristics of children discharged from a low-income pediatric intensive care unit: A 5 years' experience study

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Functional outcomes and clinical characteristics of children discharged from a low-income pediatric intensive care unit: A 5 years' experience study

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DECLARATION

I declare that this Dissertation contains my own work except where specifically acknowledged

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CERTIFICATION FOR AWARD

The undersigned certify that they have read and hereby recommend for acceptance by the University of Rwanda a dissertation entitled **"Functional outcomes and clinical characteristics of children discharged from a low-income pediatric intensive care unit: A 5 years' experience study"** in partial fulfillment of the requirements for the Degree of Master of Medicine (Pediatrics and Child health) of the University of Rwanda.

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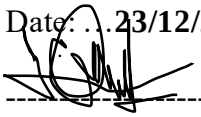

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Date: …22/12/2021…….

DEDICATION

I dedicate this work to my family and friends, my beloved wife Regine UWAYEZU and my lovely daughter GATERA Ange Norah. Without their moral support and encouragement, I would probably not have achieved anything.

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ABSTRACT

Background: The evolution of pediatric intensive care units (PICUs) has hand out to the improvement in the survival of critically ill children, in spite of that, the long-term functional outcome (after one year of admission to the PICU) of these children is often unknown in many countries including Rwanda.

Objective: This study aimed to report the prevalence and type of long-term functional outcomes and their associated clinical characteristics encountered in children who were discharged from the PICU for a period of 5 years.

Methods: A cross-sectional study done at Kigali University Teaching Hospital (PICU); a pediatric cerebral performance category (PCPC) and pediatric overall performance category (POPC) scales were used to screen for long-term functional outcomes. The results were evaluated by telephone interview. The resulting data were entered and analyzed using SPSS version 25. Multivariate logistic regression was used to determine factors associated with poor functional outcomes.

Results: In total, 158 children who were included in this study, considering PCPC and POPC: 40.5% and 20.9% were normal, 13.3% and 23.4% have a mild disability, 11.4 % and 20.3% have moderate disability, 5.1% and 5.7% have severe disability, 3.8% and 3.8% were in a coma / vegetative state, 25.9% and 25.9 % died after leaving the PICU. This means that those who achieved a PCPC 65.2% and POPC 64.6% score had good functional outcomes. Physical impairments were more observed than cognitive impairments. Have at least one comorbidity [PCPC (aOR 2.69, 95% C.I1.21-6.0, p = 0.015) and POPC (aOR 2.59, 95% CI 1.16-5.75, p = 0.019)], neurological diseases [PCPC (aOR 2.54.95% CI 0.8-7.9, p = 0.107 and POPC (aOR 2.5.95% CI 0.8-7.7, p = 0.113)], and oncological diseases [PCPC (p = 0.002) and POPC (p <0.001)], were found to be significantly correleted with poor functional outcomes.

Conclusion: Assessing Functional outcome is an important outcome measure in critically ill children. This research contributes new knowledge towards a better understanding of functional outcomes, recovery, and factors that impact aspects of functioning in children after severe illness. It shows that remaining functional morbidity persevere and is different for each patient and explain the essential of follow-up post discharge from the PICU.

KEY WORDS

Functional outcomes

Post Intensive Care Syndrome

Pediatric Intensive Care Unit

Africa; Rwanda; CHUK

LIST OF SYMBOLS AND ACRONYMS

ICU: Intensive Care Unit

PICU: Pediatric Intensive Care Unit

PACs: PICU-acquired complications

PICS: Post Intensive Care Syndrome

UTHK/CHUK: University Teaching Hospital of Kigali

UTHB/CHUB: University Teaching Hospital of Butare

HIC: High Income Countries

LMICs: Low Middle Income Countries

UR: University of Rwanda

CMHS: College of Medicine and Health Sciences

KFH: King Faisal Hospital

RMH: Rwanda Military Hospital

MOH: Minister of Health

ABG: Arterial Blood Gaz

OPD: Out Patient Department

WHO: Word Health Organization

MV: Mechanical Ventilation

CPR: Cardiopulmonary resuscitation

PCPC: Pediatric Cerebral Performance Category Pediatric

POPC: Pediatric Overall Performance Category

SOI: Acute Severity of Illness

PRISM: Pediatric Risk of Mortality

PIM: The Pediatric Index of Mortality

PEWS: Pediatric Early Warning Score

DGS: Diagnosis Grouping System

HRQoL: Health-related quality of life

FSS: Functional Status Score

HUI2: Health Utilities Index mark 2

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

Chapter 1. INTRODUCTION

BACKGROUND

The intensive care unit routinely intent to detect life-threatening conditions, reanimation and stabilization of organ failure, and finally decreasing mortality. The capacity to provide intensive and modern care has pursued to improve over the past two decennary, and as a outcome, mortality rates among children admitted to PICUs have declined dramatically for reach a historic low of 1 to 3% in developed countries(1)(2)(3). In developing countries, the mortality rate is still high. Pakistan has a mortality rate of 12.9%. Ethiopia has a mortality rate of 40%(4). The mortality rate was 25% in 2018 in PICU of Mozambique(5). In Rwanda, a study done in 2014 in PICU at CHUK showed a mortality rate of 50% (6).

Better survival in children with critical condition led to a significant increase in PACs or PICS in survivors (7). The prevalence of PACs has risen dramatically, and now far outrun mortality. PACs are unwanted and unintentional results, distinct from the admission diagnosis, and acquired during PICU admission(8). Specifically, these include short and long-term complications like mortality, physical, neurocognitive, psychosocial functional impairments, and quality of life impairments. With certain impairments persisting for 5 to 15 years(8). Consideration patient and critical care risk factors can aid to recognize patients most at danger for these complications. In addition, changeable risk factors and favorable interventions are increasingly recognized to help practical management recommendations to minimize the prevalence and effect of these long term complications (9).

PROBLEM STATEMENT

Better survival in children with serious sickness has conducted to new patterns of illness. As a result, to assess PICUs survivors well-being has become important. Assessing the outcome should therefore incorporate of an assessment of PACs or PICS, as well as physical, cognitive, psychosocial, functional and quality of life change. Knowledge of these complications could guide to change in care during the acute phase and thereafter. The primary rationale for providing pediatric intensive care (PICU) to critically ill children is intact neurological and physical survival. Each year, between

100 and 200 children are cared in Rwanda's 4 main ICUs and three out of four are in Kigali. CHUK is the only hospital with none mixed (Children and Adults). In Rwanda, there are no accessible studies on long term complications acquired during PICU admission or post-intensive care syndromes such as physical, cognitive, psychosocial, functional and quality of life impairments. Knowing that these complications are frequent and can persist for several years after leaving the PICU. This research aims to assess the functional impairments and clinical characteristics of children discharged from PICU at the Kigali University Hospital (CHUK).

1.3. RESEARCH QUESTIONS

What is the incidence, types of functional impairments observed in PICU survivors and their associated clinical characteristics?

1.4. RESEARCH AIM AND OBJECTIVE

1.4.1. Aim

The goal of this study is to determine the prevalence of functional impairment among PICU survivors and type of functional outcomes altogether with their associated clinical characteristics encountered among children who have been discharged from PICU for a 5 years period.

1.4.2. Specific Objective

[1] To determine the prevalence of functional impairment among PICU survivors.

[2] To describe the different types of functional impairments among PICU survivors.

[3] To describe their associated clinical characteristics reported in PICU survivors.

Chapter 2. LITERATURE REVIEW

Severe illness is most often associated with adverse outcomes, including cardiopulmonary arrest and mortality despite admission to the PICU(11). Resuscitation treatments including circulatory, respiratory, renal, hepatic, endocrine and/or metabolic therapies are provided in the PICU, with the intent of supporting organ systems, preventing organ failure, saving life and ultimately preserving physical, neurocognitive function and HRQoL. Despite PICU management, critical disease survivors can experience some degree of disability or functional impairment, that can persist after PICU discharge for short or long time. Evidence shows that the nature of resuscitation can affect outcomes (15–17), however the outcomes observed are both a consequence of the resuscitation provided and the underlying severity of illness that lead to the resuscitation.

The factors influencing outcome of critically ill children are multi-factorial and include:

[1] Baseline disease (primary diagnosis): Children with chronic and complex illnesses are at increased risk of deterioration in hospital and are overrepresented in the PICU. In chronically ventilated patients, the underlying diagnosis is a major determinant of outcome(18).

[2] Acute Illness Severity: Acute Illness Severity (AIS) at ICU admission is strongly correlated with ICU survival in children and adults. In critically ill children, AIS on admission to the PICU may be related to functional outcomes assessed by PCPC and POPC. Social and cognitive problems are associated with prolonged PICU admission rather than physical outcome, and hypothesizes the probable negative impact of delirium and defective glycemic control on this outcome(19).

