BMC Pregnancy and Childbirth

RESEARCH Open Access

Chlorhexidine for facility-based umbilical cord care: EN-BIRTH multi-country study

Sojib Bin Zaman[1*], Abu Bakkar Siddique[1], Harriet Ruysen[2], Ashish KC[3], Kimberly Peven[2,4], Shafiqul Ameen[1], Nishant Thakur[5], Qazi Sadeq-ur Rahman[1], Nahya Salim[6,7], Rejina Gurung[5], Tazeen Tahsina[1], Ahmed Ehsanur Rahman[1], Patricia S. Coffey[8], Barbara Rawlins[9], Louise T. Day[2], Joy E. Lawn[2†], Shams Arifeen[1†] and EN-BIRTH Study Group

Abstract

Background: Umbilical cord hygiene prevents sepsis, a leading cause of neonatal mortality. The World Health Organisation (WHO) recommends 7.1% chlorhexidine digluconate (CHX) application to the umbilicus after home birth in high mortality contexts. In Bangladesh and Nepal, national policies recommend CHX use for all facility births. Population-based household surveys include optional questions on CHX use, but indicator validation studies are lacking. '*Every Newborn* Birth Indicators Research Tracking in Hospitals' (EN-BIRTH) was an observational study assessing measurement validity for maternal and newborn indicators. This paper reports results regarding CHX.

Methods: The EN-BIRTH study (July 2017–July 2018) included three public hospitals in Bangladesh and Nepal where CHX cord application is routine. Clinical-observers collected tablet-based, timestamped data regarding cord care during admission to labour and delivery wards as the gold standard to assess accuracy of women's report at exit survey, and of routine-register data. We calculated validity ratios and individual validation metrics; analysed coverage, quality and measurement gaps. We conducted qualitative interviews to assess barriers and enablers to routine register-recording.

Results: Umbilical cord care was observed for 12,379 live births. Observer-assessed CHX coverage was very high at 89.3–99.4% in all 3 hospitals, although slightly lower after caesarean births in Azimpur (86.8%), Bangladesh. Exit survey-reported coverage (0.4–45.9%) underestimated the observed coverage with substantial "don't know" responses (55.5–79.4%). Survey-reported validity ratios were all poor (0.01 to 0.38). Register-recorded coverage in the specific column in Bangladesh was underestimated by 0.2% in Kushtia but overestimated by 9.0% in Azimpur. Register-recorded validity ratios were good (0.9 to 1.1) in Bangladesh, and poor (0.8) in Nepal. The non-specific register column in Pokhara, Nepal substantially underestimated coverage (20.7%).

(Continued on next page)

* Correspondence: sojib@icddrb.org
†Joy E Lawn and Shams Arifeen are joint senior author.
[1]Maternal and Child Health Division, International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b), 68 Shahid Tajuddin Ahmed Sarani, Mohakhali, Dhaka, Bangladesh
Full list of author information is available at the end of the article

(Continued from previous page)

Conclusions: Exit survey-report highly underestimated observed CHX coverage in all three hospitals. Routine register-recorded coverage was closer to observer-assessed coverage than survey reports in all hospitals, including for caesarean births, and was more accurately captured in hospitals with a specific register column. Inclusion of CHX cord care into registers, and tallied into health management information system platforms, is justified in countries with national policies for facility-based use, but requires implementation research to assess register design and data flow within health information systems.

Keywords: Birth, Newborn, Coverage, Validity, Survey, Hospital records, Health management systems, 7.1% chlorhexidine, Umbilical cord care, Neonatal sepsis

Key findings

What is known and what is new about this study

- Application of 7.1% chlorhexidine digluconate for umbilical cord care (CHX) is recommended by the World Health Organisation (WHO) for home births in high newborn mortality settings, and is being scaled up in many countries, including for hospital births.
- There are limited data tracking coverage at national or global levels. Although the Demographic and Health Surveys' (DHS) additional modules have optional questions, there is little country uptake and these are not yet validated.
- EN-BIRTH is the first multi-country observational study to assess validity of the use of CHX measurement (n = 12,379 observed newborns) compared to women's report on exit survey and routine register-recording.

Survey – what did we find and what does it mean?

- We used the same survey questions as the DHS optional newborn module.
- We found high observed coverage (96.6%) but also high (71.5%) "don't know" replies from women reporting on application of CHX to their newborn's umbilical cord.
- Survey-reported coverage (11.3%) vastly underestimated observed coverage (96.6%) in hospitals and was extremely inaccurate.

Register – what did we find and what does it mean?

- Registers designed with a specific column more accurately recorded the high coverage of CHX application than those with non-specific columns.
- The same register design performed differently in two separate facilities, and CHX coverage was slightly overestimated (9.0%) in one.
- Qualitative data highlighted opportunities to improve register design, completion and use, especially training and supervision.

Gap analysis for quality of care and of measurement

- Almost all newborns observed received CHX, hence the coverage gap was small, except after caesarean birth in one facility.
- Quality of care in terms of timing revealed that most newborns (92.2%) received CHX within 1 h of birth.
- Further research is needed to assess the optimal sequencing of immediate newborn care interventions to avoid separation of women and newborns, promote early breastfeeding, and ensure that CHX application enhances and does not delay time sensitive practices.

What next and research gaps

- CHX has become a part of immediate newborn care policy in many countries, including for facility births.
- For institutional births, well-designed routine registers have higher accuracy than women's exit survey-reports, but research is required on design and data flow in health management systems.
- Given the poor performance of survey-reported data for facility-based CHX use, further survey validation research should focus on home births, or postnatal application by women to explore how best to measure coverage outside facility-based systems.

Background

Globally, almost half of under-five mortality occurs during the first 4 weeks after birth, the neonatal period [1, 2]. Infection is a leading cause of neonatal mortality, particularly in high-mortality contexts in low to middle-income countries (LMICs) [3, 4]. The newborn umbilical stump is an important entry point for sepsis and systemic infections [5, 6]. Research has shown that the application of 7.1% chlorhexidine digluconate, a broad-spectrum antiseptic, to the umbilical cord (CHX) can reduce mortality, especially if applied on the first day of life as per World Health Organization (WHO) guidelines [7]. The highest gain is for very low birthweight neonates, where a dose response by birthweight is evident, and newborns benefit from early application [8–10]. Beyond day one, CHX application reduces the risk of local infection to the cord stump (from 56 to 27%) and may also reduce later mortality risk [11]. Hence this low-cost intervention could contribute to reducing the burden of mortality due to neonatal sepsis in the first week of life [8, 12–14].

The WHO recommends clean, dry cord care for all newborns and daily CHX application to the umbilical stump for the first week of life for homebirths in high neonatal mortality settings (> 30 deaths/1000 livebirths) [6, 15]. These recommendations reflect the evidence available at the time, which included randomised trials mainly conducted in high-mortality homebirth settings in South Asia, including Nepal and Bangladesh [6]. These guidelines noted the potential for CHX application to lower or replace traditional practices, including application of harmful substances such as cow dung [6]. There are now two African studies of umbilical cord cleansing for home births, but these did not report significant mortality benefits [16, 17].

Despite many concerns regarding hospital acquired infections [18, 19], no randomised trial has rigorously assessed mortality effect for facility births to date, although there is an ongoing randomised controlled trial testing a single application of 4% chlorhexidine in Uganda [20]. Analysis from 3223 facility births in Bangladesh and Nepal observed significant decreases in mortality in newborns who received CHX [21]. At least 15 countries have implemented a national policy for use of CHX; most, including Bangladesh and Nepal, have a national policy for universal CHX coverage for all births, including those in facilities [22].

