## RESEARCH

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# Kangaroo mother care: EN-BIRTH multi country validation study

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## 21 Abstract

Background: Kangaroo mother care (KMC) reduces mortality among stable neonates ≤2000 g. Lack of data
 tracking coverage and quality of KMC in both surveys and routine information systems impedes scale-up. This
 paper evaluates KMC measurement as part of the *Every Newborn*–Birth Indicators Research Tracking in Hospitals (EN BIRTH) study.

Methods: The EN-BIRTH observational mixed-methods study was conducted in five hospitals in Bangladesh, Nepal and Tanzania (TZ) from 2017 to 2018. Clinical observers collected timestamped data as gold standard for motherbaby pairs in KMC wards/corners. To assess accuracy, we compared routine register-recorded and women's exit survey-reported coverage to observed data. Using different recommended denominator options ( $\leq$ 2000 g and  $\leq$ 

2499 g). We analysed gaps in quality provision and experience of KMC. In the Tanzanian hospitals, we assessed daily skin-to-skin duration/dose and feeding frequency. Qualitative data were collected from health workers and data collectors regarding barriers and enablers to routine register design, filling and use.

**Results:** Among 840 mother-baby pairs, both exit-survey reported (99.9%) and register-recorded coverage (92.9%) were highly valid measures compared to observed 100%, with high sensitivity. KMC specific registers outperformed general registers. Enablers to register recording included perceptions of data usefulness, while barriers included duplication of data element and overburdened health workers. Gaps in KMC quality were identified for position components including wearing a hat. In Temeke TZ, 10.6% of babies received daily KMC of  $\geq$ 20 h and a further 75.3% received 12–19 h. Regular feeding  $\geq$ 8 times/day was observed for 36.5% babies in Temeke TZ and 14.6% in

- 39 Muhimbili TZ. Cup-feeding was the predominant assisted feeding method. Family support during admission was
- 40 variable, grandmothers co-provided KMC more often in Bangladesh. No facility arrangements for other family
- 41 members were reported by 45% of women at exit survey. (Continued on next page)

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**Conclusions:** Routine hospital KMC register data has potential to track coverage from hospital KMC wards/corners. 42 43 Women accurately reported KMC at exit survey and evaluation for population-based surveys could be considered. Measurement of content, quality and experience of KMC need consensus on definitions. Prioritising further KMC 44 measurement research is important so that high quality data can be used to accelerate scale-up of high impact 45 care for the most vulnerable. 46

Keywords: Birth, Maternal, Newborn, Coverage, Validity, Survey, Hospital records, Health management systems, 47 Kangaroo mother care, Preterm 48

Figure: key findings 49 What is known and what's new about this study? ta.2 ta.3 Scaling up Kangaroo mother care (KMC) has been slow despite the strong evidence base that KMC improves survival for stable babies ta.4 ≤2000 g weight. Improving data to track coverage is vital to end ta.5 ta.6 preventable preterm deaths, the leading cause of under-five mortality. ta.7 • EN-BIRTH was a large multi-country observational study to assess valta.8 idity of KMC coverage measurement (n = 840 mother-baby pairs) in exitta.9 survey and routine registers. We observed content and quality of KMC ta.10 and conducted interviews with health workers and data collectors to exta.11 plore barriers and enablers to routine register recording. ta.12 Survey: what did we find and what does it mean? ta.13 Women's exit survey report after admission to KMC ward/corner had ta.14 high sensitivity, the first validity testing for measurement. Register: what did we find and what does it mean? ta.15 ta.16 • We found that KMC coverage had high sensitivity in specific KMC registers. Despite the time load for multiple register filling, health ta.17 ta.18 workers were motivated if they saw data being used. ta.19 • KMC coverage measured from KMC specific registers was more ta.20 accurate than from general registers. Routine measurement of KMC provided in other wards and for ta.21 ta.22 babies re-admitted to KMC wards was not assessed in our study and will ta.23 be key to consider in the future. ta.24 Unnecessary duplication of KMC data elements in multiple ta.25 documents needs to be streamlined to reduce burden on nurses ta.26 Gap analysis for quality of care and measurement, where to focus ta.27 now? ta.28 · Observation showed coverage of KMC was not a good proxy for ta.29 receiving high-guality KMC. · Gaps in quality of care were identified even for initial observation all ta.30 ta.31 KMC position components and baby wearing a hat. ta.32 · Detailed analyses were conducted in the two Tanzanian hospital and ta.33 found large gaps in optimal KMC daily dose and feeding. Focus on ta.34 supporting care providers for KMC continuity needs to be prioritised to ta.35 realise the potential of this intervention. ta.36 • Arrangements for families to support mother-baby pairs during adta.37 mission was not always available. ta.38 What next, research gaps • Register data for babies admitted to KMC wards have potential for ta.39 ta.40 aggregation in routine health information systems (HMIS) to track ta.41 coverage. More research is needed to assess data flow and quality at ta.42 different levels of HMIS including how to capture KMC provided in ta.43 other newborn wards ta.44 • Exit-survey further research is needed to explore if KMC can still be ta.45 accurately reported at the typical 3-5 year population-based survey inta.46 tervals by women who provided or did not provide KMC, and if sample ta.47 size in household surveys is feasible to capture babies with birthweight ta.48 <2000 a ta.49 Measuring quality of KMC provision and experience of care is less ta.50 likely to be feasible in routine systems and further research is needed to ta.51 identify the best approach. This may include special studies or perhaps

ta.52 routinely tracking selected specific components (e.g. wearing a hat)

## Background

Annually an estimated 14.9 million preterm babies are 51 born, and prematurity complications are the leading 52 direct cause of death of children under 5 years old [1, 2]. 53 Low- and middle-income countries (LMIC) have high 54 preterm birth rates, yet hospital care for small and sick 55 newborns is characterized by inadequate staffing and ill-56 equipped or non-existent neonatal care units [3]. 57

Kangaroo mother care (KMC) is recommended by the 58 World Health Organization (WHO) as the standard of 59 care for clinically stable newborns  $\leq 2000$  grammes (g) 60 birthweight. There is evidence that KMC contributes to 61 40% reduction in neonatal mortality compared to 62 conventional neonatal care [4, 5]. KMC is defined as 63 prolonged skin-to-skin contact between baby and 64 mother/other caregiver, with frequent and exclusive 65 breastmilk feeding and close follow-up after early dis- 66 charge from hospital [5, 6]. Mechanisms of effect for 67 KMC include thermal support, protection from infec- 68 tion, appropriate stimulation and maximising a nurt- 69 uring environment. Despite strong evidence and 70 potential for major impact, KMC scale-up globally re- 71 mains slow [7-10]. 72

