Makerere University School of Public Health Higher Degrees Research and Ethics Committee

RESEARCH STUDY PROTOCOL

Smart Discharges for Mom & Baby: A cohort study to develop prognostic algorithms for post-discharge readmission and mortality among mother-infant dyads

By

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ACRONYMS AND ABBREVIATIONS

FGD	Focus Group Discussion
JRRH	Jinja Regional Referral Hospital
MakSPH IRB	Makerere University School of Public Health Institutional Review Board
MoH	Ministry of Health
MRRH	Mbarara Regional Referral Hospital
MUST	Mbarara University of Science and Technology
NICU	Neonatal Intensive Care Unit
ANC	Ante-Natal Care
PNC	Post-Natal Care
REDCap	Research Electronic Data Capture
UBC	University of British Columbia
WHO	World Health Organization
SpO2	Oxygen Saturation
MUAC	Mid-Upper Arm Circumference

OPERATIONAL DEFINITIONS OF KEY TERMS

Emancipated Minor: According to the Ugandan National Guidelines for Research Involving Humans as Research Participants, emancipated minors are defined as individuals less than 18 years of age who are pregnant, married, have a child, or cater for their own livelihood.

Health professional or provider: A trained individual with knowledge and skills to provide health care in a systematic way to people, families or communities. They include doctors, nurses, midwives, hospital administrators, and community health workers.

Hospital Discharge: The point at which inpatient hospital care ends.

Hospital Discharge Process: The multiple transitions within a patient's care journey from arriving at the hospital until 72 hours post-hospital discharge involving the patient/caregivers, healthcare workers, and the health system.

Patients: Women and girls over the age of 12 years admitted to a participating health facility to give birth. Once the mother has given birth, the newborn baby becomes part of the mother-infant patient dyad.

Primary Caregiver: The person primarily responsible for the care and upbringing of the infant or underage mother enrolled in the study as a maternal infant dyad.

Abstract

The first 6 weeks after birth remains a critical period of vulnerability for mother-newborn dyads. The WHO recommends at least 4 postnatal check-ups at a facility or by a community health worker in the first 6 weeks after birth. Yet this is not possible for many dyads because of overburdened health systems and scarce family resources. Personalized risk scores can help frontline healthcare providers identify high-risk mother-newborn dyads before discharge from hospital, and guide recommendations for essential postnatal care. The health of a child is closely linked to the health of its mother, so it is essential that we consider the mother and child as a dyad. Here, we aim to develop a to risk predictive algorithm that integrates data about the health of the mother and newborn to identify mother-newborn dyads who are at a high-risk of dying or hospital readmission during the post-delivery, post-discharge period. This is a mixed-method study at two hospitals in Uganda. We will conduct an observational cohort study to develop and internally validate our risk score and aim to recruit 7000 mother and newborn dyads from Jinja Regional Referral Hospital and Mbarara Regional Referral Hospital. We will engage with patients, families, and health workers through direct observation, journey mapping, process mapping, and focus group discussions to identify gaps and opportunities during in-hospital, discharge, and post-discharge care for informing the development of an evidence- and risk-based bundle of interventions to improve postnatal care (PNC) for dyads. We will leverage our experience developing, validating and implementing an innovative precision public health approach for improving post-discharge care for children in Uganda following hospitalization for severe infection. Ultimately, our personalized risk score, combined with interventions that target prevention or treatment of critical causes of death or illness, will inform evidence-based recommendations for PNC, and improve health outcomes for dyads. Treating the mother and newborn as a dyad ensures that when one is sick, the other can be more closely monitored to prevent their potential decline in health.

1.0 CHAPTER ONE: Background and literature review

In 2017, 290,000 mothers died from complications of pregnancy or childbirth, and 2.5 million newborns died within the first 6 weeks of their life globally[9,10]. Most of these deaths occurred in sub-Saharan Africa[9,10]. Uganda has made progress in reducing their maternal mortality and under-5 mortality rates by 25% and 42%, respectively between 1995 and 2015[4]. Unfortunately, this progress in mortality reduction has not been as rapid during the postnatal period[5].

The first six weeks following delivery bear the most significant and persistent burden of under-5 and maternal death, and severe neonatal and maternal morbidity. Efforts are currently underway to improve outcomes immediately following births at health facilities for both mothers and newborns. However, care following facility discharge presents significant challenges and accounts for a high proportion of maternal and neonatal death and morbidity. In facilities across sub-Saharan Africa, women and their newborn infants are routinely discharged from facility within 24hrs of birth[6]. Yet, 30% of mothers who die during the first 6 weeks do so after 24 hours. Thus, the postpartum period is a vulnerable time in which women are highly susceptible to infections and complications resulting from childbirth[13]. Despite this, limited studies have examined risk factors for postpartum complications specifically in LMICs where maternal mortality rate are the highest. Understanding what puts women at risk of death due to these complications is a first step to designing effective interventions during the postpartum period. This could in turn improve child outcomes, as several studies have shown maternal and child outcomes to be inextricably linked[14, 15]. Limited resources within the health system, in the context of significant poverty, hinder good adherence to the recommended frequency of postnatal visits throughout sub-Saharan Africa, resulting in many vulnerable families not receiving lifesaving interventions. Evidence driven discharge planning and post-discharge care is a neglected aspect of facility-based management worldwide[6,7,8].

Currently, the World Health Organization (WHO) recommends three in-person postnatal visits for all mothers and newborn infants born at a health facility within the first six weeks of life[6]. The evidence used in formulating this recommendation is primarily based on timing of maternal and neonatal deaths and evidence surrounding the efficacy of the components of care recommended during the postnatal period. Despite this WHO recommendation, achieving any postpartum follow-up care has been challenging in many low-resourced settings. For example, in Uganda, only 57% of women received one visit with a skilled health care provider within 41 days of delivery[3]. There is an important opportunity to tailor recommendations for timing and frequency of follow-up to individual risk, to guide the use of scarce healthcare resources. Personalized risk scores can help frontline healthcare providers identify high-risk dyads before discharge from hospital, and guide recommendations for essential PNC. This approach facilitates safer hospital to home transitions and efficient allocation of scarce resources. Adherence to the recommended PNC visits is critical for those at higher risk.

