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Quantifying nursing care delivered in newborn units: Protocol for a direct-observational study

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Quantifying nursing care delivered in newborn units: Protocol for a direct-observational study

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Abstract

Introduction: In many African countries, including Kenya, a major barrier to achieving child survival goals is the slow decline in neonatal mortality that now represents 45% of the under-5-mortality. Improved facility based care for sick or preterm newborns is central to efforts to improve newborn outcomes. In newborn care, nurses are the primary care givers and are essential in the delivery of safe and effective care. However, due to high patient workloads and limited resources, nurses may often consciously or unconsciously have to prioritise the tasks and the care they provide resulting in some tasks being left undone or partially done (missed care). Missed care has been associated with poor patient outcomes in high income countries. However, missed care, examined by direct observation, has not previously been the subject of research.

Methods and analysis: The aim of this study is to quantify the nursing care provided to newborns within newborn units. We will undertake a cross-sectional study utilising direct observational methods within newborn units in 6 health facilities in Nairobi City County across the public, private-for-profit and private-not-for-profit sectors. We will report the overall prevalence of care left undone, the common tasks that are left undone and describe any sharing of tasks with people not formally qualified to provide care that may represent coping strategies. In a secondary analysis, will will explore variations in care

done (or left undone) by sector, nursing working-shift, nurse-patient ratios and disease severity of the baby.

Ethics and dissemination: Ethical approval for this study has been granted by the Kenya Medical Research Institute (KEMRI) Scientific and Ethics Review Unit (KEMRI/SERU/CGMR-C/065/3404). Findings from this work will be shared with the participating hospitals, an expert advisory group that comprises of members involved in policy making and more widely to the international community through peer-reviewed journals and conferences.

Strengths and limitations

- New approaches to quantifying nursing care delivered or left undone. The use of direct observational methods that have not been previously used in LMICs. Most nursing research on quantifying care delivered is based on nurse- or patient- reported surveys.
- The different sectors (public, private-for-profit, private-not-for-profit) in health service provision have included in this study. However, our scope is limited by the few number of newborn to be observed within each hospital
- Highlighting the extent and magnitude of care left undone will provide important insights on the quality of care available to sick newborns, highlight human resource issues warranting attention and will likely influence recommendations on staffing norms and how care is organized and delivered in newborn units.

Introduction

Despite progress globally, most African countries including Kenya have made insufficient progress in reducing child mortality. In most countries, this can be partly attributed to only slow declines in neonatal mortality. As a consequence about 45% of child mortality is neonatal mortality[1]. Of these neonatal deaths, approximately 75% occur in the first 7 days of life and half of these within 24 hours of life[2][3]. A recent review by Bhutta and colleagues indicated that high impact low cost interventions could avert more than 71% of neonatal deaths with 82% of this effect being attributable to facility-based care[4]. However, reports from low income settings highlight that the quality of newborn care in health facilities is often poor[5][6][7]. Therefore, strengthening the quality of facility based care for newborns will be essential in improving newborn outcomes.

Human Resources for Health (HRH) inadequacies are major factors limiting neonatal service delivery quality [8]. Globally, the shortage of health workers is estimated currently at over 7 million and by 2035 the deficit is estimated to be 12.9 million[9]. The shortages in the available workforce are worst in developing countries where inequitable distribution of available health workers may compound the problems. In Kenya, Wakaba and colleagues reported that public sector nursing densities ranged between 1.2 to 0.008 per 1000 population across counties[10] compared to an internationally suggested

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3 minimum health workforce threshold of 2.5/1000 population for doctors, nurses and midwives. In
4 Nairobi County, the nurse densities ranged between 0.21 to 0.40 per 1000 population[10].
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7 There is little specific exploration of the impact of nursing workforce shortfalls on inpatient care in Low
8 and Middle-Income Countries (LMIC). Yet to improve quality of care it is essential that we understand
9 who delivers care (what tasks are done by whom), how is care delivered (how are tasks performed) and
10 critically what tasks are left undone. In most health systems, nurses are gatekeepers of the health care
11 being delivered. They are vested with the responsibility of delivering interventions prescribed by other
12 providers (doctors, nutritionists etc) in addition to providing nurse initiated interventions[11]. As a
13 consequence, few interventions reach the patient without the involvement of the nurse. Yet the few
14 existing evaluations of the quality of care provided to newborns in LMIC have focused on the more
15 medical aspects of care[6,12,13][14]. In LMIC facilities, large patient workloads, insufficient staff and
16 resources, urgent patient situations, and unexpected rises in patient volume and/or acuity on the unit
17 (among other factors) might result in all facets of nursing care being delayed or neglected. This
18 phenomenon has been described as 'implicit rationing'[15], 'missed care'[16], or 'unmet nursing care
19 needs'[17], 'care left undone'[18], or 'task incompleteness'[19]. Hereafter, we use the term missed care to
20 encompass all of these terms. Such missed care may have a particularly devastating impact on outcomes
21 in newborn units where nurses are the primary care givers to this highly dependent group.
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27 Justifying a focus on missed nursing care several studies have reported associations between missed
28 care and patient outcomes[20,21][22]. Although there is a growing literature on missed care the
29 majority is from high resource settings, with only one study in South Africa[23] providing an early formal
30 attempt to quantify the extent of the problem in this middle income country. Furthermore, almost all
31 the literature on missed care is based on nurse surveys with only two focusing on newborn care
32 provision[24,25]. Although, nurse surveys on missed care have proven useful, there is a call to undertake
33 more research with a special focus on objective observational methods as no studies of this type were
34 identified in a recent systematic review [22]. The proposed study aims to characterise the care delivered
35 (tasks done or left undone and who does these tasks) to newborns receiving care within newborn units
36 in Nairobi, Kenya by making direct observations of care being provided. This will provide in-depth and
37 objective insights on missed care with particular reference to locally agreed standards for nurses
38 providing neonatal care.
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43 **Methods and analysis**

44 This is a cross-sectional study that will utilise direct observation of care provided to individual newborns
45 with the aims of describing the nursing care given and missed within newborn units in 6 hospitals.
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47 **Study site (geographical)**

48
49 The proposed research work will be undertaken as part of a set of work being conducted in
50 collaboration with Nairobi City County. This collaboration includes work to characterise all the facilities
51 providing 24/7 inpatient newborn care in Nairobi [26] and ethnographic work to understand the wider
52 context and practice of neonatal nursing. Nairobi county has 34 health facilities providing 24/7 inpatient
53 newborn care, of these 2 health facilities declined to take part in prior quality of care surveys[27].
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3 Excluding the military health facility with restrictive admission policy, the remaining 31 health facilities
4 that form the population for this study provide 99% of all inpatient neonatal care.
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6 This current study will focus on primary referral (secondary care) facilities that have more than 100
7 neonatal admissions annually. Thirteen facilities meet these criteria and together provide care to over
8 96% of the sick-newborn population accessing care within Nairobi County. These 13 facilities will be
9 stratified by workload (newborn admissions per year ≤ 500 low; > 500 high) and six health facilities
10 purposefully selected to ensure representation of 2 hospitals in each of the public, private-not-for profit
11 and private-for-profit sectors, with one high and one low workload facility in each sector. Purposeful
12 selection will be used as it is important in this sensitive and innovative work to have the strong support
13 of the hospital administration. This initial work will therefore help illustrate the nature and magnitude of
14 the challenge of missed care but not make claims to provide a statistically representative picture of
15 missed care which would be challenging given the great diversity of facilities found in Nairobi, some with
16 as few as 10 neonatal admissions per year[27].
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21 **Study populations**

22 All newborns admitted within a newborn unit in the 6 selected health facilities over the period of the
23 study in each facility will form the potential study population. However, newborns meeting the following
24 exclusion criteria will not be observed: i) newborns requiring specialised treatment to whom the draft
25 minimum nursing standards for neonatal care[28] may not be applicable, for instance newborns with
26 gross malformations or those receiving post-operative care, ii) newborns who are critically ill and at risk
27 of death within a 12-hour observation period as defined by the clinician in charge of the newborn unit
28 for whom observation might cause distress to families, iii) newborns for whom guardians do not provide
29 consent, and iv) newborns receiving care from nurses or guardians who decline to be observed in the
30 care provision process.
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35 **Sampling procedures**

36 To describe the care being provided to sick newborns across the spectrum of inpatient services they
37 receive, we are aiming to sample time in 12 hour shifts randomly using the steps described in figure 1.
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41 ***Figure 1: Steps for the sampling procedure***

42 ***Step 1***

43 Care within the NBU can be organised in a way that babies requiring different levels of care are in
44 different sections/rooms. Intensive care employing invasive mechanical ventilation is not available
45 outside tertiary hospitals in Kenya and thus definitions for different levels of newborn care provided by
46 County Hospitals were adopted. These are taken from draft nursing standards for neonatal care that
47 categorise NBU sections (and thus babies) in the following way[28]. **Category A (high dependency unit,**
48 **HDU):** Babies on oxygen/CPAP and IV fluids who are often acutely ill and unstable and require the
49 closest monitoring. **Category B:** Babies who have stabilized but may still be ill and receiving for example
50 assisted feeding (NG feeds), IV drugs; or being observed for convulsions or apnoea. **Category C:** Babies
51 who are quite stable who should be receiving KMC, or stable abandoned babies, or recovering babies
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3 requiring completion of treatment such as the last doses of antibiotics or transitioning to oral feeding.
4 Our primary sampling strategy will be based on identifying these organisational sub-sections (Category
5 A; B; C rooms or incubator/cot spaces) in each facility. Where facilities have no clear organisational
6 demarcation into Category A, B and C sub-sections we will adapt the observations to suit the
7 organisation of care in each facility. However, we will endeavour to identify and select newborns with
8 varying degrees of illness severity who would be classified as meeting criteria for Category A, B or C care
9 for observation in such settings.
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12 13 *Step 2*

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15 In each hospital, a random sample of twelve shifts/time blocks of 12 hours (144 observation hours per
16 hospital) will be selected from within a 3 week period stratified by both weekdays and weekends as well
17 as night and day shifts as care has been shown to vary across these periods[29,30]. The 12 shifts will be
18 divided equally across the NBU sections within a hospital where there is >1 section. Where all babies are
19 cared for in one room without clear sub-sections all observation periods will be conducted in this same
20 setting with efforts to observe babies requiring different levels of care.
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23 24 *Step 3*

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26 We feel that it is logistically feasible for one observer to make direct observations of 3 babies located in
27 adjacent cots in the same ward area at one time. Therefore, for each shift and section, 3 babies who
28 meet the inclusion criteria will be purposefully selected to ensure babies are in one ward area and
29 within close proximity to allow direct observations. In smaller units where the number of babies per
30 section may be less than 3, we will observe all the babies available in the section and classify the baby as
31 eligible for care in category A, B or C.
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34 35 **Sample size**

36
37 This is an exploratory cross-sectional study and as such, we illustrate the precision with which we can
38 report proportions of tasks done (or not done) assuming different sized denominators. The size of the
39 denominator is related to the recommended frequency that tasks should be performed (see figure 2). To
40 estimate the precision of reporting we have used a sample estimation approach for cluster designs and
41 assuming a design effect of 2 to adjust for clustering of observed tasks within newborns within hospitals.
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44 At most we expect to recruit 216 newborns across 6 hospitals (36 newborns per hospital with 3 babies
45 for each of the 12 shifts/time blocks). For tasks that would be conducted with an expected frequency of
46 once in 12 hours (eg. IV pencillin administration) we might therefore observe 216 task opportunities.
47 Taking a (statistically) conservative assumption that on 50% of expected occasions the task is observed
48 to be done then we could report this with a precision $\pm 13.4\%$. Similarly, if a task should be conducted
49 every 6 hours then the denominator would be 432 expected tasks and if half were observed the
50 precision of this estimate would be $\pm 6.7\%$.
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54 Not all babies observed will require all tasks. For example, some babies may not be receiving
55 intravenous drugs. This will reduce the effective size of the denominator and reduce the precision we
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3 can report. Similarly, if babies have to leave the area of observation (for example they are moved to a
4 new ward area or are sent for X-ray etc) this may reduce the number of expected tasks that can be
5 observed. In addition, failure to recruit 3 babies at each 12-hour shift at each facility may also reduce
6 the number of tasks observed. We illustrate the effect this has on the precision of reported estimates in
7 figure 2, which illustrates that with as few as 30 expected tasks reporting a precision of $\pm 20.5\%$ is
8 possible.
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11 As this work is a first of its kind (globally as far as we are aware) we feel that providing estimates of the
12 proportion of tasks done/left undone with a precision of approximately $\pm 20\%$ will be sufficient to
13 provide valuable insights into the challenges faced by nurses in providing newborn care.
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16 **Figure 2: Precision levels for different newborn sub-populations and tasks**

17 **Procedures**

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19 For each newborn being observed, the diagnosis and disease severity information will be collected from
20 medical records. At the beginning of every shift for which observations will be made, the total number
21 of nursing tasks expected to be delivered will be determined with reference to the medical and nursing
22 records (for specific interventions) and general aspects of care each baby should receive. For each of the
23 newborns selected to participate in the study, we will make direct observations on how often certain
24 routine nursing tasks (listed in table 1) are undertaken in a 12-hour shift (7am -7pm) using an
25 observation checklist. Observations will be stopped if a baby is transferred out of a section or
26 discharged, however, we will use the data collected up to the point of exit and the number of
27 observation hours will be documented. If the babies' condition changes and their category changes but
28 they remain in the same observation area, we will document this change and revise the expected
29 number of tasks.
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33 The observer will be stationed in a ward area where they do not obstruct care provision but can observe
34 the care being provided to the newborns selected for observation. Because most of the documentation
35 activities happen at the nurses' desk/station, all tasks related to documentation cannot be observed
36 from the cot-side. The documentation tasks for the babies under observation will be evaluated at the
37 end of each 12-hour shift for which observations were made. We acknowledge that 12 hours is a long
38 period and the observer's efficiency for making observations might reduce as time progresses within an
39 observation time block and study period. We will factor in rest periods in the 12-hour shifts that coincide
40 with when nurses take their breaks for instance, during tea and lunch breaks. Further, to allow enough
41 rest between observation time blocks, we will aim to have a maximum of 3, 12-hour observation periods
42 per week per observer.
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46 The observation checklist is based on nursing standards produced after two expert group meetings held
47 in November 2015 and July 2016 at the KEMRI Wellcome Trust Research Programme offices. The nurse
48 stakeholder group comprises of expert nurses who are in the teaching profession or senior practitioners
49 and including the acting Chief Nursing Officer for Kenya. They defined a minimum standard for
50 performing nursing tasks on newborn units[28]. A sub-set of tasks were identified as critical (listed in
51 table 1) by the nurse stakeholder group that should be performed by nurses and not by other personnel
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due to the skills required when they are delivered. Where necessary tasks are broken down into manageable observable task components to facilitate observation. For instance, naso-gastric feeding is broken down into insertion of the NGT (as required), checking for gastric aspirate before feeding, counter checking feed volumes to be given with prescription, actual feeding and charting the feeds given. The purpose of observation is not to assess how well any particular aspect of a task is done (eg. the care taken in administering naso-gastric feeds) but simply to determine if the task (or task component) was or was not done at all.

