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# BMJ Open

## Development of an Early Warning Track and Trigger system for preterm or low-birth weight infants in a low resource setting: results of a mixed-methods study at a national referral hospital in Kenya

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6 Development of an Early Warning Track and Trigger system for preterm or low-birth weight  
7 infants in a low resource setting: results of a mixed-methods study at a national referral  
8 hospital in Kenya  
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## ABSTRACT

### Introduction

Fifteen million babies are born prematurely, before 37 weeks gestational age, globally. More than 80% of these are in Sub-Saharan Africa and Asia. 35% of all deaths in the first month of life are due to prematurity and the neonatal mortality rate is eight times higher in Low and Middle Income Countries (LMICs) than in Europe. Early Warning Scores (EWS) are a way of recording vital signs using standardised charts to easily identify adverse clinical signs and escalate care appropriately. A range of EWS have been developed for neonates, though none in LMICs. This paper reports the findings of early work to examine if the use of EWS is feasible in LMICs.

### Methods

We conducted an observational study to understand current practices for monitoring of preterm infants at a large national referral hospital in Nairobi, Kenya. Using hospital records, data were collected on all live born infants born at <37 weeks and/or <2500g (n=294, 255 mothers) in the first week of life. Using a chart adopted from the EWS developed by the British Association of Perinatal Medicine, we plotted infants' vital signs. In addition, we held group discussions with stakeholders in Kenya to examine opinions on use of EWS.

### Results

Recording of vital signs was variable; only 63% of infants had at least one temperature recorded and 53% had at least one heart rate and respiratory rate recorded. Stakeholders liked the traffic-light system and simplicity of the chart, though recognised challenges, such as staffing levels and ability to print in colour, to its adoption.

### Conclusion

EWS may standardise documentation and identify infants who are at higher risk of an adverse outcome. However, human and non-human resource issues would need to be explored further before development of an EWS for LMICs.

## STRENGTHS AND LIMITATIONS

- This is the first study exploring the possibility of using a neonatal early warning score in a low resource setting
- The views of a wide range of stakeholders, including senior policy-makers and clinicians are included. There was support for a neonatal early warning score, though challenges in its implementation were recognised
- Detailed data on preterm and low birth-weight infants' vital signs were recorded for the first 7 days of life, though was limited to what was routinely recorded
- Our study is consistent with other reports demonstrating poor record-keeping in newborn units in Kenya
- Data collection was limited to a tertiary referral hospital in Nairobi, however many preterm infants in low-resource settings are cared for in centres with much larger constraints

## BACKGROUND

Globally, 15 million babies are born prematurely(1); more than 80% in Sub-Saharan Africa (12.3% of all births)(1). Mortality for a preterm infant born in a low or middle income country (LMIC) is eight times higher than in Europe(2). Among the causes of neonatal mortality, prematurity remains the biggest killer with 35% of all neonatal deaths attributed to preterm birth or its complications(3). The United Nations Sustainable Development Goals (SDGs) recognise the need to significantly improve outcomes for newborn infants and have a strategic vision to end preventable newborn deaths, with all countries aiming to reduce the neonatal mortality rate (NMR) to at least 12 per 1000 live births(4).

In Kenya, where the most recent NMR was 19.6 per 1000 live births(5), infants born prematurely are currently managed in accordance with national and international guidance for essential newborn care(6-8). This includes a range of evidence-based recommendations for care in the first week of life, e.g. provision of Kangaroo Mother Care (KMC) for all clinically stable infants weighing <2000g, which is recommended for hypothermia prevention (6, 8, 9). The World Health Organisation estimates that >80% of moderate to late (32-37 weeks) preterm infants, could survive with the provision of essential newborn care(10).

Early warning scores are a way of quickly and easily identifying adverse clinical signs and are often used in adult populations in a variety of clinical areas(11), however they are less commonplace for neonatal care. A review by Mortensen(12) identified seven early warning score systems for neonates, including the Newborn Early Warning Trigger and Track (NEWTT) Framework, developed by the British Association for Perinatal Medicine (BAPM)(13). Whilst this framework states that the chart should be triggered for “high risk” infants, only late preterm infants are considered due to the fact most preterm infants born in the UK at earlier gestations are admitted for higher-dependency neonatal care with continuous monitoring. Infants who could most benefit from closer monitoring and early detection of adverse signs are preterm or low birth weight infants. Indeed Mortensen’s review stated that of the four systems published in full, two only included term babies weighing >2500g. The authors concluded that none of the available systems at the time considered “high risk” infants who had been admitted for neonatal care and recommended modifications be made to existing systems. To the best of our knowledge, there are no published early warning scores from low resource settings such as Kenya nor are such systems currently utilised. All available scoring systems were developed in high income countries where continuous vital sign monitoring is standard, yet there is evidence, within an

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3 obstetric setting, that an early warning score system is feasible and possible to implement in  
4 a low resource setting(14).  
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8 In keeping with other early warning score systems, the NEWTT, developed in the UK, adopts  
9 a traffic-light scoring system. An infant's vital signs are recorded on to a single page. If a  
10 measurement is in the red zone or there are two recordings in the amber zone, the attending  
11 nurse is alerted and immediate escalation to a review by a suitably qualified practitioner is  
12 required. The purpose of such a strategy is to alert health care professionals to the potential  
13 of deterioration in the condition of a high risk infant and give them an opportunity to intervene  
14 with appropriate care.  
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20 The aim of this study was to investigate whether an early warning score system in preterm  
21 and low birth weight infants could be implemented in a low resource setting such as Kenya.  
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## 25 **METHODS**

### 26 **Observational study**

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28 In order to understand the characteristics of infants born in this setting, first we conducted an  
29 observational study at the Kenyatta National Hospital (KNH), a tertiary referral hospital, in  
30 Nairobi, Kenya. Data were collected during an eight-week period in March-April 2019 from  
31 routinely recorded data. No interventions nor study specific actions in response to  
32 observations were required and management of the infants followed usual practice. All  
33 infants born at KNH, during the study period, who were <37 weeks gestational age and/or  
34  $\leq 2500\text{g}$  at birth were included. Data were collected from birth until day 7 or discharge/death.  
35 Outborn infants (not born at KNH and admitted postnatally) were excluded.  
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44 Research midwives, trained during a three-day workshop, collected data using paper data  
45 collection booklets. Maternal and infant characteristics were collected and all vital signs  
46 recordings (temperature, heart rate and respiratory rate) in the infant's clinical notes were  
47 collected. All data was entered into a password-protected study-specific database (Macro  
48 (©Elsevier)). Maternal and infant characteristics were summarised descriptively using the  
49 mean, standard deviation (SD), minimum and maximum for continuous variables and  
50 frequency counts and percentages for categorical variables along with the number of  
51 observations. Analyses were conducted in Stata version 15. Data on temperature, heart rate  
52 and respiratory rate were plotted onto graphs representing the NEWTT system, showing  
53 values that were within the red, amber and green zones.  
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3 The study was conducted with full ethical approval from the joint Kenyatta National Hospital-  
4 University of Nairobi Ethics Research Committee (ref P772/11/2018) and the Faculty of  
5 Medicine and Health Sciences Research Ethics Committee at the University of Nottingham  
6 (ref 161-1812). No informed consent was sought from parents since the study was  
7 observational and participants were not subjected to any intervention.  
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### 11 12 **Stakeholder meeting**

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14 In order to understand possible barriers and facilitators to the use of an early warning track  
15 and trigger system in Kenya, a stakeholder meeting was held in July 2019 in Nairobi. This  
16 was attended by 78 delegates from a range of organisations (supplementary material 1).  
17 Delegates were split into groups of approximately 8-10 and asked to consider and feedback  
18 1) what they did and didn't like about an early warning track and trigger system, 2) what  
19 would need to be in place to enable its use; and 3) what are the perceived barriers to its use.  
20 A narrative thematic analysis(15) was conducted and themes were identified from the  
21 feedback provided.  
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### 28 **Patient and public involvement**

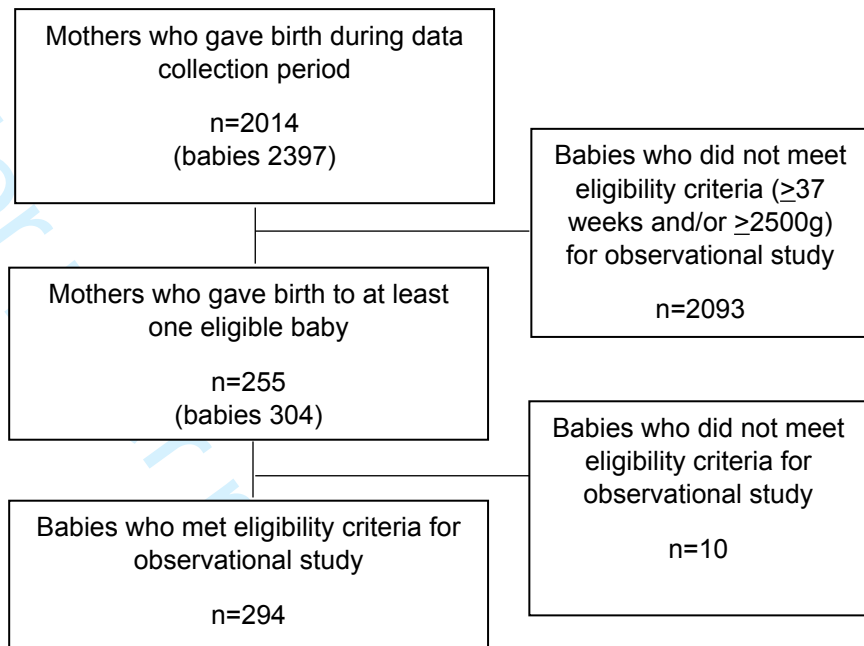
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30 Patients and the public were not involved in the design or conduct of this study. However,  
31 non-government organisations and charities representing patients and the public were  
32 involved in the stakeholder meeting.  
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## 36 **RESULTS**

### 37 38 **Observational study**

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40 Data were collected between 5 March 2019 and 30 April 2019 on the labour suite, post-natal  
41 wards and newborn unit of the participating hospital. During the data collection period 2397  
42 infants were born in KNH (Figure 1). 294 infants (255 mothers) (14.6%) met the eligibility  
43 criteria of being born at <37 weeks gestation and/or weighing <2500g. Ten infants were  
44 excluded as they had a birth weight >2500g. 206 infants were from singleton pregnancies,  
45 82 from twin pregnancies and six from triplet pregnancies.  
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11 **Figure 1: Study Flow diagram**  
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37 The mean (SD) age of the mother was 28 (6) years and just under half were educated to  
38 secondary/high school level (124/255, 49%). Infants' characteristics are included in table 1.  
39 Of the 294 infants, 123 (42%) were moderate to late preterm (33-36 weeks). The mean (SD)  
40 birth weight was 1977g (603), ranging between 460 and 4000g. Just over half were born by  
41 emergency caesarean section (168/294, 57%) and over a third (110/294, 37%) required  
42 resuscitation at birth. Post-delivery, 156/294 (53%) of infants were transferred to the  
43 Newborn/Neonatal Unit for care, 129/294 (44%) were cared for on the postnatal ward and  
44 9/294 (3%) died. At day seven, 95/294 (32%) infants remained in hospital, 58/294 (20%) had  
45 died and 141/294 (48%) were discharged home. Of the 58 infants who died, prematurity was  
46 recorded as cause of death for 44 of them (76%).  
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**Table 1. Characteristics of infants <37 weeks gestational age and/or  $\leq 2500$ g at birth born at the Kenyatta National Hospital in March-April 2019**

Characteristic	Total (n=294)
<b>Sex: number (%) of females</b>	135 (54)
<b>Mode of delivery – n (%)</b>	
Vaginal	123 (42)
Elective Caesarean section	3 (1)
Emergency Caesarean section	168 (57)
<b>Delayed cord clamping (n= 14; 280 unknown)</b>	0 (0)
<b>Birth weight (grams) Mean (SD)</b>	1977 (603)
<b>Head circumference (cm) (n= 19) Mean (SD)</b>	32.6 (2)
<b>Length (cm) (n= 4) Mean (SD)</b>	36.0 (5)
<b>Estimated gestational age at birth – n (%)</b>	
<28 weeks	26 (9)
28-32+6 weeks	70 (24)
33-36+6 weeks	123 (42)
$\geq 37$ weeks	73 (25)
unknown	2 (<1)
<b>Gestational age estimation based upon – n (%)</b>	
First trimester ultrasound	14 (5)
Clinical assessment	30 (10)
Last menstrual period and/or clinical assessment (mother)	242 (82)
Dubowitz and New Ballard score	6 (2)
Unknown	2 (<1)
<b>Number (%) of babies who required resuscitation at birth (n=287)</b>	110 (37)
<b>Type of resuscitation – not mutually exclusive (n=110)</b>	
Stimulation only	12 (11)
Ventilation	91 (83)
Continued ventilation	36 (33)
Advanced resuscitation	4 (4)
<b>Number (%) of babies who received maternal breast feeding within one hour of birth (n=260)</b>	39 (13)
<b>Number of babies who had initiation of Kangaroo Mother care soon after birth (stable babies only) (n= 180)</b>	0 (0)
<b>Number (%) of babies who had temperature within one hour of birth<sup>1</sup></b>	10 (3)
<b>Number (%) of babies who had heart rate at birth<sup>1</sup></b>	58 (20)
<b>Number (%) of babies who had respiratory rate at birth<sup>1</sup></b>	70 (24)

<sup>1</sup> recorded in clinical records

### **Recording of vital signs (heart rate, respiratory rate, temperature, in clinical records)**

Very few infants had vital signs recorded in the first hour of life; only 10/294 (3%) infants had a recorded temperature, 58/294 (20%) had a recorded heart rate and 70/294 (24%) had a recorded respiratory rate. In addition, Kangaroo Mother Care was not recorded as having been initiated in any of the 180 clinically stable infants soon after birth.

