UNIVERSITY of RWANDA

NEONATAL INTER-HOSPITAL TRANSFER: CLINICAL INFORMATION SHARING AND CONDITION OF NEONATES REFERRED TO TERTIARY HOSPITALS IN KIGALI, RWANDA

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NEONATAL INTER-HOSPITAL TRANSFER: CLINICAL INFORMATION SHARING AND CONDITION OF NEONATES REFERRED TO TERTIARY HOSPITALS IN KIGALI, RWANDA

A dissertation submitted in fulfilment of the requirements for the degree of Master of General Pediatrics: College of Medicine and Health Sciences at the University of Rwanda

by

OSCAR MWIZERWA, MD

August, 2019

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DECLARATION OF ORIGINALITY

This is to certify that the work is entirely my own and not of any other person, unless explicitly acknowledged (including citation of published and unpublished sources). The work has not previously been submitted in any form to the University of Rwanda or to any other institutions for assessment or for any other purpose.

Candidate's name: **Dr Oscar MWIZERWA**, RMDC: 2513

Candidate's signature: ……. Date: August 28, 2019

ETHICAL APPROVAL

This is to certify that the studies contained in this dissertation have been reviewed and approved by the University of Rwanda College of Medicine and Health Sciences' Institutional Review Board (CMHS - IRB). And results of this study will be available at the libraries of UR, CHUK, RMH and Ministry of Health as principal authority for implementation of recommendations deduced from the study.

The authors also endeavor to write-up and submit the final projects to a peer-reviewed journal (e.g. the Rwanda Medical Journal (RMJ), international journals and in different medical conferences).

The allocated ethical approval number: **Ref: 002/CMHS IRB/2018**

Candidate's name: **Dr Oscar MWIZERWA**, RMDC: 2513

Candidate's signature: ……. Date: August 28, 2019

DEDICATION

This dissertation is dedicated to:

My family, (my parents, my wife Yvonne, my sons Joshua A.M and Nolan A.M, brothers and sisters), who have honored me by courageously sharing the sorrows and triumphs of our lives. You are truly the inspiration for this work and I thank you for your encouragement, support and patience throughout this study. It meant so much to me during the pursuit of my master's degree and I am grateful for all that you've done for me. To each of you, I offer my sincere thanks and deepest gratitude.

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ABSTRACT 1 – Delphi study

Background: Effective communication between healthcare providers is essential for patient safety. Standardized neonatal referral forms (NRFs) ensure continuity of care between facilities.

Objective: We sought to determine the key data items, Core Clinical Information (CCI), that should be conveyed for neonatal inter-hospital transfer in resource-limited settings.

Methods: We conducted an international, three-round, modified Delphi consensus study.
Round-1 was a literature and internet search to identify existing NRFs. In rounds two and three, participants evaluated the items generated from this search and proposed additional items to be included in an NRF through an online questionnaire. Participants were Rwandan and international pediatric healthcare practitioners who had worked in Rwanda in the five years prior to the study.

Results: We identified 16 pre-existing NRFs containing 125 individual items. Ninety-one items met the pre-defined consensus criteria for inclusion in Round-2. Only 33 items were present in more than 50% of the 16 NRFs, confirming the need for this consensus study. In Round-2, participants proposed 12 new items, six of which met the pre-defined consensus criteria. In Round-3, participants scored items for importance, and 57 items met the final consensus criteria.

Conclusions: By converging diverse opinions from neonatal clinicians, we have generated a 57 items CCI list that can be used to generate an NRF for any centres that refer neonates to institutions that provide a higher level of care in resource-limited settings. The language would need to be modified where appropriate and the items assessed for local suitability. However, how the use of these CCI list/NRF affect the outcomes of neonatal transfer between health facilities in Rwanda is yet to be determined and would make an interesting piece of future research work too.

ABSTRACT 2 – Cross-sectional study

Background: When transporting sick neonates in resource-limited settings there needs to be adequate information-sharing to ensure optimal transfer of care. Currently there is no data on the adequacy of data-sharing for transported neonates in Rwanda.

Objective: We sought to evaluate the quality of the existing information sharing practice and determine the baseline outcome of neonates referred to tertiary hospitals in Rwanda.

Methods: This was a cross-sectional, longitudinal study conducted at CHUK and RMH for a six-month period. We analyzed the completeness of the referral letters using the previously designed CCI list as standard. Prevalence of morbidities, mortality and its timing in seven days from admission were determined using SPSS version 22. The level of documentation for these referral letters was compared with mortality, described odds ratios, and gained p-values.

Results: 158 neonates were enrolled. 67%, had surgical condition as primary diagnosis and 68% presented within their first week of life. The completeness of the analyzed referral letters ranged from 10 to 60%; and 33.3% was determined as median. The overall seven-days mortality was 19% and, one fifth died within the first day of admission. More than a third of neonates were admitted hypoxic, and they were three times more likely to die (OR=2.96 (CI:1.11 to 7.9), p=0.025). Low birth weight was associated to mortality, (OR= 2.37, p=0.034, 95% CI:1.05 to 5.32). There was a trend but no statistical association between low documentation (< 33.3%) and mortality, OR=1.58, (p=0.262 95% CI:0.71 to 3.52).

Conclusion: Transfer of neonates in resource limited settings poses an additional risk to mortality and morbidities. Need of an organized transfer system with focus to more vulnerable population, neonates. There is a gap in communication during neonatal transfer, that needs a harmonized referral letter and improved documentation.

Keywords:
Infant, Newborn; Referral letter; Communication; Developing Countries; Rwanda

ABBREVIATIONS

CCI	Core-clinical information
CHUK	University Teaching Hospital of Kigali
CI	Confidence interval
CMHS	College of Medicine and Health Sciences
DC	Data collector
Dr	Doctor of Medicine
ER	Emergency room
GRADE/COMET	Core Outcome Measures in Effectiveness Trials
HIV	Human Immunodeficiency Virus
HRH	Human Resource for Health
ICRS	Immediate Cardiorespiratory support
IRB	Institutional review board
MD	Doctor of Medicine
Mesh	Medical Subject Headings
NICU	Neonatal Intensive Care Unit
NRF	Neonatal Referral Form
NWG	Neonatal Working Group
OR	Odd Ratio
PI	Principal Investigator
RMH	Rwanda Military Hospital
RMJ	Rwanda Medical Journal
RN	Registered Nurse
SD	Standard Deviation
SPSS 22	The Statistical Package for the Social Sciences, version 22

DEFINITIONS OF GLOSSARY TERMS

1. **Hypothermia:** Hypothermia occurs when neonate's body temperature drops below 36.5°C (97.7°F) (1).
2. **Hypoxia:** Sub-optimal oxygen levels in the ambient air of living organisms and is estimated by pulse oximetry saturation of less 90% (2,3).
3. **Seizures:** Clinical or subclinical disturbances of cortical function due to a sudden, abnormal, excessive, and disorganized discharge of brain cells. Clinical manifestations include abnormal motor, sensory and psychic phenomena (2).
4. **Resuscitation:** There were eight resuscitation variables measured, namely; using crystalloid bolus, albumin bolus, blood transfusion (packed red blood cells); or requiring cardiorespiratory support (bag-mask ventilation, chest compressions, endotracheal intubation, inotropes and/or mechanical ventilation).

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CHAPTER I. GENERAL BACKGROUND

Introduction

Adopted in 2015 by all 193 member states of the United Nations, the Agenda for Sustainable Development is an ambitious, comprehensive initiative outlining seventeen core Development Goals aimed at eradicating extreme poverty by the year 2030. Specifically, within the overarching goal to promote "good health and well-being," is included the goal of reducing neonatal mortality "to at least as low as" 12 per 1,000 live births by the year 2030 (4).

Current neonatal practices in different countries

Neonatal mortality rate is defined as the number of deaths during the first twenty-eight days of life per 1,000 live births. In 2016, the World Health Organization estimated that nearly half (46%) of all under-five deaths occurred in the neonatal period. Therefore, successful efforts to reduce neonatal mortality will also have a positive impact on under-five mortality. Importantly, interventions to address neonatal mortality differ significantly from under-five. The neonatal mortality rate worldwide in 2015 has fallen to 19 per 1000 live births (5). In Rwanda, the neonatal mortality rate has fallen from 37 to 20 per 1000 live births over a period of 10 years (2005-2015) (6). The reason for this decline is multifactorial and one of the factors is decentralization of specialist care. Therefore, explaining the increase in the number of neonatal transfers between low-level units and more specialized hospitals.

Impact of transport on neonates

Transport of neonates carries a range of risks, and adverse outcomes in up to 40% of transported neonates have been reported (7,8), with higher mortality associated with long distance and duration of transport (9).

Impact of communication during neonatal transport

To optimize the transfer of care of these transferred neonates, it is paramount that the essential demographic and clinical information is shared between the referring and receiving sites. Neonatal Referral Forms (NRFs) are standardized referral forms that aid in ensuring high-quality hand-over of medical history, which include demographics, pre-transfer care, and, potentially, the transport course of the neonate (10–17). The quality of the shared clinical information may improve the outcome for the neonate and also reduce the repetition of investigations and treatments, thus decreasing the cost to families and facilities, and improving outcome (17). In the resource-limited setting, there is a lack of evidence about which clinical information should be communicated between hospital sites while transferring neonates (18).

Problem statement

Countries with specialized transport systems for neonates can mitigate against these risks associated with transport (19). In most resource limited settings, however, such systems do not exist (20). In some settings, such as Rwanda, a general patient referral transport system is in place, but specialized neonatal transfer is lacking (21). Two hospitals in Rwanda, (Rwamagana and Ruhengeri) were found to have different neonatal referral forms. This demonstrates that even the tools currently used in these two provincial hospitals are not fit for purpose and could not be implemented nationally without further development.

There are therefore a number of problems in Rwanda where research is lacking:

1. There is no consensus regarding the essential clinical information that should be shared to the receiving team when transferring a sick neonate between health facilities.
2. There is no data, on whether the current information being shared is sufficient for caring for the transferred neonates
3. There is no data, regarding the demographics, characteristics, clinical condition and final outcomes (mortality) of the referred/transported neonates arriving at tertiary hospitals

Researcher's interest in the study

As a pediatric resident, the principal investigator's main duties include caring for children and neonates at referral hospitals in Rwanda. Where these situations are not uncommon: receiving a neonate transferred from a district hospital 130 kilometers away. The neonate is a 2-day-old female born at 33weeks gestation with a birth weight of 1.9kg, as documented on her referral letter. The neonate has respiratory distress and is referred for respiratory support. The transfer letter does not include information about the neonate's history or the care given at the referring hospital. You note that specific clinical data (e.g. maternal history, delivery details, resuscitation measures provided, medications given, respiratory support initiated, etc.) are lacking in the transfer letter from the sending hospital. You consider that having this information readily available could expedite the type of care you provide for this neonate. Several of these scenarios pushed the PI to questions like: does the timely sharing of core clinical information enhance the efficiency and the quality of the clinical care you seek to provide for referred neonates (17,18)?

Aims

Therefore, we aimed to determine the key data items (core clinical information, or CCI) that should be conveyed for neonatal inter-hospital transfer in a resource-limited setting, using modified Delphi methods;

In the second project we sought to evaluate the quality of existing information sharing practice and determine the baseline outcomes of neonates referred to tertiary hospitals in Rwanda.

