PURPOSE OF STUDY

To explore the feasibility of implementation of Kangaroo mother care (KMC) in neonatal transport in Ghana and importantly explore the effects of the early use of KMC on neonatal morbidity and mortality.

TYPE OF STUDY

The study will be approached in two phases

- First, a pilot study, using a standardized proforma to gather data on systems as they persist currently.
- Secondly, a mixed-methods feasibility cluster non - randomised study to assess the implementation of KMC as an intervention in the early transport of preterm and low birth weight neonates from the community and lower-level health centres to the Special Care Baby Unit of Cape Coast Teaching Hospital (SCBU CCTH)

The choice of study type was guided by the following considerations:

1. Even though KMC has been in use in Ghana for many decades, the practicalities of its operation are not easily apparent to all health care workers and all communities. Health worker sensitization and community partnerships, therefore, need to be established, increased, or sustained.
2. There are few previously published studies or existing data specifically using KMC for neonatal transport in resource-constrained settings.
3. Prior studies on the use of KMC for newborn transport, were not guided by in-depth research or knowledge of the population's socio-cultural health beliefs and the urgent need to address the high mortality in preterm and low birth weight babies in resource-constrained settings and partnership with the targeted communities.

3.2 Aims and Objectives

The primary aim is to assess whether Kangaroo Mother care, when used early as a cost-effective intervention in neonatal transport is effective in reducing mortality and morbidity in preterm and low birth weight neonates in Ghana.

Secondary Objectives

- To assess the acceptability of KMC as an intervention for neonatal transport by assessing the attitude/views of the mothers/ fathers/families and health care providers/nurses towards the practice
- To assess the feasibility of implementing KMC as a measure in neonatal transport.
- To obtain data that will inform sample size calculation and design for a larger cluster RCT
- To estimate recruitment rates, attrition rates and adherence to protocol implementation.
- To provide the researcher with experience of the participants, setting, methodology and method of measurement
- To assess data collection tools

RESEARCH HYPOTHESES FOR LARGE SCALE STUDY

The research hypotheses for a large-scale cluster RCT would be as follows:

• KMC reduces mortality in preterm and low birth weight infants transferred from the peripheries to specialized units immediately after delivery.

• KMC maintains physiological stability in transferred preterm/low birth weight infants irrespective of the distance/time of travel and mode of transport

METHODS/DESIGN

Study Design

The study design is a two-arm cluster non-randomised controlled study; the maternity units or birthing centres rather than the individual participants would be the units of randomization. The intention is to diminish the risk of contamination of participants in the intervention group through two likely mechanisms. Firstly, midwives at intervention sites trained in the study procedures using aspects of the study on control participants and secondly relaying interventional procedures and information between participants in the two arms who are attending the same maternity unit for care and already known to each other.

Mother-baby pair participants attending the intervention maternity sites would receive the intervention of transfer of their babies to CCTH using KMC, described below, while participants from control sites would have their babies transferred to CCTH using the usual current operating transport mechanisms.

A mixed-methods approach will be utilised, applying both quantitative methods to study the effectiveness of KMC in neonatal transport and qualitative methods using semi-structured interviews with mothers, other caregivers and nurses, to explore the practicality and acceptability of KMC in newborn transport.

Study Setting

The study will be conducted in Cape Coast, the capital city of the Central Region of Ghana. Cape Coast metropolis is one of the six metropolises in Ghana and the only one among the 20 districts in the Central Region. It is located 163 km west of the capital of Ghana, Accra, on the Gulf of Guinea. The population of the Cape Coast metropolis, according to the 2010 Population and Housing Census, is 169,894 representing 7.7 per cent of the region's total population.

Cape Coast has 3 major hospitals: Cape Coast Metropolitan Hospital (CCMH), University of Cape Coast Hospital (UCCH) and Cape Coast Teaching Hospital (CCTH). The Cape Teaching Hospital serves as the only tertiary hospital in the region and has the only neonatal intensive care unit which serves as the referral site for newborn care from the 3 major hospitals in Cape Coast as well as surrounding level 1 health centres, maternity units and babies delivered at home. With regards to the number of deliveries per year, CCTH has 3100, CCMH- 1048 and UCCH – 970.

