## 1.    **Title of the Project**:

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.

## 2.    **Investigators and Institutional Affiliations**:

Dr Georgina Murphy [1, 2] (Principal 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

*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. Members are listed in Appendix 1.*

## 3.    **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.

## 4.      **Introduction/Background**:

Globally, substantial progress has been made in reducing child mortality, declining from 12.6 million deaths in 1990 to 6.6 million in 2012 [1]. However, the majority of countries in Africa, including Kenya, have not made sufficient progress to meet their 4th Millennium Development Goal (MDG4) targets to reduce child deaths by two thirds between 1990 and 2015. In part, this is because there has been little reduction in neonatal mortality. Consequently, neonatal mortality now accounts for over 40% of all child mortality in many of these countries [2]. In Kenya, the estimated under 5 mortality is 74/1000, 31/1000 of which are deaths during the first 28 days after birth (i.e. the neonatal period) [3]. In many African and South Asian countries, absolute rates of neonatal mortality are higher by 10 fold or more than in developed countries [2]. In order to make continued improvements in child survival, significant emphasis on, and progress in, reducing neonatal mortality will be needed. Indeed, reducing neonatal mortality is now emerging as a global priority [4].

The major causes of neonatal mortality and long-term morbidity include: pre-term birth; intra-uterine growth restriction; intrapartum-related neonatal encephalopathy in the perinatal period (often referred to as asphyxia); and infection [2]. Much of the mortality and morbidity associated with these conditions is preventable with cost-effective interventions and the provision of universal access to basic, but high quality health services [5, 6]. The need for the provision of care along a continuum is increasingly recognised [7, 8]. Interventions that women receive during pre-pregnancy, pregnancy, and childbirth have a beneficial health impact on their newborn children [8, 9]. Simple treatments such as cleansing of the umbilical cord and promotion of immediate breastfeeding can prevent a significant proportion of neonatal infections and neonatal resuscitation is a key low-cost and simple intervention for reducing intrapartum-related neonatal deaths. The provision of this basic and comprehensive emergency obstetric and newborn care (EmONC) is of vital importance for disease prevention and reduction in intrapartum mortality [10, 11]. In addition, the management of neonatal conditions through facility-based inpatient interventions, such as phototherapy for jaundice, intravenous antibiotics for sepsis, and oxygen for respiratory distress syndrome, is of vital important in reducing neonatal mortality [10, 11].

The proportion of mothers accessing facility-based care has increased in many low- and middle-income countries since the 1990s [6]. In Nairobi City County an estimated 89.4% of births take place within health facilities, compared to 42.6% on a national level [12]. Within Nairobi, approximately equal numbers of these facility-based births take place in the public and the private sector (45.7% and 43.7% of births, respectively) [12]. The promotion of facility-based care begins at the community level, where there are mothers' groups that promote appropriate maternal and neonatal health care practices [13]. These practices include encouraging health service utilisation and promoting delivery by a skilled provider [14] and have become a major goal of many health systems [15].

While international and national policies recognise the need to create demand for, and supply of, skilled delivery and maternal health facilities, rather less attention has been paid to the provision of

high quality care for high risk or sick newborns in low-resource settings. Many mothers deliver in small facilities that are poorly equipped to provide appropriate care to a severely ill newborn. Even where such sick newborns access hospital care, data from Kenyan public hospitals would suggest that the quality of care is often poor [16]. The need to strengthen facility-based care for sick newborns is of global concern and was highlighted by Bhutta and colleagues in their recent comprehensive overview of interventions and preventable deaths of mothers, newborns, and stillbirths. They reported that *'[their] estimates suggest the greatest effect [on newborn survival] would come from a focus on the care of small and ill neonates, which has been neglected to date and would prevent almost 600 000 newborn deaths per year by 2025. Much of this effect is potentially achievable through newborn care services in subdistrict and district level hospitals.'[5]* However, while useful for advocacy at a global scale these estimates do not help health service planning at meaningful administrative scales.

At a local level what is needed is (1) an estimation of the number of cases per year that will require specific forms of health services and (2) an assessment of the current capacity, quality, and utilisation of existing services providing inpatient newborn care. In ideal situations, this burden of need can be derived from health information systems that provide comprehensive data from vital registration, health facility utilisation, and cause of death notification. However, in settings where such information systems are weak (including Kenya [17]) the burden of need must often be estimated epidemiologically from knowledge about the incidence of illness episodes [18, 19]. The care required to treat major newborn conditions includes interventions such as IV fluids, nasogastric feeding, injectable antibiotics, oxygen, phototherapy, treatment for convulsions, and warming. Such interventions form part of comprehensive facility-based inpatient care for newborns, which is often delivered at secondary and tertiary level facilities [11, 20]. However, in their recent systematic review of health facility assessment tools for monitoring the ability to deliver care in low- and middle-income countries (LMICs), Nickerson et al noted *"a preference towards the evaluation of primary care services, with secondary and tertiary care being absent from many assessments, despite a need for these services in LMIC"* [21].

In Nairobi City County, over half the population of 3.14 million people are estimated to live in low-income areas [22], inequality is massive, and estimated infant mortality is higher than the national average [16]. It is for this population that we will estimate the likely burden of need for, and availability and quality of, inpatient neonatal care. With the new constitutional dispensation, the county government provides the most heavily subsidised inpatient care services to this population. Recent national government policy mandates the provision of free facility-based maternal care, guarantees Kenyans the right to the 'highest attainable standard of health which includes the right to health care services', and aims to 'attain universal coverage of critical services that positively contribute to the realization of [this] overall policy goal' [20, 23, 24]. As part of the new constitutional arrangements, the county officers also have responsibility for stewardship of health care provision in the private and not-for-profit sectors [23]. However, services provided by these sectors are poorly characterised and knowledge on which services are provided, where, by whom, and of what quality is very limited (Nairobi City County Executive for Health, personal communication). This undermines efforts at monitoring progress in, and planning for, provision of accessible high-quality care.

In order to plan improvements in the equitable provision of care, it is first necessary, therefore, to better understand how the need for newborn health services compares to the provision, capacity, quality, and accessibility of existing newborn services. Furthermore, insight into the characteristics and distribution of these services and the distribution of incidence of neonatal morbidity will be important

to inform the design of possible interventions to improve the provision and quality of, and access to, facility-based newborn care in Kenya. This work, while being done in Nairobi, will also develop methods of interest nationally as Kenya develops longer term plans for enhanced service provision.

In this study, assessment of quality of care will follow the Donabedian model encompassing measures of structure, process, and outcome.[25] The structure describes the setting in which care occurs; the process refers to what is done in giving and receiving care; and the outcome is the effect of care on the health status of the patient or population. Outcome is usually the ultimate dimension of interest. However, measuring outcome as an indication of quality has several limitations in this setting. Detailed data are rarely captured on patient outcomes in Kenya. As in other settings, data on outcome can be hard to interpret as they can be affected by more than just the healthcare received. Patient outcome can be effected by lifestyle factors, socio-economic status, and environmental factors of the population as well as the case-mix of patients attending a facility. In this study therefore, although crude outcome indicators are captured, we will focus on the structure and process dimensions of quality of care. By doing so, we hope to identify aspects of structure and process that could be improved, thus ultimately improving the quality of outcome. **Appendix 2** provides an overview of the structure, process, and outcome indicators evaluated in this study.

### 5.      **Justification for the Study**:

To make significant progress in reducing preventable neonatal morbidity and mortality in Kenya, improved provision of, and access to, high quality facility-based care will be needed. This research will provide policy makers with vital information about the extent and quality of inpatient newborn services in Nairobi City County. Additionally, it will provide an estimation of shortfall in these services for meeting the expected demand. Such information will help to inform discussion with policy makers and stakeholders on how and where to improve services to promote equitable access. In particular, the outcomes of this study will facilitate the implementation of the recently published Kenya Essential Package for Health and Kenya Health Sector Referral Strategy, both of which are governmental strategic plans for 2014-2018. Furthermore, these data will form the foundation of future work at a larger scale and studies planned to assess methods by which the delivery of neonatal care within health facilities can be improved.

### 6.      **State the Null Hypothesis**:

This is an observational study to estimate the provision and quality of, and access to, facility-based care for sick newborns in Nairobi City County. These estimates will be used to explore the potential scale of the gap between need for, and supply of, quality care to newborns within the County. As such, a null hypothesis is not appropriate.

7.  **a) <u>General Objectives</u>**:

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.