Tracking coverage of high impact evidence-based interventions is needed to drive progress to achieve Sustainable Development Goal 3.2, ending preventable neonatal mortality. Currently, umbilical cord care coverage is measured by population-based household survey programmes such as the Demographic and Health Surveys (DHS) Program and Multiple Indicator Cluster Surveys (MICS) typically conducted every 3–5 years (Additional file 1). MICS includes a standard question on cord care practices [23]; however, in DHS this is included in an optional add-on newborn care module with the question: "Was chlorhexidine applied to the stump at any time?" [24] (Additional file 1). Household surveys have many strengths, including a nationally representative sample. However, previous validity research findings for indicators of practices and interventions around the time of birth are mixed. At a minimum, women can only report on clinical interventions they have either discussed with health providers, directly experienced during a state of regular consciousness, or have witnessed [25–30]. Only one previous research study has tested validity of survey CHX measurement in Nigeria, although this had a small sample size [25].

Where CHX application is implemented in facilities, the opportunity exists to track coverage using facility register data for routine health management information systems (HMIS). These data have the advantage of being aggregated and available for use in decision making on a far more frequent basis than household survey data, and thus have the potential to regularly inform quality improvement efforts at subnational levels of the health system. Data accuracy must be trusted to promote use for planning, management, resource allocation and quality monitoring [31]. No previous research has assessed validity of register-recorded measures for CHX coverage [7].

The *Every Newborn* Action Plan, supported by all United Nations member states and > 80 development partners, includes an ambitious Measurement Improvement Roadmap [32, 33] with an urgent focus on validating indicators for care and outcomes around the time of birth. As part of this roadmap, *Every Newborn*– Birth Indicators Research Tracking in Hospitals (EN-BIRTH) study, was a mixed-methods observational study of > 23,000 hospital births in three countries (Tanzania, Bangladesh and Nepal) and aimed to validate selected newborn and maternal indicators for routine facility-based tracking of coverage, quality of care, and outcomes [34, 35]. At the time of study design Tanzania did not have a policy for CHX; therefore, this paper focuses on Bangladesh and Nepal.

Objectives

This paper is part of a supplement based on the EN-BIRTH multi-country study, *'Informing measurement of coverage and quality of maternal and newborn care'*, and focuses on application of CHX, with three main objectives:

1. **Assess NUMERATOR accuracy/validity** of measurement for a coverage indicator of single application 7.1% chlorhexidine to the umbilical cord stump via exit-survey of women's report and routine labour ward register data, compared to observation (gold standard).
2. **Analyse GAPS in coverage and quality of care, and measurement for application of 7.1% CHX to the umbilical cord stump**, including observation data to assess right time, right substance applied and experience of care (assessed via survey-report regarding recall of communication of care).
3. **Evaluate BARRIERS AND ENABLERS to routine labour ward register-recording** for CHX through qualitative interviews regarding register design, completion and use.

Methods

EN-BIRTH was an observational mixed-methods study and compared data from clinical observers about CHX application (gold standard) to women's exit-interview survey reported coverage (Additional file 2) and routine register-recorded coverage (Fig. 1). Trained clinical nurses observed participants 24 h per day throughout the woman's admission to labour and delivery ward. They recorded data on care and outcomes, including application of CHX to the umbilical cord stump (Fig. 1). All data collectors were given training to recognise the correct product for local use. Data were collected using a custom-built android tablet-based software application that included timestamps for observation data (July 2017–July 2018) in three public hospitals providing comprehensive emergency obstetric and newborn care (CEmONC) and application of CHX: Bangladesh (Maternal and Child Health Training Institute (MCHTI), Azimpur, and Kushtia General Hospital), and Nepal (Pokhara Academy Health Sciences) (Additional file 3). Participants were consenting women admitted in labour in the three study sites (Additional file 4). Metadata definitions for the CHX indicator are also shown (Additional file 4). All statistical analyses were undertaken using Stata 15.0 (Stata Corporation, College Station, TX, USA). Results were reported in accordance with STROBE statement checklists for cross-sectional studies (Additional file 5). Detailed information regarding the research protocol, methods, and analysis has been published separately [34, 35].

Labour ward registers

All three study hospitals used pre-printed routine labour ward registers. The register design in Bangladesh changed to a standardised national labour ward register during the EN-BIRTH study. The revised Bangladesh register