A global target for newborn survival was first set by 73 the Every Newborn Action Plan (ENAP), agreed by all 74 United Nations member states and taken up as 75 Sustainable Development Goal 3.2. An ambitious ENAP 76 measurement improvement roadmap selected KMC 77 coverage as a priority indicator [11, 12]. Coverage 78 indicators measure the proportion of individuals 79 receiving care (numerator) among those who need that 80 care (denominator). As KMC includes several 81 components, the challenge for a KMC numerator is 82 which components to measure. deciding The 83 denominator includes a clear birthweight cut-off at 84 ≤2000 g, although birthweight accuracy is challenging. 85 Additionally, the "clinical stability" component of the 86 definition is subject to interpretation [4]. Previous re- 87 ports have described the complexity involved in defining 88 indicators to measure the coverage of KMC [12–15]. 89

Quality of care measurement requires more than 90 "contact" coverage indicators, and "content" coverage 91

measures are needed. WHO quality of care framework 92 defines quality dimensions as provision and experience 93 of care [16]. There is currently no consensus on high 94 quality KMC but components of provision of KMC 95 position, daily duration/ "dose" of KMC and feeding 96 97 frequency and KMC supportive environment are important to consider for measurement. Descriptive 98 analyses suggest longer daily duration of KMC is more 99 beneficial, based on sub-analyses of mortality trials using 100  $\geq$ 20 h of skin-to-skin contact duration per day [5]. The 101 102 challenges of meeting this ideal, especially in busy KMC units with limited beds, is reflected in an observational 103 study in Uganda; newborns only had a mean daily dur-104 ation of 3 hours in KMC position during the week after 105 birth [17]. In addition to KMC position, supporting 106 breastmilk feeding is required for impact. Preterm new-107 borns do not have a fully developed suck reflex so they 108 require assisted feeding support: breast milk expression 109 with cup/spoon/nasogastric tube feeding (NGT). Fre-110 quency of feeding is individually tailored, dependent on 111 the baby's weight and other clinical factors, but needs to 112 be a minimum of every 3 h. 113

KMC coverage measurement is further complicated as 114 115 KMC is not a one-off intervention, but a process happening over days and weeks: initiation, continuation dur-116 117 ing admission in the facility and thereafter in the community with close follow-up [12, 14, 18]. KMC initi-118 ation depends on clinical stability, whether immediately 119 after birth or several days/weeks later. Given that neo-120 121 natal mortality peaks in the first few days after birth, late 122 initiation reduces impact [5] and several ongoing trials are investigating early KMC for unstable babies [19–21]. 123 Another KMC measurement evidence gap is for KMC 124 supportive environment, including vital close family sup-125 port for this continuous intervention [15]. 126

Data for maternal and newborn health coverage of 127 care in LMIC is mainly from population-based house-128 hold surveys such as The Demographic and Health 129 Surveys (DHS) Program and Multiple Indicator Cluster 130 Survey (MICS) [22]. KMC coverage is currently not cap-131 132 tured in these household surveys and validation research has not been conducted. As KMC is currently recom-133 mended to be initiated in health facilities, improving 134 135 routine Health Management Information Systems (HMIS) measurement is especially relevant, especially 136 137 since  $\sim 80\%$  of births now take place in facilities [23]. Consensus was reached at a technical meeting that KMC 138 ward/corner admission was an appropriate "contact" 139 coverage point and KMC indicator validity testing for 140 141 "content" coverage was prioritised [24].

The *Every Newborn* – Birth Indicators Research
Tracking in Hospitals (EN-BIRTH) study aimed to
validate selected newborn and maternal indicators
for tracking of coverage and quality of care in

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surveys and routine facility data [18]. This detailed 146 analysis of theEN-BIRTH KMC dataset is the topic 147 of this paper. 148

## **Objectives**

This paper is part of a supplement based on the EN-150BIRTH multi-country study, 'Informing measurement of151coverage and quality of maternal & newborn care', and152focuses on facility KMC with four objectives:153

- Determine NUMERATOR accuracy/validity: for survey-reported and register-recorded KMC coverage indicator measurement compared to observational data.
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   157
- Compare DENOMINATOR options for KMC 158
   coverage: including target population ≤ 2000 g (true denominator for WHO recommendation) and other 160
   low birthweight babies ≤2499 g as per District 161
   Health Information Software 2 (DHIS2). 162
- Analyse GAPS in coverage and quality of KMC 163 among admissions to KMC wards: right KMC 164
   position components, daily KMC duration (daily 165
   dose) and feeding frequency to determine how 166
   coverage gaps vary depending on the measure used. 167
- 4. Evaluate BARRIERS and ENABLERS to routine
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   register recording for KMC regarding register
   169

   design, filling and use.
   170

#### Methods

#### Study design, study settings and study population

The EN-BIRTH study was a mixed-methods observa-173 tional study comparing data from clinical observers 174 (considered the gold standard) to women's exit survey-175 reported and register-recorded coverage (Fig. 1). 176 F1 Detailed information regarding the research protocol, 177 methods and analysis have been published separately 178 [18, 25]. Data were collected between June 2017–July 179 2018 in five public Comprehensive Emergency Obstetric 180 and Newborn care (CEmONC) hospitals in three high 181 mortality burden countries: Maternal and Child Health 182 Training Institute (MCHTI), Azimpur and Kushtia Gen-183 eral Hospital in Bangladesh (BD); Pokhara Academy 184 Health Sciences in Nepal (NP); Temeke Regional Hos-185 pital and Muhimbili National Referral Hospital in 186 Tanzania (TZ). Study participants for this analysis were 187 consenting women with babies receiving routine KMC 188 after admission to KMC wards/corners including inborn 189 babies (born in the study hospitals) and outborns (born 190 elsewhere). STATA version 14 was used for all quantita-191 tive analyses [26]. Results are reported in accordance 192 with STROBE statement checklists for cross-sectional 193 studies (Additional file 1). 194