[3] Interventions: These include urgent intubation, mechanical ventilation, circulatory support with inotropes and intravenous fluids, transfusion to restore circulation, administration of drugs, monitoring and other therapies, duration of CPR is an important predictor of PICU outcome(20).

[4] Timing of treatment: Earlier identification and referral of children with progressive severe disease, based on the bedside pediatric early warning score. These interventions can improve the timeliness of ICU admission and thereby improve outcomes of care, by allowing intubation and other resuscitation in the controlled ICU environment(21).

[5] Other risk factors: Age(22), the cause of arrest, comorbidity, location of the patient at the time of arrest, and duration of hospital admission prior to PICU admission or prolonged stay in the PICU.
[6] Nature of the ICU: Open vs closed ICU (23), number of nurses, effective retention strategies and implementation of evidence-based collaborative medicine lead to better patient outcomes(24).

Functional disability refers to impediment due to the disease, as persons with the condition cannot perform particular functions in their circadian lives. Operationally, we link the concept of "functional disability" with "Impairment" in the WHO International Classification of Functioning, Disability and Health (ICF).(25). Three comprehensive evaluation tools and eight multidimensional scales were used to assess functional outcomes in critical disease survivors.

On the report of WHO, disability or impairment has three aspects: 1) Alteration in a person's body anatomy or function, or in intellectual functioning; examples of disabilities include loss of extremities, vision or memory 2) Barrier of activity, such as struggling to see, to hear, to walk, or solving problems 3) Trouble to participate in normal diurnal activities, like working, participating in social and relaxational hobbies, and getting health care and preventive services(26).

D. Fisher developed PCPC and POPC tools to easily evaluate and effectively assess disabilities following serious illness or injury in a child. PCPC for cognitive disabilities while POPC for functional impairment and both are well related with more exhaustive and well-settled psychometric scale of functioning. Both tools are valid and reliable and have been in a greater extent used in large multi-institutional works, and are taken as references to new scale of functional outcome measure(27). The scale validity was settled in two methods: First, the tools were extracted from the tools already established and used for alike reason in a distinct patient. Second, the tools were evaluated by a team of pediatric intensivist and emergency medicine specialists before their usage (28).

PEDIATRIC CEREBRAL PERFORMANCE CATEGORY SCALE (PCPC)

SCORE	CATEGORY	DESCRIPTION
1	Normal	At age-appropriate level; school-age child attends regular school
2	Mild disability	Conscious, alert, able to interact at age- appropriate level; regular school, but grades perhaps not age-appropriate, possibility of mild neurologic deficit
3	Moderate disability	Conscious, age-appropriate independent activities of daily life; special education classroom and/or learning deficit present
4	Severe disability	Conscious, dependent in others for daily support because of impaired brain function
5	Coma or vegetative state	Any degree of coma, unaware, even if awake in appearance, without interaction with the environment; no evidence of cortex function; possibility for some reflexive response, Spontaneous eye- opening, sleep-wake cycles
6	Brain death/Death	Brain death/Death

PEDIATRIC OVERALL PERFORMANCE CATEGORY SCALE (POPC)

SCORE	CATEGOLY	DESCRIPTION
1	Good overall performance	PCPC 1; healthy, alert, and capable of normal activities of daily life
2	Mild overall disability	PCPC 2; possibility of minor physical problem that is still compatible with normal life
3	Moderate overall disability	PCPC 3; possibility of moderate disability from non cerebral systems dysfunction alone or with cerebral dysfunction; performs independent activities of daily life but disabled for competitive performance at school
4	Severe overall disability	PCPC 4; possibility of severe disability from non cerebral systems dysfunction alone or with cerebral dysfunction; conscious but dependent on others for activities of daily living support
5	Coma or vegetative state	PCPC 5
6	Brain death/death	PCPC 6

An online review article published by Ong et al. in 2016 found: Three exhaustive assessment instruments and eight multidimensional tools were used to evaluate functional outcomes in pediatric severe disease survivors. Above two years post PICU discharge found 10 to 13% functional disabilities was acquired. ICU length of stay, young age, organ dysfunction and SOI were identified risk factors for acquiring functional disabilities. Physical disabilities found to be more severe and long lasting than psychosocial disabilities(30).

A 2015 study by Volakri et al, in Greece, functional outcome was assessed using the 2-year PCPC and POPC scales. Majority were having normal to mild disability PCPC and POPC scores. At discharge the greatest functional outcome was documented in postsurgical and respiratory patients accompanied by trauma, neurological and cardiovascular patients. The 92.8% of PCPC and 91.1% of POPC of PICU survivors was living independently. Overall performance was more affected than cognitive performance(27).

A prospective cohort research carried on in two Canadian tertiary care centers in 2018, evaluating critically ill children their functional recovery, found: 81.5% accomplished functional decline as a result of serious disease. At the same time 67.1% showed some functional improvement at 6 months. Neurological disease and greater baseline function during PICU admission found to be the most significant risk factors of functional decline. For these with pre PICU admission comorbidities and morbidities acquired during PICU admission were linked with a continuing need of support for daily living(19).

A prospective cohort study conducted in the inner city, PICU University of Chicago in 2017, evaluated functional status at 6 months and 3 years post PICU discharge. Nearly 38% demonstrated functional status deterioration or died and 44% survived without change in functional status. Less than 10% of children manifested functional advance over time. Indicators of SOI like needing mechanical ventilation, days ventilated, need of vasoactive agents, length of stay in PICU were associated with long-term functional outcome. New morbidity and mortality increased cumulatively over time(31).

Acquired physical impairments included lung problems and scarring (due to operations and meningococcal disease)(32), other sense of physical function (eg, personal care or ability to move) were touched. Decrease of daily living activities due to physical disabilities and degree of go back to work, wasting of the muscle and weakness were assigned to physical disabilities(33). Short term physical limitation in children in daily living activities cannot be scaring due to their pick-up speed in growth. In spite of that, a unending limitations will impose a would place a great anxiety on the patients and their families(34).

Multidimensional scares differentiate limitations between psychosocial and physical. The most common limitations was an acquired emotionally in 22% followed by cognitive limitations in 13% as shown in a research that used the HUI2(35). Degree of physical limitation were lower around 11% with mobility, pain, personal care and sensory limitations. In spite of that, limitation in emotional were the mild while the severest were in personal care(35).
The level of physical limitations was more remarkable than psychosocial limitations at discharge as it was shown in a multicenter study(22). Complementary to the previous research, where the severest limitations were seen in physical domain like respiratory and motor disfunction. The management recommendation is to start early rehabilitation in PICU and on discharge with physical and occupational therapy(9).

As survival after severe illness ameliorate, a lot of children encountered destructive long-term effects like cognitive disabilities(36–38). This is specifically distressing in children as they are still growing and optimistically have decades of life in front of them. Prompt and effective intervention are needed to avoid learning difficulties as it gives rise to significant and far-reaching outcomes in adulthood. In spite of that, children with critical illness do not receive a coherent and comprehensive follow-up care that would lead to earlier screening of cognitive limitations(39).

Cognitive limitation was noted only in a portion of post-critical diseases in children. Acquired cognitive limitations were related to neurologic injury, trauma, oncological disease, poisoning as shown in a retrospective study, with the most severe cognitive limitations was due to neurologic diseases, those needed cardiorespiratory resuscitation

and extracorporeal membrane oxygenation(36). In spite of that, the sparse pre-PICU cognitive statistics along with disease and measurement discrepancy call into question the analysis of the available results.

Depress pre-ICU intelligence and unable to recall ICU circumstance after critical illness(41) might be risk factors for post-ICU cognitive disabilities. These research, collectively, approximate the prevalence of cognitive disabilities between 25% to 78%, between 3 months and 8 years, extensively propose that there is changeability from one study to another(42). Limitations arise in scope such as attention, memory, executive function, and intelligence (processing speed). Delirium screening and minimizing it like reducing use of benzodiazepine, avoiding glycemia instability and lower blood pressure are among recommended care to certainly help maintain cognitive function (43).

Chapter 3. METHODOLOGY

3.1. STUDY DESIGN

This is a cross sectional study.

3.2. STUDY SITE

CHUK in PICU, the University teaching hospital of Kigali/CHUK is the biggest hospital found in Nyarugenge district, City of Kigali, Rwanda. It has 519 beds in total with 86 beds located in pediatrics making it to be the largest referral hospital in Rwanda. CHUK deliver standard healthcare to the patient, teaching, medical research and non-theoretical support to district hospitals. PICU has three beds with around 100-200 patients per year. This PICU is an interdisciplinary, closed and has a one full-time senior pediatrician, one senior pediatric resident with 1:1 nurse: patient ratio, no pediatric intensivist yet. They are accountable for managing all critically ill children from starting to weaning from mechanical ventilation. Each bed has mechanical ventilation with their monitors. The fourth portable mechanical ventilator is used for transportation of patient to radiology, theater or interhospital transfer such as KFH or RMH. This unit has own ABG machine but not working daily often due to lack of cartridges and no portable X-ray machine as it was demonstrated by Nyirasafari R. et al.(6).

