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# Immediate newborn care and breastfeeding: EN-BIRTH multi-country validation study

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## Abstract

**Background:** Immediate newborn care (INC) practices, notably early initiation of breastfeeding (EIBF), are fundamental for newborn health. However, coverage tracking currently relies on household survey data in many settings. “Every Newborn Birth Indicators Research Tracking in Hospitals” (EN-BIRTH) was an observational study validating selected maternal and newborn health indicators. This paper reports results for EIBF.

**Methods:** The EN-BIRTH study was conducted in five public hospitals in Bangladesh, Nepal, and Tanzania, from July 2017 to July 2018. Clinical observers collected tablet-based, time-stamped data on EIBF and INC practices (skin-to-skin within 1 h of birth, drying, and delayed cord clamping). To assess validity of EIBF measurement, we compared observation as gold standard to register records and women’s exit-interview survey reports. Percent agreement was used to assess association between EIBF and INC practices. Kaplan Meier survival curves showed timing. Qualitative interviews were conducted to explore barriers/enablers to register-recording.

**Results:** Coverage of EIBF among 7802 newborns observed for  $\geq 1$  h was low (10.9, 95% CI 3.8–21.0). Survey-reported (53.2, 95% CI 39.4–66.8) and register-recorded results (85.9, 95% CI 58.1–99.6) overestimated coverage compared to observed levels across all hospitals. Registers did not capture other INC practices apart from breastfeeding. Agreement of EIBF with other INC practices was high for skin-to-skin (69.5–93.9%) at four sites, but fair/poor for delayed cord-clamping (47.3–73.5%) and drying (7.3–29.0%). EIBF and skin to skin were the most delayed and EIBF rarely happened after caesarean section (0.5–3.6%). Qualitative findings suggested that focusing on accuracy, as well as completeness, contributes to higher quality with register reporting.

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**Conclusions:** Our study highlights the importance of tracking EIBF despite measurement challenges and found low coverage levels, particularly after caesarean births. Both survey-reported and register-recorded data over-estimated coverage. EIBF had a strong agreement with skin-to-skin but is not a simple tracer for other INC indicators. Other INC practices are challenging to measure in surveys, not included in registers, and are likely to require special studies or audits. Continued focus on EIBF is crucial to inform efforts to improve provider practices and increase coverage. Investment and innovation is required to improve measurement.

**Keywords:** Birth, Maternal, Newborn, Validity, Survey, Hospital records, Health management systems, Immediate newborn care, Breastfeeding, Skin-to-skin

## Key findings

### What is known and what is new about this study?

- Breastfeeding has strong evidence of high impact on child mortality and morbidity, is a core indicator for child health and nutrition, and is already measured in nationally representative household surveys.
- Challenges exist for measurement of breastfeeding and other immediate newborn care (INC) practices such as skin to skin, drying and cord care in many high mortality settings where most data are collected via household surveys conducted every 3–5 years, although around three quarters of births globally now occur in facilities. Routine data may have utility for more timely data on INC practices. However, there are limited studies comparing observed EIBF with both register and survey data, or exploring if EIBF can be used as a tracer for other INC practices.
- EN-BIRTH study in Bangladesh, Nepal, and Tanzania included > 23,000 births with 7802 newborns observed for at least one hour after birth and is the largest indicator validation study to date. Observations were time-stamped, and our large sample size enabled examination of timing of early initiation of breastfeeding within one hour of birth (EIBF) and newborn care practices, as well as variation between vaginal and caesarean births.

### Measurement of early initiation of breastfeeding: what did we find?

- Observer-assessed coverage of EIBF was low (10.9%) in these hospitals, particularly after caesarean birth (3.6%). Exit survey-reported coverage of EIBF ('put to breast') was 53.2%. Register-recorded coverage overestimated observer-assessed coverage of EIBF in four sites (88.6%). One site (Pokhara, Nepal) had no column regarding breastfeeding. No other INC practices were recorded in registers. Qualitative data suggested that register-recording can be improved with streamlined data collection systems that reduce the workload for frontline staff.

### Association with other INC practices: what did we find?

- Within observer-assessed data, EIBF had high percentage agreement with skin-to-skin within an hour of birth in four facilities (70.3–93.9%), and with delayed cord clamping in three facilities (64.6–73.5%). Coverage of immediate drying was very high (~ 99%), and early breastfeeding was very low (10.9%), hence agreement between these indicators was poor (< 29% in all hospitals).

### Timing of breastfeeding and INC practices: what did we find?

- Observer-assessed drying (median 0.83 min) and delayed cord clamping (median 1.88 min) were provided rapidly after birth for almost all newborns. EIBF coverage was low, and median time to initiation was > 1 h for all five facilities and markedly delayed for caesarean births.

### What next in programmes and research gaps?

- We recommend renewed focus on improving nationally representative, reliable measurement of EIBF. Survey questions to assess steps (put to breast/attachment/sucking) in the breastfeeding process should be considered, and questionnaires could be adapted with less focus on a rigid time interval to see if this increases accuracy.
- Other INC practices are important but are more complex to track in surveys and routine registers; these could be assessed via audits or specific studies.
- Root-cause analysis could help identify why certain facilities perform better in providing timely care and help improve practice. These data

## Key findings (Continued)

are needed to inform both health care provider practices and health system actions to address gaps.

- Implementation research on register design, implementation, and data flow into health management information systems is also required.

## Background

Almost half of all deaths in children under the age of five occur in the first month of life (neonatal period), totalling 2.4 million deaths, with one million dying on their birthday [1–4]. Most can be prevented with high quality maternal and newborn care, including provision of immediate newborn care (INC) practices as prioritised by the World Health Organisation (WHO) [5].

INC practices include skin-to-skin contact during the first hour of life, immediate drying, delayed cord clamping (1–3 min after birth), and early initiation of breastfeeding within one hour of birth (EIBF) [5]. EIBF has high-quality evidence regarding impact on improving neonatal and under-five mortality and morbidity [6–8], and for improved long-term growth and child development outcomes [9–13]. Delayed cord clamping is also supported by high-quality evidence, and while there are no proven mortality gains, health benefits include lower rates of anaemia [14, 15]. Outcome measures for skin-to-skin and immediate drying often focus on short-term hypothermia reduction (excluding premature babies) [5]. However, the benefits from skin-to-skin care include the promotion of breastfeeding initiation and bonding between mother and child, with potential for improved cardiovascular system stability although evidence is largely observational [12, 16–18]. As such, WHO issued a “strong” recommendation for early skin-to-skin contact as soon after birth as possible for all clinically stable neonates [19].

Population-based surveys, such as the Demographic and Health Survey (DHS) and Multiple Indicator Cluster Surveys (MICS) are the main source of coverage data for INC practices in low-and-middle income countries (LMICs). These are undertaken every three to five years in about 60 countries. Currently, core questionnaires for both DHS and MICS include questions to capture EIBF

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79 and skin-to-skin initiation. Other components of immediate and essential newborn care (such as drying) are in  
 80 an optional module specific to newborn care [20] (Additional file 1). Of five studies assessing validity of breast-  
 81 feeding measures using women's report in survey, three  
 82 met the criteria for individual validity analyses [21–23];  
 83 overall accuracy of breastfeeding in survey-report was  
 84 inconsistent (Additional File 2) [21–25]. A similar pattern is seen for women's report of skin-to-skin initiation  
 85 [21, 25] and immediate drying [21, 23–25]. Collection of  
 86 accurate survey data around the time of birth is challenging due to recall biases of women particularly regarding  
 87 interventions provided around the time of birth when  
 88 multiple events are happening simultaneously; pain and/or medications may impede recall; and if newborns are  
 89 separated from their mothers to deliver care or interventions [21–23, 25, 26] (Additional File 2).

96 Facility birth rates are increasing, with over three-quarters of births worldwide now in facilities [27], and  
 97 many countries starting to include newborn data within  
 98 their routine systems [28–30] aligning with multiple global initiatives [31–33]. Hence, routine facility data collected through health management information systems  
 99 (HMIS) have potential as a source for coverage, yet validation research has focussed on survey-reported data.  
 100 To our knowledge, no studies have assessed register-recorded coverage of breastfeeding, although some have  
 101 assessed in-patient records and found low percent agreement between women's recall and clinical records [34].

108 The timing and sequencing of INC practices represents one dimension of quality of care not generally  
 109 included in large-scale survey tools [35], but that might  
 110 have potential within routine HMIS. Skin-to-skin, immediate drying, delayed cord clamping (1–3 min after  
 111 birth), and EIBF are all time bound interventions recommended soon after birth [5]. This research offers a  
 112 unique opportunity to examine time-stamped data and  
 113 assess to what extent we can accurately capture timing  
 114 for these selected INC practices and if these data could  
 115 be useful to inform improvements in quality of care.