**b) <u>Specific Objectives</u>**:
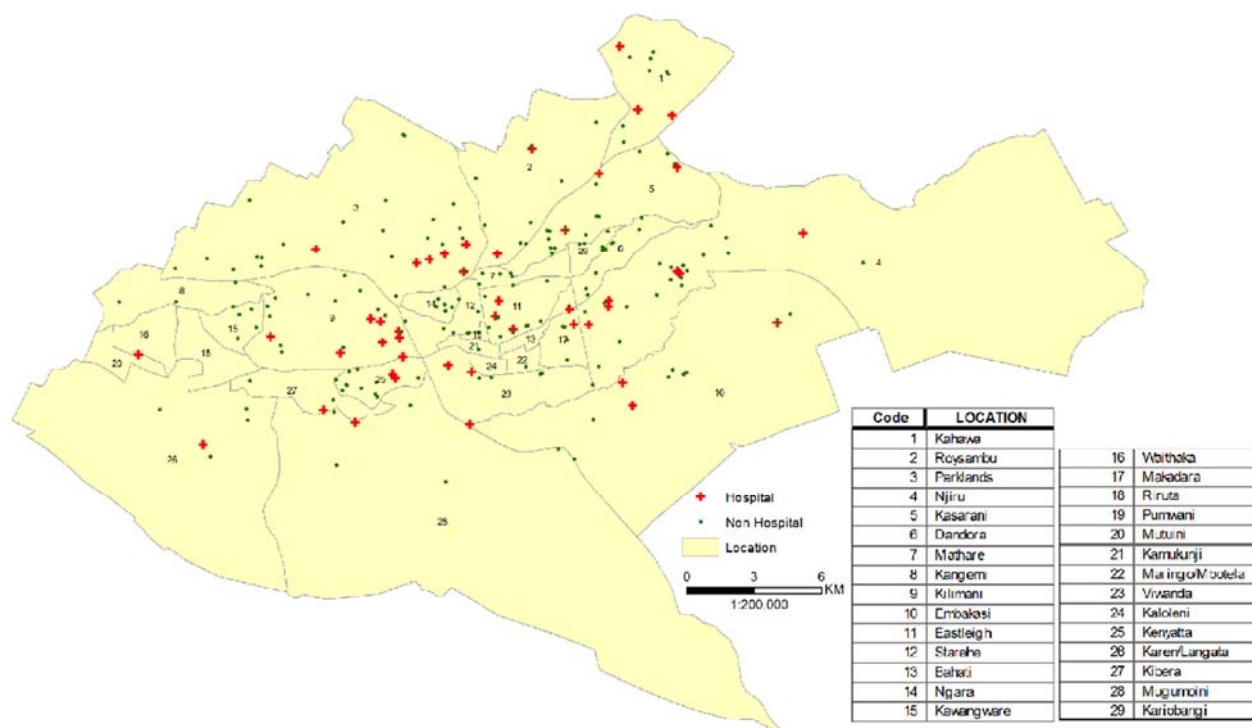
i.   Estimate the magnitude and distribution of the **burden** of expected neonatal morbidity in Nairobi City County.
ii.  Map the location of existing facilities capable of **providing** inpatient newborn care.
iii. Estimate the **utilisation** of facilities providing inpatient newborn care and profile the case-mix of neonatal morbidities treated at these facilities.
iv.  Assess the **quality** of EmONC and inpatient newborn care provided in terms of structure and process.
v.   Describe any **shortfall** between the expected incidence of disease (burden) and the capacity for caring for sick neonates (supply).

8.    **<u>Design and Methodology</u>**:

a)    **Study site (geographical)**

This research will focus on Nairobi City County, Kenya, and the health facilities there within (**figure 1**). Nairobi City County has a population of 3.14 million [26], with over half the population living in low-income areas where infant mortality is higher than the national average. This reflects the massive inequity in Nairobi (the GINI coefficient, an index of inequality, for Nairobi is as high as 0.59, a value well above the national average) with the proportion of the most poor estimated to have risen in Nairobi since the late 1990's in contrast to the situation in rural areas [22]. Available data from Kenya's census and other surveys will be used to develop a population distribution and density map at suitable geographic scale (census enumeration zone) that will provide the basis for estimating the likely number of births and episodes of neonatal illness per year in each area. Within Nairobi we will identify the facilities providing inpatient newborn care. These facilities will be the focus of subsequent data collection based on inclusion criteria described below in section 8(b).

**Figure 1:** Nairobi City County healthcare facilities with available coordinates in public, private, and not-for-profit sectors. (Red markers indicate facilities named as hospitals)



| Code | LOCATION | | |
|------|----------|------|------------|
| 1 | Kahawa | | |
| 2 | Roysambu | 16 | Waithaka |
| 3 | Parklands | 17 | Makadara |
| 4 | Njiru | 18 | Riruta |
| 5 | Kasarani | 19 | Pumwani |
| 6 | Dandora | 20 | Mutuini |
| 7 | Mathare | 21 | Kamukunji |
| 8 | Kangemi | 22 | Maringo/Mbotela |
| 9 | Kilimani | 23 | Viwanda |
| 10 | Embakasi | 24 | Kaloleni |
| 11 | Eastleigh | 25 | Kenyatta |
| 12 | Starehe | 26 | Karen/Langata |
| 13 | Bahati | 27 | Kibera |
| 14 | Ngara | 28 | Mugumoini |
| 15 | Kawangware | 29 | Kariobangi |

## b)      Study populations

The focus of this study is on newborns requiring inpatient care in health facilities in Nairobi City County due to conditions including pre-term birth, low birth weight, small for gestational age, anaemia, severe infection, jaundice, intrapartum-related neonatal encephalopathy, respiratory distress syndrome, and major congenital malformations. We are interested in the population of ill newborns that arises from the general Nairobi population. We are also interested in the 'population' of facilities providing care to these ill newborns. Data collection for this study will therefore take place in facilities within Nairobi City County that provide maternity services and inpatient newborn care 24 hours a day for 7 days a week (24/7). These facilities will be identified according to the inclusion and exclusion factors outlined in **figure 2** and described in more detail below in section 8d.

**Figure 2:** Flow chart of inclusion and exclusion criteria
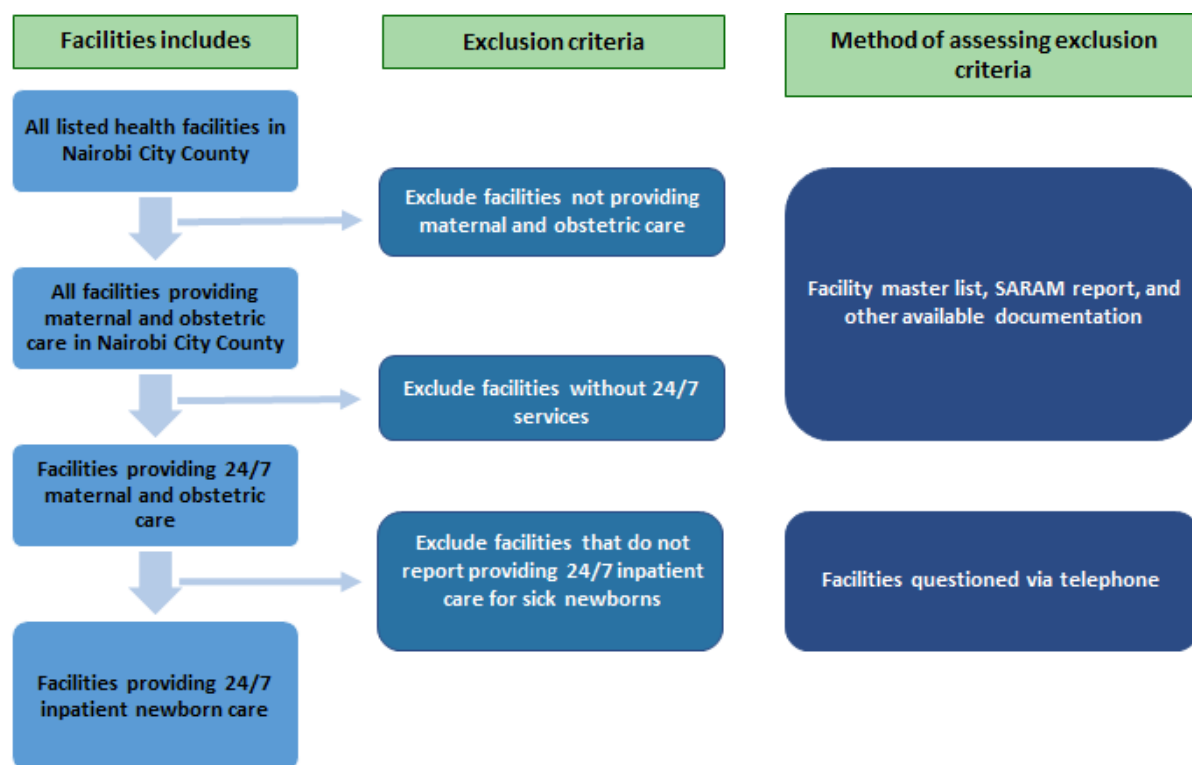


### c)      Sampling

We anticipate approximately 30 eligible facilities providing 24/7 maternity services and inpatient newborn care. All of these facilities will, therefore, be invited to partake in the study. If facilities decline to participate entirely (an eventuality we do not feel is likely) or decline to participate in any of the specific steps outlined below this will be recorded to inform final interpretation of any results.