Objectives:

1. To determine the consensus regarding the core clinical information (CCI) that should be conveyed for neonatal inter-hospital transfer in a resource-limited setting
2. To evaluate the quality of existing information sharing practice during neonatal transfer in Rwanda
3. To determine the baseline outcomes of neonates referred to tertiary hospitals in Rwanda

CHAPTER II. METHODS –DELPHI STUDY

Study design: We used an international, three-round, modified electronic Delphi study to identify the CCI that would be essential to communicate during neonatal transfer. Reporting of the study is in accordance with the Sinha and Williamson checklists for creating a "Core Outcome Set" using Delphi techniques (22,23). The Delphi technique is a widely used and accepted method for gathering data from respondents within their domain of expertise. The technique is designed as a group communication process which aims to achieve a convergence of opinion on a specific real-world issue (24). The Delphi methodology was chosen as a consensus tool as it allows large numbers of individuals across diverse locations and areas of expertise to be included anonymously, thus avoiding domination of the consensus process by one or a few experts. It also can be undertaken remotely, removing the need for participants to travel. The modified Delphi is similar to the full Delphi regarding procedures (rounds and panels of experts) and intent (arriving at a consensus). However, it differs in the way it begins with a set of pre-selected items to help improve response rates as well as providing a solid initial grounding to participants (25).

Participant selection: Participants from four groups of clinicians were eligible to be included: (i) Rwandan clinicians working in pediatric practice, including all pediatric specialists and senior residents practicing in Rwanda, identified via the available Rwanda pediatric email group; (ii) Members of the Rwandan Neonatal Working Group (NWG) including pediatricians, public health specialists and policymakers, identified through the chair of the NWG; (iii) General Practitioners (clinicians working in district hospitals) identified through the NWG; (iv) International clinicians with work experience in Rwanda through the Human Resources for Health (HRH) project (26) identified from the Ministry of Health database of HRH faculty.

Round-1: A full literature and internet search was undertaken to identify pre-existing Neonatal Referral Forms (NRFs) and research articles describing NRFs and/or CCI required for hospital transfer of a neonate in the resource-limited setting. The search strings included MeSH terms and synonyms for "Neonates," "transportation of patients," and "resource-limited settings" (Appendix 1). Secondly, we contacted local (Rwandan) healthcare facilities as well as experienced pediatricians in the region (Malawi, Uganda, and Kenya) to identify any NRFs relevant to our setting. We aimed for a minimum of ten NRFs. Due to the low number identified from the resource-limited setting, the search was then repeated for NRFs from outside of this setting. The individual items found in each NRF were then coded. During the coding process, items were intentionally removed if they were judged not to be relevant to the resource-limited setting where there is no dedicated transport team (e.g., therapeutic hypothermia). Consensus in this round was pre-defined as any item that was used in two or more of the identified NRFs. These items were then used to create the first draft of our CCI list in preparation for rounds two and three of the Delphi process.

Round-2 (open-ended questionnaire): In Round-2, the draft CCI list from Round-1 was divided into eight themes/sections (e.g. labor details). Participants were informed about the process involved in gaining the first draft CCI in Round-1.

Each section contained a list of the included items in the first draft of the CCI. The list of items was then presented to participants with an open question using a "free text" option at the end of each section. Participants were presented with a scenario: "We want you to imagine that you are either transferring or receiving a sick neonate who is being transferred between facilities in a resource-limited setting (e.g., Rwanda)." They were then asked what additional clinical items they would add to that section/theme.

Consensus was pre-defined as any additional item suggested independently by two or more participants; these were then added to the second draft CCI for Round-3. Non-participation in Round-2 did not exclude participation in Round-3, but additional participants were not invited as the Delphi progressed. Information regarding the study was provided to participants at the same time as the questionnaire and completion of the questionnaires implied informed consent of participation.

Round-3 (closed questions): All items from the second draft of the CCI were listed in their themes/sections. Each item was presented with feedback from Round-2 and -3 in the form of the percentage of articles/NRFs that contained the item, or if it was a new addition from Round-2. After piloting this questionnaire, several items which described similar clinical information were combined to minimize bias from questionnaire fatigue (e.g., stimulation, bag-mask ventilation, etc. were combined into “resuscitation”) (Table 1). The participants were provided with the same clinical scenario as Round-2 and were then asked to rank the importance of each CCI item on a 1-9 point Likert scale. Consensus for inclusion in the final CCI was pre-defined as greater than 70% of participants scoring 7–9 (important) AND less than 15% of participants scoring 1-3 (not important) as per GRADE/COMET criteria (27,28). Participants were informed of the pre-defined consensus to engage them in the process. Participants gave their year of birth and initials in Round-2 and -3 to assess attrition rate.

Data Collection and Analysis: The questionnaires were hosted and completed using Google Forms® and distributed to participants via email. Participants were given two weeks to answer each questionnaire from Round-2 and Round-3 with email reminders sent after one week. We aimed for a minimum of 15 respondents in each round (24). Google Forms® provides data in a downloadable Microsoft Excel® spreadsheet which was used to code and describe statistics (i.e., median, mean, standard deviation, attrition rate (where appropriate)).

Ethical Considerations

Funding: No funding was obtained for this study.
Competing interests: None declared.
Risks: The study protocol was reviewed and approved by the University of Rwanda There were no significant physical, emotional, social, financial or legal risks to participants identified.

Confidentiality: The questionnaire was fully anonymized, and email invitations were sent individually to maintain confidentiality. Participant demographics and response data were obtained via Google forms®, which is password-protected and accessed only by the principal investigator and both supervisors of this project.

CHAPTER III. RESULTS – Delphi

Round-1: We identified a total of 16 NRFs. Initial searches related to the resource-limited setting identified two NRFs from Rwandan Provincial hospitals (Rwamagana and Ruhengeri). Fourteen NRFs were identified from upper-middle and high-income countries: eight from the United Kingdom and five from the United States and one from South Africa. These 16 NRFs contained a total of 125 individual items of which ten items were immediately removed as being not relevant to the CCI in a resource-limited setting (e.g., therapeutic hypothermia). Ninety-one of the remaining 115 items (79%) met the pre-defined criteria for consensus to be included in the first draft of the CCI. These items were listed individually, grouped under eight relevant sections to aid interpretation by participants (Table 1). Each NRF contained a mean of 34 items (min=11, max=52). Only 33 of the 91 identified items (36%) were present in more than half of the 16 NRFs, confirming the need for this consensus study.

Response Rate: 124 participants were contacted. Response rate was 32 (25%) and 33 (27%) participants for Round-2 and Round-3, respectively. This was sufficient for our sample size of 15 required for consensus in each round. Eleven of the 32 (33%) participants from Round-2 also completed Round-3; thus, 22 of 33 (67%) participants in Round-3 were new responders. Participants had a mean of 14 years and 13 years of pediatric experience, respectively (Table 2).

Round-2: All sections/themes had additional items suggested by participants. Fifty-two items were suggested that were already present in the Round-1 CCI and were therefore excluded. Thirty-three new items were suggested. Twelve (36%) of these were independently suggested by two or more participants and therefore met the pre-defined definition of consensus and were added to the existing 91 items from Round-1 to form the draft CCI list of 103 items for Round-3 (Table 1).

Piloting of the questionnaire between Round-2 and Round-3 revealed that 28 items could be combined into seven merged items (Table 1 and Figure 1). For example, in Round-2 seven different types of birth resuscitation were described (e.g., bag-valve mask, stimulation, etc.); these were combined to form a single item of "resuscitation at birth." This was to reduce questionnaire fatigue, which was reported by the piloting participants. Therefore, after combining the several items the list reduced from 103 to 82 items.

Figure 1: Flow-diagram of Delphi process

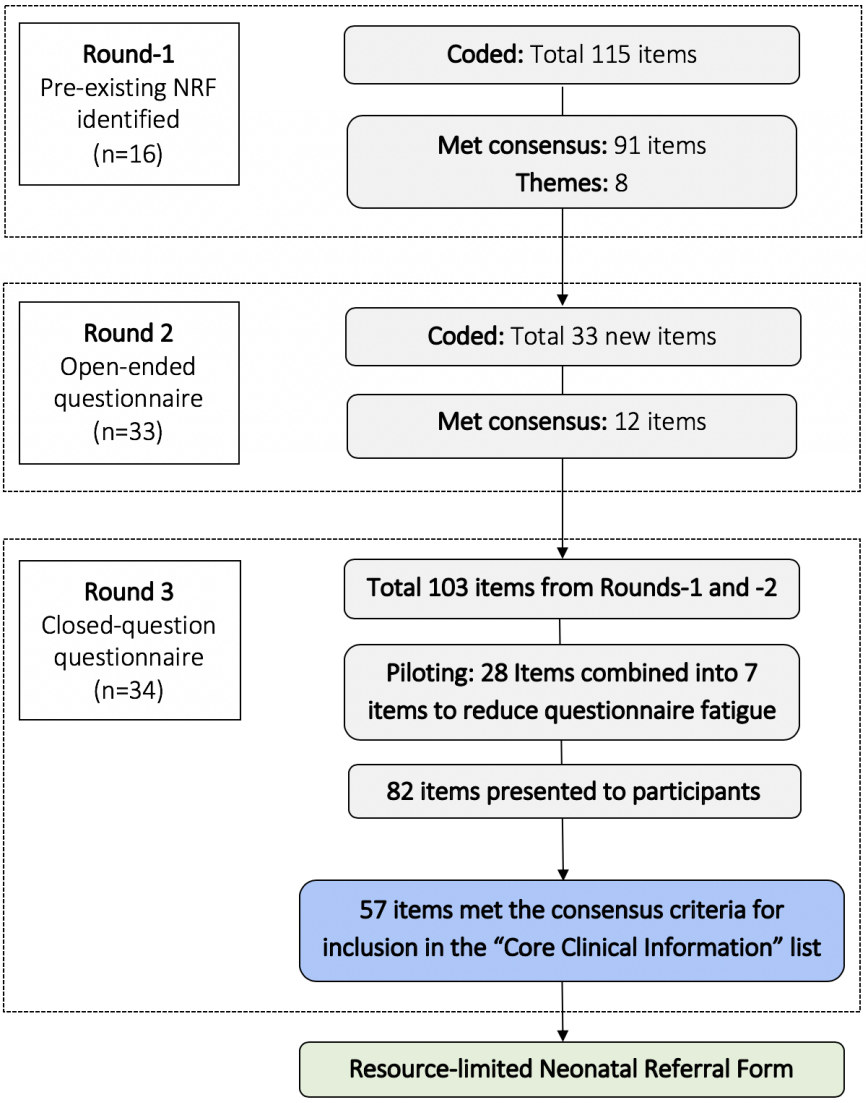


Table 1: Delphi-rounds for CCI items

	Round-1			Round-2		Round-3	
CCI domain/section	Total number of items described in at least 1 NRF	Number of items found only in 1 NRF	Number of items for first draft of CCI (described in at least ≥2 NRFs (included)	New items from participants meeting consensus	Items combined into 7 items to minimise questionnaire fatigue	Total number of items presented in Round-3	Final number of items for the CCI list
Hospital details (Introduction)	16	6	10	0	1	9	8
Patient Identification	13	4	9	2	0	11	8
Clinical history at referral	6	3	3	1	0	4	4
Maternal medical and antenatal history	17	4	13	6	0	19	9
Labor details	14	4	11	2	0	13	11
Neonatal past medical history	19	1	17	1	13	5	4
Management at the referring hospital	20	1	19	0	7	12	11
Miscellaneous	10	1	9	0	0	9	2
Totals	**115**	**24**	**91**	**12**	**28**	**82**	**57**

Table 2: Baseline characteristics of participants of Round-2 and Round-3 of Delphi process

		Round-2 (n=33)	Round-3 (n=34)
Age (years)	Mean (SD)	42.2 (±12.5)	40.9 (±10.7)
Level of expertise	General Pediatrician	11 (34%)	18 (55%)
	Senior Resident	13 (41%)	8 (24%)
	Pediatric subspecialist (non-neonatologist)	5 (16%)	3 (9%)
	Neonatologist	1 (3%)	3 (9%)
	Other	2 (6%)	1 (3%)
Location	East Africa	22 (69%)	20 (61%)
	USA	8 (25%)	12 (36%)
	Other	2 (6%)	1 (3%)
Primary institution	Referral Hospital	27 (84%)	23 (70%)
	District Hospital	2 (6%)	7 (21%)
	Others	3 (9%)	3 (9%)
Employment status	Full-time	25 (78%)	29 (88%)
	Part-Time	4 (13%)	3 (9%)
	Retired	3 (9%)	1 (3%)
Country of medical degree	Rwanda	18 (56%)	16 (49%)
	USA	9 (28%)	11 (33%)
	Other	5 (15%)	6 (18%)
Experience post-graduation from medical school	Mean (SD)	14.1 (±13.1)	12.9 (±10.5)

Round-3: The questionnaire was again divided into the same eight sections/domains, to form a second draft CCI list. Eighty-two items were presented individually for scoring of "importance" in Round-3 (Appendix 2). Of these, 57 items (70%) met the pre-defined consensus criteria to be included in the final CCI list (Appendix 3). Seven (58%) of the 12 items suggested in Round-2 met the inclusion criteria for the final CCI list.