#### 195 Methods and analysis by objectives

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#### 196 **Objective 1: determine NUMERATOR accuracy/ validity**

Researcher clinical observers worked in shifts covering 197 24 h per day. Observation was performed without 198 interacting with the mother-baby pair. Timestamped ob-199 servation data were collected on components of KMC 200 care. The observer did the initial observation as soon as 201 possible after admission to KMC ward/corner. Admis-202 sion weight was collected from individual case notes. 203 Regular follow-up point observations for KMC position, 204 and feedings were hourly in KMC wards in Tanzania 205 and every 12h in KMC corners in Bangladesh and 206 Nepal. Women were interviewed after discharge before 207 exit from hospital with close-ended questions regarding 208 KMC. Researchers extracted individual mother-baby 209 210 KMC data from routine hospital registers. Register designs were were described and summarised. Data were 211 212 collected using a custom-built android tablet-based app developed in such a way that interviewer and register ex-213 tractor data collectors could not access clinical observa-214 tion data, however, data were linked at individual level. 215 216 Metadata for observation, survey and register are shown 217 in Additional file 2.

Definitions of KMC coverage during admission to the
 T1 219 KMC ward/corner are shown in Table 1. To assess
 accuracy at population-level (in the facility), we

independently calculated and compared observed, exit 221 survey-reported and register-recorded KMC coverage for 222 all mother-baby pairs admitted to KMC ward/corner 223 (Fig. 1). Individual-level validity "diagnostic test" 224 methods were calculated using 2-way tables, excluding 225 missing pairwise data. Where column total were  $\geq 10$  226 counts, we calculated sensitivity, specificity, negative pre-227 dictive value, positive predictive value, area under the 228 curve, and inflation factor; otherwise we present percent 229 agreement [27]. All calculations were stratified by hos-230 pital and with 95% confidence intervals (assuming a bi- 231 nomial distribution and using STATA's proportion and 232 metaprop commands). We calculated  $I^2$  and  $\tau^2$  to assess 233 heterogeneity between hospitals and combined hospital-234 specific results using random effects meta-analysis 235 approach. 236

To determine reliability of the observational data, we 237 calculated inter-rater Cohen's Kappa coefficients for the 238 same 5% sample observed by both supervisors and data 239 collectors. We also calculated Kappa coefficients for a 240 5% sample of double-extracted study register data. 241

# Objective 2: compare DENOMINATOR options for KMC coverage

We explored KMC coverage measurement using two 244 possible newborn admission weight denominator 245

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t1.1 Table 1 Definition of terms for KMC sample and measurement, EN-BIRTH Study

t1.2	2 KMC measurement component		EN-BIRTH study sample	Description		
t1.3 t1.4	KMCTotal eligible populationcontact"Contact with services" (A)		Point observation - initial KMC observation	Mother/baby pairs admitted to KMC ward/corner, initial observation		
t1.5 t1.6	KMC continuity		Point observation - KMC Position point	Regular direct clinical observation, hourly in Tanzanian sites, 12 hourly in Bangladesh and Nepal		
t1.7			Point observation - KMC feeding point	Regular direct clinical observation,– hourly in Tanzanian sites, 12 hourly in Bangladesh and Nepal		
t1.8 t1.9	KMC coverage	KMC position/skin-to-skin (B)	Observation KMC initiation and point observation KMC position, register-record data extraction and exit-survey report	KMC upright/ vertical position and/or skin-to-skin care from any point observation during admission to discharge		
t1.10 t1.11 t1.13 t1.14	KMC Content/ Quality	Wearing hat (C)	Observation KMC initiation	Baby wearing hat (for thermoregulation)		
		KMC 5 Position components (D)	Observation KMC initiation	<ol> <li>Upright (vertical) position</li> <li>Skin-to-skin – newborn with caregiver's chest</li> <li>Legs flexed in a 'frog position'</li> <li>Cheek of newborn in contact with caregiver's chest</li> <li>Fixed firmly to caregiver's chest (with cloth or wrap)</li> </ol>		
t1.15		KMC daily dose (E)	KMC baby days with ≥20 position point observations	Hours of per 24-h using point observation as proxy for 1 hour of KMC.		
t1.16		KMC regular feeding (F)	KMC baby days with ≥8 feeding point observations	Feeds per 24-h using point observation as proxy for one feed.		
t1.17 t1.18		KMC Supportive environment	Point observation KMC position and exit-survey report,	Caregiver - mother or other family member Arrangement Pre-discharge counselling		

t1.19 (A) (B) (C) (D) (E) (F) (G) (H) refer to columns in Fig. 4

options: 1)  $\leq 2000$  g as the true denominator for 246 247 'newborns in need of KMC' as recommended by WHO, 2) ≤2499 g as some national programmes recommend 248 KMC for all low birthweight (LBW) babies. We used 249 KMC ward/corner admission weight as outborns may 250 not be weighed at birth and inborns may be 251 transferred after stabilisation on other neonatal wards 252 for days/weeks. 253

#### **Objective 3: analyse GAPS in coverage and quality of KMC** 254 and measurement 255

We measured coverage of key recommended 256 components of KMC as markers of high-quality content 257 KMC, to determine how coverage gaps vary depending 258 on the measure used. 259

#### Dimension: provision of care - components of KMC 260

261 We designed a gap analysis figure for (A) total eligible population of newborns admitted to KMC. Among those 262 receiving any KMC (upright/vertical and/or skin-to-skin) 263 264 (B), the KMC components used as markers of high qual-265 ity KMC or "right" position content evaluated were:

#### All five hospitals (observed at initial observation) (C) 266

Wearing a hat, (D) Five newborn position components: 267

268 1. Upright/vertical 2. Skin-to-skin contact on caregiver's

chest 3. Legs flexed in a 'frog position' 4. Cheek in con- 269 tact with caregiver's chest 5. Fixed with cloth/wrap to 270 caregiver's chest. 271

Two Tanzanian hospitals (observed and survey- 272 report) We further selected the subset of KMC baby 273 Q4 days with sufficient point observations in each 24-h 274 period to capture KMC quality for: daily duration 275 (hereafter called KMC daily dose)  $\geq 20$  position point 276 observations and  $\geq 8$  feeding observations. We calcu-277 lated: (E) KMC skin-to-skin daily dose ≥20 h/day 278 (assuming each point observation was a proxy for 1 279 hour of KMC), 12–19h and <12h per day [5] (F) 280 regular feeding  $\geq 8$  times/day. 281

