1. Purpose and scope

Standard Operating Procedures (SOPs) are required to assure quality, to reduce errors, and to standardise activities and tasks throughout the Nairobi Newborn Study. This document outlines the process for the first visit to a facility in order to establish their eligibility and/or gain their permission to include them in the study.

2. Staffing, equipment, and resources

The study investigators will be responsible for obtaining permission from facility authorities to conduct the study in eligible facilities. Access to transport and the documents attached as appendices are required for carrying out the procedure outlined in this SOP.

3. Procedure

3.1. Preparation

i. Before leaving the office, make sure that you have all of the following documentation:
   - Letter from the Nairobi City County with attached facility list
   - Facility permission form (several copies)
   - Lay summary (several copies)
   - Information about eligible facilities sheet
   - Facility list: permission document
   - Facility list: eligibility document
   - A copy of the ethics approval letter
   - Tally sheet
   - Structural assessment documentation: Form and SOP

ii. Also bring identification with you in case it is requested.

3.2. Arriving at the facility

i. When you arrive at the facility, explain who you are and ask to speak to an appropriate person in charge.

ii. If this person is not available, then ask if there is someone else you might be able to speak to.

iii. If not, ask when it would be best to return. Take the contact details of the person who you need to speak to and note the instructions you have been given. Leave a copy of the NCC letter (appendix 2) with the receptionist along with your name and contact details, requesting that the information be passed on to the person in charge.

iv. When you do meet the appropriate person, explain who you are and show them the letter from NCC.

Note: If the eligibility of the facility is already determined then skip to 3.4.
3.3. Establishing eligibility

i. Ask the facility if they are open and caring for patients 7 days a week and for 24 hours a day. If no, proceed to iv. If yes, continue.

ii. Ask the facility if they keep sick newborn babies as inpatients for more than 24 hours i.e. provide (24/7) inpatient care for sick newborn babies. (Note: inpatient care for newborns must be 24/7 for the answer to be ‘yes’. Facilities that are open 24/7 but their newborn unit is not open 24/7 are not eligible for the study). If they answer that they are able to but don’t, then ask if they have kept a newborn as an inpatient in the last 2 months. If no, proceed to iv. If yes, continue.

iii. Inform the contact that the facility will be eligible for a forthcoming study. Ask them if you can explain the study further and seek their permission to include them in the study (proceed to 3.4).

iv. The facility is not eligible for the study. Explain why they are not eligible and thank them for their time. If they request contact details or a copy of the NCC letter, provide these. Proceed to 3.5.

3.4. Seeking permission

i. Show them the facility permission form (appendix 3) and answer any questions they have about the study. (be sure to be prepared to answer questions before you go to the facility)

ii. Discuss the study with them and ask for them to sign the permission form.

iii. If they would like further information, please do what you can to provide it. It is important to try to convince a facility to partake, but it is equally important not to appear pushy. If they would like time to think about it, discuss with colleagues, etc, do what you can to be helpful and cooperative. You can leave information (such as the NCC letter, the permission information sheet, and the lay summary (appendix 4)) with them and return at their convenience.

Decliners

iv. If they decline to partake, ask if they might be at least willing to provide some few pieces of information to help understand something about those facilities that are eligible but not partaking. Show them the information about eligible facility sheet (appendix 5), on which you would like to collect some information about the facility and admissions.

v. Proceed to 3.5.

Acceptors

iv. If they agree to partake then ask them to sign the permission form and fill in the necessary sections. Provide them with a copy of the permission form and information sheet to keep.

v. Obtain information for the information about eligible facility sheet (appendix 5).

vi. In order to complete this sheet, ask if you can tally the newborn admissions for 1st April 2014 to 31st March 2015 from the newborn admissions register using the tally sheet (appendix 6).

vii. Ask if you can perform the structural assessment. Proceed with SOP3.

viii. If it does not suit them for you to tally and/or perform the structural assessment, ask when it would be better to come back. Ask who you should ask for when you come back to collect these data. Record all of these details on the information about eligible facilities sheet.
ix. Before leaving the facility, ensure you have obtained information about who to contact about coming back and when would be suitable for you to return for further data collection. For facilities in which you have completed tallying and structural assessment, explain that identification of all facilities is ongoing so there might be some time between now and when you return to continue data collection.

x. Leave a copy of any information they would like, e.g. a lay summary, a copy of the ethics approval, and the NCC letter.