Step 1: Assessing the population burden of disease

There are no sampling considerations in this step of the study as this will be a literature review with incidence estimates applied to the total Nairobi City County population.

Step 2: Utilisation – Review of admission registers

Tallies from newborn admission registers will be used to obtain an estimation of the number of cases admitted per year at each eligible and participating facility. All newborn admission registers for a period of one year (March 2014 to February 2015 inclusive) will be included in this utilisation and case-mix assessment. There are, therefore, no sampling considerations.

In order to supplement information gained from the neonatal registers and further explore the catchment area for a facility, maternal admission registers will be reviewed and information about residency and pregnancy outcome of women attending the facility to deliver will be obtained. Where facilities deliver 500 or fewer women per year the register for a full year (March 2014 to February 2015 inclusive) will be reviewed. Registers from those facilities that deliver more than 500 women during

the sampling time-frame (March 2014 to February 2015 inclusive) will be sampled. The total number of admissions during the sampling time-frame will be established in each facility. The appropriate proportion of weeks will then be sampled to obtain a total number of weeks expected to yield 500 deliveries per facility. Sampled weeks will be evenly distributed throughout the year. For the largest facility likely to be included, Pumwani Maternity Hospital, 500 deliveries represent approximately 2% of annual deliveries. In this scenario of the largest facility, with a sample of 500, we would be able to estimate a sample proportion (of residency and pregnancy outcome) of 50% with a 4.34% margin of error. For medium sized facilities with approximately 4000-7000 deliveries each year, this margin of error would be 4.10-4.22%.

Step 3: Structural assessment – Resource inventory

All eligible facilities providing permission will be visited and a structural (resource) assessment completed.

Step 4: Process assessment –Nursing questionnaire

All nursing staff on-duty at the time of a scheduled research team visit providing care to sick newborns or on the maternity ward will be invited to partake in a questionnaire. Where more than three nurses are on-duty in the maternity ward or newborn unit, a random sample of half (rounded upwards) of the nurses from that ward and/or unit with more than three nurses will be selected for interview from a list of all on-duty nurses. E.g. If there are >3 on-duty on the maternity ward and ≤3 nurses on-duty in the newborn unit, then the maternity ward will be sampled but all nurses in the newborn unit will be invited to interview. If >3 nurses are on-duty in both the maternity ward and newborn unit then half of the nurses will be independently selected from both the ward and unit.

If a nurse from the sample declines to partake in the interview then another nurse will be randomly selected from the list in their stead. Nurses who report to provide both types of care at the facility will only be counted once in the sampling. They will be counted as part of the ward/unit in which they are primarily providing care at the time of the research team visit.

Step 5: Process assessment – Review of inpatient newborn case records

Across all facilities taking part in this study, we plan to sample 800 newborn case records. With a total population of 100,000 admissions (above which there is little change in sample size estimations), 800 records would estimate a 50% sample proportion with a margin of error of 3.45%. Given that the data generated from these reports will be clustered in facilities, we might expect a design effect, which will be accounted for during analysis. Allowing for a design effect of 2, a sample size of 800 records would estimate a 50% sample proportion with a margin of error of 4.89%. In exploratory analyses, if we compare two groups of facilities with population ratios 1:1 and allowing for a design effect of 2, we will be able to detect a 30-35% relative difference from a base proportion of 50% using a sample size of 400 for each group (totalling to 800) with 90% power and 5% margin of error (table 1). Care will be taken during any stratification of facilities to ensure that confidentiality is retained and facilities are not identifiable when stratified during analyses of quality of care.
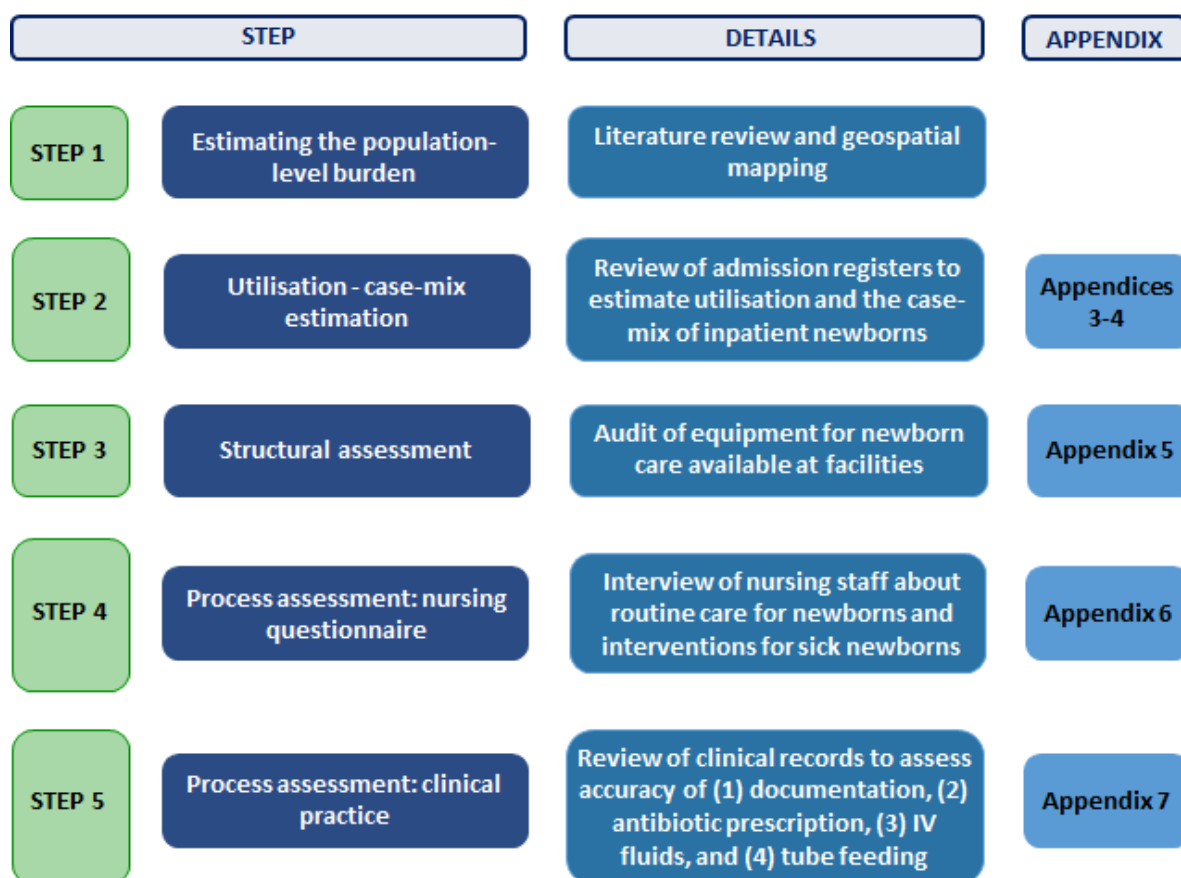
**Table 1:** Sample sizes required to detect relative difference with 90% power and 5% margin of error, allowing for a design effect of 2.

| Base | Relative difference | | | | | | |
|------|------|------|------|------|------|------|------|
| | 10% | 15% | 20% | 25% | 30% | 35% | 40% |
| 0.3 | 9646 | 4246 | 2364 | 1496 | 1026 | 744 | 562 |
| 0.4 | 6286 | 2784 | 1560 | 992 | 684 | 500 | 378 |
| 0.5 | 4268 | 1908 | 1076 | 690 | 480 | 352 | 268 |
| 0.6 | 2924 | 1322 | 754 | 488 | 342 | 254 | 196 |
| 0.7 | 1964 | 904 | 524 | 346 | 246 | 184 | 142 |
| 0.8 | 1244 | 592 | 352 | 238 | 172 | 130 | 104 |

Once the total number of neonatal admissions per facilities for a year is estimated, the sample of 800 records will be distributed across facilities such that the same proportion of records is sampled from each facility. The sample at each facility will be obtained by selecting the most recent case record and going back in time through the records until the appropriate sample size is obtained.