The number of recorded observations per infant per day was analysed (Table 2). On day 1, less than half of the infants (136/294, 46%) had at least one temperature recording, 130/294 (44%) had at least one heart rate recording and 129/294 (44%) had at least one respiratory

rate recording. The number of infants with at least one recording in each of the domains increased throughout the hospital admission: on day 7, 86/104 (83%) of infants had at least one temperature recording, 85/104 (82%) had at least one heart rate recording and 83/104 (80%) had at least one respiratory rate recording. This also includes infants who were then discharged on or died on day 7 (n=9), in addition to the 95 infants who remained in hospital. For these 95, each infant had a mean (SD) of 18 (5.1) temperature recordings, 18 (6.8) heart rate recordings and 17 (6.6) respiratory rate recordings throughout their admission.

Over the entire study period, 185/294 (63%) infants had at least one temperature recorded, 156/294 (53%) had at least one heart rate recording and 155/294 (53%) had at least one respiratory rate recording. Retrospectively, each recording for each domain (temperature, heart rate, respiratory rate) was mapped to a single red, amber or green zone on the UK NEWTT by the researchers. These recordings were not charted on the NEWTT in real time by the clinical staff and we did not collect data on what action(s), if any, were taken in response to a red or amber recording. Although, the NEWTT indicates escalation of care for one recording in the red zone or two recordings in the amber zone, we only included single recordings since it was impossible to know whether an action was taken after one single amber recording.

**Table 2: Number of infants with vital signs recordings (temperature, heart rate, respiratory rate) per day for the 7-day data collection period**

Day	Babies in hospital	At least one temperature recording	At least one heart rate recording	At least one respiratory rate recording
1	294	136 (46%)	130 (44%)	129 (44%)
2	272	165 (61%)	139 (51%)	139 (51%)
3	222	147 (66%)	130 (59%)	128 (58%)
4	194	127 (65%)	119 (61%)	119 (61%)
5	139	110 (79%)	107 (77%)	107 (77%)
6	115	90 (78%)	89 (77%)	90 (78%)
7	104	86 (83%)	85 (82%)	83 (80%)

97/185 (52.4%) had at least one temperature recording in the moderate hypothermic range (<36°C) and 145/185 (78.4%) had at least one recording between 36-36.49°C. Of the 97 infants who had a recorded temperature of <36°C, 92 had any subsequent temperature recording, almost half (41/92, 46%) of which were taken >6 hours later (range 30 mins-46 hours). Of those, 29 infants' (32%) subsequent temperature remained <36°C (Table 3).

**Table 3: Subsequent temperature recordings for 92 infants who had an initial temperature recorded of <36°C**

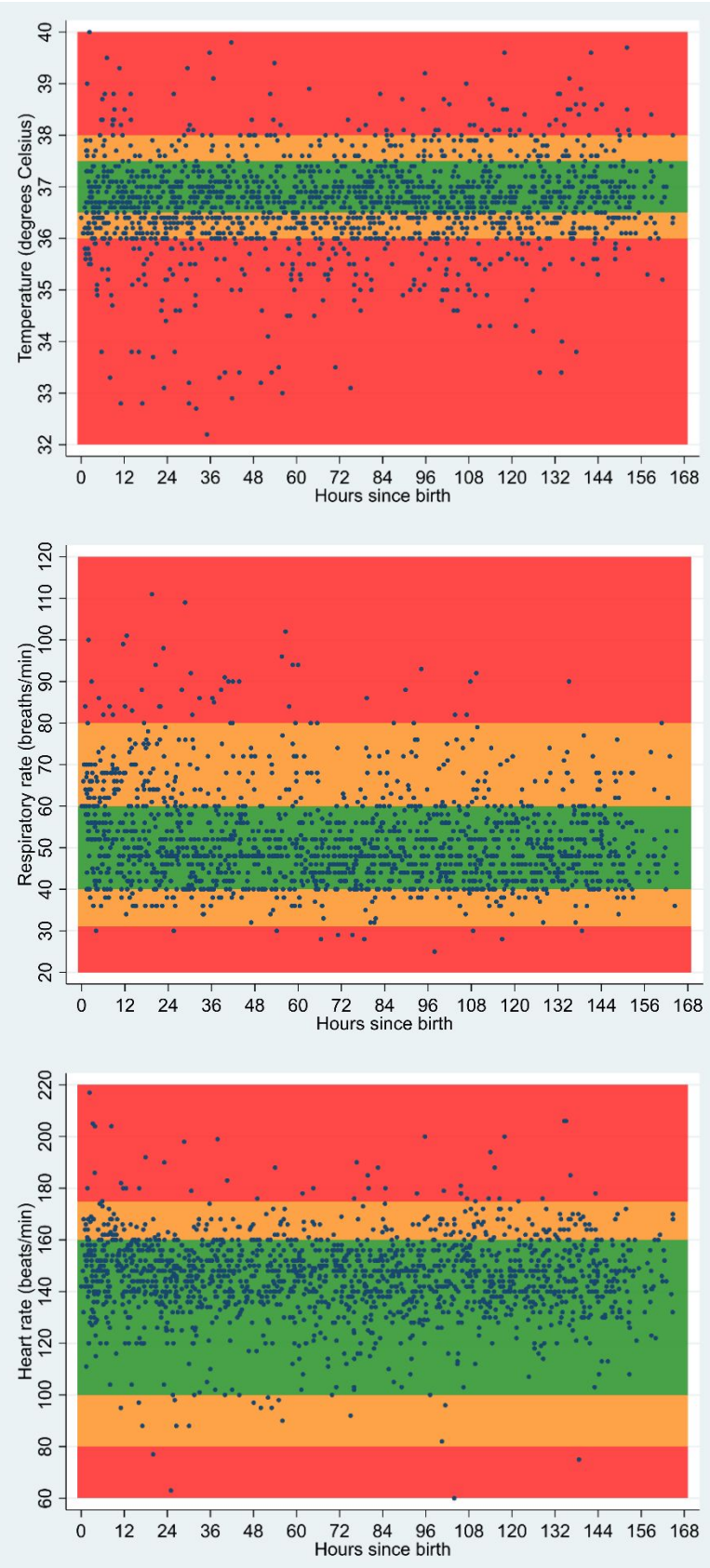
Temperature (°C)	< 4 hours (n = 25) (27%)	4 to 6 hours (n = 26) (28%)	> 6 hours (n = 41) (46%)
< 36	10 (40%)	7 (27%)	12 (29%)
36-<36.5	5 (20%)	5 (19%)	11 (27%)
36.5-37.5	9 (36%)	11 (42%)	15 (37%)
> 37-38	-	3 (12%)	3 (7%)
>38	1 (4%)	-	-

Tachycardia, defined as a heart rate of >161 beats/minute, was noted in 98/156 infants (62.8%), and 34/156 (21.8%) had at least one recording >175 beats per minute (red zone). High respiratory rate (> 80 breaths/min; red zone) was recorded, at least once, in 24/155 (15.5%) and 109/155 (70.3%) had at least one recording of 61-80 bpm (upper amber zone). A respiratory rate of <30 beats/min (red zone) was recorded at least once in 9/155 (6%) and 73/155 (47%) had at least one recording of 30-39 beats/min (lower amber zone). Figure 2 shows recordings for the 95 infants who were still in hospital at day 7 plotted onto colour-coded graphs representing the NEWTT.

**Figure 2 – Vital sign recordings of preterm, low birth weight infants born and admitted to a tertiary referral hospital in Kenya for first 7 days of life (n = 95)**

*Data from infants who were in hospital at day 7. Each dot represents a vital sign recording. Since infants had multiple vital signs recordings during their admission, they could have several values across each of the colour zones at multiple time points Graph adapted from NEWTT*

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### **Stakeholder meeting**

Seventy eight stakeholders attended the one-day meeting to discuss the development of this tool in a low-resource setting such as Kenya. Stakeholder types are shown in Supplementary material 1. Feedback groups contained a variety of stakeholder types. The main themes that emerged from stakeholder discussions were 1) simplicity and ease of use of the tool, 2) sustainability and resource and 3) training and implementation. Example quotes are included for each theme.

#### ***Simplicity and ease of use***

Stakeholders reported they liked the coloured traffic-light system since this enabled easy interpretation of the data, recognition of need for action and earlier identification of danger signs.

“the colours are good and explains why”

“it would be easy to identify infants at risk”

Several stakeholders also commented they liked the combined presentation of several vital signs on one chart, rather than having lots of paper notes which can easily become untidy or misplaced. One policy-maker commented that “[the chart’s] simplicity would make universal coverage easier”. Some also considered whether it would be possible to digitise the system, for example by creating an app, though recognised whilst this would negate the use for coloured printing, it would not relieve issues with availability of resources.

#### ***Sustainability and resources***

Several stakeholders commented that although they liked the traffic-light system approach, it may be difficult to print the document since colour printing is expensive and often not available.

“printing coloured is a challenge”

The main concern for the majority of stakeholders were the availability of healthcare staff to make and document the recordings. It was recognised that such a system would be acceptable if it replaced the current system of recording vital signs but would not be acceptable as additional workload. Further to this the major barrier to implementation of this or any similar early warning score was recognised as the lack of resources, both staff and interventions, to be able appropriately escalate the care of those infants who would be identified as sick. The early warning track and trigger system requires immediate escalation

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3 to a more senior neonatologist if a value falls into a red zone or two values in an amber  
4 zone; stakeholders felt this may not be possible given staffing levels on neonatal units in this  
5 setting.  
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9 “We have low staff:patient ratios. This [EWS] has very intense observational needs in  
10 a staff-constrained set-up”  
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### 13 ***Training and implementation***

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15 Some stakeholders felt that staff working on the newborn/neonatal unit may not like it since it  
16 may “feel like more work” although others recognised that whilst initial resistance may be  
17 encountered this could be overcome by educating staff members of the potential value of  
18 such a system. Many stakeholders commented that training on its use would be paramount,  
19 which should include not only how to complete the tracking system and trigger escalation,  
20 but its potential to reduce neonatal mortality. A non-governmental organisation  
21 representative commented that whilst implementing such a system may be a good idea, it  
22 would “require national level harmonisation” and that a close working relationship with the  
23 Ministry of Health would be important, since it would need to be endorsed at both a national  
24 and organisational level.  
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33 “it should be integrated into existing tools and the curriculum”

34 “harmonise/integrate this with existing tools to avoid double work”  
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## 38 **DISCUSSION**