3.5. Leaving the facility
i. Regardless of whether permission was granted or not or they were eligible, show them the ‘facility list: permission’ and ask if they know of any potentially eligible facilities that do not appear on your list. Also show them the ‘facility list: eligibility’ and ask if they know of any of these facilities and whether or not they are likely to be eligible or not. Record any response.

ii. Fill out the facility list: eligibility (appendix 7) or facility list: permission (appendix 8), depending on which list the facility appears.

iii. Thank the person you have been talking to and ask if they have any questions before you leave. Provide your contact details in case they want to get in touch in future.

iv. Ensure you have all of your documentation and have obtained all of the necessary information to proceed with the study.

4. Related procedures and documents
- Letter from the Nairobi City County with attached facility list
- Facility permission form (several copies)
- Lay summary (several copies)
- Information about eligible facilities sheet
- Facility list: permission document
- Facility list: eligibility document
- A copy of the ethics approval letter
- Tally sheet
- Structural assessment documentation: Form and SOP

5. SOP-user signature log

By signing in the table below, I confirm I have red and am familiar with the SOP for obtaining permission and facility engagement.

<table>
<thead>
<tr>
<th>Name</th>
<th>Signature</th>
<th>Date</th>
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</table>
Summary

Important documentation.

- Letter from the Nairobi City County with attached facility list
- Facility permission form (several copies)
- Lay summary (several copies)
- Information about eligible facilities sheet
- Facility list: permission document
- Facility list: eligibility document
- A copy of the ethics approval letter
- Tally sheet
- Structural assessment documentation: Form and SOP

Newborn unit in a facility OPEN 24/7 OR cared for inpatient newborns in the last 2 months?

YES

NO  (Fill out eligible facility sheet- App 7)

1. Seeking permission
   - (Yes immediately)Facility permission form (App 3)
   - (To think about it) Lay summary (App 4), permission information sheet, NCC letter

2. Decliners
   - Eligible facility sheet (App 5)

3. Acceptors
   - Sign permission and information sheet
   - Eligible facility sheet (App 5)
   - Newborns admission > Tally sheet (App 6)
   - Structural Assessment form (SOP 3)

4. Leaving the facility
   - Facility list: eligibility (appendix 7) or
   - Facility list: permission (appendix 8)
   - Ask if they know anything about other nearby facilities.
Appendix 1: List of all facilities

Not phoned and eligible
1. Kenyatta national hospital
2. Aga khan hospital
3. Mbagathi District hospital
4. Nairobi Hospital
5. Mama Lucy Kibaki hospital
6. Nairobi west hospital
7. Pumwani maternity Hospital

Phoned and eligible
1. The Karen Hospital
2. Mater Hospital
3. Radiant Pangani Hospital
4. St Francis Com Hospital
5. Mp Shah Hospital
6. Nairobi Women’s Hospital (Hurlingham)
7. Nairobi Women’s Hospital (Adams)
8. Alliance Hospital
9. Ruaraka Uhai Neema Hospital
10. Avenue Hospital
11. Coptic Hospital
12. Gertrudes children’s Hospital
13. Guru Nanak Hospital
14. Langata Hospital
15. Maria immaculate health centre
16. Mother and Child hospital
17. Nairobi East Hospital
18. Nairobi South Hospital
19. Skyhill Medical Centre
20. Afwan Medical Clinic
21. Meridian Equator Hospital
22. Metropolitan Hospital
23. South B Hospital Limited
24. Family care medical centre
25. Komarock Modern Medical Care

Phone, need to establish eligibility
1. Memorial Hospital
2. Al Amin Nursing Home
3. Andulus medical clinic
4. Bristol Park Hospital
5. Huruma Nursing Home