### d)      Data collection procedures

This study will begin by estimating the population level burden of major neonatal conditions through review of the literature and geospatial mapping (step 1). Data collection will then focus on estimating the availability and quality of facility-based inpatient newborn care and will be conducted in four steps (steps 2-5). The first of these steps will be a review of admission registers in order to estimate utilisation and characterise the case-mix of patients accessing facilities providing inpatient newborn care (step 2). We will then conduct a structural (resource) assessment of these health facilities (step 3). After which, we will administer a questionnaire to nursing staff at facilities to assess their knowledge of the correct procedures to follow when delivering care and about interventions and equipment at the facility (step 4). Lastly, a retrospective case audit will be done to assess the degree to which prescribed care corresponds to that recommended by the Basic Paediatric Protocol national guidelines using a set of key practice indicators (step 5) [27, 28]. **Figure 3** provides an overview of the steps in this study and their associated appendices.

**Figure 3:** Overview of study procedures



| STEP | | DETAILS | APPENDIX |
|---|---|---|---|
| STEP 1 | Estimating the population-level burden | Literature review and geospatial mapping | |
| STEP 2 | Utilisation - case-mix estimation | Review of admission registers to estimate utilisation and the case-mix of inpatient newborns | Appendices 3-4 |
| STEP 3 | Structural assessment | Audit of equipment for newborn care available at facilities | Appendix 5 |
| STEP 4 | Process assessment: nursing questionnaire | Interview of nursing staff about routine care for newborns and interventions for sick newborns | Appendix 6 |
| STEP 5 | Process assessment: clinical practice | Review of clinical records to assess accuracy of (1) documentation, (2) antibiotic prescription, (3) IV fluids, and (4) tube feeding | Appendix 7 |

Step 1: Estimation of the population level burden of major neonatal conditions

To estimate the need for inpatient newborn services, birth rates in Nairobi City County will first be estimated using census data and demographic surveillance reports. Existing systematic reviews (e.g. [29] and see [30]) will then be updated to derive plausible morbidity incidence estimates (per 1,000 live births) for key newborn conditions. These conditions include pre-term birth, low birth weight, small for gestational age, anaemia, severe infection, jaundice, intrapartum-related neonatal encephalopathy, respiratory distress syndrome, and major congenital malformations. Where systematic reviews are not available for the morbidity incidence of a condition of interest, published literature will be searched for relevant studies and reports. The available literature will be discussed with the expert group in order to decide on the incidence estimates that are most applicable to the Nairobi City County. Based on these findings, estimates with appropriate credible ranges will then be made of the anticipated need for neonatal services. This will be done using spatial-temporal regression modelling and small area estimation approaches that, where possible, take account of variability in maternal and socio-economic risk factors, amongst others, across Nairobi's population [31, 32]. The unit of analysis for this modelling will be enumeration zones where census data are available, e.g. information on live births. If maternal and socio-economic risk factors are included in the model, then the unit of analysis is likely to be larger and dependent on information available from individual demographic surveillance reports.

Identification of facilities to be included in steps 2-5

Before beginning data collection, eligible facilities must first be identified. We will begin by collating and reviewing existing datasets of health facilities with which co-applicants are already familiar given prior work on modelling access and burden of disease in Kenya [33, 34]. In particular, data will be obtained from the recent 'Service Availability and Readiness Assessment and Mapping (SARAM)' survey conducted by the Ministry of Health and partners in 2013. Such data, combined with earlier work to develop the Kenyan Health Facility Master List [34, 35], population data, and data obtained from Nairobi City County on facility workloads (**https://hiskenya.org/**) and human resource complements [36] will be used as the initial platform to characterise the health services in Nairobi (see **appendix 3** for list of variables collected by the Kenyan Health Facility Master List).

From the complete list of all health facilities in Nairobi City County we are interested in identifying facilities that provide 24/7 maternity services and inpatient newborn care. Based on existing information (advisory group opinion – experts from public and private sector health care, the Ministry of Health, and Nairobi City Council – please see **appendix 1** for list of members), it is anticipated that approximately 30 facilities will be identified that provide such care. A much larger number of small facilities provide basic obstetric care (including many private nursing homes) but refer sick newborns (or complicated deliveries) to these larger facilities. We will identify facilities providing 24/7 maternity services and inpatient newborn care in a stepwise process as outlined in **figure 2**. This process of identifying facilities for inclusion in the study was designed in consultation with the expert advisory group. This selection process is designed to focus on facilities that are attempting to provide comprehensive essential obstetric care and inpatient care for sick newborns rather than smaller facilities that do not intend to, and are not organised to, provide these services. These smaller facilities are instead expected to refer the baby and mother to facilities (that are the focus of this proposed work) where comprehensive essential obstetric care and newborn care should be provided. Once the list of eligible facilities has been compiled, expert opinion and a snow-balling technique will be used to ensure all the private and not-for-profit sector facilities routinely providing 24/7 inpatient neonatal care, but not formally registered, are identified and included.

All eligible health facilities in Nairobi City County providing permission will be included in this study. These facilities will be approached with the approval of, and with introduction by, the Nairobi City Council, the Ministry of Health, and the Kenya Paediatric Association. Where relevant, this introduction will be done after contacting the overall authority for the facility. For example, in the case of private facilities, the provider in charge of a network of facilities will first be contacted for their permission. Working with the expert advisory group, we will create a list of contacts for the eligible private and not-for-profit facilities. These contacts will be invited to a forum with the researchers to discuss the study and their potential involvement in it. The private and not-for-profit sectors will also be engaged through existing fora, such as the Christian Health Association of Kenya.

Step 2: Utilisation – Review of case-mix from admission registers

Data collection in facilities identified as providing inpatient newborn care (as outlined in section 8b) will begin with an assessment of the utilisation of those facilities. Information about the number of patients being admitted to each facility and characteristics of those patients will be collected as outlined in **table 2**. Information about the workload (number of admissions per year) of facilities and the length of stay of inpatients will provide insight into the total utilisation of the facility. Residency

and referral data will provide insight into access to and referral patterns between facilities. Patient diagnosis and outcome data will allow us to assess the case-mix of patients receiving care. All of this information will be obtained from the newborn admission registers at each facility. All registers for inpatient newborns for the preceding year will be included for assessment.

**Table 2:** Data collection for description of utilisation of and access to health facilities

| Data needed | Method of data collection | Information needed for: |
|---|---|---|
| Workloads | Data captured from facility information systems and/or tallying of admission registers for the previous year. | Estimating utilisation |
| Length of stay | Recorded from newborn admission register | Estimating utilisation |
| Patient diagnosis | Recorded from newborn admission register | Describing case-mix of patients utilising facilities |
| Patient outcome | Recorded from newborn admission register | Describing case-mix of patients utilising facilities |
| Residence of patients | Recorded from neonatal admission register and supplemented with information about women delivering at the facility from maternal admission registers. | Mapping of access |
| Referrals | Recorded from newborn and maternal admission registers. Ask nurse in charge about common practice. | Mapping of access and referral patterns |

Information on inpatient newborn workloads at each facility will be supplemented with further information about the pregnant women admitted to the facility to deliver their babies. At each facility, we will review maternal admission registers for information of women's residency and their pregnancy outcomes. Such information will add insight for estimation of the catchment area of the facilities and access patterns of newborn patients[1]. The selection of the mothers' admission registers is outlined in section 8c.

These data on utilisation and access will be used for comparison with the expected need for services, derived from literature-based estimates of incidence of major neonatal conditions applied to the Nairobi City County population (as described in section 8e below).

Data will be collected by a trained survey team abstracting information from admission registers into a structured electronic tool (for current tools, pending piloting, see **appendix 4** for the neonatal admissions register tool and **appendix 5** for the maternal admissions register tool) and using strict standard operating procedures. The questionnaire will first be piloted in a non-participating facility. In facilities with electronic admission registers, access to these registers will be requested and the relevant fields of data will be abstracted into our RedCap database. Depending on the format in which the facility collects their electronic data, this abstraction will either be done automatically (ensuring

---

[1] We expect information on residency to be recorded as 'location' and 'sub-location'. These estimates are therefore likely to provide only a broad overview of the patterns of access. However, a similar method of estimating patient residency based on register information was recently used to map paediatric patients in Mombasa [Berkley J., unpublished]. This map showed distinctly similar patterns of access when compared to a map generated using GPS coordinates of where the patients lived.

that only the data variables in our data capture tool are stored) or by manual data entry as per paper registers.