The development of an evidence base upon which to build recommendations for the timing and intensity of postnatal care in resource-poor countries is urgently needed. This study aims to address this gap in care coverage using a precision medicine approach to postpartum follow-up. Our approach to risk stratification integrates data about the health of both the mother and newborn. This ensures that when one is sick, the other can be more closely monitored to prevent their potential decline in health. We are working to expand our innovative precision public health approach to improving post-discharge care for mother-newborn dyads. Our aim is to build a discharge risk prediction score that identifies high-risk dyads before hospital discharge. To achieve this, we will conduct an observational cohort study in 7,000 dyads discharged together after live births at JRRH and MRRH. With the data collected from this study, we will be able to develop prediction models with up to 30 candidate predictors for both maternal and newborn outcomes separately.

2.0 CHAPTER TWO: Problem statement, justification, and conceptual framework

2.1 Problem statement

Neonatal outcomes are highly correlated with the health of the mother, an example of this is shown repeatedly by poor rates of survival of infants after maternal death[1,2]. Prediction of risk, based on the mother and infant as a pair, is a major gap in current research and yet vital to the survival of both the mom and the infant. In our prior epidemiological study of post-discharge outcomes among 3,236 dyads, we found that most readmissions were due to infectious illness and occurred early in the post-discharge period. Of the 2,926 dyads with complete follow-up data 7.1% of dyads reported at least 1 outcome. 3.6% of newborns were readmitted, 0.8% died, and 2.7% of mothers were readmitted. For readmitted newborns, the most common diagnosis was sepsis (63%), and 19% were in respiratory distress at readmission. For readmitted mothers, the most common diagnoses were surgical site infections (51%), puerperal sepsis (43%), malaria (19%), and other infections (5%). Considering the health of the mother and newborn as a dyad is an innovative and effective approach as the health of a child is closely linked to the health if its mother. A mother's morbidity or mortality affects the health of all her children – and newborns whose mothers died during the first 6 weeks have an even greater risk of dying that those whose mothers survive[15]. Thus, we can improve maternal and child health outcomes by identifying both mothers and babies at increased risk of mortality or serious morbidity after hospital discharge and allocating scarce resources for targeted follow-up to those most vulnerable. This allows us to not only improve health outcomes but benefits the health system with efficient use of resources.

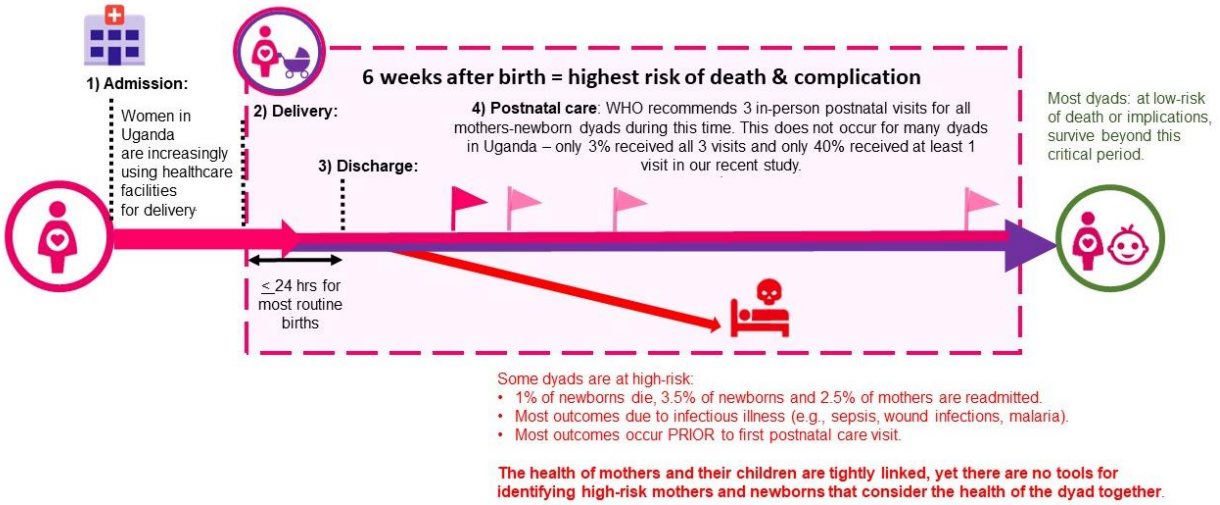
2.2 Justification of the study

Since 2011, we have been working with partners in Uganda to develop, validate, and implement an innovative program for children aged 6 months to 5 years who have been discharged following hospitalization for Sepsis/Severe Infection. In this quality improvement program, we call Smart Discharges, healthcare workers use an individualized risk prediction score to identify children at high risk of death or complications after discharge from a hospital

following treatment for suspected severe infection. They can then use this score to guide delivery of a counseling and community-referral program. While all participants receive counselling, only high-risk, vulnerable children receive down-referrals to community health facilities. We have shown that this approach has reduced post-discharge child mortality after in-hospital treatment for serious illness by as much as 30%. Now, we are working to expand our innovative precision public health approach to improving post-discharge care for mother-newborn dyads.

Our aim is to use our findings to inform the development an evidence-based bundle of care for both the mother and newborn. This package will ensure that low-risk mother-infant pairs receive less burdensome (yet pragmatic and feasible) postpartum care, while high risk pairs receive a more extensive bundle of interventions (such as education, nutrition, healthcare interaction and community support). The Smart Discharges for Mom and Baby package will include support targeting aspects of both clinical and emotional wellbeing. Additional extensions of this work will include validation of our risk models in women who deliver at home (26.6% of births in Uganda) or suffer a stillbirth (2.4% of births in Uganda) to ensure that more women and babies can benefit from the proposed intervention[3].

2.3 Conceptual framework



Our conceptual framework is clearly embodied within the concept of precision public health. Ensuring all mothers receive the recommended 3 postnatal care (PNC) visits following a facility delivery is challenging from a resource perspective. The majority of mothers survive beyond the critical first 6 weeks. However, a proportion of dyads remain vulnerable during this period. Health systems, particularly those in resource limited settings, must be able to ensure those most in need of care can appropriately receive such care. As such, our work is guided by improving our ability to identifying these vulnerable dyads and then developing a scalable and sustainable approach to ensuring the intensity of care is linked to the degree of risk.

3.0 CHAPTER THREE: Research Question and Objectives

3.1 Hypothesis

Maternal and infant characteristics collected at the time of discharge following a facility delivery can predict the risk of maternal or neonatal death or need for re-admission within six weeks of birth.