119 The *Every Newborn* Action Plan, endorsed by all United Nations member states, includes an ambitious Measurement  
 120 Improvement Roadmap [36, 37] underlining the imperative  
 121 to validate indicators for maternal and newborn care. Measurement regarding care at birth needs to advance from  
 122 health service contact alone (e.g., skilled attendance) to also  
 123 tracking effective coverage, including content and quality of care [37, 38]. Accurate and more frequent data are essential  
 124 to accelerate progress to Sustainable Development Goals, including Universal Health Coverage. However, many  
 125 countries do not have regular and reliable data regarding  
 126 INC practices. The EIBF indicator was prioritised within the  
 127 *Every Newborn* Measurement Improvement Roadmap [36,  
 128 39], given evidence of impact and survey data availability in

many countries. This indicator was also proposed by WHO  
 133 as a potential tracer for other INC indicators having  
 134 plausibility of linkage; for example, EIBF may coincide with  
 135 skin-to-skin care [40]. 136

### The *Every Newborn*

137 Birth Indicators Research Tracking in Hospitals (EN-  
 138 BIRTH) study was an observational study of >23,000  
 139 hospital births in three countries (Tanzania, Bangladesh,  
 140 and Nepal); detailed methods and selected validity  
 141 results are reported elsewhere [41, 42]. 142

### Objectives

143 This paper is part of a supplement based on the EN-  
 144 BIRTH study, '*Informing Measurement of Coverage and  
 145 Quality of Maternal and Newborn Care*'. Here we focus  
 146 on the measurement of EIBF and if EIBF can be used as  
 147 a tracer for selected INC practices. There are four  
 148 objectives: 149

1. **Assess NUMERATOR accuracy/validity** for  
 150 measurement of EIBF in exit-interview survey of  
 151 women's report and in routine labour ward registers  
 152 compared to clinical observation (gold standard).  
 153 The **denominator** for EIBF is 'live births'. This is  
 154 consistent with current guidelines and measurement  
 155 platforms, which also use live births [43–45]. 156
2. **Review early initiation of breastfeeding as a  
 157 potential TRACER indicator for other INC  
 158 practices:** Compare observer-assessed coverage of  
 159 EIBF to observer-assessed coverage of other immediate  
 160 newborn care practices (skin-to-skin, drying,  
 161 delayed cord clamping). 162
3. **TIMING as a dimension of quality of care:** By  
 163 describing time to initiation of breastfeeding and  
 164 the time to the selected INC practices using Kaplan  
 165 Myer analysis shown by mode of birth. 166
4. **Evaluate BARRIERS AND ENABLERS** to routine  
 167 labour ward register-recording through qualitative  
 168 data collection regarding register design, and filling. 169

### Methods

170 EN-BIRTH included five comprehensive emergency  
 171 obstetric and neonatal care (CEmONC) hospitals:  
 172 Maternal and Child Health Training Institute, Azimpur,  
 173 and Kushtia General Hospital in Bangladesh; Pokhara  
 174 Academy Health Sciences in Nepal; and Muhimbili  
 175 National Hospital and Temeke Regional Hospital in  
 176 Tanzania (Additional file 3). Data collection was from July  
 177 2017 to July 2018 (Additional file 4). Consenting women  
 178 and newborns admitted to the labour and delivery wards  
 179 were observed during birth and the immediate  
 180 postpartum period. Observations were terminated once  
 181 women and newborns were transferred out of labour and  
 182

183 delivery ward. Exit interview surveys were conducted with  
 184 women in the hospitals immediately after discharge  
 185 (Additional file 4). All EN-BIRTH data collection tools are  
 186 open source [46]. In line with current WHO recommen-  
 187 dations, we defined EIBF as occurring within the first hour  
 188 of life (Additional file 5) [47, 48]. For objectives one and  
 189 two, we excluded observations which lasted for less than  
 190 one hour after birth as inclusion of these observations  
 191 could have caused an underestimate in EIBF coverage  
 192 when compared with register-recorded or survey reported  
 193 data. Newborns would not have been counted irrespective  
 194 of who initiated breastfeeding after the observation was  
 195 terminated, but during their first hour of life.

196 Gold standard observer-assessed coverage data were  
 197 collected by trained clinical researchers using a custom-  
 198 built android tablet-based application, across the 24-h  
 199 day. The software enabled observers to capture the prac-  
 200 tice whenever it occurred, and each entry was time-  
 201 stamped (Fig. 1) [42]. Data collectors were trained to  
 202 touch a specific button for recording the observed prac-  
 203 tice (skin to skin, drying, cord clamping or breastfeed-  
 204 ing) once when it was initiated (colour coding the  
 205 variable green on the application) (Additional file 5).  
 206 Training materials were standardised across sites and  
 207 supported with a printed manual available at each site

208 [42]. In order to assess for bias, background characteris-  
 209 tics of women observed for less than one hour were  
 210 compared with those of included cases.

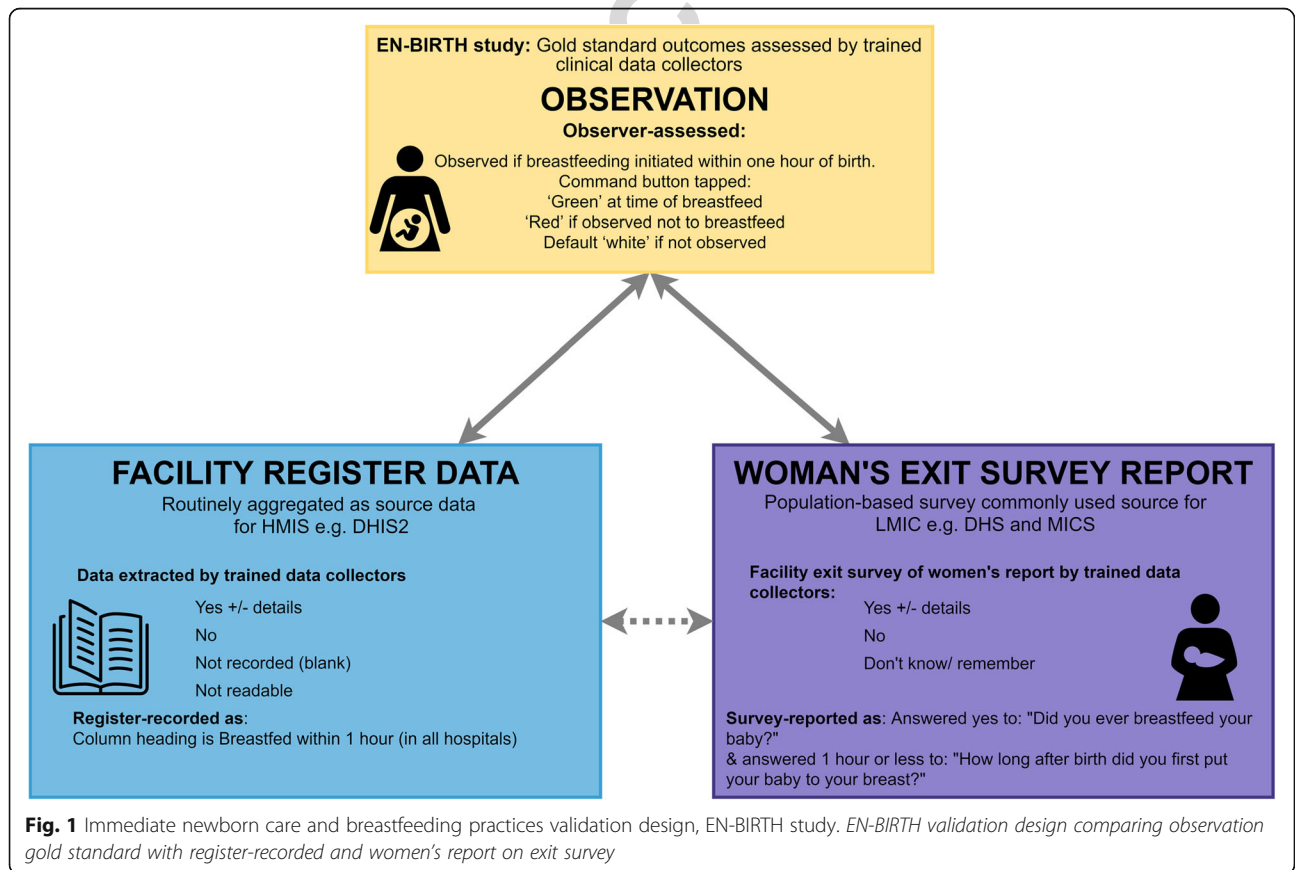
211 One year of pre-study register data were extracted and  
 212 compared to register-records during the study period to  
 213 assess if the presence of external researchers in the hos-  
 214 pital affected register recording [49]. Inter-rater reliability  
 215 testing was completed for a subset of 5% of observed cases  
 216 and data extraction [41]. All quantitative analyses were  
 217 undertaken using Stata (version 14). Detailed information  
 218 regarding the research protocol, methods, and overall val-  
 219 idation analysis has been published separately [50].

220 Results are reported in accordance with STROBE  
 221 statement checklists for cross-sectional studies (Addi-  
 222 tional file 6). We were granted ethical approval by insti-  
 223 tutional review boards in all implementing countries in  
 224 addition to the London School of Hygiene & Tropical  
 225 (Additional file 7).

226 **Labour ward registers.**

227 Pre-printed labour ward registers varied in design.  
 228 During the study, the Bangladesh sites transitioned to a  
 229 standardised national register (Additional file 3).  
 230 Tanzania and the revised Bangladesh registers used for  
 231 this analysis had a specific column for EIBF, in both

F1



f1.1  
 f1.2  
 f1.3

**Fig. 1** Immediate newborn care and breastfeeding practices validation design, EN-BIRTH study. EN-BIRTH validation design comparing observation gold standard with register-recorded and women's report on exit survey

232 register designs this used the wording “breastfed within  
233 1 hour of birth”. The Tanzania register requires staff to  
234 enter “yes” or “no” (Additional file 8), whilst the  
235 Bangladesh register required a tick for breastfed, and  
236 blank for not done. Nepal had no column to register-  
237 record breastfeeding. An overview of register design is  
238 available in Additional file 8.

