KEMRI | Wellcome Trust

UNIVERSITY OF OXFORD

Nairobi Newborn Study Handbook

Introduction

The Nairobi Newborn Study is a project under the programme Health Services that Deliver: Improving Care for Sick Newborns (HSD-N). HSD-N is a 4.5 year project (Jan 2015 – July 2019) funded by the Joint Health Systems Research Initiative by the UK Medical Research Council, Wellcome Trust, Department of International Development, and the European Economic and Social Research Council.

Handbook content

Study investigators

Dr Georgina Murphy [1, 2] (Principal Investigator)
Dr Jalemba Aluvaala [2, 3]
Dr Nancy Abuya [2, 4]
Dr David Gathara [2]
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. Nairobi City County, Kenya

An expert advisory group, including partners from the Ministry of Health, Nursing Council of Kenya, University of Nairobi, and Nairobi City County, will support this study. This expert group will regularly meet at the beginning, in the middle, and at the end of the study to discuss plans, progress, and dissemination of information, respectively.

KEMRI | Wellcome Trust

UNIVERSITY OF OXFORD

1. Overview

Abstract

Progress has been made in Kenya towards reducing child mortality as part of efforts aligned with the 4th Millennium Development Goal (MDG4). However, little advancement has been made in reducing mortality among newborns, which now accounts for 40% of all child deaths. The frequently unanticipated nature of neonatal illness, its severity, and the high dependency of newborns on skilled care that results make the provision of inpatient hospital services one key component of strategies to improve newborn survival.

This project aims to assess the availability and quality of inpatient newborn care in hospitals in Nairobi City County across the public, private, and not-for-profit sectors and contrast this to the estimated need for such services, therefore describing the gap between capacity and demand. We will begin with estimating the population level burden using morbidity incidence estimates from literature review (step 1). Empirical data collection will focus on estimating the availability and quality of inpatient newborn services in facilities and will be conducted in four further steps. A retrospective audit of admission registers will be conducted to estimate the utilisation of facilities and case-mix of patients (step 2). A structural assessment of facilities will be done to gain insight into capacity (step 3). A questionnaire will be administered to nursing staff focusing on the process of delivering key obstetric and neonatal interventions (step 4). Finally, we will conduct a retrospective case audit to assess adherence to guidelines by clinicians (step 5). The expected shortfall in supply to meet demand will be geospatially mapped in order to provide insight into the areas of the county with greatest need for improved access to care. The research will be conducted in partnership with local and national policy-makers as part of efforts to provide evidence for long-term policy on service provision

Aim

The overall aim of this project is to quantify and characterise the supply of facility-based inpatient newborn care, in terms of capacity, quality, and accessibility, and to estimate the expected demand for inpatient neonatal care in Nairobi City County to guide strategy on addressing any gaps identified.

Objectives

1. Estimate the magnitude and distribution of the burden of expected neonatal morbidity in Nairobi City County.
2. Map the location of existing facilities capable of providing inpatient newborn care.
3. Estimate the utilisation of facilities providing inpatient newborn care and profile the case-mix of neonatal morbidities treated at these facilities.
4. Assess the quality of EmONC and inpatient newborn care provided in terms of structure and process.
5. Describe any shortfall between the expected incidence of disease (burden) and the capacity for caring for sick neonates (supply).

2. Team structure and duties

a. Project coordinator

The project coordinator is responsible for planning the project, liaising with government officials, making the initial introductions of the survey to eligible facilities and supporting the team supervisors and the survey teams. Work will also include managing the databases (including ensuring confidentiality), producing summaries of results, report writing and dissemination of findings.

b. Team supervisor

The team supervisor is responsible for introducing the project and the team members to the participating facilities on arrival at the survey site and explaining the nature of the survey. He/she will monitor the performance of the teams and independently collecting a sample of data to compare with the data collected by team members as part of a quality assurance process. Before leaving the facility the team supervisor will thank the hospital staff and answer any questions from the senior facility staff. Formal feedback to individual facilities will be conducted after initial analysis and will be the responsibility of the Project Coordinator.