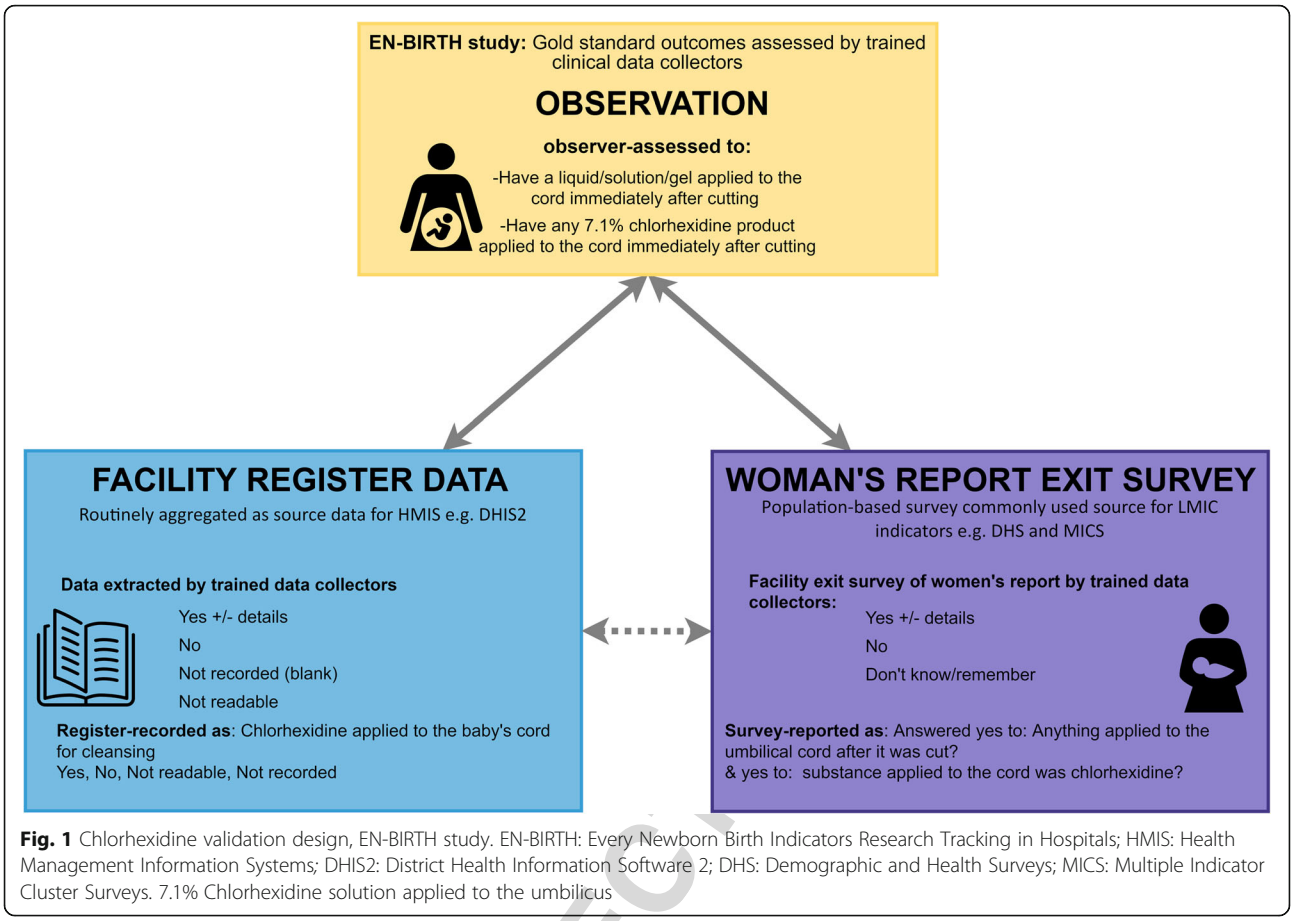


Fig. 1 Chlorhexidine validation design, EN-BIRTH study. EN-BIRTH: Every Newborn Birth Indicators Research Tracking in Hospitals; HMIS: Health Management Information Systems; DHIS2: District Health Information Software 2; DHS: Demographic and Health Surveys; MICS: Multiple Indicator Cluster Surveys. 7.1% Chlorhexidine solution applied to the umbilicus

had a new specific column for documenting CHX application labelled, *7.1% Chlorohexidine used on the umbilical cord*. A blank box was provided where staff were instructed to tick for 'given' and leave blank for 'not given'. In Pokhara, Nepal, CHX application is recorded in a non-specific column labelled "general remarks" and health workers were instructed to document 'CHX is given' or leave blank if 'not given'. Only results from revised registers for the Bangladesh sites are presented in this paper.

Methods and analysis by objective

Objective 1: numerator validation

We compared exit survey-reported and register-recorded coverage to observer-assessed coverage of CHX and stratified by hospital and mode of birth: vaginal births and caesarean births. Percentages of "don't know" replies for exit survey questions, and 'not recorded or not readable' for register-recorded data were also calculated. In line with how DHS/MICS typically analyse 'yes/no/don't know' questions, we compared survey-reported results with "don't know" considered as "no" against "don't know" excluded. Similarly, for register-recorded coverage, we compared results with "not recorded" considered as "no" and also excluded.

We calculated absolute differences between measured coverage (survey or register) and observed coverage to understand under- or over-estimation at the population level. Using two-way tables, we calculated individual-level validity statistics: sensitivity, specificity, and percent agreement (true positive + true negative / total) of register-recorded and survey-reported CHX coverage to observed coverage. Area under the curve, inflation factor, positive predictive value, and negative predictive value were also calculated. We report results where column totals were ≥ 10 in the two-by-two tables. Pooled results for validity analyses were calculated using random effects meta-analysis, presented with i^2, τ^2, and heterogeneity statistic (Q). We calculated "validity ratios" (against gold standard), heat-mapping results using standard data quality review cut-offs (over/underestimate by 0 to 5%, by 6–10%, by 11–15%, by 16–20 and > 20%) [36]. All calculations included 95% confidence intervals where appropriate.

Objective 2: gap analysis for quality of care in relation to measurement

We analysed four gaps for CHX use in hospitals: 1) Coverage gap between the target population (all live births) and the observed coverage of CHX. 2) Quality of

care gap for content - between those newborns observed to have *anything* applied to the cord and those correctly having CHX applied. Current WHO guidelines suggest CHX application within the first day, however 'correct' time was taken to be within 1 hour of birth, because observations were restricted to the labour and delivery ward in this study. 3) Measurement gap for register records (observed and register-recorded coverage gap). 4) Measurement gap for survey reports (observed and survey-reported coverage of any cord cleansing after birth).

Objective 3: barriers and enablers to data collection

As part of the EN-BIRTH study, qualitative interviews were conducted to understand the barriers and enablers for routine register-recording of interventions around birth. Qualitative data were collected from a purposive sample of health workers (nurses/midwives and doctors) and EN-BIRTH study data collectors. Interviews were recorded, transcribed, translated and NVIVO (QSR International Pty Ltd. Version 12) software was used for data management.

Detailed qualitative methods and overall results are available in an associated paper [37]. Qualitative analysis began with identifying emerging themes based on the Performance of Routine Information System Management (PRISM) conceptual framework [38]. This paper specifically presents themes relating to the recording of umbilical application of CHX.

Results

Sample description and selection

Among 12,379 live births observed for CHX use on labour ward in Bangladesh and Nepal, 10,772 livebirths (87.0%) were included for register extraction (Fig. 2). 95.3% of women completed an exit survey (12,097 women interviewed out of the possible 12,692 women observed) which correspond to 95.5% livebirths (11,827 live births out of the possible 12,379 live births observed).

Birth outcomes and background characteristics are shown in Table 1. Almost three-quarters (72.8%) of births in Azimpur were via caesarean section compared to 40.3% in Kushtia and 15.5% in Nepal. Overall, more than 60% of the women were aged between 20 and 29 years, and 2.7% were < 18 years. Completion of secondary education was lowest in Kushtia (Bangladesh, 36.1%) and highest in Pokhara (Nepal, 61.2%). Approximately 13.4% of newborns were < 2500 grammes across the three facilities.

Objective 1: numerator validation

To calculate coverage we used the recommend denominator of all live births. In this analyses we included the following denominators; observer-assessed (n = 12,379 live births), register-recorded (n = 11,002 live births), and exit survey-reported (n = 11,827 livebirths). Observer-assessed coverage of CHX application within 1 hour of birth was high in all three hospitals for both vaginal births (97.7, 95% CI 94.4–99.6%) and caesarean sections (97.1, 95% CI 94.4–99.6%) (Fig. 3).