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41 This is the first study exploring the possibility of using a neonatal EWS in LMICs. EWS are  
42 recommended for use in routine practice in the UK(13) and may have the potential for  
43 supporting early recognition of unwell infants(16). However, before any practice can be  
44 transferred from one health-care setting to another it is important to test the feasibility of  
45 implementing the practice in the target setting(17).  
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51 EWSs are predicated on regular recordings of vital signs. At KNH, local guidelines stipulate  
52 newborn infants should have vital signs checked every 4-6 hours(18), however our study  
53 demonstrates that the routine recording of vital signs in infants' notes was infrequent; only  
54 half had any heart or respiratory rate recordings and around two thirds had any temperature  
55 recording during their admission. Indeed even for the infants with a low temperature (<36°C)  
56 that would be in the red zone on a EWS, many of them did not have a subsequent  
57 temperature recorded within 4-6 hours. Interestingly, the number of infants with at least one  
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3 recording increased during their admission. This could be because fewer infants remained in  
4 hospital throughout the 7 days and those that remained are more likely to be infants who are  
5 unwell and require longer hospital care. It is likely, therefore, that these infant were  
6 prioritised by the staff and monitored more closely. The first 24 hours of life for an infant are  
7 critical and 25-45% of all neonatal deaths occur in this period(19); it is of importance, then,  
8 that less than half of infants in the observational study had vital signs recorded on day 1 of  
9 life and only a very small handful of infants had any vital signs recorded within the first hour  
10 of life. These findings are in-keeping with other studies, for example, about 40% infants had  
11 vital signs chart available in the Nairobi Newborn Study, which was a retrospective review of  
12 33 neonatal facilities in Nairobi City County(20).  
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20 Our study included detailed data on preterm and LBW infants' vital signs' recordings, which  
21 included temperature, for the first seven days of life. Keeping newborn infants warm is a key  
22 aspect of essential newborn care(21). Hypothermia is common in all newborns, particularly  
23 preterm and LBW infants, regardless of country of birth. In a large systematic review of  
24 neonatal hypothermia(22) prevalence ranged from 32-85% in 21 hospital-based studies in  
25 Africa and Asia (with the exception of one study which reported 8% prevalence(23)).  
26 Temperature data collected in our study is consistent with other studies reporting  
27 hypothermia. Infants' temperatures ranged from 32.1°C-40°C. Of the 2249 recorded  
28 temperatures during the 7-day data collection period, over a third (859/2249, 38%) were  
29 <36.4°C. Almost a third of infants who had a recorded temperature of <36°C, had a  
30 subsequent temperature recording of <36°C. If infants were more closely monitored and  
31 care escalated if a low temperature was identified, for example by using simple colour-coded  
32 chart such as an EWS, it may be possible for action to be taken sooner, thus potentially  
33 preventing further hypothermia.  
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44 A standardised template, such as an EWS chart, could support better record keeping.  
45 Stakeholders identified that the simple traffic-light system could be easily adaptable to local  
46 practice. However, concerns about lack of resources weighed heavily in their mind. This  
47 included lack of material resources such as inability to print in colour and the larger issue of  
48 shortfalls in numbers of healthcare professionals available for newborn care. The lack of  
49 adequate resources for neonatal care in Kenya is well documented(20, 24). In such  
50 situations, our results show that any new intervention is likely to be useful only if it does not  
51 increase the workload of the healthcare staff.  
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58 The Nairobi Newborn Study(20) suggested that implementation of standardised medical and  
59 nursing notes could improve care. A priority setting exercise to improve global newborn  
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3 health recommended that the development of simple clinical algorithms to refer neonates  
4 with signs of infection and consequently reduce newborn mortality was a top priority(25).  
5 Although currently there is no evidence that using neonatal EWS improves outcomes in  
6 LMICs, research in closely related clinical areas are encouraging: in Ethiopia, the  
7 introduction of a modified obstetric early warning score (MOEWS) in a referral hospital,  
8 improved practice in several domains(26).  
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14 The desired improvement in outcomes can only be achieved from EWSs if there is an  
15 appropriate escalation of care when required. In this study, infants' vital signs were  
16 retrospectively plotted to the red and amber zones on the NEWTT, using data available via  
17 clinical records. Whether clinical action was taken as a result of an adverse vital sign is  
18 unknown since this data was not collected. We are therefore only able to report the number  
19 of infants who may have hypothetically triggered an escalation of care, by the fact a value  
20 was plotted to a single red or amber zone. At the stakeholder meeting, the lack of  
21 adequately trained medical and nursing staff was again seen as an impediment to such  
22 escalation, particularly if the practice were to be implemented widely. The KNH is a tertiary  
23 referral centre. Most preterm infants in LMICs including within Kenya are cared for in centres  
24 with significantly larger constraints than the KNH. In this context, it is worth considering if the  
25 use of EWSs may enable staff to identify patients with greater need sooner and hence  
26 facilitate more efficient use of limited resources. A suitably adopted neonatal EWS could  
27 replace existing documentation systems and may improve the situation by replacing a  
28 cumbersome process of documentation with a more streamlined method.  
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39 This is the first study investigating the possibility of using a neonatal EWS in LMICs. We  
40 used mixed methods to explore current practice, and report the opinions of a range of  
41 relevant stakeholders into understanding the potential use of neonatal EWS in Kenya.  
42 However, we recognise that the study was conducted in a large tertiary hospital which is  
43 relatively well resourced. As this is an exploratory study, our aim was to scope current  
44 practice and explore the possibility of using EWS in KNH before considering the bigger  
45 challenge of rolling it to more remote settings.  
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52 In addition, we limited data collection to what is currently routinely recorded. The next step  
53 would be to test the feasibility of replacing the current system of documenting vital signs with  
54 a EWS chart to explore if such tools can improve documentation without an unacceptable  
55 increase in workload. Further work is planned and will include emphasis on training for the  
56 use of EWSs.  
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3 Use of MOEWS in obstetrics in LMICs has highlighted the need of a “partnership approach”  
4 and leadership from local teams(26). Our findings include the possibilities of resistance to  
5 change in keeping with the adoption theory, which proposes that any group consists of a  
6 mixture of “innovators, early adopters, early majority, late majority, laggards” and resistance  
7 to change is expected(27). There are several steps outlined in innovation research that are  
8 transferable to this healthcare context; ‘relative advantage’, ‘compatibility’, ‘complexity’,  
9 ‘trialability’, ‘observability’(27). In the context of implementing a neonatal EWS, emphasising  
10 relative advantage (e.g. ease of use); ensuring that the new system ‘fits’ (compatibility);  
11 supporting with easily accessible training (complexity); having a period of trialling before  
12 implementing (trialability); and being clear to staff about any outcomes (observability) could  
13 facilitate adoption. The follow-up of implementation of MOEWS in Ethiopia showed that  
14 attitudes to new practice improved over time(26).  
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## 23 **CONCLUSION**

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27 Development of neonatal EWS in LMICs requires testing the acceptability and feasibility of  
28 recording vital signs using locally-adapted neonatal EWS charts. Further work is required to  
29 ensure that such charts facilitate monitoring of vital signs without increasing workload. A  
30 partnership approach with local leadership and training programmes incorporating the  
31 principles of the adoption theory are vital. This preparatory work must precede any clinical  
32 trials investigating whether implementation of neonatal EWS could reduce neonatal mortality  
33 in LMICs.  
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46 programming).  
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## 52 **CONTRIBUTORSHIP**

53  
54  
55 EM was the overall Principal Investigator and conceived the idea and wrote the first draft of  
56 the manuscript. SO was the overall clinical lead. ZQ was the Principal Investigator and JO  
57 was the Study Coordinator in Kenya. GG and AO provided obstetric expertise and facilitated  
58 data collection. FW was the lead neonatologist in Kenya. LB undertook statistical analyses.  
59  
60

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2  
3 JD provided mentorship to the research group. PP provided midwifery expertise. MO  
4 assisted with qualitative analysis. All authors contributed to the manuscript and approved the  
5 final draft.  
6  
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## 8 9 **DATA SHARING**

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12 Data is available upon reasonable request to the corresponding author.  
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## 15 16 **COMPETING INTERESTS**

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19 None declared.  
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### Supplementary material 1 – Stakeholder types

Stakeholder type	Number of stakeholders
Ministry of Health representative	15
World Health Organisation (WHO) representative	2
Senior nursing staff	2
Newborn Unit Nurse	4
Neonatologist / Paediatrician	8
Public health consultant	1
Obstetrician	6
Hospital managers	3
Midwife	1
NGO representative <sup>1</sup>	17
Kenya Paediatric Association representative	3
Researcher	8
Research team (UK and Kenya)	8

<sup>1</sup> NGOs represented: Population Council Kenya, Pharm Access Foundation, Options, JH Piego, Path, UNICEF, Global Health strategies, Still a Mum, Beyond Zero

# BMJ Open

## Feasibility of using an Early Warning score for preterm or low-birth weight infants in a low resource setting: results of a mixed-methods study at a national referral hospital in Kenya

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6 Feasibility of using an Early Warning score for preterm or low-birth weight infants in a low  
7 resource setting: results of a mixed-methods study at a national referral hospital in Kenya  
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## ABSTRACT

### Introduction

Fifteen million babies are born prematurely, before 37 weeks gestational age, globally. More than 80% of these are in Sub-Saharan Africa and Asia. 35% of all deaths in the first month of life are due to prematurity and the neonatal mortality rate is eight times higher in Low and Middle Income Countries (LMICs) than in Europe. Early Warning Scores (EWS) are a way of recording vital signs using standardised charts to easily identify adverse clinical signs and escalate care appropriately. A range of EWS have been developed for neonates, though none in LMICs. This paper reports the findings of early work to examine if the use of EWS is feasible in LMICs.

### Methods

We conducted an observational study to understand current practices for monitoring of preterm infants at a large national referral hospital in Nairobi, Kenya. Using hospital records, data were collected over an 8-week period in 2019 on all live born infants born at <37 weeks and/or <2500g (n=294, 255 mothers) in the first week of life. Using a chart adopted from the EWS developed by the British Association of Perinatal Medicine, we plotted infants' vital signs. In addition, we held group discussions with stakeholders in Kenya to examine opinions on use of EWS.

### Results

Recording of vital signs was variable; only 63% of infants had at least one temperature recorded and 53% had at least one heart rate and respiratory rate recorded. Stakeholders liked the traffic-light system and simplicity of the chart, though recognised challenges, such as staffing levels and ability to print in colour, to its adoption.

### Conclusion

EWS may standardise documentation and identify infants who are at higher risk of an adverse outcome. However, human and non-human resource issues would need to be explored further before development of an EWS for LMICs.

## STRENGTHS AND LIMITATIONS

- This is the first study exploring the possibility of using a neonatal early warning score in a low resource setting
- The opinions of a wide range of stakeholders, including senior policy-makers and clinicians are included.
- Detailed data on preterm and low birth-weight infants' vital signs were recorded for the first 7 days of life, though was limited to what was routinely recorded
- The tool includes physiological parameters for term and late preterm infants, whereas our study included any preterm or low-birth weight infant
- Data collection was limited to a tertiary referral hospital in Nairobi, however many preterm infants in low-resource settings are cared for in centres with much larger constraints

## BACKGROUND

Globally, 15 million babies are born prematurely(1); more than 80% in Sub-Saharan Africa (12.3% of all births)(1). Mortality for a preterm infant born in a low or middle income country (LMIC) is eight times higher than in Europe(2). Among the causes of neonatal mortality, prematurity remains the biggest killer with 35% of all neonatal deaths attributed to preterm birth or its complications(3). The United Nations Sustainable Development Goals (SDGs) recognise the need to significantly improve outcomes for newborn infants and have a strategic vision to end preventable newborn deaths, with all countries aiming to reduce the neonatal mortality rate (NMR) to at least 12 per 1000 live births(4).

In Kenya, where the most recent NMR was 19.6 per 1000 live births(5), infants born prematurely are currently managed in accordance with national and international guidance for essential newborn care(6-8). This includes a range of evidence-based recommendations for care in the first week of life, e.g. provision of Kangaroo Mother Care (KMC) for all clinically stable infants weighing <2000g, which is recommended for hypothermia prevention (6, 8, 9). The World Health Organisation estimates that >80% of moderate to late (32-37 weeks) preterm infants, could survive with the provision of essential newborn care(10).

Early warning scores are a way of quickly and easily identifying adverse clinical signs and are often used in adult populations in a variety of clinical areas(11), however they are less commonplace for neonatal care. A review by Mortensen(12) identified seven early warning score systems for neonates, including the Newborn Early Warning Trigger and Track (NEWTT) Framework, developed in the UK by the British Association for Perinatal Medicine (BAPM)(13) for infants primarily on postnatal wards with little or no increased surveillance (supplementary material 1). Whilst this framework states that the chart should be triggered for “high risk” infants, only late preterm infants (34-36<sup>+6</sup> weeks) are considered due to the fact most preterm infants born in the UK at earlier gestations are admitted for higher-dependency neonatal care with continuous monitoring. Infants who could most benefit from closer monitoring and early detection of adverse signs, particularly in low resource settings where continuous monitoring is not available in neonatal units, are preterm or low birth weight infants. Indeed Mortensen’s review stated that of the four systems published in full, two only included term babies weighing >2500g. The authors concluded that none of the available systems at the time considered “high risk” infants who had been admitted for neonatal care and recommended modifications be made to existing systems. For example, the reference ranges included in the NEWTT were based upon neonatal physiological parameters in term and late preterm infants and adjustments may need to be made based

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3 on gestational age(14). To the best of our knowledge, there are no published early warning  
4 scores from low resource settings such as Kenya nor are such systems currently utilised. All  
5 available scoring systems were developed in high income countries where continuous vital  
6 sign monitoring in neonatal units is standard, yet there is evidence, within an obstetric  
7 setting, that an early warning score system is feasible and possible to implement in a low  
8 resource setting(15).  
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14 In keeping with other early warning score systems, the NEWTT adopts a traffic-light scoring  
15 system. An infant's vital signs are recorded on to a single page. If a measurement is in the  
16 red zone or there are two recordings in the amber zone, the attending nurse is alerted and  
17 immediate escalation to a review by a suitably qualified practitioner is required. The purpose  
18 of such a strategy is to alert health care professionals to the potential of deterioration in the  
19 condition of a high risk infant and give them an opportunity to intervene with appropriate  
20 care.  
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27 The aim of this study was to investigate whether an early warning score system in preterm  
28 and low birth weight infants could be implemented in a low resource setting such as Kenya.  
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## 31 **METHODS**

### 32 **Observational study**

33  
34 In order to understand the characteristics of infants born in this setting, first we conducted an  
35 observational study at the Kenyatta National Hospital (KNH), a tertiary referral hospital, in  
36 Nairobi, Kenya. Data were collected during an eight-week period in March-April 2019 from  
37 routinely recorded data. No interventions nor study specific actions in response to  
38 observations were required and management of the infants followed usual practice. All  
39 infants born at KNH, during the study period, who were <37 weeks gestational age and/or  
40 <2500g at birth were included. Data were collected from birth until day 7 or discharge/death.  
41 Outborn infants (not born at KNH and admitted postnatally) were excluded.  
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50 Research midwives, trained during a three-day workshop, collected data using paper data  
51 collection booklets. Maternal and infant characteristics were collected and all vital signs  
52 recordings (temperature, heart rate and respiratory rate) in the infant's clinical notes were  
53 collected. All data were entered into a password-protected study-specific database (Macro  
54 (©Elsevier)) by the study coordinator. Data quality checks were undertaken remotely by the  
55 UK team. Maternal and infant characteristics were summarised descriptively using the mean,  
56 standard deviation (SD), minimum and maximum for continuous variables and frequency  
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3 counts and percentages for categorical variables along with the number of observations.  
4 Analyses were conducted in Stata version 15 (StataCorp LLC, Texas). Data on temperature,  
5 heart rate and respiratory rate were retrospectively plotted onto graphs representing the  
6 NEWTT system, showing values that were within the red, amber and green zones, using the  
7 reference ranges specified in the NEWTT.  
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12 The study was conducted with full ethical approval from the joint Kenyatta National Hospital-  
13 University of Nairobi Ethics Research Committee (ref P772/11/2018) and the Faculty of  
14 Medicine and Health Sciences Research Ethics Committee at the University of Nottingham  
15 (ref 161-1812). No informed consent was sought from parents since the study was  
16 observational and participants were not subjected to any intervention.  
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### 22 **Stakeholder meeting**

23 In order to understand possible barriers and facilitators to the use of an early warning track  
24 and trigger system in Kenya, a stakeholder meeting was held in July 2019 in Nairobi. This  
25 was attended by 78 delegates from a range of organisations (supplementary material 2).  
26 Delegates were split into groups of approximately 8-10 and asked to consider and feedback  
27 1) what they did and didn't like about an early warning track and trigger system, 2) what  
28 would need to be in place to enable its use; and 3) what are the perceived barriers to its use.  
29 Feedback was written by groups using flipchart paper and verbal feedback given. A narrative  
30 thematic analysis(16) was conducted and themes were identified from the feedback  
31 provided.  
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### 40 **Patient and public involvement**

41 Patients and the public were not involved in the design or conduct of this study. However,  
42 non-government organisations and charities representing patients and the public were  
43 involved in the stakeholder meeting.  
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## 47 **RESULTS**

### 48 **Observational study**

49 Data were collected between 5 March 2019 and 30 April 2019 on the labour suite, post-natal  
50 wards and newborn unit of the participating hospital. During the data collection period 2397  
51 infants were born in KNH (Figure 1). 294 infants (255 mothers) (14.6%) met the eligibility  
52 criteria of being born at <37 weeks gestation and/or weighing <2500g. Ten infants, from  
53 multiple births, were subsequently excluded as they did not meet the eligibility criteria. 206  
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infants were from singleton pregnancies, 82 from twin pregnancies and six from triplet pregnancies.