## Dimension: experience of care - supportive KMC environment

To assess a dimension of quality of experience of care, 284 we observed the caregiver at each point observation and 285 calculated the proportion of KMC given by the mother 286 alone or with a family member's help. We asked women 287 to report reasons for not doing KMC, grouping them as 288 mother-related and baby-related. At exit-survey, we 289 asked whether there were practical arrangements for 290 family members to be involved during KMC admission 291 and if pre-discharge counselling had been received. 292

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#### 293 **Objective 4: evaluate BARRIERS and ENABLERS to routine** register recording 294

We evaluated KMC register documentation issues as 295 part of the wider barriers and enablers objective in the 296 EN-BIRTH study hospitals. Two tools were designed: a) 297 298 Semi-structured in-depth interview (IDI) guide and b) Semi-structured focus group discussion (FGD) guide, 299 both informed by the Performance of Routine Informa-300 tion System Management (PRISM) conceptual frame-301 work [28]. We interviewed two purposively sampled 302 groups of respondents: hospital health workers involved 303 in KMC register recording and data collectors, sampling 304 until saturation was reached. Qualitative data were 305 coded using pre-identified codes based on PRISM using 306 NVIVO 12 for data management. Our analysis was 307 based on applying the same conceptual framework 308 methodology as an associated EN-BIRTH paper explor-309 ing barriers and enablers to routine labour ward register 310 recording [18]. We applied the conceptual framework to 311 the KMC register recording process to find emerging 312 themes across all hospitals by thethree register process 313 categories 1) Design 2) Filling and 3) Perceived utility. 314 Categories were: 315

#### data were extracted (Fig. 2). Just over half of the KMC 319 pairs were from the two Tanzanian hospitals. Most 320 women (92.5%) had completed primary education, 15.9% 321 were adolescents ≤19 years and 24.4% of babies were 322 born by caesarean section (Additional file 3). Admission 323 weight were available for 98% and mean weight lowest at 324 Muhimbili TZ, 1238 g and ranging 1570-1742 g in other 325 hopsital. 55.5% of newborns were female, and 11% were 326 outborn.14.4% had missing gestational age, with the 327 highest in Temeke TZ at 30.4% (Table 2). Average age 328 **T**2 at admission to KMC ward/corner was 14.8 days in 329 Muhimbili and between 2.9-8.1 days in the other sites. 330 Average length of stay was 7 days, with 21.2% admitted 331 for >15 days, especially in Muhimbili TZ. Mean dis-332 charge weight was 1629 g, although 23.6% were missing. 333 Pre-discharge mortality was only 1.1% (Table 3). 334

Standardised KMC registers were used in the hospitals 335 in Bangladesh and Tanzania, but KMC was recorded in 336 a non-specific column in the Nepalese sick newborn 337 register (Additional file 4. Inter-rater reliability for gold 338 standard observation was high/substantial, except in 339 Nepal (Additional file 5). 340

#### Results 316

317 Among 840 KMC mother-baby pairs observed, 77.6% of

318 women had completed exit surveys and 96.7% of register

#### **Objective 1: determine NUMERATOR accuracy/ validity** 341

Compared to 100% observed KMC coverage (vertical/ 342 upright position and/or skin-to-skin), exit survey-reported 343 coverage was accurate at 99.9%. Register-recorded coverage 344



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**T**3

2.2	Characteristics	Bangladesh		Nepal	Tanzania		Total
2.3 2.4		Azimpur Tertiary	Kushtia District	Pokhara Regional	Temeke Regional	Muhimbili National	
t2.5		n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
t2.6	Total	27	136	203	224	250	840
t2.7	Sex of the baby						
t2.8	Male	8(29.3)	67(49.3)	95(46.8)	108 (48.2)	101 (40.4)	379 (45.1)
t2.9	Female	19 (70.4)	69 (50.7)	108 (53.2)	114 (50.9)	148 (59.2)	458 (54.5)
t2.10	Ambiguous	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	1 (0.1)
t2.11	Missing	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	2 (0.2)
t2.12	Place of delivery						
t2.13	Inborn	24 (88.9)	104 (76.5)	172 (84.7)	205 (91.5)	244 (97.6)	749 (89.2)
t2.14	Outborn	3 (11.1)	32 (23.5)	31 (15.3)	19 (8.5)	6 (2.4)	91 (10.8)
t2.15	Gestational age (completed weeks)						
t2.16	< 28 (extreme preterm)	0 (0.0)	1 (0.7)	2 (0.9)	5 (2.3)	13 (5.2)	21 (2.5)
t2.17	28–31 (very preterm)	2 (7.4)	24 (17.7)	12 (5.9)	42 (18.8)	125 (50.0)	205 (24.4)
t2.18	32–36 (moderate/late preterm)	11 (40.0)	84 (61.8)	61 (30.1)	79 (35.3)	92 (36.8)	327 (38.9)
t2.19	> 37–40	13 (48.2)	26 (19.1)	81 (39.9)	26 (11.6)	8 (3.2)	154 (18.3)
t2.20	> 40	0 (0.0)	0 (0.0)	8 (3.9)	4 (1.8)	0 (0.0)	12 (1.4)
t2.21	Don't know	1 (3.7)	1 (0.7)	39 (19.2)	68 (30.4)	12 (4.8)	121 (14.4)
t2.22	Admission weight/g						
t2.23	500–999 g	0 (0.0)	1 (0.7)	3 (1.5)	0 (0.0)	37 (14.8)	41 (4.9)
t2.24	1000-1499 g	3 (11.1)	30 (22.1)	27 (13.3)	68 (30.4)	166 (66.4)	294 (35.0)
t2.25	1500–1999 g	19 (70.4)	89 (65.4)	96 (47.3)	147 (65.6)	43 (17.2)	394 (46.9)
t2.26	2000–2499 g	1 (3.7)	14 (10.3)	74 (36.5)	5 (2.2)	0 (0.0)	94 (11.2)
t2.27	2500–4999 g	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.1)
t2.28	Not recorded/missing	4 (16.0)	1 (0.7)	3 (1.6)	4 (1.8)	4 (1.6)	16 (1.9)
t2.29	Weight KMC indicated (WHO)						
t2.30	≤ 2000 g	23 (85.2)	129 (94.9)	198 (97.5)	219 (97.8)	246 (98.4)	815 (97.0)
t2.31	Mean admission weight /g	1726	1642	1742	1570	1238	1529