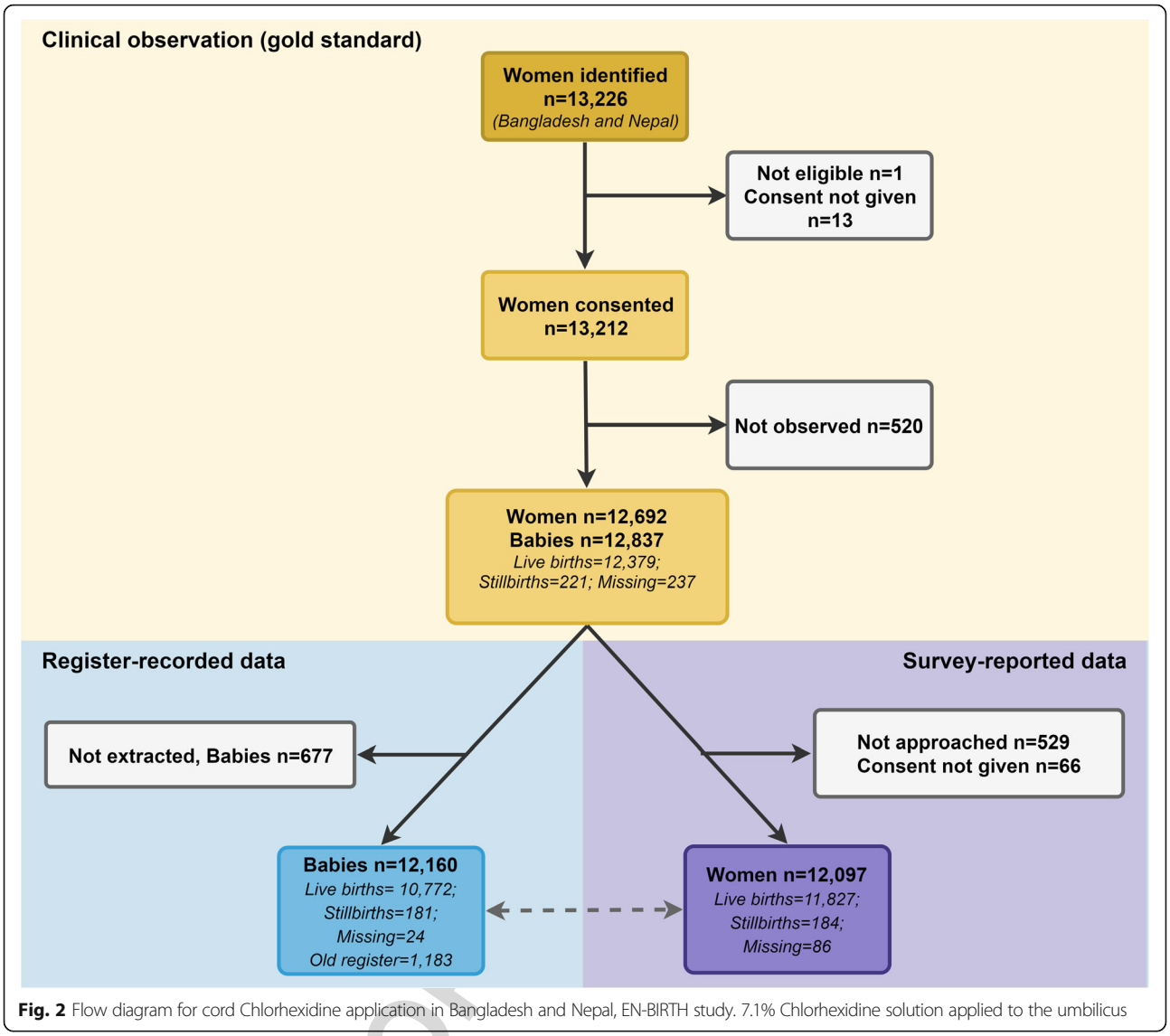
Exit-interview survey-reported validation

CHX coverage was consistently underestimated by survey compared with gold standard in all three sites for vaginal births and caesarean births (Fig. 3). Responses yielded high "don't know" replies for both vaginal births and caesarean section (68.5, 95% CI 47.9–85.9% / 76.4, 95% CI 66.6–85.0% respectively). Percent agreement was low (18.1, 95% CI 5.5–35.9%), and analysis criteria (> 10 column count) was only met for one facility (Table 2). Survey-reported timing of CHX (within 1 hour of birth) showed high specificity 94.7% (95% CI 74.3–100.0%) but low sensitivity 6.7% (95%CI 0.0–23.9%) in all facilities (Additional file 6), including "don't knows". Most women (56.1% in Kushtia to 79.4% in Pokhara) reported that the health worker did not inform them or they do not know if anything was applied to their newborns umbilical cord (Additional file 7).

Register-recorded validation

Register-recorded CHX application coverage was variable between the three hospital registers. Most accurate was the register-recorded coverage in Kushtia (Bangladesh), underestimating by only 0.2% (Table 3). This identical register captured CHX in a specific column and overestimated coverage by 9.0% in Azimpur (Bangladesh). The least accurate register-recorded coverage was from the non-specific column in Pokhara, underestimating coverage by 20.7% (Fig. 4). Register performance to measure CHX application was consistently better for vaginal than caesarean births (Table 3). In Pokhara, register-recorded coverage was underestimated by 15.1% for vaginal births (99.4–84.3%) and 60.4% for caesareans (99.2–39.0%). Percent agreement was high especially for vaginal births (83.9%) and increased when "don't know" responses are excluded (98.9%), although all facilities had a column count < 10 (Additional file 8). In Bangladesh, register instructions dictated that the column was left blank when CHX was not applied, which was problematic for analysis because there was no true measure of 'not given'.

Comparison of heat-mapped validity ratios for exit-survey or register-recorded measures compared with observer-assessed suggested that register data for CHX was more accurate (ratio 0.94) than women's report (ratio 0.12). It was categorised as 'good' for vaginal birth and caesareans (ratios ~ 1.00) in both Bangladesh hospitals. Vaginal births were 'moderate' (ratio 0.85) and



f2.1 f2.2 **Fig. 2** Flow diagram for cord Chlorhexidine application in Bangladesh and Nepal, EN-BIRTH study. 7.1% Chlorhexidine solution applied to the umbilicus

F5 caesareans 'poor' (ratio 0.40) in Nepal (Fig. 5). Validity ratios for survey-reported results were categorised as 'poor' (ratio range 0.01 to 0.38) in all facilities (Fig. 5).

Objective 2: gaps analysis for coverage, quality of care in relation to measurement

Almost all newborns in these facilities were observed to receive CHX. The coverage gap was very small for the F6 target population of all livebirths (Fig. 6). Within these facilities, there was close observed alignment between application of anything and CHX to the cord, however this leads to a measurement gap in survey report where women were more able to report that something was applied (17.8%), rather than CHX (12.3%) (Additional file 9). Quality of care gap analysis showed timing distribution (less than 1 h of birth) was similar among each facility and by mode of birth. Survey reported "don't knows" were higher in Azimpur and Pokhara considering all modes of birth.

Objective 3: barriers and enablers to data collection

These findings were specific to recording practices for CHX, but more detailed qualitative results are available in a supporting paper [37]. Respondents in all hospitals talked of the complexity of multiple registers (both formal and informal register books) to record interventions around birth, including CHX (Fig. 4).

In Bangladesh the revised register design was an enabler:

> *"Previously we did not document the care of chlorhexidine in registers as it did not (have) space to write. Now this new register has a specific column where we can document whether chlorhexidine was*

Table 1 Characteristics of women observed in labour and delivery wards, EN-BIRTH study EN-BIRTH study (n = 12,837)

	Bangladesh Azimpur Tertiary n (%)	Bangladesh Kushtia District n (%)	Nepal Pokhara Regional n (%)	All sites n (%)
A). Total Newborns who were observed (Denominator)	2936	2459	7442	12837
Birth outcome - live birth	2896 (98·6)	2308 (93·9)	7175 (96·4)	12379(96.4)
Newborn condition at L&D discharge				
Alive	2895(98.6)	2302(93.6)	7171(96.4)	12368(96.3)
Stillbirths	11(0.4)	74(3)	126(1.7)	211(1.6)
Neonatal death	1(0)	6(0.2)	4(0.1)	11(0.1)
Baby not delivered	2(0.1)	2(0.1)	6(0.1)	10(0.1)
Birth outcome not observed	27(0.9)	75(3.1)	135(1.8)	237(1.8)
Mode of birth				
Normal vaginal birth	767(26.4)	1364(56.6)	5840(79.2)	7971(62.8)
Vaginal breech/ Vacuum/ Forceps	1(0)	0(0)	349(4.7)	350(2.8)
Caesarean Section	2119(72.8)	972(40.3)	1140(15.5)	4231(33.3)
Not observed	23(0.8)	76(3.2)	41(0.6)	140(1.1)
Birthweight of baby < 2500 g	353(11.9)	473(19.3)	897(12.1)	1723(13.4)
Sex Female/Girl baby	1427(49)	1128(46.8)	3335(45.3)	5890(46.4)
B). Total women who were observed	2910	2412	7370	12,692
Women's Age[a]				
< 18 years	25(0.9)	3(0.1)	311(4.2)	339(2.7)
18–19 years	475(16.3)	197(8.2)	817(11.1)	1489(11.7)
20–24 years	1158(39.8)	954(39.6)	3080(41.8)	5192(40.9)
25–29 years	867(29.8)	736(30.5)	2114(28.7)	3717(29.3)
30–34 years	297(10.2)	373(15.5)	827(11.2)	1497(11.8)
35+ years	88(3)	149(6.2)	221(3)	458(3.6)
Mean (SD)	23.9(4.5)	24.9(4.9)	24.2(4.7)	24.3(4.7)
Women's education[a]				
No education	39(1.3)	77(3.2)	268(3.6)	384(3)
Primary incomplete	111(3.8)	127(5.3)	252(3.4)	490(3.9)
Primary complete	339(11.6)	347(14.4)	302(4.1)	988(7.8)
Secondary incomplete	985(33.8)	954(39.6)	1637(22.2)	3576(28.2)
Secondary complete or higher	1273(43.7)	870(36.1)	4509(61.2)	6652(52.4)
Missing	163(5.6)	37(1.5)	402(5.5)	602(4.7)
Mean (SD)	8.8(4.1)	8.2(3.6)	9.6(4.4)	9.1(4.2)