The mean (SD) age of the mother was 28 (6) years and just under half were educated to secondary/high school level (124/255, 49%). Infants' characteristics are included in table 1.

**Table 1. Characteristics of infants <37 weeks gestational age and/or <2500g at birth born at the Kenyatta National Hospital in March-April 2019**

Characteristic	Total (n=294)
<b>Sex: number (%) of females</b>	135 (54)
<b>Mode of delivery – n (%)</b>	
Vaginal	123 (42)
Elective Caesarean section	3 (1)
Emergency Caesarean section	168 (57)
<b>Delayed cord clamping (n= 14; 280 unknown)</b>	0 (0)
<b>Birth weight (grams) Mean (SD)</b>	1977 (603)
<b>Head circumference (cm) (n= 19) Mean (SD)</b>	32.6 (2)
<b>Length (cm) (n= 4) Mean (SD)</b>	36.0 (5)
<b>Estimated gestational age at birth – n (%)</b>	
<28 weeks	26 (9)
28-32+6 weeks	70 (24)
33-36+6 weeks	123 (42)
≥37 weeks	73 (25)
unknown	2 (<1)
<b>Gestational age estimation based upon – n (%)</b>	
First trimester ultrasound	14 (5)
Clinical assessment	30 (10)
Last menstrual period and/or clinical assessment (mother)	242 (82)
Dubowitz and New Ballard score	6 (2)
Unknown	2 (<1)
<b>Number (%) of babies who required resuscitation at birth (n=287)</b>	110 (37)
<b>Type of resuscitation – not mutually exclusive (n=110)</b>	
Stimulation only	12 (11)
Ventilation	91 (83)
Continued ventilation	36 (33)
Advanced resuscitation	4 (4)
<b>Number (%) of babies who received maternal breast feeding within one hour of birth (n=260)</b>	39 (13)
<b>Number of babies who had initiation of Kangaroo Mother care soon after birth (stable babies only) (n= 180)</b>	0 (0)
<b>Number (%) of babies who had temperature within one hour of birth<sup>1</sup></b>	10 (3)
<b>Number (%) of babies who had heart rate at birth<sup>1</sup></b>	58 (20)
<b>Number (%) of babies who had respiratory rate at birth<sup>1</sup></b>	70 (24)

<sup>1</sup> recorded in clinical records

### **Recording of vital signs (heart rate, respiratory rate, temperature, in clinical records)**

Very few infants had vital signs recorded in the first hour of life; only 10/294 (3%) infants had a recorded temperature, 58/294 (20%) had a recorded heart rate and 70/294 (24%) had a



recorded respiratory rate. In addition, Kangaroo Mother Care was not recorded as having been initiated in any of the 180 clinically stable infants soon after birth.

The number of recorded observations per infant per day was analysed (Table 2). On day 1, less than half of the infants (136/294, 46%) had at least one temperature recording, 130/294 (44%) had at least one heart rate recording and 129/294 (44%) had at least one respiratory rate recording. The number of infants with at least one recording in each of the domains increased throughout the hospital admission: on day 7, 86/104 (83%) of infants had at least one temperature recording, 85/104 (82%) had at least one heart rate recording and 83/104 (80%) had at least one respiratory rate recording. This also includes infants who were then discharged on or died on day 7 (n=9), in addition to the 95 infants who remained in hospital. For these 95, each infant had a mean (SD) of 18 (5.1) temperature recordings, 18 (6.8) heart rate recordings and 17 (6.6) respiratory rate recordings throughout their admission.

Over the entire study period, 185/294 (63%) infants had at least one temperature recorded, 156/294 (53%) had at least one heart rate recording and 155/294 (53%) had at least one respiratory rate recording. Retrospectively, each recording for each domain (temperature, heart rate, respiratory rate) was mapped to a single red, amber or green zone on the UK NEWTT by the researchers. These recordings were not charted on the NEWTT in real time by the clinical staff and we did not collect data on what action(s), if any, were taken in response to a red or amber recording. Although, the NEWTT indicates escalation of care for one recording in the red zone or two recordings in the amber zone, we only included single recordings since it was impossible to know whether an action was taken after one single amber recording.

**Table 2: Number of infants with vital signs recordings (temperature, heart rate, respiratory rate) per day for the 7-day data collection period**

Day	Babies in hospital	At least one temperature recording	At least one heart rate recording	At least one respiratory rate recording
1	294	136 (46%)	130 (44%)	129 (44%)
2	272	165 (61%)	139 (51%)	139 (51%)
3	222	147 (66%)	130 (59%)	128 (58%)
4	194	127 (65%)	119 (61%)	119 (61%)
5	139	110 (79%)	107 (77%)	107 (77%)
6	115	90 (78%)	89 (77%)	90 (78%)
7	104	86 (83%)	85 (82%)	83 (80%)

97/185 (52.4%) had at least one temperature recording in the moderate hypothermic range (<36°C) and 145/185 (78.4%) had at least one recording between 36-36.49°C. Of the 97 infants who had a recorded temperature of <36°C, 92 had any subsequent temperature recording, almost half (41/92, 46%) of which were taken >6 hours later (range 30 mins-46 hours). Of those, 29 infants' (32%) subsequent temperature remained <36°C (Table 3).

**Table 3: Subsequent temperature recordings for 92 infants who had an initial temperature recorded of <36°C**

Temperature (°c)	< 4 hours (n = 25) (27%)	4 to 6 hours (n = 26) (28%)	> 6 hours (n = 41) (46%)
< 36	10 (40%)	7 (27%)	12 (29%)
36-<36.5	5 (20%)	5 (19%)	11 (27%)
36.5-37.5	9 (36%)	11 (42%)	15 (37%)
> 37-38	-	3 (12%)	3 (7%)
>38	1 (4%)	-	-

Tachycardia, defined as a heart rate of >161 beats/minute, was noted in 98/156 infants (62.8%), and 34/156 (21.8%) had at least one recording >175 beats per minute (red zone). High respiratory rate (>80 breaths/min; red zone) was recorded, at least once, in 24/155 (15.5%) and 109/155 (70.3%) had at least one recording of 61-80 bpm (upper amber zone). A respiratory rate of <30 beats/min (red zone) was recorded at least once in 9/155 (6%) and 73/155 (47%) had at least one recording of 30-39 beats/min (lower amber zone). Figure 2 shows recordings for the 95 infants who were still in hospital at day 7 plotted onto colour-coded graphs representing the NEWTT's reference ranges.

### Stakeholder meeting

Seventy eight stakeholders attended the one-day meeting to discuss the development of this tool in a low-resource setting such as Kenya. Stakeholder types are shown in Supplementary material 2. Feedback groups contained a variety of stakeholder types. The main themes that emerged from stakeholder discussions were 1) simplicity and ease of use of the tool, 2) sustainability and resource and 3) training and implementation. Example quotes are included for each theme.

### *Simplicity and ease of use*

Stakeholders reported they liked the coloured traffic-light system since this enabled easy interpretation of the data, recognition of need for action and earlier identification of danger signs.

“the colours are good and explains why”

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3 “it would be easy to identify infants at risk”  
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6 Several stakeholders also commented they liked the combined presentation of several vital  
7 signs on one chart, rather than having lots of paper notes which can easily become untidy or  
8 misplaced. One policy-maker commented that “[the chart’s] simplicity would make universal  
9 coverage easier”. Some also considered whether it would be possible to digitise the system,  
10 for example by creating an app, though recognised whilst this would negate the use for  
11 coloured printing, it would not relieve issues with availability of resources.  
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### 16 17 ***Sustainability and resources***

18 Several stakeholders commented that although they liked the traffic-light system approach, it  
19 may be difficult to print the document since colour printing is expensive and often not  
20 available.  
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25 “printing coloured is a challenge”  
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28 The main concern for the majority of stakeholders were the availability of healthcare staff to  
29 make and document the recordings. It was recognised that such a system would be  
30 acceptable if it replaced the current system of recording vital signs but would not be  
31 acceptable as additional workload. Further to this the major barrier to implementation of this  
32 or any similar early warning score was recognised as the lack of resources, both staff and  
33 interventions, to be able appropriately escalate the care of those infants who would be  
34 identified as sick. The early warning track and trigger system requires immediate escalation  
35 to a more senior neonatologist if a value falls into a red zone or two values in an amber  
36 zone; stakeholders felt this may not be possible given staffing levels on neonatal units in this  
37 setting.  
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46 “We have low staff:patient ratios. This [EWS] has very intense observational needs in  
47 a staff-constrained set-up”  
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### 50 51 ***Training and implementation***

52 Some stakeholders felt that staff working on the newborn/neonatal unit may not like it since it  
53 may “feel like more work” although others recognised that whilst initial resistance may be  
54 encountered this could be overcome by educating staff members of the potential value of  
55 such a system. Many stakeholders commented that training on its use would be paramount,  
56 which should include not only how to complete the tracking system and trigger escalation,  
57 but its potential to reduce neonatal mortality. A non-governmental organisation  
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3 representative commented that whilst implementing such a system may be a good idea, it  
4 would “require national level harmonisation” and that a close working relationship with the  
5 Ministry of Health would be important, since it would need to be endorsed at both a national  
6 and organisational level.  
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11 “it should be integrated into existing tools and the curriculum”

12 “harmonise/integrate this with existing tools to avoid double work”  
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## 15 16 **DISCUSSION**