Prior to the start of the study, the observation checklist will be extensively piloted over a period of 6 weeks to determine the quantity and quality of data that can be reasonably gathered and will be adapted as needed.

Table 1: Routine and critical tasks for observation

Routine tasks	Critical tasks
Patient assessment at the beginning of each shift Cleaning of the baby Changing baby's linen Changing the baby's position Checking incubator settings Attendance at ward round and active note taking Weighing Elimination care Communication/counselling parents Cord care Vital signs <ul style="list-style-type: none"> • Pulse rate • Temperature • Respiratory rate • Oxygen saturation Documentation <ul style="list-style-type: none"> • Updating the nursing cardex • Discharge and admission registration 	Nasal gastric feeding <ul style="list-style-type: none"> • Insertion of the NGT • Testing whether it is in the correct position • Checking for gastric aspirate before feeding • Preparation of feeds and counter checking feed volumes • Actual feeding and charting the feeds Intravenous drug/fluid administration <ul style="list-style-type: none"> • Review treatment sheet • Checking cannula sites – care • Regulating flow • Input/output charting for fluids • Document treatments given Oxygen therapy <ul style="list-style-type: none"> • Fixing of oxygen/nasal prongs • Checking tube position and nostril –care, damage • Initiating and regulating oxygen flow • Documenting oxygen treatment Photo therapy <ul style="list-style-type: none"> • Baby positioning • Eye pad in place • Checking eyes for damage • Check and monitor phototherapy settings • Documentation of phototherapy Support for KMC

For purposes of this study, we adopted the definition of missed care reported in wider literature[22,31], and was therefore defined as care that the nursing advisory group regard as necessary (primarily nursing tasks) as part of routine newborn care that are left undone or are

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3 delivered by any person other than the nurse and who is not under direct observation/supervision by
4 the nurse. For example, tasks done by a senior student nurse who is being supervised to conduct
5 nasogastric feeding by a qualified nurse in the room at the time and focused on the supervision will be
6 regarded as done. If the same student does the task while the nurse supervising is in a different part of
7 the ward it will be regarded as not done (with a record of who completed the task made). Additional
8 data to be collected related to each block of observation time will include data on the nurse patient
9 ratio for the ward as a whole, what additional staff are present within the unit e.g nursing students,
10 support staff etc and patient workloads within the different sections of the ward.
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14 **Practical considerations to undertake direct observations**

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16 Observations will be made by a person familiar with the hospital environment, equipment, processes
17 (like ward rounds) and language but who is not a nurse or clinician (doctor/clinical officer). Given the
18 potential sensitivity of this form of observation it is important that this person is considered a
19 professional rather than an outsider (who might not be bound by professional codes of confidentiality).
20 Having an observer who has an understanding of the setting but who is not a clinician or nurse may
21 also overcome problems of the observer making judgements about what is being observed based on
22 their own standards of practice or being influenced as they make observations by professional
23 allegiances (eg. a nurse observer may not wish to record that a task is left undone). There might also be
24 ethical challenges for an observer with a clinical/nurse background who might feel obliged to intervene
25 in the provision of care or become co-opted to complete tasks. An observer who is not licensed to offer
26 the form of interventions/care being given to babies will still however be able to report to health care
27 providers within the unit in the event they identify gaps or situations in which newborns are put at risk.
28 For instance, if they saw a newborn was convulsing or vomiting they would alert the nurse. Suitable
29 backgrounds for observers might include nutritionists, health records officers, ward based clerical
30 workers, or laboratory or pharmacy staff with at least two-year's experience within hospital settings. In
31 this study nutritionists will be recruited to undertake the observations.
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37 We will recruit six observers who meet the above criterion. The observers will be trained for a period of
38 2 weeks by one of the study personnel who has a nursing background and has 2 years' experience
39 providing care to newborns within a newborn unit. Standard operating procedures will be developed
40 and will serve as a guide for the observational work. During the training period, the observers and the
41 trainer will do observations and comparisons will be made. Any differences will be discussed and where
42 necessary the SOPs will be revised to improve on clarity.
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46 To reduce the Hawthorne effect where nurses might change the way they provide care when they are
47 being observed, the observer will spend at least 1 week in the facility before starting the observational
48 work. This will also allow him/her to familiarise themselves with the environment, to explain the study
49 to staff and parents and for the staff within the NBU to get used to them. In addition, the observer will
50 make it clear that the observations are not an assessment but a means of understanding what care it is
51 possible to provide given existing resource constraints. Formal study observations will then begin in the
52 period after the one-week familiarisation period. This approach is supported by evidence that health
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care providers change their practice slightly when the observations start but these changes are short-lived and quickly dissipate with health care providers soon reverting to their previous practice[32,33].

Data Management and analysis

Data will be collected on paper-based observation checklists, one for each baby that is the focus of observation. No participant identifiable data will be collected and data collection instruments will be identified only by a unique study ID allocated to each baby. The place, date and time of the shift will also be anonymised by using only specific codes for observation shifts. Data on the paper-based observation checklists will be checked for completeness by a supervisor at the end of each day. The checklists will be double-entered into a custom-made database using Research Electronic Data Capture (REDCap) with inbuilt range and consistency checks. The entered data will be checked at the end of each day using pre-coded scripts for entry errors and completeness. Data will be exported for cleaning and analyses in Stata version 13 (Stata Corporation, Texas, USA).

Descriptive analysis will be undertaken on the pooled data across hospitals to determine the overall prevalence of care left undone and the common tasks that are left undone. We will also report the average number of tasks left undone per newborn and the common tasks left undone per newborn. Secondary analysis will be undertaken to explore variations in care done (or left undone) by the various sub-categories that will include: sector, nursing shift, nurse-patient ratios and category of the baby (disease severity).

Ethical considerations

The focus of our direct observations of care is what happens to newborns and we will not record any names or other identifying features of people who may be providing care to these newborns. We will only report pooled results stratified by sector, patient-nurse staffing ratios and category/severity of disease so as to preserve the confidentiality of the health facilities.

During the one-week familiarisation period, we will seek written individual informed consent from all nurses who will be providing care within the NBU. Nurses not available during this introductory period but who provide care during an observation shift will be asked for individual informed consent before the start of the observations. Additionally, at the beginning of every shift for which direct observations will be made, group verbal informed consent will be sought from nurses after an explanation of the study has been made (this is in addition to the 1-week familiarisation during which the study will be explained). We will also provide printed study briefs targeting health care providers explaining the study but also indicating that they are free to decline from being observed as an approach to on-going consent.

Written informed consent will be sought from the mothers of babies considered for direct observations at the beginning of each observation period. In cases where nurses or parents decline consent, babies under their care will not be considered for direct observation. It will be made clear that at any stage nurses or parents can withdraw consent/permission for observation, temporarily or for the rest of a shift, without explanation and with no penalty. Observations will only be undertaken where both the mother and nurses have provided consent to the study respectively.

Ethical approval for this study has been granted by the Kenya Medical Research Institute (KEMRI) Scientific and Ethics Review Unit (Approval No. KEMRI/SERU/CGMR-C/065/3404).

Dissemination of findings

An expert advisory group, including partners from the Ministry of Health, Nursing Council of Kenya, Nairobi City County, Kenya Medical Training College, Kenyatta University, and hospitals providing inpatient neonatal services has been involved in the development of the standards of nursing care being used to understand missed care in this study. This expert group has provided support for the study and is itself a key consumer of the results as these members are directly involved in policy making and training. This group will also provide a key channel for wider dissemination of the findings.

Highlighting the extent and magnitude of care left undone will provide important insights on the quality of care available to sick newborns, highlight human resource issues warranting attention and will likely influence recommendations on staffing norms and how care is organised and delivered in newborn units. Further, findings from this work will help guide the design of approaches and interventions for improving facility based care for this highly vulnerable population.

At the end of the study, findings will be provided to and discussed with participating hospitals and other relevant stakeholders. More widely, the international scientific community will be targeted via publications in peer reviewed journals as well as conferences.

Global public health relevance

Facility based care has been cited as one key approach to reduce neonatal mortality if evidence-based, high impact low cost interventions are appropriately delivered at high coverage[4]. Globally, improving quality of newborn care provided by facilities might save 600 000 small and ill neonates annually[4] while data from Kenya suggest that by 2030, 6000 newborn lives could be saved through the provision of childbirth and newborn care intervention packages alone[34].

The Kenyan government is promoting facility based delivery by making maternity care free for women. This has resulted in an increase in utilisation of maternal and newborn health services, potentially increasing the number of newborns accessing care in health facilities. At the same time significant challenges exist in nurse staffing and availability of wider resources[27] and this may limit any impact of increased access to care. The extent of nursing missed care in newborn units in LMIC and how it impacts on quality of care delivered has not previously been described. This is despite care in the newborn unit being heavily dependent on nurses. By characterising care left undone, we will identify important potential gaps in care delivered within newborn units that can inform discussions on how best to address these gaps and improve quality of care in Kenyan hospitals.

This study will be the first attempt, of which we are aware, to develop and apply observational missed care tools to understanding neonatal nursing care provision in LMIC. In fact a recent review by Jones and colleagues identified that only questionnaires have previously been used to quantify missed care[22]. An alternative method for data collection that we considered was the use of video in the newborn unit with later evaluation of what is done (or not done). However, informal discussions indicated this might be

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3 controversial at this stage nonetheless this is a potential area for future research. We anticipate that
4 this study will, therefore, be of global interest and provide an opportunity for application of the
5 methods developed to other neonatal settings or in other disciplines to better understand nursing care
6 provision and quality gaps. Further, findings of this work will be important in contributing to thinking on
7 nurse staffing norms and how care is organised and delivered in LMIC newborn units influencing longer
8 term policy on human resource planning. Most directly the findings will feed into the 'Kenya Task
9 Sharing Policy and Guidelines for Health Care Services'[35], an initiative being led by Ministry of Health
10 alongside other stakeholders as one of the ways of tackling health workforce shortages.
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14 **Authors' contributions**

15
16 DG, ME and GAVM designed the study with contributions from RK and ET. DG, NA, and GS were
17 responsible for the coordination and supervision of data collection. DG wrote the study protocol with
18 substantial and critical input from all co-authors. All authors read and approved the final version of the
19 manuscript.
20
21

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23
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28
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30 **Competing interests**

31 None
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35 **Figure legends**

36
37 Figure 1: Steps for the sampling procedure

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39 Multi-stage sampling procedure within a hospital for selecting newborns for direct observation
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42
43 Figure 2: Precision levels for different newborn sub-populations and tasks

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45 Estimated levels of precision for the different newborn sub-populations and tasks observed that the
46 study will report since not all newborns observed will require all tasks .
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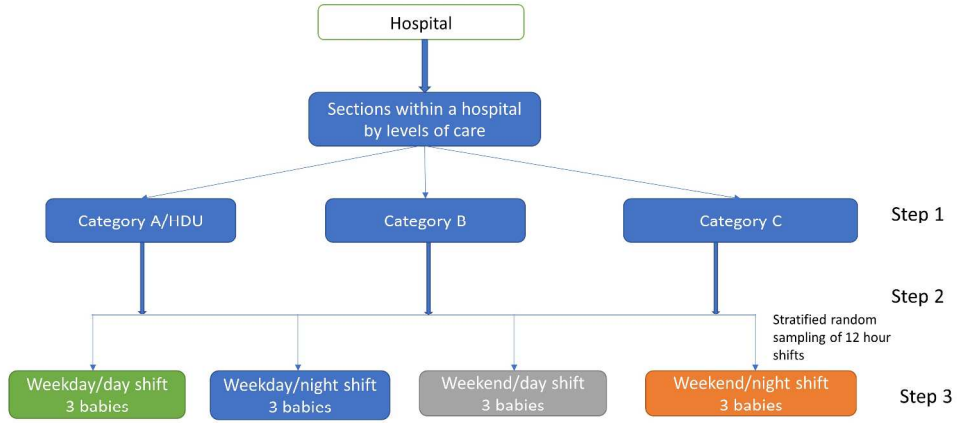
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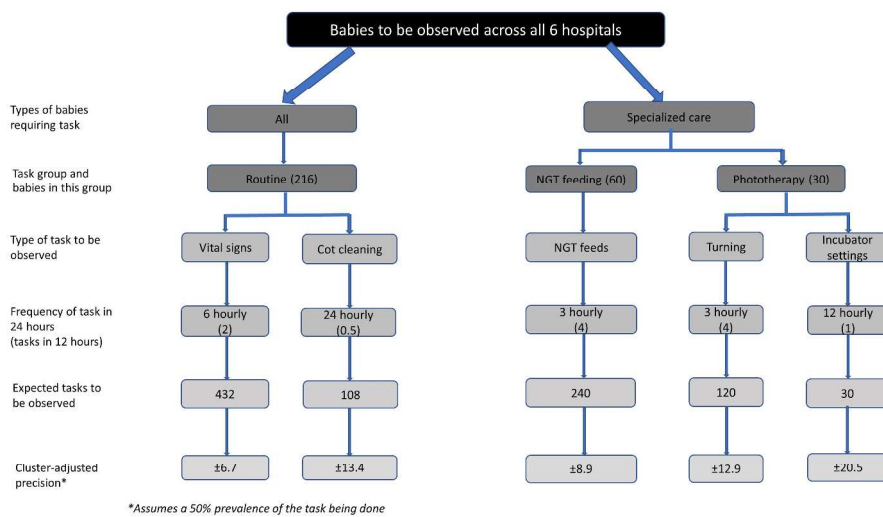
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Multi-stage sampling procedure within a hospital for selecting newborns for direct observation