Step 3: Structure assessment

The structure assessment has three components (for current tools, pending piloting, see **appendix 6** for the assessment form). Firstly, the nurse-in-charge will be asked about staffing at the facility. Information will be requested about the number and types of staff working on a full-time and part-time basis at the facility. In order to provide further insight for step 2 of this study, the nurse-in-charge will also be asked about common referral practices of the facility. Secondly, an infrastructure assessment will be conducted by observation. This assessment will record information on the number of cots for sick newborns, availability of a clean source of water, reliable electricity, laboratory services, safety features for staff and patients, and sanitation such as a sink with soap for hand washing. The third section of the structure assessment will be an equipment inventory to record the availability of equipment, drugs, feeds, and job aides needed to provide high quality care for sick newborns. Equipment will be considered to be present if it is both in working condition and accessible in the location in which sick newborns are cared for or, in the case of equipment for care directly after delivery, accessible on the delivery ward. The structure assessment will be performed by a trained assessor in consultation with facility staff using strict standard operating procedures. Information from the structure assessment will provide insight into the structural quality of facilities providing inpatient newborn care and their capacity to perform key interventions for newborn care. Similar tools for structure assessment of newborn care have previously been used successfully by investigators [27, 37].

Step 4: Process assessment –Nursing questionnaire

A facility may have the structural capacity to provide care for sick newborns, however, it is also important to understand the quality of the process of care delivery. We are, therefore, also interested in gaining insight into the knowledge and experience of nursing staff with regard to EmONC and management of sick newborns.

In order to gain insight into the nursing care provided at the point of newborn delivery and during newborn inpatient care, a questionnaire will be administered to on-duty nurses. The questionnaire will be composed of four sections and will focus on key interventions for routine care (such as routine delivery care and elements of comprehensive emergency obstetric care, breastfeeding, immediate postnatal care, and infection management), newborn resuscitation, and management of severally ill newborns (including administering antibiotics, fluids, feeds, oxygen, and treatment for jaundice and convulsions) (for the current questionnaire, pending piloting, see **appendix 7**).

- Section 1 will collect information about the nurse's training, type of employment, and basic demographic details. The name of the nurses will not be recorded and confidentiality will be assured.

- Section 2 will be formed of knowledge-based questions and will be tailored to the work area of nurses (maternity department / newborn ward). Assessors will pose questions regarding the steps nursing staff should take when delivering key interventions in comprehensive emergency obstetric and newborn care (a) during childbirth and (b) for sick newborns. Most questions will require multiple responses/answers corresponding to key steps that must be

taken in order to deliver the required care for the intervention referred to in the question. These steps (and therefore answer options) will be bases on the national Emergency Obstetric and Neonatal Care guidelines and the Kenyan Basic Paediatric Protocol Guidelines and agreed by the expert advisory group. Answers provided by a nurse for a specific question will be checked off this list of possible answers/key steps (similar methods are described in Kim *et al* [38]).

- Section 3 of the questionnaire will ask nurses to comment on whether they experience that key interventions are always, sometimes, or never performed at the facility on occasions when the nurse feels that the intervention is needed.

- Lastly, section 4 will ask nurses to comment on the frequency with which the equipment they need to perform key interventions has previously been available to them at the facility.

Management staff at the facility will be contacted prior to the visit to arrange a convenient time for the assessment. However, they will be requested not to inform the nursing staff of the visit before the day of assessment, therefore reducing the opportunity for staff to revise their knowledge before being interviewed. Only nursing staff providing written informed consent will be interviewed. Interviews will be conducted by a trained survey team using strict standard operating procedures. The questionnaire will first be piloted in a non-participating facility.

Step 5: Process assessment – Review of clinical medical records

Further insight into the quality of the process of care provided at these facilities can be obtained by retrospectively reviewing the case records of inpatient newborns. From these records it is possible to ascertain the care that was prescribed for a patient by a clinician. This provision of care can then be compared with the care recommended by the Kenyan Basic Paediatric Protocol Guidelines for the recorded patient diagnosis. Review of case records also provides insight into the adequacy with which case details are documented.

Based on the sampling process outlined in section 8b, 800 inpatient records will be sampled for review from facilities. From the newborn medical records we will record information on the accuracy of antibiotic and feeding prescriptions, evidence of monitoring of vital signs, and adequacy of clinical documentation of the initial assessment of a sick newborn, using methods shown to be feasible [27, 39, 40] (for current tools, pending piloting, see **appendix 8**). Specifically, dosages and types of prescribed antibiotics (as recorded on the treatment sheets) at admission will be compared against those recommended in national guidelines. Prescriptions of intravenous fluids and feeds will be assessed in the same manner. Evidence of monitoring of vital signs, weight, and fluids will be defined as the presence of a chart(s) in which these were recorded at intervals. The availability of information on initial clinical assessment from the record will also be records in order to describe the adequacy of documentation.

Data will be collected by a trained survey team abstracting information from medical case records into a structured questionnaire (see **appendix 8**) and using strict standard operating procedures. The questionnaire will first be piloted in a non-participating facility. A 10% random sample of records will be independently abstracted by a team supervisor and results of the two procedures will be compared. Where disagreement occurs between the two abstractions of the same record, this discrepancy will

be discussed by the data entry clerks and the team supervisor to decide on the correct recording. Where agreement cannot be reached, a decision will be made by a study investigator after hearing the reasons for the disagreement.

In facilities with electronic medical records, access to these records will be requested and the relevant fields of data will be abstracted into our RedCap database. Depending on the format in which the facility collects their electronic data, this abstraction will either be done automatically (ensuring that only the data variables in our data capture tool are stored) or by manual data entry as per paper records.

### e)        Data analysis

Describing availability of health care for sick newborns

Our analysis will begin by describing the availability of care for sick newborns in Nairobi City County. Facilities deemed to provide inpatient newborn care will be mapped. This map will include information on the type, ownership, size, workload, and level of care provided by each facility. The level of care will be described in terms of the structure of the facilities (step 2 of this study). This information on structure will be used to categorise facilities into basic and comprehensive levels of neonatal care in consultation with the expert advisory group. Specific details on the services each facility has the capacity to provide will also be made available to Nairobi City County and the Ministry of Health.

This description of the overall availability, characteristics, and location of services within Nairobi City County will enhance the Kenya Health Facilities Master List and should be of use to local and national policy-makers as part of efforts to improve service provision. Additionally, such information will be useful for facilities when designing appropriate referral plans in line with the recently published 2014-2018 Kenya Health Sector Referral Strategy [41].

Indicators of quality of care

Quality of newborn care will be assessed by classifying it into the three components defined by Donabedian [25]: (1) structure, characteristics of the setting in which care is administered, and (2) process, the essential procedures in the delivery of care. Structural capacity indicators include the percentage of facilities with: (a) infrastructure indicators— such as a clean water source, reliable electricity, and a sink with soap for hand washing; (b) EmONC and inpatient neonatal care equipment— such as bag and mask, oxygen cylinder, suction machine/nasal aspirator, incubator, baby scale, cup to measure expressed breast milk, and intravenous fluid and infusion set; (c) Job aides — such as feeding charts, fluids charts, APGAR charts, treatment sheets, and guidelines and protocols; (d) essential drugs necessary for EmONC and care of sick newborns — such as ampicillin, gentamicin, diazepam and dexamethasone, and (e) profile of human resources for EmONC and management of sick newborns. (2) Process indicators included: (a) nursing knowledge questionnaire score; (b) frequency of performance of signal functions according to nurses; (c) adequacy of medical record documentation; (d) accuracy of antibiotic prescription by clinicians; (e) accuracy of feeding prescribed by clinicians; and (f) evidence of regular monitoring of vital signs. (3) The outcome indicator captured will be the discharge outcome of newborns i.e. alive, dead, referred, or absconded. We will work with the expert advisory group to explore ways to most informatively summarise these elements of quality for policy

makers and stakeholders. This information will provide insight into the strengths and weaknesses of the provision of care for sick newborns in Nairobi City County.

<u>Describe the gap between need and access</u>

It is anticipated that there will be a shortfall in service provision, with some ill newborns not receiving the standard of care they require. We will formally explore this by comparing an estimation of need for care (step 1 of this study) with the information we collect in this study on the access to, and utilisation of, an appropriate level of care (step 2).