3.2 Objectives

Our primary objective is to inform the development of an integrated maternal and newborn risk-based post-discharge care program. Specifically, we aim to (1) develop and internally validate clinical risk prediction models for identifying dyads at high-risk of death or hospital readmission in the 6 week post-delivery post-discharge period, and (2) identify gaps and opportunities during in-hospital, discharge, and post-discharge care to inform the future development of an evidence-and risk-based bundle of interventions to improve PNC for dyads.

4.0 CHAPTER FOUR: Methodology

4.1 Study design

This is a mixed-methods study using both quantitative and qualitative techniques to explore and map the current postnatal discharge processes in Uganda using data from two distinct hospital settings.

- **Phase I)** We will conduct an observational cohort study informed through direct observation of the mother and newborn dyad prior to facility discharge and after delivery and follow-up telephone interviews conducted at six-weeks post-discharge.
- **Phase II)** We will conduct journey mapping with a subset of dyads enrolled in the observational cohort using direct observation and follow-up telephone interviews.
- **Phase III)** We will conduct a process mapping exercise using focus group discussion methodology with select facility staff.
- **Phase IV)** We will conduct focus group discussions with a subset of mothers enrolled in the observational cohort, as well as their family members.

Table 1. Study design overview

Phase	Methods	Participants
Aim 1: develop and internally validate clinical risk prediction models		
Phase I	Direct observation and patient interviews	Mother and newborn dyads
Aim 2: identify gaps and opportunities during in-hospital, discharge, and post-discharge care		
Phase II	Patient journey mapping using direct observation and patient interviews	Mother and newborn dyads
Phase III	Process mapping exercise	Facility health workers

Phase IV	Focus group discussion	Mothers, fathers, and grandmothers

4.2 Work Plan and Timeline

STUDY TIMELINE

	2021		2022				2023				2024	
	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2
AIM 1: ***Develop and internally validate clinical risk prediction models for identifying dyads at high-risk of death or readmission***												
Ethics approval												
Staff hiring & training												
Patient enrollment												
Patient follow-up												
Data analysis												
AIM 2: ***Identify gaps and opportunities during in-hospital, discharge, and post-discharge care to inform the development of an evidence- and risk-based bundle of interventions to improve postnatal care for dyads***												
Ethics approval												
Journey mapping												
Focus-group discussions												
Data analysis												
Selection of intervention												
Knowledge Translation												
Manuscripts & symposia												
Stakeholder meeting												

4.3 Study Sites

Study activities will be conducted at two hospitals (Mbarara Regional Referral Hospital (MRRH) and Jinja Regional Referral Hospital (JRRH)) in Uganda in the districts of Mbarara and Jinja.

Table 2: Characteristics of the proposed study sites.

District (Region)	Hospital	Type	Location	District population	Annual deliveries
Mbarara (Western)	Mbarara Regional Referral Hospital	Public	Semi-rural	490,000	7,500
Jinja (Eastern)	Jinja Regional Referral Hospital	Public	Urban	483,000	6,000

4.4 Study Population

Phase I: Observational Cohort Study

We will recruit 7,000 mother and newborn dyads from the two participating hospitals. Based on previously observed outcome and loss to follow-up rates, we will be able to measure the prevalence of maternal and newborn hospital readmission or death within a margin of error of 1% and develop prediction models with up to 30 candidate predictors for both maternal and newborn outcomes separately with this sample size.

Inclusion:

- Women and adolescent girls aged 12 and above delivering a single or multiple babies at the study hospital during the active recruitment phase.

Exclusion:

- Inability, for whatever reason, to provide informed consent.
- Language barrier
- Mother is from a refugee camp
- Mother has no access to phone or other means for follow-up
- Mother lives outside of hospital catchment area

We will continue to follow-up with all patients enrolled in the study. This includes enrolled mothers whose baby dies after discharge as well as enrolled babies whose mothers die. In the event that the mother dies, we will follow-up with the caregiver of the baby.

Table 3. Phase I sample size

Participants:	Sample size (n=7,000)
Maternal Infant Dyads	3,500 per facility (n=7,000)

Phase II: Patient Journey Mapping

We will randomly select 100 mothers (50 per facility) from the phase I cohort of 7,000 dyads to participate in journey mapping due to intense time to capture.

Inclusion:

- Women and adolescent girls aged 12 and above delivering a single or multiple babies at the study hospital during the active recruitment phase.
- Enrolled in Phase 1.

Exclusion:

- Inability, for whatever reason, to provide informed consent.

Exclusion:

- Inability, for whatever reason, to provide informed consent.
- Language barrier
- Mother is from a refugee camp
- Mother has no access to phone or other means for follow-up
- Mother lives outside of hospital catchment area

Table 4. Phase II sample size

Participants:	Sample size (n=100)
Maternal Infant Dyads	50 per facility (n=100)

Phase III: Process Mapping

We will purposively select a sample of 6 healthcare providers and 2 hospital administrators from each of the 2 study sites for participation in a process mapping exercise based on their level of experience, availability, and consultations from site leads (Table 4).

Inclusion:

- Healthcare providers including physicians, nurses, medical students, and residents, who have been working in the maternity ward at participating health facilities for at least 2 months.
- Hospital administrators with some oversight on maternity ward operations.

Table 4. Phase III sample size

Participants:	Sample size (n=16)
Healthcare Providers	6 per facility (n=12)
Hospital Administrators	2 per facility (n=4)

Phase IV: Focus Group Discussion

We will recruit 12 adult mothers, 12 teenage mothers, 12 fathers, and 12 grandmothers (n=48) at each of the two study sites for a total sample of 96 focus group discussion (FGD) participants. FGDs for teenage mothers will be conducted separately from adult mothers. FGDs will be conducted in a private space at each of the participating facilities. We will conduct one FGD for adult primary caregivers, one FGD for teenage primary caregivers, one FGD for fathers, and one for grandmothers at each facility for a total of 7 FGDs per facility.

Inclusion:

- Mothers, fathers, and grandmothers of children who were enrolled in phase I and who were recently discharged from a participating health facility.
- Active involvement in or knowledgeable about the maternal infant dyad's peri-discharge experience.
- Have provided written informed consent.