338x190mm (300 x 300 DPI)

Review only



Precision levels for different newborn sub-populations and tasks

338x190mm (300 x 300 DPI)

Review only

BMJ Open

Quantifying nursing care delivered in Kenyan newborn units: Protocol for a cross-sectional direct-observational study

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Manuscripts

1 Quantifying nursing care delivered in Kenyan newborn units: Protocol for a cross-sectional direct- 2 observational study

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23 Abstract

24 **Introduction:** In many African countries, including Kenya, a major barrier to achieving child survival goals
25 is the slow decline in neonatal mortality that now represents 45% of the under-5-mortality. In newborn
26 care, nurses are the primary care givers in newborn settings and are essential in the delivery of safe and
27 effective care. However, due to high patient workloads and limited resources, nurses may often
28 consciously or unconsciously prioritise tasks and the care they provide resulting in some tasks being left
29 undone or partially done (missed care). Missed care has been associated with poor patient outcomes in
30 high income countries. However, missed care, examined by direct observation, has not previously been
31 the subject of research.

32 **Methods and analysis:** The aim of this study is to quantify essential neonatal nursing care provided to
33 newborns within newborn units. We will undertake a cross-sectional study utilising direct-observational
34 methods within newborn units in 6 health facilities in Nairobi City County across the public, private-for-
35 profit and private-not-for-profit sectors. A total of 216 newborns will be observed between 1st
36 September 2017 to 30th May 2018. Stratified random sampling will be used to select random 12-hour
37 observation periods while purposive sampling will be used to identify newborns for direct-observation.

38 We will report the overall prevalence of care left undone, the common tasks that are left undone and
39 describe any sharing of tasks with people not formally qualified to provide care.

40 **Ethics and dissemination:** Ethical approval for this study has been granted by the Kenya Medical
41 Research Institute Scientific and Ethics Review Unit. Written informed consent will be sought from
42 mothers and nurses. Findings from this work will be shared with the participating hospitals, an expert
43 advisory group that comprises of members involved in policy making and more widely to the
44 international community through conferences and peer-reviewed journals.

Strengths and limitations

- The use of direct observational methods to quantifying nursing care delivered or left undone an approach that has not been previously used in LMICs.
- Different sectors (public, private-for-profit, private-not-for-profit) in health service provision have been included in this study.
- The study provides a 24-hour assessment of neonatal nursing care provision including care provided on weekends and weekdays.
- Our scope is limited by the few number of newborns to be observed within each hospital.
- Despite our efforts to minimize the Hawthorne effect, we cannot rule out the possibility of nurses changing the way they provided care during the observational periods.

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Introduction

47 Despite progress globally, most African countries including Kenya have made insufficient progress in
48 reducing child mortality. In most countries, this can be partly attributed to only slow declines in neonatal
49 mortality. As a consequence, about 45% of mortality for children under-5 years is attributable to
50 neonatal mortality[1]. Of these neonatal deaths, approximately 75% occur in the first 7 days of life and
51 half of these within 24 hours of life[2][3]. A recent review by Bhutta and colleagues indicated that high
52 impact low cost interventions could avert more than 71% of neonatal deaths with 82% of this effect
53 being attributable to facility-based care[4]. However, reports from low income settings highlight that the
54 quality of newborn care in health facilities is often poor[5][6][7]. Therefore, strengthening the quality of
55 facility based care for newborns will be essential in improving newborn outcomes.

56
57 Human Resources for Health (HRH) inadequacies is a major factor limiting delivery of quality neonatal
58 services [8]. Globally, the shortage of health workers is estimated currently at over 7 million and by 2035
59 the deficit is estimated to be 12.9 million[9]. The shortages in the available workforce are worst in
60 developing countries where inequitable distribution of available health workers may compound the
61 problems. In Kenya, Wakaba and colleagues reported that public sector nursing densities ranged
62 between 0.008 to 1.2 per 1000 population across counties[10] compared to an internationally suggested

63 minimum health workforce threshold of 2.5/1000 population for doctors, nurses and midwives. In
64 Nairobi County, the nurse densities ranged between 0.21 to 0.40 per 1000 population[10].

65 There is little specific exploration of the impact of nursing workforce shortfalls on inpatient care in Low
66 and Middle-Income Countries (LMIC). Yet to improve quality of care it is essential that we understand
67 who delivers care (what tasks are done by whom), how care is delivered (how are tasks performed) and
68 critically analyse what tasks are left undone. In most health systems, nurses are gatekeepers of the
69 health care being delivered. They are vested with the responsibility of delivering interventions
70 prescribed by other providers (doctors, nutritionists etc) in addition to providing nurse initiated
71 interventions[11]. As a consequence, few interventions reach the patient without the involvement of
72 the nurse. Yet the few existing evaluations of the quality of care provided to newborns in LMIC have
73 focused on the more medical aspects of care[6,12,13][14]. In LMIC facilities, large patient workloads,
74 insufficient staff and resources, urgent patient situations, and unexpected rises in patient volume and/or
75 acuity on the unit (among other factors) might result in all facets of nursing care being delayed or
76 neglected. This phenomenon has been described as 'implicit rationing'[15], 'missed care'[16], or 'unmet
77 nursing care needs'[17], 'care left undone'[18], or 'task incompleteness'[19]. Hereafter, we use the term
78 missed care to encompass all of these terms. Such missed care may have a particularly devastating
79 impact on outcomes in newborn units where nurses are the primary care givers to this highly dependent
80 group.

81 Justifying a focus on missed nursing care several studies have reported associations between missed
82 care and patient outcomes[20,21][22]. Although there is a growing literature on missed care the
83 majority is from high resource settings, with only one study in South Africa[23] providing an early formal
84 attempt to quantify the extent of the problem in this middle income country. Furthermore, almost all
85 the literature on missed care is based on nurse surveys with only two focusing on newborn care
86 provision[24,25]. Although, nurse surveys on missed care have proven useful, there is a call to undertake
87 more research with a special focus on objective observational methods as no studies of this type were
88 identified in a recent systematic review [22]. The proposed study aims to characterise the care delivered
89 (tasks done or left undone and who does these tasks) to newborns receiving care within newborn units
90 in Nairobi, Kenya by making direct observations of care being provided. This will provide in-depth and
91 objective insights on missed care with particular reference to locally agreed standards for nurses
92 providing neonatal care.

93 **Methods and analysis**

94 This is a cross-sectional study that will involve direct observation of care provided to individual
95 newborns with the aim of describing the essential neonatal nursing care given or missed within newborn
96 units. It will be undertaken in 6 hospitals in Nairobi City County, Kenya, in the period 1st September 2017
97 to 30th May 2018.

98 **Study site**

99 The proposed research work will be undertaken as part of a broader set of work being conducted in
100 collaboration with Nairobi City County. This collaboration includes work to characterise all the facilities
101 providing inpatient newborn care 24 hours, 7 days a week (hereafter referred to as 24/7) in Nairobi [26],

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3 102 quality of clinical care provided newborns[27], and ethnographic work to understand the wider context
4 103 and practice of neonatal nursing. Based on findings from the broader study, Nairobi county has 34
5 104 health facilities providing 24/7 inpatient newborn care, of these 2 health facilities declined to take part
6 105 in prior quality of care surveys[27]. Excluding the military health facility with restrictive admission policy,
7 106 the remaining 31 health facilities that form the population for this study provide 99% of all inpatient
8 107 neonatal care.

11 108 This current study will focus on primary referral (secondary care) facilities that have more than 100
12 109 neonatal admissions annually. Thirteen facilities meet these criteria and together provide care to over
13 110 96% of the sick-newborn population accessing care within Nairobi County[27]. These 13 facilities will be
14 111 stratified by workload (newborn admissions per year ≤ 500 low; >500 high) and six health facilities
15 112 purposefully selected to ensure representation of 2 hospitals in each of the public, private-not-for profit
16 113 and private-for-profit sectors, with one high and one low workload facility in each sector. Purposeful
17 114 selection will be used as it is important in this sensitive and innovative work to have the strong support
18 115 of the hospital administration. This initial work will therefore help illustrate the nature and magnitude of
19 116 the challenge of missed care but not make claims to provide a statistically representative picture of
20 117 missed care which would be challenging given the great diversity of facilities found in Nairobi, with some
21 118 health facilities having as low as 10 neonatal admissions per year[27].

26 119 **Study populations**

28 120 All newborns admitted within the newborn unit in the 6 selected health facilities over the period of the
29 121 study in each facility will form the potential study population. However, newborns meeting the following
30 122 exclusion criteria will not be observed: i) newborns requiring specialised treatment to whom the draft
31 123 minimum nursing standards for neonatal care[28] may not be applicable, for instance newborns with
32 124 gross malformations or those receiving post-operative care, ii) newborns who are critically ill and at risk
33 125 of death within a 12-hour observation period as defined by the clinician in charge of the newborn unit
34 126 for whom observation might cause distress to families, iii) newborns for whom guardians do not provide
35 127 consent, and iv) newborns receiving care from nurses or guardians who decline to be observed in the
36 128 care provision process.

40 129 **Sampling procedures**

42 130 To describe the care being provided to newborns admitted in newborn units and the spectrum of
43 131 inpatient services they receive, we are aiming to sample time in 12-hour shifts randomly using the steps
44 132 described in figure 1.

47 133 ***Figure 1: Steps for the sampling procedure***

49 134 *Step 1*

51 135 Care within the newborn unit can be organised in a way that babies requiring different levels of care are
52 136 in different sections/rooms. Intensive care employing invasive mechanical ventilation is not available
53 137 outside tertiary hospitals in Kenya and thus definitions for different levels of newborn care provided by
54 138 County Hospitals were adopted. These are taken from draft nursing standards for neonatal care that

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3 139 categorise newborn unit sections (and thus babies) in the following way[28]. **Category A (high**
4 140 **dependency unit, HDU):** Babies on oxygen/CPAP and intravenous fluids who are often acutely ill and
5 141 unstable and require the closest monitoring. **Category B:** Babies who have stabilized but may still be ill
6 142 and receiving, for example, assisted feeding (nasal-gastric feeds), intravenous drugs; or being observed
7 143 for convulsions or apnoea. **Category C:** Babies who are quite stable who should be receiving KMC, or
8 144 stable abandoned babies, or recovering babies requiring completion of treatment such as the last doses
9 145 of antibiotics or transitioning to oral feeding. Our primary sampling strategy will be based on identifying
10 146 these organisational sub-sections (Category A; B; C rooms or incubator/cot spaces) in each facility.
11 147 Where facilities have no clear organisational demarcation into Category A, B and C sub-sections, we will
12 148 adapt the observations to suit the organisation of care in each facility. However, we will endeavour to
13 149 identify and select, for observation, newborns with varying degrees of illness severity who would be
14 150 classified as meeting criteria for Category A, B or C in such settings.

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19 151 *Step 2*

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21 152 In each hospital, stratified-random sampling will be used to generate a random sample of twelve
22 153 shifts/time blocks of 12 hours (144 observation hours per hospital) from within a 3 week period
23 154 stratified by disease severity (category A, B, C), weekdays and weekends as well as night and day shifts
24 155 as care has been shown to vary across these periods[29,30]. The 12 shifts will be divided equally across
25 156 the newborn unit sections within a hospital where there is more than one section. Where all babies are
26 157 cared for in one room without clear sub-sections all observation periods will be conducted in this same
27 158 setting with efforts to observe babies requiring different levels of care.

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31 159 *Step 3*

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33 160 We feel that it is logistically feasible for one observer to make direct observations of 3 babies located in
34 161 adjacent cots in the same ward area at one time. Therefore, for each shift and section, 3 babies who
35 162 meet the inclusion criteria will be purposefully selected to ensure babies are in one ward area and
36 163 within close proximity to allow direct observations. In smaller units where the number of babies per
37 164 section may be less than 3, we will observe all the babies available in the section and classify them as
38 165 eligible for care in category A, B or C.

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42 166 **Sample size**

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44 167 This is an exploratory cross-sectional study and as such, we illustrate the precision with which we can
45 168 report proportions of tasks done (or not done) assuming different sized denominators. The size of the
46 169 denominator is related to the recommended frequency that tasks should be performed (see figure 2). To
47 170 estimate the precision of reporting we have used a sample estimation approach for cluster designs and
48 171 assuming a design effect of 2 to adjust for clustering of observed tasks around individual newborns
49 172 within hospitals.

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53 173 At most we expect to recruit 216 newborns across 6 hospitals (36 newborns per hospital with 3 babies
54 174 for each of the 12 shifts/time blocks). For tasks that would be conducted with an expected frequency of
55 175 once in 12 hours (e.g. intravenous pencillin administration) we might therefore observe 216 task

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3 176 opportunities. Taking a (statistically) conservative assumption that on 50% of expected occasions the
4 177 task is observed to be done then we could report this with a precision of $\pm 13.4\%$. Similarly, if a task
5 178 should be conducted every 6 hours then the denominator would be 432 expected tasks and if half were
6 179 observed the precision of this estimate would be $\pm 6.7\%$.