## 239 **Methods and analysis by objective**

### 240 **Objective 1: numerator validation**

241 Results were reported by hospital and mode of birth (vaginal  
242 and caesarean births). Random effects pooled estimates were  
243 used to calculate breastfeeding coverage across five hospital  
244 sites. We calculated percent agreement between observer-  
245 assessed coverage and measured coverage (survey or regis-  
246 ter), and the proportion of ‘don’t know’ responses from sur-  
247 veys, and ‘not recorded/not readable’ results from routine  
248 registers. We calculated individual-level validity metrics (sen-  
249 sitivity and specificity) for practices with  $\geq 10$  counts in  $2 \times 2$   
250 table columns. 95% confidence intervals (CIs) were calcu-  
251 lated, assuming binominal distribution. Pokhara did not have  
252 a register column for breastfeeding and was therefore ex-  
253 cluded from register-recoded analysis.

### 254 **Objective 2: assess early initiation of breastfeeding as a 255 tracer indicator for other INC practices**

256 Tracer coverage indicators reduce the number of  
257 indicators being tracked, but to be useful must accurately  
258 represent all other coverage indicators they replace. We  
259 aimed to assess if EIBF can be used as a tracer for other  
260 INC practices (skin-to-skin, drying, and delayed cord  
261 clamping). To this end, we calculated the percent  
262 agreement between pairs of observed interventions (EIBF  
263 and skin-to-skin, EIBF and drying, EIBF and delayed cord  
264 clamping), by summing the number of newborns who re-  
265 ceived both interventions and the number who received  
266 neither intervention, divided by the number of newborns  
267 observed.

### 268 **Objective 3: timing as a dimension of quality of care**

269 Quality of care is characterised across multiple domains  
270 of care provision. In this study, we assessed the timing  
271 of INC practices using the custom-built EN-BIRTH soft-  
272 ware and collected time-stamped observational data.  
273 Time to event analysis for skin-to-skin, drying, cord  
274 care, and breastfeeding initiation was undertaken using  
275 the Kaplan Meier method. All live births were included,  
276 excluding babies given bag and mask or who weighed  
277 less than 1500 g. For this objective, results were censored  
278 when the observation terminated, or up to a maximum  
279 duration of 12 h of observation.

### Objective 4: barriers and enablers to data collection 280

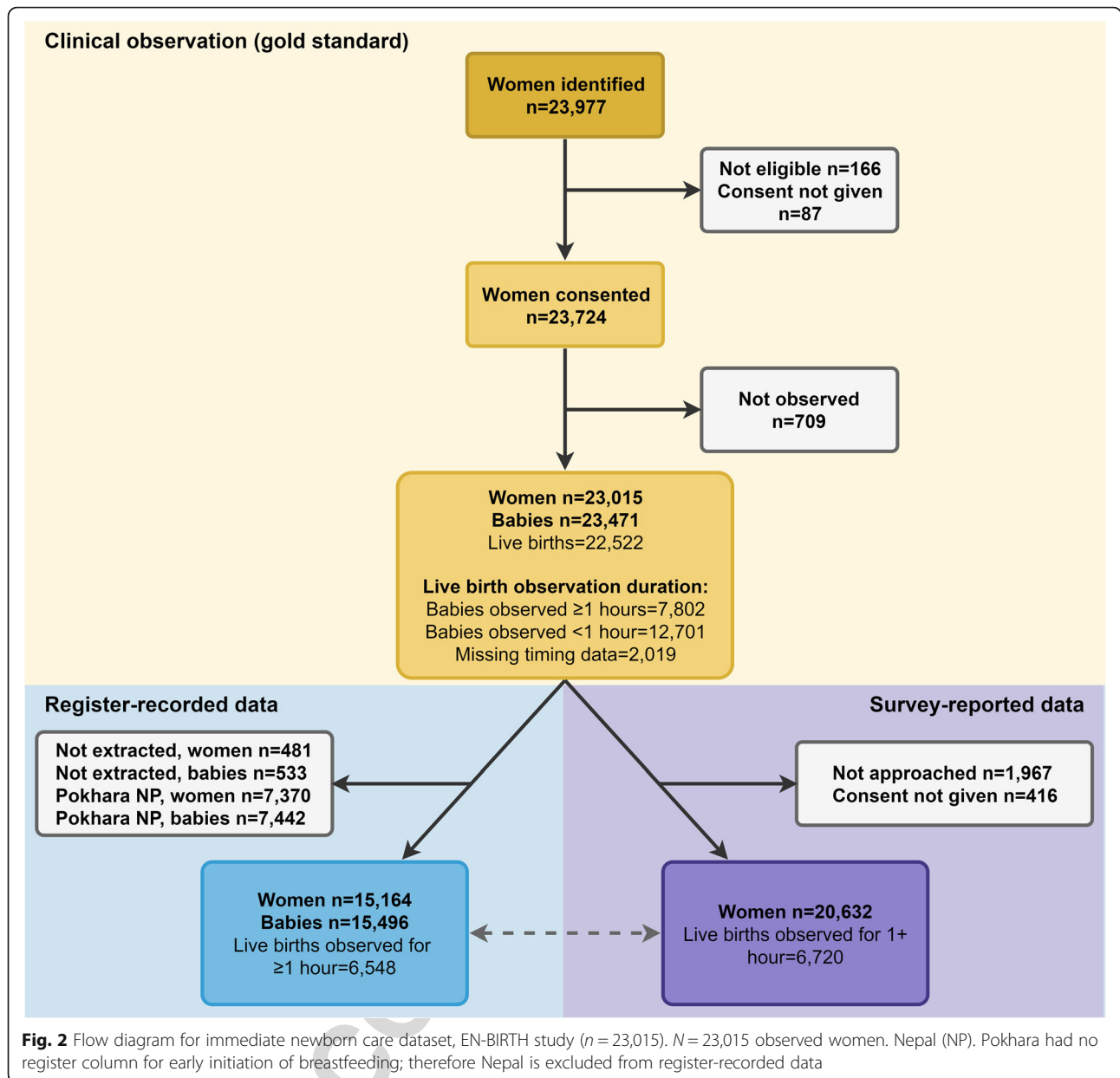
281 As part of the wider EN-BIRTH study, focus group dis-  
282 cussions and in-depth qualitative interviews were con-  
283 ducted to understand the barriers and enablers to the  
284 use of routine registers in recording various aspects of  
285 perinatal care and outcomes [51]. Detailed qualitative  
286 methods and overall results are available in an associated  
287 paper [51]. In summary, we purposively sampled two  
288 groups of respondents: hospital health workers providing  
289 perinatal care in EN-BIRTH sites (nurses/midwives/doc-  
290 tors) and data collectors involved in the EN-BIRTH  
291 study (clinical observers/data extractors/supervisors) for  
292 participation in focus group discussions and in depth in-  
293 terviews (Additional file 9). Semi-structured in-depth  
294 interview guides and semi-structured focus group guides  
295 were developed based on the Performance of Routine In-  
296 formation System Management (PRISM) conceptual  
297 framework [52]. Audio recordings of each interview were  
298 transcribed, translated, and managed with pre-identified  
299 codebook nodes into NVIVO (version 12). Codes in-  
300 cluded constructs for technical, organisational, and be-  
301 havioural factors. We also asked the participants to  
302 complete a checklist to assess which health worker usu-  
303 ally provides care for breastfeeding, for documentation,  
304 and the order and timing of recording breastfeeding  
305 events in the register. These close-ended questions were  
306 asked by the researcher to respondents, immediately  
307 after their IDI (but not to FGD respondents).

## Results 308

309 This multi-country analysis included 23,724 consenting  
310 women, with 23,471 babies and 23,015 women being ob-  
311 served (Fig. 2). Overall, there were 22,522 live births. **F2**  
312 Observation data for at least one hour was available for  
313 7802 live newborns (single and multiple births), and  
314 there were 7412 newborn register-records, and 6720  
315 exit-survey interviews. Table 1 presents the background **T1**  
316 characteristics of 7636 women and 7802 newborns ob-  
317 served for  $\geq 1$  h. More than two-thirds of births across all  
318 five sites were to women under age 30 years. Nearly 22%  
319 of women had a caesarean, although mode of birth var-  
320 ied widely across facilities. In Azimpur, Kushtia and  
321 Muhimbili caesarean rates were highest at 53.3, 30.9,  
322 and 47.5%, respectively. Almost three quarters (77.3%) of  
323 births were full term (37+ weeks).

### Objective 1: numerator validation 324

325 Coverage of EIBF was 10.9% (95% CI 3.8–21.0) for births  
326 observed  $\geq$ one hour (Fig. 3). Coverage was highest in **F3**  
327 Temeke at 26.0% and lowest in Azimpur at 1.8%, where  
328 the caesarean section rate was 53.2% (Fig. 3). For  
329 caesarean births overall, the EIBF rate was 2.4% (95% CI  
330 1.2–3.9) compared to 14.4% (95% CI 5.4–26.7) for  
331 vaginal births (Additional file 10).