Participants:	Sample size (n=96)
Mothers	12 per facility (n=24)
Teenage Mothers	12 per facility (n=24)
Fathers	12 per facility (n=24)
Grandmothers	12 per facility (n=24)

4.5 Recruitment

Phase I and II: Observational Cohort Study and Patient Journey Mapping

Research nurses will recruit and obtain consent from eligible women after they have been admitted to the facility for delivery and prior to discharge. Eligible women will be informed of the study and asked if they wish to participate. If the eligible participant is a minor, the parent or legal guardians(s) of the participant will be approached first by the research nurse. Consent will not be sought until after the patient has received an initial assessment by health workers at the time of admission for delivery, and research nurses may wait until after delivery to approach eligible women so as to not interfere with standard care. Women who suffer a loss or who are caring for a severely ill infant, will be given the option to defer the interview portion of data collection until the six-week postnatal follow-up period. During the consenting process, all women will be told they are free to withdraw from the study at any point without needing to give a reason for withdrawal. Data collected up to the point of withdrawal will be de-identified and retained for analysis.

Phase III: Process Mapping

Prior to the initiation of any study activities, healthcare providers and administrators will be notified of research activities through each respective hospital's human resources department. Process mapping participants will be asked to provide written informed consent at the beginning of the exercise. No identifying information of site staff participants will be collected or shared with participating facilities.

Phase IV: Focus Group Discussion

Caregivers/family members will be purposively selected to participate in FGD from a convenience sample of children enrolled in the initial phase of the study as a maternal infant dyad. The mother will be recruited by a research assistant who will brief her about the study at the time of discharge. If the mother verbally agrees, the research assistant will also ask for permission to contact the baby's father and grandmother for recruitment via phone.

4.6 Data collection

4.6.1 Training of research assistants

Research assistants will be trained by a study staff member in both quantitative and qualitative methodologies including process mapping facilitation, telephone interviewing, FGD facilitation, and direct patient observation. Ethical conduct regarding participant recruitment, consent, confidentiality, and data security will also be covered in training sessions. Research assistants will have clinical experience in the hospital environment and will be fluent in the dominant language spoken in the regions where each hospital is located.

4.6.2 Data Collection Tools

At the point of care, phase I and II data will be collected on a mobile device and phase III and IV data will be audio recorded. Data collection will be performed by dedicated study staff. Direct observations will be recorded in English using customized observation surveys and field logs. Patient interviews and observation surveys will collect patient demographic data and clinical data. Semi-structured phone interview guides will collect post-discharge process data. Data from process mapping exercises will be captured using paper-based worksheets and digital audio recordings. Audio from FGDs will be digitally recorded, transcribed verbatim in the language spoken during the recording and analyzed for emerging themes. Transcriptions will be translated to English (when needed) and de-identified prior to analysis.

4.6.3 Study Procedures

Phase I: Observational Cohort Study

I. Admission

a. The study team will collect admission variables and health and pregnancy history through chart review and interviews with the participant. Data will not be collected during periods of maternal stress. In this case, incomplete interview questions will be deferred to the discharge interview.
    1. Admission variables: These questions include mode of transport, maternal demographic and socioeconomic variables (e.g., distance travelled to the hospital, age, location of residence). Data collected will also include vital signs (e.g., temperature, blood pressure, heart rate).
    2. Health and pregnancy history: This includes questions on number of previous pregnancies, comorbidities, prior admissions, and medication history.

II. Delivery
    a. Maternal variables: The study team will collect data related to the delivery including mode of delivery, method of induction, noted vaginal or perineal tearing, and any other major events or conditions occurring during delivery.
    b. Neonatal variables: Data will be collected related to the delivery including sex, Apgar score, weight, and resuscitation with oxygen therapy at birth.

III. Discharge
    a. Clinical Data Collection: A maternal and neonatal clinical examination will occur prior to discharge.
        1. Maternal Clinical Exam: Research nurses will record clinical signs and symptoms including SpO2, heart rate, blood pressure, respiratory rate, and body temperature. We will also collect a small sample of blood (200 microlitres) to test hematocrit levels.
        2. Neonatal Clinical Exam: Research nurses will record clinical signs and symptoms data including weight, SpO2, body temperature, and urination and defecation status. Data will also be collected on the infant's health status prior to discharge including NICU admission.
    b. Patient Interview: Following delivery, and prior to discharge, research nurses will conduct a structured interview and collect data including breastfeeding status, any symptoms experienced (e.g., headache, chest pain, difficulty emptying bladder, etc.).

IV. 6 Week Maternal and Newborn Follow-up (Outcomes)
    a. Telephone Interview: Research nurses and field officers will follow-up all dyads at 6 weeks postpartum to collect data on post-discharge care seeking and health outcomes, as well as newborn care practices. A verbal autopsy will be performed in all cases of newborn or maternal death. If

the mother or newborn was readmitted or died, data on clinical signs and symptoms and diagnoses during readmission or at death will be collected.

Phase II: Journey Mapping

I. Journey mapping: We will ask a randomly selected group of mother-infant dyads (n=100) additional questions to ascertain their movement through the hospital, perspectives on the current system of post-natal care, and post-discharge pathways, at various time periods including in the postnatal patient interview, 72 hour post-discharge follow-up, and at the 6 week follow-up telephone interview.

Phase III: Process Mapping

II. We will establish one working group (n=8) per facility who will be engaged in a process mapping exercise which is a qualitative methodology commonly used in quality improvement interventions. Process mapping exercises will be facilitated by a research assistant to gain an understanding of the post-natal discharge process as it currently operates and to identify inefficiencies to care and potential solutions. Working groups will engage in a brainstorming session using paper, pens, and sticky notes to map out the discharge pathways of their respective facilities. Group members will work together to identify all stages of the process and indicate the individuals involved at each stage. When the working group reaches consensus and deems the flowchart complete and accurate, it will then be analyzed by members to identify problems, bottlenecks, and non-value-added steps such as unnecessary work, duplication, or communication breakdowns. After process inefficiencies are identified, teams will brainstorm, first individually then as a group, to identify potential solutions. The process mapping exercise will take 90-120 minutes per facility. The facilitator will use prompts to motivate participants to discuss topics in greater detail as needed. All process data will be mapped to a stage of the discharge process to provide a comprehensive model of post-natal discharge processes from the provider perspective.