CHAPTER IV. DISCUSSION – Delphi

We sought to determine the key data items (CCI) that should be conveyed for neonatal inter-hospital transfer in the resource-limited setting. By adhering to Delphi techniques for consensus building, we have generated a CCI list of 57 clinical items to close the communication gap in inter-hospital transfer in Rwanda. Given our thorough background search and rigorous methodology, our CCI list is clinically relevant. Additionally, given the breadth of experience of our participants, we anticipate that this CCI list be used to design a Neonatal Referral Form(NRF) readily adaptable to any resource-limited setting.

It is generally accepted that clear records are an essential component of neonatal inter-hospital transfer (29). However, within the literature, there is limited evidence for how such data should be communicated. For example, the NRFs we identified in Round-1 were heterogeneous in nature, with only thirty-three (36%) of the ninety-one items identified being present in more than half of the 16 NRFs. Therefore, many NRFs may be excluding important data points because robust methods were not employed to develop them. We found that NRF contained a mean of 34 items which is significantly less than the 57 items we have included in our CCI list. Items in our 57-item CCI list, that were unique to resource-limited settings included modes of transport (motorcycle, walking), pregnancy conditions (tuberculosis), and perinatal infant care (tetracycline eye ointment).

Communication errors have been established as an indicator that represents a significant event during transport (30). By encouraging strict adherence to data collection and sharing, NRFs can assist with providing a standardized patient handoff, which has been identified as a quality metric for neonatal transport (31,32). In addition, NRFs can allow for the tracking of data to assist with clinical benchmarking for transport outcomes, a much-needed measure in neonatal inter-hospital transfer (33,34).

Strengths

We believe there are several strengths of our study. First, by utilizing the Delphi consensus process, we have managed to incorporate core items that all NRFs tend to include while creating a standard CCI list for use specifically in a resource-limited setting. Second, the participants in the consensus process have a broad length of experience and diverse backgrounds and training. Their broad expertise helped contribute extensive and informed feedback in Rounds-2 and -3 of the Delphi. Third, given that two-thirds of the participants were from East African countries, we feel that the consensus process produced a CCI list that is generalizable to other resource-limited settings.

Limitations and biases

We identified several possible limitations to our study. First, only two of the 16 NRFs obtained in Round-1 were from the resource-limited setting. The content validity of the 14 other NRFs may, therefore, be limited for our setting, though this is minimized by the expert stakeholders in Rounds-2 and -3. Second, the participants involved were all physicians. parents and nursing staff were not included. It was felt that parents were unlikely to understand the terminology or the nature of the clinical information being presented. However, adding nursing staff could have affected our results by eliminating certain items or introducing additional novel items in our CCI list. Third, only four board-certified neonatologists participated in our study. In practice, many of the general pediatricians who participated in our study, particularly from resource-limited settings, care primarily for neonates but simply do not have official certification as subspecialists. Hence, we feel that the expertise of our participants remains highly relevant for the setting and aims of our study.

Regarding potential biases, there are 91 items in the first draft of the CCI list. Asking participants to score the importance of all of these items could result in "questionnaire fatigue" and bias the results of the later outcomes. To mitigate against this possibility, the questionnaire was split into eight themes/sections, and some items were combined in the final last round.

CHAPTER V. CONCLUSION – Delphi

A modified Delphi-method is gaining its use in various areas. By converging opinions of a diverse group of international pediatric care professionals, we have created an organized CCI list of 57 items to be share between facilities during transfer of sick neonates in resource-limited setting.

Recommendations

Despite our study limitations, we anticipate that our CCI list be used to generate an NRF that can be used at any center that refers neonates to institutions that provide a higher level of care in the resource-limited setting. The language would need to be modified where appropriate and the items assessed for local suitability. How use of the generated NRF affects the outcomes of neonatal transfer between health facilities in Rwanda is yet to be determined and would make an interesting piece of future research work too.

CHAPTER II. METHODS –CROSS SECTIONAL STUDY

Study design : A cross-sectional, longitudinal study: Reporting of this study has been verified in accordance with the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) checklist (35). Using this design, we sought to evaluate existing information sharing practice and determine the baseline outcome of referred neonates in Rwanda.

Setting: Multi-centre study at the University Teaching Hospital of Kigali (CHUK) and Rwanda Military Hospital (RMH). Both CHUK and RMH serve as teaching hospitals for the medical and nursing/midwifery schools of the University of Rwanda (UR) (36).

CHUK: It is the largest, public, the main of five tertiary referral hospitals in Rwanda (37). CHUK is located in Kigali city. Its Pediatric Emergency Room (ER) which receives children from birth to 15-years-of-age, has twelve beds and receives an average of 150 children per month of which approximately 20% are aged up to 28 days.

RMH: It is also one of five tertiary referral hospitals in Rwanda (36,38) . It is located in Kigali; it serves as the main referral site to ten of forty-three district hospitals in the country. Neonatal referrals from district hospitals and private hospitals in Kigali are transferred directly to the neonatology unit or Neonatal Intensive Care Unit (NICU), rather than the ER. Both units receive neonates aged up to 28 days-of-life.

Study population: Neonates, aged 0-28 days, referred/arriving to public tertiary care hospitals in Kigali, Rwanda were included. Intra-hospital transfers, neonates without a referral note (e.g. lost referral note, self-transfers), neonates whose caregivers were under 18 years-of-age and those neonates whose caregivers declined to participate were excluded.

Sample size calculation

A sample size was determined to gain the required number of neonates to determine the prevalence of neonatal mortality in referred neonates. Using mortality prevalence, a sample size calculation has been performed using the Kelsey formula (Appendix 4). Preliminary data were obtained from the Pediatric Emergency Room (ER) diary at CHUK for one month and it was found that 28 neonates of 33 admitted neonates were referred from another health facility. This gave an anticipated annual population of 336 referred neonates (N).

Regarding 7-day mortality. The neonatal database at CHUK was reviewed for 2017-2018 (neonates >32 weeks gestation) and the mortality rate was 38 deaths from 147 admissions (25.8%). This has been used as the estimated proportion ($\hat{p}$).

A 95% CI required a sample size (n) of **158 participants** using the above formula. This sample size calculation uses an “anticipated” mortality rate.

Sampling and Period: Neonates were opportunistically recruited over a six-month period from June to November 2018 until the sample size was achieved.

Outcomes

Primary outcomes:

a. Proportion of the CCI list items (created in Part one of this study) found in the referral letters of included neonates,

Secondary outcomes:

b. Prevalence and timing of neonatal mortality within seven days of admission.
c. Neonatal morbidities on arrival, defined as having one or more of hypothermia, hypoxia, seizures and requiring resuscitation.

Confounders:

d. Diagnosis at admission,
e. Social economic status (Ubudehe Groups 1&2 defined as low SES) (39)
f. Timing of admission (night time and days of the weekend)

Data Collection Tool (Questionnaire): a data collection tool was designed specifically for this study (appendix 5). The questionnaire included 108 variables in three sections:

1. Demographic and clinical information of the neonate on arrival
2. Fifty-seven CCI items to assess the quality of the neonate's referral letter
3. In-hospital outcomes (mortality) for seven days

The questionnaire was entirely in English language, it was piloted on two participants (collection and entry) and modifications made prior to extensive use.

Procedures at enrolment and follow up:

Data collectors (DC) training: All data at RMH was collected by the principal investigator (PI). At CHUK the PI trained two registered nurses in the Pediatric ER. The training included explanation of the general concepts of the study and the data collection tools. Quality of data were ensured by the PI observing the data-collectors and cross-checking of data. The PI then allowed them start data collection under supervision until the PI has ensured mastery of the process. The first five cases for each DC where entered to provide feedback for better subsequent data collections. During data entry of subsequent cases, two participants were found as duplicates. These were excluded and feedback given to the team until the last participant without another incident.

Recruitment: Caregivers of neonates meeting inclusion criteria were given a consent form at the point of recruitment (after arrival at CHUK/Pediatric Emergency Room or NICU at RMH); which was immediately after admission or when the caregiver was psychologically stable to understand the consent form in those neonates admitted in critical situation.

Confidentiality: Each recruited neonate was given a study number, which was used to save the participant's names, date of birth and Hospital identification number on a separate tool (Unique participant identifier code sheet) in ordered to maximize participants' privacy. And this information was required to follow up these participants 24 hours and seven days later for their outcomes.

Data collection process: Data were taken from the patient clinical file and inputted into the paper questionnaire. If data were not available from the patient file (e.g. time of birth, family socio-economic status (Ubudehe Category), the caregiver was interviewed to gain the required information. Data were then checked for clinical events/outcomes at eight hours of admission. Mortality was also checked at twenty-four hours and seven days after admission. These data were sourced from the patient-files either during the inpatient stay or from the hospital records if the patient had been discharged.

Data management

Data were transferred from the paper data-collection tools into Microsoft Excel for cleaning and coding. They were then exported and analyzed using SPSS.

Statistical analysis: Electronic software (SPSS) was used for analysis. Categorical data were described as odds ratios (OR), using Pearson's Chi-squared to gain p-values.

Outcomes:

- The proportion of CCI items available in the referral letters was described for each participant (continuous data/scale). Initial review of the 158 neonates revealed a median of 33.3% of the CCI being documented in referral letters. Therefore, CCI was converted to two ordinal (categorical) data groups
    - Low CCI documentation (< 33.3% of CCI documented)
    - High CCI documentation (≥ 33.3 % of CCI documented)
        - This was compared with Mortality (binary data), described as odds ratios, using Pearson's Chi-squared to gain p-values

To assess the validity of the CCI gained from the Delphi-study (Part one) a Pearson's correlation was undertaken comparing the mean importance for each CCI item (on 1-9 scale) gained from the Delphi compared to the frequency (percentage) that the CCI item was described in referral letters.

Ethical Considerations – Cross sectional

Funding & Sponsors: No funding has been sought for this project.
Potential conflict of interest: No potential conflicts of interest.
Confidentiality: Neonate information were collected using the data collection tool. These were then labelled using a Unique Patient Identifier (UPI). Due to the longitudinal nature of this study data were collected at separate occasions from different sources. Therefore, neonate identifying details were needed.
Confidentiality: Participant's identification details (name, DOB, hospital ID) were kept in a second database, linking to the UPI for each neonate and were only accessible by the PI and DCs. All data entered, were password protected and only the PI and study supervisors had access to the password.

Informed consent: At the point of enrolment caregivers of participants were asked to sign a consent form (Appendices 6), written in English or Kinyarwanda dependent on participant choice. Literate caregivers self-read the consent form whereas caregivers who could not read (or by their choice), a data collector (PI or trained data-collector) read the consent form for them without adding any judgment value. Caregivers were given opportunity to ask questions for better understanding before signing the form.