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9 180 Not all babies observed will require all tasks. For example, some babies may not be receiving
10 181 intravenous drugs. This will reduce the effective size of the denominator and reduce the precision we
11 182 can report. Similarly, if babies have to leave the area of observation (for example they are moved to a
12 183 new ward area or are sent for X-ray etc) this may reduce the number of expected tasks that can be
13 184 observed. In addition, failure to recruit 3 babies at each 12-hour shift at each facility may also reduce
14 185 the number of tasks observed. We illustrate the effect this has on the precision of reported estimates in
15 186 figure 2, which illustrates that with as few as 30 expected tasks, reporting a precision of $\pm 20.5\%$ is
16 187 possible.

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20 188 As this work is a first of its kind (globally as far as we are aware) we feel that providing estimates of the
21 189 proportion of tasks done/left undone with a precision of approximately $\pm 20\%$ will be sufficient to
22 190 provide valuable insights into the challenges faced by nurses in providing newborn care.

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25 191 **Figure 2: Precision levels for different newborn sub-populations and tasks**

26 27 192 **Procedures**

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29 193 For each newborn being observed, the diagnosis and disease severity information will be collected from
30 194 medical records as this informs the expected number of tasks. At the beginning of every shift for which
31 195 observations will be made, the total number of nursing tasks expected to be delivered will be
32 196 determined with reference to the medical and nursing records (for disease severity and specific
33 197 interventions like phototherapy) and general aspects of care each baby should receive. For each of the
34 198 newborns selected to participate in the study, we will make direct observations on how often certain
35 199 routine nursing tasks (listed in table 1) are undertaken in a 12-hour shift (7am -7pm or 7pm to 7am)
36 200 using an observation checklist. Observations will be stopped if a baby is transferred out of a section or
37 201 discharged, however, we will use the data collected up to the point of exit and the number of
38 202 observation hours will be documented. If the babies' condition changes and their category changes but
39 203 they remain in the same observation area, we will document this change and revise the expected
40 204 number of tasks. In both instances the effective denominator for expected nursing tasks will be changed
41 205 as required.

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47 206 The observer will be stationed in a ward area where they do not obstruct care provision but can observe
48 207 the care being provided to the newborns selected for observation. Because most of the documentation
49 208 activities happen at the nurses' desk/station, all tasks related to documentation cannot be observed
50 209 from the cot-side. The documented tasks for the babies under observation will be evaluated at the end
51 210 of each 12-hour shift for which observations will be made. We acknowledge that 12 hours is a long
52 211 period and the observer's efficiency for making observations might reduce as time progresses within an
53 212 observation time block and study period. We will factor in rest periods in the 12-hour shifts that coincide
54 213 with when nurses take their breaks, for instance, during tea and lunch breaks, periods which we

214 anticipated limited or no tasks will be undertaken. Further, to allow enough rest between observation
 215 time blocks, we will aim to have a maximum of 3, 12-hour observation periods per week per observer
 216 with at least a 24-hour rest period between observations. The 12-hour periods were selected because
 217 they span nursing shift change overs that allowed documentation of care round-the-clock and made
 218 random selection of time blocks more feasible.

219 The observation checklist (supplementary file 1) is based on nursing standards produced after two
 220 expert group meetings held in November 2015 and July 2016 at the KEMRI Wellcome Trust Research
 221 Programme offices. The nurse stakeholder group comprised expert nurses who are in the teaching
 222 profession or senior practitioners and including the acting Chief Nursing Officer for Kenya. They defined
 223 a minimum standard for performing nursing tasks on newborn units[28]. A sub-set of tasks identified as
 224 critical (listed in table 1) by the nurse stakeholder group was explicitly marked as to only be performed
 225 by nurses and not by other personnel due to the skills required when they are delivered. Where
 226 necessary tasks are broken down into manageable observable task components to facilitate
 227 observation. For instance, naso-gastric feeding is broken down into insertion of the NGT (as required),
 228 checking for gastric aspirate before feeding, counter checking feed volumes to be given with
 229 prescription, actual feeding and charting the feeds given. The purpose of observation is not to assess
 230 how well any particular aspect of a task is done (eg. the care taken in administering naso-gastric feeds)
 231 but simply to determine if the task (or task component) was (or was not) done at all.

232 Prior to the start of the study, the observation checklist (supplementary file 1) will be extensively piloted
 233 over a period of 6 weeks to determine the quantity and quality of data that can be reasonably gathered
 234 and will be adapted as needed. The tool will be piloted in one public health facility that will not be used
 235 as a study site in the final study by the research assistant who will subsequently be responsible for
 236 training the data clerks. During piloting, we will observe care provision in each of the nursing 12-hour
 237 time blocks to explore what tasks can be observed, what number of newborns will be logistically feasible
 238 to observe, the different nursing routines in the different shifts and the documents used for reporting
 239 on nursing activities.

240 Table 1: Routine and critical tasks for observation

Routine tasks	Critical tasks
Patient assessment at the beginning of each shift	Naso-gastric feeding
Cleaning of the baby	<ul style="list-style-type: none"> • Insertion of the NGT
Changing baby's linen	<ul style="list-style-type: none"> • Testing whether it is in the correct position
Changing the baby's position	<ul style="list-style-type: none"> • Checking for gastric aspirate before feeding
Checking incubator settings	<ul style="list-style-type: none"> • Preparation of feeds and counter checking feed volumes
Ward round attendance and active note taking	<ul style="list-style-type: none"> • Actual feeding and charting the feeds
Weighing	Intravenous drug/fluid administration
Elimination care	<ul style="list-style-type: none"> • Reviewing treatment sheet
Communication/counselling parents	<ul style="list-style-type: none"> • Checking cannula sites – care
Cord care	<ul style="list-style-type: none"> • Regulating flow
Vital signs measurement	<ul style="list-style-type: none"> • Input/output charting for fluids • Document treatments given

<ul style="list-style-type: none"> • Pulse rate • Temperature • Respiratory rate • Oxygen saturation <p>Documentation</p> <ul style="list-style-type: none"> • Updating the nursing cardex • Discharge and admission registration 	<p>Oxygen therapy</p> <ul style="list-style-type: none"> • Fixing of oxygen/nasal prongs • Checking tube position and nostril –care, damage • Initiating and regulating oxygen flow • Documenting oxygen treatment <p>Photo therapy</p> <ul style="list-style-type: none"> • Baby positioning • Placing/checking eye pad is in place • Checking eyes for damage • Checking and monitoring phototherapy settings • Documenting of phototherapy <p>Support for KMC</p>
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242 For purposes of this study, we adopted the definition of missed care reported in wider
 243 literature[22,31], and was therefore defined as care that the nursing advisory group regard as
 244 necessary (primarily essential neonatal nursing tasks) as part of routine newborn care that are left
 245 undone or are delivered by any person other than the nurse or a qualified health care provider
 246 (nutritionist, doctor, clinical officer etc). However, tasks that will be done by a senior student nurse
 247 under direct observation/supervision by the nurse will be considered as done and documented as not
 248 done if no supervision is observed. For example, tasks done by a senior student nurse who is being
 249 supervised to conduct naso-gastric feeding by a qualified nurse in the room at the time and focused on
 250 the supervision will be regarded as done. If the same student does the task while the nurse supervising
 251 is in a different part of the ward it will be regarded as not done (with a record of who completed the
 252 task made). Additional data to be collected related to each block of observation time will include data
 253 on the nurse-patient ratio for the ward as a whole, what additional staff are present within the unit e.g.
 254 nursing students, support staff etc. and patient workloads within the different sections of the ward.

255 **Practical considerations for undertaking direct observations**

256 Observations will be made by a person familiar with the hospital environment, equipment, processes
 257 (like ward rounds) and language but who is not a nurse or clinician (doctor/clinical officer). Given the
 258 potential sensitivity of this form of observation, it is important that this person is considered a
 259 professional rather than an 'outsider' (who might not be bound by professional codes of
 260 confidentiality). Having an observer who has an understanding of the setting but who is not a clinician
 261 or nurse may also overcome problems of the observer making judgements about what is being
 262 observed based on their own standards of practice or being influenced as they make observations by
 263 professional allegiances (eg. a nurse observer may not wish to record that a task is left undone). There
 264 might also be ethical challenges for an observer with a clinical/nurse background who might feel
 265 obliged to intervene in the provision of care or become co-opted to complete tasks. An observer who is
 266 not licensed to offer the form of interventions/care being given to babies will still however be able to
 267 report to health care providers within the unit in the event they identify gaps or situations in which

268 newborns are put at risk. For instance, if they see a newborn convulsing or vomiting, they will alert the
269 nurse. Suitable backgrounds for observers might include nutritionists, health records officers, ward
270 based clerical workers, or laboratory or pharmacy staff with at least two-year's experience within
271 hospital settings. In this study nutritionists will be recruited to undertake the observations.

272 We will recruit six observers who meet the above criterion. The observers will be trained for a period of
273 2 weeks by one of the study personnel who has a nursing background and has 2 years' experience
274 providing care to newborns within a newborn unit. Standard operating procedures (SOPs) will be
275 developed and will serve as a guide for the observational work. During the training period, the
276 observers and the trainer will do observations and comparisons will be made. Any differences will be
277 discussed and where necessary the SOPs will be revised to improve on clarity. Supervision during the
278 data collection period will be undertaken by study staff with a nursing background with routine weekly
279 reviews of the observation checklists for completion and consistency.

280 To reduce the Hawthorne effect where nurses might change the way they provide care when they are
281 being observed, the observer will spend at least 1 week in the health facility before starting the
282 observational work. This will also allow him/her to familiarise themselves with the environment, to
283 explain the study to staff and parents and for the staff within the newborn unit to get used to them. In
284 addition, the observer will make it clear that the observations are not an assessment but a means of
285 understanding what care is possible to provide given existing resource constraints. Formal study
286 observations will then begin in the period after the one-week familiarisation period. This approach is
287 supported by evidence that health care providers change their practice slightly when the observations
288 start but these changes are short-lived and quickly dissipate with health care providers soon reverting
289 to their previous practice[32,33]. In addition, the 12-hour observation periods are randomly generated
290 and the hospitals will not be aware of the day, shift or category of babies the observer would next
291 come to do observations for.

292 **Practical and public involvement**

293 Patients and the public were not involved in the development of the research question or outcome
294 measures. However, as part of the broader set of work within which this study is embedded, there is
295 ongoing work to understand patient experiences focusing on experiences of mothers with newborns
296 admitted within the newborn unit. We hope findings from our study will compliment those from the
297 patient experiences work and will provide insights on aspects of care that are important to mothers but
298 also inform the design of interventions to improve care.

299 **Data Management and analysis**

300 Data will be collected on paper-based observation checklists, one for each baby that is the focus of
301 observation. No participant identifiable data will be collected and data collection instruments will be
302 identified only by a unique study ID allocated to each baby. The place, date and time of the shift will also
303 be anonymised by using only specific codes for observation shifts at data entry. Data on the paper-based
304 observation checklists will be checked for completeness by a supervisor at the end of each day. The
305 checklists will be double-entered into a custom-made database using Research Electronic Data Capture

306 (REDCap) with inbuilt range and consistency checks. The entered data will be checked at the end of each
307 day using pre-coded scripts for entry errors and completeness. Data will be exported for cleaning and
308 analyses in Stata version 13 (Stata Corporation, Texas, USA).

309 Descriptive analysis will be undertaken on the pooled data across hospitals to determine the overall
310 prevalence of care left undone and the common tasks that are left undone. We will also report the
311 average number of tasks left undone per newborn and the common tasks left undone per newborn.
312 Secondary analysis will be undertaken to explore variations in care done (or left undone) by the various
313 sub-categories that will include: sector, nursing shift, nurse-patient ratios and category of the baby
314 (disease severity).

315 **Ethical considerations**

316 The focus of our direct observations of care is what happens to newborns and we will not record any
317 names or other identifying features of people who may be providing care to these newborns. We will
318 only report pooled results stratified by sector, nurse-patient staffing ratios and category/severity of
319 disease so as to preserve the confidentiality of the health facilities.

320 During the one-week familiarisation period, we will seek written individual informed consent from all
321 nurses who will be providing care within the newborn unit. Additional consent forms and study briefs
322 will be left in the ward to allow nurses not available during this introductory period but who provide
323 care in the newborn unit to review and indicate their willingness to participate. During an observation
324 shift these nurses will be asked for individual informed consent before the start of the observations.
325 Additionally, at the beginning of every shift for which direct observations will be made, group verbal
326 informed consent will be sought from nurses after an explanation of the study has been made (this is in
327 addition to the 1-week familiarisation during which the study will be explained). We will also provide
328 printed study briefs targeting health care providers explaining the study but also indicating that they are
329 free to decline from being observed as an approach to on-going consent.

330 Written informed consent will be sought from the mothers of babies considered for direct observations
331 at the start of each observation period. In Kenya, pregnant adolescents between ages (15 – 17 years) are
332 considered ‘emancipated minors’ and their written informed consent will be obtained[34–36]. The start
333 of the direct observation shift (7am or 7pm) is just before when mothers are in the newborn unit for the
334 3-hourly feeding session at 6am or 6pm, as such mothers will be approached during this period. In
335 instances, where mothers indicate more time is required to make a decision or to consult they will be
336 allowed to do so and another mother whose baby meets the criteria for observation will be approached.
337 In cases where nurses or parents decline consent, babies under their care will not be considered for
338 direct observation. It will be made clear that at any stage nurses or parents can withdraw
339 consent/permission for observation, temporarily or for the rest of a shift, without explanation and with
340 no penalty. Observations will only be undertaken where both the mother and nurses have provided
341 consent to the study respectively.