The team supervisor will be responsible for organizing the data collection process together with his/her team and ensuring that it is complete. The particular responsibilities of this role are to ensure the completion of the structural assessment, nursing questionnaire, and data entry from maternal and newborn admission registers and newborn medical records, with assistance from the team where appropriate. The on-site supervisor will additionally assist research assistants with their data collection and liaise on a day-to-day basis with the facility administration and staff.

c. Research assistants

The research assistants are primarily responsible for carrying out the nursing questionnaire and supporting management of the study and associated paperwork. They will be familiar and up-to-date will all aspects of data collection and study administration so as to be on hand to help with additional aspects of the study as needs be.

d. Data entry officers

The data entry officers are responsible for abstracting data from the maternal and newborn admission registers and the newborn medical records into RedCap. Since the officers will be on-site at facilities, they will also act as a point of contact between the study team and the facility management when necessary.

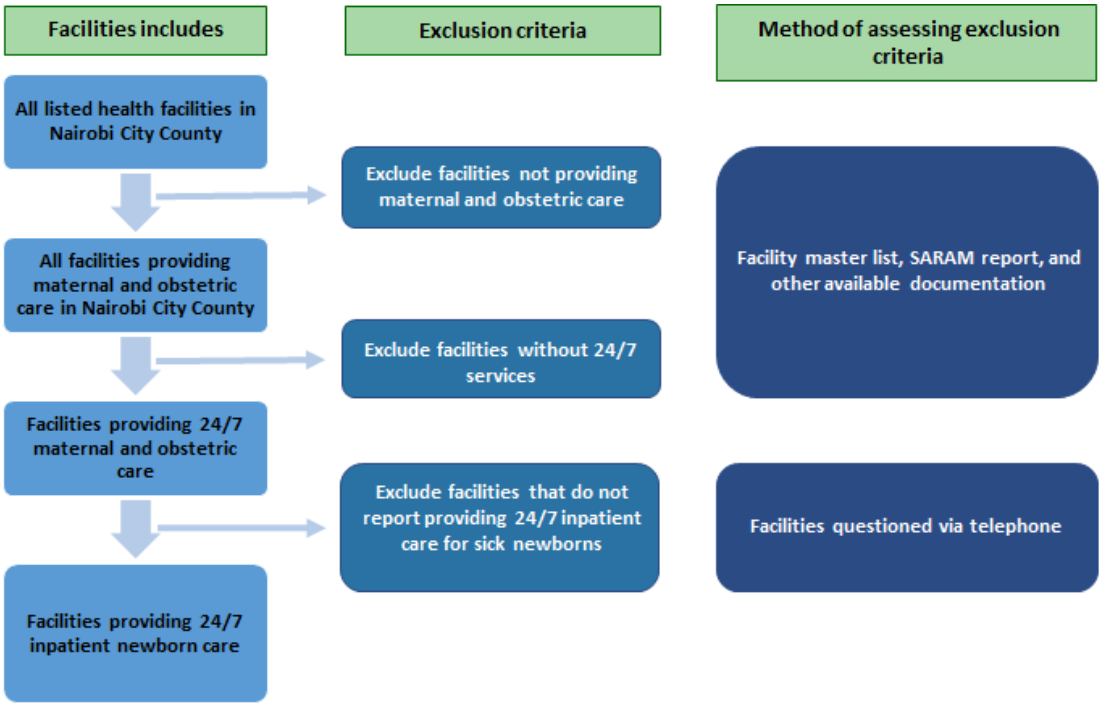
3. Guiding principles in the conduct of this study

- The teams should work together, flexibly, to achieve the project aims. In some cases "on the ground" decisions about the work allocated to people will need to be made by the team, taking account of particular skills.
- Good relations between the study team and the facility staff must be ensured at all times. Be polite and courteous, acknowledging that they are helping us with our project and their cooperation is integral to the success of this study.
- It is important that all records made are **accurate and legible**. If it is not possible to provide an answer then indicate that the data is missing or unobtainable, **do not guess** to make the questionnaire appear complete. Ideally write a note explaining why the data could not be collected on the questionnaire.
- Ensure all sheets have identification numbers on them in case the pages become separated.
- The aim of the survey is not to find fault with people, nor facilities, nor to appear like an external judge of performance. The aim is to understand what is currently happening, explore the difficulties of providing care to sick newborns and learn from examples of good practice. The ultimate aim is to assist the process of improving care of sick newborns in general.
- Survey staff may observe practices they personally disagree with. This should not become a point of conflict. The survey staff member should discuss the issue with the most senior member of the team and this person should discuss it with the facility staff if necessary. The interests of the patient must come first but it is important that disagreements are handled professionally. In the case of an emergency situation then survey staff with appropriate qualifications should be willing to offer assistance if it is requested. However, survey staff should not become involved in the day to day care of patients at survey sites.
- **The information provided is confidential.** Health workers and hospital administrators assist the survey in providing information on the understanding that the information will be treated in confidence. It is not permissible to discuss the information collected with anyone outside the team. Facility staff will be given an immediate feedback session at the end of the survey and more detailed feedback after the entire survey is completed. This feedback will concentrate on general issues and will not describe individual cases in detail unless the identity of the subject can be protected.