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f2.2  
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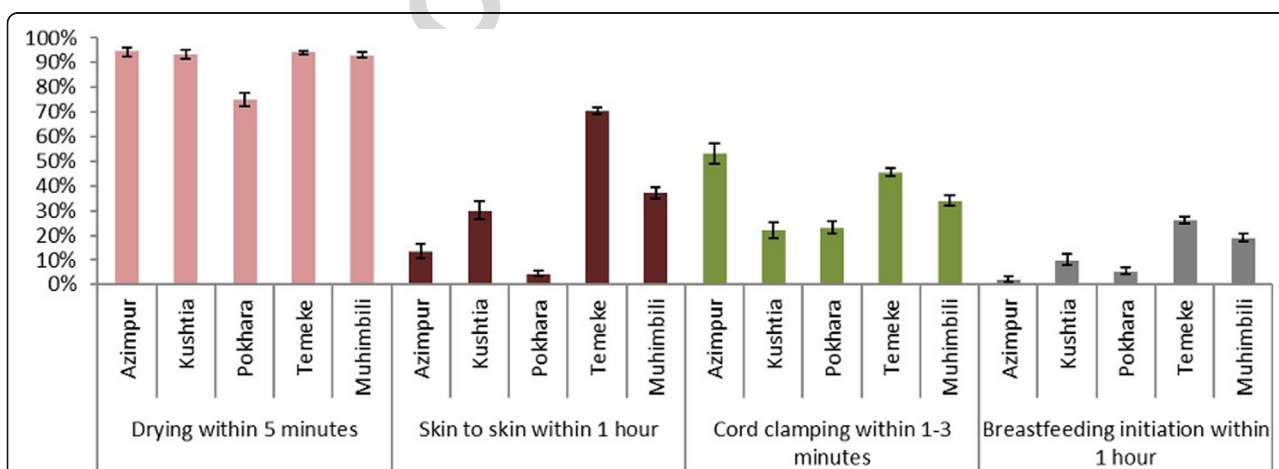
332 Register-recorded coverage was over-estimated in all  
 F4 333 sites with a column for this data element (Fig. 4, Add-  
 334 itional file 8). Survey-reported coverage of “put to  
 335 breast” was also higher than the observed prevalence.  
 336 Percentage agreement for register-recorded data was  
 337 24.6% (95% CI 8.5–45.7) with high sensitivity 93.2%  
 338 (95%CI 68.7–100) and low specificity 13% (95%CI 0.0–  
 339 43.5) (Additional file 11). By facility, Kushtia (98.2%) and  
 340 Temeke (97.3%) had the highest sensitivity, while specifi-  
 341 city ranged from 2.8% (95%CI 1.6–4.7) in Kushtia to  
 342 55.4% (95%CI 52.8–58.0) in Muhimbili (Add-  
 343 itional file 11). Sensitivity was 93.8% (70.7–100.0) for va-  
 344 ginal births and 27.6% (12.7–47.2) for caesarean births.  
 345 Specificity of register-recorded coverage was 8.9% (0.2–

27.5) for vaginal births and 69.4% (66.1–72.5) for caesar- 346  
 eans (Additional file 11). 347  
 Percentage agreement for the survey-report was 53.8% 348  
 (95% CI 40.2–67.2) with a sensitivity of 76.9% (95%CI 349  
 70.7–82.7), and specificity of 50.0% (95%CI 32.3–67.7). 350  
 Sensitivity was 82.5% (95%CI 76.4–88) for vaginal births 351  
 and 0.0% (95%CI 0.0–2.6) for caesarean births. The per- 352  
 centage agreement was highest in Temeke (74.8) and 353  
 lowest in Kushtia (41.9%). Specificity of survey-report 354  
 was 35.9% (95%CI 25.8–46.7) for vaginal births and 355  
 85.3% (95%CI 62.6–98.5) for caesareans (Add- 356  
 itional file 10). Background characteristics for partici- 357  
 pants with ≥1 h of observation and those observed less 358  
 than an hour were assessed and showed that a larger 359

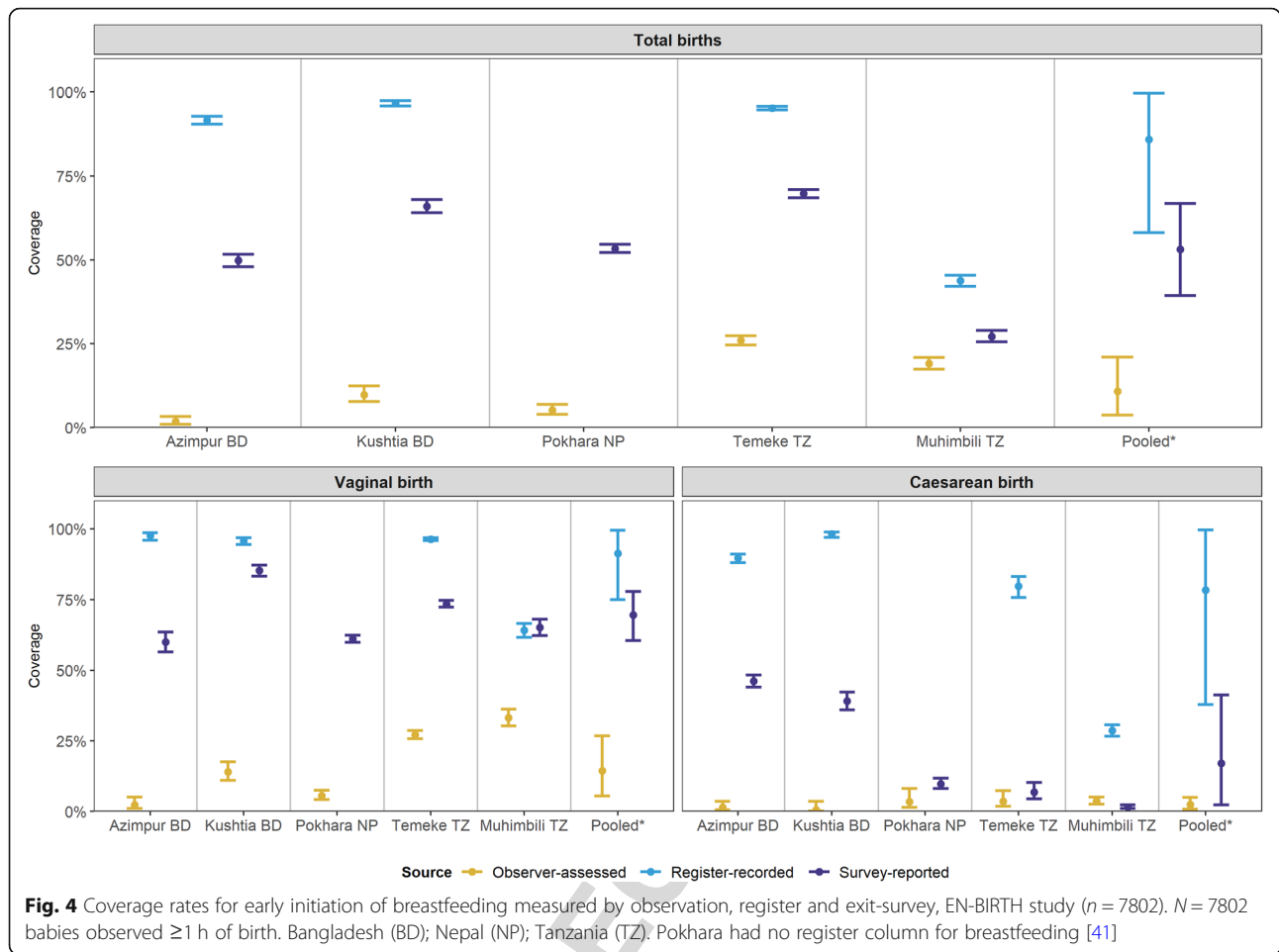
t1.1 **Table 1** Characteristics of women observed in labour and delivery wards, EN-BIRTH study (n = 7636)

	Bangladesh		Nepal	Tanzania		Total
	Azimpur	Kushtia	Pokhara	Temeke	Muhimbili	
	Tertiary	District	Regional	Regional	National	
	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
t1.6 Total women	545	608	938	3771	1774	7636
t1.7 <b>Woman's Age</b>						
t1.8 < 18 years	5(0.9)	1(0.2)	38(4.1)	10(0.3)	2(0.1)	56(0.7)
t1.9 18–19 years	96(17.6)	46(7.6)	124(13.2)	429(11.4)	83(4.7)	778(10.2)
t1.10 20–24 years	217(39.8)	257(42.3)	394(42)	1299(34.4)	345(19.4)	2512(32.9)
t1.11 25–29 years	142(26.1)	164(27)	247(26.3)	943(25)	566(31.9)	2062(27)
t1.12 30–34 years	66(12.1)	102(16.8)	112(11.9)	654(17.3)	478(26.9)	1412(18.5)
t1.13 35+ years	19(3.5)	38(6.3)	23(2.5)	436(11.6)	300(16.9)	816(10.7)
t1.14 <b>Woman's education</b>						
t1.15 No Education	7(1.3)	22(3.6)	25(2.7)	117(3.1)	32(1.8)	203(2.7)
t1.16 Primary incomplete	24(4.4)	26(4.3)	31(3.3)	47(1.2)	16(0.9)	144(1.9)
t1.17 Primary complete	78(14.3)	81(13.3)	47(5)	17(0.5)	2(0.1)	225(2.9)
t1.18 Secondary incomplete	181(33.2)	237(39)	196(20.9)	2281(60.5)	617(34.8)	3512(46)
t1.19 Secondary complete	229(42)	236(38.8)	608(64.8)	1292(34.3)	1097(61.8)	3462(45.3)
t1.20 Don't know	26(4.8)	6(1)	31(3.3)	17(0.5)	10(0.6)	90(1.2)
t1.21 <b>Gestational age at admission (weeks)</b>						
t1.22 < 28 weeks	1(0.2)	3(0.5)	0(0)	1(0)	8(0.5)	13(0.2)
t1.23 28–31 weeks	0(0)	11(1.8)	0(0)	26(0.7)	89(5)	126(1.7)
t1.24 32–36 weeks	110(20.2)	123(20.2)	47(5)	843(22.4)	469(26.4)	1592(20.8)
t1.25 37+ weeks	434(79.6)	471(77.5)	891(95)	2901(76.9)	1208(68.1)	5905(77.3)
t1.26 <b>Mode of birth</b>						
t1.27 Vaginal birth	255(46.8)	420(69.1)	799(85.2)	3581(95)	931(52.5)	5986(78.4)
t1.28 Caesarean section	290(53.2)	188(30.9)	139(14.8)	188(5)	842(47.5)	1647(21.6)
t1.29 Missing	0(0)	0(0)	0(0)	2(0.1)	1(0.1)	3(0)

t1.30 N = 7636 women and 7802 newborns observed for at least one hour



f3.1 **Fig. 3** Observer-assessed coverage of immediate newborn care practices, EN-BIRTH study. Drying (n = 7784); skin-to-skin (n = 7773); Cord clamping  
 f3.2 within 1–3 min (n = 7791); breastfeeding initiation within 1 h (n = 7802).   
 f3.3   
 f3.4 iming parameters as recommended by the World Health Organisation, WHO recommendations on newborn health: guidelines approved by the WHO Guidelines Review Committee. 2017, Geneva



Q4  
f4.2  
f4.3

360 proportion of women observed for less than 1 h had a  
361 caesarean birth (Additional file 12).