3.3. STUDY POPULATION

All children who were discharged from PICU meeting the inclusion criteria between the period of January 2015 to December 2019.

3.4. SELECTION OF STUDY POPULATION

3.4.1. Inclusion criteria

In this study, we included all children with age between 1 month to 17 years discharged from PICU during the study period.

3.4.2. Exclusion criteria

All neonates, those without or with phone contact but were off, those with wrong phone contact, these referred to other hospital and parents who refuse to participate in the study were excluded.

3.5. SAMPLING AND SAMPLE SIZE CALCULATION

We calculated sample size using the formula used to estimate the population means.

Formula: $n=Z^2 RV / D^2$

Where:

n=minimum sample size required

Z: Z-score corresponding to the level of 95% confidence interval which equals to 1.96

D: maximum tolerable error (0.05)

RV: population relative variance= 0.086 was calculated using the performance scores from the pilot study

So, n=133 participants

The study used consecutive sampling, one of the non-probability sampling methods, where all accessible patients who have been discharged in PICU service was selected and included in the study

3.6. SAMPLING AND ENROLMENT

Clinical records were reviewed to identify all children admitted in PICU/CHUK thereafter these who were discharged during the study period of 5 years (2015 to 2019), were identified. We got parental or caretaker listed phone number through their physical patient's file (Medical Record system) or electronic medical record (open clinic system) of those discharged. Then after explaining the purpose of the study and getting an informed consent (the consent form was verbal only because of transportation and financial issues during covid 19 pandemic was a barrier) by the principal investigator. The principal investigator conducted a telephonic interview of around 5 to 10 minutes with the parents or care givers while completing the questionnaire (PCPC/POPC) (proxy report) or direct interview with the child if reached adulthood age. PI asked specific questions regarding component of the questionnaire containing different questions focusing on child development, activities of daily living, ability to interact with the environment, school attendance and performance or particular education and/or study deficit present, dependency on others for day-to-day support, any abnormal physical problem were noted. The scoring of the PCPC/POPC was based on the answers of the of the parents, caregivers or the children. A score was given to each answer.

The PCPC/POPC tools was extracted from the previous studies and was in English version. Before using it in this current study, it was assessed and agreed between the PI and supervisors, then was translated into Kinyarwanda by English speakers. The Kinyarwanda version was cross-checked by supervisors and the PI, thereafter the Kinyarwanda version was co-translated in English by another person to compare to the original tool. Finally, the tool was approved to be used in data correction.

For better clarification the parents or care takers were asked pre and post PICU status of the child. Thereafter, we reviewed their clinical file during PICU admission to retrieve their clinical information to complete a designed questionnaire on clinical characteristics. Among clinical information, we determined the patient diagnosis using DGS. This system may be used for reporting, research, assessment needs, and means planning(44). Data were collected after getting the institutional Review Board (IRB) approval.

3.7. MEASUREMENT OF OUTCOMES AND STUDY INSTRUMENTS

3.7.1. Questionnaire/data collection tool

D. Fisher developed PCPC and POPC tools to easily evaluate and effectively assess disabilities following serious illness or injury in a child. PCPC for cognitive disabilities while POPC for functional impairment and both are well related with more exhaustive and well-settled psychometric scale of functioning. Both tools are valid and reliable and have been in a greater extent used in large multi-institutional works, and are taken as references to new scale of functional outcome measure(27). The scale validity was settled in two methods: First, the tools were extracted from the tools already established and used for alike reason in a distinct patient. Second, the tools were evaluated by a team of pediatric intensivist and emergency medicine specialists before their usage(28). After interview, the patient was categorized on the scale from 1 to 6 as mentioned before. The clinical characteristics were corrected using a designed and pretested questionnaire.

3.7.2. Primary outcome

To describe functional outcomes in PICU survivors (see in annexes).

3.7.3. Secondary outcome

To describe clinical characteristics in PICU survivors (see in annexes).

3.8. DATA ANALYSIS AND MANAGEMENT

Epidata version 3.1 was used to enter collected data and then exported to IBM SPSS statistics 25th version for analysis. Descriptive data were presented as follow: Using frequencies and percentages in tables for categorical data and median & means values for continuous data according to their disposition. The performance score was categorized as Good and poor performance level where chi-square test and logistic regression (Odds ratios) were used to study the relationship between the outcome (performance level) and exposures (age, diagnosis, therapeutic interventions, length of PICU stay, co-morbidities, origin, …). $P < 0.05$ were taken as statistical significance for association.

Questionnaires were kept in a locked cupboard where the investigator was having access to them and they will be stored till 4 years after study completion then will be destroyed.

3.9. RISKS

There are no physical risks or discomforts to participants in this study, as it consists only of a confidential between patient and physician.

3.10. BENEFITS TO SUBJECTS

No direct benefits mentioned for participating in the research. In spite of that, the policy-makers may use the information shared by subjects when deciding whether and how to improve PICU management in the future, follow up to minimize long term functional impairments.

Study will be academic insights into the global dynamics of management and follow up of critically ill children. The project therefore holds considerable potential for both immediate policy relevance and impact in participating jurisdictions, as well as truly global health impacts among critically children in future.

3.11. LIMITATIONS AND BIAS

Some parents were not having phone contact other were off during telephone contact, other were having wrong phone contact and other had emotionally guided and limited knowledge while interviewing.

3.12. COMPENSATION/REIMBURSEMENT

Subjects didn't receive any compensation for their involvement in the study, nor where they incur any out-of-pocket costs for participating in the research. The interviewer used his phone call to avoid any costs to subjects.

3.13. ETHICAL CONSIDERATIONS

3.13.1. Informed consent

Informed consent was obtained via a verbal consent form (the consent form was verbal because transportation and financial issues during covid 19 pandemic was barrier and it was acceptable in research).

3.13.2. Ethical Approval

Both the UR/CMHS institutional review board, Approval Notice: No 172/CMHS IRB/2021 (appendix) and CHUK research and ethics committee, Ref.: EC/CHUK/065/2021 (appendix) reviewed and approved the study.

3.13.3. Confidentiality assurances

After getting the consent to participate in the study, the subject agrees to allow these people to see their research data. The data generated from this research was kept secured in a locked location. Only the research team members are having entrance to the data. This could include external research team members.

3.13.4. Conflict of interest (real or apparent)

No conflicts of interest to state in this study.

3.13.5. Intended use of results

Results will be disseminated through journal publications and we wish to present it in one of Scientific's conferences. In the near term, this work is expected to improve functional state and quality of life of children who survive after admission to the PICU and better follow-up and our PICU quality improvement. This study gave insight on long term functional impairments in PICU survivors.

This work will also remind our PICU health workers that the habit of over sedation is among the modifiable risk factors, starting rehabilitation as soon as possible, minimize procedures, delirium screening, so that PICU acquired complications will be reduced.

For children at risk and children with impairments, we explained to the parents or caregivers about the disability and they were explained as well about the negative impact on their children and some require long time to resolve, Children with impairments or disabilities or medical comorbidities that need to be addressed by pediatrician, they were advised to start or keep follow up at CHUK or to the nearest district hospital or specialized center

This study will help primary investigator to fulfill academic requirement as pediatric resident.

Chapter 4: RESULTS

During 5 years study period from January 2015 to December 2019, a total PICU admission was 691 children, 241 neonates were excluded, 450 patients (65.1%) was meeting the inclusion criteria of aging between 1 month to 17 years. Among those 450 patients, a total of 200 patients (44.5%) died in PICU and 250 patients (55.5%) was discharged from PICU. Among those 250 patients who were discharged from PICU, only of 158 patients (63.2%) and their parents were consented and we obtained their functional outcome via phone interview. The remaining 92 patients, 26 were not having any telephone contact in their patient's file (Medical Record system) or electronic medical record (open clinic system), 46 their phone contacts were off, 17 were having wrong contact, 2 parents refused to consent,1 patient referred to KFH.