Phase IV: Focus Group Discussion

We will conduct focus group discussions with mothers and family members to explore needs and the value of post-discharge care, and social and economic barriers to seeking this care. For teenage mothers, as teenage pregnancy is associated with trauma, stigma, and discrimination, these participants may experience distress during the FGD. To mitigate this, FGDs for teenage mothers will be separated from adult mothers. Research Assistants (RAs) will be trained by an experienced qualitative researcher on how to ensure that the rights of subjects and confidentiality of data are protected and respected. RAs will be

instructed on how to create an open, inclusive, and confidential space with participants at the beginning of the discussion as well as how to intervene if the discussion becomes discriminatory towards other participants. RAs will reassure participants that their participation is entirely voluntary and that they can withdraw from the study at any time. If participants experience negative feelings during the discussion, they will be referred to the facility's medical social worker for counselling.

Focus groups will begin with questions and conversations to build trust among participants. For mothers, grandmothers, and fathers, discussions will focus on illness recognition, health seeking/decision-making, postnatal care interventions, and interactions with the health system during the peri and post-discharge period. Data collected will include questions about the hospital stay, communication with the healthcare team, the discharge process, barriers faced upon discharge, and post-discharge PNC visits. Discussions will be conducted in the primary local language (e.g., Runyankole and Lusoga), audio-recorded, transcribed, and translated to English.

4.7 *Study Outputs*

Phase I: A pair of internally validated prediction models (one each for mom and baby) for identifying dyads at high-risk of death or hospital readmission after discharge following live birth in-hospital. Our candidate predictors for our models will be maternal and infant characteristics collected at the time of admission and discharge following a facility delivery.

Phase II-IV: A descriptive account of all aspects of the discharge process and postnatal care follow-up visits for facility-based deliveries, including identification of barriers and solutions to effective postnatal care from the perspective of patients, caregivers, and facility staff. We will use this information to inform the development of a bundle of interventions, with separate components for high-risk mothers and high-risk newborns, and a locally supported and culturally safe strategy for implementing this bundle of interventions.

4.8 *Outcomes (Phase I)*

The primary outcome is maternal and/or neonatal death or need for re-admission within six weeks of birth.

Secondary outcomes include:

1. Post-natal care visits during the 6-week post-discharge period
2. post-discharge health seeking practices for mothers/newborns during the 6-week post-discharge period
3. Causes of readmission/mortality among those who experience such outcomes, based on verbal autopsies and admission symptom/diagnosis questionnaires

4.9 Study Limitations

This study is subject to several potential limitations. First, losses to follow-up may reduce our effective sample size, thus diminishing our power to detect significance in some variables. However, our prior work in this area suggests that our losses to follow-up will be less than 5%. Furthermore, our study sample size has compensated for these potential losses to follow-up and we thus do not anticipate this to be an issue. Second, heterogeneity in outcomes may impact modelling of post-discharge events. We observed this to be a potential limitation in our prior work, in that the predictors were different between newborns and mothers, and even among mothers, between those with caesarean sections and those who delivered vaginally. To improve our probability of success, therefore, our sample size was developed to be able to model at least 3 separate outcomes. We anticipate that this will be sufficient to create a set of models which are comprehensive to capture various outcomes. Finally, With limited numbers of focus group discussions, this study may not reach thematic saturation. If this is deemed to be the case we will add additional focus groups, following a protocol amendment.

4.10 Data Analysis

Data will be spot checked by a core study staff member for quality verification and will be cleaned and coded by a research assistant. Data will be cleaned, coded, and analyzed using R Statistical Software for quantitative data and NVivo Software for qualitative data. Coded qualitative data from transcriptions and written narratives will be reviewed during team meetings and consensus will be reached on any discrepancies.

Quantitative Analysis: We will summarise all risk factors for mothers and newborns that do and do not experience poor outcomes and estimate univariate associations. For newborns, data will be reported by sex. Derivation of prediction models will be based on optimization of the area under the receiver operating curve (AUROC) and specificity across a variety of modeling and variable selection approaches (e.g., logistic regression, elastic net, support vector machines). Model performance will be based on appropriate resampling techniques for internal validation (e.g., cross-validation, bootstrapping). We will focus on developing parsimonious predictive models (e.g., 5-10 predictor variables) with high sensitivity (>80%). AUROC, sensitivity, and specificity will be reported for each model, along with positive and negative predictive values. Site specific metrics will be compared to ensure consistency across settings, and recalibration may be considered if individual site performance is lower than expected. Finally, we will assess combined sensitivity and specificity when each individual model is applied to the dyad. Outside of prediction modelling, our sample size will allow us to detect an odds ratio of at least 1.30 for a given risk factor with 80% power and 5% significance and relative precision of 25%. Statistical analysis of quantitative data from journey mapping observation surveys and patient interviews will be performed using R Statistical software to obtain descriptive statistics of the frequency and distribution of each variable.

Qualitative Analysis: We will analyze data collected descriptively and report summary statistics. We will develop a diagram of the discharge process, identifying key areas for improvement during the peri-discharge and post-discharge process[11]. We will analyze FGDs using a framework method, which allows themes to be developed inductively from participants and deductively from existing literature[12]. Through an iterative process, transcripts will be coded and analyzed for descriptive and interpretive themes using NVivo. Descriptive themes include barriers to care and post-discharge health-seeking behavior, while interpretive themes focus on caregiver perspectives of maternal and neonatal death and the role of the health system. We will generate frequencies to describe reported medical symptoms, health-seeking behavior, and barriers to care, and summarize common themes. We will use member checking to improve the validity of our results, creating a summary document of the main findings that will be reviewed by health workers who participated in the focus groups. Feedback from patients and families will be obtained over telephone with research nurses who will explain the main findings verbally.

4.11 Data Management

Study data will be managed using customized Research Electronic Data Capture (REDCap) tools hosted at the University of British Columbia, with secure access by all investigators in Uganda and Canada. REDCap is a secure, web-based application designed to support data capture for research studies. Data will be entered into the REDCap database by a trained research nurse or research assistant after each activity is completed and audio recordings are transcribed. Members of the study team will ensure that the rights of subjects and confidentiality of data are protected and respected. Research assistants will be trained on how to keep data secure and confidential during direct-observation activities. No information that discloses the identity of participants will be released or published without their specific consent to the disclosure. However, research records identifying participants may be inspected in the presence of the Investigator for the purpose of monitoring the research. No records which identify the participants by name or initials will be allowed to leave the Investigators' offices. Each participant will be assigned a personal identifier to collect discharge process and follow-up data. All paper-based and digital audio recording data will be stored in a locked cabinet in a locked office at Walimu. Access to identifiers will be limited to those requiring this data for follow-up (i.e., only study personnel involved in telephone interviews). No analysts, co-investigators or principal investigators not directly involved in the follow-up will have access to this data. Access to identifiers will require 2-way authentication: in addition to the normal password process, a secure code (sent via SMS to the user) will be required for access to this data. Identifiable data will be securely stored and destroyed after 10 years.