The map of the magnitude and distribution of the burden of newborn conditions in Nairobi City County developed in step 1 of this study will be compared with information collected about which patients are accessing and utilising care at facilities that have the ability to provide inpatient newborn care. The case-mix and numbers of patients attending these facilities will be compared with the estimated magnitude of the population-level burden of major neonatal conditions. Information about the residency of delivering women attending the clinic will be used to inform the estimated residency patterns of neonatal inpatients, therefore enabling a map of access to the facilities that provide inpatient newborn care to be created using geospatial mapping techniques. These facilities will be stratified by size and sector to enable estimates of service delivery patterns and geographic measures of access across the public, private, and non-governmental sectors to be developed for Nairobi City County. This map of access will be compared with the map of burden of disease in order to provide details of the distribution of the gap and of areas within Nairobi City County with greatest need for improved access to inpatient care for sick newborns.

Finally, we will explore approaches to estimating the possible number of lives saved by providing adequate access to inpatient care for sick newborns in Nairobi City County using internationally developed, open access modelling tools [42].

**f)      Study limitations**

This study has been designed to be of the highest feasible quality within the context of some unavoidable limitations. There are two possible limitations of this study. Firstly, the estimation of population level burden of disease (incidence estimates) is reliant on such data being available in the literature as direct estimation is outside the remit of this study. Ideally, these estimates would be based on a population-wide study conducted in Nairobi City County. However, in the absence of such data we are reliant on estimates from studies and reviews based on data from other populations. In some cases, there are thorough systematic reviews available with modelled estimates for Kenya. For other conditions, these reviews are not available and a decision will be made about the generalizability of specific study populations to the Nairobi City County population. We therefore expect that the estimates applied to this population will be somewhat crude. For the purposes of this study, our ability to confidently identify gaps between need and availability of care for sick newborns will therefore be dependent on the level of confidence with which we can estimate the population burden of disease. Secondly, our ability to estimate the utilisation and case-mix of facilities and the quality of care delivered by clinicians will be limited by the availability and quality of data recorded on the registers and records in facilities.

**9.      Data management**:

Data from the structure assessment (step 3) will be recorded on paper and data entered by trained data entry officers (**appendix 6**). The nursing staff questionnaire (step 4) will be recorded on electronic questionnaires using a laptop (**appendix 7**). These data will be captured using REDCap and will be exported for cleaning and analyses in Stata version 13 (Stata Corporation, Texas, USA). No names of staff members will be recorded on the staff questionnaires.

Staff consent forms are not anonymised. Given the small number of staff members likely to be interviewed at each facility, consent forms could potentially act as a means to identify the staff interviewed at each facility. These consent forms will therefore be kept separate from the digital questionnaire data in a secure cabinet that is only accessible to the research team.

The second type of data that this study deals with is derived from routine maternal and newborn admission registers and medical records of newborns who have already been discharged from hospital. These are, and will remain, official hospital documents and the research team will not collect or copy them (the approach is identical to an anonymised retrospective audit of case records). Secondary data from these routine records will be abstracted according to strict standard operating procedures and into a structured electronic questionnaire. These secondary data will be abstracted on-site at the hospitals without personal identifiers so data are anonymised. As part of the proposal's scientific and ethical review, permission to use these anonymised secondary data will be sought, and must also be gained, by the research team from the owners of the facilities (e.g. Ministry of Health) and the facilities themselves. The research team will only have access to anonymised, secondary data from medical records.

All data will be stored in secure KEMRI-Wellcome Trust Research Programme servers with specified researchers provided password protected access. Data held on these servers are backed-up in mirror servers also within the KEMRI-Wellcome Trust Research Programme.

## 10.        **Time Frame/Duration of the Project**:

| Task | Nov '14 | Dec '14 | Jan '15 | Feb '15 | Mar '15 | Apr '15 | May '15 | Jun '15 | Jul '15 | Aug '15 | Sep '15 | Oct '15 | Nov '15 | Dec '15 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Seek Ethical Permissions | ▓ | ▓ | ▓ | | | | | | | | | | | |
| Literature review and mapping to estimate morbidity | ▓ | ▓ | ▓ | | | | | | | | | | | |
| Identifying included facilities | | | | ▓ | ▓ | | | | | | | | | |
| Piloting of study tools and training of study staff | | | | | ▓ | ▓ | | | | | | | | |
| Structural assessment and nurse questionnaire | | | | | | | ▓ | ▓ | ▓ | | | | | |
| Review of registers | | | | | | | ▓ | ▓ | ▓ | | | | | |
| Review of clinical records | | | | | | | ▓ | ▓ | ▓ | | | | | |
| Data analysis | | | | | | | | | | ▓ | ▓ | ▓ | | |
| Write Up | | | | | | | | | | | | | ▓ | ▓ |
| Dissemination in Kenya | | | | | | | | | | | | | ▓ | ▓ |

## 11.        **Ethical Consideration**:

No empirical data collection will begin until the proper ethical approvals have been received. No intrusive procedures or hazardous substance will be used in this project.

Data collection will be conducted in four steps. The first and fourth steps of data collection involve entering data from newborn medical records and admission registers and maternal admission registers. Only data specifically outlined in the data capture tools (samples shown in **appendices 4, 5, and 8**) will be captured. No names or other identifiable data will be recorded. Instead, the data will be anonymised and each patient will be assigned a unique identifier number. Similarly, names of clinicians will not be recorded from medical records. However, the number of staff at a facility may be small, therefore there is a risk of these data being identifiable when information is being feedback to facilities on an individual basis. Care will therefore be taken in reporting findings from review of medical records to ensure that only summarised data are presented and no details of individual clinical cases can be interpreted from the reported findings. The methods used during these steps of the study are a form of service evaluation and in many countries studies using such data are exempt from ethical review.

The second part of data collection is a structural assessment of equipment. This assessment will not result in sensitive data about individuals or their performance. The third step involves interviewing members of staff. The names of staff members will not be recorded. However, as for data from clinical records, it might not be possible to confidently secure the identity of staff at smaller facilities. Therefore, as above, care will be taken in reporting of interview data to ensure that only summarised data are presented and no details of individual members of staff can be interpreted from the reported findings. Results from individual facilities will not be disclosed and instead only broad comments on levels of knowledge across groups of facilities will be made. Only members of the research team will have access to the primary interview data.

a. **Permission and consent process**

This work is being conducted together with the national Ministry of Health, the Kenya Paediatric Association, and the Nairobi City County who are included in the project advisory group. Permission to perform the structural assessment (study step 3) and review of registers and records (steps 2 and 5) will be sought from Nairobi City County, who will facilitate this study by providing appropriate letters of introduction, and relevant authorities at individual facilities, including facility directors and staff in charge of neonatal care. An information sheet detailing the study will be provided to the authorities in charge at eligible facilities when seeking these permissions (see **appendix 9**). Written informed consent will be sought (and must be obtained) from nursing staff before interviewing them about procedures of care. The consent form can be found in **appendix 10**. Facilities and members of staff will be clearly informed that their participation is voluntary and that they are able to decline to participate at this point or later in the course of the project if they wish. There will be no penalty.

b. **Benefits and costs**

There will be no immediate benefit or compensation for any participating facility or individual. Assessments will involve minimal disruption – requiring someone to show the assessor around the neonatal unit (step 3 of the study), nursing staff to participate in a short interview (step 4 of the study), and someone to provide the study data entry clerk with access to admission registers and medical records (steps 2 and 5 of the study). We will work with facilities to find ways to minimise disruption, for example, by finding times that best suit them for data collection to take place. Use of secondary data from medical records poses no risk to individuals if appropriate measures to preserve confidentiality are put in place. In many countries studies using such data are exempt from ethical review. For example, reports in the British Medical Journal investigating variations in mortality across hospitals in the UK are based on data from electronic records of admission for almost 8 million people [43]. In Kenya the Ministry of Medical Services has mandated the conduct of routine audit based on retrospective case record review since 2009.

Facilities may benefit from the feedback of general findings about the capacity and utilisation of their facilities (as described below in section 11c). Such information may be helpful for individual facilities to better understand how their facility compares to others within Nairobi City County and to inform discussions on how to allocate resources to improve the provision of care for sick newborns.

A potential risk for newborn patients would be the publication of identifiable information from their medical records. However, as described above, no identifiable data will be recorded. Furthermore, medical records will be kept onsite in the facilities either in their original location or in a secured cupboard or room. Only summary level data will be published on the assessment of process (nursing questionnaire and medical record reviews) to avoid the potential risk of inferences about the identity of nursing and clinical staff being made.

c. **Feedback of findings**

<u>Feedback to individual facilities</u>

Feedback meetings will be held with facilities during which preliminary aggregate results will be presented. Facilities will have the option to request more specific feedback on their individual results for utilisation, resources, and case record review. However, as knowledge is being assessed on a small

number of nurses, specific feedback in this area will be withheld. Facilities will have the opportunity to ask questions and share thoughts with researchers about the findings and process of the project.