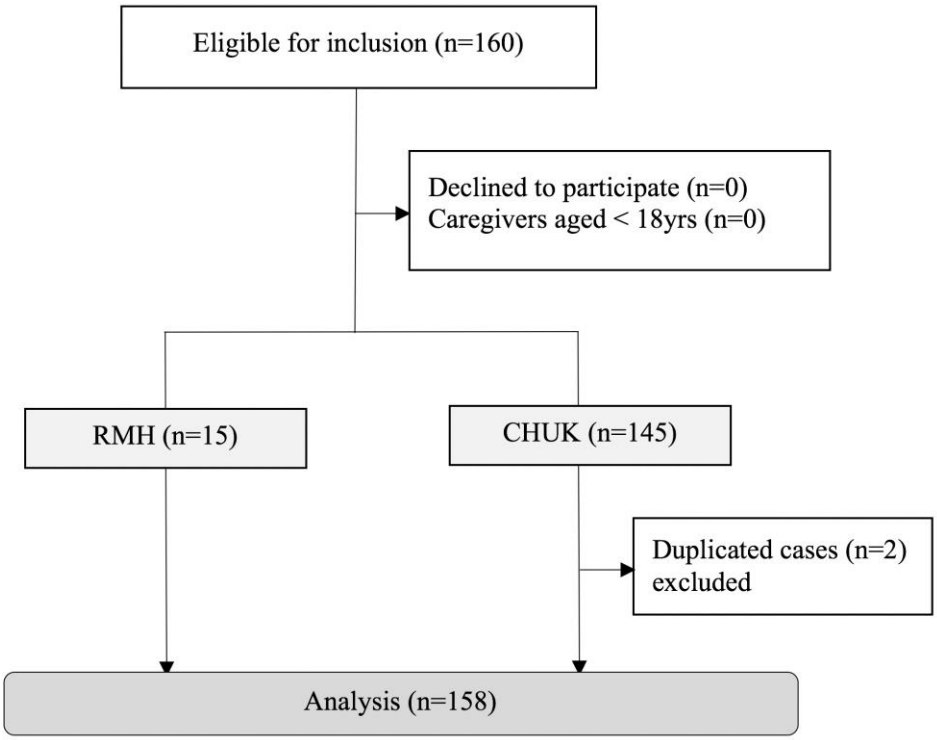
Incentives for participants: No incentives given to participants and no additional care provided to study participants (study participation did not affect neonate care).

Risks to participants: It is known that harms may result for participants from simply agreeing to be a participant in research and these were mitigated where possible. The principle of beneficence entails maximizing benefits and minimizing harms to research participants. All research involves some degree of risk; however, some research is considered to be of *minimal risk.* There were no physical, legal or financial risks to participants. Some of the data could be perceived to be sensitive (e.g. maternal HIV status) were not required in this project. However, it is our judgement that the processes of the study involve minimal emotional risk to caregivers whose neonates were critically ill. These was mitigated by delaying recruitment and interviewing caregivers in less public place (e.g. counseling room). And Caregivers were that informed that they could withdraw their consents at any point of the study.

CHAPTER III. RESULTS – Cross sectional

A total of 160 neonates were enrolled in the study. Two duplicate participants, who were inadvertently collected twice by two independent data-collectors, were excluded, which made 158 participants as per our pre-calculated sample size. None of the eligible caregivers declined participation (Figure 2).

Figure 2: Recruitment strategy



Missing data: A total of 79 (0.5%) of 17,064 data-points were missing. Ninety-eight variables had complete data on all 158 participants. Eleven of the 108 variables (10.2%) had a mean of seven participants missing data. Time of birth was the variable that was most compromised with 17 participants not having the available data. All participants that had missing data were still included in the analysis.

Demographics: The study population was diverse in terms of gestational age (72% were term), gender (63% male), birth weight (≥2.5 kg in 67%), site of birth, and mode of delivery (73% born by vaginal delivery). 91%, were collected at CHUK and 67%, had surgical condition as primary diagnosis and 68%, presented within their first week of life (Table 3).

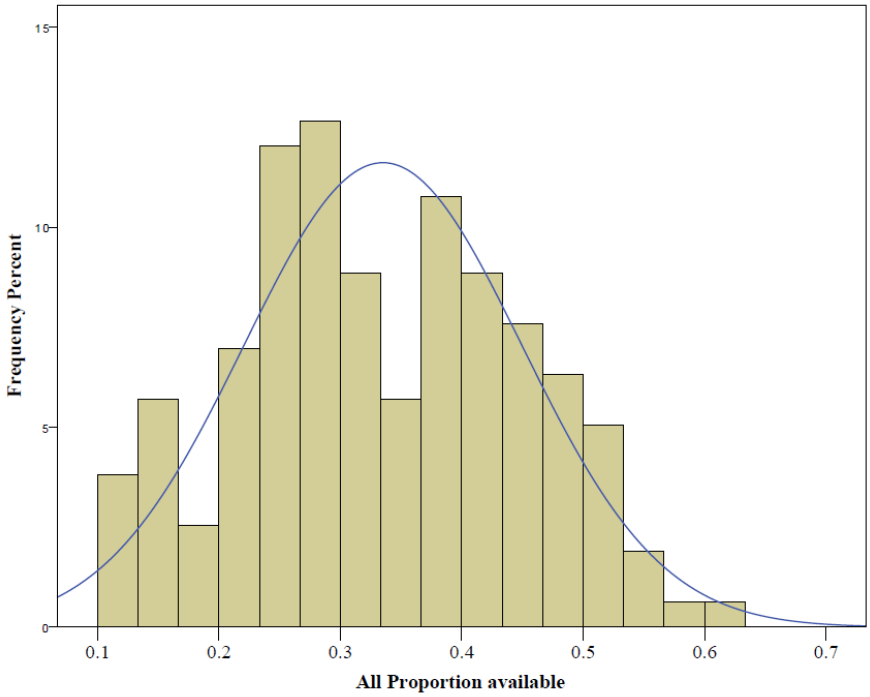
Table 3: Participants and baseline data

	CHUK (n=143, 90.5%)	RMH (n=15, 9.5%)	Total (n=158)
Gender (male)	89 (62.2%)	11 (73.3%)	100 (63.3%)
Gestational groups			
Term (≥37 weeks)	110 (76.9%)	4 (26.7%)	114 (72.2%)
<37 weeks	24 (16.8%)	9 (60.0%)	33 (20.9%)
Unknown	9 (6.3%)	2 (13.3%)	11 (7.0%)
Birth weight groups (kg): ≥2.5	94 (65.7%)	11 (73.3%)	105 (65.5%)
<2.5	49 (34.3%)	4 (26.7%)	52 (33.5%)
Site of birth			
Public facility	134 (93.7%)	9 (60.0%)	143 (90.5%)
Others	9 (6.3%	6 (40.0%)	15 (9.5%)
Mode of transport			
Ambulance	138 (96.5%)	15 (100%)	153 (96.8%)
Others	5 (3.5%)	0	5 (3.2%)
Mode of delivery:			
Vaginal	107 (74.8%)	9 (60.0%)	116 (73.4%)
Caesarean	36 (25.2%)	6 (40.0%)	42 (26.6 %)
Age groups			
≤7days	94 (65.7%)	13 (86.7%)	107 (67.7%)
>7days	49 (34.3%)	2 (13.3%)	51 (32.3%)
Ubudehe Category			
1 & 2	90 (63.0%)	5 (33.3%)	95 (60.1%)
3 & Unknown	53 (37.1%)	10 (66.7%)	63 (39.8%)
Time of admission			
Day (7am-7pm)	73 (51.0%)	4 (26.7%)	77 (48.7%)
Night	70 (49.0%)	11 (73.3%)	81 (51.3%)
Day of admission			
Monday-Friday	108 (75.5%)	10 (66.7%)	118 (74.7 %)
Weekend	35 (24.5%)	5 (33.3%)	40 (25.3%)
Primary Diagnosis			
Medical	38 (26.6%)	14 (93.3%)	52 (32.9%)
Surgical	105 (73.4%)	1 (6.7%)	106 (67.1%)
Number of CCI items			
Mean	32.9% (SD:11.6)	39.4% (SD:8.5)	33.5% (p=0.035)
Median	31.6%	38.6%	33.3% (p=0.028)

CHUK = Centre Hospitalier Universitaire de Kigali; RMH = Rwanda Military Hospital;
RMH = Rwanda Military Hospital; SD: Standard Deviation

Quality of referral letters: The median number of CCI items described in each referral letter was 33.3%. We therefore classified the quality of each referral letter as "High" or "Low" CCI documentation using the median (33.3%). There were eight participants who had exactly 33.3% CCI documented and they were included in the "High" amount of data available leading to unequal groups despite the median being used (Table 5). The histogram shows (Figure 3) the distribution of the quality (contents) of the analyzed referral letters. This demonstrates the completeness compared to the CCI list ranges between 10 to 60%. One outlier was found completed at 64%.

Figure 3: Overall quality of referral letters



Mortality based on quality of content of referral letters: There is a trend of association between low quality referral letter and mortality but this was not statistically significant, OR=1.58, (p=0.262 95% CI:0.71 to 3.52).

Mortality and morbidities: The overall mortality during the study period was 19% and among them, one fifth died within the first day of admission (Table 4). Hypoxia (40%) and instability requiring resuscitation (27%) were the most prevalent morbidities in our study population (Table 4).

Table 4: Prevalence of mortality and morbidity

	CHUK (n=143)	RMH (n=15)	Total (n=158)
Death within day 1	6 (4.2 %)	0	6 (3.8%)
Death within days 2 to 7	22 (15.4%)	2 (13.3%)	24 (15.2%)
Total deaths	28 (19.6%)	2 (13.3%)	30 (19%)
Hypothermia	53 (37.1%)	10 (66.7%)	63 (39.9%)
Resuscitation	35 (24.5%)	8 (53.3%)	43 (27.2%)
Hypoxia	17(11.9%)	5 (33.3%)	22 (13.9%)
Seizures	7 (4.9 %)	2 (13.3%)	9 (5.7 %)

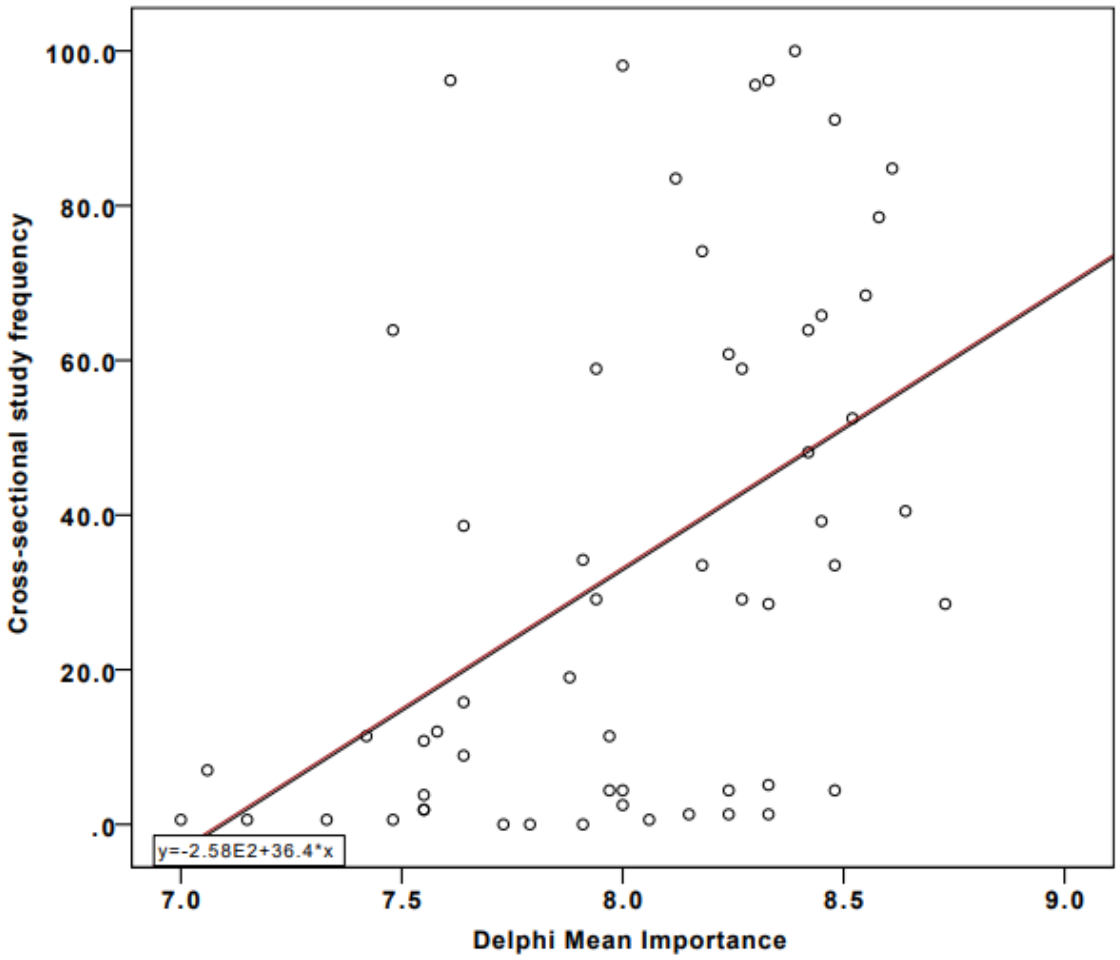
More than a third of neonates were admitted hypoxic (Table 4), and these patients were three times more likely to die (OR=2.96 (CI:1.11 to 7.9), p=0.025). Almost one third of our participants, 27.2%, required at least one of the eight components of resuscitation at admission but this was not a strong risk factor to die, p=0.196, (Table 5). Low birth weight was found to be strongly associated to mortality, compared to normal birth weight neonates, OR= 2.37 (p=0.034, 95% CI:1.05 to 5.32), (Table 5). Male sex, admission at night and admission during weekend days were not strong predictors of mortality during study period, p=0.262, p=0.801 and p=0.850 respectively.