362 **Objective 2: assess agreement between EIBF with other**  
363 **INC practices**

364 We assessed coverage of four INC practices: skin-to-skin  
365 contact, drying, delayed cord clamping, and EIBF using  
366 observation data (Fig. 3). Drying within 5 min after birth  
367 was over 90% in all hospitals apart from Pokhara  
368 (75.0%). Provision of skin-to-skin contact within an hour  
369 of birth ranged from 13.5% of babies (Azimpur) to 70.5%  
370 (Temeke). Cord clamping was universal, but timing varied  
371 between facilities with less than half of babies receiving  
372 delayed cord clamping during the optimum 1–3 min  
373 window.

374 Observed coverage of EIBF was low in all facilities;  
375 consequently, it was not possible to assess the  
376 breastfeeding relationship with high coverage INC  
377 practices. The exception is skin-to-skin contact during  
378 the first hour, which demonstrated close percent agree-  
379 ment in four facilities: 93.9% in Pokhara (Nepal), 85.8%  
380 in Azimpur, 70.3% in Kushtia (Bangladesh) and 69.5% in  
381 Muhimbili (Tanzania). Using Kappa cut-offs, delayed

cord clamping had a moderate-to-good agreement with  
EIBF, ranging from 47.3% in Azimpur (Bangladesh) to  
73.5% in Pokhara (Nepal). Percent agreement between  
EIBF and drying was poor and ranged from 7.3% in  
Azimpur (Bangladesh) to 29.0% in Temeke (Tanzania)  
(Fig. 5).

388 **Objective 3: timing as a marker of quality of care**

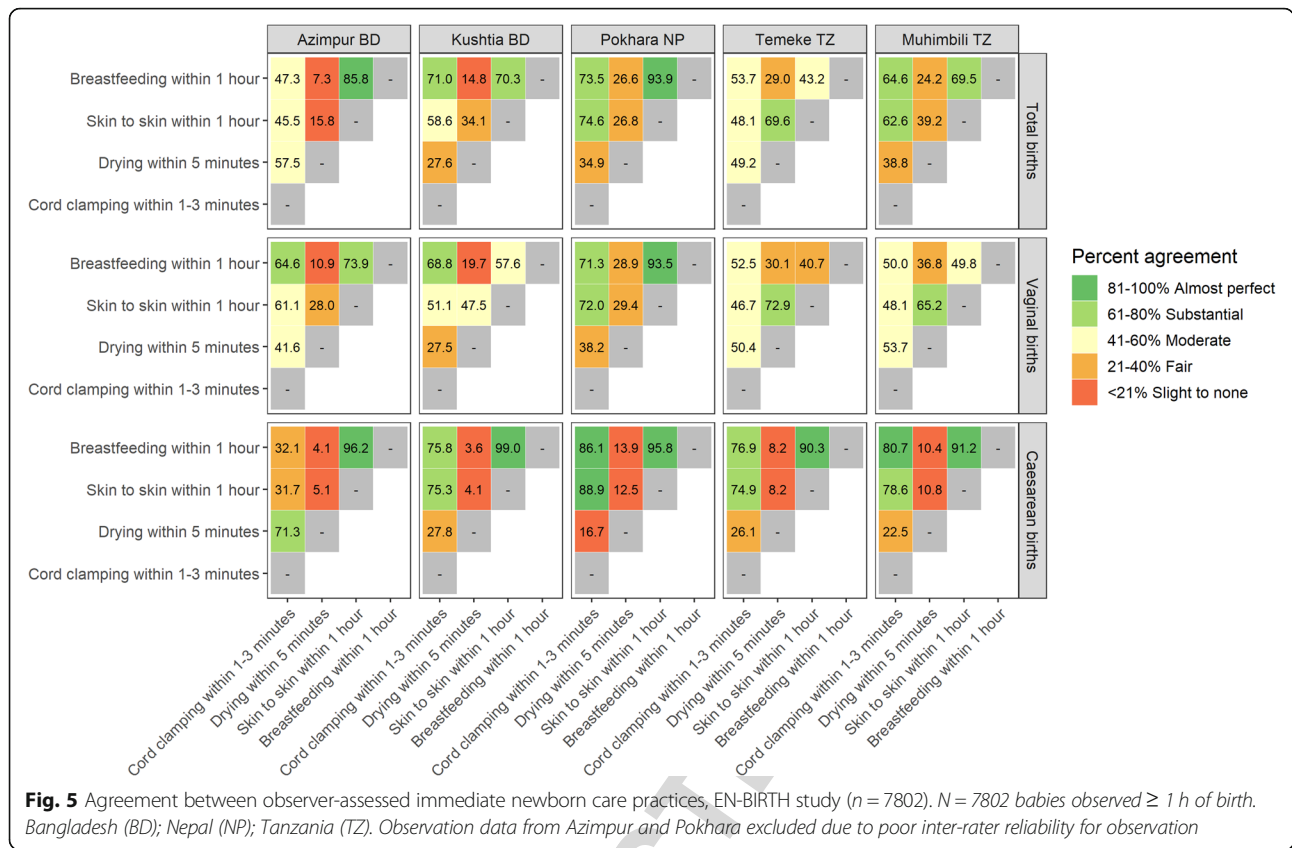
389 Kaplan Meier curves were plotted, showing the time  
390 from birth to initiation of skin-to-skin, drying, cord  
391 clamping, and breastfeeding (Fig. 6). Temeke had the  
392 maximum probability of EIBF with a median time to initiation  
393 very close to an hour. This was followed by  
394 Muhimbili, however the median time was nearly three  
395 hours. For vaginal births, the results were similar to the  
396 overall estimations. The probability of EIBF in Kushtia,  
397 Pokhara, and Azimpur within one hour was lower than  
398 0.3. For caesarean births EIBF was well after one hour in  
399 all facilities with a median time of 240 min in Temeke,  
400 the best performing facility.

401 The timing of drying was consistent across all five  
402 facilities and all modes of birth, with almost all babies  
403 dried within five minutes. Median time for drying was

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387 **F5**

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391 **F6**  
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f5.1  
f5.2  
f5.3

404 around one minute in four facilities but slower in  
 405 Pokhara (Fig. 6). In Temeke and Muhimbili (Tanzania),  
 406 the median time was close to one minute for initiation  
 407 of skin-to-skin for vaginal births compared to one hour  
 408 in Kushtia (Bangladesh). Babies born in Azimpur and  
 409 Pokhara were least likely to get skin-to-skin contact in  
 410 the first hour of life. The probability of skin-to-skin initiation  
 411 for caesarean births was less than 0.1 in the first  
 412 hour (Fig. 6). For vaginal births, the median time for  
 413 cord clamping was between 1 and 3 min in Azimpur,  
 414 Temeke and Muhimbili. Babies born in Pokhara were  
 415 likely to have cord clamped before 1 min, while this was  
 416 over 3 min in Kushtia (Fig. 6). For caesarean births, median  
 417 time for cord clamping was less than a minute except  
 418 for Azimpur and Kushtia.

419 **Objective 4, barriers and enablers to data collection**

420 Three main categories were identified as influencing  
 421 data collection and use in the EN-BIRTH study overall  
 422 qualitative analysis: 1) register design, 2) register filling  
 423 and 3) register use [51]. Register design and filling were  
 424 influenced by the complexity of local data collection systems  
 F7 425 and time pressures faced by frontline staff. Figure 7  
 426 shows a summary of barriers and enablers for recording

of breastfeeding practices as identified in the EN-BIRTH 427  
 study. No respondents cited use of register data regarding 428  
 breastfeeding. 429