For more details look in the tables and chart below

4.1. Flow chart for study participants' recruitment

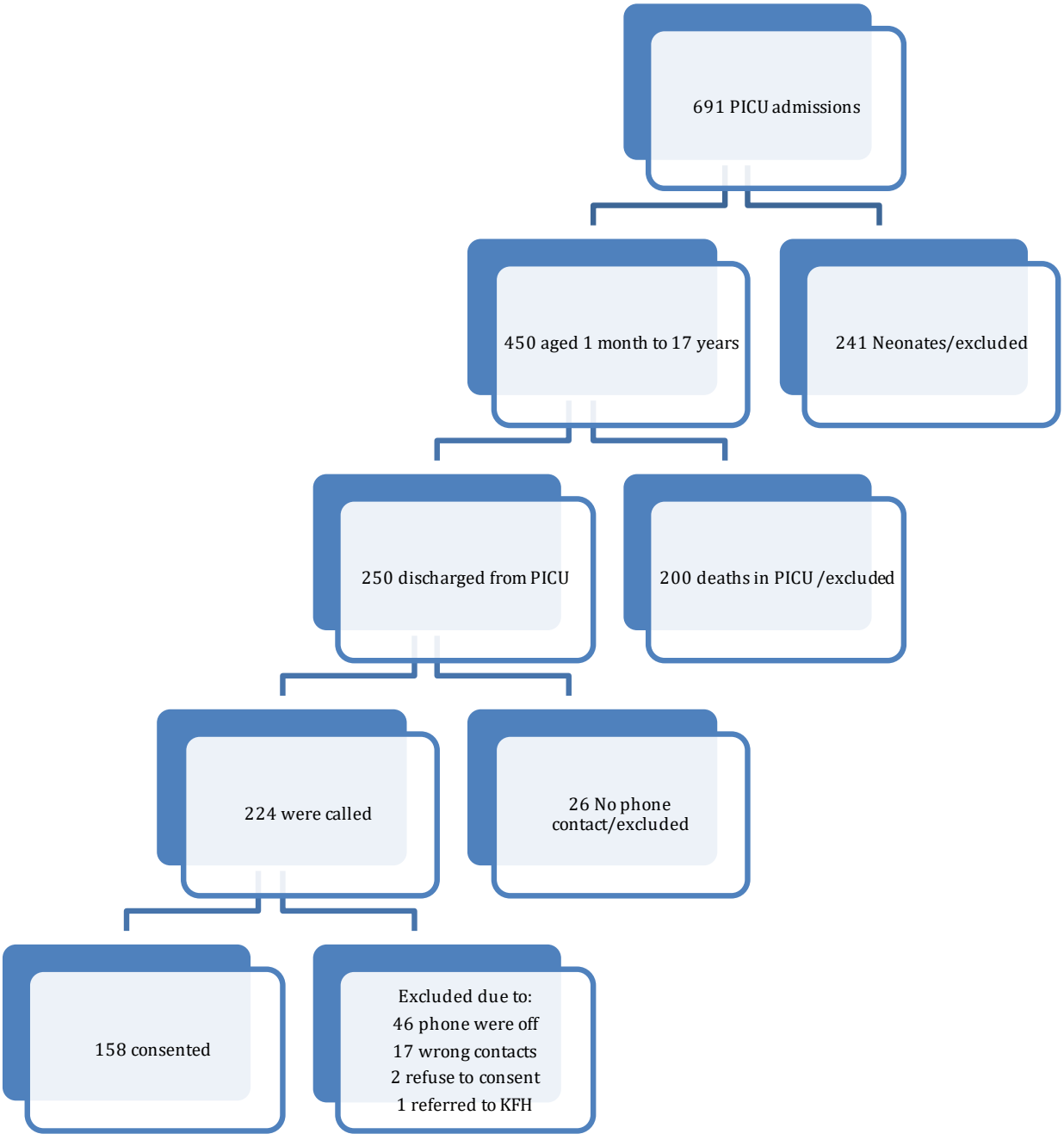

Figure 1 1. Flow chart for study participants' recruitment

4.2. Sociodemographic characteristics of the participants

Table 1: Sociodemographic characteristics of the participants

Characteristics	Frequency	%
Gender		
Male	105	66.5
Female	53	33.5
Age at admission		
Median (Q1-Q3)	**4 (2-8)**	
<2 years	48	30.4
2-5 years	51	32.3
6-12 years	48	30.4
13-15 years	8	5.1
16-17 years	3	1.9
Origin of the patients		
Theater	62	39.2
Ped ER	59	37.3
Adult ER	18	11.4
Pediatric wards	7	4.4
Surgery wards	4	2.5
Transfer from other hospitals	5	3.1
Adult HDU/ICU	2	1.3
Home	1	0.6
Length of stay in PICU (days)	**6 (2-25)**	

The median age at admission was 4 years and Male gender represented 66.5% of the participants. Thirty nine percent of the participants were admitted in the pediatric intensive care from theater, 37.3% from pediatric emergency room, and 11.4% of the participants were admitted from adult emergency room. The median length of stay in the intensive care unit was 6 days. Find more details in table 1 above

4.3. Clinical characteristics of study participants

Table 2 1: Clinical characteristics as causes of admission

Diagnosis	Frequency	%
Trauma	36	22.8
Sepsis/Sepsis related diagnosis	31	19.6
Respiratory diseases	23	14.6
Neurological diseases	18	11.4
Surgical	14	8.9
Oncological diseases	12	7.6
Toxicologic emergencies (incl. environmental)	4	2.5
ENT, dental, and mouth diseases	7	4.4
Gastrointestinal diseases	4	2.5
Cardiovascular diseases	4	2.5
Urinary tract diseases	3	1.9
Endocrine, metabolic, and nutritional diseases	2	1.3

Table 2 1: Twenty two percent of the participants were admitted in the intensive care unit for trauma reasons, 19.6% for sepsis related conditions, 14.6% for respiratory diseases, 11.4% for neurological diseases, 8.9% for surgical conditions and 7.6% for toxicological emergencies.

Table 2 2: Clinical characteristics as comorbidities

Comorbidities	Frequency	%
Epilepsy	8	5.1
Cardiopathy	5	3.2
Rhinosinusitis	3	1.9
Adenoid hypertrophy	3	1.9
Hydrocephalus	3	1.9
Asthma	2	1.3
Mental retardation	2	1.3
Brain tumor	2	1.3
Imperforated anus	1	0.6
Trisomy 21	1	0.6
Osteosarcoma	1	0.6
Hypertension	1	0.6
Diabetes	1	0.6
Cystic fibrosis	1	0.6
COSM	1	0.6
Chronic kidney disease	1	0.6

Table 2 2: Epilepsy was the prevalent comorbidity among the participants at 5%.

Table 2 3: Clinical characteristics as treatment interventions

Characteristics	Frequency	%
Interventions		
Intubated and ventilated without inotropes	126	79.7
Noninvasive ventilation	21	13.3
Intubated and ventilated with inotropes	11	7.0

Table 2 3: Seventy nine percent of participants were intubated and ventilated 7.0% were intubated and ventilated and given inotropes while 13.3% of participants were only ventilated. Find more details in table 2 above.

4.4. Performance score among study participants using PCPC and POPC

Table 4: Performance scores among study participants

Score	Performance scores	Frequency	%
	Pediatric Cerebral Performance Category		
1	Normal	64	40.5
2	Mild disability	21	13.3
3	Moderate disability	18	11.4
4	Severe disability	8	5.1
5	Coma/Vegetative state	6	3.8
6	Brain death/death	41	25.9
	Pediatric Overall Performance Category		
1	Normal	33	20.9
2	Mild disability	37	23.4
3	Moderate disability	32	20.3
4	Severe disability	9	5.7
5	Coma/Vegetative state	6	3.8
6	Brain death/death	41	25.9

When evaluating the performance score post PICU discharge among our study participants, 40.5% of the participants were normal, 13.3% had mild disability, 11.4% had moderate disability, 5.1% had severe disability, 3.8% were in coma/vegetative state while 25.9% were dead or brain death considering the PCPC score and when considering the POPC score, 20.9% of the participants were normal, 23.4% had mild disability, 20.3% had moderate disability, 5.7% had severe disability, 3.8% were in coma/vegetative state and 25.9% were dead or brain dead.