342 Ethical approval to conduct this study in all hospitals has been granted by the Kenya Medical Research
343 Institute (KEMRI) Scientific and Ethics Review Unit (Approval No. KEMRI/SERU/CGMR-C/065/3404) while
344 permission to undertake the study in the respective hospitals was sought from each of the hospital’s
345 administrative offices.

346 **Dissemination of findings**

347 An expert advisory group, including partners from the Ministry of Health, Nursing Council of Kenya,
348 Nairobi City County, Kenya Medical Training College, Kenyatta University, and hospitals providing
349 inpatient neonatal services has been involved in the development of the standards of nursing care being
350 used to understand missed care in this study. This expert group has provided support for the study and
351 is in itself a key consumer of the results as these members are directly involved in policy making and
352 training. This group will also provide a key channel for wider dissemination of the findings.

353 Highlighting the extent and magnitude of care left undone will provide important insights on the nursing
354 care available to newborns admitted within newborn units, highlight human resource issues warranting
355 attention and will likely influence recommendations on staffing norms and how care is organised and
356 delivered in newborn units. Further, findings from this work will help guide the design of approaches
357 and interventions for improving facility based care for this highly vulnerable population.

358 At the end of the study, findings will be provided to and discussed with participating hospitals and other
359 relevant stakeholders. More widely, the international scientific community will be targeted via
360 publications in peer reviewed journals as well as conferences.

361 **Global public health relevance**

362 Facility based care has been cited as one key approach to reduce neonatal mortality if evidence-based,
363 high impact low cost interventions are appropriately delivered at high coverage[4]. Globally, improving
364 quality of newborn care provided by facilities might save 600 000 small and ill neonates annually[4]
365 while data from Kenya suggest that by 2030, 6000 newborn lives could be saved through the provision
366 of childbirth and newborn care intervention packages alone[37].

367 The Kenyan government is promoting facility based delivery by making maternity care free for women.
368 This has resulted in an increase in utilisation of maternal and newborn health services, potentially
369 increasing the number of newborns accessing care in health facilities. At the same time significant
370 challenges exist in nurse staffing and availability of wider resources[27] and this may limit any impact of
371 increased access to care. The extent of missed nursing care in newborn units in LMIC and how it impacts
372 on quality of care delivered has not previously been described. This is despite care in the newborn unit
373 being heavily dependent on nurses. By characterising care left undone, we will identify important
374 potential gaps in care delivered within newborn units that can inform discussions on how best to
375 address these gaps and improve quality of care in Kenyan hospitals.

376 This study will be the first attempt, of which we are aware, to develop and apply direct observational
377 missed care tools to understanding neonatal nursing care provision in LMIC. In fact, a recent review by
378 Jones and colleagues identified that only questionnaires have previously been used to quantify missed
379 care and these might be limited by reporting bias[22]. However, we acknowledge that direct
380 observational methods have limitations on the number and actual tasks that can be observed, might be
381 influenced by observer bias and are at risk of Hawthorne effect. As such, the tasks in our observation
382 checklist (supplementary file 1) are limited to essential neonatal nursing tasks provided at the bedside
383 that can be observed while those linked to documentation will involve review of medical records at the

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3 384 nurses' desk since documentation of care is done at the nurses' desk and not at the cot-side. Moreover,
4 385 observing the documentation of a task or reviewing records for evidence of documentation is likely to
5 386 provide similar results. An alternative method for data collection that we considered was the use of
6 387 video in the newborn unit with later evaluation of what is done (or not done). However, informal
7 388 discussions indicated this might be controversial at this stage due to the ethical and medico-legal issues
8 389 that might emanate from this approach and the administrative approvals required for video recording in
9 390 hospitals, nonetheless this is a potential area for future research. The selection of health facilities was
10 391 purposive, as support by the hospital administration was important due to the nature of data collection
11 392 and the sensitivity associated with direct observation of care. As such, we cannot rule out selection bias
12 393 as facilities providing better care might have been more likely to agree to partake in the study. However,
13 394 this is the first such study using direct observational methods to quantify missed care and in a LMIC and
14 395 therefore the findings will still be important. We anticipate that this study will, therefore, be of global
15 396 interest and provide an opportunity for application of the methods developed to other neonatal settings
16 397 or in other disciplines to better understand nursing care provision and quality gaps. Further, findings of
17 398 this work will be important in contributing to thinking on nurse staffing norms and how care is organised
18 399 and delivered in LMIC newborn units. This will be crucial in influencing longer term policy on human
19 400 resource planning. Most directly the findings will feed into the 'Kenya Task Sharing Policy and Guidelines
20 401 for Health Care Services'[38], an initiative being led by Ministry of Health alongside other stakeholders
21 402 as one of the ways of tackling health workforce shortages.

22 403 **Authors' contributions**

23 404 DG, ME and GAVM designed the study with contributions from RK and ET. DG, NA, and GS were
24 405 responsible for the coordination and supervision of data collection. DG wrote the study protocol with
25 406 substantial and critical input from all co-authors. All authors read and approved the final version of the
26 407 manuscript.

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31 412 by a Wellcome Trust Senior Research Fellowship (#097170).

32 413 **Competing interests**

33 414 None

34 415

35 416 **Figure legends**

36 417 Figure 1: Steps for the sampling procedure

37 418 Multi-stage sampling procedure within a hospital for selecting newborns for direct observation

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3 420 Figure 2: Precision levels for different newborn sub-populations and tasks
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5 421 Estimated levels of precision for the different newborn sub-populations and tasks observed that the
6 422 study will report since not all newborns observed will require all tasks.
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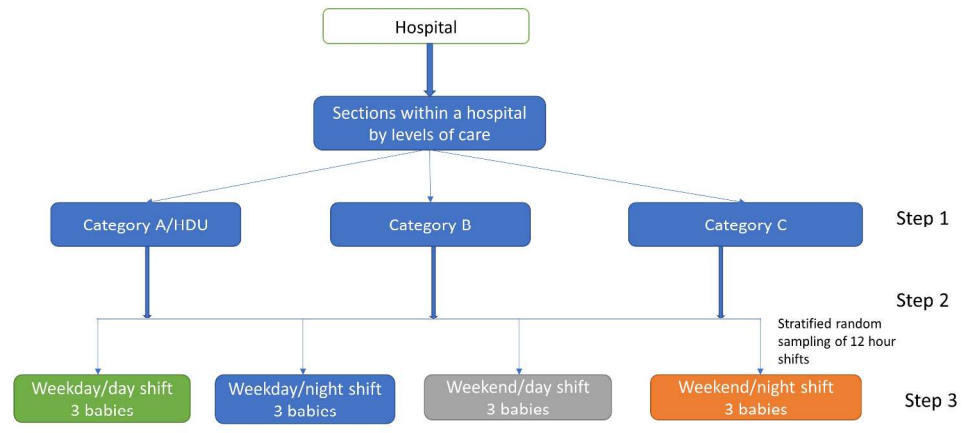
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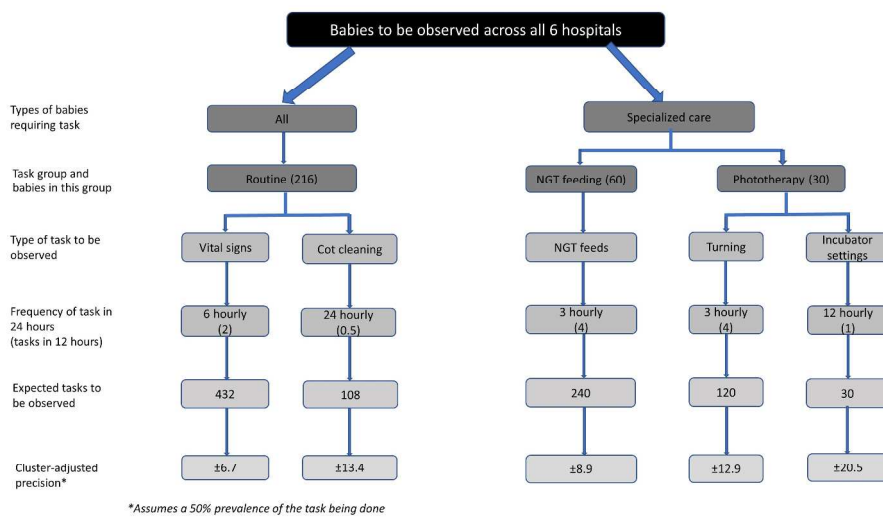
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Multi-stage sampling procedure within a hospital for selecting newborns for direct observation

338x190mm (300 x 300 DPI)

Review only



Precision levels for different newborn sub-populations and tasks

338x190mm (300 x 300 DPI)

Review only

Quantifying neonatal nursing care observational checklist

Hospital logistics

1. Start of observation: Date Time
2. End of observation: Date Time
3. Shift: Weekday day Weekday night
Weekend day Weekend night
4. Total number of patients in the ward:
5. Total Number of:
 - Admissions
 - Discharges
 - Referrals
 - Death
6. Number of nurses on shift:
 - Straight day shift
 - Morning shift
 - Afternoon shift
 - Night shift
7. Number of other staff providing care other than the nurse:
 - Doctor
 - Clinician
 - Health care assistant
 - Student nurse
 - Student CO
 - Upgrading nurse students

Others _____

Bio data

8. Child category: A. (Critical/HDU)
 B. (Acute)
 C. (Stable)

9. Date of admission

10. Age (days/ If day 1 of life give hours)

11. Gender: Male

Female

12. Admission diagnosis: _____

13. Current diagnosis: _____

14. Birth weight (grams)

15. Current weight (grams) Date taken

16. Type of delivery: SVD CS AVD

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Tasks	Frequency of task	Expected number tasks to be done(12 hours/shift)	Tasks done				Time task done				Comments
Routine Tasks											
Handing over		1	<input type="checkbox"/>								
Patient assessments performed each shift		1	<input type="checkbox"/>								
Cleaning of baby		1	<input type="checkbox"/>								
Change of linen		1	<input type="checkbox"/>								
Checking incubator settings		1	<input type="checkbox"/>								
Nurse attends ward round with doctor(s)		1	<input type="checkbox"/>								
Weight check		1	<input type="checkbox"/>								
Elimination care		1	<input type="checkbox"/>								
Discharge planning		1	<input type="checkbox"/>								
Communication/counselling to parent		1	<input type="checkbox"/>								
Hand washing/ Hand rub using sanitizer		1	<input type="checkbox"/>								
Cord care		1	<input type="checkbox"/>								
Checking cannula site		1	<input type="checkbox"/>								
Regular Tasks											
Checking vital signs*	4/6 Hourly	3	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>						
Temperature check*	4/6 Hourly	3	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>						
Pulse check*	4/6 Hourly	3	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>						
Respiratory rate check*	4/6 Hourly	3	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>						
SpO2 check*	4/6 Hourly	3	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>						
Turning	4 Hourly	3	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>						
Cup/spoon feeding	3 Hourly	4	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>					
Breast feeding	3 Hourly	4	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>				
*Dependent on neonate category											

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Tasks	Frequency of task	Expected number tasks to be done(12 hours/shift)	Tasks_done				Time task done				Comments
Critical Tasks											
Naso gastric tube feeding											
Checking for correct position of tube	3 Hourly	4	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Checking gastric aspirate before feeding	3 Hourly	4	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Checking actual volume of feeds	3 Hourly	4	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Actual feeding	3 Hourly	4	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Positioning baby after feeding	4 Hourly	4	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Phototherapy											
Turning/positioning	4 Hourly	3	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Skin assessment	6 Hourly	2	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Checking eyes if protected from damage	6 hourly	2	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Changing eye pad	12 Hourly	1	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Eye care	12 Hourly	1	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Oxygen therapy											
Checking tube position and nostril-care, damage	3 Hourly	4	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Regulating oxygen flow	12 Hourly	1	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Intravenous drug administration											
Dilutions and checking compatibility		2	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Review of treatment sheet		2	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Flushing cannula before administering drug		2	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Administration of medication		2	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Flushing cannula after giving medication		2	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

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Tasks	Frequency of task	Expected number tasks to be done(12 hours/shift)	Tasks_done	Time task done	Comments
Intravenous Fluid administration					
Review of treatment sheet		1	<input type="checkbox"/>	<input type="checkbox"/>	
Priming of giving set		1	<input type="checkbox"/>	<input type="checkbox"/>	
Flushing cannula before starting the fluid		1	<input type="checkbox"/>	<input type="checkbox"/>	
Administration and regulating flow rate		1	<input type="checkbox"/>	<input type="checkbox"/>	
Kangaroo Mother Care					
Support for KMC		1	<input type="checkbox"/>	<input type="checkbox"/>	
Supervision of mother during KMC		1	<input type="checkbox"/>	<input type="checkbox"/>	
Documentation of tasks					
Tasks	Done	Not done	Comments		
Neonatal assessment (nursing cardex)	<input type="checkbox"/>	<input type="checkbox"/>			
Planned care (cardex/care plan)	<input type="checkbox"/>	<input type="checkbox"/>			
Vital signs (observation charts/cardex)	<input type="checkbox"/>	<input type="checkbox"/>			
Treatment (treatment sheets)	<input type="checkbox"/>	<input type="checkbox"/>			
Ward round comments (cardex)	<input type="checkbox"/>	<input type="checkbox"/>			
Phototherapy (cardex)	<input type="checkbox"/>	<input type="checkbox"/>			
Feeds (feeding chart)	<input type="checkbox"/>	<input type="checkbox"/>			
Oxygen therapy (cardex)	<input type="checkbox"/>	<input type="checkbox"/>			
Health talks/ Communication to parent (cardex)	<input type="checkbox"/>	<input type="checkbox"/>			
Fluids (input output chart)	<input type="checkbox"/>	<input type="checkbox"/>			

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4	Turning/position(cardex and/or turning chart)	<input type="text"/>	<input type="text"/>
5			
6	Alternate weight check	<input type="text"/>	<input type="text"/>
7	Treatment		
8			Times administered in the last 24 hours
9			
10			
11			
12			
13			
14	Drug name	Frequency	Comments
15			
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Tasks observed for other babies

Task	Observed	Comment
Administration of vaccines		
Taking venous blood		
Taking heel prick		
Blood/exchange transfusion		
CPAP(setup of machine n tubings)		
Resuscitation		

Other tasks observed not mentioned above

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Quantifying nursing care delivered in Kenyan newborn units: Protocol for a cross-sectional direct-observational study

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1 Quantifying nursing care delivered in Kenyan newborn units: Protocol for a cross-sectional direct- 2 observational study

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23 Abstract

24 **Introduction:** In many African countries, including Kenya, a major barrier to achieving child survival goals
25 is the slow decline in neonatal mortality that now represents 45% of the under-5-mortality. In newborn
26 care, nurses are the primary care givers in newborn settings and are essential in the delivery of safe and
27 effective care. However, due to high patient workloads and limited resources, nurses may often
28 consciously or unconsciously prioritise the care they provide resulting in some tasks being left undone or
29 partially done (missed care). Missed care has been associated with poor patient outcomes in high
30 income countries. However, missed care, examined by direct observation, has not previously been the
31 subject of research in LMICs.