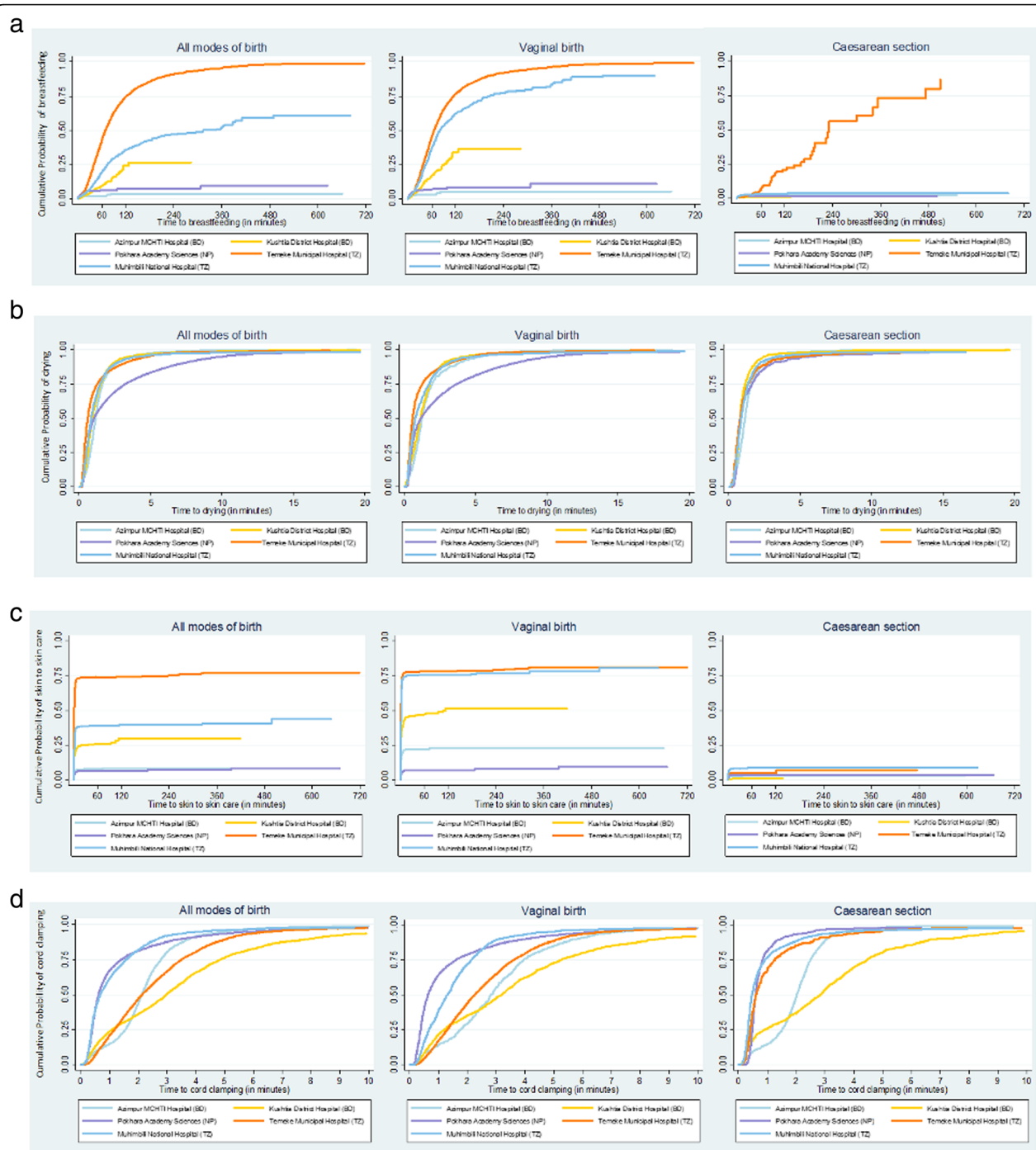
430 **Register design**

Both health workers and EN-BIRTH study clinical observers 431  
 reported factors related to register design, notably the complexity 432  
 of the documentation system, as a major barrier to recording in 433  
 registers. One site had no column at all for EIBF, while staff in 434  
 other hospitals reported duplicitous data demands with the same 435  
 data elements being recorded in multiple documents: 436

437  
 438  
 “there are many registers, it takes time to do all the 439  
 documentation” 440

(Health worker, Muhimbili, Tanzania) 441

In Muhimbili (TZ), EIBF was documented in a national labour 442  
 ward register before being tallied by hand and input into the HMIS. 443  
 Breastfeeding initiation was also supposed to be recorded on the 444  
 woman’s file, case notes, treatment sheet, and in the “informal 445  
 midwifery book”. 446  
 447



**Fig. 6** Kaplan-Meier plots of timing for immediate newborn care practices, EN-BIRTH study. *a* Breastfeeding Initiation (All: 16,511, Vaginal births: 11,564, Caesarean births: 4944). *b* Initiation of Drying (All: 18,585, Vaginal births: 12,774, Caesarean births: 5808). *c* Skin-to-Skin Initiation (All: 17218, Vaginal births: 12,199, Caesarean births: 5016). *d* Cord-clamping (All: 18,586, Vaginal births: 12,775, Caesarean births: 5808) Bangladesh (BD); Nepal (NP); Tanzania (TZ).

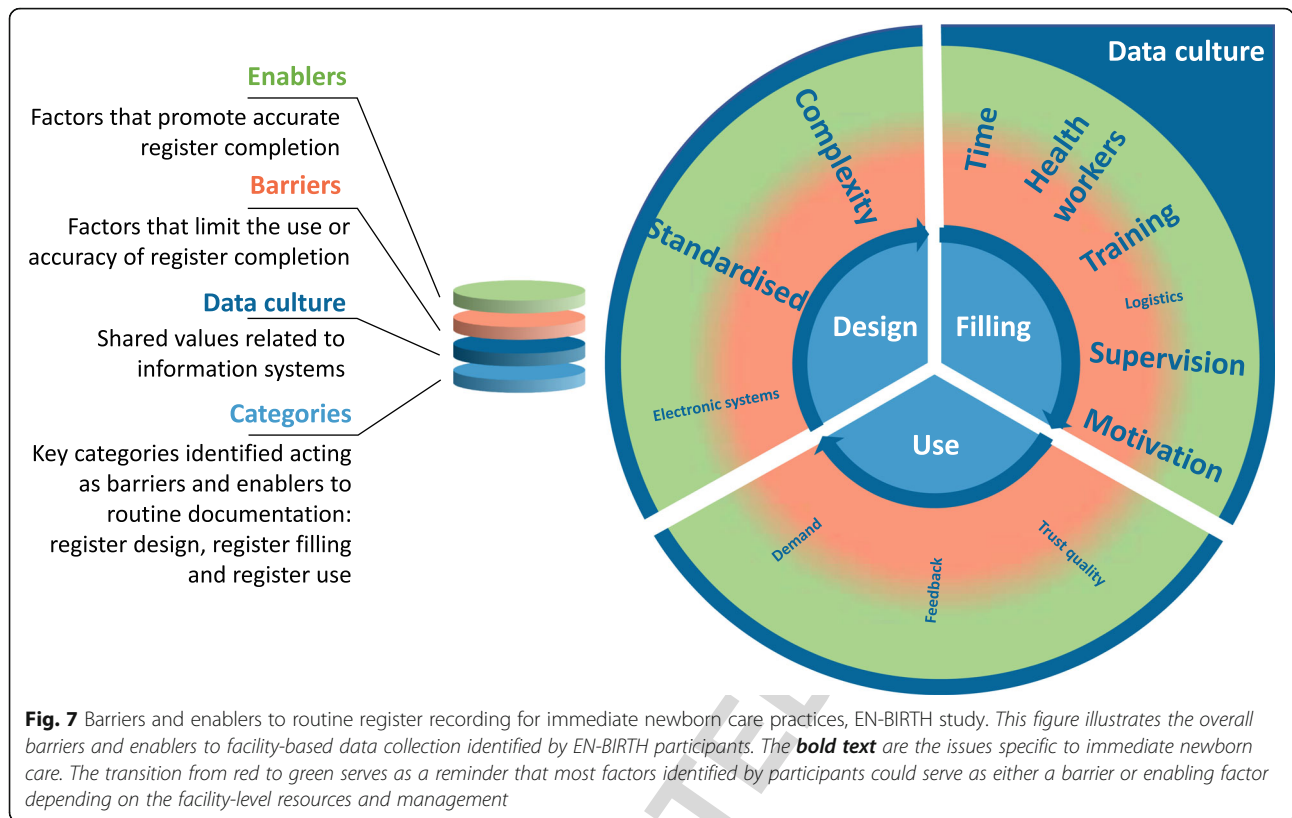
f6.1  
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448 **Register filling**

449 Respondents stated barriers to register filling included  
450 valuing completeness over accuracy. Data collectors in  
451 Tanzania reported that EIBF may be recorded in the  
452 register before newborns had even started breastfeeding:

“ ... the nurse usually writes that the baby has been  
breastfed, even if by that time the baby might not  
have been breastfed ... ” (Data Collector, Temeke,  
Tanzania)

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f7.1  
f7.2  
f7.3  
f7.4  
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458 These findings were consistent with evidence from  
459 Bangladesh data collectors, and are reflected in the  
460 low observed breastfeeding coverage compared with  
461 high register-recorded practice in both sites. Multiple  
462 locations for documentation contributed to the com-  
463 plexity of the record-keeping system and these chal-  
464 lenges were compounded when breastfeeding was  
465 initiated after discharge from the labour wards:

466 “We don’t fill information about first time breast  
467 feeding because they start it in other places  
468 [wards].” (Health worker, Muhimbili, Tanzania)

469 Respondents in all five sites also reported that  
470 breastfeeding was not routinely initiated or recorded in  
471 the operation theatres, this was especially the case for  
472 Bangladesh:

473  
474 “Breastfeeding is not done in the operation theatre.  
475 They never do it in operation theatres.” (Data Col-  
476 lector, Kushtia, Bangladesh)

477  
478 “They usually do not initiate it in the in the theatre,  
479 it is initiated in the post-caesarean ward.” (Data Col-  
480 lector, Temeke, Tanzania)

481 Across all sites, the primary midwifery or nursing 481  
482 carer was responsible for documentation for women 482  
483 having vaginal births, except Pokhara (Nepal) where 483  
484 labour ward registers do not include a column for 484  
485 breastfeeding initiation (Additional file 13). Respondents 485  
486 did not know who would record breastfeeding if it was 486  
487 actually done after caesarean section in the operating 487  
488 theatre (Additional files 13 and 14). 488

489 Data collectors and health workers reported that 489  
490 breastfeeding in Bangladesh is usually assisted by 490  
491 nurses or women’s attendants and is documented in 491  
492 the neonatal register, case notes, discharge letter, and 492  
493 monthly summary sheet. In Nepal, nurse-midwives 493  
494 advise women to initiate breastfeeding within 1 h, but 494  
495 there is no register-recorded documentation. 495