The neonatal unit is currently equipped with 6 incubators, 30 cots and has facilities for respiratory support with continuous positive airway pressure. KMC is currently used in CCTH for the care of stable newborns who are being prepared for discharge and nurses in the unit have regular in-service training on KMC to improve the practice.

The newborn unit in CCTH was chosen for this study because it is my clinical area, and the hospital has a growing research community and teaching facilities.

SITE RANDOMISATION

Centre recruitment

Four (4) primary care/ maternity units with the highest referral/transfer to the Special care baby unit of the Cape Coast Teaching Hospital would be recruited following a review of the admission-discharge records over the past 2 years and 2-month piloting of a designed proforma ***(Appendix- 1).*** Two of these sites would be randomized as intervention sites and the other two, as control sites. Selected sites will be randomised when all necessary ethical approvals have been obtained. The process will be completed to give optimal balance for socioeconomic status, the size of the maternity, ethnic mix and distance from the Special Care baby unit, CCTH

Participant recruitment

Intervention sites would have posters displayed at the antenatal units, delivery suites and children's ward providing information about the trial during the sensitization and training period. Potentially eligible participants will be approached at their earliest antenatal appointment (using known risk factors for preterm delivery), an appropriately chosen time postnatally when the mother or the appropriate caregiver can give consent to the trained midwives/health care workers, who will provide an information sheet and describe the study. The decision to approach eligible women/families will be made by the midwife/health care worker taking cognisance of the mother's health and mental state to minimize obtaining consent at a period of vulnerability.

The midwife/health care worker will provide the mother/caregiver with a comprehensive information sheet and ensure adequate time is given for them to read the material/read and explained it to them in the local language and to ask any questions they have about the study. Mothers/caregivers will be reminded they retain the right to not participate in the study and also to withdraw consent for participation at any time without any form of impact on the care to themselves or their babies.

Midwives/health workers will be trained in Good Clinical Practice and all study procedures. A screening form will be completed to record the number of mothers/caregivers approached about the study, eligibility, and at what stage women declined to take part in the study.

All staff involved in the study and involved in data collection will be trained to adequately collect and record physiologic parameters and outcome measures. Information on adverse events during the transport process itself, pre-and post-transport stabilization at the intervention sites would be reported and recorded by all staff involved.

Adverse events expected in this trial include the possibility of a neonate not tolerating the KMC with resultant difficulty in breathing. However previous studies on KMC in stable babies have reported no such adverse effect but guidelines for dealing with such occurrences will be part of the training of the health workers **(appendix 3)**

Inclusion criteria

- Newborns < 2500 grams and/or 28 to 37 weeks gestation at birth
- Newborns less than 28days old
- Apgar score of at least 5 in the first and fifth minutes of life
- Not requiring any ventilatory support, intravenous fluids, or vasopressors
- Fathers or family members willing to participate in situations where a mother is medically unwell for the transfer

Exclusion criteria

- Apgar score of less than 5 at 10 minutes of age
- Term neonates or neonates > 28days of age
- preterms requiring prolonged resuscitation and oxygen therapy after 4 hours of life.
- newborns with major congenital malformations and foetal chromosomal abnormalities
- Hypoxic ischaemic encephalopathy/prenatal asphyxia
- Mothers with postnatal complications who are unable to give consent and have no dedicated family member to consent for inclusion in the study
- Parents/guardians refusal to consent
- Mothers with detected pregnancy-related complications e.g. multiple pregnancies, recurrent miscarriage or pre-eclampsia;

This list is not considered as all-inclusive. If the midwife/health worker considers that the woman has other serious complications that would affect her suitability to participate in the transfer, and there is no guardian/relative to consent for the study, the midwife may use her discretion to exclude the mother from the study noting on the recruitment form the reason for exclusion

A mother withdrawn on clinical grounds by the study team will still complete follow-up if she is willing. Such data would contribute to questions about the acceptability of the intervention.