32 **Methods and analysis:** The aim of this study is to quantify essential neonatal nursing care provided to
33 newborns within newborn units. We will undertake a cross-sectional study utilising direct-observational
34 methods within newborn units in six health facilities in Nairobi City County across the public, private-for-
35 profit and private-not-for-profit sectors. A total of 216 newborns will be observed between 1st
36 September 2017 to 30th May 2018. Stratified random sampling will be used to select random 12-hour
37 observation periods while purposive sampling will be used to identify newborns for direct-observation.

38 We will report the overall prevalence of care left undone, the common tasks that are left undone and
39 describe any sharing of tasks with people not formally qualified to provide care.

40 **Ethics and dissemination:** Ethical approval for this study has been granted by the Kenya Medical
41 Research Institute Scientific and Ethics Review Unit. Written informed consent will be sought from
42 mothers and nurses. Findings from this work will be shared with the participating hospitals, an expert
43 advisory group that comprises of members involved in policy making and more widely to the
44 international community through conferences and peer-reviewed journals.

Strengths and limitations

- The use of direct observational methods to quantifying nursing care delivered or left undone is an approach that has not been previously used in LMICs.
- Different sectors (public, private-for-profit, private-not-for-profit) in health service provision have been included in this study.
- The study provides a 24-hour assessment of neonatal nursing care provision including care provided on weekends and weekdays.
- Our scope is limited by the few number of newborns to be observed within each hospital.
- Despite our efforts to minimize the Hawthorne effect, we cannot rule out the possibility of nurses changing the way they provided care during the observational periods.

45

46

Introduction

47 Despite progress globally, most African countries including Kenya have made insufficient progress in
48 reducing child mortality. In most countries, this can be partly attributed to only slow declines in neonatal
49 mortality. As a consequence, about 45% of mortality for children under-5 years is attributable to
50 neonatal mortality[1]. Of these neonatal deaths, approximately 75% occur in the first 7 days of life and
51 half of these within 24 hours of life[2][3]. A recent review by Bhutta and colleagues indicated that high
52 impact low cost interventions could avert more than 71% of neonatal deaths with 82% of this effect
53 being attributable to facility-based care[4]. However, reports from low income settings highlight that the
54 quality of newborn care in health facilities is often poor[5][6][7]. Therefore, strengthening the quality of
55 facility based care for newborns will be essential in improving newborn outcomes.

56
57 Human Resources for Health (HRH) inadequacies is a major factor limiting delivery of quality neonatal
58 services [8]. Globally, the shortage of health workers is estimated currently at over 7 million and by 2035
59 the deficit is estimated to be 12.9 million[9]. The shortages in the available workforce are worst in
60 developing countries where inequitable distribution of available health workers may compound the
61 problems. In Kenya, Wakaba and colleagues reported that public sector nursing densities ranged
62 between 0.008 to 1.2 per 1000 population across counties[10] compared to an internationally suggested

63 minimum health workforce threshold of 2.5/1000 population for doctors, nurses and midwives. In
64 Nairobi County, the nurse densities ranged between 0.21 to 0.40 per 1000 population[10].

65 There is little specific exploration of the impact of nursing workforce shortfalls on inpatient care in Low
66 and Middle-Income Countries (LMIC). Yet to improve quality of care it is essential that we understand
67 who delivers care (what tasks are done by whom), how care is delivered (how are tasks performed) and
68 critically analyse what tasks are left undone. In most health systems, nurses are gatekeepers of the
69 health care being delivered. They are vested with the responsibility of delivering interventions
70 prescribed by other providers (doctors, nutritionists etc) in addition to providing nurse initiated
71 interventions[11]. As a consequence, few interventions reach the patient without the involvement of
72 the nurse. Yet the few existing evaluations of the quality of care provided to newborns in LMIC have
73 focused on the more medical aspects of care[6,12,13][14]. In LMIC facilities, large patient workloads,
74 insufficient staff and resources, urgent patient situations, and unexpected rises in patient volume and/or
75 acuity on the unit (among other factors) might result in all facets of nursing care being delayed or
76 neglected. This phenomenon has been described as 'implicit rationing'[15], 'missed care'[16], or 'unmet
77 nursing care needs'[17], 'care left undone'[18], or 'task incompleteness'[19]. Hereafter, we use the term
78 missed care to encompass all of these terms. Such missed care may have a particularly devastating
79 impact on outcomes in newborn units where nurses are the primary care givers to this highly dependent
80 group.

81 Justifying a focus on missed nursing care several studies have reported associations between missed
82 care and patient outcomes[20,21][22]. Although there is a growing literature on missed care the
83 majority is from high resource settings, with only one study in South Africa[23] providing an early formal
84 attempt to quantify the extent of the problem in this middle income country. Furthermore, almost all
85 the literature on missed care is based on nurse surveys with only two focusing on newborn care
86 provision[24,25]. Although, nurse surveys on missed care have proven useful, there is a call to undertake
87 more research with a special focus on objective observational methods as no studies of this type were
88 identified in a recent systematic review [22]. The proposed study aims to characterise the care delivered
89 (tasks done or left undone and who does these tasks) to newborns receiving care within newborn units
90 in Nairobi, Kenya by making direct observations of care being provided. This will provide in-depth and
91 objective insights on missed care with particular reference to locally agreed standards for nurses
92 providing neonatal care.

93 **Methods and analysis**

94 This is a cross-sectional study that will involve direct observation of care provided to individual
95 newborns with the aim of describing the essential neonatal nursing care given or missed within newborn
96 units. It will be undertaken in 6 hospitals in Nairobi City County, Kenya, in the period 1st September 2017
97 to 30th May 2018.

98 **Study site**

99 The proposed research work will be undertaken as part of a broader set of work being conducted in
100 collaboration with Nairobi City County. This collaboration includes work to characterise all the facilities
101 providing inpatient newborn care 24 hours, 7 days a week (hereafter referred to as 24/7) in Nairobi [26],

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2
3 102 quality of clinical care provided newborns[27], and ethnographic work to understand the wider context
4 103 and practice of neonatal nursing. Based on findings from the broader study, Nairobi county has 34
5 104 health facilities providing 24/7 inpatient newborn care, of these, two small health facilities declined to
6 105 take part in prior quality of care surveys and were estimated to have less than 50 neonatal admissions
7 106 each per year[27]. Excluding the military health facility with restrictive admission policy, the remaining
8 107 31 health facilities that form the population for this study provide 99% of all inpatient neonatal care.

11 108 This current study will focus on primary referral (secondary care) facilities that have more than 100
12 109 neonatal admissions annually. As such, the two health facilities that declined to participate in prior
13 110 quality of care surveys do not meet this criterion and are unlikely to introduce selection bias. Thirteen
14 111 facilities meet these criteria and together provide care to over 96% of the sick-newborn population
15 112 accessing care within Nairobi County[27]. These 13 facilities will be stratified by workload (newborn
16 113 admissions per year ≤ 500 low; >500 high) and six health facilities purposefully selected to ensure
17 114 representation of two hospitals in each of the public, private-not-for profit and private-for-profit
18 115 sectors, with one high and one low workload facility in each sector. Purposeful selection will be used as
19 116 it is important in this sensitive and innovative work to have the strong support of the hospital
20 117 administration. This initial work will therefore help illustrate the nature and magnitude of the challenge
21 118 of missed care but not make claims to provide a statistically representative picture of missed care which
22 119 would be challenging given the great diversity of facilities found in Nairobi, with some health facilities
23 120 having as low as 10 neonatal admissions per year[27].

29 121 **Study populations**

31 122 All newborns admitted within the newborn unit in the 6 selected health facilities over the period of the
32 123 study in each facility will form the potential study population. However, newborns meeting the following
33 124 exclusion criteria will not be observed: i) newborns requiring specialised treatment to whom the draft
34 125 minimum nursing standards for neonatal care[28] may not be applicable, for instance newborns with
35 126 gross malformations or those receiving post-operative care, ii) newborns who are critically ill and at risk
36 127 of death within a 12-hour observation period as defined by the clinician in charge of the newborn unit
37 128 for whom observation might cause distress to families, iii) newborns for whom guardians do not provide
38 129 consent, and iv) newborns receiving care from nurses or guardians who decline to be observed in the
39 130 care provision process.

43 131 **Sampling procedures**

45 132 To describe the care being provided to newborns admitted in newborn units and the spectrum of
46 133 inpatient services they receive, we are aiming to sample time in 12-hour shifts randomly using the steps
47 134 described in figure 1.

50 135 ***Figure 1: Steps for the sampling procedure***

52 136 *Step 1*

54 137 Care within the newborn unit can be organised in a way that babies requiring different levels of care are
55 138 in different sections/rooms. Intensive care employing invasive mechanical ventilation is not available

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3 139 outside tertiary hospitals in Kenya and thus definitions for different levels of newborn care provided by
4 140 County Hospitals were adopted. These are taken from draft nursing standards for neonatal care that
5 141 categorise newborn unit sections (and thus babies) in the following way[28]. **Category A (high**
6 142 **dependency unit, HDU):** Babies on oxygen/CPAP and intravenous fluids who are often acutely ill and
7 143 unstable and require the closest monitoring. **Category B:** Babies who have stabilized but may still be ill
8 144 and receiving, for example, assisted feeding (nasal-gastric feeds), intravenous drugs; or being observed
9 145 for convulsions or apnoea. **Category C:** Babies who are quite stable who should be receiving KMC, or
10 146 stable abandoned babies, or recovering babies requiring completion of treatment such as the last doses
11 147 of antibiotics or transitioning to oral feeding. Our primary sampling strategy will be based on identifying
12 148 these organisational sub-sections (Category A; B; C rooms or incubator/cot spaces) in each facility.
13 149 Where facilities have no clear organisational demarcation into Category A, B and C sub-sections, we will
14 150 adapt the observations to suit the organisation of care in each facility. However, we will endeavour to
15 151 identify and select, for observation, newborns with varying degrees of illness severity who would be
16 152 classified as meeting criteria for Category A, B or C in such settings.

21 22 153 *Step 2*

23
24 154 In each hospital, stratified-random sampling will be used to generate a random sample of twelve
25 155 shifts/time blocks of 12 hours (144 observation hours per hospital) from within a three week period
26 156 stratified by disease severity (category A, B, C), weekdays and weekends as well as night and day shifts
27 157 as care has been shown to vary across these periods[29,30]. The 12 shifts will be divided equally across
28 158 the newborn unit sections within a hospital where there is more than one section. Where all babies are
29 159 cared for in one room without clear sub-sections all observation periods will be conducted in this same
30 160 setting with efforts to observe babies requiring different levels of care.

31 32 161 *Step 3*

33
34 162 We feel that it is logistically feasible for one observer to make direct observations of three babies
35 163 located in adjacent cots in the same ward area at one time. Therefore, for each shift and section, three
36 164 babies who meet the inclusion criteria will be purposefully selected to ensure babies are in one ward
37 165 area and within close proximity to allow direct observations. In smaller units where the number of
38 166 babies per section may be less than three, we will observe all the babies available in the section and
39 167 classify them as eligible for care in category A, B or C.

40 41 168 **Sample size**

42
43 169 This is an exploratory cross-sectional study and as such, we illustrate the precision with which we can
44 170 report proportions of tasks done (or not done) assuming different sized denominators. The size of the
45 171 denominator is related to the recommended frequency that tasks should be performed (see figure 2). To
46 172 estimate the precision of reporting we have used a sample estimation approach for cluster designs and
47 173 assuming a design effect of 2 to adjust for clustering of observed tasks around individual newborns
48 174 within hospitals.

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3 175 At most we expect to recruit 216 newborns across six hospitals (36 newborns per hospital with three
4 176 babies for each of the 12 shifts/time blocks). For tasks that would be conducted with an expected
5 177 frequency of once in 12 hours (e.g. intravenous penicillin administration) we might therefore observe
6 178 216 task opportunities. Taking a (statistically) conservative assumption that on 50% of expected
7 179 occasions the task is observed to be done then we could report the proportion of such a task being done
8 180 with a precision of $\pm 13.4\%$. Similarly, if a task should be conducted every six hours then the
9 181 denominator would be 432 expected tasks and if half were observed the precision of this estimate
10 182 would be $\pm 6.7\%$.

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14 183 Not all babies observed will require all tasks. For example, some babies may not be receiving
15 184 intravenous drugs. This will reduce the effective size of the denominator and reduce the precision we
16 185 can report. Similarly, if babies have to leave the area of observation (for example they are moved to a
17 186 new ward area or are sent for X-ray etc) this may reduce the number of expected tasks that can be
18 187 observed. In addition, failure to recruit three babies at each 12-hour shift at each facility may also
19 188 reduce the number of tasks observed. We illustrate the effect this has on the precision of reported
20 189 estimates in figure 2, which illustrates that with as few as 30 expected tasks, reporting a precision of \pm
21 190 20.5% is possible.