496  
497 “We advise the patient, we say, to feed milk within 497  
498 one hour. We have written in the chart to encour- 498  
499 age breastfeeding, but it’s not there in registers.” 499

500 (Health worker, Pokhara, Nepal) 500

501 Health workers in all three settings reported being 501  
502 busy, and that data recording could be time consuming: 502

503  
504 “ ... documentation requires time. In the ward we 504  
505 have 35-40 patients, we need to discharge, fill 505

506 registers, make birth certificates so time is required”  
507 (Health worker, Pokhara, Nepal)

508 There was a potential conflict between administrative  
509 responsibilities such as recording and reporting of data,  
510 and provision of clinical care:

511  
512 “You have to ... respond to her with whatever she  
513 wants and [you] forget to document” (Health  
514 worker, Muhimbili, Tanzania)

## 515 Discussion

516 Breastfeeding indicators are rightfully part of the WHO  
517 core 100 global indicators for child health and nutrition,  
518 given breastfeeding has strong evidence of high impact  
519 for reducing mortality and morbidity [53]. It has been  
520 measured in large-scale, population-based household  
521 surveys for decades (Additional file 1). Importantly,  
522 breastfeeding is also considered to be a marker of re-  
523 spectful maternity care and baby friendly services pro-  
524 moting zero separation of women and their newborns.  
525 EN-BIRTH’s large sample size and time-stamped data  
526 allowed us to assess validity of measures in both surveys  
527 and registers, examine the relationship of EIBF with  
528 other immediate newborn care practices, and also con-  
529 sider differences between vaginal and caesarean births.  
530 Coverage of initiation of breastfeeding within 1 h was  
531 shockingly low (10.9, 95% CI 3.8–21.0 overall) and very  
532 few babies born by caesarean were breastfed, even within  
533 several hours. Our results show that EIBF was over-  
534 estimated in both register-recorded and survey-reported  
535 data compared to the gold standard of observation.

536 EIBF was harder to measure than most of the other  
537 indicators assessed for EN-BIRTH and has also been  
538 found to have low accuracy in other survey validation  
539 studies [54] (Additional file 2). Over-estimation of EIBF  
540 in both survey and registry data could be due to three  
541 possible reasons. Firstly, inaccuracies in reporting tim-  
542 ing, whereby the newborn was breastfed, but after one  
543 hour. There are well recognized issues for accurate re-  
544 port of timing, and evidence suggests these issues are ex-  
545 acerbated around the time of birth and the immediate  
546 postnatal period when both women and health workers  
547 may misjudge time [22, 25]. In addition, recent evidence  
548 from eight countries in Asia and the Pacific suggests a  
549 strong dose relationship between skin-to-skin and initi-  
550 ation of breastfeeding within 90 min following birth [18].  
551 These findings suggest that the window of breastfeeding  
552 initiation may be wider than one hour, and highlight the  
553 importance of ensuring health workers have adequate  
554 training and support in the implementation of early  
555 breastfeeding counselling.

556 Secondly, breastfeeding is a multistep process and it is  
557 possible that data collectors, health workers, or women

may identify different parts of the breastfeeding process 558  
as the time of EIBF; such as “putting the baby to the 559  
breast” or sucking. We note that breastfeeding initiation 560  
is not a one-time, easily recorded event like cord cutting 561  
or uterotonic injection. EN-BIRTH data collectors re- 562  
ceived standardised training on observing “initiation of 563  
breastfeeding” (Fig. 1, Additional file 4), but may still 564  
have applied their own interpretation to the exact time 565  
of initiation. In the current DHS and MICS survey ques- 566  
tion structure, women are asked, “Did you ever breast- 567  
feed your baby?” and then, “How long after birth was the 568  
baby was put to breast?” and this is also open to vari- 569  
ation in interpretation, counting different points in the 570  
process of initiation [55]. Formative research could help 571  
better understand how these processes are interpreted. 572  
For example, if register design can improve accuracy by 573  
including one part of the process of EIBF, such as “put 574  
to breast” or sucking. 575

576 Thirdly, breastfeeding may be misreported by health 576  
workers or by women, possibly deliberately affected by 577  
social desirability for approval [22, 25]. Qualitative results 578  
suggested that the documentation culture in Bangladesh 579  
and Tanzania valued register completeness over accuracy, 580  
which exposes the need for training and supportive 581  
supervision to improve the accuracy of information 582  
included in registers. Health workers were divided across 583  
many tasks and did not always prioritise supporting 584  
women in initiating breastfeeding, nor accurate 585  
documentation. These testimonies also highlight the 586  
heavy workload on health providers, with consequences 587  
for how staff prioritise and complete their tasks, and 588  
might increase pressure for staff to record what they 589  
believe is the desirable answer [56]. Local monitoring and 590  
supervision to track different quality of care dimensions 591  
for breastfeeding are needed in the study settings, 592  
alongside practical facility-level solutions such as the ward 593  
layout to ensure record keeping can be completed in a 594  
convenient location near service users and the clinical 595  
area, and implementation of local protocols and training 596  
programs. However, changing EIBF and documentation 597  
practices is likely to also require health system actions that 598  
encompass improvements to human resources, infrastruc- 599  
ture, supply and mechanisms for accountability [57]. 600

601 Drying of the newborn and skin-to-skin contact were 601  
challenging to measure in survey report for the EN- 602  
BIRTH study [58], and this is consistent with other re- 603  
search [59]. Indeed, accuracy is expected to worsen over 604  
the three to five-year timespan used for DHS and MICS, 605  
compared to the exit survey timing in EN-BIRTH. Skin- 606  
to-skin is currently included in the DHS core question- 607  
naire, drying in the DHS optional newborn module, and 608  
delayed cord clamping is not included in DHS or MICS 609  
(Additional file 1). For drying, survey-reported percent 610  
agreement was > 80% in 4/5 hospitals, but for skin-to- 611

612 skin initiation was < 50% in three hospitals [58]. Results  
613 regarding individual level validation for survey-report of  
614 these INC indicators are detailed in a companion paper  
615 [58]. Cord cutting and drying or clamping are universally  
616 practiced for most births; quality of care improvement  
617 requires data on timing, and hygienic practices which  
618 are better assessed via audit, and other facility-level clinical  
619 quality improvement approaches. As such, we do  
620 not recommend inclusion of questions in surveys regarding  
621 cord clamping or drying or immediate skin to  
622 skin for all babies (which differs from kangaroo mother  
623 care) [60].

624 Our observed data suggests EIBF was a good tracer  
625 indicator for skin-to-skin initiation within an hour of  
626 birth in four of five assessed facilities (Azimpur, Kushtia,  
627 Pokhara, and Muhimbili). There is compelling plausibility  
628 for the agreement between skin-to-skin and breastfeeding [18].  
629 We also found good agreement between  
630 EIBF and delayed cord clamping in three facilities (Kushtia,  
631 Pokhara, and Muhimbili). Coverage of delayed cord  
632 clamping and immediate drying was very high while  
633 coverage of EIBF was very low; EIBF in this study was  
634 not related to immediate drying, although we note that  
635 drying was practiced rapidly for virtually all newborns  
636 and EIBF was very low. This echoes prior secondary analysis  
637 of DHS data, which reported EIBF to be poorly correlated  
638 to other INC practices, although we note that  
639 the correlated data were based on survey-report with  
640 low accuracy and thus had inherent limitations [61].

641 Our time-to-event analysis using the Kaplan Meier  
642 curves highlights the rapid timing of skin-to-skin initiation  
643 drying, and cord clamping, but major delays in  
644 breastfeeding, especially for babies born via caesarean.  
645 Given the increasing rate of caesareans, this represents  
646 an urgent research gap [62]. One EN-BIRTH hospital  
647 had an observed caesarean rate > 70%, which is high –  
648 double the recommended acceptable range of 10–15%  
649 [62]. Given the importance of INC practices, and especially  
650 the relationship between EIBF and skin-to-skin  
651 [18], urgent work is required to better understand and  
652 address the barriers and enablers for newborn care after  
653 caesarean birth, in addition to reducing non-medically  
654 indicated caesarean sections.

655 In these CEmONC hospitals, low rates of  
656 breastfeeding indicate gaps in quality of care. Given  
657 the well-evidenced, extensive benefits of EIBF, low  
658 coverage and delays are startling and may reflect separation  
659 of mother and baby. Breastfeeding initiation is  
660 crucial for establishing breastfeeding and for multiple  
661 other benefits for mother and baby [5], hence other  
662 essential newborn care interventions such as vitamin  
663 K, eye care, immunisations, and assessment of birth-weight,  
664 gestational age, or congenital conditions  
665 should not be prioritised above uninterrupted skin to

skin and EIBF where possible. More work to assess  
sequencing and prioritisation of practices is required.