Table 5: Mortality based on referral letters contents and other admission morbidities

Mortality (study period)	Mortality rate	Unadjusted odds ratio, (df = 1)
Amount of CCI data		
Low (< 33.3%)	17/75 (22.7%)	OR=1.58 (CI:0.71 to 3.52), p=0.262
High (≥ 33.3%)	13/83 (15.7%)	
Gender		
Male	17/100 (17%)	OR=1.41 (CI: 0.63 to 3.17), p=0.40
Female	13/58 (22.4%)	
Prematurity		
<37 weeks	7/33 (21.2%)	OR=1.27 (CI:0.48 to 3.31), p=0.632
>37 weeks	20/114 (17.5%)	
Birth weight		
<2.5 Kg	15/53 (28.3%)	OR=2.37 (CI:1.05 to 5.32), p=0.034
≥2.5 kg	15/105 (14.3%)	
Primary diagnosis		
Surgical	19/106 (17.9%)	OR=1.23 (CI: 0.54 to 2.82), p=0.627
Medical	11/52 (21.2%)	
Hypothermia		
Yes	15/63 (23.8%)	OR=1.67 (CI: 0.75 to 3.71), p=0.21
No	15/95 (15.8%)	
Seizures		
Yes	3/9 (33.3%)	OR=2.26 (CI: 0.53 to 9.61), p=0.258
No	27/149 (18.1%)	
Hypoxia		
Yes	8/22 (36.4%)	OR=2.96 (CI:1.11 to 7.9), p=0.025
No	22/136 (16.2%)	
Resuscitation		
Yes	11/43 (25.6%)	OR=1.74 (CI: 0.75 to 4.04), p=0.196
No	19/115 (16.5%)	
(Ubudehe 1&2):		
Yes	15/95 (15.8%)	OR=0.60 (CI:0.27 to 1.34), p=0.211
No	15/63 (23.8%)	
Admitted Night		
Yes	16/81 (19.8%)	OR=1.11 (CI:0.50 to 2.48), p=0.801
No	14/77 (18.2%)	
Admitted weekend		
Yes	8/40 (20.0%)	OR=1.09 (CI:0.44 to 2.69), p=0.850
No	22/118 (18.6%)	

Correlation: To assess if participants in the Delphi-study had rated the importance of items in a manner that is correlated with clinical practice, the Mean importance (1-9) was compared to the frequency that item was included in referral letters. A moderately strong correlation was found (r =0.47, p<0.001) (Figure 4).

Figure 4: correlation between Delphi results and CS study results



r=0.47 (moderate); r = coefficient of correlation

CHAPTER IV. DISCUSSION – Cross sectional

Study objective and key results: Our aim was to evaluate the quality of existing referral letters using the standard (CCI items) identified in our previous Delphi-study. The referral letters of transferred neonates were found to be of poor quality in terms of completeness (Figure 3). This is similar to what was found in Nigeria (17) in 2005 where the contents of referral letters from general practitioners to a tertiary Pediatric emergency were grossly inadequate; but the population was non-neonatal specific. This finding justifies the need of a standardized NRF for use nationwide and possible further training of healthcare professionals (HCPs) to optimize and harmonize clinical information sharing. Such an NRF can be created using the CCI list from the above Delphi-study.

The results found are important. To our knowledge, this is the first study to evaluate the existing practice in clinical information sharing while transferring neonates in the resource-limited setting, existing literature is non-neonatal specific. It was found in the same pediatric population that good quality information sharing saves clinicians and patients time, ensures a smooth transition of care; and minimizes the cost of care (17).

Mortality: We also aimed to determine the prevalence and timing of mortality for transferred neonates. Overall, almost one fifth of study population died before the 7^{th} day of admission. The mortality rate we found was equivalent to other studies in Brazil (2010), India (2013) and Argentina (2010) where the overall mortality (until discharge or death) of transported neonates was 18 %, 20 % and 18% respectively (7,40,41). However, this is higher to hospital born neonates mortality of 16% of Neonatology unit at CHUK that considered all the hospital stay (42).

None of our cases were dead on arrival. But rather, many of them were admitted with clinical co-morbidities, such as hypothermia, clinical instability requiring immediate cardio-respiratory support (ICRS within 8 hours), seizures and hypoxia. The later and low birth weight were found strongly associated with mortality, ($p<0.05$).

Furthermore, we have determined the mortality and morbidities of these neonates at the receiving hospitals. This emphasizes on the need of an organized patient transport system (communication tools, referral letter (NRF), etc.) to improve quality of transfer (43,44).

Strengths of this study: To our knowledge, this is the first study, that has targeted the quality of the information shared during neonatal transfer and determining the outcome of the transferred neonates.

Limitations: Limitations include the study population was from two referral hospitals that cannot fully represent neonates referred to all the five tertiary hospitals in Rwanda. One hospital (CHUK) was also more represented in the recruitment process. Limitations also included assessing neonates referred to public institutions (excluding private hospital).

The study design does not allow for an assessment of other factors that may influence a neonate's outcome such as care prior to or during transportation, transport modalities etc. These were beyond the scope of this project but need to be included in further researches.

Again, regarding the condition of infants in the first eight hours of admission. Using the information available it is impossible to completely establish whether this reflects the neonates condition prior to or during transport and so when resuscitation or any other adverse events should have occurred.

Potential biases: our study design was subject to minimal biases. Some of the data-extracted could have been data-collector dependent.

Validity of the results: One of our study sites (CHUK), is the largest and more public teaching and referral hospital, situated in the center and capital city of the country where there is a heavier concentration of specialties (i.e. Neonatologist, Pediatric surgeon, Neurosurgeon, Pediatric anesthesiologist, Pediatric cardiologist, Pediatric hemato-oncologist, Medical geneticist, many general pediatricians and residents) compared to other referral hospitals. All these make it a prototype site where you expect to find neonates referred for diverse reasons in a resource-limited country. Thus, the results of our study are fit for practical use in similar settings. They derive their internal validity from the above facts and they have external validity in similar settings where patients transport systems are still not organized. In terms of external validity, our results do not represent the findings one would expect between health-centers and district hospitals.

Application of results: These baseline findings support the need for a national NRF to ensure adequate completeness of information sharing between sites when transferring a sick neonate in Rwanda.

CHAPTER V. CONCLUSION AND RECOMMENDATIONS -Cross sectional

Transfer of neonates in resource limited settings poses an additional risk to mortality and morbidities. Need of an organized transport system with focus to more vulnerable population, such as neonates. Considering the fact that all the referral letters analyzed, had less than two third of the CCI list, there is a gap in communication, that needs a harmonized referral letter and improved documentation. And the neonatal transport modalities should be point of future work.

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APPENDICES

Appendix 1: Search terms (MeSH terms in italics)

	(Premature birth OR infant, premature OR infant, extremely premature OR *infant, newborn* OR premature *OR* prematurity OR prematur* OR neonat* *OR Infant, Low Birth Weight OR Infant* OR Infant care)
AND	(patient hand off OR patient transfer OR patient transport OR Transportation of patients)
AND	*(Developing Countries* OR developing country OR countries, developing OR nations, developing OR developing nations OR *Poverty* OR resource poor countr* OR resource-poor country OR low income country OR low-income country OR *Global Health* OR third word OR India OR Africa OR Asia OR South America OR Papua New Guinea OR Asia-Pacific)
NOT	*(Surfactant OR trauma OR surgery OR neurosurgery OR in-utero OR inutero OR prenatal OR gene OR genetic OR genetics OR outbreak OR Fertility OR embryo OR cpap OR global health OR congenital anomalies OR congenital malformations OR intensive care OR matern* OR stillbirth*)*
Limits	Humans, English
Search date	March 10th , 2017
Findings	147 articles of which eight were relevant for our PICO question (reviewing their references, five more articles were hand searched and found relevant)

Appendix 2: Round-3 responses and consensus application

Domains	ITEM (% of NRFs in Round-1 that included this item)	Include or not	IMPORTANT (7-9), total	EQUIVOCAL (4-6), total	NOT-IMPORTANT (1-3), total	MEAN	ST DEVIATION
Introduction / Hospital details	Date/time of referral (81%)	INCLUDE	97.0%	3.0%	0.0%	8.48	0.83
	Name of referring hospital (94%)	INCLUDE	97.0%	3.0%	0.0%	8.39	0.90
	Pre-transfer communication undertaken (if Yes who and when? or NO) (56%)	INCLUDE	93.9%	6.1%	0.0%	8.27	0.98
	Reason / Benefits for transfer (19%)	INCLUDE	93.9%	6.1%	0.0%	8.33	1.05
	Referring clinician (name, qualification, phone number) (94%)	INCLUDE	93.9%	6.1%	0.0%	8.30	1.05
	Mode of transfer/transport (ambulance, private car, KMC etc.) (50%)	INCLUDE	90.9%	9.1%	0.0%	8.18	0.98
	Accepting clinician (name, qualification, phone number) (38%)	INCLUDE	87.9%	12.1%	0.0%	7.94	1.25
	Type of transfer (acute, elective, parental request) (38%)	INCLUDE	75.8%	21.2%	3.0%	7.48	1.60
	Accepting Hospital details (name, Ward, Bed Number) (19%)	EXCLUDE	48.5%	42.4%	9.1%	6.33	2.12
Patient Identification	Gestational age (weeks) (56%)	INCLUDE	100.0%	0.0%	0.0%	8.73	0.57
	Birth weight (kg) (75%)	INCLUDE	97.0%	3.0%	0.0%	8.64	0.78
	Date of Birth (age) (75%)	INCLUDE	97.0%	3.0%	0.0%	8.61	0.75
	Current age (day of life) (56%)	INCLUDE	93.9%	6.1%	0.0%	8.45	0.90
	Current weight (kg) (50%)	INCLUDE	93.9%	6.1%	0.0%	8.33	1.14