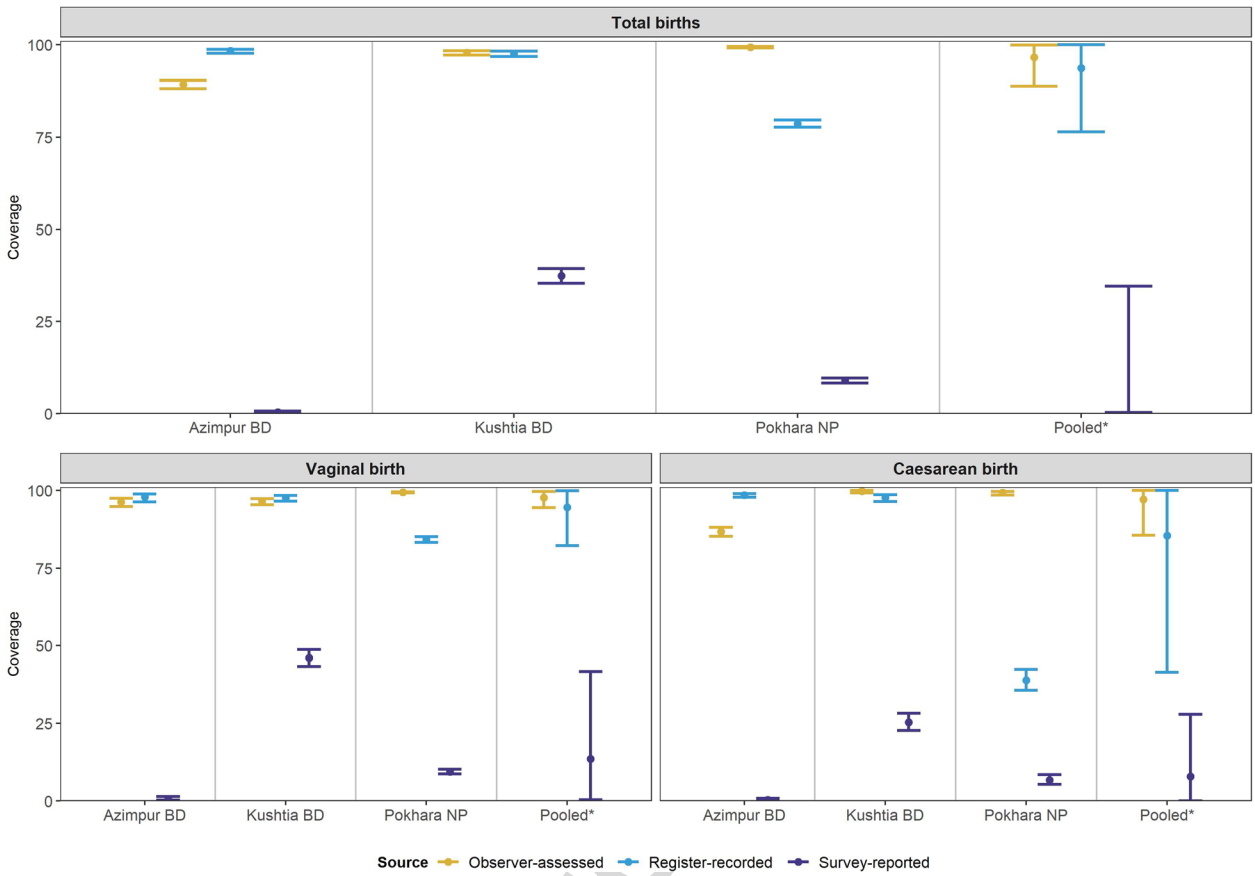
Data were collected from [a]women's registration and [b]survey report

applied or not." (Health worker, Azimpur MCHTI, Bangladesh)

Most respondents from Bangladesh and some in Nepal agreed that it is useful to have a specific column on CHX in the register:

"Now, more information is added to the delivery register than before. For example, information related chlorhexidine was not included before." (Health worker, Kushtia, Bangladesh)

In Bangladesh, respondents from Kushtia reported that they were not confident to record in the new register due to a lack of formal training. This was in contrast to Azimpur, where more formal supervision and training was provided during the rollout of revised national registers:



f3.1 **Fig. 3** Coverage rates for Chlorhexidine cord application measured by observation, register and exit-survey, EN-BIRTH study (n = 12,379). Register-
f3.2 recorded (n = 11,002 livebirths) and exit survey-reported (n = 11,827 livebirths) in the EN-BIRTH Study, split by three hospitals. BD: Bangladesh; NP:
f3.3 Nepal. *7.1%* Chlorhexidine solution applied to the umbilicus
f3.4

"We haven't received any formal training from the hospital. The in-charge has told us verbally how to fill up the register and write information in other informal books." (Health Worker, Azimpur, Bangladesh)

Discussion

EN-BIRTH is the largest observational study to assess validity of coverage measurement for CHX application through women's exit-interview survey to date, and the first to assess validity of routine hospital registers. Our multi-site, multi-country design enabled comparisons between and within countries. The large sample size enabled the first assessment of how caesarean section affects CHX coverage measurement.

For household surveys, CHX coverage questions are already included in the optional newborn module of DHS. Our data collectors also used the visual prompt (a picture showing CHX bottle) to the mother in line with survey procedures used by DHS for this question. Survey-reported validation results showed substantial underestimation of coverage, especially after caesarean section. "Don't know" responses exceeded 50% regarding if *any* substance, or CHX specifically, was applied to the cord. These findings are consistent with other research that shows low accuracy of survey-report for clinical interventions around the time of birth [25, 28–30].