4.5. Multiple regression analysis of Factors associated with poor PCPC score

Table 5 1: Factors associated with poor PCPC score among study participants

Predictors	PCPC		OR (95% CI)	p	AOR (95% CI)	p
	Normal-Moderate	Severe to Brain dead				
Gender of the patient						
Female	36 (67.9%)	17 (32.1%)				
Male	67 (63.8%)	38 (36.2%)	1.20 (0.59-2.42)	0.608		
Age at admission						
≤ 5 years	56 (73.7%)	20 (26.3%)				
> 5 years	30 (50.8%)	29 (49.2%)	2.70 (1.31-5.57)	0.007		
Intervention						
I1	8 (72.7%)	3 (27.3%)				
I2	81 (64.3%)	45 (35.7%)	1.43 (0.36-5.67)	0.61		
I3	13 (61.9%)	8 (38.1%)	1.64 (0.33-8.07)	0.542		
Having at least 1 comorbidity						
Yes	17 (43.6%)	22 (56.4%)	3.37 (1.59-7.14)	0.001	2.69 (1.21-6.0)	0.015
No	86 (72.3%)	33 (27.7%)				
Epilepsy						
Yes	4 (50.0%)	4 (50.0%)	1.94 (0.46-8.08)	0.362		
No	99 (66.0%)	51 (34.0%)				
Cardiopathy						
Yes	1 (20.0%)	5 (80.0%)	8.00 (0.87-73.4)	0.066		
No	102 (66.7%)	51 (33.3%)				
Length of stay						
≤7 days	68 (70.1%)	29 (29.9%)				
>7 days	35 (57.4%)	26 (42.6%)	1.74 (0.89-3.39)	0.104		
Trauma						
Yes	26 (76.5%)	8 (23.5%)	0.50 (0.21-1.20)	0.123		
No	77 (62.1%)	47 (37.9%)				
Sepsis						
Yes	19 (59.4%)	13 (40.6%)	1.37 (0.62-3.03)	0.44		
No	84 (66.7%)	42 (33.3%)				
Respiratory disorders						
Yes	17 (77.3%)	5 (22.7%)	0.50 (0.17-1.45)	0.206		
No	86 (63.7%)	49 (36.3%)				
Neurological						
Yes	6 (35.3%)	11 (64.7%)	4.04 (1.40-11.62)	0.01	2.54 (0.8-7.9)	0.107
No	97 (68.8%)	44 (31.2%)				
Oncological diseases						
Yes	0 (0.00%)	9 (100%)		0.002*		
No	103 (69.1%)	46 (30.9%)				

Surgical			
Yes	14 (100%)	0 (0.0%)	<0.001*
No	89 (61.8%)	55 (38.2%)	

I1: Intubated and ventilated with inotropes, I2: Intubated and ventilated without inotropes; I3: Noninvasive Ventilation; *Chi-square test used

Considering the performance scores with PCPC, children who were admitted aged above five years were 2.70 times more likely to have the scores leading to severe disability to brain death compared to children admitted at five years and below with a statically significant difference (p=0.007). Children who had at least one comorbidity were 3.37 times more likely to have scores matching severe to brain death (poor functional outcome) compared to those who did not have any comorbidity and the difference was statistically significant (p=0.001). Children who had Oncological diseases were almost more likely to die after PICU discharge and was statistically significant (p=0.002). while these admitted for surgical reason were almost having good performance(p<0.001). There was no statistically significant difference in PCPC scoring across gender and type of intervention done in PICU. To overcome the possible bias a multiple regression analysis was done where factors associated with poor PCPC were having at least one comorbidity, neurological and oncological diagnosis (p<0.05).

4.6. Multiple regression analysis of Factors associated with poor POPC score

Table 5 2: Factors associated with poor POPC score among study participants

Predictors	POPC		OR (95% CI)	p	AOR (95% CI)	p
	Normal-Moderate	Severe to Brain dead				
Gender of the patient						
Female	36 (67.9%)	17 (32.1%)				
Male	66 (62.9%)	39 (37.1%)	1.25 (0.62-2.52)	0.53		
Age at admission						
≤ 5 years	56 (73.7%)	20 (26.3%)				
> 5 years dxc	29 (49.2%0	30 (50.8%)	1.41 (1.40-5.96)	0.004		
Intervention						
I1	8 (72.7%)	3 (27.3%)				
I2	81 (64.3%)	45 (35.7%)	1.48 (0.37-5.86)	0.576		
I3	13 (61.9%)	8 (38.1%)	1.64 (0.33-8.06)	0.542		
Having at least 1 comorbidity						
Yes	17 (43.6%)	22 (56.4%)	3.23 (1.53-6.83)	0.002	2.59 (1.16-5.75)	0.019
No	85 (71.4%)	34 (28.6%)				
Epilepsy						
Yes	4 (50.0%)	4 (50.0%)	1.88 (0.45-7.84)	0.384		
No	98 (65.3%)	52 (34.7%)				
Cardiopathy						
Yes	1 (20.0%)	4 (80.0%)	7.77 (0.85-71.29)	0.07		
No	101 (66.0%)	52 (34.0%)				
Length of stay						
≤7 days	68 (70.1%)	29 (29.9%)				
>7 days	34 (55.7%)	27 (44.3%)	1.86 (0.95-3.62)	0.068		
Trauma						
Yes	25 (73.5%)	9 (26.5%)	0.59 (0.25-1.37)	0.22		
No	77 (62.1%)	47 (37.9%)				
Sepsis						
Yes	19 (59.4%)	13 (40.6%)	1.32 (0.59-2.92)	0.493		
No	83 (65.9%)	43 (34.1%)				
Respiratory disorders						
Yes	17 (77.3%)	5 (22.7%)	0.49 (0.17-1.41)	0.186		
No	85 (63.0%)	51 (37.0%)				
Neurological						
Yes	6 (35.3%)	11 (64.7%)	3.91 (1.36-11.24)	0.011	2.50 (0.8-7.7)	0.113
No	96 (68.1%)	45 (31.9%)				
Oncological diseases						
Yes	0 (0.00%)	9 (100%)		<0.001*		
No	102 (68.5%)	47 (31.5%)				

Surgical			
Yes	14 (100%)	0 (0.0%)	0.002*
No	88 (61.1%)	56 (38.9%)	

I1: Intubated and ventilated with inotropes, I2: Intubated and ventilated without inotropes; I3: Noninvasive Ventilation; *Chi-square test used

Considering the performance scores with POPC, children who were admitted aged above five years were 1.41 times more likely to have the scores leading to severe disability to brain death compared to children admitted at five years and below with a statically significant difference (p=0.004). Children who had at least one comorbidity were 3.23 times more likely to have scores matching severe to brain death compared to those who did not have any comorbidity and the difference was statistically significant (p=0.002). Children who had Oncological diseases were almost more likely to die after PICU discharge and was statistically significant(p<0.001). while these admitted for surgical reason were almost having good performance(p<0.001). There was no statistically significant difference in POPC scores across gender and type of intervention done in PICU. To overcome the possible bias a multiple regression analysis was done where factors associated with poor PCPC were having at least one comorbidity, neurological and oncological diagnosis (p<0.05).

Chapter 5: DISCUSSION

5.1. Incidence and type of functional impairment among PICU survivors

The intention of this research was to report the prevalence and type of functional impairment among PICU survivors altogether with their associated clinical characteristics. Our finding suggests that among 158 children who were consented for the study during 5 years period, when considering PCPC and POPC: 40.5% and 20.9% were normal, 13.3% and 23.4% had mild disability, 11.4% and 20.3% had moderate disability, 5.1% and 5.7% had severe disability, 3.8% and 3.8% were in coma/vegetative state, 25.9% and 25.9% has died after PICU discharge and having at least one comorbidity, having diseases like neurological, oncological were associated with poor functional recovery.

Post PICU - Proportion of children with normal cerebral function is twice that of those with normal overall functioning. [this relationship holds out even when you combine those with mil disability]. A child with normal cerebral function will be expected to attend the normal classroom. School will need to have the ability to support the child with normal cerebral function and who has mild to moderate functional disability. Considering our results, the majority (74.1%) of our children discharged from our PICU were living in the course of follow-up, quarter (25.9%) were dead. Our results were slightly lower than the finding of Taylor et al. in Parkville, Australia where 83.8% were live at the follow up time and 16.2% were dead(45). Our results were similar with the study done in Victoria, Australia by Butt W. et al. where 80% were alive and 20% were dead(46). Having advanced PICU and different condition of their population could explain those finding.

Of our children who were alive, majority of them had a favorable outcome or good performance (PCPC: 65.2% and POPC: 64.6%) and were living independent life, without support of others for daily living activities while minority of them had an unfavorable outcome or poor performance (PCPC: 8.9% and POPC: 9.5%) and were living with dependence to others for daily living activities. These finding are slightly lower than the finding of Volakli et al in Thessaloniki, Greece where survivors of critical disease had PCPC (92.8%) and POPC (91.1%) scores to live an independent existence(27). Similar finding in the previous study done by Taylor et al. where 10.3% of PICU survivors had an disadvantageous outcome and were expected to live dependent on external care, 89.7% had a advantageous outcome and were expected to

live an independent life(45). While in the study of Butt W. et al. they found 91% of survivors were likely to live an independent existence(46). The reason behind might be their PICU is advanced in term of equipment and quality of care, so that some children whom would have been permitted to die were kept alive, but survived with disability and having majority with good performance can be explained by our majorities of our discharge were trauma, surgical.