**Table 2** Characteristics of babies admitted to KMC ward/corners, EN-BIRTH study (n = 840) t2 1

t2.32 Further details in Additional file 3

was 92.9% from standardised KMC registers, more accurate 345 Bangladesh hospitals, 97.8–100%, compared 346 in to Tanzanian hospitals 84.8-85.2% (Fig. 3). Individual-level **F3** 347 statistics had high sensitivity for both survey-reported and 348

register-recorded coverage (Additional file 6). 349

#### **Objective 2: compare DENOMINATOR options for KMC** 350 coverage 351

352 An all LBW ( $\leq$ 2499 g) denominator option gave very similar results for survey-reported and register-recorded 353 coverage compared to the ≤2000 g denominator results 354 (Additional file 7). 355

## 356 Objective 3: analyse GAPS in coverage and quality of 357 KMC and measurement

F4 358 Figure 4 illustrates the provision of care gap analysis for 359 newborns stratified by hospital for (A) eligible admitted babies ≤2000 g, (B) KMC coverage (upright position/ 360 skin-to-skin (C) wearing a hat (D) all five position 361 components, with no substantial difference for the all 362 LBW category. Only 13.2% of mothers used a special 363 KMC wrap, otherwise using a cloth/shawl to secure 364 the baby in position. The coverage of key 365 recommended components of KMC are presented in 366 Additional files 8 and 9. 367

Experience of KMC supportive environment results 368 found mothers alone provided KMC 97.9% of the time 369 in Muhimbili TZ and 50.5% in Kushtia BD, with the 370 baby's grandmother as the main family support (Fig. 5a). 371 F5 Survey report from 41.1% highlighted lack of ward 372 arrangements to enable family support. Reasons 373 preventing KMC during admission varied by site and 374 were predominantly mother-related, including: needing 375 to get food – highest in Muhimbili TZ (66.0%), needing 376

3.2	Characteristics	Bangladesh		Nepal	Tanzania		Total
3.3 3.4		Azimpur Tertiary	Kushtia District	Pokhara Regional	Temeke Regional	Muhimbili National	
3.5		n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
3.6	Total	27	136	203	224	250	840
3.7	Age of baby at admission						
8.8	0–1 days	8 (29.6)	11 (8.1)	130 (64)	31 (13.8)	0 (0.0)	180 (21.4)
3.9	2–6 days	13 (48.1)	71 (52.2)	46 (22.7)	153 (68.3)	41 (16.4)	324 (38.6)
3.10	7–28 days	6 (22.2)	50 (36.8)	25 (12.3)	37 (16.5)	183 (73.2)	301 (35.8)
3.11	29- < 60 days	0 (0.0)	4 (2.9)	2 (1.0)	2 (0.9)	25 (10)	33 (3.9)
3.12	Missing	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	2 (0.2)
3.13	Mean age during admission	4.6	8.1	2.9	4.7	14.8	7.8
3.14	Length of stay (From admission	to discharge -days	5)				
3.15	0–7 days	15 (55.6)	133 (90.8)	184 (90.6)	163 (72.8)	64 (25.6)	559 (66.6)
3.16	8–14 days	8(29.6)	0 (0.0)	4 (2.0)	34 (15.2)	57 (22.8)	103 (12.3)
3.17	15–21 days	4 (14.8)	0 (0.0)	0 (0.0)	12 (5.4)	47 (18.8)	63 (7.5)
3.18	22–28 days	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.9)	38 (15.2)	40 (4.8)
3.19	29–55 days	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.5)	35 (14.0)	36 (4.3)
3.20	Missing	0 (0.0)	3 (2.2)	15 (7.4)	12 (5.4)	9 (3.6)	39 (4.6)
3.21	Mean Length of stay	7.1	1.8	1.5	5.2	16.1	7.1
3.22	Discharge weight (in grams)						
3.23	500–999 g	0 (0.0)	0 (0.0)	4 (2.1)	0 (0.0)	1 (0.4)	5 (0.6)
3.24	1000–1999 g	18 (72.0)	89 (66.9)	69 (36.5)	197 (89.6)	183 (74.4)	556 (68.4)
3.25	2000–2499 g	5 (20.0)	8 (6.0)	30 (16.9)	9 (4.1)	5 (2.0)	57 (7.0)
3.26	2500–2599 g	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.4)	2 (0.3)
3.27	Not readable	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.1)
3.28	Not recorded/missing	2 (8.0)	35 (26.3)	86 (45.5)	14 (6.4)	55 (22.4)	192 (23.6)
3.29	Mean discharge weight	1875	1589	1600	1666	1596	1629
3.30	Baby's condition at discharge						
3.31	Alive	27 (100)	133 (97.8)	192 (94.6)	213 (95.1)	241 (96.4)	806 (96)
3.32	Neonatal Death	0 (0.0)	0 (0.0)	3 (1.5)	4 (1.8)	2 (0.8)	9 (1.1)
3.33	Missing	0 (0.0)	3 (2.2)	8 (3.9)	7 (3.1)	7 (2.8)	25 (3.0)

 $\overline{Q5}$ B.1 **Table 3** KMC babies admitted and discharge characteristics, EN-BIRTH Study (n = 840)

t3.34 Further details in Additional file 3

a rest – highest in Pokhara NP (76.9%), and needing to wash – highest in Kushtia BD (41.7%) (Fig. 5b). Predischarge counselling was reported by 57.9%, topics included KMC position 24.7%, feeding practices 25.5% and need for follow-up visits 15%.