No contact details, need to establish eligibility
1. 7Kr Mrs Health Centre
2. Afya Bora Health Care
3. Alice Nursing Home
4. Bahati Health Centre
5. Cidi Mukuru Clinic
6. Compassionate Hospital
7. Huruma Maternity Hospital
8. Jamii Medical Hospital
9. Kayole II Sub-District Hospital
10. Makadara Health Centre
11. Mary Mission
12. Moi Air Base Hospital
13. Mwangaza ulio Na Tumaini clinic
14. Ngara Health Centre (City Council of Nairobi)
15. Pine Medical Clinic
16. Pipeline Nursing Home
17. Provide International Health Care (Mathare)
18. Provide International Korogocho
19. Romieva Medical Centre
20. Salama Nursing Home
21. Saola Maternity and Nursing Home
22. St Clare Medical Clinic
23. St Joseph Nursing Home
24. St Michael Community Nursing Home
25. True Light Medical Clinic
26. Tumaini Mwangaza (Korogocho)
27. Waithaka Health Centre
28. Westlands Health Centre
8th May 2015

To: All Health Facility in Charges

RE: Work to understand and improve the provision of neonatal hospital care in Nairobi City County

The Nairobi City County is committed towards improving health of all city residents and has prioritised the provision of hospital based neo-natal care in selected health facilities. In view of this, the county, in partnership with the University of Nairobi, Strathmore University, The Kenya Paediatric Association and the KEMRI-Wellcome Trust Research Programme wish to conduct a three (3) year study that seeks to understand the quality of neo-natal care/services as provided in health facilities that include the public, private, and not-for-profit or faith-based providers.

The initial component of the study will focus on inpatient services available for sick and preterm newborns and will seek to answer the following questions:

1. What resources facilities have for providing inpatient care for sick newborns and intrapartum and postpartum care for mothers and newborns?
2. How many sick newborns facilities are caring for and with what problems?
3. What knowledge health care workers have and what training needs there are?

The findings of the study will help inform long term strategies to be put in place towards improving the quality of neo-natal health care within the county. A study team will make visits to facilities as listed in the appendix during the period of this study.

The team will work with facility in-charges or their nominees to document available resources, determine the number of deliveries and inpatient neonatal cases captured in available registers/records, enquire from staff about their training and knowledge (using an anonymous questionnaire) and conduct a brief review of inpatient records for selected neonatal admissions. The work involved may take several days depending on the size of the facility but the study team will not inconvenience facility staff in any way.
The study team will visit health facilities (listed in the appendix) to explain the procedures that will be applied during the study. Any questions that may arise will be addressed during the visit and thereafter permission will be sought to undertake the study. The study team will provide facilities with their own specific contact details.

All participants including facility staff involved in the study will remain anonymous in strict compliance with ethical requirements. In addition, the problems identified at the facilities will remain confidential. Information collected from a facility will not be available to people other than the study team and the report produced will not present any results for facilities by name – instead only overall results will be presented. Feedback on results of this study will be given to facilities upon request.

I wish to assure you that the work to be undertaken has the full support of Nairobi City County and has also been approved by the KEMRI Ethics Review Committee (SSC No. 2999).

In addition, Nairobi City County officers that can be contacted should there be any concerns are:

Dr. Alfred Owiti: Deputy Medical Officer of Health - Nairobi City County.  
Phone: 020 2025980, 0722 797266 (cell)

Dr. Nkatha Meme: Operation Research Team Leader  
Phone: 0721341831

Dr. Nancy Abuya; study team leader from Nairobi City County  
Phone: 0724 992 182 (cell)

Nairobi City County will remain grateful for the support received from all health service providers in the health sector towards improved quality neonatal care in the county. In particular, your support is requested to enable the study team to have access to your facility to conduct the work briefly as outlined above. Your co-operation will be highly appreciated.

DR. S. OCHOLA  
COUNTY DIRECTOR OF MEDICAL SERVICES

CC  
Chief Officer Health Services  
Nairobi City County
Inpatient newborn care in Nairobi City County

Estimating the gap between the need for and the availability, utilisation, and quality of facility-based inpatient newborn care in Nairobi.