<u>Wider communication of findings</u>

Opportunities will be available during the study to share progress updates and early findings with the project advisory group and, when preliminary results are available, with the Ministry of Health and other interested health care providers more widely. In particular members of the project advisory group and investigators are already members of policy making groups or forums such as the Inter-agency Coordinating Committee for Child and Newborn Health. Results of this study will be made more widely available through development of local reports provided to facilities and health care provider groups and subsequently presentation at local and international meetings and publication in peer-reviewed journals.

Although names of facilities will not be included in reports, information about workloads, admission patterns, and types of services a facility provides will be considered non-sensitive and will be made available in a form by which individual facilities might be identifiable (e.g. mapping of results). Similiar information, including the names and locations of facilities, is already being collected and published as part of the Kenyan Facility Master List project. However, information about the quality of care delivered (as determined by the structural assessment, nursing questionnaire, and case record review) at facilities will be available only in aggregate form such that individual facilities are not identifiable. Information on quality of care of an individual facility will not be published or communicated in other forms to external groups.

d. **Data sharing from this study**

The data obtained from secondary sources (i.e. facility admission registers and medical records) belongs to the facility from which it was obtained. We will be able to share these data with others who first obtain permission from the responsible authorities to access them. Primary data collected by the research team will be under the custodianship of KEMRI-Wellcome Trust Research Programme. Applications may be made for access to these data.

Names of facilities will not be included in any shared datasets. Additionally, when data on quality of care is included in the requested dataset, the location, and any other information that may make a facility identifiable (e.g. its type if 'type' is unique to single or a small group of facilities), will also be removed from the dataset before sharing.

e. **Community engagement**

This project will involve close working collaboration with Nairobi City Council. We will primarily be engaging with frontline health workers, county health management teams, and national level stakeholders through regular feedback meetings and consultations. In addition, we will work to engage with and provide feedback to the private and not-for-profit sectors through appropriate fora (for example through the Christian Health Association of Kenya) and through professional association meetings that span all sectors (e.g. The National Nursing Association of Kenya and Kenya Paediatric Association annual conferences).

f.  **Work on animals**

Not applicable.

## 12.      <u>Expected Application of the Results</u>:

The results from this project are expected to help policy makers and health care providers plan for improved availability, accessibility, and quality of health care services for newborns. By providing information about the gaps in service provision, strategies may be developed with a view to optimally utilise limited resources to improve newborn care facilities. Furthermore, these results will form the basis for future research to consider interventions to improve care in neonatal units in Kenya and potentially more widely. Lastly, by highlighting any potential shortfalls in neonatal services, we hope to inform the public debate on child mortality and, more specifically, increase awareness of issues surrounding neonatal mortality and its prevention.

## 13.      <u>References</u>:

1.      United Nations Inter-agency Group for Child Mortality Estimation, *Levels and Trends in Child Mortality*. 2013, UNICEF: New York.
2.      Lawn, J.E., et al., *Every Newborn: progress, priorities, and potential beyond survival.* Lancet, 2014. **384**(9938): p. 189-205.
3.      Gates, M. and A. Binagwaho, *Newborn health: a revolution in waiting.* Lancet, 2014. **384**(9938): p. e23-5.
4.      World Health Organization, *Research for universal health coverage: World health report 2013*. 2013, WHO: Geneva.
5.      Bhutta, Z.A., et al., *Can available interventions end preventable deaths in mothers, newborn babies, and stillbirths, and at what cost?* The Lancet, 2014.
6.      Wang W, et al., *Levels and Trends in the Use of Maternal Health Services in Developing Countries.  No. 26.*, in *DHS Comparative Reports*. 2011: Calverton, Maryland, USA.
7.      Kerber, K.J., et al., *Continuum of care for maternal, newborn, and child health: from slogan to service delivery.* Lancet, 2007. **370**(9595): p. 1358-69.
8.      Lassi, Z.S., et al., *The interconnections between maternal and newborn health--evidence and implications for policy.* J Matern Fetal Neonatal Med, 2013. **26 Suppl 1**: p. 3-53.
9.      Bhutta, Z.A., et al., *Linkages among reproductive health, maternal health, and perinatal outcomes.* Semin Perinatol, 2010. **34**(6): p. 434-45.
10.     Gabrysch, S., et al., *New signal functions to measure the ability of health facilities to provide routine and emergency newborn care.* PLoS Med, 2012. **9**(11): p. e1001340.
11.     The Partnership for Maternal, N.C.H., *A Global Review of the Key Interventions Related to Reproductive, Maternal, Newborn and Child Health (RMNCH).* 2011, PMNCH: Geneva.
12.     Statistics, K.N.B.o., *Kenya Demographic and Health Survey 2008-09*. 2010, Kenya National Bureau of Statistics.
13.     Prost, A., et al., *Women's groups practising participatory learning and action to improve maternal and newborn health in low-resource settings: a systematic review and meta-analysis.* Lancet, 2013. **381**(9879): p. 1736-46.
14.     World Health Organization, *Antenatal care in developing countries. Promises, achievements and missed opportunities: an analysis of trends, levels and differentials. .* 2003, WHO: Geneva.
15.     Mason, E., et al., *From evidence to action to deliver a healthy start for the next generation.* Lancet, 2014. **384**(9941): p. 455-67.

16.     Emina, J., et al., *Monitoring of health and demographic outcomes in poor urban settlements: evidence from the Nairobi Urban Health and Demographic Surveillance System.* J Urban Health, 2011. **88 Suppl 2**: p. S200-18.

17.     Kihuba, E., et al., *Assessing the ability of health information systems in hospitals to support evidence-informed decisions in Kenya.* Glob Health Action, 2014. **7**: p. 24859.

18.     Alegana, V.A., et al., *Estimation of malaria incidence in northern Namibia in 2009 using Bayesian conditional-autoregressive spatial-temporal models.* Spat Spatiotemporal Epidemiol, 2013. **7**: p. 25-36.

19.     Alegana, V.A., et al., *Modelling the incidence of Plasmodium vivax and Plasmodium falciparum malaria in Afghanistan 2006-2009.* PLoS One, 2014. **9**(7): p. e102304.

20.     Republic of Kenya Ministry of Health, *The Kenya Essential Package for Health: The Kenya Health Sector Strategic and Investment Plan, 2014-2018*. 2014.

21.     Nickerson, J.W., et al., *Monitoring the ability to deliver care in low- and middle-income countries: a systematic review of health facility assessment tools.* Health Policy Plan, 2014.

22.     Programme, T.O.G.K., *Urban Poverty and Vulnerability in Kenya*. 2009, OXFAM: Nairobi.

23.     *The Constitution of Kenya 2010. Fourth Schedule.*

24.     Ministry of Medical Services and Ministry of Public Health and Sanitation, *Kenya Health Policy 2012-2030.*

25.     Donabedian, A., *The quality of care. How can it be assessed?* JAMA, 1988. **260**(12): p. 1743-8.

26.     Statistics, K.N.Bo., *2009 Kenya Population and Housing Census*. 2009, Kenya National Bureau of Statistics.

27.     Aluvaala, J., et al., *Assessment of neonatal care in clinical training facilities in Kenya.* Arch Dis Child, 2014.

28.     Ntoburi, S., et al., *Development of paediatric quality of inpatient care indicators for low-income countries - A Delphi study.* BMC Pediatr, 2010. **10**: p. 90.

29.     Blencowe, H., et al., *Estimates of neonatal morbidities and disabilities at regional and global levels for 2010: introduction, methods overview, and relevant findings from the Global Burden of Disease study.* Pediatr Res, 2013. **74 Suppl 1**: p. 4-16.

30.     Lee, A.C., et al., *Intrapartum-related neonatal encephalopathy incidence and impairment at regional and global levels for 2010 with trends from 1990.* Pediatr Res, 2013. **74 Suppl 1**: p. 50-72.

31.     Rao, J.N.K., *Small Area Estimation*. 2003, Hoboken, New Jersey: John Wiley & Sons, Inc.

32.     Diggle, P. and J.P. Ribeiro, *Model Based Geostatistics*. 2007: Springer.

33.     Noor, A.M., et al., *Creating spatially defined databases for equitable health service planning in low-income countries: the example of Kenya.* Acta Trop, 2004. **91**(3): p. 239-51.

34.     Noor, A.M., et al., *A spatial national health facility database for public health sector planning in Kenya in 2008.* Int J Health Geogr, 2009. **8**: p. 13.