4. Selecting eligible facilities

The figure summarises the procedure for identifying eligible facilities for the study. Ultimately, we aim to include all facilities in Nairobi City County providing inpatient newborn care for 24 hours a day for 7 days a week (24/7).

Figure: Summary of strategy for identifying eligible facilities.



3.1 Identification using reports and expert opinion

i. Using the Masters Facility List, all those facilities within Nairobi City County were selected (n=948)
ii. Facilities recorded as having no beds were presumed to not provide inpatient services and were excluded. (n=233)
iii. It was noted that among those excluded due to bed numbers of zero, 13 facilities were listed as 'other hospitals', thus the information about beds may have been inaccurate. These facilities were included back into the selected facilities. (n=246)
iv. This list was reviewed by experts in paediatric medicine who are familiar with Nairobi. They determined that 75 of the facilities were known to them not to provide inpatient services to newborns. These facilities were thus excluded. (n=171)
v. Of these 171 facilities, 81 were indicated on the master facility list as not being open 24 hours a day. They were thus excluded. (n=90)
vi. This list of facilities was once again reviewed by experts. It was noticed that two facilities that are known to provide inpatient newborn care were missing from the list (excluded as indicated to not be open 24 hours). These two facilities were thus included (n=92)

vii. On review of the list, it was apparent that one facility had been included in the master facility list under two slight variants of its name. These two fields were merged into one. (n=91)

viii. Of the 91 facilities, the study team was confident that 7 facilities were eligible as members of the team were familiar with the services provided at those facilities. **[7 eligible]**

3.3 Contacting facilities

i. To determine the eligibility of the remaining 84 facilities, contact details were sought and the facilities were telephoned. Contact details were available for 56 facilities but no contact information could be found for 28 facilities.

ii. Those facilities that were contacted, were done so in accordance to the instructions below.

iii. After phoning the 56 facilities it was determined that **25 were eligible**, 1 was a duplicate, the eligibility of 5 was not clear, 25 were not eligible. [7 + 25 = 32 eligible]

iv. Plans were made to visit the 5 facilities with indeterminate eligibility and the 28 facilities without contact details in order to establish their eligibility.

3.4 Visiting facilities

i. See SOP2 in section 5 for details of visiting facilities.

ii. Of the 33 facilities visited, **1 was eligible**, 23 were not eligible, 6 could not be found, and 3 were military facilities which were deemed not to be under the jurisdiction of Nairobi City County and therefore not eligible. At least two attempts were made to find the 6 remaining facilities; social media and professional contacts were also drawn on in attempts to find these facilities. An additional 6 possible facilities were recommended during visits. Of these facilities, which were then also visited, **4 were found to be eligible**. [32 + 1 + 4 = 37 eligible]

iii. Thus a total of **37 eligible facilities** within Nairobi City County were selected.

iv. During further visits it was determined that two of the facilities that were initially deemed as eligible (Skyhill Medical Centre, eligibly determined by phone, and Mid Hill Maternity Home, eligibly determined by recommendation) were not in fact eligible for the study. Thus, **35 facilities were determined to be eligible for the study.**

KEMRI | Wellcome Trust

UNIVERSITY OF OXFORD

Instructions for contacting facilities

Using the facility list of possibly eligible facilities, telephone each facility to obtain the necessary information to assess eligibility as outlined below.

i. Introduce yourself as a research assistant with the KEMRI Wellcome Trust Research Programme.
ii. Explain that we are trying to identify facilities that provide 24/7 inpatient care for sick newborns in Nairobi.
iii. If quizzed further about who you are and why you want to know about the facility, explain as follows:

Who we are: You are ringing on behalf of researchers at the KEMRI Wellcome Trust Research Programme in Nairobi. 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. For this study we are working closely with the Ministry of Health, Nairobi city Council, and Kenya Paediatric Association among others.