Institutions and researchers

<table>
<thead>
<tr>
<th>Institution</th>
<th>Investigators/Principal Investigator</th>
</tr>
</thead>
<tbody>
<tr>
<td>KEMRI-Wellcome Trust Research Programme</td>
<td>Newton Opiyo, Jacintah Mwachiro, Bernard Mitto, Abdisalan Noor, Mike English and Georgina Murphy (Principle Investigator)</td>
</tr>
<tr>
<td>Nuffield Department of Medicine, Oxford University</td>
<td>Georgina Murphy (Principle Investigator) and Mike English</td>
</tr>
<tr>
<td>University of Nairobi, Department of Paediatrics and Child Health</td>
<td>Jalemba Aluvaala</td>
</tr>
<tr>
<td>University of Nairobi, Department of Obstetrics and Gynaecology</td>
<td>Margaret Kilonzo</td>
</tr>
</tbody>
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1. Who is doing this research?

This study is being done as part of a collaboration between the KEMRI Wellcome Trust Research Programme in Kenya and the University of Oxford in the UK. KEMRI is a government organisation that carries out medical research to find better ways of preventing and treating illness in the future for everybody’s benefit. Sometimes research involves only asking questions to health providers, about what they know, feel or do.

All research at KEMRI has to be approved before it begins by several national and international committees who look carefully at planned work. They must agree that the research is important, relevant to Kenya and follows nationally and internationally agreed research guidelines. This includes ensuring that all participants’ safety and rights are respected.

This study is being guided by a group of senior personnel from: the Ministry of Health; Nairobi City Council; the University of Nairobi; the Kenya Paediatric Association; and Pumwani Maternity Hospital.

2. Why is this study being done?

Although Kenya is making progress in reducing deaths among children, there has been little reduction in deaths among newborn babies. Many of these deaths could be prevented with high quality inpatient care. In this study, we are trying to establish what care is currently available to sick newborns in Nairobi. In order to plan improvements in the equitable provision of care, it is first necessary to better understand how the provision of, access to, and quality of care might be improved to prevent newborn deaths and long-term disability. We are conducting this research in partnership with local and national policy-makers as part of efforts to provide evidence for long-term policy on service provision.

The study is taking place in facilities in Nairobi City County that provide inpatient care for sick newborns 24 hours a day for 7 days a week (24/7). At each participating facility, we plan to collect information from a number of sources.

i. First, we will ask the nurse in charge some basic questions about the resources at the facility and look at the equipment available for emergency obstetric and newborn care (EmONC) and management of sick newborns.
Inpatient Newborn Care in Nairobi City County Study

Information sheet for facility participation

ii. Secondly, we will estimate utilisation of the facility by looking at the admission registers from a previous year to see how many newborns were admitted and what their diagnoses and outcomes were. We are also interested in understanding from where the patients are accessing the facility (their residency and referrals), so would like to look at admission registers of both newborns and mothers delivering at the facility to find this information.

iii. Thirdly, nurses on duty at the time of our visit will be invited to partake in a questionnaire about their knowledge and practice of EmONC and management of sick newborns.

iv. Lastly, we are interested in understanding how neonatal care is delivered by clinicians and would, thus, like to look at a selection of newborn medical records to see what care has been recorded.

3. Why have I been chosen to take part in the study?

Your facility has been identified as providing 24/7 inpatient care to sick newborns. We are inviting all facilities within Nairobi City County that provide this type of care to participate in the study.

4. For what am I being asked to provide permission?

As the authority in charge of the facility, we are asking for your permission for your facility to be included in this study. There are many sections to this study. We would like to invite you to partake in the following parts of the study (listed below) but if there are parts you would not wish your facility to be involved in you can opt out of any part without penalty:

(a) **Structural assessment:** If you agree, 1-2 assessors will spend approximately 20-30 minutes at your facility with a checklist and questionnaire. They will first ask the nurses in charge of the delivery ward and neonatal care some basic questions about staffing at your facility. Information will be requested about the number and types of staff working on a full-time and part-time basis. Secondly, the assessors will walk around your maternity ward and newborn unit (or equivalent) with your staff and will check off on their list the equipment for EmONC and the management of sick newborns that they find to be present.