#### 382 Tanzanian hospitals only

## 383 "Right" content - KMC daily dose

Among target group ≤2000 g babies, KMC baby days with ≥20 point observations were available in Temeke (*n* = 6804). "Right" content, or ≥ 20 h of KMC skin-toskin, was achieved for 10.6% of KMC baby days; 12–19 h by a further 75.4%; and < 12 h for 14.0%. Upright/vertical position and skin-to-skin both had a median time of 16 389 h (Fig. 4, column E, Additional file 10). 390

391

#### "Right" content – regular feeding

Feeding point observations  $\geq 8$  per KMC baby day for 392 mother-baby pairs  $\leq 2000$  g were 8212 in Temeke and 393 1352 in Muhimbili. Minimum or "Right feeding" frequency of  $\geq 8$  times per day was achieved on 35.6% 395 KMC baby days in Temeke and 14.6% in Muhimbili. 396 Observed mode of feeding for breastfeeding alone was 397 higher in Temeke 17.7%, compared to 3.6% in 398 Muhimbili. Assisted feeding was predominantly by 399 cup, 31.9% of observed feeds were cup alone and a 400 further 33.4% were cup and breastfeeding. Mothers 401

![](_page_8_Figure_2.jpeg)

![](_page_8_Figure_3.jpeg)

f3.1 f3.2 f3.3

f4.1 f4.2 f4.3 f4.4

![](_page_9_Figure_2.jpeg)

450

460

472

402 fed their babies >99% of the time and NGTs were 403 used for <2% of feeds (Fig. 4, column F, Add-404 itional file 11, Additional file 12).

## 405 Objective 4: evaluate BARRIERS and ENABLERS to routine 406 register recording

407 We conducted IDIs with 2-4 nurses working in KMC wards or KMC corners on neonatal wards (n = 14) and 408 EN-BIRTH study data collectors (n = 56) to reach satur-409 ation. One FGD was conducted in each hospital for 410 triangulation (n = 5). Emerging themes specific for KMC 411 registers around three process domains (Add-412 itional file 13) were: 413

#### 414 Register design

Interview respondents explained that the KMC register 415 is one of many documents to be completed, including 416 patient case notes, monthly summary sheets, admission 417 registers, ward round books, and the discharge book. 418 Health workers explained that readmission to KMC is 419 not uncommon when babies become unstable; register 420 design currently does not accommodate this, which 421 affects measurement: 422

423 Today a child was admitted [again], she was under KMC [last month] but her condition went 424 worse so she had to be shifted to neonatal ward, 425 after some time that child got well and was 426 shifted back to KMC this month. Now, I was 427 428 asked what should be done, should they record her as a new admission, or she should continue 429 with the previous one? I told them, no, the previ-430 ous data has been already sent, so the child 431 should be admitted afresh, in this month'. (Health 432 worker, Temeke Regional Hospital, TZ) 433

#### 434 Register filling

In all five hospitals, nurses took sole responsibility to
document in registers. Documentation was described as
overwhelming:

438 'From KMC, honestly, if you look at the proportion
439 between documentation and care the one which is
440 given first priority by nurses is care and then we for441 get to document. Because you find that there are
442 many patients... ....and time is too short....'. (Health
443 worker, Muhimbili TZ)

444

'The main issue is manpower. Because of less people,
there might be a chance of information being missed
in documentation....if anything is missed during shift
change that can hamper another shift'. (Health
worker, Pokhara NP)

#### Register data use

Registers were valued in supporting patient care and 451 were required for reporting and quality improvement. 452

'The treatments depend on the documentation e.g.453the weight of the baby. Doctor provide the treat-454ments based on the documentation. In my opin-455ion, there is a strong relationship between the456care and the documentation... Our works has no457value without the documentation'. (Health worker,458Kushtia BD)459

'Record keeping helps us to provide quality services,<br/>it helps us to trace a patient who was discharged461but she has come back, you get to see her previous is-<br/>sues which were documented.....'. (Health worker,<br/>Temeke, TZ)463

Despite many areas to document, health care workers 466 reported that documentation is necessary. 467

'I think there are so many documents here in the468ward because each document is important and supposed to be submitted somewhere'. (Health worker,469Muhimbili, TZ)471

## Discussion

EN-BIRTH is the first study to assess validity of KMC 473 coverage measurement compared to observation and 474 explore dimensions of quality of care for a multi-country 475 cohort in LMIC context. Admission to a KMC ward was 476 an excellent marker of having received KMC, opening 477 the way for tracking coverage from contact with KMC 478 services. Data for action is urgently needed to accelerate 479 scale-up of KMC for stable babies whilst research continues to establish whether unstable babies will also 481 benefit [29]. 482

Register data measurement of KMC coverage was 483 accurate using specific KMC registers. However, register 484 documentation in a non-specific column (in a general 485 inpatient register for sick newborns) was incomplete at 486 Pokhara NP. In the other four hospitals, where specific 487 KMC registers had been implemented, the high accuracy 488 offers potential to link KMC register admission data to 489 HMIS systems, including DHIS2. However, KMC regis-490 ters are typically only located in KMC ward/corners, so 491 tracking KMC coverage from these registers may under- 492 estimate intermittent KMC provided in other neonatal 493 wards. This gap will be important to address if KMC for 494 unstable newborns is introduced. Readmissions to KMC 495 ward/corners could inflate KMC coverage and this needs 496 further consideration [30]. Clearly defining the denomin-497 ator for routine HMIS tracking will be critical, especially 498

since LBW rate (≤2499 g) is already a core 100 health in-499 dicator but the KMC clinical need definition is currently 500 ≤2000 g. Also the subtle definition differences of exclud-501 ing babies weighing exactly 2500 g for LBW indicator, 502 yet including those weighing 2000 g for KMC indicator 503 504 adds a dimension of measurement complexity from aggregated routine data. In Tanzania the national policy 505 for KMC includes all LBW babies and in our study 506 hospitals' KMC wards we found 3% of our sample had 507 admission weights > 2000 g. We collected KMC ward/ 508 509 corner admission weight for consistency, but notably mean age of admission varied by hospital. Register docu-510 mentation was perceived by nurses as important, yet its 511 priority competed against care for women and babies. 512 Our findings may be generalizable to other similar 513 settings where specific KMC registers are being imple-514 mented. However, our qualitative findings highlighted 515 the challenge of programme specific measurement add-516 ing to burden of duplication of data element documenta-517 tion with patient notes. Consideration to reduce any 518 unnecessary duplication can enable health workers to 519 efficiently use their time to support KMC mother-baby 520 dyads as well as use the data they collect for quality im-521 provement decisions e.g. increased frequency of feeding 522 or daily dose of KMC. 523