After the study period, a de-identified copy of the data will be prepared for deposition in a repository with open access with proper governance mechanisms. We will make every effort to prevent re-identification of subjects by coding data that has the potential of being identifiable. For example, we will convert all dates into meaningful decimal numbers (date of birth into days since birth and date of recruitment will be reduced to month of recruitment) and all locations will be coded into data that is useful but not specific (such as address converted to distance and

direction from facility). We will ensure that data elements with small numbers of subjects (less than 10) will be coded or lumped to avoid identification. The de-identified study data will be made available using a data hosting service (e.g., the Pediatric Sepsis Data CoLaboratory's Scholar's Portal Dataverse, Vivli, etc.) (https://dataverse.scholarsportal.info/dataverse/Pedi_SepsisCoLab). Scholar's Portal Dataverse is a virtual archive for Canadian research data with a rigorous data governance structure. To gain access to the Sepsis CoLab's Dataverse, members must first sign a Memorandum of Understanding, whereas access to de-identified patient data requires signing a data sharing agreement. Data will also be shared through peer reviewed publications.

5.0 CHAPTER FIVE: Ethical considerations

5.1 Ethical Review and Approval Process

We will obtain ethics approval from the Makerere University School of Public Health (MakSPH) Institutional Review Board, the Uganda National Council of Science and Technology (UNCST) in Uganda and the University of British Columbia in Canada. Any future revisions to study procedures will be submitted as formal amendments and approved by the MakSPH IRB and the University of British Columbia prior to implementation. Administrative clearance will also be obtained from the respective hospitals, and informed consent will be obtained from all participants before data collection begins.

5.2 Informed Consent

Written informed consent will be obtained from all study participants, as well as the parents or guardians of eligible minor participants. A signed and dated copy of the consent form will be kept in the documentation file at all times. All participants will be aware of the study rationale, as well as any potential risks. The consent forms make it clear that standard care will not be compromised if they do not consent to participate in this study. Consent will be obtained from minors following local protocols, which is to consider underage girls as emancipated minors with full independence to consent to participating in research. Obtaining written informed consent from minors will also require a parent/guardian signature or thumbprint. Participants and parents will voluntarily sign and date the consent form if they wish to participate in the study and will be provided with a copy of the consent form. There will be five separate consent forms: one each for minors and non-minors participating in the observational cohort study, one for healthcare workers participating in process mapping, and one each for minors and non-minors participating in focus group discussions. Consent forms will be available in English, Runyankole and Lusoga (the English versions of these forms are included with this protocol; they will be translated into other languages prior to the study start date). Patients/caregivers enrolled in journey mapping will be provided with a bar of soap and a kilo of sugar as a token of appreciation for their time participating in the study. Caregivers participating in FGDs will be provided with 30,000 UGX each to compensate for their time and transportation costs.

5.3 Risks/Benefits to Participants

This is a minimal-risk study, as defined by all relevant ethics review boards in Canada and Uganda. The overall risks to participants are similar to those associated with standard clinical practice for facility deliveries and postnatal care. All dyads will receive routine care throughout their admission, in accordance with local hospital policies and national health guidelines. No study procedures will interfere with standard care, and consent will not be sought until after the patient has received an initial assessment by health workers. Relevant collected data (e.g., anthropometric data, vital signs) will be available to health workers for use during clinical care. Mothers or family members of dyads enrolled in the study may have painful memories triggered during follow-up, especially if the mother or newborn has died. To minimize this risk, all study staff will undergo empathy training and training on protocols for scenarios of extreme distress. If a mother is concerned about their health or the health of their child during follow-up, they will be referred to the nearest health facility or community health worker for assessment.

Risk of COVID-19 infection remains an ongoing concern. Study staff will follow all public health orders and infection control procedures at our study sites to reduce the spread of infection between staff and between staff and patients. Further, we will develop and implement a study-specific COVID-19 risk mitigation plan outlining study-specific infection control measures and protocols for contact tracing and follow-up for any confirmed or suspected COVID-19 cases among study participants and staff.

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Appendix A: Variables Collected

Table 6. Variables Collected

Time Period	Data Collection Tool	Variables
Admission	**Admission Variables**	Maternal Age
		Refereed
		Who decided it was time to come to the hospital
		How long did it take to get to the hospital (hours)
		Mode of transport to the hospital (walk, motorcycle, private vehicle, ambulance, etc.)
		Date and Time of admission
		Does the woman know her approximate due date?
		How was the due date defined (LMP, not sure, ultrasound, woman herself, missing)
		Due date (if known)
		Admission vital signs (temperature, BP, HR)
		Were you delayed >1 hour by any of the following: a. Terrain (boat, swamp, flood, etc) b. Cost of transport c. General transport delay (waiting for bus, schedules, etc.)
Admission	**Health & Pregnancy History**	Number of pregnancies in lifetime
		Number of pregnancies with baby born greater than 500g and 20 weeks gestation
		Chronic health conditions before pregnancy
		HIV related details during pregnancy (new diagnosis, ARV, etc.)
		Malaria with antimalarials during pregnancy
		Conditions diagnosed during pregnancy - select all that apply (diabetes, pre-eclampsia, eclampsia, hypertension, antepartum hemorrhage/vaginal bleeding, PPROM, preterm labor, malaria, HIV, UTI, TB, Anemia, Other infection, None)
		Admission during pregnancy, duration (no, <28 days, >28 days), reason
		Taking medication for (high blood pressure, antimalarial, ARVs, antibiotics)
		Sought care from traditional birth attendant
		Took herbs while pregnant
		Saw a midwife, nurse, doctor for ANC care
		Number of times ANC care was sought with midwife, nurse, doctor
		Prenatal vitamins during pregnancy