One in 4 children discharged from PICU dies within a year of that admission. – observe that death may be due to the illness, complications of PICU care, limited access to ongoing healthcare [catastrophic poverty for the family because of the child's illness], family feeling investment in child's health is a waste, or sheer neglect especially for the child with marked functional disability. Of the deaths, 6.3% occurred between PICU discharge and hospital stay while 19.6% occurred following hospital discharge, majority occurred in the first year after PICU discharge. The results are similar with the finding of Taylor et al. in Australia where 5% of the deaths occurred in the hospital and 46% of the deaths occurred after hospital discharge(45). That could explain by some PICU survivors are severe handicapped so that they cannot survive for long time or they are vulnerable to unfavorable conditions. More physical impairment was observed that cognitive impairment in our study. Same results was found in the study of Volakli et al. where they found the influence of critical sickness was larger on overall function than in cognitive function (27). The reason is that physical impairments tend to persist longer or permanent while cognitive impairments tend to resolve faster.

5.2. Factors associated with poor functional outcome or Association between functional impairment and clinical characteristics

Having at least one comorbidity at PICU admission was correlated with poor functional outcome, and the parent most commonly cited epilepsy (seizures) and having cardiopathy. A health issue was labeled as comorbid when it was not a causative reason for admission to PICU. For instance, a child hospitalized for traumatic brain injury might be likely to have a normal functional recovery after discharge; however, a coexisting diagnosis of epilepsy may end with limitations that influence subsequent functioning. These findings are compatible with those found in Sydney, Australia by Morrison et al. where factors of poor QoL contained the presence of comorbidities, prolonged duration of stay in PICU, and a diagnostic grouping of malignancy. Better outcome was associated with diagnostic set of cardiac, trauma, and respiratory diseases

, similar to our own results (47) and also same findings in Canadian PICU where antecedent of comorbidities and acquired morbidities from PICU were correlated with persistent caregiver support requirement (19).

Children with neurological disease at admission have increased vulnerability towards poor outcome, having neurological diseases at PICU admission was also linked with poor functional sequel. The finding were consistent with those found in multicenter study in America where the biggest new sequalae were found in patient with neurological diagnoses (7.3%)(22). Similar study in Singapore found acquire functional morbidities was linked with having neurological diseases(30) and the one done by Volakli et al. were found worst PCPC/POPC for cardiovascular, neurologic and trauma patients (27).

Children with oncological disease had uniform fatal outcome within a year. similarly in all previous studies showed the same result, our study found almost all children discharged from PICU died in one year post discharge reason can be (cancer treatment is now under developing process, high recurrency rate despite treatment, was discharged as palliative care...) In our study we didn't find any association between age, gender, treatment interventions, LOS in PICU, diagnosis (Trauma, Respiratory, Others) with poor function post PICU discharge. Contrary to the study done in Victoria, Australia by Butt W. et al.,found that young children who survived did not have an increased risk of handicap (46).

Apart from admission diagnosis, medical management, SOI, individual self-esteem, the existence of comorbidities, access to maximal rehabilitation and help from significant people all impact the ability to get better (48). Upgrading our comprehension on how critical illness affect the level of functioning will allow us to identify early children at risk, families counselling, and point rehabilitation and social assistance for children with their families.

5.3. Study strength and limitations

Telephonic interview as a way of outcome assessment, the time for assessing the functional recovery comparing to the admission time was different among children, majority of the information were collected by proxy interview for each child and this is a single center study and results are not generalizable to the whole country. One way method reliable to assess long term functional disability is the interview via phone contact (49) and obviously is good practically and cost-effective method for both the

researcher and family. Another barrier for telephonic interview is the loss of contact when the time from admission and the time for assessing disabilities increase. Even though we established risk factors, we are not able to elicit any explanation of functional deficit from our results because it is a cross sectional study. Another limitation of this study may be a recall bias and acquiescence bias as the verbally administered questionnaire was used.

Chapter 6: CONCLUSION AND RECOMMENDATION

6.1. Conclusion

Assessing functional outcome is crucial in children recovered from critical illness. This thesis come up with a new understanding of functional disabilities and the factors that impact aspects of functioning post critical illness recovery. It point up that residual functional disability persists and are distinct for every one and explain the role of follow-up after PICU discharge.

6.2. Recommendations

Recommendations to the health facilities (CHUK, District hospitals) and researchers

- ✓ If resources are limited, patient with oncological disease might not be prioritized for ventilatory support.
- ✓ A more detailed study to identify modifiable risk factors – PICU care is very expensive and one would want improved outcomes.
- ✓ All children who have been admitted to PICU should be assessed using the two tools to enable appropriate placing in school.
- ✓ In-depth studies on the pattern of overall functional disability to inform the type of rehabilitation services/support to be placed in the school.
- ✓ Earlier admission and enhanced care may improve outcome.
- ✓ How to maximize functional recovery and in time improving the quality of survivorship in critically ill children.

Recommendations to Ministry of Health

- ✓ Develop the guidelines regarding pediatric critical care and their survivors follow up

Recommendation to the Government of Rwanda

- ✓ Schools should be capacitated to support children with normal cerebral function with overall functional disability.

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APPENDICES

Appendix 1: Data collection form

QUESTIONNAIRE FOR ASSESSING FUNCTIONAL STATUS IN PICU SURVIVAL

PEDIATRIC CEREBRAL PERFORMANCE CATEGORY SCALE (PCPC)

SCORE	CATEGORY	DESCRIPTION
1	Normal	At age-appropriate level; school-age child attends regular school
2	Mild disability	Conscious, alert, able to interact at age- appropriate level; regular school, but grades perhaps not age-appropriate, possibility of mild neurologic deficit
3	Moderate disability	Conscious, age-appropriate independent activities of daily life; special education classroom and/or learning deficit present
4	Severe disability	Conscious, dependent in others for daily support because of impaired brain function
5	Coma or vegetative state	Any degree of coma, unaware, even if awake in appearance, without interaction with the environment; no evidence of cortex function; possibility for some reflexive response, Spontaneous eye- opening, sleep-wake cycles
6	Brain death/Death	Brain death/Death

PEDIATRIC OVERALL PERFORMANCE CATEGORY SCALE (POPC)

SCORE	CATEGOLY	DESCRIPTION
1	Good overall performance	PCPC 1; healthy, alert, and capable of normal activities of daily life
2	Mild overall disability	PCPC 2; possibility of minor physical problem that is still compatible with normal life
3	Moderate overall disability	PCPC 3; possibility of moderate disability from non cerebral systems dysfunction alone or with cerebral dysfunction; performs independent activities of daily life but disabled for competitive performance at school
4	Severe overall disability	PCPC 4; possibility of severe disability from non cerebral systems dysfunction alone or with cerebral dysfunction; conscious but dependent on others for activities of daily living support
5	Coma or vegetative state	PCPC 5
6	Brain death/death	PCPC 6

QUESTIONNAIRE ON PATIENT DEMOGRAPHIC AND CLINICAL CARACTERISTICS

Demographic and clinical Characteristic		
Initials/ID		
Address		
Phone number		
Age (months)		
Gender	Male	
	Female	
Reason for admission (Diagnosis)	Sepsis/Sepsis related diagnosis	
	Respiratory diseases	
	Neurological diseases	
	Circulatory and cardiovascular diseases	
	Oncological diseases	
	Surgical	
	Eye diseases	
	Child abuse	
	Endocrine,metabolic and nutritional diseases	
	ENT, dental, and mouth diseases	
	Fluid and electrolyte disorders	
	Gastrointestinal diseases	
	Genital and reproductive diseases	
	Musculoskeletal and connective tissue diseases	
	Psychiatric, behavior, and substance abuse	
	Skin, dermatologic, and soft tissue diseases	
	Toxicologic emergencies (incl. environmental)	
	Trauma	
	Urinary tract diseases	
	Other	
Theurapeutic intervensions	not intubated,	
	intubated but not ventilated,	
	ventilated but not intubated,	
	intubated and ventilated but no inotrope,	
	intubated and ventilated with inotrope	
Length of intensive care unit stay (days)	Date of admission	
	Date of discharge	
	Total days	
Chronic illness before PICU admission or Disabilities on admission		
Origin	Other hospitals	
	Wards	
	Emergency ped or adult	
	Surgical department	
	Outpatient department	

Appendix 2: IRB Ethical approval

UNIVERSITY of RWANDA

COLLEGE OF MEDICINE AND HEALTH SCIENCES

DIRECTORATE OF RESEARCH & INNOVATION

CMHS INSTITUTIONAL REVIEW BOARD (IRB)

Kigali, 24th /May /2021

Dr Gatera Richard
School of Medicine and Pharmacy, CMHS, UR

Approval Notice: No 172/CMHS IRB/2021

Your Project Title ***"Functional Outcomes and Clinical Characteristics of Children Discharged from a Low Income Pediatric Intensive Care Unit: A 5 Years' Experience Cohort Study"*** 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		
Dr Stefan Jansen	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 21st May 2021, **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 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,