(b) **Utilisation of the facility:** If you agree, we would like to review your facility’s neonatal admission registers and the admission registers for women delivering their babies at your facility. From the neonatal admission register we will look at one year of admissions and note the total number of admissions, the diagnosis and outcome of the patients, and information on residency and referral. From the mothers’ admission registers we will look at one year of admissions or select 500 admissions from within a year, whichever is fewer, and note the location and sub-location of residency of the women and details of their pregnancy. A data entry officer will enter this information from these registers into a computer. We will NOT record any data that identifies women or babies by name. This data entry officer will work from a designated area of your choosing in your facility so that registers are not taken off site. Registers will be returned to their original location so as to minimize disturbance to your record keeping system.

(c) **Nursing questionnaire:** If you agree, we will approach all (or half if there are more than three) nursing staff who provide care to sick newborns and are on duty at the time of our visit. We will do the same for nursing staff providing care during, and directly after, childbirth on the delivery wards. These nurses will be asked to partake in a questionnaire about their level of experience, their knowledge of maternal and newborn interventions, availability of equipment, and the frequency with which newborn interventions are delivered at the facility. Please note that we will only request the participation of...
these nurses with your permission. However, each nurse selected to be interviewed will be asked for written informed consent and will only be included in the study if they provide this consent. They will be free to decline to participate; this will be their own choice. We will not record the names of those completing these questionnaires and will not give anyone the individual’s results. We will only use the information to provide summary results from all facilities or groups of facilities.

(d) Review of clinical records: If you agree, we will request access to your facility’s neonatal medical records. We will sample a selection of these records for review. From this sample of records, we will capture information on the prescription of antibiotics, intravenous fluids, and feeds, on the presence of monitoring charts, and on the availability of information on clinical signs. As with (b) above, a data entry officer will enter this information from these records into a computer. We will NOT record any data that identifies mothers or babies by name nor any data that identifies the person who provided the care for the baby. This data entry officer will work from a designated area of your choosing in your facility so that records are not taken off site. Records will be returned to their original location so as to minimize disturbance to your record keeping system.

5. Can I decline to grant permission for the study to take place in my facility?

All participation in research is voluntary. You are free to decide if you are happy for your facility to take part or not. If you do agree first, you can change your mind at any time without giving a reason; there will be no consequences. Also, as we have said, you can opt out of any part of the study if you wish.

6. Are there any risks or disadvantages to me or my facility taking part in this study?

The equipment assessment will take approximately 20-25 minutes. The assessor may require the assistance of a member of your staff to show them around the delivery ward and newborn unit (or equivalent). We will only record the presence or absence of equipment on a check list. Additionally, the assessor will ask the nurse in charge about number and types of staff at the facility, which will take approximately 5 minutes. The nursing questionnaire will take approximately 30 minutes for each nurse. These questionnaires will be confidential and no names will be recorded. We will work with you to find ways to minimise disruption by discussing times that best suit you and the staff for data collection to take place.

The amount of time needed to review admission and medical records will depend on the size of your facility. We expect this to take approximately two weeks in medium sized facilities, but longer in larger facilities and shorter in smaller facilities. The research team will only require the assistance of a member of staff in order to locate the registers and records and a sitting space from which they can record information. We will not record any patient or staff names or any other information that could be used to identify the patient or individuals involved in the patients’ care. All information will be anonymised.

Care will also be taken in reporting findings from nursing questionnaires and review of medical records to ensure that only summarised data are presented and no details of individual nurses or individual clinical cases can be interpreted from the reported findings. We do not believe there are any risks to taking part in this research.

7. Are there any benefits to me and my facility of taking part in this study?

There are no individual benefits to taking part. In participating, you will contribute to knowledge about the quality of, and need for neonatal care, in Nairobi City County. This knowledge may help us to learn how to support healthcare facilities and staff in better ways to improve services and may then help people in Kenya.
Inpatient Newborn Care in Nairobi City County Study
Information sheet for facility participation

and elsewhere in the future. At the completion of the assessment, we will provide you with feedback on results from the study.

8. What will happen with the information collected from my facility?

All of our documents are stored securely in locked cabinets and on password protected computers. Only the research team will have access to the information we collect.