A recent study from Nigeria showed much lower "don't know" replies (5%), and high sensitivity and specificity [25]. Nigeria uses a multi-day regime in contrast to Bangladesh and Nepal, where a single application is the national standard. In settings using the multi-day approach, families are responsible for continuing daily CHX as part of cord care, and it is therefore an imperative that they receive information and training on how to do this. Using our timestamped data, we learned that CHX was applied very quickly after birth (median time 2–4 min), so it is likely that the mother is not aware of the multi-step process of clamping, tying, cutting the cord, and applying CHX. In the Nigerian study, it is possible that CHX application was outside the immediate postpartum period, perhaps later during the first day (or days after birth). The context of this study was in primary health care facilities, in contrast to our study in

t2.1 **Table 2** Individual-level validation in exit survey report of Chlorhexidine cord-application, EN-BIRTH Study ($n = 6748$)

t2.2		Azimpur (BD) Tertiary		Kushtia (BD) District		Pokhara (NP) Regional		Pooled (Random effects)	
t2.3		N (%)	(CI)	N (%)	(CI)	N (%)	(CI)	N%	(CI)
t2.4	Exit-survey denominator	2826 livebirths		2253 livebirths		6748 livebirths			
t2.5	All modes of birth combined								
t2.6	Observer prevalence %	2582 (89.3)		2257 (97.9)		7112 (99.4)		96.6	(88.8,99.9)
t2.7	Survey-reported prevalence %	12 (0.4)		840 (37.3)		604 (9)		11..3	(0.3,34.6)
t2.8	Don't know responses %	2189 (77.5)		1251 (55.5)		5355 (79.4)		71.5	(57.3,83.7)
t2.9	INCLUDES DON'T KNOW AS NO								
t2.10	10 Cell Counts	No		Yes		No			
t2.11	% agreement	11.0		38.4		9.5		18.1	(5.5,35.9)
t2.12	Sensitivity	**	**	37.7	35.6, 39.7	**	**	11.5	(0.3,34.9)
t2.13	Specificity	**	**	71.7	56.5, 84	**	**	93.0	(66.0,100.0)
t2.14	EXCLUDES DON'T KNOW								
t2.15	> 10 Cell Counts	No		No		No			
t2.16	% agreement	11.5		83.7		44.2		45.8	(10.0,84.3)
t2.17	Sensitivity	2.1	1.1, 3.6	84.7	82.3, 86.9	44.1	41.4, 46.8	39.7	2.7, 86.7
t2.18	Specificity	100	94.1, 100	23.5	6.8, 49.9	60	14.7, 94.7	70	3.2, 100
t2.19	Vaginal births								
t2.20	Observer prevalence %	731 (96.3)		1290 (96.5)		6075 (99.4)		97.7	(94.4,99.6)
t2.21	Survey-reported prevalence %	4 (0.5)		601 (45.9)		536 (9.3)		13.6	(0.3,41.7)
t2.22	Don't know responses %	565 (76.5)		629 (48.1)		4508 (78.6)		68.5	(47.9,85.9)
t2.23	INCLUDES DON'T KNOW AS NO								
t2.24	> 10 Cell Counts	No		Yes		No			
t2.25	% agreement	4.2		47.8		9.9		17.4	(1.6,4.4)
t2.26	Sensitivity	**	**	46.9	44.1, 49.7	**	**	13.9	(0.3,42.5)
t2.27	Specificity	**	**	72.7	57.2, 85	**	**	91.6	(70.3100.0)
t2.28	EXCLUDES DON'T KNOW								
t2.29	> 10 Cell Counts	No		No		No			
t2.30	% agreement	5.2	2.4, 9.6	88.2	85.6, 90.6	44.4	41.6, 47.3	44.4	7.5, 85.6
t2.31	Sensitivity	2.4	0.7, 6	89.8	87.2, 92	44.3	41.5, 47.2	42.8	5, 86.8
t2.32	Specificity	100	47.8, 100	25	7.3, 52.4	60	14.7, 94.7	63.2	11.5, 100
t2.33	Caesarean births								
t2.34	Observer prevalence %	1850 (86.8)		967 (99.8)		1037 (99.2)		97.1	(85.6100.0)
t2.35	Survey-reported prevalence %	8 (0.4)		239 (25.3)		66 (6.7)		7.9	(0.0,27.9)
t2.36	Don't know responses %	1624 (77.9)		622 (65.9)		823 (83.7)		76.4	(66.6,85.0)
t2.37	INCLUDES DON'T KNOW AS NO								
t2.38	> 10 Cell Counts	No		No		No			
t2.39	% agreement	13.4		25.4		7.1		**	**
t2.40	Sensitivity	**	**	**	**	**	**	**	**
t2.41	Specificity	**	**	**	**	**	**	**	**
t2.42	EXCLUDES DON'T KNOW								
t2.43	> 10 Cell counts	No		No		No			
t2.44	% agreement	13.9	10.9, 17.4	74.1	69, 78.8	42.3	34, 50.8	42.4	7.4, 82.7
t2.45	Sensitivity	2	0.9, 3.9	74.4	69.2, 79.1	42.3	34, 50.8	34.7	0, 88.4
t2.46	Specificity	100	93.6, 100	0	0, 97.5	–	–	34.7	0, 88.4

t2.47 $n = 12,379$ observed livebirths, $n = 11,827$ livebirths with survey
t2.48 ** = result suppressed due to 10 or fewer count per column of two-by-two table
t2.49 7.1% Chlorhexidine solution applied to the umbilicus

t3.1 **Table 3** Individual-level validation of register recording for Chlorhexidine cord-application, EN-BIRTH Study ($n = 6711$)

t3.2		Azimpur (BD) Tertiary		Kushtia (BD) District		Pokhara (NP) Regional		Pooled (Random effects)	
t3.3		N (%)	(CI)	N (%)	(CI)	N (%)	(CI)	N (%)	(CI)
t3.4	Register-recorded denominator	2222 livebirths		1839 livebirths		6711 livebirths			
t3.5	All modes of birth combined								
t3.6	Observer prevalence %	2582 (89.3)		2257 (97.9)		7112 (99.4)		99.6	(88.8,99.9)
t3.7	Register-recorded prevalence %	2185 (98.3)		1796 (97.7)		5282 (78.7)		93.7	(76.4100.0)
t3.8	Not recorded	13 (0.6)		41 (2.2)		1394 (20.8)		5.4	(0.0,23.5)
t3.9	Not readable	0 (0)		0 (0)		4 (0.1)		0.0	(0.0,0.1)
t3.10	INCLUDES NOT RECORDED AND NOT READABLE AS NO								
t3.11	> 10 Cell counts	No		No		Yes			
t3.12	% agreement	88.6		96.4		78.7		89.0	(76.4,97.1)
t3.13	Sensitivity	**	**	**	**	79	78, 80	93.8	(76.7100.0)
t3.14	Specificity	**	**	**	**	25	12.7, 41.2	8.8	(0.0,0.280)
t3.15	EXCLUDES NOT RECORDED AND NOT READABLE								
t3.16	> 10 Cell counts	No		No		No			
t3.17	% agreement	88.6		96.4		98.9		95.5	(87.7,99.5)
t3.18	Sensitivity	**	**	**	**	**	**	**	**
t3.19	Specificity	**	**	**	**	**	**	**	**
t3.20	Vaginal births								
t3.21	Observer prevalence %	731 (96.3)		1290 (96.5)		6075 (99.4)		97.7	(94.4,99.6)
t3.22	Register-recorded prevalence %	547 (97.9)		1073 (97.6)		4963 (84.3)		94.5	(82.2,99.9)
t3.23	Not recorded	7 (1.3)		25 (2.3)		894 (15.2)		4.9	(0.0,17.1)
t3.24	Not readable	0 (0)		0 (0)		3 (0.1)		0.0	(0.0,0.1)
t3.25	INCLUDES NOT RECORDED AND NOT READABLE AS NO								
t3.26	> 10 Cell counts	No		No		No			
t3.27	% agreement	94.4		95.4		83.9		91.9	(82.1,98.0)
t3.28	Sensitivity	**	**	**	**	**	**	**	**
t3.29	Specificity	**	**	**	**	**	**	**	**
t3.30	EXCLUDES NOT RECORDED AND NOT READABLE								
t3.31	> 10 Cell counts	No		No		No			
t3.32	% agreement	94.4		95.4		98.9		96.6	(92.5,99.1)
t3.33	Sensitivity	**	**	**	**	**	**	**	**
t3.34	Specificity	**	**	**	**	**	**	**	**
t3.35	Caesarean births								
t3.36	Observer prevalence %	1850 (86.8)		967 (99.8)		1037 (99.2)		97.1	(85.6100.0)
t3.37	Register-recorded prevalence %	1638 (98.5)		723 (97.7)		318 (39)		85.5	(41.5100.0)
t3.38	Not recorded	6 (0.4)		16 (2.2)		495 (60.7)		12.9	(0.0,58.9)
t3.39	Not readable	0 (0)		0 (0)		1 (0.1)		0.0	(0.0,0.1)
t3.40	INCLUDES NOT RECORDED AND NOT READABLE AS NO								
t3.41	> 10 Cell Counts	No		No		No			
t3.42	% agreement	86.6		**		40.2		79.5	(43.2,99.3)
t3.43	Sensitivity	**	**	**	**	**	**	**	**
t3.44	Specificity	**	**	**	**	**	**	**	**