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19 This is the first study exploring the possibility of using a neonatal EWS in LMICs. EWS are  
20 recommended for use in routine practice in the UK(13) and may have the potential for  
21 supporting early recognition of unwell infants(17). However, before any practice can be  
22 transferred from one health-care setting to another it is important to test the feasibility of  
23 implementing the practice in the target setting(18).  
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28 EWSs are predicated on regular recordings of vital signs. At KNH, local guidelines stipulate  
29 newborn infants should have vital signs checked every 4-6 hours(19), however our study  
30 demonstrates that the routine recording of vital signs in infants’ notes was infrequent; only  
31 half had any heart or respiratory rate recordings and around two thirds had any temperature  
32 recording during their admission. Indeed even for the infants with a low temperature (<36°C)  
33 that would be in the red zone on a EWS, many of them did not have a subsequent  
34 temperature recorded within 4-6 hours. Interestingly, the number of infants with at least one  
35 recording increased during their admission. This could be because fewer infants remained in  
36 hospital throughout the 7 days and those that remained are more likely to be infants who are  
37 unwell and require longer hospital care. It is likely, therefore, that these infants were  
38 prioritised by the staff and monitored more closely. The first 24 hours of life for an infant are  
39 critical and 25-45% of all neonatal deaths occur in this period(20); it is of importance, then,  
40 that less than half of infants in the observational study had vital signs recorded on day 1 of  
41 life and only a very small handful of infants had any vital signs recorded within the first hour  
42 of life. These findings are in-keeping with other studies, for example, about 40% infants had  
43 vital signs chart available in the Nairobi Newborn Study, which was a retrospective review of  
44 33 neonatal facilities in Nairobi City County(21). In addition, none of the 180 stable infants  
45 had KMC initiated shortly after birth, despite clear evidence that KMC, when compared to  
46 standard care, reduces neonatal mortality in preterm infants and infants weighing  
47 <2000g(22). It will be important to ensure that early implementation of KMC is considered in  
48 the further development of an EWS in this setting.  
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5 Our study included detailed data on preterm and LBW infants' vital signs' recordings, which  
6 included temperature, for the first seven days of life. Keeping newborn infants warm is a key  
7 aspect of essential newborn care(23). Hypothermia is common in all newborns, particularly  
8 preterm and LBW infants, regardless of country of birth. In a large systematic review of  
9 neonatal hypothermia(24) prevalence ranged from 32-85% in 21 hospital-based studies in  
10 Africa and Asia (with the exception of one study which reported 8% prevalence(25)).  
11 Temperature data collected in our study is consistent with other studies reporting  
12 hypothermia. Infants' temperatures ranged from 32.1°C-40°C. Of the 2249 recorded  
13 temperatures during the 7-day data collection period, over a third (859/2249, 38%) were  
14 <36.4°C. Almost a third of infants who had a recorded temperature of <36°C, had a  
15 subsequent temperature recording of <36°C. If infants were more closely monitored and  
16 care escalated if a low temperature was identified, for example by using simple colour-coded  
17 chart such as an EWS, it may be possible for action to be taken sooner, thus potentially  
18 preventing further hypothermia.  
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28 A standardised template, such as an EWS chart, could support better record keeping.  
29 Stakeholders identified that the simple traffic-light system could be easily adaptable to local  
30 practice. However, concerns about lack of resources weighed heavily in their mind. This  
31 included lack of material resources such as inability to print in colour and the larger issue of  
32 shortfalls in numbers of healthcare professionals available for newborn care. The lack of  
33 adequate resources for neonatal care in Kenya is well documented(21, 26). In such  
34 situations, our results show that any new intervention is likely to be useful only if it does not  
35 increase the workload of the healthcare staff.  
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43 The Nairobi Newborn Study(21) suggested that implementation of standardised medical and  
44 nursing notes could improve care. A priority setting exercise to improve global newborn  
45 health recommended that the development of simple clinical algorithms to refer neonates  
46 with signs of infection and consequently reduce newborn mortality was a top priority(27).  
47 Although currently there is no evidence that using neonatal EWS improves outcomes in  
48 LMICs, research in closely related clinical areas are encouraging: in Ethiopia, the  
49 introduction of a modified obstetric early warning score (MOEWS) in a referral hospital,  
50 improved practice in several domains(28).  
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57 The desired improvement in outcomes can only be achieved from EWSs if there is an  
58 appropriate escalation of care when required. In this study, infants' vital signs were  
59 retrospectively plotted to the red and amber zones on the NEWTT, using data available via  
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3 clinical records. Whether clinical action was taken as a result of an adverse vital sign is  
4 unknown since this data was not collected. We are therefore only able to report the number  
5 of infants who may have hypothetically triggered an escalation of care, by the fact a value  
6 was plotted to a single red or amber zone. Since the observational study was undertaken to  
7 understand current practice, the NEWTT was applied without any modifications. The  
8 physiological parameters used therefore pertain to term or late preterm infants and further  
9 work will be required to modify these parameters to be more suitable for use in preterm and  
10 low birth weight infants.  
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17 At the stakeholder meeting, the lack of adequately trained medical and nursing staff was  
18 again seen as an impediment to such escalation, particularly if the practice were to be  
19 implemented widely. The KNH is a tertiary referral centre. Most preterm infants in LMICs  
20 including within Kenya are cared for in centres with significantly larger constraints than the  
21 KNH. In this context, it is worth considering if the use of EWSs may enable staff to identify  
22 patients with greater need sooner and hence facilitate more efficient use of limited  
23 resources. A suitably adapted neonatal EWS, using physiological parameters relevant to  
24 preterm infants, could replace existing documentation systems and may improve the  
25 situation by replacing a cumbersome process of documentation with a more streamlined  
26 method.  
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34 This is the first study investigating the possibility of using a neonatal EWS in LMICs. We  
35 used mixed methods to explore current practice, and report the opinions of a range of  
36 relevant stakeholders into understanding the potential use of neonatal EWS in Kenya.  
37 However, we recognise our study has some limitations. Firstly, the study was conducted in a  
38 large tertiary hospital which is relatively well resourced. As this is an exploratory study, our  
39 aim was to scope current practice and explore the possibility of using EWS in KNH before  
40 considering the bigger challenge of rolling it to more remote settings. We used the existing  
41 NEWTT chart, designed for term and late preterm infants (rather than all preterm infants), to  
42 plot vital signs. Outcome data in large datasets is needed to determine whether the  
43 thresholds that define the red and amber zones are applicable to all preterm and low  
44 birthweight babies. We limited data collection to what is currently routinely recorded. The  
45 next step would be to test the feasibility of replacing the current system of documenting vital  
46 signs with a EWS chart to explore if such tools can improve documentation without an  
47 unacceptable increase in workload. Further work is planned and will include emphasis on  
48 training for the use of EWSs.  
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3 Use of MOEWS in obstetrics in LMICs has highlighted the need of a “partnership approach”  
4 and leadership from local teams(28). Our findings include the possibilities of resistance to  
5 change in keeping with the adoption theory, which proposes that any group consists of a  
6 mixture of “innovators, early adopters, early majority, late majority, laggards” and resistance  
7 to change is expected(29). There are several steps outlined in innovation research that are  
8 transferable to this healthcare context; ‘relative advantage’, ‘compatibility’, ‘complexity’,  
9 ‘trialability’, ‘observability’(29). In the context of implementing a neonatal EWS, emphasising  
10 relative advantage (e.g. ease of use); ensuring that the new system ‘fits’ (compatibility);  
11 supporting with easily accessible training (complexity); having a period of trialling before  
12 implementing (trialability); and being clear to staff about any outcomes (observability) could  
13 facilitate adoption. The follow-up of implementation of MOEWS in Ethiopia showed that  
14 attitudes to new practice improved over time(28).  
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## 23 **CONCLUSION**

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27 Development of neonatal EWS in LMICs requires testing the acceptability and feasibility of  
28 recording vital signs using locally-adapted neonatal EWS charts. Further work is required to  
29 ensure that such charts facilitate monitoring of vital signs without increasing workload. A  
30 partnership approach with local leadership and training programmes incorporating the  
31 principles of the adoption theory are vital. This preparatory work must precede any clinical  
32 trials investigating whether implementation of neonatal EWS could reduce neonatal mortality  
33 in LMICs.  
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## 51 **CONTRIBUTORSHIP**

52  
53  
54  
55 EM was the overall Principal Investigator and conceived the idea and wrote the first draft of  
56 the manuscript. SO was the overall clinical lead. ZQ was the Principal Investigator and JO  
57 was the Study Coordinator in Kenya. GG and AO provided obstetric expertise and facilitated  
58 data collection. FW was the lead neonatologist in Kenya. LB undertook statistical analyses.  
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2  
3 JD provided mentorship to the research group. PP provided midwifery expertise. MO  
4 assisted with qualitative analysis. All authors contributed to the manuscript and approved the  
5 final draft.  
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## 8 9 **DATA SHARING**

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12 Data is available upon reasonable request to the corresponding author.  
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14

## 15 16 **COMPETING INTERESTS**

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19 None declared.  
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## 30 31 32 **LICENCE STATEMENT**

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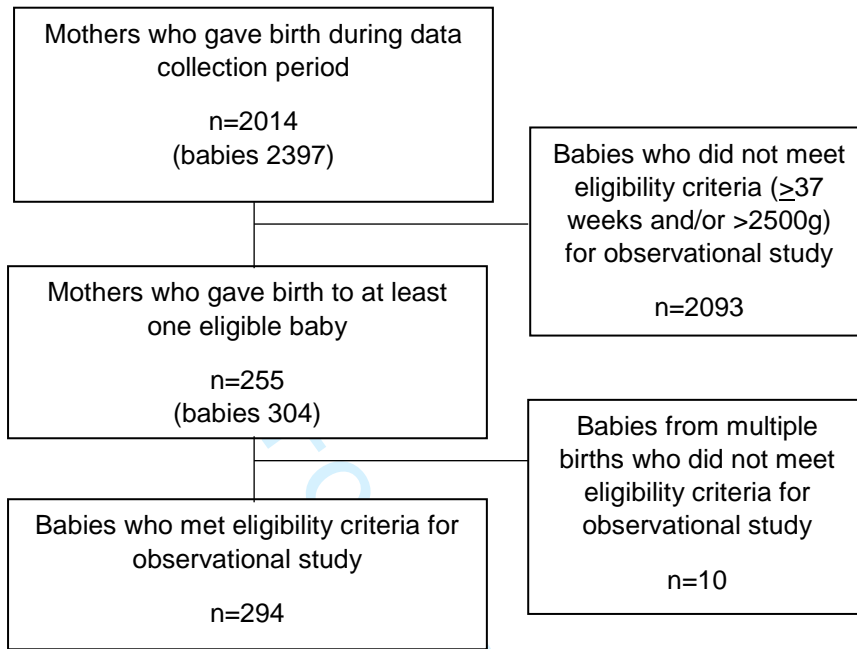
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#### 46 **Figure 1: Study Flow diagram**

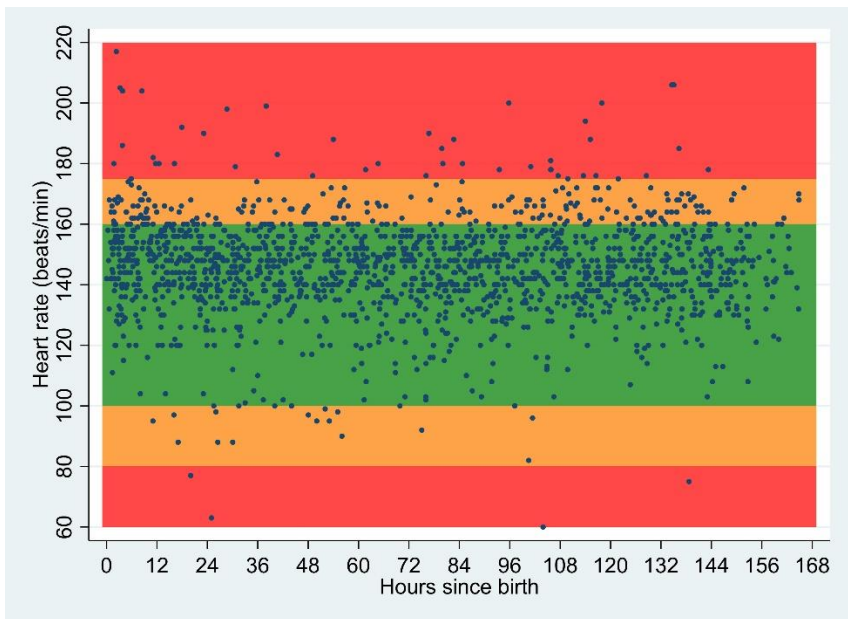
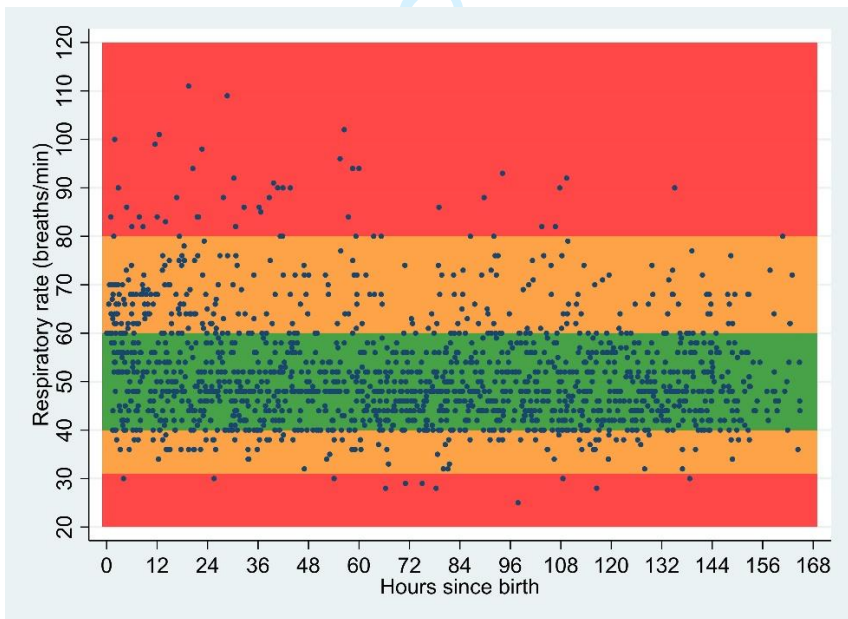
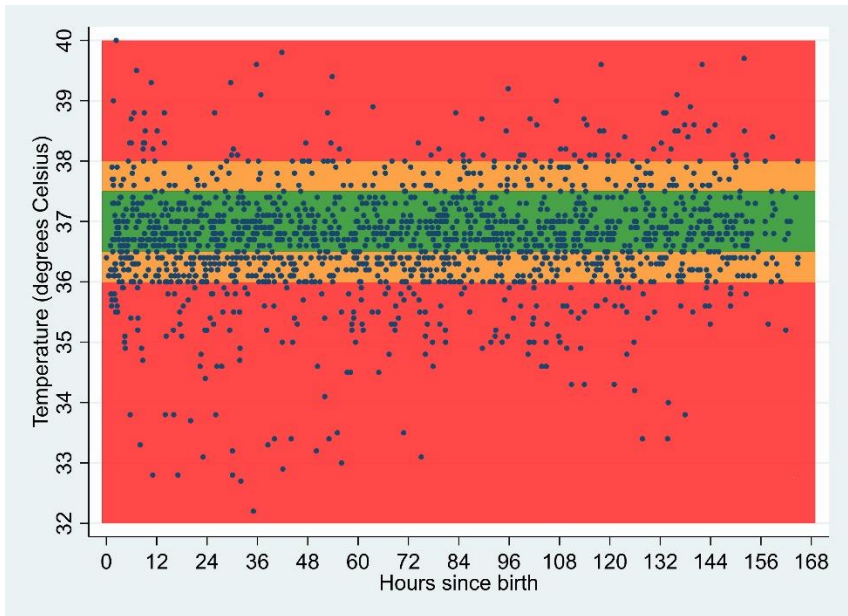
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#### 50 **Figure 2 – Vital sign recordings of preterm, low birth weight infants born and admitted** 51 **to a tertiary referral hospital in Kenya for first 7 days of life (n = 95)**

52 *Data from infants who were in hospital at day 7. Each dot represents a vital sign recording.*  
53 *Since infants had multiple vital signs recordings during their admission, they could have*  
54 *several values across each of the colour zones at multiple time points Graph adapted from*  
55 *NEWTT*  
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# Newborn Early Warning Trigger and Track (NEWTT)


Patient label

Action	Continue observations as planned		
	1 in amber	Escalate concern to senior midwife and review 30 mins	
	2 in amber	Immediate escalation to ANNP / Doctor	
	1 in red	Immediate escalation to ANNP / Doctor	
Reason for Observations		Signed	
Frequency and Duration of Observations			
Date			
Time			
Temperature	38		
	37		
	36		
	Heart Rate	180	
		170	
160			
150			
140			
130			
120			
110			
100			
90			
80			
Respirations	80		
	70		
	60		
	50		
	40		
30			
Grunting			
SaO <sub>2</sub> / Colour	Pale or Blue or SaO <sub>2</sub> < 90%		
	SaO <sub>2</sub> 91 – 94%		
	Pink >95%		
Behaviour	Floppy/ not feeding		
	Jittery/ irritable/ poor feeding		
	Active/ feeding well		
	Blood Glucose		
Bilirubin			
Initials			

# Newborn Early Warning Trigger and Track (NEWTT)

**At Risk Infants – Please tick box as appropriate. Record reason for observation, frequency and duration overleaf .**

**Sepsis**



PROM > 18hours Preterm

PROM > 24 hours Term

Maternal Temperature > 38°C

Chorioamnionitis

Maternal GBS in vaginal swab/ or MSU

Confirmed invasive GBS sepsis in previous baby

**Intrapartum**

Meconium Stained Liquor (requiring intervention)

Cord arterial pH ≤ 7.1

Base Excess ≥ - 12mmol/l

APGAR ≤ 7 at 5 minutes

Other – Specify reason  
.....