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25 191 As this work is a first of its kind (globally as far as we are aware) we feel that providing estimates of the
26 192 proportion of tasks done/left undone with a precision of approximately $\pm 20\%$ will be sufficient to
27 193 provide valuable insights into the challenges faced by nurses in providing newborn care.

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30 194 **Figure 2: Precision levels for different newborn sub-populations and tasks**

31
32 195 **Procedures**

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34 196 For each newborn being observed, the diagnosis and disease severity information will be collected from
35 197 medical records as this informs the expected number of tasks. At the beginning of every shift for which
36 198 observations will be made, the total number of nursing tasks expected to be delivered will be
37 199 determined with reference to the medical and nursing records (for disease severity and specific
38 200 interventions like phototherapy) and general aspects of care each baby should receive. For each of the
39 201 newborns selected to participate in the study, we will make direct observations on how often certain
40 202 routine nursing tasks (listed in table 1) are undertaken in a 12-hour shift (7am -7pm or 7pm to 7am)
41 203 using an observation checklist. Observations will be stopped if a baby is transferred out of a section,
42 204 changes condition and becomes critically ill (requires specialised treatment which the minimum draft
43 205 nursing standards for neonatal care do not apply) or discharged, however, we will use the data collected
44 206 up to the point of exit and the number of observation hours will be documented. If the babies' condition
45 207 changes and their category changes but they remain in the same observation area, we will document
46 208 this change and revise the expected number of tasks. In both instances the effective denominator for
47 209 expected nursing tasks will be changed as required.

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53 210 The observer will be stationed in a ward area where they do not obstruct care provision but can observe
54 211 the care being provided to the newborns selected for observation. Because most of the documentation
55 212 activities happen at the nurses' desk/station, all tasks related to documentation cannot be observed

213 from the cot-side. The documented tasks for the babies under observation will be evaluated at the end
 214 of each 12-hour shift for which observations will be made. We acknowledge that 12 hours is a long
 215 period and the observer's efficiency for making observations might reduce as time progresses within an
 216 observation time block and study period. We will factor in rest periods in the 12-hour shifts that coincide
 217 with when nurses take their breaks, for instance, during tea and lunch breaks, periods which we
 218 anticipated limited or no tasks will be undertaken. Further, to allow enough rest between observation
 219 time blocks, we will aim to have a maximum of three, 12-hour observation periods per week per
 220 observer with at least a 24-hour rest period between observations. The 12-hour periods were selected
 221 because they span nursing shift change overs that allowed documentation of care round-the-clock and
 222 made random selection of time blocks more feasible.

223 The observation checklist (supplementary file 1) is based on nursing standards produced after two
 224 expert group meetings held in November 2015 and July 2016 at the KEMRI Wellcome Trust Research
 225 Programme offices. The nurse stakeholder group comprised expert nurses who are in the teaching
 226 profession or senior practitioners and including the acting Chief Nursing Officer for Kenya. They defined
 227 a minimum standard for performing nursing tasks on newborn units[28]. A sub-set of tasks identified as
 228 critical (listed in table 1) by the nurse stakeholder group was explicitly marked as to only be performed
 229 by nurses and not by other personnel due to the skills required when they are delivered. Where
 230 necessary tasks are broken down into manageable observable task components to facilitate
 231 observation. For instance, naso-gastric feeding is broken down into insertion of the NGT (as required),
 232 checking for gastric aspirate before feeding, counter checking feed volumes to be given with
 233 prescription, actual feeding and charting the feeds given. The purpose of observation is not to assess
 234 how well any particular aspect of a task is done (eg. the care taken in administering naso-gastric feeds)
 235 but simply to determine if the task (or task component) was (or was not) done at all.

236 Prior to the start of the study, the observation checklist (supplementary file 1) will be extensively piloted
 237 over a period of six weeks to determine the quantity and quality of data that can be reasonably
 238 gathered and will be adapted as needed. The tool will be piloted in one public health facility that will not
 239 be used as a study site in the final study by the research assistant who will subsequently be responsible
 240 for training the data clerks. During piloting, we will observe care provision in each of the nursing 12-hour
 241 time blocks to explore what tasks can be observed, what number of newborns will be logistically feasible
 242 to observe, the different nursing routines in the different shifts and the documents used for reporting
 243 on nursing activities.

244 Table 1: Routine and critical tasks for observation

Routine tasks	Critical tasks
Patient assessment at the beginning of each shift	Naso-gastric feeding
Cleaning of the baby	<ul style="list-style-type: none"> • Insertion of the NGT • Testing whether it is in the correct position • Checking for gastric aspirate before feeding • Preparation of feeds and counter checking feed volumes • Actual feeding and charting the feeds
Changing baby's linen	
Changing the baby's position	
Checking incubator settings	
Ward round attendance and active note	

1 taking 2 Weighing 3 Elimination care 4 Communication/counselling parents 5 Cord care 6 Vital signs measurement 7 • Pulse rate 8 • Temperature 9 • Respiratory rate 10 • Oxygen saturation 11 Documentation 12 • Updating the nursing cardex 13 • Discharge and admission registration 14 15 16 17 18 19 20 21 22 23 24 25 26 27	Intravenous drug/fluid administration • Reviewing treatment sheet • Checking cannula sites – care • Regulating flow • Input/output charting for fluids • Document treatments given Oxygen therapy • Fixing of oxygen/nasal prongs • Checking tube position and nostril –care, damage • Initiating and regulating oxygen flow • Documenting oxygen treatment Photo therapy • Baby positioning • Placing/checking eye pad is in place • Checking eyes for damage • Checking and monitoring phototherapy settings • Documenting of phototherapy Support for KMC
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246 For purposes of this study, we adopted the definition of missed care reported in wider
 247 literature[22,31], and was therefore defined as care that the nursing advisory group regard as
 248 necessary (primarily essential neonatal nursing tasks) as part of routine newborn care that are left
 249 undone or are delivered by any person other than the nurse or a qualified health care provider
 250 (nutritionist, doctor, clinical officer etc). However, tasks that will be done by a senior student nurse
 251 under direct observation/supervision by the nurse will be considered as done and documented as not
 252 done if no supervision is observed. For example, tasks done by a senior student nurse who is being
 253 supervised to conduct naso-gastric feeding by a qualified nurse in the room at the time and focused on
 254 the supervision will be regarded as done. If the same student does the task while the nurse supervising
 255 is in a different part of the ward it will be regarded as not done (with a record of who completed the
 256 task made). Additional data to be collected related to each block of observation time will include data
 257 on the nurse-patient ratio for the ward as a whole, what additional staff are present within the unit e.g.
 258 nursing students, support staff etc. and patient workloads within the different sections of the ward.

259 **Practical considerations for undertaking direct observations**

260 Observations will be made by a person familiar with the hospital environment, equipment, processes
 261 (like ward rounds) and language but who is not a nurse or clinician (doctor/clinical officer). Given the
 262 potential sensitivity of this form of observation, it is important that this person is considered a
 263 professional rather than an 'outsider' (who might not be bound by professional codes of
 264 confidentiality). Having an observer who has an understanding of the setting but who is not a clinician
 265 or nurse may also overcome problems of the observer making judgements about what is being
 266 observed based on their own standards of practice or being influenced as they make observations by

267 professional allegiances (eg. a nurse observer may not wish to record that a task is left undone). There
268 might also be ethical challenges for an observer with a clinical/nurse background who might feel
269 obliged to intervene in the provision of care or become co-opted to complete tasks. An observer who is
270 not licensed to offer the form of interventions/care being given to babies will still however be able to
271 report to health care providers within the unit in the event they identify gaps or situations in which
272 newborns are put at risk. For instance, if they see a newborn convulsing or vomiting, they will alert the
273 nurse. Suitable backgrounds for observers might include nutritionists, health records officers, ward
274 based clerical workers, or laboratory or pharmacy staff with at least two-year's experience within
275 hospital settings. In this study nutritionists will be recruited to undertake the observations.

276 We will recruit six observers who meet the above criterion. The observers will be trained for a period of
277 two weeks by one of the study personnel who has a nursing background and has two years' experience
278 providing care to newborns within a newborn unit. Standard operating procedures (SOPs) will be
279 developed and will serve as a guide for the observational work. During the training period, the
280 observers and the trainer will do observations and comparisons will be made. Any differences will be
281 discussed and where necessary the SOPs will be revised to improve on clarity. Supervision during the
282 data collection period will be undertaken by study staff with a nursing background with routine weekly
283 reviews of the observation checklists for completion and consistency.

284 To reduce the Hawthorne effect where nurses might change the way they provide care when they are
285 being observed, the observer will spend at least one week in the health facility before starting the
286 observational work. This will also allow him/her to familiarise themselves with the environment, to
287 explain the study to staff and parents and for the staff within the newborn unit to get used to them. In
288 addition, the observer will make it clear that the observations are not an assessment but a means of
289 understanding what care is possible to provide given existing resource constraints. Formal study
290 observations will then begin in the period after the one-week familiarisation period. This approach is
291 supported by evidence that health care providers change their practice slightly when the observations
292 start but these changes are short-lived and quickly dissipate with health care providers soon reverting
293 to their previous practice[32,33]. In addition, the 12-hour observation periods are randomly generated
294 and the hospitals will not be aware of the day, shift or category of babies the observer would next
295 come to do observations for.

296 **Practical and public involvement**

297 Patients and the public were not involved in the development of the research question or outcome
298 measures. However, as part of the broader set of work within which this study is embedded, there is
299 ongoing work to understand patient experiences focusing on experiences of mothers with newborns
300 admitted within the newborn unit. We hope findings from our study will compliment those from the
301 patient experiences work and will provide insights on aspects of care that are important to mothers but
302 also inform the design of interventions to improve care.

303 **Data Management and analysis**

1
2
3 304 Data will be collected on paper-based observation checklists, one for each baby that is the focus of
4 305 observation. No participant identifiable data will be collected and data collection instruments will be
5 306 identified only by a unique study ID allocated to each baby. The place, date and time of the shift will also
6 307 be anonymised by using only specific codes for observation shifts at data entry. Data on the paper-based
7 308 observation checklists will be checked for completeness by a supervisor at the end of each day. The
8 309 checklists will be double-entered into a custom-made database using Research Electronic Data Capture
9 310 (REDCap) with inbuilt range and consistency checks. The entered data will be checked at the end of each
10 311 day using pre-coded scripts for entry errors and completeness. Data will be exported for cleaning and
11 312 analyses in Stata version 13 (Stata Corporation, Texas, USA).

12
13
14
15 313 Descriptive analysis will be undertaken on the pooled data across hospitals to determine the overall
16 314 prevalence of care left undone and the common tasks that are left undone. We will also report the
17 315 average number of tasks left undone per newborn and the common tasks left undone per newborn.
18 316 Secondary analysis will be undertaken to explore variations in care done (or left undone) by the various
19 317 sub-categories that will include: sector, nursing shift, nurse-patient ratios and category of the baby
20 318 (disease severity). Missing or incomplete data will be coded as a category and where necessary
21 319 presented as such. When reporting on effective number of tasks done (or left undone),
22 320 missing/incomplete data will be excluded from the effective denominator the task would have
23 321 contributed to and hence avoid spurious inflation of the denominator

24 322 **Ethical considerations**

25 323 The focus of our direct observations of care is what happens to newborns and we will not record any
26 324 names or other identifying features of people who may be providing care to these newborns. We will
27 325 only report pooled results stratified by sector, nurse-patient staffing ratios and category/severity of
28 326 disease so as to preserve the confidentiality of the health facilities.

29
30 327 During the one-week familiarisation period, we will seek written individual informed consent from all
31 328 nurses who will be providing care within the newborn unit. Additional consent forms and study briefs
32 329 will be left in the ward to allow nurses not available during this introductory period but who provide
33 330 care in the newborn unit to review and indicate their willingness to participate. During an observation
34 331 shift these nurses will be asked for individual informed consent before the start of the observations.
35 332 Additionally, at the beginning of every shift for which direct observations will be made, group verbal
36 333 informed consent will be sought from nurses after an explanation of the study has been made (this is in
37 334 addition to the one-week familiarisation during which the study will be explained). We will also provide
38 335 printed study briefs targeting health care providers explaining the study but also indicating that they are
39 336 free to decline from being observed as an approach to on-going consent.

40
41 337 Written informed consent will be sought from the mothers of babies considered for direct observations
42 338 at the start of each observation period. In Kenya, pregnant adolescents between ages (15 – 17 years) are
43 339 considered 'emancipated minors' and their written informed consent will be obtained[34–36]. The start
44 340 of the direct observation shift (7am or 7pm) is just before when mothers are in the newborn unit for the
45 341 3-hourly feeding session at 6am or 6pm, as such mothers will be approached during this period. In
46 342 instances, where mothers indicate more time is required to make a decision or to consult they will be
47 343 allowed to do so and another mother whose baby meets the criteria for observation will be approached.

344 In cases where nurses or parents decline consent, babies under their care will not be considered for
345 direct observation. It will be made clear that at any stage nurses or parents can withdraw
346 consent/permission for observation, temporarily or for the rest of a shift, without explanation and with
347 no penalty. Observations will only be undertaken where both the mother and nurses have provided
348 consent to the study respectively.

349 Ethical approval to conduct this study in all hospitals has been granted by the Kenya Medical Research
350 Institute (KEMRI) Scientific and Ethics Review Unit (Approval No. KEMRI/SERU/CGMR-C/065/3404) while
351 permission to undertake the study in the respective hospitals was sought from each of the hospital's
352 administrative offices.