Domains	ITEM (% of NRFs in Round-1 that included this item)	Include or not	IMPORTANT (7-9), total	EQUIVOCAL (4-6), total	NOT-IMPORTANT (1-3), total	MEAN	ST DEVIATION
	Place of birth (Home, Private facility, Public center, en-route) (13%)	INCLUDE	87.9%	9.1%	3.0%	7.94	1.60
	Patient name (81%)	INCLUDE	84.8%	9.1%	6.1%	8.00	1.89
	Gender (69%)	INCLUDE	78.8%	21.2%	0.0%	7.61	1.68
	Insurance coverage (NEW ITEM - suggested by 6 participants)	EXCLUDE	63.6%	27.3%	9.1%	6.88	2.25
	Hospital ID (56%)	EXCLUDE	51.5%	36.4%	12.1%	6.42	2.26
	Religion of the caregiver (NEW ITEM - suggested by 2 participants)	EXCLUDE	36.4%	30.3%	33.3%	5.12	2.80
Maternal medical and antenatal history	Maternal HIV Status (if positive: Regimen, Recent viral load & CD4 count) (25%)	INCLUDE	93.9%	3.0%	3.0%	8.15	1.54
	Antenatal screening (Toxoplasmosis, Rubella, Hep B&C, Syphilis) (13%)	INCLUDE	93.9%	0.0%	6.1%	8.06	1.54
	Maternal Blood group & Rhesus (19%)	INCLUDE	90.9%	6.1%	3.0%	7.79	1.62
	Pathologies during this pregnancy (Anemia, Preeclampsia, TB, DM, Asthma, Infections & others) (19%)	INCLUDE	90.9%	3.0%	6.1%	8.00	1.56
	Treatment received during pregnancy (6%)	INCLUDE	81.8%	12.1%	6.1%	7.55	1.73
	Type of pregnancy (single, twin, triplet, etc.) (6%)	INCLUDE	75.8%	21.2%	3.0%	7.42	1.66
	Tetanus vaccination during pregnancy (NEW ITEM - suggested by 2 participants)	INCLUDE	72.7%	21.2%	6.1%	7.33	2.03

Domains	ITEM (% of NRFs in Round-1 that included this item)	Include or not	IMPORTANT (7-9), total	EQUIVOCAL (4-6), total	NOT-IMPORTANT (1-3), total	MEAN	ST DEVIATION
	Maternal illicit drugs history (NEW ITEM - suggested by 2 participants)	INCLUDE	72.7%	18.2%	9.1%	7.00	1.90
	Estimated date of delivery by dates (EDD) (19%)	INCLUDE	72.7%	18.2%	9.1%	7.06	2.19
	Last Normal Menstrual Period (LMP) (19%)	EXCLUDE	66.7%	18.2%	15.2%	6.82	2.43
	Obstetric ultrasound (NEW ITEM - suggested by 3 participants)	EXCLUDE	63.6%	30.3%	6.1%	6.85	1.94
	Number of antenatal visits (25%)	EXCLUDE	63.6%	30.3%	6.1%	6.73	1.92
	Obstetric formula (Gravida, Parity, Deaths, Abortions, live children) (44%)	EXCLUDE	63.6%	27.3%	9.1%	6.82	2.02
	Mother's phone number (13%)	EXCLUDE	63.6%	24.2%	12.1%	6.70	2.28
	Maternal smoking history (NEW ITEM - suggested by 2 participants)	EXCLUDE	60.6%	30.3%	9.1%	6.70	2.02
	Mother's age/DOB (25%)	EXCLUDE	60.6%	30.3%	9.1%	6.70	2.04
	Maternal alcohol history (NEW ITEM - suggested by 3 participants)	EXCLUDE	60.6%	27.3%	12.1%	6.76	2.11
	All maternal lab copies or summary (NEW ITEM - suggested by 2 participants)	EXCLUDE	57.6%	36.4%	6.1%	6.48	1.95
	Mother's name (31%)	EXCLUDE	54.5%	33.3%	12.1%	6.70	2.20
Labor details	Labor complications (PPH, Previa, Abruption, etc.) (NEW ITEM - suggested by 2 participants)	INCLUDE	100.0%	0.0%	0.0%	8.33	0.78
	Steroids given (doses and time of last dose) (31%)	INCLUDE	93.9%	6.1%	0.0%	8.24	0.94
	Rupture of membrane time (19 %)	INCLUDE	90.9%	9.1%	0.0%	8.33	1.05

Domains	ITEM (% of NRFs in Round-1 that included this item)	Include or not	IMPORTANT (7-9), total	EQUIVOCAL (4-6), total	NOT-IMPORTANT (1-3), total	MEAN	ST DEVIATION
	Maternal Anesthesia, sedative and/or painkillers given (NEW ITEM - suggested by 4 participants)	INCLUDE	87.9%	9.1%	3.0%	7.73	1.48
	Amniotic fluid quality (clear, meconium stained, estimated quantity) (19%)	INCLUDE	84.8%	12.1%	3.0%	8.00	1.52
	Temperature before/during/after labor (19%)	INCLUDE	84.8%	9.1%	6.1%	7.91	1.86
	Fetal Distress (NRFHR) (13%)	INCLUDE	81.8%	18.2%	0.0%	7.97	1.42
	Mode of delivery (Spontaneous vaginal, Breech, Assisted vaginal, Caesarian and indication + type of anesthesia etc.) (25%)	INCLUDE	81.8%	18.2%	0.0%	7.88	1.36
	Any other drugs prior/during labor (Antibiotics, Oxytocin,…) (25%)	INCLUDE	78.8%	18.2%	3.0%	7.55	1.54
	Magnesium sulphate given in labor (13%)	INCLUDE	75.8%	21.2%	3.0%	7.55	1.54
	Duration (hours) (6%)	INCLUDE	75.8%	12.1%	12.1%	7.15	2.15
	Presentation (cephalic, breech,…) (6%)	EXCLUDE	72.7%	12.1%	15.2%	6.97	2.27
	Onset (time) (6%)	EXCLUDE	60.6%	24.2%	15.2%	6.48	2.33
Clinical history at referral	Clinical adverse events during the last 24 hrs (bradycardia, apnea, seizures, desaturation, resuscitation etc.) (19%)	INCLUDE	100.0%	0.0%	0.0%	8.52	0.76
	Clinical condition of newborn prior to transfer (44%)	INCLUDE	100.0%	0.0%	0.0%	8.58	0.71
	Working diagnosis at transfer (69%)	INCLUDE	97.0%	3.0%	0.0%	8.12	0.96
	Summary of clinical course at the referring facility (NEW ITEM - suggested by 4 participants)	INCLUDE	90.9%	9.1%	0.0%	8.24	1.17

Domains	ITEM (% of NRFs in Round-1 that included this item)	Include or not	IMPORTANT (7-9), total	EQUIVOCAL (4-6), total	NOT-IMPORTANT (1-3), total	MEAN	ST DEVIATION
Neonatal past medical history	Resuscitation at birth (No action or Stimulation or Suctioned or Oxygen or Mask Ventilation or Endotracheal Ventilation or Chest compressions) (38%)	INCLUDE	97.0%	3.0%	0.0%	8.48	0.80
	Drugs history at birth (Vitamin K injection (single dose), Tetracycline eye ointment, Surfactant or Immunizations or Other drugs at birth or Allergies) (38%)	INCLUDE	93.9%	3.0%	3.0%	8.24	1.41
	APGAR score at 1st min, 5th min (63%)	INCLUDE	90.9%	3.0%	6.1%	7.97	1.67
	APGAR score at 10 minutes (NEW ITEM - suggested by 5 participants)	INCLUDE	75.8%	18.2%	6.1%	7.55	1.94
	Distress indicators (Venous cord pH, Arterial cord pH) (25%)	EXCLUDE	0.0%	66.7%	33.3%	3.73	1.35
Management at the referring facility	Antibiotics given (name & doses) (50%)	INCLUDE	100.0%	0.0%	0.0%	8.55	0.75
	INFECTIONS (issues related to infection, exposure to Infect) (56%)	INCLUDE	97.0%	3.0%	0.0%	8.42	0.90
	LABORATORY & IMAGING results (FBC, CRP, Bilirubin, Cultures, X-ray, U/S, CT scan, U&E, Glycemia)	INCLUDE	97.0%	3.0%	0.0%	8.45	0.83
	Oxygen saturations (pre/post ductal) (69%)	INCLUDE	97.0%	3.0%	0.0%	8.48	0.80
	CIRCULATION: Vitals (Heart rate, Blood Pressure, Temperature), Fluids given, Inotropes (69%)	INCLUDE	93.9%	6.1%	0.0%	8.42	0.90
	Respiratory support: none, low flow oxygen: head box, nasal prongs, HFT, CPAP, VENT (ETT, Depth) (75%)	INCLUDE	93.9%	3.0%	3.0%	8.27	1.38

Domains	ITEM (% of NRFs in Round-1 that included this item)	Include or not	IMPORTANT (7-9), total	EQUIVOCAL (4-6), total	NOT-IMPORTANT (1-3), total	MEAN	ST DEVIATION
	NEUROLOGY: Level of consciousness, HIE grade (mild, moderate, severe), pain/sedative drugs (44%)	INCLUDE	90.9%	9.1%	0.0%	8.18	1.13
	FEEDS (last feed type & amount, NG aspirate in ml) (50%)	INCLUDE	84.8%	15.2%	0.0%	7.91	1.21
	TUBES TYPE (NO or YES: Urinary, Orogastric tube/Nasal gastric tubes, Chest drain, Abdominal drain, size, insertion length/date, insertion site) (56%)	INCLUDE	84.8%	9.1%	6.1%	7.64	1.73
	LINES Placed (NO or YES: Central line, Peripheral line, Intra-osseous (63%)	INCLUDE	81.8%	18.2%	0.0%	7.58	1.35
	Ventilation settings (ETT/size & Depth, PIP/PEEP, Rate, Fio2, InspTime) (69%)	INCLUDE	72.7%	21.2%	6.1%	7.48	2.12
	Blood gas results (56%)	EXCLUDE	63.6%	27.3%	9.1%	6.94	2.21
Miscellaneous	Patient records sent (maternal record, nurse flow sheet, triage sheet, x-ray report, discharge letter, other) (38%)	INCLUDE	84.8%	12.1%	3.0%	7.64	1.56
	Outcome at the receiving hospital (TRIPS Score, Alive & died, Died in transit, Died within 24hrs of transfer, Died beyond 24hrs, Alive & counter-referred) (25%)	INCLUDE	78.8%	15.2%	6.1%	7.64	1.78
	Caregiver aware of the transfer (25%)	EXCLUDE	72.7%	12.1%	15.2%	6.94	2.54
	Recommendations given to referring unit (19%)	EXCLUDE	66.7%	27.3%	6.1%	7.18	1.84
	Personnel on board during transfer (69%)	EXCLUDE	63.6%	33.3%	3.0%	6.94	1.71
	Date of approval/update of form at the bottom (19%)	EXCLUDE	63.6%	21.2%	15.2%	6.33	2.45
	Parents (mother referred or not, or wishes to travel) (25%)	EXCLUDE	60.6%	27.3%	12.1%	6.70	2.21

Domains	ITEM (% of NRFs in Round-1 that included this item)	Include or not	IMPORTANT (7-9), total	EQUIVOCAL (4-6), total	NOT-IMPORTANT (1-3), total	MEAN	ST DEVIATION
	Caregiver plan (feeding choice) (13%)	EXCLUDE	60.6%	21.2%	18.2%	6.30	2.39
	Hospital letterhead (63%)	EXCLUDE	39.4%	30.3%	30.3%	5.36	2.73

The gradient of colour coding reflects consensus, with Green representing items meeting the pre-defined consensus criteria and Red not meeting the pre-defined consensus criteria.