Table 3 Individual-level validation of register recording for Chlorhexidine cord-application, EN-BIRTH Study ($n = 6711$) *(Continued)*

	Azimpur (BD) Tertiary		Kushtia (BD) District		Pokhara (NP) Regional		Pooled (Random effects)	
	N (%)	(CI)	N (%)	(CI)	N (%)	(CI)	N (%)	(CI)
EXCLUDES NOT RECORDED AND NOT READABLE								
> 10 Cell counts	No		No		No			
% agreement	86.6		**		99.1		95.7	(85.5100.0)
Sensitivity	**	**	**	**	**	**	**	**
Specificity	**	**	**	**	**	**	**	**

$n = 12,379$ observed livebirths, $n = 10,772$ livebirths with register records
** = result suppressed due to 10 or fewer count per column of two-by-two table
7.1% Chlorhexidine solution applied to the umbilicus

busy CEmONC hospitals. Women could have experienced less separation from their newborn and thus been able to see the CHX applied to the cord, or indeed may have had to buy the CHX, or apply it personally. Alternatively, the variation between findings may be associated with the quality of health worker communication to women. Exit survey findings suggest that health worker communication needs improvement. Only 0.1–5.6% of women reported that health workers told them why CHX was used. This lack of awareness could be driven by the proximity of events to birth, or a communication failure between health workers and women.

The register data underestimated coverage in two hospitals, performing poorly in one out of three. Register design was found to be an important factor in the accuracy of register-recorded coverage in this study; registers with specific columns outperformed those with non-specific columns. However, in Bangladesh registers, completion instructions meant it was not possible to understand whether the intervention was deliberately 'not given' or was not recorded in the register for other reasons (i.e. forgotten). Global guidance around register design and indicator prioritisation is required, although implementation and supportive supervision are also crucial. Both hospitals in Bangladesh used the same register design and instructions; however, they did not perform equally. This may be related to different implementation strategies, as Azimpur staff received more detailed training and ongoing support during register rollout.

To date, validation research for tracking of cord care practices has focused on population-based survey platforms with no published evaluation regarding routine facility-based measurement systems. This is a major gap, given as many as 20 countries have a national policy for CHX that includes facilities, and demonstrates the need for inclusion of CHX as part of the WHO policy portal [22]. To our knowledge, EN-BIRTH is the first study to assess validity of CHX measurement from routine registers. Register design was found to be an important factor in the accuracy of register-recorded coverage in this study, registers with specific columns outperforming non-specific columns. However, the specific column in Azimpur was ticked when CHX was not given and demonstrates the need for consistent implementation, as well as design.

The increasing proportion of caesarean section births worldwide has important implications for both care and measurement. In one hospital in our study, women who

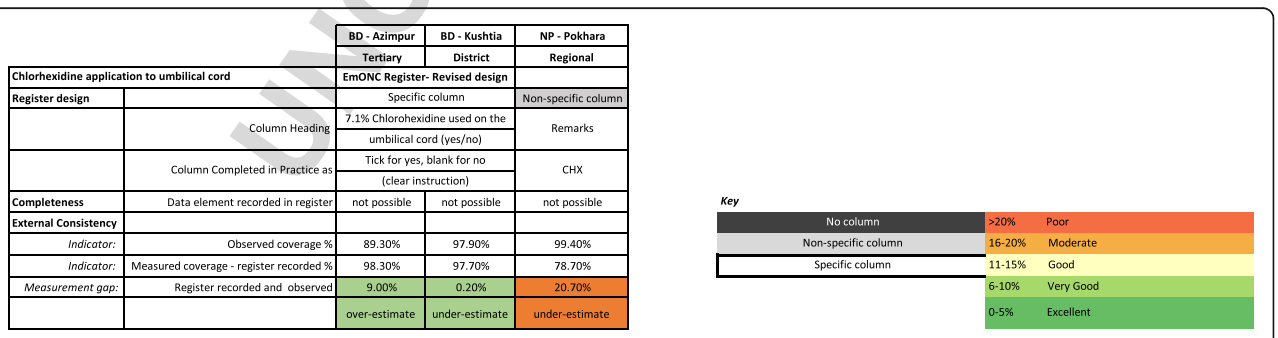


Fig. 4 Facility register design and completion approaches for Chlorhexidine application by site, EN-BIRTH study ($n = 12,379$). $n = 12,379$ observed livebirths, $n = 10,772$ register extracted livebirths. BD: Bangladesh; NP: Nepal. 7.1% Chlorhexidine solution applied to the umbilicus. In Bangladesh, the registers were revised to standardised national EmONC register (Additional file 3), neither original facility register had any column for CHX documentation. Completeness calculations are "not possible" for Bangladesh registers as the design if for blank to mean intervention/practice is not done. Reference: Cut-off ranges adapted from WHO Data Quality Review, Module 2 "Desk review of data quality" [36]

Chlorhexidine application to umbilical cord	Ratio	BD - Azimpur Tertiary Revised register	BD - Kushtia District Revised register	NP - Pokhara Regional	All sites pooled (Random Effects)	95% CI
All modes of birth combined	Survey: Observed	0.01	0.38	0.09	0.12	0.00 - 0.35
	Register: Observed	1.1	0.99	0.79	0.94	0.86 - 1.00
Vaginal births	Survey: Observed	0.01	0.46	0.09	0.14	0.00 - 0.42
	Register: Observed	1	1.01	0.85	0.97	0.87 - 1.00
Caesarean births	Survey: Observed	0.01	0.05	0.06	0.08	0.00 - 0.28
	Register: Observed	1.13	0.98	0.4	0.88	0.40 - 1.00

< 0.80	OR	>1.20	Poor
0.80 to 0.84	OR	1.16 to 1.20	Moderate
0.85 to 0.89	OR	1.11 to 1.15	Good
0.90 to 0.94	OR	1.06 to 1.10	Very Good
0.95 to 0.99	OR	1.00 to 1.05	Excellent
Data not captured in register			

f5.1 **Fig. 5** Heat Map of Validity Ratios for Chlorhexidine cord application, EN-BIRTH study. BD: Bangladesh; NP: Nepal. Using cut off ranges adapted
f5.2 from WHO Data Quality Review, Module 2 "Desk review of data quality" [36]. Survey-reported to observed and register-recorded to observed.
f5.3 Observation $n = 12{,}379$ livebirths, register-recorded $n = 10{,}002$ livebirths and exit survey-reported $n = 11{,}827$ women with livebirths. 7.1%
f5.4 Chlorhexidine solution applied to the umbilicus
f5.5

had caesarean underestimated CHX coverage by 75%. In the other two sites there was very little difference between vaginal and caesarean births. Newborns may be cared for separately from their mothers after surgery, and caesarean birth may exacerbate communication gaps, especially if the woman had a general anaesthetic or was unwell following surgery.