666 Register design also plays a role, the Pokhara (Nepal)  
667 register did not have a column to capture EIBF. In three  
668 out of four EN-BIRTH sites with a specific column,  
669 register-recorded coverage was above 90%. In Tanzania,  
670 Temeke and Muhimbili had different register-recorded  
671 coverage (95.3 and 43.8% respectively) despite sharing  
672 the same register design and having similar observer-  
673 assessed EIBF rates (26 and 19.1% respectively). Hospitals  
674 in Bangladesh introduced revised registers during  
675 the study period, and register-recorded breastfeeding  
676 coverage in Azimpur increased from 0 to > 90%, and in  
677 Kushtia from 57.3 to 96.8%, despite a maximum  
678 observer-assessed EIBF coverage of 9.8% [41]. These  
679 findings suggest that a focus on data accuracy is important,  
680 rather than register completeness alone. Further research  
681 regarding register filling and context to  
682 understand better these variations in performance,  
683 which may be rooted in facility-specific differences such  
684 as governance and leadership, could help. Facilitating  
685 ownership and use of data could also support improved  
686 data quality [63], especially in the operating theatres  
687 where health workers reported being unclear on who  
688 was responsible for recording in registers, or what data  
689 were used for reporting in HMIS (Additional files 13  
690 and 14). Introducing data quality assurance systems,  
691 training on indicator definitions, and receiving feedback  
692 on data could help improve recording practices [64].  
693

694 Strengths of this study include the large sample size,  
695 and rigorous multi-country design with gold standard  
696 with direct observation by clinically trained researchers.  
697 Observer data could be subject to errors, but this risk  
698 was minimised through a custom-built electronic data  
699 capture system, standardised training and refresher sessions,  
700 and quality assurance through double observation  
701 and data entry [42].  
702

703 However, there were also limitations. Observation was  
704 discontinued when women were transferred out of  
705 labour and delivery wards, so we were unable to record  
706 EIBF beyond the immediate postpartum period. As the  
707 current definition of EIBF includes a one-hour time  
708 period, the 12,701 women who were not observed for >  
709 1 h needed to be excluded from this analysis. This may  
710 have introduced bias as women observed for  $\geq 1$  h were  
711 more likely to have had a vaginal birth (Additional file 10).  
712 Having observation data across the full  
713 sample for a longer period would enable a more detailed  
714 analysis regarding timing, especially validation at two  
715 hours post-birth [11]. Despite low prevalence of data  
716 categorised as “not readable”, inter-rater reliability findings  
717 suggested poor agreement between register data extractors  
718 in Kushtia (Bangladesh), Temeke and Muhimbili  
719 (Tanzania) (Additional file 15). This highlights the

720 potential challenges of data extraction and a need for  
721 evidence-based register design and implementation  
722 processes to ensure data quality as it moves up the  
723 HMIS [41].

724 Further research is needed to improve reliable and  
725 consistent measurement of the EIBF indicator, as well as  
726 comparability between survey and routine register data.  
727 Research on register design, implementation, and flow  
728 into HMIS is key. Root cause analysis tools could be  
729 adapted to identify local solutions for improving quality  
730 of maternal and newborn care in health facilities, in line  
731 with WHO standards [65].

## 732 Conclusions

733 In this large multi-site study, all INC practices evaluated  
734 had suboptimal coverage and challenges in measure-  
735 ment. EIBF had very low coverage (less than one in five),  
736 and even lower for women with caesarean births. Given  
737 the global epidemic of caesareans, more focus on sup-  
738 porting women and newborns with EIBF is crucial. Un-  
739 less measurement accuracy is improved, EIBF coverage  
740 changes may be missed. Register-recorded and survey-  
741 reported coverage both over-estimated observed cover-  
742 age of EIBF, demonstrating a need for further research  
743 to improve instructions and register design/survey ques-  
744 tions. Our analysis suggests that agreement between  
745 EIBF and skin-to-skin initiation is high. However, imme-  
746 diate drying and delayed cord clamping are even more  
747 challenging to measure in surveys and unlikely to be  
748 captured in registers, so they will likely require special  
749 audits and studies. Renewed focus is needed to promote  
750 zero separation of women and their babies, increase  
751 coverage of EIBF and INC practices irrespective of mode  
752 of birth, and to ensure and measure INC practices in-  
753 cluding respectful care practices for every woman and  
754 their newborn at birth.

## 755 Supplementary Information

756 The online version contains supplementary material available at <https://doi.org/10.1186/s12884-020-03421-w>.  
757

759 **Additional File 1.** Doc. Definition of immediate newborn care indicators  
760 (EN-BIRTH, DHS & MICS questionnaires)

761 **Additional File 2.** Doc. Previous studies regarding validation for  
762 measures of immediate newborn care practices +AUC defined as  $\geq 0.6$ , IF  
763 0.75–1.25. 1Register-recorded as composite indicator with “keeping  
warm”

764 **Additional File 3.** Doc. National context and number of births in EN-  
765 BIRTH study hospital

766 **Additional File 4.** Data collection dates by site, EN-BIRTH study. Sample  
767 size was calculated to observe at least 106 observations per intervention  
768 per country, based on estimated coverage of intervention during forma-  
769 tive research.

770 **Additional File 5.** Doc. Observation, survey and register indicator  
771 definitions, EN-BIRTH study.  $\sqrt{\quad}$  used for analysis (\*not in Pokhara)  $\sqrt{\quad}$  data  
772 available at source  
822

**Additional File 6.** Doc. STROBE Checklist. +Give information separately  
for cases and controls in case-control studies and, if applicable, for ex-  
posed and unexposed groups in cohort and cross-sectional studies. Note:  
An Explanation and Elaboration article discusses each checklist item and  
gives methodological background and published examples of transparent  
reporting. The STROBE checklist is best used in conjunction with this arti-  
cle (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>,  
Annals of Internal Medicine at <http://www.annals.org/>,  
and Epidemiology at <http://www.epidem.com/>). Information on the  
STROBE Initiative is available at [www.strobe-statement.org](http://www.strobe-statement.org).

**Additional File 7.** Doc Ethical approval by institutional review boards,  
EN-BIRTH Study. Voluntary informed written consent was obtained from  
all participants and their care providers. All women were provided with a  
description of the study procedures in their preferred language at admis-  
sion, and offered the right to refuse, or withdraw consent at any time  
during the study. Facility staff were identified before data collection  
began and approached for recruitment and consent. No health worker  
refused participation and all maintained the right to withdraw through-  
out the study. This study was granted ethical approval by institutional re-  
view boards in all operating counties in addition to the London School  
of Hygiene & Tropical Medicine.

**Additional File 8.** Doc. Hospital register design and completion  
approaches by site, EN-BIRTH study ( $n = 6548$ ). Completeness calculations  
are “not possible” for Bangladesh register instructions state, blank is to  
mean intervention/practice is not done. Cut-off ranges adapted from  
WHO Data Quality Review, Module 2 “Desk review of data quality”  $N =$   
6548 register-recorded live births observed for  $\geq 1$  h after birth

**Additional File 9.** Excel. Respondents for focus group discussion and in-  
depth interviews for EN-BIRTH Study

**Additional File 10.** Doc. Individual-level validation in exit-survey report  
of early initiation of breastfeeding, EN-BIRTH study ( $n = 7802$ )  $\dagger =$  result  
suppressed due to 10 or fewer count per column of two-by-two Table.  
 $N = 7802$  babies observed for  $\geq 1$  h after birth

**Additional File 11.** Doc. Individual-level validation of register recording  
for early initiation of breastfeeding, EN-BIRTH study ( $n = 7802$ )  $N/A =$  data  
element not captured by routine register.  $\dagger =$  result suppressed due to 10  
or fewer count per column of two-by-two Table.  $N = 7802$  babies ob-  
served for  $\geq 1$  h after birth

**Additional File 12.** Doc. Characteristics of women observed in labour  
and delivery wards for  $< 1$  h, EN-BIRTH study ( $n = 12,554$ ).  $N = 12,554$   
women observed for less than 1 h with a live birth

**Additional File 13.** Doc. Assessment of routine recording  
responsibilities for breastfeeding, EN-BIRTH study

**Additional File 14.** Doc. Register recording order and prioritisation for  
breastfeeding, EN-BIRTH study

**Additional File 15.** Doc. Inter-observer agreement for early initiation of  
breastfeeding using Kappa, EN-BIRTH study. Kappa agreement cut offs:  $<$   
0.71 considered high/substantial disagreement for observation, and  $< 0.9$   
considered high/substantial disagreement for data extraction, Day et al.

## Abbreviations

BD: Bangladesh; CEmONC: Comprehensive emergency obstetric and  
neonatal care; CIFF: Children’s Investment Fund Foundation; DHS: The  
Demographic and Health Survey Program; EIBF: Early initiation of  
breastfeeding; EN-BIRTH: *Every Newborn*-Birth Indicators Research Tracking in  
Hospitals study; HMIS: Health Management Information Systems;  
icddr,b: International Centre for Diarrheal Disease Research, Bangladesh;  
IHI: Ifakara Health InstituteDar es SalaamTanzania; INC: Immediate newborn  
care; LMIC: Low and Middle Income Countries; LSHTM: London School of  
Hygiene & Tropical Medicine; MICS: Multiple Indicator Cluster Survey;  
NP: Nepal; PRISM: Performance of Routine Information System Management;  
TZ: Tanzania; UNICEF: United Nations International Children’s Emergency  
Fund; WHO: World Health Organization

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- 867 **Ethics and consent to participate**  
868 This study was granted ethical approval by institutional review boards in all  
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870 Medicine (Additional file 7).  
871 Voluntary informed written consent was obtained from all observed  
872 participants, their families for newborns, and respondents for the qualitative  
873 interviews. Participants were assured of anonymity and confidentiality. All  
874 women were provided with a description of the study procedures in their  
875 preferred language at admission, and offered the right to refuse, or withdraw  
876 consent at any time during the study. Facility staff were identified before  
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880
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889 The EN-BIRTH study was conceived by JEL, who acquired the funding and  
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894 led the development of the software application, data dashboards, and data-  
895 base development with VG and the LSHTM team. IH (notably DS) coordi-  
896 nated work on barriers and enablers for data collection and use, working  
897 closely with LTD. QSR was the main lead for data management working  
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899 and first draft of the manuscript, working closely with AER, LTD, KP, JEL and  
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