Appendix 3: Final CCI list

Sections	Items
Hospital details	1. Accepting clinician (name, qualification, phone number) 2. Date/time of referral 3. Mode of transfer/transport (ambulance, private car, KMC etc.) 4. Name of referring hospital 5. Pre-transfer communication undertaken (if Yes who and when? or NO) 6. Reason / Benefits for transfer 7. Referring clinician (name, qualification, phone number) 8. Type of transfer (acute, elective, parental request)
Patient Identification	9. Birth weight (kg) 10. Current age (day of life) 11. Current weight (kg) 12. Date of Birth (age) 13. Gender 14. Gestational age (weeks) 15. Patient name 16. Place of birth (Home, Private facility, Public center, en-route)
Maternal medical and antenatal history	17. Maternal illicit drugs history 18. Tetanus vaccination during pregnancy 19. Antenatal screening (Toxo, Rubella, Hep B & C, Syphilis) 20. Estimated date of delivery by dates (EDD) 21. Maternal Blood group & Rhesus 22. Maternal HIV Status (if positive: Regimen, Recent viral load & CD4 count) 23. Pathologies during this pregnancy (Anaemia, Preeclampsia, TB, DM, Asthma, Infections & others) 24. Treatment received during pregnancy 25. Type of pregnancy (single, twin, triplet..)
Labor details	26. Labor complications (PPH, Previa, Abruption,) 27. Maternal Anesthesia, sedative and/or painkillers given 28. Amniotic fluid quality (clear, meconium stained, estimated quantity) 29. Any other drugs prior/during labor (Antibiotics, Oxytocin,) 30. Duration (hours) 31. Fetal Distress (NRFHR) 32. Magnesium sulfate given during labor 33. Mode of delivery (Spontaneous vaginal, Breech, Assisted vaginal, Caesarean and indication + type of anesthesia etc.) 34. Rupture of membrane time

	35. Steroids given (doses and time of last dose) 36. Temperature before/during/after labor
Clinical history at referral	37. Summary of clinical course at the referring facility 38. Clinical adverse events during the last 24 hrs (bradycardia, apnea, seizures, desaturation, resuscitation etc.) 39. Clinical condition of newborn prior to transfer 40. Working diagnosis at transfer
Neonatal past medical history	41. APGAR score at 10 minutes 42. APGAR score at 1st min, 5th min 43. Drugs history at birth (Vitamin K injection (single dose), Tetracycline eye ointment, Surfactant or Immunizations or Other drugs at birth or Allergies) 44. Resuscitation at birth (No action or Stimulation or Suctioned or Oxygen or Mask Ventilation or Endotracheal Ventilation or Chest compressions)
Management at the referring facility	45. Antibiotics given (name & doses) 46. CIRCULATION: Vitals (Heart rate, Blood Pressure, Temperature), Fluids given, Inotropes 47. FEEDS (last feed type & amount, NG aspirate in ml) 48. INFECTIONS (issues related to infection, exposure to Infect) 49. LABORATORY & IMAGING results (FBC, CRP, Bilirubin, Cultures, X-ray, U/S, CT scan, U&E, Glycaemia) 50. LINES Placed (NO or YES: Central line, Peripheral line, Intra-osseous 51. NEUROLOGY: Level of consciousness, HIE grade (mild, moderate, severe), pain/sedative drugs 52. Oxygen saturations (pre/post-ductal) 53. Respiratory support: none, low flow oxygen: headbox, nasal prongs, HFT, CPAP, VENT (ETT, Depth) 54. TUBES TYPE (NO or YES: Urinary, Orogastric tube/Nasal gastric tubes, Chest drain, Abdominal drain, size, insertion length/date, insertion site) 55. Ventilation settings (ETT/size & Depth, PIP/PEEP, Rate, Fio2, InspTime)
Miscellaneous	56. Outcome at the receiving hospital (TRIPS Score, alive & Died, died in transit, died within 24hrs of transfer, died beyond 24hrs, Alive & counter-referred) 57. Patient records sent (maternal record, nurse flow sheet, triage sheet, x-ray report, discharge letter, other)

Appendix 4. Sample size formula for cross sectional study (CS)

Kelsey formula (http://www.openepi.com/SampleSize/SSPropor.htm) using:

$$n = \mathbf{deff} \times \frac{\mathbf{N\hat{p}\hat{q}}}{\frac{\mathbf{d^2}}{\mathbf{1.96^2}}(\mathbf{N-1}) + \mathbf{\hat{p}\hat{q}}}$$

Where:

n = sample size

deff = design effect = 1

N = population size

$\hat{p}$ =the estimated proportion

$\hat{q}$ = 1- $\hat{p}$

p = desired absolute precision or absolute level of precision = 5%

Appendix 5: Data collection tool for CS

Data collection tool of the study on "Neonatal inter-hospital transport: Clinical information sharing and condition of neonates transferred to tertiary hospital in Rwanda." **Contact person:** mosenga2000@gmail.com & +250 783 33 34 38

Date/time of recruitment:…../……/201… …….h……min

Patient Identification	
Participant number	……
Sex:	M ☐ F ☐ U – unknown ☐
DOB:	___/___/___ DNA ☐
Time of birth:	__: __ am/pm DNA ☐
GA:	_____ weeks DNA ☐
BW	_____ kg DNA ☐
Current Weight:	kg
Current age (DoL):	_____ days
Place of birth	H - Home ☐ PF - Private facility ☐ PC - Public center ☐ R - en-route ☐ O – Other ☐ DNA ☐
Mode of delivery	V – vaginal ☐ B - Breech ☐ A - Assisted vaginal ☐ Cs – Caesarian ☐ DNA ☐
Arrival	
Hospital	K - CHUK ☐ B - CHUB☐ R - RMH☐
Date of arrival at Hospital	…./……./201… DNA ☐
Time of arrival:	…….h…… am/pm DNA ☐
Daytime/nighttime	D-Daytime ☐ N-Night ☐ DNA ☐
Day of arrival:	M ☐ T ☐ W ☐ Th ☐ F ☐ S ☐ Su ☐ DNA ☐
Type of transfer	A - Acute ☐ E - elective ☐ P - parental request ☐ DNA ☐
Mode of transfer/transport	A – ambulance ☐ PC - private car ☐ W –walking ☐ M–Moto ☐ O–Other ☐ DNA ☐
Antibiotics prior to transfer	Y - yes ☐ N - no ☐ DNA ☐
Condition at Arrival	
Dead:	Y - yes ☐ N - no ☐ DNA ☐
Heart rate:	…… DNA ☐
Spo2:	……..% O_2 ☐ RA ☐ DNA ☐
Temperature:	…….. °c DNA ☐
Seizures:	Y - yes ☐ N - no ☐ DNA ☐
Respiratory distress:	Y - yes ☐ N - no ☐ DNA ☐
Blood sugar:	…… mg/dl or Unrecordable ☐ DNA ☐
Fluid boluses	Y - yes ☐ N - no ☐ DNA ☐
PRBC	Y - yes ☐ N - no ☐ DNA ☐
Crystalloids	Y - yes ☐ N - no ☐ DNA ☐
Albumin	Y - yes ☐ N - no ☐ DNA ☐
CRS	Y - yes ☐ N - no ☐ DNA ☐
If yes: Chest compressions	Y - yes ☐ N - no ☐ DNA ☐
BMV	Y - yes ☐ N - no ☐ DNA ☐
CPR	Y - yes ☐ N - no ☐ DNA ☐
Intubation	Y - yes ☐ N - no ☐ DNA ☐
Inotropes:	Y - yes ☐ N - no ☐ DNA ☐
Diagnosis (Provisional main):	DNA ☐
Details of Transportation / patient	
Ubudehe category	1 ☐ 2 ☐ 3 ☐ 4 ☐ Unknown ☐
Province of origin:	K- Kigali ☐ N-Northern ☐ W-Western ☐ S-southern☐ E-Eastern ☐
Date/time left referring Hospital:	___/___/___ ….h…. DNA ☐
Accompanied by mother:	Y - yes ☐ N - no ☐ DNA ☐
Accompanied by transfer note:	Y - yes ☐ N - no ☐ DNA ☐ if **Yes**, continue to the next pages

Analysis of transfer note contents

CODE	Item	Presence
I1	Date/time of referral	Y - yes ☐ N - no ☐
I2	Pre-transfer communication undertaken (if Yes who and when? or no)	Y - yes ☐ N - no ☐
I3	Type of transfer (acute, elective, parental request)	Y - yes ☐ N - no ☐
I4	Name of referring hospital	Y - yes ☐ N - no ☐
I5	Referring clinician (name, qualification, phone number)	Y - yes ☐ N - no ☐
I6	Accepting clinician (name, qualification, phone number)	Y - yes ☐ N - no ☐
I7	Reason / Benefits for transfer	Y - yes ☐ N - no ☐
I8	Mode of transfer/transport (ambulance, private car etc.)	Y - yes ☐ N - no ☐
P1	Patient name	Y - yes ☐ N - no ☐
P2	Gender	Y - yes ☐ N - no ☐
P3	Date of Birth (age)	Y - yes ☐ N - no ☐
P4	Place of birth (Home, Private facility, Public center, en-route)	Y - yes ☐ N - no ☐
P5	Birth weight (kg)	Y - yes ☐ N - no ☐
P6	Gestational age (weeks)	Y - yes ☐ N - no ☐
P7	Current weight (kg)	Y - yes ☐ N - no ☐
P8	Current age (day of life)	Y - yes ☐ N - no ☐
C1	Working diagnosis at transfer	Y - yes ☐ N - no ☐
C2	Clinical condition of newborn prior to transfer	Y - yes ☐ N - no ☐
C3	Clinical adverse events during the last 24 hrs (bradycardia, apnea, seizures, desaturation , resuscitation etc.)	Y - yes ☐ N - no ☐
C4	Summary of clinical course at the referring facility	Y - yes ☐ N - no ☐
M1	Type of pregnancy (single, twin, triplet…)	Y - yes ☐ N - no ☐
M2	Estimated date of delivery by dates (EDD)	Y - yes ☐ N - no ☐
M3	Maternal Blood group & Rhesus	Y - yes ☐ N - no ☐
M4	Maternal HIV Status (if positive: Regimen, Recent viral load & CD4 count)	Y - yes ☐ N - no ☐
M5	Antenatal screening (Toxo, Rubella, Hep B & C, Syphilis)	Y - yes ☐ N - no ☐
M6	Pathologies during this pregnancy (Anemia, Preeclampsia, TB, DM, Asthma, Infections & others)	Y - yes ☐ N - no ☐
M7	Treatment received during pregnancy	Y - yes ☐ N - no ☐
M8	Tetanus vaccination during pregnancy	Y - yes ☐ N - no ☐
M9	Maternal illicit drugs history	Y - yes ☐ N - no ☐
L1	Duration (hours)	Y - yes ☐ N - no ☐
L2	Steroids given (doses and time of last dose)	Y - yes ☐ N - no ☐ NA ☐
L3	Rupture of membrane time / length	Y - yes ☐ N - no ☐
L4	Amniotic fluid quality (clear , meconium stained, estimated quantity)	Y - yes ☐ N - no ☐
L5	Temperature before/during/after labor	Y - yes ☐ N - no ☐
L6	Fetal Distress (NRFHR)	Y - yes ☐ N - no ☐
L7	Magnesium sulfate given in labor	Y - yes ☐ N - no ☐
L8	Any other drugs prior/during labor (Antibiotics, Oxytocin,…_)	Y - yes ☐ N - no ☐
L9	Mode of delivery (Spontaneous vaginal, Breech, Assisted vaginal, Caesarian and indication + type of anesthesia etc.)	Y - yes ☐ N - no ☐
L10	Labor complications (PPH, Previa, Abruption, etc.)	Y - yes ☐ N - no ☐
L11	Maternal Anesthesia, sedative and/or painkillers given	Y - yes ☐ N - no ☐
N1	APGAR score at 1st min , 5th min	Y - yes ☐ N - no ☐
N2	APGAR score at 10 minutes	Y - yes ☐ N - no ☐
N3	Resuscitation at birth (No action or Stimulation or Suctioned or Oxygen or Mask Ventilation or Endotracheal Ventilation or Chest compressions)	Y - yes ☐ N - no ☐
N4	Drugs history at birth (Vitamin K injection (single dose), Tetracycline eye ointment, Surfactant or Immunizations or Other drugs at birth or Allergies)	Y - yes ☐ N - no ☐

Appendix 6: Consents forms for CS

a. **Consent form English:** Information to caregiver

"Neonatal inter-hospital transport: Clinical information sharing and condition of neonates transferred to tertiary hospitals in Rwanda."