524 Exit survey-report of KMC was also found to be highly accurate at the time of discharge from KMC ward/cor-525 ners. Further evaluation to determine whether use in 526 household survey is feasible should be considered. This 527 528 could include measuring recall decay over the typical 3 529 to 5-year interval of population-based surveys, and also whether women who had not practiced KMC misreport 530 having done so [31, 32]. Importantly, the household 531 surveys' sample size needs to be considered to ensure 532 sufficient power to accurately measure KMC coverage 533 for babies ≤2000 g [33]. These steps would facilitate as-534 sessment of inclusion of KMC indicators in household 535 surveys such as DHS and MICS. 536

High-quality KMC, in both dimensions of quality of 537 provision and experience of care is needed to have 538 539 impact, but currently there is no consensus on definition. Prolonged skin-to-skin contact in KMC pos-540 ition is the cornerstone of KMC, although currently 541 542 there is a lack of evidence for the optimal daily dose [6, 14, 15]. Wearing a hat is an important component of 543 544 KMC for babies' thermoregulation, especially in LMICs where ward temperatures are often unregulated. Yet 545 families may not have access to appropriate sized hats 546 for their preterm child. We found baby hat wearing 547 548 coverage was lowest at 57.4% in Kushtia BD and highest 549 93.5% in Muhimbili the site with the baby's lowest mean weight and highest mean admission age, enabling hat 550 availability after stabilisation in another ward. . We sug-551 gest tracking of hat coverage may have potential for 552

routine measurement as a tracer of content of care for 553 these vulnerable infants. We found a median of 16 h in 554 Temeke hospital TZ, which was much higher than in an 555 observational study conducted in Uganda [17]. Preterm 556 babies require assisted feeding and we found a large 557 quality gap. More than 8 feeds per day were only ob-558 served on 35.6% KMC baby days in Temeke TZ, and 559 even lower 14.6% in Muhimbili TZ, despite the lowest 560 mean admission weight of < 1300 g. Cup feeding was 561 used frequently in both Tanzanian hospitals but NGT 562 feeding rates were very low. The two Tanzanian study 563 hospital KMC wards are different in layout which may 564 affect quality of care. Temeke KMC ward is one room 565 with every mother-baby dyad visible from the nursing 566 compared to Muhimbili's KMC ward over several rooms 567 with the nursing station outside. 568

The KMC mother-baby dyad cohorts in the five study 569 hospitals were notably different. Muhimbili TZ admitted 570 smaller babies, older at admission after stabilisation on 571 other neonatal wards, and longer KMC ward stays than 572 that other hospitals. As consensus is developed regard- 573 ing components of high quality provision and experience 574 of care for KMC mother-baby dyads, complexity of ag-575 gregate measurement of coverage and quality for diverse 576 cohorts may need consideration. Disaggregating by ad- 577 mission weight may be complex due to regaining weight 578 newborns lose immediately after birth. Birthweight may 579 not be available for outborns or be heaped for inborns 580 [30]. Longitudinal Individual longitudinal data linking 581 KMC monitoring of outcome, nutrition and develop-582 ment is already a reality in the most established KMC 583 national programmes [34]. 584

Supportive KMC environment from health workers 585 and family is crucial for the success of this process of 586 care, which may need to continue for weeks. 587 Arrangements for other family members to be present 588 in during KMC admission is an important first step, 589 but it was not common in these hospitals, but may 590 improve if examples of supportive care is routinely 591 measured [3, 6, 10, 17, 35]. 592

593

## Strengths and limitations

The EN-BIRTH study is the first observational study to 594 assess validity of measurement of KMC coverage. The 595 qualitative data added insights into routine register re-596 cording from the health worker perspective. We estab-597 lished for the first time that in the LMIC context, 598 contact with KMC services correlated well with receiving 599 KMC. Our sample size of 840 mother-baby pairs from 600 five hospitals in Bangladesh, Nepal and Tanzania en-601 abled analyses on many dimensions of quality of care in 602 the LMIC context. However, there are also limitations. 603 The sample size varied across the study hospital, lowest 604 at 27 in Azimpur which perhaps reflecting lower levels 605

of KMC implementation. We were unable to individually 606 link observed KMC mother-baby pairs with target popu-607 lation stable babies  $\leq 2000$  g either born in the hospital 608 labour ward or transferred from other neonatal wards, 609 thus could not assess true denominator for coverage. 610 611 Access for this population to KMC wards would be important to track for contact coverage. Frequency of 612 KMC continuation observations was not consistent 613 across all the study hospitals and only in the Tanzanian 614 hospitals could analysis be done with hourly point obser-615 vation data for feeding and in Temeke only for position. 616 The differing ward/ corner layouts may have affected 617 point observation comparisons, in a similar way that 618 they might affect quality of care, an important consider-619 ation for a continuous practice as KMC. We were only 620 able to interview 77% of the observed sample as women 621 exited rapidly after discharge before the researchers 622 could approach them, especially in the KMC corner of 623 Pokhara NP, with mean length of stay only 1.5 days. Our 624 study hospitals are all large hospitals, and the mothers in 625 our sample had higher levels of education than national 626 averages, so our findings might not be generalizable to 627 measurement from KMC provided in other types of fa-628 629 cilities. It is possible that the presence of researchers on the KMC wards/corners could have resulted in improved 630 631 care or register documentation by health workers [25]. In Pokhara, the inter-rater reliability agreement for ob-632 servation were unexpectedly low and might have affected 633 validation results in that site. The more detailed analyses 634 on daily dose of KMC and feeding were only from the 635 636 Tanzanian hospitals, where KMC practice is more established compared to the Asian hospitals. We did not cap-637 ture whether feeding was exclusively with breastmilk, 638 which could be a dimension of quality for KMC. It was 639 also beyond the scope of this study to explore how spe-640 641 cific KMC implementation affected coverage and quality of KMC provision and experience. 642