**Metabolic : Blood Sugar Monitoring**

Maternal Diabetes

Maternal β Blockers

Birthweight <2<sup>nd</sup> centile

Other – Specify reason  
.....

**Other**

IPPV > 5 minutes

Maternal pethidine < 6 hours before delivery

< 37 weeks gestation

Other – Specify reason .....

**Weight on 2<sup>nd</sup> centile in Kg.**

GA	Boys	Girls
35	1.65	1.60
36	1.90	1.80
37	2.10	2.00
38	2.30	2.20
39	2.50	2.45
40	2.65	2.60
41	2.8	2.75
42	2.9	2.85

**Infants that need immediate review by Doctor /ANNP**

**Jaundice < 24 hours**

**Bilious Vomiting**

**Abnormal Movements**

**Hypoglycaemia**

**Apnoea**

**These criteria are a guide only to increase surveillance on infants of potential concern. It can be expanded upon to meet local requirements and guidelines.**

## Supplementary material 2 – Stakeholder types

Stakeholder type	Number of stakeholders
Ministry of Health representative	15
World Health Organisation (WHO) representative	2
Senior nursing staff	2
Newborn Unit Nurse	4
Neonatologist / Paediatrician	8
Public health consultant	1
Obstetrician	6
Hospital managers	3
Midwife	1
NGO (non-government organisation) representative <sup>1</sup>	17
Kenya Paediatric Association representative	3
Researcher	8
Research team (UK and Kenya)	8

<sup>1</sup> NGOs represented: Population Council Kenya, Pharm Access Foundation, Options, JH Piego, Path, UNICEF, Global Health strategies, Still a Mum, Beyond Zero

# BMJ Open

## Feasibility of using an Early Warning score for preterm or low-birth weight infants in a low resource setting: results of a mixed-methods study at a national referral hospital in Kenya

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<b>Primary Subject Heading</b>:	Global health
Secondary Subject Heading:	Paediatrics
Keywords:	NEONATOLOGY, Maternal medicine < OBSTETRICS, PERINATOLOGY

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 Manuscripts





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3 **Target journal: BMJ Global Health**  
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6 Feasibility of using an Early Warning score for preterm or low-birth weight infants in a low  
7 resource setting: results of a mixed-methods study at a national referral hospital in Kenya  
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10 Eleanor Mitchell<sup>1</sup>, Zahida Qureshi<sup>2</sup>, Fredrick Were<sup>3</sup>, Jane Daniels<sup>1</sup>, George Gwako<sup>2</sup>, Alfred  
11 Oso<sup>2</sup>, Jacqueline Opira<sup>4</sup>, Lucy Bradshaw<sup>1</sup>, Mary Oliver<sup>5</sup>, Phoebe Pallotti<sup>6</sup>, Shalini Ojha<sup>7,8</sup>  
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27 Nottingham, UK  
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33 Word count: 4122  
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## ABSTRACT

### Introduction

Fifteen million babies are born prematurely, before 37 weeks gestational age, globally. More than 80% of these are in Sub-Saharan Africa and Asia. 35% of all deaths in the first month of life are due to prematurity and the neonatal mortality rate is eight times higher in Low and Middle Income Countries (LMICs) than in Europe. Early Warning Scores (EWS) are a way of recording vital signs using standardised charts to easily identify adverse clinical signs and escalate care appropriately. A range of EWS have been developed for neonates, though none in LMICs. This paper reports the findings of early work to examine if the use of EWS is feasible in LMICs.

### Methods

We conducted an observational study to understand current practices for monitoring of preterm infants at a large national referral hospital in Nairobi, Kenya. Using hospital records, data were collected over an 8-week period in 2019 on all live born infants born at <37 weeks and/or <2500g (n=294, 255 mothers) in the first week of life. Using a chart adopted from the EWS developed by the British Association of Perinatal Medicine, we plotted infants' vital signs. In addition, we held group discussions with stakeholders in Kenya to examine opinions on use of EWS.

### Results

Recording of vital signs was variable; only 63% of infants had at least one temperature recorded and 53% had at least one heart rate and respiratory rate recorded. Stakeholders liked the traffic-light system and simplicity of the chart, though recognised challenges, such as staffing levels and ability to print in colour, to its adoption.

### Conclusion

EWS may standardise documentation and identify infants who are at higher risk of an adverse outcome. However, human and non-human resource issues would need to be explored further before development of an EWS for LMICs.

## STRENGTHS AND LIMITATIONS

- This is the first study exploring the possibility of using a neonatal early warning score in a low resource setting
- The opinions of a wide range of stakeholders, including senior policy-makers and clinicians are included.
- Detailed data on preterm and low birth-weight infants' vital signs were recorded for the first 7 days of life, though was limited to what was routinely recorded
- The tool includes physiological reference ranges for term and late preterm infants, whereas we studied preterm or low-birth weight infants
- Data collection was limited to a tertiary referral hospital in Nairobi, however many preterm infants in low-resource settings are cared for in centres with much larger constraints

## BACKGROUND

Globally, 15 million babies are born prematurely(1); more than 80% in Sub-Saharan Africa (12.3% of all births)(1). Mortality for a preterm infant born in a low or middle income country (LMIC) is eight times higher than in Europe(2). Among the causes of neonatal mortality, prematurity remains the biggest killer with 35% of all neonatal deaths attributed to preterm birth or its complications(3). The United Nations Sustainable Development Goals (SDGs) recognise the need to significantly improve outcomes for newborn infants and have a strategic vision to end preventable newborn deaths, with all countries aiming to reduce the neonatal mortality rate (NMR) to at least 12 per 1000 live births(4).

In Kenya, where the most recent NMR was 19.6 per 1000 live births(5), infants born prematurely should be managed in accordance with national and international guidance for essential newborn care(6-8), though this may not always reflect what happens in practice. Guidance includes a range of evidence-based recommendations for care in the first week of life, e.g. provision of Kangaroo Mother Care (KMC) for all clinically stable infants weighing <2000g, which is recommended for hypothermia prevention (6, 8, 9). The World Health Organisation estimates that >80% of moderate to late (32-37 weeks) preterm infants, could survive with the provision of essential newborn care(10).

Early warning scores are a way of quickly and easily identifying adverse clinical signs and are often used in adult populations in a variety of clinical areas(11), however they are less commonplace for neonatal care. A review by Mortensen(12) identified seven early warning score systems for neonates, including the Newborn Early Warning Trigger and Track (NEWTT) Framework, developed in the UK by the British Association for Perinatal Medicine (BAPM)(13) for infants primarily on postnatal wards with little or no increased surveillance (supplementary material 1). Whilst this framework states that the chart should be triggered for “high risk” infants, only late preterm infants (34-36<sup>6</sup> weeks) are considered due to the fact most preterm infants born in the UK at earlier gestations are admitted for higher-dependency neonatal care with continuous monitoring. Infants who could most benefit from closer monitoring and early detection of adverse signs, particularly in low resource settings where continuous monitoring is not available in neonatal units, are preterm or low birth weight infants. Indeed Mortensen’s review stated that of the four systems published in full, two only included term babies weighing >2500g. The authors concluded that none of the available systems at the time considered “high risk” infants who had been admitted for neonatal care and recommended modifications be made to existing systems. For example, the reference ranges included in the NEWTT were based upon neonatal physiological

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3 parameters in term and late preterm infants and adjustments may need to be made based  
4 on gestational age(14). To the best of our knowledge, there are no published early warning  
5 scores from low resource settings such as Kenya nor are such systems currently utilised. All  
6 available scoring systems were developed in high income countries where continuous vital  
7 sign monitoring in neonatal units is standard, yet there is evidence, within an obstetric  
8 setting, that an early warning score system is feasible and possible to implement in a low  
9 resource setting(15).  
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16 In keeping with other early warning score systems, the NEWTT adopts a traffic-light scoring  
17 system. An infant's vital signs are recorded on to a single page. If a measurement is in the  
18 red zone or there are two recordings in the amber zone, the attending nurse is alerted and  
19 immediate escalation to a review by a suitably qualified practitioner is required. The purpose  
20 of such a strategy is to alert health care professionals to the potential of deterioration in the  
21 condition of a high risk infant and give them an opportunity to intervene with appropriate  
22 care.  
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28 The aim of this study was to investigate whether an early warning score system in preterm  
29 and low birth weight infants could be implemented in a low resource setting such as Kenya.  
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## 33 **METHODS**

### 34 **Observational study**

35  
36 In order to understand the characteristics of infants born in this setting, first we conducted an  
37 observational study at the Kenyatta National Hospital (KNH), a tertiary referral hospital, in  
38 Nairobi, Kenya. Data were collected during an eight-week period in March-April 2019 from  
39 routinely recorded data. No interventions nor study specific actions in response to  
40 observations were required and management of the infants followed usual practice. All  
41 infants born at KNH, during the study period, who were <37 weeks gestational age and/or  
42 <2500g at birth were included. Data were collected from birth until day 7 or discharge/death.  
43 Outborn infants (not born at KNH and admitted postnatally) were excluded.  
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52 Research midwives, trained during a three-day workshop, collected data using paper data  
53 collection booklets. Maternal and infant characteristics were collected and all vital signs  
54 recordings (temperature, heart rate and respiratory rate) in the infant's clinical notes were  
55 collected. All data were entered into a password-protected study-specific database (Macro  
56 (©Elsevier)) by the study coordinator. Data quality checks were undertaken remotely by the  
57 UK team. Maternal and infant characteristics were summarised descriptively using the mean,  
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3 standard deviation (SD), minimum and maximum for continuous variables and frequency  
4 counts and percentages for categorical variables along with the number of observations.  
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6 Analyses were conducted in Stata version 15 (StataCorp LLC, Texas). Data on temperature,  
7 heart rate and respiratory rate were retrospectively plotted onto graphs representing the  
8 NEWTT system, showing values that were within the red, amber and green zones, using the  
9 reference ranges specified in the NEWTT.  
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14 The study was conducted with full ethical approval from the joint Kenyatta National Hospital-  
15 University of Nairobi Ethics Research Committee (ref P772/11/2018) and the Faculty of  
16 Medicine and Health Sciences Research Ethics Committee at the University of Nottingham  
17 (ref 161-1812). No informed consent was sought from parents since the study was  
18 observational and participants were not subjected to any intervention.  
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### 23 **Stakeholder meeting**

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25 In order to understand possible barriers and facilitators to the use of an early warning track  
26 and trigger system in Kenya, a stakeholder meeting was held in July 2019 in Nairobi. This  
27 was attended by 78 delegates from a range of organisations (supplementary material 2).  
28 Delegates were split into groups of approximately 8-10 and asked to consider and feedback  
29 1) what they did and didn't like about an early warning track and trigger system, 2) what  
30 would need to be in place to enable its use; and 3) what are the perceived barriers to its use.  
31 Feedback was written by groups using flipchart paper and verbal feedback given. A narrative  
32 thematic analysis(16) was conducted and themes were identified from the feedback  
33 provided.  
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### 41 **Patient and public involvement**

42 Patients and the public were not involved in the design or conduct of this study. However,  
43 non-government organisations and charities representing patients and the public were  
44 involved in the stakeholder meeting.  
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## 49 **RESULTS**

### 50 **Observational study**

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52 Data were collected between 5 March 2019 and 30 April 2019 on the labour suite, post-natal  
53 wards and newborn unit of the participating hospital. During the data collection period 2397  
54 infants were born in KNH (Figure 1). 294 infants (255 mothers) (14.6%) met the eligibility  
55 criteria of being born at <37 weeks gestation and/or weighing <2500g. Ten infants, from  
56 multiple births, were subsequently excluded as they did not meet the eligibility criteria. 206  
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infants were from singleton pregnancies, 82 from twin pregnancies and six from triplet pregnancies.

The mean (SD) age of the mother was 28 (6) years and just under half were educated to secondary/high school level (124/255, 49%). Infants' characteristics are included in table 1.

**Table 1. Characteristics of infants <37 weeks gestational age and/or <2500g at birth born at the Kenyatta National Hospital in March-April 2019**

Characteristic	Total (n=294)
<b>Sex: number (%) of females</b>	135 (54)
<b>Mode of delivery – n (%)</b>	
Vaginal	123 (42)
Elective Caesarean section	3 (1)
Emergency Caesarean section	168 (57)
<b>Delayed cord clamping (n= 14; 280 unknown)</b>	0 (0)
<b>Birth weight (grams) Mean (SD)</b>	1977 (603)
<b>Head circumference (cm) (n= 19) Mean (SD)</b>	32.6 (2)
<b>Length (cm) (n= 4) Mean (SD)</b>	36.0 (5)
<b>Estimated gestational age at birth – n (%)</b>	
<28 weeks	26 (9)
28-32+6 weeks	70 (24)
33-36+6 weeks	123 (42)
≥37 weeks	73 (25)
unknown	2 (<1)
<b>Gestational age estimation based upon – n (%)</b>	
First trimester ultrasound	14 (5)
Clinical assessment	30 (10)
Last menstrual period and/or clinical assessment (mother)	242 (82)
Dubowitz and New Ballard score	6 (2)
Unknown	2 (<1)
<b>Number (%) of babies who required resuscitation at birth (n=287)</b>	110 (37)
<b>Type of resuscitation – not mutually exclusive (n=110)</b>	
Stimulation only	12 (11)
Ventilation	91 (83)
Continued ventilation	36 (33)
Advanced resuscitation	4 (4)
<b>Number (%) of babies who received maternal breast feeding within one hour of birth (n=260)</b>	39 (13)
<b>Number of babies who had initiation of Kangaroo Mother care soon after birth (stable babies only) (n= 180)</b>	0 (0)
<b>Number (%) of babies who had temperature within one hour of birth<sup>1</sup></b>	10 (3)
<b>Number (%) of babies who had heart rate at birth<sup>1</sup></b>	58 (20)
<b>Number (%) of babies who had respiratory rate at birth<sup>1</sup></b>	70 (24)

<sup>1</sup> recorded in clinical records

### **Recording of vital signs (heart rate, respiratory rate, temperature, in clinical records)**

Very few infants had vital signs recorded in the first hour of life (Table 1) and Kangaroo Mother Care was not recorded as having been initiated in any of the 180 clinically stable infants soon after birth.