PROCEDURES

Stabilisation

All neonates enrolled on the study would undergo a period of initial stabilisation during which time they would receive conventional care. Conventional care involves keeping the baby warm using a radiant warmer or whatever means of warming is available oxygen therapy if required and either breastfeeding, use of a nasogastric tube, or cup for expressed breast milk.

Conventional care (control group and KMC group)

Conventional care for neonates would start in the delivery room, where the nurse receives the neonate after delivery, quickly dries and wraps in a towel and provides the necessary resuscitation as prescribed by the Helping Babies Breathe algorithm. The babies had their noses and mouths suctioned, and oxygen was given as needed. A quick physical examination to check for any anatomical anomalies was done by the receiving health worker and babies were given a vitamin K injection intramuscularly and tetracycline ophthalmic ointment applied. Vital signs (temperature, heart rate, respiratory rate and saturation rate) would be checked by the nurse and feeding either at the breast or using expressed breastmilk via cup or nasogastric tube provided. Participants attending control sites will receive conventional care and the babies transferred to CCTH using the current established mode of transfer.

Kangaroo Mother Care group (intervention group)

Neonates at the intervention sites would receive the same initial stabilization and conventional care as neonates at the control sites. Participants (mother-baby pairs) who are identified by trained health workers at the intervention sites for transfer and who give consent for participation in the study, would be taught the appropriate procedure for KMC and the babies transferred to the special care baby unit, CCTH with the intervention. The

intervention sites would be assessed for their confidence and competence in using KMC and any identified issues would be improved with training on KMC before the start of the study.

Components of the Study Intervention

Intervention site midwives/ health workers following recruitment into the study would provide conventional care as described above. Initial observations (heart rate, respiratory rate, oxygen saturation and blood glucose) will be obtained and recorded. Neonates with low blood sugar (< 2.6mmol/L) would be given a milk feed and the blood sugar stabilized before transfer.

The neonate wearing a cap and diaper would be transferred gently and placed upright against the caregiver's (mother, father, relative) bare chest. The neonate's head would be turned to one side in a slightly extended position with hips was flexed and abducted. The arms would be flexed, and the neonate secured using a fabric (KMC sling or mothers usual cover cloth) The fabric is wrapped around the caregiver and infant in a sling-like fashion such that it covers the whole body of the infant securely. It is then tied in a firm knot on the side of the mother. An additional blanket or cloth would be placed over the mother and infant during transport to provide warmth

Participants would be accompanied by a nurse or trained health worker if the facility is adequately staffed to provide such support otherwise the caregiver would be instructed to place his/her hands to support the back and the neck of the neonate and monitor the respiration. Caregiver-neonate pairs would be transported in the standard usual mode of transport and neonates kept in the kangaroo position on the chest of the caregivers during the entire transport.

Monitoring

Measurement of heart rate respiratory rate, temperature, and oxygen saturation would be performed before transfer with kangaroo care transport or usual transport then checked every 30minutes during transport (where there is an accompanying health worker), and immediately upon arrival at CCTH.

In situations where there is no health worker to accompany the KMC transport, the caregiver would be taught to closely monitor the colour and breathing of the baby.

Heart rate and oxygen saturation would be monitored by pulse oximetry and respiratory rate, obtained by counting the rate per minute

Data collection

Data would be collected using routine data collection forms and questionnaires. The data would be collected by the nurses/health care workers pre-transfer, during transfer and on arrival in CCTH

Sample size

A formal power calculation hinged on detecting evidence for effectiveness has not been performed because the study is a feasibility trial. Based on the recent review of admissions to the neonatal unit in CCTH (from our published work), I anticipate that there will be between 5 to 15 referrals from each of the 4 selected sites per month. One hundred and twenty mother-

baby pairs will be recruited in total, over 9 months (6 months for recruiting a minimum of 5 pairs/month plus 3 months extra) to allow for dropouts and slower recruitment rates. There will be 60 in the intervention arm compared to the same number from the control sites which is a pragmatic chosen sample size to allow us to identify evidence of feasibility, desirability, recruitment rates, any problems with the intervention or research methods and sufficient for calculating the intra-cluster correlation coefficient.