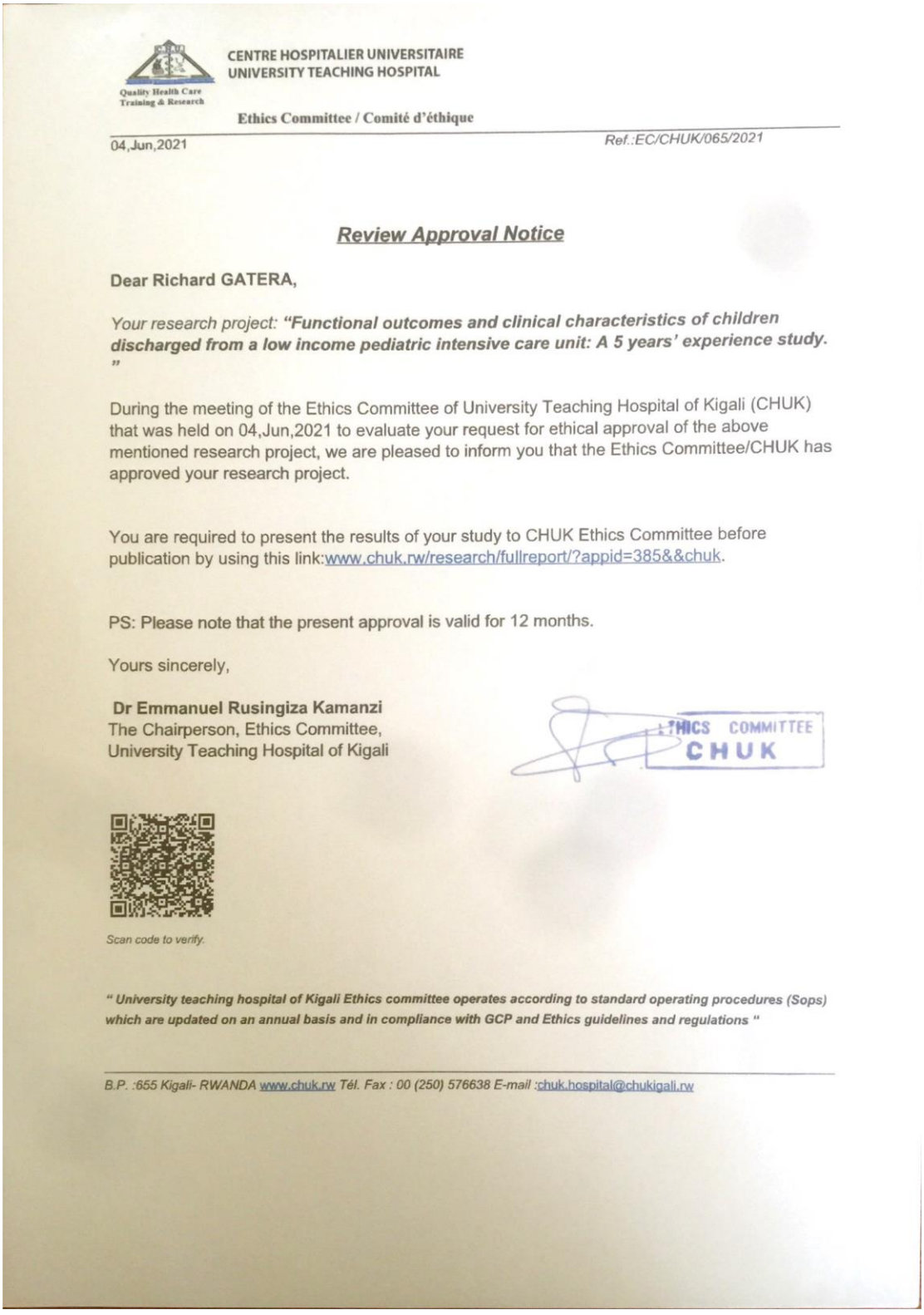
Date of Approval: The 24th May 2021

Expiration date: The 24th May 2022

Dr Stefan Jansen
Ag. 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

Appendix 3: CHUK Ethics committee review approval notice



CENTRE HOSPITALIER UNIVERSITAIRE
UNIVERSITY TEACHING HOSPITAL

Quality Health Care
Training & Research

Ethics Committee / Comité d'éthique

04,Jun,2021 Ref.:EC/CHUK/065/2021

Review Approval Notice

Dear Richard GATERA,

Your research project: ***"Functional outcomes and clinical characteristics of children discharged from a low income pediatric intensive care unit: A 5 years' experience study. "***

During the meeting of the Ethics Committee of University Teaching Hospital of Kigali (CHUK) that was held on 04,Jun,2021 to evaluate your request for ethical approval of the above mentioned research project, we are pleased to inform you that the Ethics Committee/CHUK has approved your research project.

You are required to present the results of your study to CHUK Ethics Committee before publication by using this link:www.chuk.rw/research/fullreport/?appid=385&&chuk.

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

Yours sincerely,

Dr Emmanuel Rusingiza Kamanzi
The Chairperson, Ethics Committee,
University Teaching Hospital of Kigali

ETHICS COMMITTEE
CHUK

Scan code to verify.

" 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.chuk.rw Tél. Fax : 00 (250) 576638 E-mail :chuk.hospital@chukigali.rw

PART I. Informationform for the study participants – English Version

Dear parents or caregivers of the child who was discharged from our PICU/CHUK between 2015 to 2019, we are inviting to participate in research on: "**Functional outcomes and Clinical characteristics of children discharged from low-income pediatric intensive care unit: A 5 years' experience study**".

1. **Purpose of the study**:

We are about to conduct a study at CHUK which is aiming to screen the level of functional impairments and clinical characteristics in our PICU survivors.
This study will be a cross section study that will be conducted on all PICU survivors in a 5 years period (2015-2019).

2. **Description of the Process:**

The clinical record will be reviewed to complete demographic and clinical characteristics such as age, sex, origin, diagnosis, therapeutic interventions, length of stay, Comorbidities, severity of illness and organ dysfunction of children who survived PICU.

Afterward the Principal investigator will interview parents or care givers while completing the questionnaire (PCPC/POPC). PI will ask specific questions regarding component of the questionnaire containing different questions focusing on child development, activities of daily living, ability to interact with the environment, school attendance and performance or special education classroom and/or learning deficit present, dependency on others for daily support, any abnormal physical problem will be noted. For better clarification the parents or care takers will be asked pre and post PICU status of the child.

The scoring of the PCPC/POPC will be based on the answers of the of the parents or caregivers. A score will be given to each answer. The PCPC/POPC has six score from normal or good overall performance, Mild or overall disability, Moderate or overall disability, Severe or overall disability, Coma or vegetative state to Brain death/death.

For children at risk and children with impairments, we will explain parents or caregivers about the disability and they will be explained as well about the negative impact on their children and some require long time to resolve, Children with impairments or disabilities or medical comorbidities that need to be addressed by pediatrician, they will be advised to start or keep follow up at CHUK or to the nearest district hospital or specialized center. Medical comorbidities that can be addressed at health centers we will inform the health center chief.

This study will be conducted with the approval of the Institutional Research Board of the CMHS and the national ethical committee.

There is no any experimentation planned in this study.

3. **Risk or discomfort:**

There is no physical harm in this study. There is no planned psychological or moral harm in this study however parents can be distressed by being informed that their children have functional impairments or have any other medical comorbidity and this will be addressed according to ethical consideration and considering also available management in our settings. The research team will be opened to discuss any discomfort and let the participant decide freely.

4. **Benefits:**

For children with PICS or medical comorbidities that can be addressed will be followed at CHUK or nearest health facility.

5. **There are no alternative treatment or special management** proposed to the participant with Impairments.

6. **Confidentiality:**

We can ensure you high level of confidentiality because the information you will give will be recorded under a study number and stored in a secured location.

7. **Voluntary participation, Refusal or withdraw:**

The participation in this study is totally voluntary, it requires you to know well what the purpose of the study and give an informed and signed consent. Any informed participant is free to consent or refuse and it is possible to withdraw yourself from the study if uncomfortable with the procedures used.

8. **Who to contact if any question or concern**, you can call the Principal Investigator or the representatives of the CMHS IRB.