The number of recorded observations per infant per day was analysed (Table 2). On day 1, less than half of the infants (136/294, 46%) had at least one temperature recording, 130/294 (44%) had at least one heart rate recording and 129/294 (44%) had at least one respiratory rate recording. The number of infants with at least one recording in each of the domains increased throughout the hospital admission: on day 7, 86/104 (83%) of infants had at least one temperature recording, 85/104 (82%) had at least one heart rate recording and 83/104 (80%) had at least one respiratory rate recording. This also includes infants who were then discharged on or died on day 7 (n=9), in addition to the 95 infants who remained in hospital. For these 95, each infant had a mean (SD) of 18 (5.1) temperature recordings, 18 (6.8) heart rate recordings and 17 (6.6) respiratory rate recordings throughout their admission.

Over the entire study period, 185/294 (63%) infants had at least one temperature recorded, 156/294 (53%) had at least one heart rate recording and 155/294 (53%) had at least one respiratory rate recording. Retrospectively, each recording for each domain (temperature, heart rate, respiratory rate) was mapped to a single red, amber or green zone on the UK NEWTT by the researchers. These recordings were not charted on the NEWTT in real time by the clinical staff and we did not collect data on what action(s), if any, were taken in response to a red or amber recording. Although, the NEWTT indicates escalation of care for one recording in the red zone or two recordings in the amber zone, we only included single recordings since it was impossible to know whether an action was taken after one single amber recording.

**Table 2: Number of infants with vital signs recordings (temperature, heart rate, respiratory rate) per day for the 7-day data collection period**

Day	Babies in hospital	At least one temperature recording	At least one heart rate recording	At least one respiratory rate recording
1	294	136 (46%)	130 (44%)	129 (44%)
2	272	165 (61%)	139 (51%)	139 (51%)
3	222	147 (66%)	130 (59%)	128 (58%)
4	194	127 (65%)	119 (61%)	119 (61%)
5	139	110 (79%)	107 (77%)	107 (77%)
6	115	90 (78%)	89 (77%)	90 (78%)
7	104	86 (83%)	85 (82%)	83 (80%)

97/185 (52.4%) had at least one temperature recording in the moderate hypothermic range (<36°C) and 145/185 (78.4%) had at least one recording between 36-36.49°C. Of the 97

infants who had a recorded temperature of  $<36^{\circ}\text{C}$ , 92 had any subsequent temperature recording, almost half (41/92, 46%) of which were taken  $>6$  hours later (range 30 mins-46 hours). Of those, 29 infants' (32%) subsequent temperature remained  $<36^{\circ}\text{C}$  (Table 3).

**Table 3: Subsequent temperature recordings for 92 infants who had an initial temperature recorded of  $<36^{\circ}\text{C}$**

Temperature ( $^{\circ}\text{C}$ )	<b><math>&lt; 4</math> hours (n = 25) (27%)</b>	<b>4 to 6 hours (n = 26) (28%)</b>	<b><math>&gt; 6</math> hours (n = 41) (46%)</b>
$< 36$	10 (40%)	7 (27%)	12 (29%)
36- $<36.5$	5 (20%)	5 (19%)	11 (27%)
36.5-37.5	9 (36%)	11 (42%)	15 (37%)
$> 37-38$	-	3 (12%)	3 (7%)
$>38$	1 (4%)	-	-

Tachycardia, defined as a heart rate of  $>161$  beats/minute, was noted in 98/156 infants (62.8%), and 34/156 (21.8%) had at least one recording  $>175$  beats per minute (red zone). High respiratory rate ( $>80$  breaths/min; red zone) was recorded, at least once, in 24/155 (15.5%) and 109/155 (70.3%) had at least one recording of 61-80 bpm (upper amber zone). A respiratory rate of  $<30$  breaths/min (red zone) was recorded at least once in 9/155 (6%) and 73/155 (47%) had at least one recording of 30-39 breaths/min (lower amber zone). Figure 2 shows recordings for the 95 infants who were still in hospital at day 7 plotted onto colour-coded graphs representing the NEWTT's reference ranges.

### Stakeholder meeting

Seventy eight stakeholders attended the one-day meeting to discuss the development of this tool in a low-resource setting such as Kenya. Stakeholder types are shown in Supplementary material 2. Feedback groups contained a variety of stakeholder types. The main themes that emerged from stakeholder discussions were 1) simplicity and ease of use of the tool, 2) sustainability and resource and 3) training and implementation. Example quotes are included for each theme.

#### ***Simplicity and ease of use***

Stakeholders reported they liked the coloured traffic-light system since this enabled easy interpretation of the data, recognition of need for action and earlier identification of danger signs.

“the colours are good and explains why”

“it would be easy to identify infants at risk”

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3 Several stakeholders also commented they liked the combined presentation of several vital  
4 signs on one chart, rather than having lots of paper notes which can easily become untidy or  
5 misplaced. One policy-maker commented that “[the chart’s] simplicity would make universal  
6 coverage easier”. Some also considered whether it would be possible to digitise the system,  
7 for example by creating an app, though recognised whilst this would negate the use for  
8 coloured printing, it would not relieve issues with availability of resources.  
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### 13 14 ***Sustainability and resources***

15 Several stakeholders commented that although they liked the traffic-light system approach, it  
16 may be difficult to print the document since colour printing is expensive and often not  
17 available.  
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22 “printing coloured is a challenge”  
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25 The main concern for the majority of stakeholders were the availability of healthcare staff to  
26 make and document the recordings. It was recognised that such a system would be  
27 acceptable if it replaced the current system of recording vital signs but would not be  
28 acceptable as additional workload. Further to this the major barrier to implementation of this  
29 or any similar early warning score was recognised as the lack of resources, both staff and  
30 interventions, to be able appropriately escalate the care of those infants who would be  
31 identified as sick. The early warning track and trigger system requires immediate escalation  
32 to a more senior neonatologist if a value falls into a red zone or two values in an amber  
33 zone; stakeholders felt this may not be possible given staffing levels on neonatal units in this  
34 setting.  
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43 “We have low staff:patient ratios. This [EWS] has very intense observational needs in  
44 a staff-constrained set-up”  
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### 47 ***Training and implementation***

48 Some stakeholders felt that staff working on the newborn/neonatal unit may not like it since it  
49 may “feel like more work” although others recognised that whilst initial resistance may be  
50 encountered this could be overcome by educating staff members of the potential value of  
51 such a system. Many stakeholders commented that training on its use would be paramount,  
52 which should include not only how to complete the tracking system and trigger escalation,  
53 but its potential to reduce neonatal mortality. A non-governmental organisation  
54 representative commented that whilst implementing such a system may be a good idea, it  
55 would “require national level harmonisation” and that a close working relationship with the  
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3 Ministry of Health would be important, since it would need to be endorsed at both a national  
4 and organisational level.  
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8 “it should be integrated into existing tools and the curriculum”

9 “harmonise/integrate this with existing tools to avoid double work”  
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## 12 **DISCUSSION**

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15 This is the first study exploring the possibility of using a neonatal EWS in LMICs. EWS are  
16 recommended for use in routine practice in the UK(13) and may have the potential for  
17 supporting early recognition of unwell infants(17). However, before any practice can be  
18 transferred from one health-care setting to another it is important to test the feasibility of  
19 implementing the practice in the target setting(18).  
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25 EWSs are predicated on regular recordings of vital signs. At KNH, local guidelines stipulate  
26 newborn infants should have vital signs checked every 4-6 hours(19), however our study  
27 demonstrates that the routine recording of vital signs in infants' notes was infrequent; only  
28 half had any heart or respiratory rate recordings and around two thirds had any temperature  
29 recording during their admission. Indeed even for the infants with a low temperature (<36°C)  
30 that would be in the red zone on a EWS, many of them did not have a subsequent  
31 temperature recorded within 4-6 hours. Interestingly, the number of infants with at least one  
32 recording increased during their admission. This could be because fewer infants remained in  
33 hospital throughout the 7 days and those that remained are more likely to be infants who are  
34 unwell and require longer hospital care. It is likely, therefore, that these infants were  
35 prioritised by the staff and monitored more closely. The first 24 hours of life for an infant are  
36 critical and 25-45% of all neonatal deaths occur in this period(20); it is of importance, then,  
37 that less than half of infants in the observational study had vital signs recorded on day 1 of  
38 life and only a very small handful of infants had any vital signs recorded within the first hour  
39 of life. These findings are in-keeping with other studies, for example, about 40% infants had  
40 vital signs chart available in the Nairobi Newborn Study, which was a retrospective review of  
41 33 neonatal facilities in Nairobi City County(21). In addition, none of the 180 stable infants  
42 had KMC initiated shortly after birth, despite clear evidence that KMC, when compared to  
43 standard care, reduces neonatal mortality in preterm infants and infants weighing  
44 <2000g(22). It will be important to ensure that early implementation of KMC is considered in  
45 the further development of an EWS in this setting.  
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3 Our study included detailed data on preterm and LBW infants' vital signs' recordings, which  
4 included temperature, for the first seven days of life. Keeping newborn infants warm is a key  
5 aspect of essential newborn care(23). Hypothermia is common in all newborns, particularly  
6 preterm and LBW infants, regardless of country of birth. In a large systematic review of  
7 neonatal hypothermia(24) prevalence ranged from 32-85% in 21 hospital-based studies in  
8 Africa and Asia (with the exception of one study which reported 8% prevalence(25)).  
9 Temperature data collected in our study is consistent with other studies reporting  
10 hypothermia. Infants' temperatures ranged from 32.1°C-40°C. Of the 2249 recorded  
11 temperatures during the 7-day data collection period, over a third (859/2249, 38%) were  
12 <36.4°C. Almost a third of infants who had a recorded temperature of <36°C, had a  
13 subsequent temperature recording of <36°C. If infants were more closely monitored and  
14 care escalated if a low temperature was identified, for example by using simple colour-coded  
15 chart such as an EWS, it may be possible for action to be taken sooner, thus potentially  
16 preventing further hypothermia.  
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27 A standardised template, such as an EWS chart, could support better record keeping.  
28 Stakeholders identified that the simple traffic-light system could be easily adaptable to local  
29 practice. However, concerns about lack of resources weighed heavily in their mind. This  
30 included lack of material resources such as inability to print in colour and the larger issue of  
31 shortfalls in numbers of healthcare professionals available for newborn care. The lack of  
32 adequate resources for neonatal care in Kenya is well documented(21, 26). In such  
33 situations, our results show that any new intervention is likely to be useful only if it does not  
34 increase the workload of the healthcare staff.  
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41 The Nairobi Newborn Study(21) suggested that implementation of standardised medical and  
42 nursing notes could improve care. A priority setting exercise to improve global newborn  
43 health recommended that the development of simple clinical algorithms to refer neonates  
44 with signs of infection and consequently reduce newborn mortality was a top priority(27).  
45 Although currently there is no evidence that using neonatal EWS improves outcomes in  
46 LMICs, research in closely related clinical areas are encouraging: in Ethiopia, the  
47 introduction of a modified obstetric early warning score (MOEWS) in a referral hospital,  
48 improved practice in several domains(28).  
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55 The desired improvement in outcomes can only be achieved from EWSs if there is an  
56 appropriate escalation of care when required. In this study, infants' vital signs were  
57 retrospectively plotted to the red and amber zones on the NEWTT, using data available via  
58 clinical records. Whether clinical action was taken as a result of an adverse vital sign is  
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3 unknown since this data was not collected. We are therefore only able to report the number  
4 of infants who may have hypothetically triggered an escalation of care, by the fact a value  
5 was plotted to a single red or amber zone. Since the observational study was undertaken to  
6 understand current practice, the NEWTT was applied without any modifications. The  
7 physiological parameters used therefore pertain to term or late preterm infants and further  
8 work will be required to modify these parameters to be more suitable for use in preterm and  
9 low birth weight infants. For example, since respiratory rates and heart rates are likely higher  
10 in preterm infants than term or late term infants, the need for escalation of care may be  
11 overestimated, using the current unmodified version of the NEWTT.  
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19 At the stakeholder meeting, the lack of adequately trained medical and nursing staff was  
20 again seen as an impediment to such escalation, particularly if the practice were to be  
21 implemented widely. The KNH is a tertiary referral centre. Most preterm infants in LMICs  
22 including within Kenya are cared for in centres with significantly larger constraints than the  
23 KNH. In this context, it is worth considering if the use of EWSs may enable staff to identify  
24 patients with greater need sooner and hence facilitate more efficient use of limited  
25 resources. A suitably adapted neonatal EWS, using physiological parameters relevant to  
26 preterm infants, could replace existing documentation systems and may improve the  
27 situation by replacing a cumbersome process of documentation with a more streamlined  
28 method.  
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36 This is the first study investigating the possibility of using a neonatal EWS in LMICs. We  
37 used mixed methods to explore current practice, and report the opinions of a range of  
38 relevant stakeholders into understanding the potential use of neonatal EWS in Kenya.  
39 However, we recognise our study has some limitations. Firstly, the study was conducted in a  
40 large tertiary hospital which is relatively well resourced. As this is an exploratory study, our  
41 aim was to scope current practice and explore the possibility of using EWS in KNH before  
42 considering the bigger challenge of rolling it to more remote settings. We used the existing  
43 NEWTT chart, designed for term and late preterm infants (rather than all preterm infants), to  
44 plot vital signs. Outcome data in large datasets is needed to determine whether the  
45 thresholds that define the red and amber zones are applicable to all preterm and low  
46 birthweight babies. We limited data collection to what is currently routinely recorded. The  
47 next step would be to test the feasibility of replacing the current system of documenting vital  
48 signs with a EWS chart to explore if such tools can improve documentation without an  
49 unacceptable increase in workload. Further work is planned and will include emphasis on  
50 training for the use of EWSs.  
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3 Use of MOEWS in obstetrics in LMICs has highlighted the need of a “partnership approach”  
4 and leadership from local teams(28). Our findings include the possibilities of resistance to  
5 change in keeping with the adoption theory, which proposes that any group consists of a  
6 mixture of “innovators, early adopters, early majority, late majority, laggards” and resistance  
7 to change is expected(29). There are several steps outlined in innovation research that are  
8 transferable to this healthcare context; ‘relative advantage’, ‘compatibility’, ‘complexity’,  
9 ‘trialability’, ‘observability’(29). In the context of implementing a neonatal EWS, emphasising  
10 relative advantage (e.g. ease of use); ensuring that the new system ‘fits’ (compatibility);  
11 supporting with easily accessible training (complexity); having a period of trialling before  
12 implementing (trialability); and being clear to staff about any outcomes (observability) could  
13 facilitate adoption. The follow-up of implementation of MOEWS in Ethiopia showed that  
14 attitudes to new practice improved over time(28).