The study: In this study, we are trying to establish what care is currently available to sick newborns in Nairobi. At this stage we are narrowing down a long list of facilities to identify those that provide 24/7 inpatient care for sick newborns. Those facilities that do provide this type of care will then be eligible for the study in which we would like to do an assessment of the care provided at the facility. If the facility is identified as being eligible then we will explain the study in full detail with the appropriate authorities (e.g. the owner) of the facility. It will be up to them to decide to partake or not. We have full ethical approval for the study.

What are want: For now we would like to know if the facility is open and caring for patients 7 days a week 24 hours a day and if it has the ability to keep sick newborns as inpatients for more than 24 hours.

Noting down the answers on the facility form (appendix), ask for the following information:

iv. 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 viii. If yes, continue.
v. 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 viii. If yes, continue.
vi. Inform the contact that the facility will be eligible for a forthcoming study and ask who would be the most appropriate person to contact in the future to discuss the study further (i.e. person in charge of the facility). Note the name, position, and contact details of this person. Explain that the preparation of the study will take some time so it might take a while (several weeks) for us to be in touch again.
vii. If not already available, ask for the address of the facility and details on who the authority of the facility is (i.e. who/what organisation is the owner).
viii. Ask if they have a rough idea of approximately how many maternal admissions and newborn inpatient admissions they have every year.
ix. Thank the contact for their help. Offer them your name and contact number in case they want to contact you in the future.

KEMRI | Wellcome Trust

UNIVERSITY OF OXFORD

Name of facility	Contact number	Open 24/7?	NBU?	NBU 24/7?	Name of person to contact in future	Position of this person	Phone number of this person	Address of facility	Ownership? (local gov, private org, etc)	Maternal admissions per year	Newborn admissions per year	Comment

5. Establishing eligibility and obtaining permission from facilities

Document #1-3:

1. SOP2.0: Establishing eligibility and obtaining permission from facilities

    Appendix 1: List of all facilities

    Appendix 2: Nairobi City County Letter

    Appendix 3: Facility information and permission form

    Appendix 4: Lay summary

    Appendix 5: Information about eligible facility sheet

    Appendix 6: Tally sheet for newborn admissions

    Appendix 7: List of facilities to be visited to determine eligibility

    Appendix 8: List of facilities to be visited to seek permission

2. SOP2.1: Visiting facilities to obtain permission
3. Facility information and permission form

6. Data collection tools, SOPs, and associated documentation

Documents #4-19

4a. Structural assessment tool version 1
4b. Structural assessment tool version 2

Errors were corrected in structural assessment version 1 on 3rd August 2015. Assessments completed using version 1 of the structural assessment were updated to reflect version 2.

5a. SOP3.0: Structural assessment version 1
5b. SOP3.0: Structural assessment version 2
5c.SOP3.1-Structural assessment data entry version 1

SOP3.0 was updated on 3rd August 2015 to clarify the definition of when an item is considered to be 'on ward' and when 'in store'.

6. SOP5.0: Nursing interview
7. Nursing interviewee selection form
8. Consent form for nursing questionnaire
9. Nursing questionnaire tool
10. SOP5.1: Nursing questionnaire instructions
11. SOP5.2: Vignette instructions for nursing questionnaire

12. SOP4.0: Process of data entry from registers and records
13. Maternal admissions sampling sheet
14. Maternal admissions register tool
15. SOP4.1: Data entry from maternal admission register
16. Neonatal admissions register tool
17. SOP4.2: Data entry from newborn admission register
18. Neonatal medical record tool
19. SOP4.3: Data entry from neonatal medical records

7. Data management

Document **#20: Data management SOP**

8. Feedback of results to facilities

[pending]

9. Protocol

Document #21

21. Study protocol (without lay summary or appendices)

10.Ethical approval letters

Documents #22-23

22. SSC approval letter

23. ERC approval letter