### 643 Research for improving measurement

Measurement of the process of KMC is complex and 644 further research is needed. Tracking KMC from KMC 645 ward/corner facility data into HMIS has potential; 646 implementation research is needed to understand data 647 648 flow and quality, including efficient aggregation for the true denominator  $\leq 2000$  g. It is unlikely that all stable 649 650 babies ≤2000 g have full access to KMC specific services, so interoperability between labour ward birthweight data 651 and routine KMC data is an important area for research 652 [14, 15]. To capture KMC coverage in the facility also 653 654 requires including KMC provided on other wards 655 including linking to special and intensive newborn care wards where babies are admitted for stabilisation before 656 transition to Moreover, exploring how to best measure 657 population coverage for facility KMC as both inborn and 658

babies admitted for KMC outborn are needs 659 consideration. Measuring quality of the process of KMC 660 (daily dose, feeding, weight gain etc.), and the experience 661 of care is unlikely to be feasible in routine registers or 662 population-based survey. Research is needed to explore 663 other approaches, including case audits and special stud-664 ies, with similar definitions across sites so comparisons 665 can be made. Measurement research for standardised in-666 dicators of long-term health and well-being to maximise 667 developmental and nutritional outcomes for KMC survi-668 vors is a key research priority [36]. Innovation regarding 669 measurement of a KMC supportive environment - in-670 cluding appropriate physical space, health worker experi-671 ence of care, and supportive supervision - is needed. 672

#### Conclusions

Scale-up of KMC is a priority intervention and our 674 results show that coverage of KMC could be tracked in 675 routine systems by using count data on admission to 676 KMC, best measured with a specific KMC ward register. 677 Further work is needed to understand if KMC can be 678 tracked by household surveys, especially while coverage 679 is low. Clear, measurable definitions of high quality 680 KMC are needed for maximal impact of this 681 intervention - with huge potential to improve outcomes 682 for vulnerable newborns to survive and thrive. 683

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Additional file 1. STROBE checklist.	688
Additional file 2. Metadata definitions of selected indicators for validity testing, EN-BIRTH study. Observation compared to women's exit survey report or register, data extraction.	689 690 691
Additional file 3. Background characteristics of women observed in KMC ward, EN-BIRTH study.	692 693
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Additional file 8. Markers for Quality of KMC by hospital, EN-BIRTH study $\leq$ 2000 g, $n = 815$ observed.	709 710
Additional file 9. Markers for Quality of KMC by hospital, EN-BIRTH study all weights, $n = 840$ observed.	711 712 723

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713 714	Additional file 10. Box plots KMC daily dose: upright/vertical position, skin-to-skin, EN-BIRTH study Temeke Hospital, Tanzania ( $n = 6804$ point observations).	
715 716	<b>Additional file 11.</b> Observed feeding practices for KMC mother-baby pairs, EN-BIRTH study Tanzania sites ( $n = 22,793$ point observations).	
717 718	Additional file 12. Flow diagram for analyses of KMC continuity – Tanzania sites, ≤2000 g EN-BIRTH study.	
719 720 721	Additional file 13. Barriers and Enablers to Routine Reporting and Documentation for KMC in the EN-BIRTH study. Additional file 14. Ethical approval of local institutional review boards,	

**EN-BIRTH** study. 722 774

#### 725 Abbreviations

- BD: Bangladesh; CEmONC: Comprehensive Emergency Obstetric and 726
- 727 Newborn care; CIFF: Children's Investment Fund Foundation; DHS: The
- 728 Demographic and Health Survey Program; DHIS2: District Health Information
- 729 Software 2; ENAP: Every Newborn Action Plan now branded as Every Newborn;
- 730 EN-BIRTH: Every Newborn-Birth Indicators Research Tracking in Hospitals
- 731 study; FGD: Focus group discussion; g: grammes; HMIS: Health Management
- 732 Information Systems; icddr,b: International Centre for Diarrheal Disease
- 733 Research, Bangladesh; IDI: in-depth interview; IHI: Ifakara Health Institute;
- KMC: Kangaroo mother care; LMIC: Low-Middle Income Country; LSHT 734
- M: London School of Hygiene & Tropical Medicine; MARCH: Centre for 735
- 736 Maternal, Adolescent, Reproductive & Child Health, LSHTM; MCHTI: Maternal
- 737 and Child Health Training Institute, Azimpur, Bangladesh; MUHAS: Muhimbili
- University of Health and Allied Sciences; MICS: Multiple Indicator Cluster 738
- 739 Survey; NGT: nasogastric tube; NP: Nepal; PRISM: Performance of Routine 740
- Information System Management; TZ: Tanzania; UNICEF: United Nations 741 International Children's Emergency Fund; WHO: World Health Organization

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Authors' contributions

The EN-BIRTH study was conceived by JEL, who acquired the funding and 801 led the overall design. QSR was the main lead for data management, work-802 ing closely with LTD. Each of the three country research teams input to all 803 the data collection tools and review processes and data collection and gual-804 ity. The iccdr,b team (notably AER, TT, TH, QSR, SA and SBZ) led the develop-805 ment of the software application, data dashboards and database 806 development with VSG and the LSHTM team. IHI and MUHAS team coordi-807 808 nated work on barriers and enablers for data collection and use, working closely with LTD. For this paper the analysis was led by JS working closely 809 with NS, KM, TJK, KP, LTD and JEL. NS and JS drafted the manuscript with 810 LTD and JEL. All authors revised the manuscript and gave final approval of 811 the version to be published and agree to be accountable for the work in-812 cluding: icddr,b Bangladesh: SZ; Golden Community and Ministry of Health, 813 Nepal: NK, OB; Ifakara Health Institute, Muhimbili National Hospital, and 814 MUHAS, Tanzania: DS, NM, KS, KM; LSHTM: HR, SK, SM; as well as others: AK, 815 TJK, HB, AA, TDH. 816

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#### Availability of data and materials

The datasets generated during and/or analysed during the current study are 828 available on LSHTM Data Compass repository, https://datacompass.lshtm.ac. 829 uk/955/. 830

#### Ethics approval and consent to participate

This study was granted ethical approval by institutional review boards in all operating counties in addition to the London School of Hygiene & Tropical Medicine (Additional file 14).

Voluntary informed written consent was obtained from all observed participants and their families for newborns, who were assured of anonymity and confidentiality. All women were provided with a description of the study procedures in their preferred language at admission, and offered the right to refuse, or withdraw consent at any time during the study. Facility staff were identified before data collection began and no health worker refused to be observed whilst providing care. Voluntary informed written consent was obtained from the respondents for the qualitative interviews who were assured of anonymity and confidentiality. EN-BIRTH is study number 4833, registered at https://www.researchregistry. com.

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#### 846 Consent for publication

847 Not applicable.

- 848 Competing interests
- 849 The authors declare that they have no competing interests.

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