## 23 **CONCLUSION**

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27 Development of neonatal EWS in LMICs requires testing the acceptability and feasibility of  
28 recording vital signs using locally-adapted neonatal EWS charts. Further work is required to  
29 ensure that such charts facilitate monitoring of vital signs without increasing workload. A  
30 partnership approach with local leadership and training programmes incorporating the  
31 principles of the adoption theory are vital. This preparatory work must precede any clinical  
32 trials investigating whether implementation of neonatal EWS could reduce neonatal mortality  
33 in LMICs.  
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40  
41  
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46 programming).  
47  
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## 51 **CONTRIBUTORSHIP**

52  
53  
54  
55 EM was the overall Principal Investigator and conceived the idea and wrote the first draft of  
56 the manuscript. SO was the overall clinical lead. ZQ was the Principal Investigator and JO  
57 was the Study Coordinator in Kenya. GG and AO provided obstetric expertise and facilitated  
58 data collection. FW was the lead neonatologist in Kenya. LB undertook statistical analyses.  
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2  
3 JD provided mentorship to the research group. PP provided midwifery expertise. MO  
4 assisted with qualitative analysis. All authors contributed to the manuscript and approved the  
5 final draft.  
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## 8 9 **DATA SHARING**

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12 Data is available upon reasonable request to the corresponding author.  
13  
14

## 15 16 **COMPETING INTERESTS**

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18  
19 None declared.  
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27 630131).  
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## 30 31 32 **LICENCE STATEMENT**

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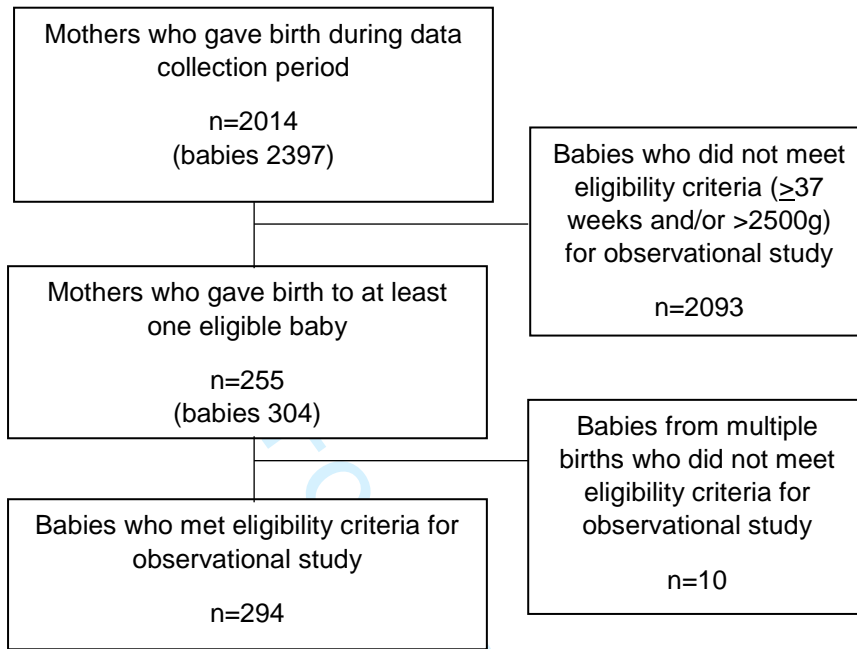
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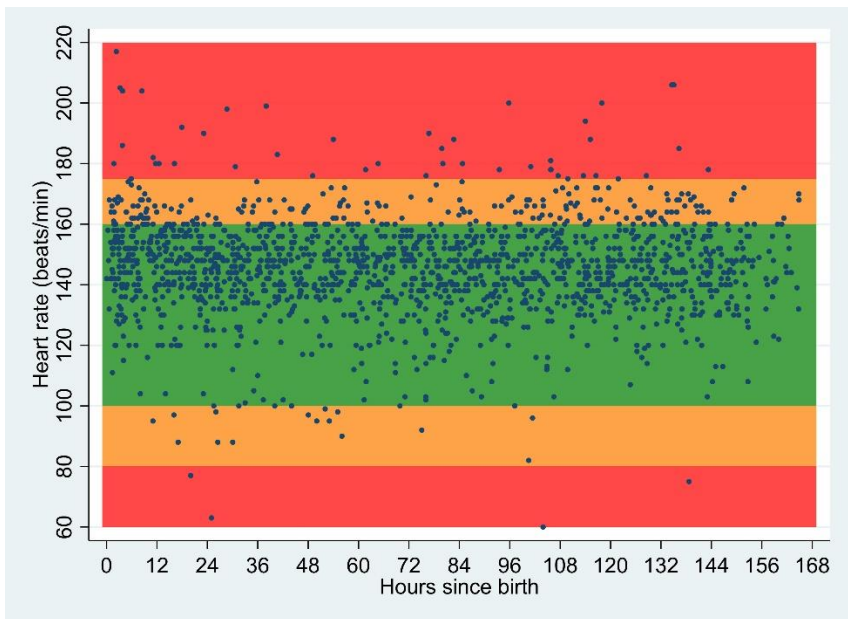
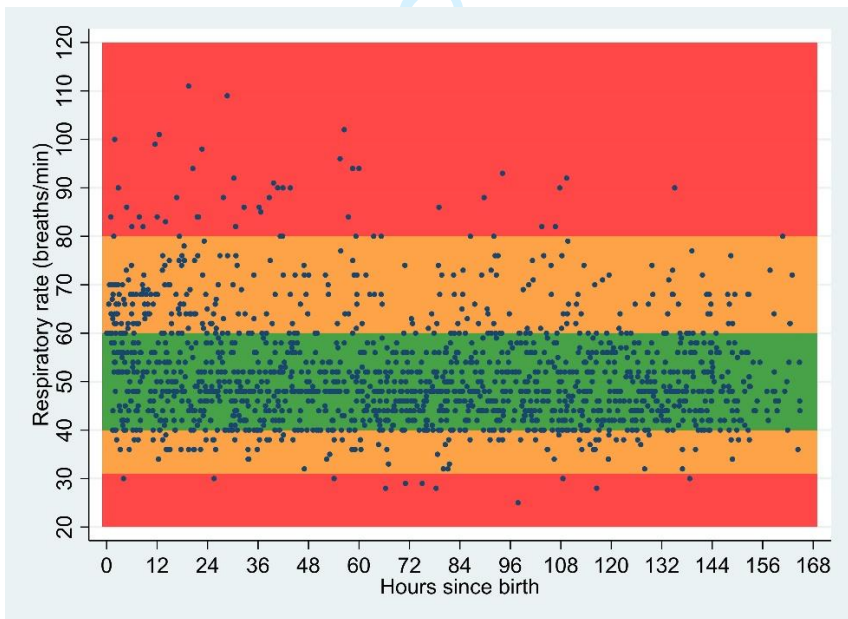
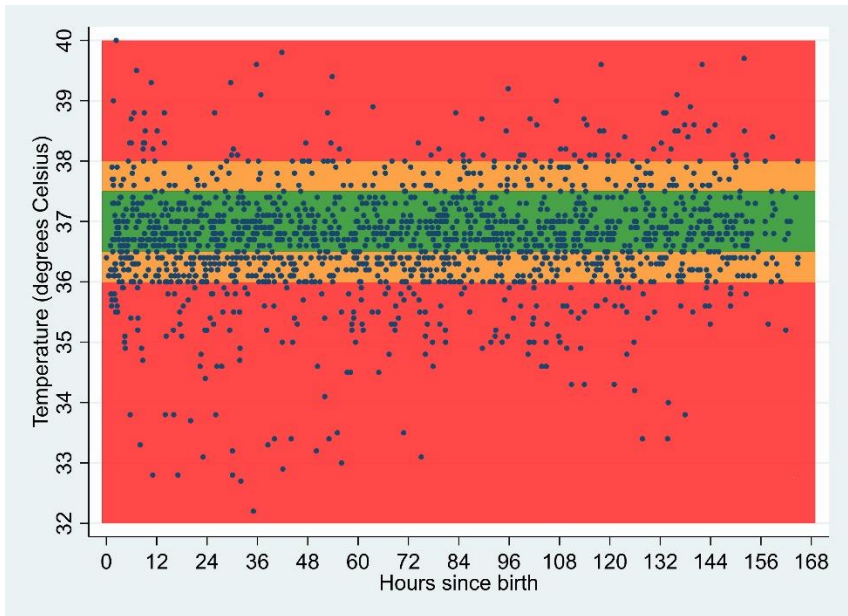
### Figure 1: Study Flow diagram

### Figure 2 – Vital sign recordings of preterm, low birth weight infants born and admitted to a tertiary referral hospital in Kenya for first 7 days of life (n = 95)

*Data from infants who were in hospital at day 7. Each dot represents a vital sign recording. Since infants had multiple vital signs recordings during their admission, they could have several values across each of the colour zones at multiple time points Graph adapted from NEWTT*



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# Newborn Early Warning Trigger and Track (NEWTT)


Patient label

Action	Continue observations as planned		
	1 in amber	Escalate concern to senior midwife and review 30 mins	
	2 in amber	Immediate escalation to ANNP / Doctor	
	1 in red	Immediate escalation to ANNP / Doctor	
Reason for Observations		Signed	
Frequency and Duration of Observations			
Date			
Time			
Temperature	38		
	37		
	36		
	Heart Rate	180	
		170	
		160	
		150	
		140	
		130	
		120	
110			
100			
90			
Respirations	80		
	80		
	70		
	60		
	50		
	40		
	30		
	Grunting		
	SaO <sub>2</sub> / Colour	Pale or Blue or SaO <sub>2</sub> < 90%	
		SaO <sub>2</sub> 91 – 94%	
Pink >95%			
Behaviour	Floppy/ not feeding		
	Jittery/ irritable/ poor feeding		
	Active/ feeding well		
	Blood Glucose		
Bilirubin			
Initials			

# Newborn Early Warning Trigger and Track (NEWTT)

**At Risk Infants – Please tick box as appropriate. Record reason for observation, frequency and duration overleaf .**

**Sepsis**



PROM > 18hours Preterm

PROM > 24 hours Term

Maternal Temperature > 38°C

Chorioamnionitis

Maternal GBS in vaginal swab/ or MSU

Confirmed invasive GBS sepsis in previous baby

**Intrapartum**

Meconium Stained Liquor (requiring intervention)

Cord arterial pH ≤ 7.1

Base Excess ≥ - 12mmol/l

APGAR ≤ 7 at 5 minutes

Other – Specify reason  
.....

**Metabolic : Blood Sugar Monitoring**

Maternal Diabetes

Maternal β Blockers

Birthweight <2<sup>nd</sup> centile

Other – Specify reason  
.....

**Other**

IPPV > 5 minutes

Maternal pethidine < 6 hours before delivery

< 37 weeks gestation

Other – Specify reason .....

**Weight on 2<sup>nd</sup> centile in Kg.**

GA	Boys	Girls
35	1.65	1.60
36	1.90	1.80
37	2.10	2.00
38	2.30	2.20
39	2.50	2.45
40	2.65	2.60
41	2.8	2.75
42	2.9	2.85

**Infants that need immediate review by Doctor /ANNP**

**Jaundice < 24 hours**

**Bilious Vomiting**

**Abnormal Movements**

**Hypoglycaemia**

**Apnoea**

**These criteria are a guide only to increase surveillance on infants of potential concern. It can be expanded upon to meet local requirements and guidelines.**

## Supplementary material 2 – Stakeholder types

Stakeholder type	Number of stakeholders
Ministry of Health representative	15
World Health Organisation (WHO) representative	2
Senior nursing staff	2
Newborn Unit Nurse	4
Neonatologist / Paediatrician	8
Public health consultant	1
Obstetrician	6
Hospital managers	3
Midwife	1
NGO (non-government organisation) representative <sup>1</sup>	17
Kenya Paediatric Association representative	3
Researcher	8
Research team (UK and Kenya)	8

<sup>1</sup> NGOs represented: Population Council Kenya, Pharm Access Foundation, Options, JH Piego, Path, UNICEF, Global Health strategies, Still a Mum, Beyond Zero