1. Dr GATERA Richard (Principal Investigator): (+25 0783896635). Email: richgat 2000@gmail.com
2. Dr Febronie MUSHIMIYIMANA (Pediatrician, Supervisor) :(+250788752779). Email: mushime@gmail.com
3. Dr NIZEYIMANA Francoise(Pediatric anaesthesiologist, supervisor):(+250788811676). Email: nizefra83@yahoo.fr
4. Dr Christian UMUHOZA(Pediatrician, Supervisor):(+250788753718). Email: crissumuh@gmail.com
5. Dr Aimable KANYAMUHUNGA (Pediatrician, hemato-oncologist, cosupervisor:(0788670200). Email: kanyamuhungaa@gmail.com

PART I. Information form for the study participants – Kinyarwanda Version

Babyeyi cyangwa barezi babana basezerewe muri PICU, turi kubasaba kwitabira ubushakashatsi kuri:"**Functional outcomes and clinical characteristics of children discharged from a low income pediatric intensive care unit: A 5 years' experience study".**

1. **impanvu y'ubushakashatsi:**

Ubushakashatsi buzakorerwa kubana basezerewe muri PICU/CHUK hagati y'umwaka wa 2015 kugeza 2019, tuzaba dushaka kurebako ntangaruka zigihe kirekire igihe bari barwariye PICU byabagizeho, ninako tuzaba tunareba kandi impanvu ishobora kuba yarabiteye kubazaba bafite izo ngaruka zitifuzwa zigihe kirekire.

2. **uko ubushakashatsi buzakorwa:**

Ukora ubushakashatsi azabanza kureba abana bose basezerewe PICU/CHUK, arebe umyirondoro yabo, impamvu yatumye baza PICU, arebe ibyo bakorewe, amakuru y'uburwayi bwakarande bari basanganywe mbere yo kujya mubitaro, hanyuma ahamagare kuri telephone ababyeyi cyangwa abarera abo bana yifashishije ibibazo bibazwa abana basezerewe muri PICU bashaka kumenya ingaruka baba babana nazo zigihe kirerekire(PCPC/POPC).Hanyuma abyuzuze kumpapuro z'ubushakashatsi. Impapuro z'ubushakashatsi PCPC/POPC ziriho ibibazo binyuranye bijyanye n'imikurire y'ubwonko n'igihagararo, Niba bakenera ubufasha kugirango babashe gukora ibikorwa byo mubuzima busanzwe nko kwikorera amasuku, nko kwikarabya, kwijyana mubwiherero, kwiyambika, kwigaburira, kugenda, ibijyanye n'ishuri niba abasha kujyayo buri gihe kandi atsinda bijyanye n'imyaka ye, niba hari ubusebwa bafite yasigiwe nokuba yararwariye mundembe. Nyuma amanota akusanywe bijyanye nuko umubyeyi yasubije. Bitewe namanota azaba akusanijwe kumpapuro ndetse n'amakuru y'uburwayi umwana twasanze afite, umubyeyi azajya abwirwa amakuru y'uko umwana we ahagaze, kuwo tuzasanga ntakibazo afite tuzabimumenyesha, kuwotuzasanga umwana afite ibibazo cyangwa se afite ibyago byo kuba yadindira aramutse atitawehonabwo tuzabimumenyesha. Abo tuzasanga bafite ibibazo bisaba gukurikiranirwa kubitaro bikuru bya CHUK bazakomeza bahakurikiranirwe ,abo

bisaba gukemurirwa kubitaro bikuru tuzabohereza kubitaro bikuru bibegereye kubonana na muganga w'abana. Abana bazaba bafite uburwayi bushobora kuvurirwa kukigo nderabuzima nabo bazoherezwayo.
Ubu bushakashatsi bwemewe gukorwa aruko kaminuza nkuru y'Urwanda yabyemeye.

3. **Ingaruka**

Nta ngaruka mbi ziteganyijwe muri ubu bushakashatsi, abagize itsindary'ubushakashatsi bazaganiriza abarera abana,uzunva afite ikibazo mugihe cy'ubushakashatsi, urimubushakashatsi afite uburenganzira kucyemezo cyose we ubwe yafata igihe yumva abangamiwe n'ubushakashatsi.

4. **inyungu**

Ubu bushakashatsi buzaha amakuru abagenamigambi bashobora gufata izindi ngamba zihariye zigamije kurinda no gufasha abana b'abanyarwanda basezerewe mundembe.

5. **Ntamuti uzatangwa kubana bazasanganwa ingaruka zitifuzwa** ariko bazakomeza gukurikiranwa nibaramuka basanganywe ikibazo.

6. **Ibanga**

Ubushakashatsi buzakorwa muburyo bubika amakuru neza kandi mw'ibanga. umushakashatsi azuzuza impapuroz'ubushakashatsi badashyizeho amazina y'abana babo, hazajya hashyirwaho inumeroy'ubushakashatsi.

7. **Kwemera cyangwa guhakana kujya mu bushakashatsi**.

Ni ubushake kwemera kuza muri ubu bushakashatsi.kuzamo bisaba gusa kuba wumva neza impanvu y'ubushakashatsi ndetse ukanemera gusinya impapuro z'uko wemera kuba mu bushakashatsi. Uwemeye kwinjira mu bushakashatsi bafite uburenganzira bwo kuvamo igihe cyose yumva adashaka gukomeza.

8. **Igihe cyose ugize ikibazo ushobora guhamagara umwe muraba bakurikira:**

1. Dr GATERA Richard (Umushakashatsi): (+25 0783896635). Email: richgat 2000@gmail.com

2. Dr Febronie MUSHIMIYIMANA (Pediatrician, Supervisor) :(+250788752779). Email: mushime@gmail.com

3. Dr NIZEYIMANA Francoise(Pediatric anaesthesiologist,supervisor):(+250788811676). Email: nizefra83@yahoo.fr

4. Dr Christian UMUHOZA(Pediatrician, Supervisor):(+250788753718). Email: crissumuh@gmail.com

5. Dr Aimable KANYAMUHUNGA (Pediatrician, hemato-oncologist, cosupervisor:(0788670200). Email: kanyamuhungaa@gmail.com

PART II: Certificate of Consent/Verbal consent via telephone

Study number…….

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research.

Name of Participant_____

Signature of Participant _____

Date _____

Day/month/year

If illiterate

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Name of witness_____ AND Thumb of participant

Signature of witness _____

Date _____

Day/month/year

PART III: Certificate of Consent-Kinyarwanda version

Ubushakashatsi no……

Nasomye amakuru y'ubushakashatsi cyangwa bansomeye amakuru y'ubushakashatsi. Nahawe umwanya wo kubaza ibibazo kuri ubu bushakashatsi ,igisubizo nabajije cyose cyasubijwe neza. Nemereye umwana wanjye kujya muri ubu bushakashatsi. Mfite uburenganzira bwo kuvana umwana wanjye muri ubu bushakashatsi igihe cyose nabishakira kandi ntibingireho ingaruka mumivurirwe ye.

Amazina y'umubyeyi w'umwana_____

Umukono w'umubyeyi w'umwana _____

italiki _____umunsi/ukwezi/umwaka.

Niba umubyeyi/umurwaza atarize

Ndahamyako umubyeyi/umurezi w'umwana yasomewe neza amasezerano yo kwemera kujya mu bushakashatsi,kandi ko umubyeyi/umurezi yahawe amahirwe yo kubaza ibibazo,ndemeza kandi ko umurwayi afite uburenganzira bwo kuvana umwana we muri ubu bushakashatsi igihe cyose yabishakira.

Amazina y'umuhamya_____ igikumwe cy'umubyeyi.

Umukono w'umuhamya _____

Italiki_____umunsi/ukwezi/umwaka.

PART IV: STATEMENT BY THE RESEARCHER/PERSON TAKING CONSENT.

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been persuaded into giving consent, and the consent has been given freely and voluntarily.

A copy of this ICF has been provided to the participant.

Name of Researcher/person taking the consent_____

Signature of Researcher /person taking the consent_____

Date _____ Day/month/year

PART V: INFORMATION FORM

For parents or caregivers of infants who participated in this research,Thank you for participating in this study: "**Functional outcomes and clinical characteristics of children discharged from a low income pediatric intensive care unit: A 5 years' experience study**"./ Babyeyi cyangwa barezi b'abana turabashimira kwemera kwitabira ubu bushakashatsi kuri: "**Functional outcomes and clinical characteristics of children discharged from a low income pediatric intensive care unit: A 5 years' experience study**".

Below there are findings of the development and medical comorbidity founded of your child/munsi hari amakuru y'ibyo twabonye nyuma yo kuzuza impapuro z'ubushakashatsi ndetse no kubazwa amakuru.

☐ FAILED/HARIKIBAZO:

☐ PASSED/NTAKIBAZO:

MEDICAL COMORBIDITY:

NB: WHEN IT IS MARKED **FAILED** YOU ARE ADVISED TO CONSULT WITH THIS FORM THE NEAREST HEALTH CENTER OR DISTRICT HOSPITAL AND GET HELP/NIBA KURUPAPURO RWAWE HARAKAMENYETSO AHANDITSEHO **HARIKIBAZO**, UMWANA WAWE BIVUZEKO AKENEYE GUFASHWA.