		Prior admissions (number of admissions, date, length of stay, self-reported diagnosis during admission)
		UTI history, if yes: a. If admitted – where/when? b. IV antibiotics – Yes/No c. Other?
		Pre-delivery hematocrit
		Substance use – select all that apply (smoking, alcohol, other drugs)
		Did you take any of the following while pregnant: Abx, antimalarials, antihypertensives, ARVs, prenatal vitamins, herbs
		During your pregnancy, did you or any household member have to eat less food than you felt you was needed?
		Abortion history – Yes/No
		Previous caesarian section – Yes/No
		Previous infertility – Yes/No
		Known placental disorders
Delivery	**Maternal Variables**	Date/Time of delivery
		Mode of delivery
		Episiotomy – Y/N
		Vaginal tearing and recorded degree of tearing
		Induced labour and method of induction
		PPH noted (estimated blood loss, blood transfusion needed, how many units of blood)
		Obstructed labour
		Meconium in amniotic fluid
		Number of babies delivered
		Number of vaginal exams (self-reported)
		Date/Time labour started
		Fetal position
		Administration of oral fluids, IV fluids, and antibiotics
		Placenta disruptions (placental previa, placental abruption)
		Number of vaginal exams
		Early or delayed cord clamping
Delivery	**C-Section Variables**	Before anesthesia (Y/N): special procedures needed (central line, art line), Hb, platelet, glucose, magnesium, antibiotic prophylaxis (cefazolin, azithromycin, other)
		Before skin incision (Y/N): Antibiotics were given and when, plan for post-op analgesia, gestational age, reason for c section, pregnancy issues,

		medications (anesthetics, opioids, magnesium, betamethasone, other), early or delayed cord clamping
		Debriefing: VTE prophylaxis checklist, anticoagulation and timing, placenta pathology, special management needed, blood loss, urine output, fluid intake
Delivery	**Neonatal Variables**	Baby born alive
		Sex of the baby
		Apgar score 1 minute
		Apgar score 5 minutes
		Weight of the baby (kg)
		Resuscitation with oxygen therapy at birth
Discharge	**Maternal Variables**	Have you been able to start breastfeeding
		Systolic BP
		Diastolic BP
		SpO2
		HR
		Respiratory Rate
		Temperature
		Hematocrit
		Discharge status (routine, AMA, referral, death, other)
		Symptoms at maternal interview check all that apply (headache, visual changes, chest pain, shortness of breath, nausea and vomiting, abdominal pain, foul smelling vaginal discharge, stiff neck, cough, difficulty emptying bladder)
		During this admission was she given antibiotics (Y/N) also add route (IV/PO)
		Date/Time of discharge
		Scheduled follow up date
		Lab tests conducted Y/N & results
		Intent for minimal outside contact with community for first 6 weeks
Discharge	**Neonatal Variables**	Baby being discharged with mom
		Disposition of baby – admitted to NICU, died, referred, other.
		Baby pooped
		Baby peed
		Length
		Head circumference
		Weight
		Temperature

		SpO2 Right hand/any foot
		Date, time of discharge and follow up captured under maternal
		Discharged on antibiotics?
Discharge	**Maternal Socioeconomic Variables**	Residence (District, Other District, Sub-county, Other Sub-County, Parish, Other Parish, Village, County/Constituency, Chairman captured)
		Number of people in household
		Number of children in household including baby
		Marital status
		Do you live with the father of the baby
		Maternal level of education (no school. P4-7, S1-6, post-secondary)
		SES Index (score out of 8), includes the following questions a. Finished floor material b. flush toilet c. LPG/electricity for cooking fuel d. improved source of drinking water (with defn) e. more than one room in home f. electricity g. television h. refrigerator i. smart phone j. car, motorbike, bicycle, truck
		Have any other of your children died – Y/N
72-hour post-discharge	**Maternal and Newborn Follow-up Telephone Interview**	Travel time from hospital to home
		Mode of transport from hospital to home
		Did the time of discharged affect trip home?
		Barriers encountered on journey home
		Patient experience measures (Likert scales – e.g., felt healthcare worker spent enough time preparing them for discharge, were things explained in a way that was easy to understand, quality of discharge experience, etc.)
6 weeks post-discharge	**Maternal Variables – Follow-up Interview**	Is the mother alive
		Did she seek care at any time after being home post delivery
		How may routine postpartum visits were made after discharge following birth
		Number of days after birth first PNC visit was made
		Admitted for one or more nights for any reason after being home with her baby post-delivery
		During admission any of the following (vaginal bleeding, abnormal tiredness, convulsions, shortness of breath, vision changes, severe headaches, abdominal pain, abdominal tenderness, foul smelling

		vaginal discharge, fever/body hotness, diarrhea, vomiting everything, cough, loss of consciousness, other)
		Diagnosis (was she told she had pre-eclampsia, eclampsia, HIV, malaria, heavy bleeding, surgical site infection, puerperal sepsis, other infection, diarrhea, vomiting, PPD/psychosis, other)
		Admission date
		Number of nights she was in hospital due to these conditions
		Was hospital care sought prior to her death?
		Was the care sought for routine postpartum follow-up?
		How many routine postpartum visits were made after discharge following birth?
		How many days after birth was the first PNC visit made?
		Did mom get sick during first 6 weeks (Y/N)
		If yes, did she seek care (Y/N)
		If yes, was she re-admitted (Y/N – also how many times and when)
		During this illness, did she experience any of the following symptoms
		Are you based in the same home that you were in prior to delivery
		Support present during post-partum period (list: ex. mother, mother-in-law, etc.)
		Verbal autopsy for mothers who die
6-week post-discharge	**Neonatal Variables – Follow-up interview**	Is the newborn alive at the time of the follow up interview
		Did the newborn die without ever having been discharged following birth
		Date of death
		Place of death
		Was hospital care sought prior to their death
		How many PNC check-ups were completed after leaving the hospital following birth
		How many days old was his baby when the first PNC check was done after leaving the hospital following birth
		Was the newborn admitted for one or more nights at a facility for any reason after being home post-delivery?
		Number of days from discharge till readmission
		Symptoms during illness (rash, cough, diarrhea, fever/hotness of body, vomiting everything, abnormally sleepy, changes in urine colour, making less urine than usual, blood in stool, seizure/convulsions, yellow soles, feeding status, no symptoms, don't know)
		Baby's feeding/drinking status currently