Outcome measures

The primary outcome measure is survival until the discharge of preterm and low birth weight neonates.
Secondary outcomes will include investigations into the impact of the intervention on improvement in morbidity such as

- thermal stability (hypothermia),
- glucose control (hypoglycaemia),
- oxygen saturation (hypoxia).

Baseline characteristics such as

- Modes of transportation
- Mode of delivery
- Risk factors for sepsis
- Maternal mental health
- Parents/guardians accompanying neonate,
- Travel time,
- Distance of travel
- Type/timing of communication,

Would be gathered and their impact on the primary outcomes analysed.

QUALITATIVE STUDY

The qualitative approach would involve the use of semi-structured interviews with mothers/caregivers involved in the transfer and nurses/health care workers
All interviews would be conducted and digitally recorded in English, or the chosen language of the participant and the recording transcribed verbatim by myself. The transcribed verbatim interviews would be translated into English by myself and reviewed and back-translated by a staff nurse in CCTH. This is to ensure accurate interpretation of the data using the exact words of the participants. Digital recording of the interviews is to ensure that all the necessary details of the interview are captured and recall bias minimized. It will also allow for a focus on the content of the interview.
Semi-structured interviews would be appropriate for the qualitative aspect of this study as they provide some control over the questions asked to the caregivers and nurses during the interview process while at the same time offering freedom in terms of expression, allowing mothers/caregivers and nurses to express their views on study methodology, initial care at stabilization, the transfer process and KMC for the transfer

Sampling and sample size

After considering various qualitative methods, interviews would be carried out on a sample of 30 mothers/caregivers and 20 nurses. It is anticipated that 50% of the mothers/caregivers recruited from the intervention sites would volunteer to be interviewed and this number should be adequate to provide adequate information to gain insight into mothers 'experiences into the transfer process and the acceptability of KMC for transfer. The nursing sample would be from the number of nurses involved in the transfer process volunteering to participate.

Recruitment

Nurses

Nurses/ health care workers working at the recruitment sites and involved in initial stabilization, or the transfer process would be approached for their consent to participate. They would be informed that the interview is voluntary, and their answers anonymized. Their consent would be obtained using a structured consent form (appendix)

Mothers/Caregivers

All mothers/caregivers' will be informed during the first meeting that there was an interview during the trial and that it would be voluntary. They would also be informed their answers would remain anonymous and confidential. Their consent using a structured consent form would be obtained before the interview. It is anticipated that 30 mothers/caregivers would be recruited for the interview (20 from the intervention and 10 from the control arm).

Data collection

The interview schedule will include 13 semi-structured questions for mothers/caregivers in the KMC group and 13 for control group mothers/caregivers **(Appendix 4).** The interview schedule for nurses will be made up of seven questions **(Appendix 5).** The questions were developed to cover both the acceptability of the study/intervention and the personal experiences of KMC. All interviews are intended to be carried out in a quiet place at the SCBU, CCTH, consulting rooms in the paediatric outpatients CCTH or the referral

Ethical approval

The study will be conducted in fulfilment with the guidelines for physicians involved in research on human participants adopted by the 18th World Medical Assembly, Helsinki 1964 and later revisions. Ethical approval would be applied from the Cape Coast Teaching hospital/the University of Cape Coast School of Medical Sciences, Ethics committee.

The original contribution to knowledge likely to emerge from this study.

Neonatal transfer from the community and lower-level health centres to established centres designed to provide higher levels of care remains a challenge because of the lack of a well-established ambulance service and lack of basic transport facilities. The high neonatal mortality and morbidity in resource-constrained settings which are contributed significantly by deaths in the preterm/LBW could be reduced by safely transporting babies to these centres. Despite the use of KMC in these resource-constrained settings and the strong evidence available on how it offers physiological stability to newborns, previous studies have not explored its use in the transport of newborns in the first few hours after delivery because they are considered clinically unstable.

This study will add to new knowledge on the use of KMC in the immediate transfer of preterm and low birth weight babies.