The knowledge gained from this research will be shared in summary form. We are collecting information from a number of facilities and will make a report based on all these assessments. The report on findings across facilities will be shared with staff within your facility in a forum so that people have the chance to comment on the findings. Final reports will be shared with the Ministry of Health and other health stakeholders in Kenya and with others interested in this research. Information about quality of care will only be provided in summary form across groups of facilities in these reports.

In future, information collected or generated during this study may be used to support new research by other researchers in Kenya, the UK, and other countries. In all cases, we will only share information with other researchers in ways that do not reveal individual participants’ identities. For example, we will ensure that no information that could identify people, such as their names and specific details about where they live, is contained in the information stored or shared. Any future research using information from this study must first be approved by a local or national expert committee to make sure that the interests of participants and their communities are protected.

9. Who can I contact if I have questions about the study?

You are free to ask me any question about this research. If you have any further questions about the study, you are free to contact the research team using the contacts below:

Dr Jalemba Aluvaala, KEMRI Wellcome Trust Research Programme, P. O. Box 43640 – 00100 Nairobi, Kenya
Telephone: [0722217034] or 20 2719936  Email: JAluvaala@kemri-wellcome.org

Dr Georgina Murphy, Centre for Tropical Medicine and Global Health, Nuffield Department of Medicine Research Building, University of Oxford, Old Road campus, Roosevelt Drive, Headington, Oxford, OX3 7FZ, UK
Telephone: [07131 53679] or 20 2719936  Email: Georgina.murphy@ndm.ox.ac.uk

If you want to ask someone independent anything about this research please contact:

The Secretary - KEMRI Ethics Review Committee, P. O. BOX 54840-00200, Nairobi, Tel number: 020 272 2541
Mobile: 0722 205 901 or 0733 400 003
PERMISSION FORM

NB: Verbal permission can be obtained for participation in this study. In such situations, the person requesting the permission can sign below and document the name of the person providing the permission and the sections of the study for which permission was granted.

To be completed by the permission GRANTER (or by the requester to reflect the verbal answers provided by the granter):

Please initial beside the statement with which you agree on behalf of the facility you represent

<table>
<thead>
<tr>
<th>Statement</th>
<th>Initials</th>
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<tbody>
<tr>
<td>I have had the study explained to me. I have understood all that has been read/explained and had my questions answered satisfactorily.</td>
<td></td>
</tr>
<tr>
<td>I agree for the facility to partake in the structural assessment.</td>
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<tr>
<td>I agree to allow access to the facility’s admission register for collection of data on utilisation.</td>
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<tr>
<td>I agree to allow nursing staff in the facility to be asked to partake in a knowledge questionnaire.</td>
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<tr>
<td>I agree to allow access to the facility’s neonatal medical records for review for clinical practice.</td>
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</tr>
<tr>
<td>I understand that I can change my mind at any stage and it will not affect me or the facility in any way.</td>
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</table>

Signature: __________________________________________ Date: ________________

Name: __________________________________________ (Please print your name)

Facility you represent: __________________________________________ (Please print facility name)

To be completed by the permission REQUESTER:

Date: __________________________

Facility name: __________________________

Facility address: __________________________

Name of person from whom permission was requested: __________________________

Position of person from whom permission was requested: __________________________

I have followed the study SOP to obtain permission. S/he apparently understood the nature and the purpose of the study. S/he has been given opportunity to ask questions which have been answered satisfactorily. S/he provides permission for the participation of the facility they represent as outlined above.

Investigator’s signature: __________________________________________ Date: ________________

Investigator’s name: __________________________________________ (Please print your name)
Inpatient Newborn Care in Nairobi City County Study

Lay summary

Inpatient newborn care in Nairobi City County – Estimating the gap between the need for and the availability, utilisation, and quality of facility-based inpatient newborn care

What is the problem/background?

Although Kenya is making progress in reducing childhood mortality, little progress has so far been made in reducing deaths among newborns (0-28 days old). Newborn deaths now accounts for 40% of all child deaths. Many of these deaths among newborns could be prevented if they had access to high quality healthcare. The vast majority of mothers in Nairobi now deliver their babies within health facilities. However, many of these facilities do not have the capacity to deal with problems that may arise for the baby during delivery (such as not being about to breath) or in the first month of life (such as severe infection). In order for the government, health facilities, and others to plan improvements in the equitable provision of care, they first need an understanding of what care is currently available to sick newborns.