		For how many weeks after delivery was the child exclusively breastfed?
		Is child being exclusively or Non-exclusively breastfed
		For neonates who were readmitted were you told the child had (sepsis, respiratory distress, endocrine/metabolic disease, trauma/injury)
		Are they still in hospital due to this/these conditions
		How many nights were they in hospital due to this/these conditions?
		Did you seek care for the newborn at a facility at any time after being home post-delivery?
		Was this care for routine vaccinations or postnatal baby check-ups?
		How many postnatal baby check ups were completed after leaving hospital following birth?
		How many days old was this baby when the first postnatal check was done after leaving hospital following birth?
		For children who died: Verbal autopsy
		Timing of PNC visits: time from discharge to PNC visit and subsequent visits

Appendix B: Journey Mapping Variables

Table 10. Journey Mapping Data Collection

Time Period	Data Collection Tool	Variables
Admission	Admission Variables	Time of departure from home
		Mode of transport from home to hospital (e.g., personal vehicle, Boda Boda, Bus, other)
		Date of arrival at hospital
		Date of admission
		Time of admission
		Describe any barriers observed (e.g., long wait times, language barrier between mom and healthcare worker)
Discharge	Patient Interview Questionnaire	Are mom and baby being discharged together?
		Date and time of discharge Describe any barriers observed (e.g., language barrier between mom and healthcare worker)
		Did mom receive discharge education, if so, types of topics discussed?
		Was a referral made for postnatal follow-up care? If so, when and where?
		If mother died during hospitalization: a. Date of death b. Who was the infant discharged to c. Did mom received discharge education prior to death?
		If child died during hospitalization - Date of death
72-hour post-discharge	Maternal and Newborn Follow-up Telephone Interview	Travel time from hospital to home
		Mode of transport from hospital to home
		Did the time of discharged affect trip home?
		Barriers encountered on journey home
		Patient experience measures (Likert scales – e.g., felt healthcare worker spent enough time preparing them for discharge, were things explained in a way that was easy to understand, quality of discharge experience, etc.)
		Travel time from hospital to home
6 weeks post-discharge	Maternal and Newborn Follow-up and Telephone Interview	If postnatal care was sought, what motivated you to attend a follow-up visit?
		If referred but did not attend a follow-up, why not?

Appendix C: Maternal Outcomes

Table 6. Maternal Causes of readmission (n=80)

Admission Diagnosis	**n (%)**
Surgical site infection	41 (51.2%)
Puerperal sepsis	34 (42.5%)
Malaria	15 (18.8%)
Other Infection	4 (5.0%)
Heavy Bleeding	2 (2.5%)
PPD/psychosis	2 (2.5%)
Pre-eclampsia	1 (1.2%)
Eclampsia	1 (1.2%)
HIV	1 (1.2%)
Diarrhea	1 (1.2%)
Vomiting	1 (1.2%)
Other	8 (10.0%)
Admission Symptoms	**n (%)**
Abdominal Pain	45 (56.2%)
Fever (<7 days)	34 (42.5%)
Abdominal tenderness when touches	32 (40.0%)
Foul smelling vaginal discharge	23 (28.8%)
Severe headache (<24 hours)	23 (28.8%)
Abnormal tiredness	12 (15.0%)
Heavy Vaginal Bleeding	7 (8.8%)
Severe headache (>24 hours)	5 (6.2%)
Changes in vision	5 (6.2%)
Vomiting	4 (5.0%)
Shortness of breath	3 (3.8%)
Fever (>7days)	2 (2.5%)
Convulsions	2 (2.5%)
Diarrhea (<14 days)	2 (2.5%)
Diarrhea (>14 days)	1 (1.2%)
Cough (>14 days)	1 (1.2%)
Cough (<14 days)	1 (1.2%)

Other	6 (7.1%)

Table 7. Maternal Care seeking

Care seeking (n=80 readmitted+0 deaths)	
Did she seek care after being home with her baby post-delivery n (%)	
Yes	78 (97.5%)
No	2 (2.5%)
Number of routine postpartum visits n (%)	
0	4 (5.0%)
1	33 (41.2%)
2	32 (40.0%)
≥3	11 (13.8%)
Number of days from birth to first postnatal care visit [interquartile range]	7.00 [7.00-14.00]
Number of days from discharge to readmission median [interquartile range]	5.00 [3.00-13.5]

Appendix D: Neonate Outcomes

Table 8. Neonatal Outcomes (n=134)

Readmission n=108	n (%)
Diagnosis	
Sepsis	68 (63.0%)
Respiratory distress	21 (19.4%)
Endocrine/Metabolic Disease	2 (1.9%)
Trauma/Injury	2 (1.9%)
Deaths n=26	
Period from delivery to death (days) median [interquartile range]	5.00 [3.00-14.8]
Period from discharge to death (days) median [interquartile range]	4.00 [1.25-13.8]
Location of death n (%)	
Home	9 (34.6%)
Hospital	13 (50.0%)

En route to hospital	4 (15.4%)
Was hospital care sought prior to death n (%)	
Yes	16 (61.5%)
No	10 (43.5%)
Symptoms (n=131)	
Fever/hotness of body < 7 days	72 (55.0%)
Cough < 14 days	7 (5.3%)
Fever/hotness of body > 7 days	5 (3.8%)
Abnormal sleeping	5 (3.8%)
Changes in urine color	4 (3.1%)
Seizure/Convulsions	4 (3.1%)
Diarrhea < 14 days	3 (2.3%)
Rash	12 (9.2%)
Vomiting	10 (7.6%)
Yellow Soles	10 (7.6%)
None of these symptoms	10 (7.6%)
Cough > 14 days	1 (0.8%)
Diarrhea > 14 days	1 (0.8%)
Less urine than usual	1 (0.8%)
Blood in stool	1 (0.8%)
Unknown	1 (0.8%)

Table 9. Neonatal Care Seeking

Care Seeking n = 131 (108 readmitted+23 dead)	
Did you seek care for the newborn at a facility after being home post delivery n (%)	
Yes	108 (82.4%)
No	0 (0%)
Missing	23 (17.6%)
How many post natal baby check ups were completed after leaving hospital following birth	
0	3 (2.3%)
1	1 (0.8%)
2	33 (25.2%)
≥3	50 (38.2%)
Missing	44 (33.6%)

How many days old was this baby when the first post natal check was done after leaving hospital following birth median [interquartile range]	8.00 [3.75-21.0]
Number of days from discharge to readmission median [interquartile range]	2.00 [0-8.00]