353 **Dissemination of findings**

354 An expert advisory group, including partners from the Ministry of Health, Nursing Council of Kenya,
355 Nairobi City County, Kenya Medical Training College, Kenyatta University, and hospitals providing
356 inpatient neonatal services has been involved in the development of the standards of nursing care being
357 used to understand missed care in this study. This expert group has provided support for the study and
358 is in itself a key consumer of the results as these members are directly involved in policy making and
359 training. This group will also provide a key channel for wider dissemination of the findings.

360 Highlighting the extent and magnitude of care left undone will provide important insights on the nursing
361 care available to newborns admitted within newborn units, highlight human resource issues warranting
362 attention and will likely influence recommendations on staffing norms and how care is organised and
363 delivered in newborn units. Further, findings from this work will help guide the design of approaches
364 and interventions for improving facility based care for this highly vulnerable population.

365 At the end of the study, findings will be provided to and discussed with participating hospitals and other
366 relevant stakeholders. More widely, the international scientific community will be targeted via
367 publications in peer reviewed journals as well as conferences.

368 **Global public health relevance**

369 Facility based care has been cited as one key approach to reduce neonatal mortality if evidence-based,
370 high impact low cost interventions are appropriately delivered at high coverage[4]. Globally, improving
371 quality of newborn care provided by facilities might save 600 000 small and ill neonates annually[4]
372 while data from Kenya suggest that by 2030, 6000 newborn lives could be saved through the provision
373 of childbirth and newborn care intervention packages alone[37].

374 The Kenyan government is promoting facility based delivery by making maternity care free for women.
375 This has resulted in an increase in utilisation of maternal and newborn health services, potentially
376 increasing the number of newborns accessing care in health facilities. At the same time significant
377 challenges exist in nurse staffing and availability of wider resources[27] and this may limit any impact of
378 increased access to care. The extent of missed nursing care in newborn units in LMIC and how it impacts
379 on quality of care delivered has not previously been described. This is despite care in the newborn unit
380 being heavily dependent on nurses. By characterising care left undone, we will identify important

381 potential gaps in care delivered within newborn units that can inform discussions on how best to
382 address these gaps and improve quality of care in Kenyan hospitals.

383 This study will be the first attempt, of which we are aware, to develop and apply direct observational
384 missed care tools to understanding neonatal nursing care provision in LMIC. In fact, a recent review by
385 Jones and colleagues identified that only questionnaires have previously been used to quantify missed
386 care and these might be limited by reporting bias[22]. However, we acknowledge that direct
387 observational methods have limitations on the number and actual tasks that can be observed, might be
388 influenced by observer bias and are at risk of Hawthorne effect. As such, the tasks in our observation
389 checklist (supplementary file 1)_are limited to essential neonatal nursing tasks provided at the bedside
390 that can be observed while those linked to documentation will involve review of medical records at the
391 nurses' desk since documentation of care is done at the nurses' desk and not at the cot-side. Moreover,
392 observing the documentation of a task or reviewing records for evidence of documentation is likely to
393 provide similar results. An alternative method for data collection that we considered was the use of
394 video in the newborn unit with later evaluation of what is done (or not done). However, informal
395 discussions indicated this might be controversial at this stage due to the ethical and medico-legal issues
396 that might emanate from this approach and the administrative approvals required for video recording in
397 hospitals, nonetheless this is a potential area for future research. The selection of health facilities was
398 purposive, as support by the hospital administration was important due to the nature of data collection
399 and the sensitivity associated with direct observation of care. As such, we cannot rule out selection bias
400 as facilities providing better care might have been more likely to agree to partake in the study. However,
401 this is the first such study using direct observational methods to quantify missed care and in a LMIC and
402 therefore the findings will still be important. We anticipate that this study will, therefore, be of global
403 interest and provide an opportunity for application of the methods developed to other neonatal settings
404 or in other disciplines to better understand nursing care provision and quality gaps. Further, findings of
405 this work will be important in contributing to thinking on nurse staffing norms and how care is organised
406 and delivered in LMIC newborn units. This will be crucial in influencing longer term policy on human
407 resource planning. Most directly the findings will feed into the 'Kenya Task Sharing Policy and Guidelines
408 for Health Care Services'[38], an initiative being led by Ministry of Health alongside other stakeholders
409 as one of the ways of tackling health workforce shortages.

410 **Authors' contributions**

411 DG, ME and GAVM designed the study with contributions from RK and ET. DG, NA, and GS were
412 responsible for the coordination and supervision of data collection. DG wrote the study protocol with
413 substantial and critical input from all co-authors. All authors read and approved the final version of the
414 manuscript.

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419 by a Wellcome Trust Senior Research Fellowship (#097170).

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3 420 **Competing interests**

4
5 421 None

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7 422

8
9 423 **Figure legends**

10 424 Figure 1: Steps for the sampling procedure

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12 425 Multi-stage sampling procedure within a hospital for selecting newborns for direct observation

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15
16 427 Figure 2: Precision levels for different newborn sub-populations and tasks

17
18 428 Estimated levels of precision for the different newborn sub-populations and tasks observed that the
19 429 study will report since not all newborns observed will require all tasks.

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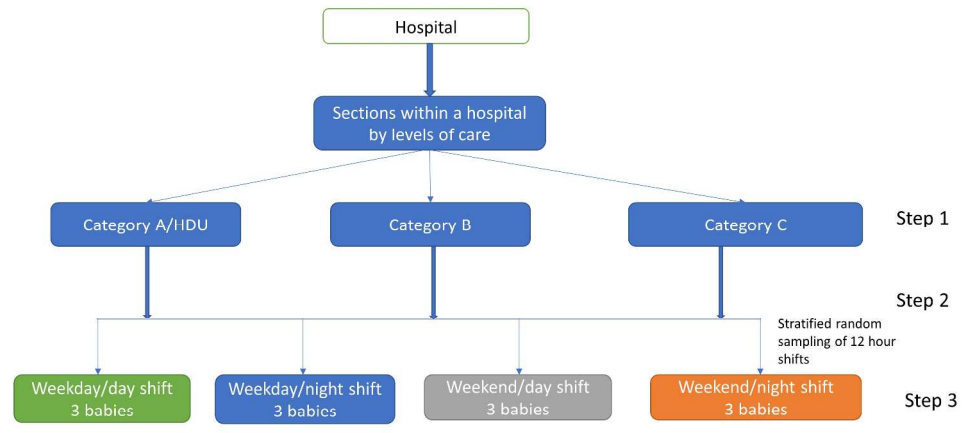
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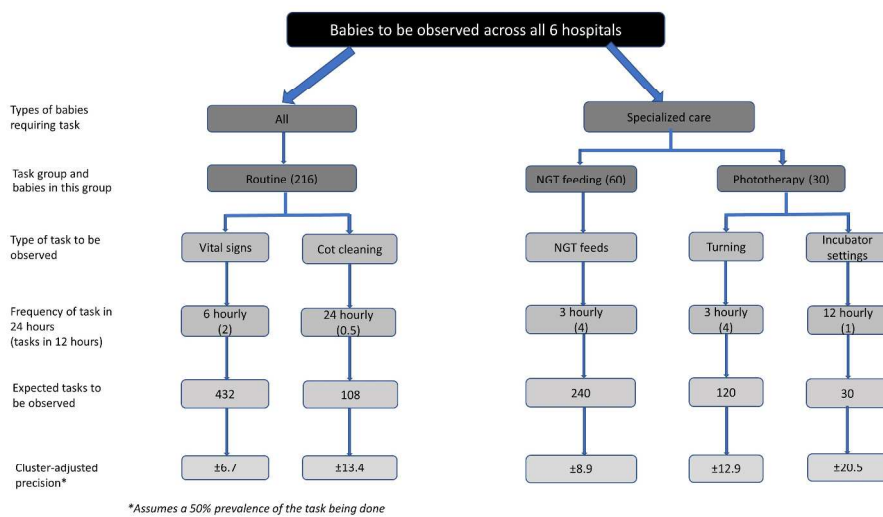
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Multi-stage sampling procedure within a hospital for selecting newborns for direct observation

338x190mm (300 x 300 DPI)

Review only



Precision levels for different newborn sub-populations and tasks

338x190mm (300 x 300 DPI)

Review only

Quantifying neonatal nursing care observational checklist

Hospital logistics

1. Start of observation: Date Time
2. End of observation: Date Time
3. Shift: Weekday day Weekday night
Weekend day Weekend night
4. Total number of patients in the ward:
5. Total Number of:
 - Admissions
 - Discharges
 - Referrals
 - Death
6. Number of nurses on shift:
 - Straight day shift
 - Morning shift
 - Afternoon shift
 - Night shift
7. Number of other staff providing care other than the nurse:
 - Doctor
 - Clinician
 - Health care assistant
 - Student nurse
 - Student CO
 - Upgrading nurse students

Others _____

Bio data

8. Child category: A. (Critical/HDU)
 B. (Acute)
 C. (Stable)

9. Date of admission

10. Age (days/ If day 1 of life give hours)

11. Gender: Male

Female

12. Admission diagnosis: _____

13. Current diagnosis: _____

14. Birth weight (grams)

15. Current weight (grams) Date taken

16. Type of delivery: SVD CS AVD

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Tasks	Frequency of task	Expected number tasks to be done(12 hours/shift)	Tasks done				Time task done				Comments
Routine Tasks											
Handing over		1	<input type="checkbox"/>								
Patient assessments performed each shift		1	<input type="checkbox"/>								
Cleaning of baby		1	<input type="checkbox"/>								
Change of linen		1	<input type="checkbox"/>								
Checking incubator settings		1	<input type="checkbox"/>								
Nurse attends ward round with doctor(s)		1	<input type="checkbox"/>								
Weight check		1	<input type="checkbox"/>								
Elimination care		1	<input type="checkbox"/>								
Discharge planning		1	<input type="checkbox"/>								
Communication/counselling to parent		1	<input type="checkbox"/>								
Hand washing/ Hand rub using sanitizer		1	<input type="checkbox"/>								
Cord care		1	<input type="checkbox"/>								
Checking cannula site		1	<input type="checkbox"/>								
Regular Tasks											
Checking vital signs*	4/6 Hourly	3	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>						
Temperature check*	4/6 Hourly	3	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>						
Pulse check*	4/6 Hourly	3	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>						
Respiratory rate check*	4/6 Hourly	3	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>						
SpO2 check*	4/6 Hourly	3	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>						
Turning	4 Hourly	3	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>						
Cup/spoon feeding	3 Hourly	4	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>					
Breast feeding	3 Hourly	4	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>				
*Dependent on neonate category											

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Tasks	Frequency of task	Expected number tasks to be done(12 hours/shift)	Tasks_done				Time task done				Comments
Critical Tasks											
Naso gastric tube feeding											
Checking for correct position of tube	3 Hourly	4	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Checking gastric aspirate before feeding	3 Hourly	4	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Checking actual volume of feeds	3 Hourly	4	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Actual feeding	3 Hourly	4	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Positioning baby after feeding	4 Hourly	4	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Phototherapy											
Turning/positioning	4 Hourly	3	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Skin assessment	6 Hourly	2	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Checking eyes if protected from damage	6 hourly	2	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Changing eye pad	12 Hourly	1	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Eye care	12 Hourly	1	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Oxygen therapy											
Checking tube position and nostril-care, damage	3 Hourly	4	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Regulating oxygen flow	12 Hourly	1	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Intravenous drug administration											
Dilutions and checking compatibility		2	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Review of treatment sheet		2	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Flushing cannula before administering drug		2	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Administration of medication		2	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Flushing cannula after giving medication		2	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

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Tasks	Frequency of task	Expected number tasks to be done(12 hours/shift)	Tasks_done	Time task done	Comments
Intravenous Fluid administration					
Review of treatment sheet		1	<input type="checkbox"/>	<input type="checkbox"/>	
Priming of giving set		1	<input type="checkbox"/>	<input type="checkbox"/>	
Flushing cannula before starting the fluid		1	<input type="checkbox"/>	<input type="checkbox"/>	
Administration and regulating flow rate		1	<input type="checkbox"/>	<input type="checkbox"/>	
Kangaroo Mother Care					
Support for KMC		1	<input type="checkbox"/>	<input type="checkbox"/>	
Supervision of mother during KMC		1	<input type="checkbox"/>	<input type="checkbox"/>	
Documentation of tasks					
Tasks	Done	Not done	Comments		
Neonatal assessment (nursing cardex)	<input type="checkbox"/>	<input type="checkbox"/>			
Planned care (cardex/care plan)	<input type="checkbox"/>	<input type="checkbox"/>			
Vital signs (observation charts/cardex)	<input type="checkbox"/>	<input type="checkbox"/>			
Treatment (treatment sheets)	<input type="checkbox"/>	<input type="checkbox"/>			
Ward round comments (cardex)	<input type="checkbox"/>	<input type="checkbox"/>			
Phototherapy (cardex)	<input type="checkbox"/>	<input type="checkbox"/>			
Feeds (feeding chart)	<input type="checkbox"/>	<input type="checkbox"/>			
Oxygen therapy (cardex)	<input type="checkbox"/>	<input type="checkbox"/>			
Health talks/ Communication to parent (cardex)	<input type="checkbox"/>	<input type="checkbox"/>			
Fluids (input output chart)	<input type="checkbox"/>	<input type="checkbox"/>			

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Turning/position(cardex and/or turning chart)	<input type="text"/>	<input type="text"/>	
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Alternate weight check	<input type="text"/>	<input type="text"/>	
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Treatment			
Drug name	Frequency	Times administered in the last 24 hours	Comments

Tasks observed for other babies

Task	Observed	Comment
Administration of vaccines	<input type="checkbox"/>	
Taking venous blood	<input type="checkbox"/>	
Taking heel prick	<input type="checkbox"/>	
Blood/exchange transfusion	<input type="checkbox"/>	
CPAP(setup of machine n tubings)	<input type="checkbox"/>	
Resuscitation	<input type="checkbox"/>	

Other tasks observed not mentioned above		