35.     Ministry of Medical Services and Ministry of Public Health and Sanitation, *Master Facility List*. 2010, Division of Health Information Systems, Department of Standards and Regulatory Services: Kenya.

36.     Wakaba, M., et al., *The public sector nursing workforce in Kenya: a county-level analysis.* Hum Resour Health, 2014. **12**: p. 6.

37.     Kosgei, R.J., et al., *Quality of care in Kenyan Public Hospitals: SIRCLE Survey*. 2013, Health Services Implementation, Research, and Clinical Excellence Collaboration.

38.     Kim, Y.M., et al., *Assessing the capacity for newborn resuscitation and factors associated with providers' knowledge and skills: a cross-sectional study in Afghanistan.* BMC Pediatr, 2013. **13**: p. 140.

39.     Gathara, D., et al., *Quality of hospital care for sick newborns and severely malnourished children in Kenya: a two-year descriptive study in 8 hospitals.* BMC Health Serv Res, 2011. **11**: p. 307.

40.     Mwaniki, P., et al., *Assessment of paediatric inpatient care during a multifaceted quality improvement intervention in Kenyan district hospitals--use of prospectively collected case record data.* BMC Health Serv Res, 2014. **14**: p. 312.

41.     Kenyan Ministry of Health, D.o.E.a.D.R.M., *Kenya Health Sector Referral Strategy (2014– 2018)*. 2014: Nairobi.

42.     Johns Hopkins Bloomberg School of Public Health. *LiST: The Lives Saved Tool*.  [cited 2014 10th October]; Available from: http://www.jhsph.edu/departments/international-health/centers-and-institutes/institute-for-international-programs/list/.

43.     Jarman, B., et al., *Explaining differences in English hospital death rates using routinely collected data.* BMJ, 1999. **318**(7197): p. 1515-20.

**14.**        **Budget**:

| Item | KSH | $ (@80KSH/$) |
|---|---|---|
| 1 x Assistant research officer (Grade 6.1) for 12 months | 1,561,380 | 19,517 |
| 6 x Field worker/data clerk (Grade 3.1) for 3 months | 778,950 | 9,737 |
| Air travel from Oxford to Kenya – 4 trips | 510,000 | 6,375 |
| Travel and accommodation costs in Kenya (13 weeks) | 530,000 | 6,625 |
| Data collection expenses | 60,000 | 750 |
| Local office costs and travel | 340,000 | 4,250 |
| Dissemination | 170,000 | 2,125 |
| **GRAND TOTAL** | **3,950,330** | **49,379** |

This project is part of the KEMRI-Wellcome Trust Reserch Programme Collaboration and as such will not incur separate overheads.
Equipment for data collection will be supplied at no cost from existing items available for survey work.


**15.**        **Justification of the Budget:**

The salary costs of the Principal Investigator (PI) will be covered by Oxford University. It is anticipated the PI will make up to 4 trips to Kenya during the project period with a total stay of approximately 13 weeks. The project will require the support of an assistant research officer with an MSc or equivalent for 12 months who will be trained and supervised by the PI to build their research experience and skills. The assistant research officer will partake in study coordination, data collection, support for data management and analysis, and report writing. The project will also require the support of six field workers/data clerks to data enter information from admissions registers and medical records. With one week of training, we expect one data clerk to collect data from one facility each two weeks. We assume that data collection will occur in 30 facilities. Therefore, data collection should be completed by six data clerks in 3 months (one week training + ten weeks data collection + two weeks to wrap up data collection and address any data cleaning queries). There will be some costs of data collection, local travel within Nairobi, and office costs for the PI, assistant research officer, and data entry clerks over the project period. A budget for local dissemination at stakeholder meetings and professional association meetings is included.

## 16.      **Appendices:**

**Role of each participating investigator.**

| Investigator | Role |
|---|---|
| Dr Georgina Murphy | Design and conduct of operational research. Development of project strategy. Management of data collection, data analysis and report writing. |
| Dr Jalemba Aluvaala<br>Prof Mike English | Technical advice on development and use of information collection tools and analysis of health systems data. Technical advice on important quality of care parameters for neonatal care in Kenya. Development of project strategy. |
| Dr Newton Opiyo<br>Ms Jacintah Mwachiro | Technical advice on development and use of information collection tools and analysis of health systems data. Technical advice on important quality of care parameters for neonatal care in Kenya. |
| Dr Margaret Kilonzo | Technical advice on important quality of important quality of care parameters for emergency obstetric and newborn care in Kenya. |
| Dr Abdisalan Noor | Technical advice, design, and conduct of geospatial modelling and mapping. |
| Advisory group | Engagement with Ministry of Health, Nairobi County Council, professional organisations, the private sector, and the not-for profit sector. Development of a support network. Provision of introduction to health facility authorities. Expert advice on aims, objectives, methods, and implications of the research project. |

**Appendix 1**: Dr Margaret Kilonzo CV and list of expert advisory group

**Appendix 2:** Quality indicators

**Appendix 3**:  Variables collected by Kenyan Health Facilities Master List

**Appendix 4:** Neonatal admission register data capture tool

**Appendix 5:** Maternal admission register data capture tool

**Appendix 6:** Structural assessment data collection tool

**Appendix 7:** Questionnaire administered to nursing staff

**Appendix 8:** Neonatal medical record data capture tool

**Appendix 9:** Information sheet for study permission from facility authorities

**Appendix 10:** Consent form for nursing staff questionnaire

## Appendix 1: Advisory group and Curriculum Vitae

**Table A2: List of advisory group members and representatives**

| Institution | Representative |
|---|---|
| Kenya Ministry of Health, Directorate of Preventive and Promotive Care | Dr. Rachel Nyamai, Head Division of Maternal, Newborn, Child & Adolescent Health |
| Kenya Ministry of Health, Directorate of Clinical Care | Dr. Annah Wamae, Head Division of Specialist Services |
| Nairobi City Council | Dr Lois Mutai |
| University of Nairobi | Prof. Fred Were<br><br>Prof. Aggrey Wasunna<br><br>Prof. Koigi Kamau |
| Kenya Paediatric Association | Dr David Githanga<br><br>Prof. Fred Were |
| Nursing Council of Kenya | Mrs. Elizabeth Oywer, Director |
| Pumwani Maternity Hospital | Dr Catherine Mutinda, Paediatrician |
| Private sector representative | *To be determined* |
| NGO/faith-based sector representative | *To be determined* |

## MARGARET K KILONZO - CV

Tutorial fellow, Department of Obstetrics and Gynaecology, University of Nairobi, Kenya

**Education**

2014: Master of Medicine in Obstetrics and Gynaecology, University of Nairobi

2006: Bachelor of Medicine and Bachelor of Surgery (MBChB), University of Nairobi

**Employment history**

2013-current: Tutorial fellow, department of Obstetrics and Gynaecology, University of Nairobi

2010-2013: Part-time medical officer, The Mater Hospital labour ward

2009-2010- Medical officer, Hagadera Refugee camp Hospital

2008-2009: Medical officer Loitokitok District Hospital

2007: Internship- Kericho District Hospital

**Training**

2014: Attended a five day training on responsible conduct of research, a five day training on Bioethics and a five day training on proposal grants writing

**Conference presentation**

2014: A comparative study of prevalence of hepatitis B among HIV positive and HIV negative pregnant women in Kenyatta National Hospital, Nairobi, Kenya.

## Appendix 2: Quality indicators

**Table A1: Quality indicators to be assessed in the Inpatient Newborn Care in Nairobi City County Study, according to the Donabedian model.**

| Structure | Process | Outcome |
|---|---|---|
| **(a) Infrastructure**: such as a clean water source, reliable electricity, and a sink with soap for hand washing<br><br>**(b) Equipment:** such as bag and mask, oxygen cylinder, suction machine/nasal aspirator, incubator, baby scale, cup to measure expressed breast milk, and intravenous fluid and infusion set<br><br>**(c) Job aides:** such as feeding charts, fluids charts, APGAR charts, treatment sheets, and guidelines and protocols<br><br>**(d) Essential drugs:** such as ampicillin, gentamicin, diazepam and dexamethasone<br><br>**(e) Profile of human resources:** such as numbers of nurses, doctors, and consultants. | **(a) Nursing knowledge questionnaire score**<br><br>**(b) Frequency of performance of signal functions according to nursing questionnaire**<br><br>**(c) Adequacy of medical record documentation**<br><br>**d) Accuracy of prescription by clinicians:** for antibiotics, feeds, and fluids<br><br>**(e) Evidence of regular monitoring of vital signs** | **(a) Discharge outcome:** alive, dead, referred, or absconded |