Dear caregiver,

You are invited to allow the neonate you are caring for to participate in this research project by signing this consent form and answering few questions if necessary.

• It will take you approximately 10 minutes to complete the task.

• By signing this consent form, you are giving your consent so that the neonate you are caring for may participate in this research project

I. ABOUT THIS RESEARCH PROJECT

Title: Neonatal inter-hospital transport: Clinical information sharing and condition of neonates transferred to a tertiary hospital in Rwanda.

Aim: This study aims to identify the core clinical information (CCI) that should be provided to a referral centre when transferring a sick neonate from another health facility for better care and to determine baseline outcomes of neonates referred to one of five tertiary hospitals in Rwanda, CHUK.

Methods: This study has two dependent stages.

The first stage will help get a consensus based list of Core Clinical Information items using Delphi technique;

The second stage is a cross-sectional, longitudinal part that will help compare the existing referral forms contents with the already designed CCI list (result of stage 1) and gather neonate's demographic and clinical information at the receiving hospital at arrival (using a paper based questionnaire) and key outcomes during the first 7 days of admission.

NB: Your baby will only be involved in this second stage.

Confidentiality: Your names will only be required in signing the consent and will not appear anywhere in the report of this project as well as your baby's. And all information will be kept confidential by the principal investigator according to Ethics law.

Risks: There are minimal risks, to mention emotional and your time you will spent answering few questions to the principal investigator, but this process will happen not in a public environment.

Potential benefits: This study will help have a standard CCI list to improve communication for referred sick neonates in Rwanda

Right to Refuse or Withdraw: The decision to participate in this study is entirely up to you. You may refuse to take part in the study or refuse to provide any information at any time without affecting the care your neonate should receive.

II.CONTACT INFORMATION

If any question related to this research project, feel free to contact any of these persons:

1. Dr Oscar Mwizerwa (Pediatric Resident, Principal Investigator): (+250)783 333 438, Email: mosenga2000@gmail.com

2. Dr Christian Umuhoza (Pediatrician, Supervisor): (+250)788 753 718, Email: crissumuh@yahoo.fr

3. Dr. Peter Cartledge (Pediatrician): (+250)738 555 550, Email: peterthomascartledge@googlemail.com

4. Prof Kato J Njunwa (Chair-person of IRB committee), (+250)788490522

5. Prof. Jean Bosco Gahutu (Vice-Chair of IRB committee), (+250)783340040, Email:jbgahutu@yahoo.com

Consent form for participation in a study on

"Neonatal inter-hospital transport: Clinical information sharing and condition of neonates transferred to a tertiary hospital in Rwanda."

Hospital ID:……. Date: …….

By signing the form below, I confirm that the consent form has been explained to me in terms that I understand.

I consent for allowing my newborn baby to be involved in this research study. I understand that the information may be used in the written medical record of my child, for purposes of medical teaching, or publication in medical textbooks or journal and electronic publications. By consenting to this study participation I understand that I will not receive payment from any party. Refusal to consent to this study participation will in no way affect the medical care my child is receiving or will receive.

I understand that the results of this study may be read by members of general public, in addition to scientists and medical researchers that regularly use these publications in their professional education. Although my baby's information will be used without identifying information such the name of child, I understand that it is possible that someone may recognize that my child had participated in a such study, but the chances of this has been minimized.

Names of Caregiver:…… Names of Witness: ……

Signature: ……. Signature: ……

b. Consent form Kinyarwanda: Ubusobanuro ku bushakashatsi:

"Gutwara impinja hagati y'ibitaro bitandukanye: guhana amakuru y'uburwayi ndetse n'irengero ry'impinja zoherezwa ku bitaro bya Kaminuza mu Rwanda."

Murwaza (Mubyeyi),

Turagusaba gusinya iyi nyandiko kugirango wemerere uruhinja uherekeje (rwawe) kujya muri ubu bushakashatsi kandi wemera no gusubiza ibibazo bimwe uza kubazwa bijyanye n'ubshakashatsi gusa.

• Bishobora kuza gutwara iminota icumi (10) gusubiza ibyo bibazo

I. INCAMAKE Y'UBUSHAKASHATSI

Inyito: Gutwara impinja hagati y'ibitaro bitandukanye: guhana amakuru y'uburwayi ndetse n'irengero ry'impinja zoherezwa ku bitaro bya Kaminuza mu Rwanda.

Intego: kumenya amakuru akwiriye guhanahanwa hagati y'abaganga ku mbinja zirwaye zikeneye koherezwa mu bindi bitaro ndetse no kumenya irengero ry'impinja ziba zoherejwe mu bitaro bya Kaminuza mu Rwanda, CHUK.

Uko bizakorwa: Ubu bushakashatsi burimo ibice bibiri.

Igice cya mbere kizafasha kumenya lisiti y'amakuru akwiriye guhanahanwa hagati y'abaganga ku mbinja zirwaye zikeneye koherezwa mu bindi bitaro, tuzakoresha uburyo bwitwa Delefi (Delphi technique);

Igice cya kabiri kizadufasha:

- Kugereranya amakuru aba ku mpapuro za tarasiferi (transfer from) zizana n'impinja n'amakuru nyakuri akwiriye (nk'uko tuzabibona mu gice cya mbere).
- Gukurikirana impinja zohererwa CHUK maze tukamenya ibijyanye no koroherwa cyangwa kuremba kwabo mu minsi irindwi (7) kuva bageze CHUK.
- Icyitonderwa: Muri iki gice niho dukeneye ubufasha bwanyu

Ibikwa ry'amakuru: Amakuru yose ajyanye n'ubu bushakashatsi ahabwa kandi akabikwa mu ibanga nk'uko amabwiriza agenga ubushakashatsi abiteganya. Kandi amazina yanyu n'ay'umwana ntazigera agaragazwa muri raporo z'ubu bushakashatsi.

Ingaruka zo kwitabira: Uretse umwanya muto biza gutwara, nta zindi ngaruka zirimo. Dore ko bidateze kubangamira ubuvuzi uyu mwana akwiriye guhabwa.

Inyungu mu kwitabira: Ubu bushakashatsi bwitezeho gufasha mu kuvugurura ubuvuzi bw'impinja mu Rwanda

Ingaruka zo kutitabira: Kwitabira ubushakashatsi ubwo ari bwo bwose, n'ubu burimo, ni amahitamo ya buri wese. Kutitabira nabyo ni uburenganzira bwa buri wese.

II.ABO KWITABAZA

Uramutse ubangamiwe, ushaka guhindura icyemezo cyawe cyangwa hari icyo ushaka gusobanuza byizumbuyeho, wakwitabaza aba bakurikira:

1. Dr Oscar Mwizerwa (Uwibanze muri ubu bushakashatsi): (+250)783 333 438, Email: mosenga2000@gmail.com

2. Dr Christian Umuhoza (Ukurikiranira hafi ubu bushakashatsi): (+250)788 753 718, Email: crissumuh@yahoo.fr

3. Dr. Peter Cartledge (Undi kurikiranira hafi ubu bushakashatsi): (+250)738 555 550, Email: peterthomascartledge@googlemail.com

4. Prof Kato J Njunwa (Ukuriye ikigo kigenzura iyubahirizwa ry'amategeko agenga ubushakashatsi muri Kaminuza y'Urwanda), (+250)788490522

Kwemera kujya mu bushakashaki ku:

“Gutwara impinja hagati y’ibitaro bitandukanye: guhana amakuru y’uburwayi ndetse n’irengero ry’impinja zoherezwa ku bitaro bya Kaminuza mu Rwanda.”

Nomero y'uruhinja: ……. Itariki: ……

Mbere yo gusinya iki cyemezo, nabanje gusobanurirwa ibirimo mu rurimi numva.

Ndemerako amakuru y'uruhinja rwanjye yakoreshwa n'abaganga mu bushakashatsi.

Maze gusobanurirwa n'abaganga ko amakuru y’uburwayi bw’umwana wanjye akenewe mu gufasha abandi baganga kungurana ubumenyi ndetse no gufasha abandi bana barwaye nk'uwanjye kuvurwa byisumbuyeho, nemeyeko amakuru y’uburwayi bw’umwana wanjye yakoreshwa muri ubu bushakashatsi. Nemeyeko ibizava muri ubu bushakashatsi bizakoreshwa mu bitangazamakuru byanditswe cyangwa bikorera kuri Murandasi ndetse n'ibitabo byose bikoreshwa mu kwigisha abaganga. Ndabyemeye, kandi nta gihembo cyabiteganyirijwe ndetse ndamutse ntabyemeye nziko nta ngaruka byagira ku buvuzi umwana wanjye ahabwa.

Nasobanuriwe ko ayo makuru abasha gusomwa n'abandi bantu bose bakoresha ibi bitabo cyangwa ibitangazamakuru bya kiganga ariko byose mu rwego rwo kwigisha. Nziko n'ubwo nta mazina y'umwana wanjye azatangazwa, hari ubwo aya makuru ashobora gutuma abantu bamenyako umwana wanjye yagiye muri ubu bushakashatsi ariko ibi bitegenijwe kwirindwa uko bishoboka.

Amazina y' Umubyeyi (umurwaza): ……. Amazina y'Umuhamya: ……

Umukono ---------- ----------

Appendix 7: Ethical Clearance

UNIVERSITY OF RWANDA

COLLEGE OF MEDICINE AND HEALTH SCIENCES

Department To
Chair of Institutional Review Board (IRB)
College of Medicine and Health Sciences (CMHS)
University of Rwanda
Kigali – Rwanda

Re: Recommendation letter for IRB application
Regarding Resident: Dr. Oscar MWIZERWA
Project title: "Neonatal inter-hospital transport: Clinical information sharing and condition of infants transferred to a tertiary hospital in Rwanda.".
Date approved by department: 21st November 2017

Dear Sir,

I am pleased to write a letter of recommendation in support of the above resident's research project which has been approved at the level of the Department of Pediatrics, hence this letter of recommendation.

During the academic meeting we reviewed the ethical considerations of this project. We ask for your kind consideration of this project at the IRB. As the project is undertaken by a resident with no funding we kindly ask that you waive the fee for the IRB application.

For any question, please do not hesitate to contact me

Sincerely,

Dr KABAYIZA Jean Claude
Pediatrician / CHUK
RMDC 0185

Jean Claude KABAYIZA MD, PhD
Head of Department, Pediatrics and Child Health
School of Medicine and Pharmacy
University of Rwanda

UNIVERSITY OF RWANDA

COLLEGE OF MEDICINE AND HEALTH SCIENCE

CMHS INSTITUTIONAL REVIEW BOARD (IRB)

Kigali, 4th /01/2018

Dr MWIZERWA Oscar
School of Medicine and Pharmacy, CMHS, UR

Approval Notice: No 002 /CMHS IRB/2017

Your Project Title ***"Neonatal Inter-Hospital Transport: Clinical Information Sharing And Condition Of Neonates Transferred To A Tertiary Hospital In Rwanda"*** has been evaluated by CMHS Institutional Review Board.

Name of Members	Institute	Involved in the decision		
		Yes	No (Reason)	
			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 Lactitia	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 24th December 2017, **Approval has been granted to your study.**

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

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 4th January 2018

Expiration date: The 4th January 2019

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

CENTRE HOSPITALIER UNIVERSITAIRE
UNIVERSITY TEACHING HOSPITAL

Quality Health Care
Training & Research

Ethics Committee / Comitéd'éthique

January 19th, 2018 **Ref.: EC/CHUK/517/2018**

Review Approval Notice

Dear Mwizerwa Oscar,

Your research project: ***"Neonatal inter-hospital transport: Clinical information sharing and condition of neonates transferred to a tertiary hospital in Rwanda."***

During the meeting of the Ethics Committee of University Teaching Hospital of Kigali (CHUK) that was held on 19/01/2018 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>>.

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