What questions are we trying to answer?

The proposed research will ask the following questions: (1) Which public, private, and not-for-profit health facilities in Nairobi City County are capable of providing inpatient care for sick newborns 24 hours a day for 7 days a week (24/7)? (2) How does this supply of care compare to the estimated demand/need for care among sick newborn in Nairobi City County i.e. who needs care but can’t access it? (3) What is the quality of care being provided to sick newborns in these health facilities?

Where is the study taking place, how many people does it involve and how are they selected?

The study will take place in Nairobi City County, Kenya. All health facilities that are open 24/7 and providing maternity services and inpatient care for sick newborns will be invited to partake in the study. We expect this to be approximately 30 facilities across the public, private, and not-for profit sector.

What does the study involve for those who are in it?

At the facilities that agree to take part in the study, we will collect information from a number of sources. (1) Firstly, we will look at their admission registers to see how many newborn patients they care for in a year and what conditions those patients have. We will also look at the residency of these patients and of women attending the facilities to delivery their babies. This will give us insight into the utilization of and access to 24/7 inpatient newborn care. (2) Secondly, we will do a structural assessment. Using a checklist, we will visit the facilities and check what staff, infrastructure, and equipment they have for providing emergency obstetric and newborn care (EmONC) and for managing newborn conditions through inpatient services. (3) Thirdly, we will use a questionnaire to ask nursing staff about their level of training and experience, their knowledge of EmONC and caring for sick newborns, and the care provided and equipment available at their facility. (4) Lastly, we will review medical records of newborn inpatients to see how well the care prescribed by doctors aligns with guidelines for how care should be given e.g. are the correct drugs being used and at the correct dosage?

What are the benefits and risks/costs of the study for those involved?

There are no immediate or direct benefits or risks for any of the study participants. We will endeavour to ensure that this research causes minimal disruption to the work of staff in participating health facilities. The
identity of the individuals partaking in the study will be protected and the quality of care provided at individual facilities will not be published.

How will the study benefit society?

This study will contribute to knowledge about the quality of and need for neonatal care in Nairobi City County. This knowledge will help to inform discussion with policy makers and stakeholders on how to improve care for sick newborns in Nairobi City County. Any insight into accessibility and quality of neonatal care will hopefully, more broadly, help people in Kenya and elsewhere in the future. Ultimately, we hope that this work will add to global efforts in reducing deaths and disability among newborns.

When does the study start and finish?

This study will begin in March 2015 and should be completed with the information ready for dissemination in Kenya by the end of 2015.

Investigators and Institutional Affiliations:

Dr Georgina Murphy 1,2 (Principle Investigator)
Dr Jalemba Aluvaala 2,3
Dr Newton Opiyo 2
Ms Jacintah Mwachiro 2
Dr Margaret Kilonzo 4
Dr Abdisalan Noor 2
Prof Mike English 1,2

1. Nuffield Department of Medicine, University of Oxford, UK
2. KEMRI-Wellcome Trust Research Programme, Nairobi, Kenya
3. University of Nairobi, Department of Paediatrics and Child Health, Nairobi, Kenya
4. University of Nairobi, Department of Obstetrics and Gynaecology, Nairobi, Kenya
Information about eligible facility

Facility name:

Ownership:

Level:

Medical Supervisor:

Matron:

Contact person (name and position):

Address and directions (to be completed by study team):

Phone numbers:

Permission sheet signed?

Annual maternal admissions:

☐ Estimated ☐ Tallied

Annual newborn admissions:

☐ Estimated ☐ Tallied

Restrictions on when to visit for assessment (only for those participating):

Suggestions of other eligible facilities:

Comments:
NEWBORN ADMISSIONS REGISTER TALLY

SHEET ALL ADMISSIONS

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<th>HOSPITAL</th>
<th>MONTH</th>
<th>YEAR</th>
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Facilities to be visited to determine eligibility

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<th>Facility name</th>
<th>Eligible?</th>
<th>Why not?</th>
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<th>Structure?</th>
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## Facilities to be visited to seek permission

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