Interestingly, the high coverage and timely application of CHX is in marked contrast to low coverage for breastfeeding, where we found early initiation in the first hour after birth to be just 19% averaged across all five EN-BIRTH study sites [39]. Immediate newborn care is part of essential newborn care and includes a number of practices such as delayed cord clamping, breastfeeding, and skin-to-skin contact, which are needed in the first few minutes after birth. Pre-discharge interventions such as eye care, vitamin K, newborn assessment, cord care and immunisations are required; all should be implemented with a focus on zero separation of women and their newborns [15].

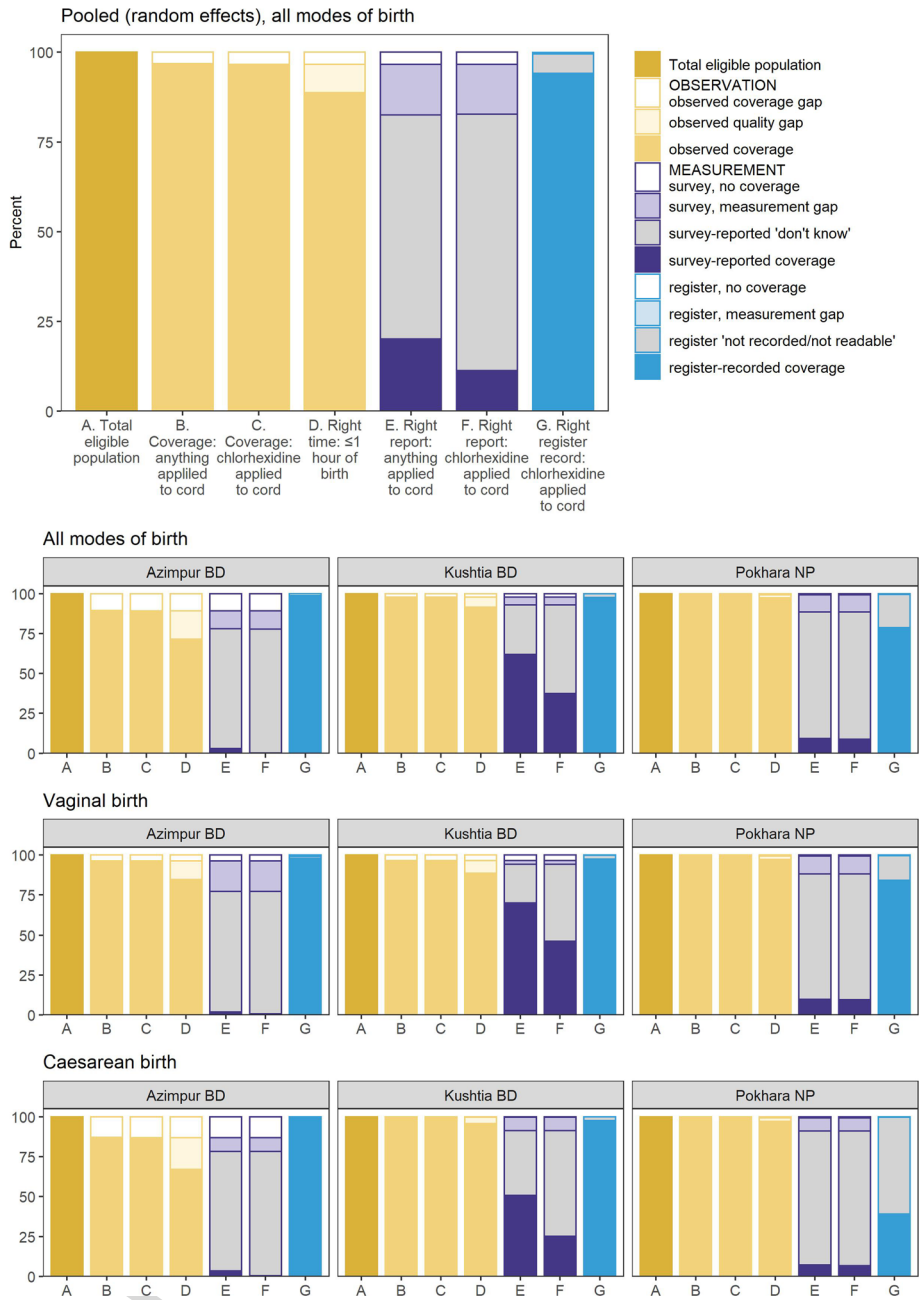
The immediate newborn care practice with the strongest evidence base is early initiation of breastfeeding, with high impact for reducing newborn morbidity and mortality and contributing to health gains for the woman [40–42]. CHX application does not yet have strong evidence regarding facility-based application or for requiring application within minutes. Under time pressure, health workers might prioritise more easily achieved simple tasks, such as CHX application, over potentially time-consuming practices like assisting a mother and baby to breastfeed. Other possibilities of why CHX was prioritised at our study sites might include location of the CHX product (which is only available on the labour ward, rather than postnatal wards) or short admission stays where staff take the opportunity immediately. There are important research questions around the sequencing for immediate and essential newborn care practices to optimise mortality impact, especially with increasing time pressures on the few midwives and other health care professionals.

Strengths and limitations

Strengths of this study include direct observation as the gold standard, data collection by trained providers using a custom-built tablet application with timestamping, the large sample size and the multi-country, multi-site contexts.

In terms of limitations, we note that validation results are based on CEmONC hospitals, which might not be generalizable to lower levels of care or for women who birth at home or in private facilities. The presence of researchers could have influenced how health workers completed routine registers (Hawthorne effect) [43]; however, assessment of pre- and during study register data quality is published separately and shows very little difference over time [35].

Our survey questions were aligned to the current DHS optional survey module questions regarding applications to the umbilical cord. However, EN-BIRTH asked



f6.1 **Fig. 6** Gap analysis for Chlorhexidine cord application coverage and quality, EN-BIRTH study (n = 12,379). Register-records n = 11,002 livebirths,
f6.2 and exit survey-report n = 11,827 women with livebirths. 'Right time' < 1 h was used here as the observation period is only during admission to
f6.3 labour and delivery wards. The current WHO recommendations advise that Chlorhexidine application should be completed within the first week
f6.4 of life. REF: World Health Organization. Recommendations on Postnatal care of the mother and newborn. WHO Library Cataloguing- Oct 2013.
f6.5 2014. 7.1% Chlorhexidine solution applied to the umbilicus
f6.6

537 women at exit interviews with a short recall period, ra-
538 ther than 3–5 years later, as is usual practice in
539 population-based surveys. Hence, our results could over-
540 estimate the validity of measurement for these survey
541 questions, since women may be more likely to accurately
542 report care in this shorter time interval (very soon after
543 birth). Conversely, many women reported "don't know"
544 and it is possible that for home births they may have
545 known more about what was done to their newborn's
546 cord.

Research to improve measurement

547 Assessment for impact of CHX in facility settings is
548 ongoing, with results from a trial in Uganda expected
549

soon [20]. For countries that already have a policy of facility-based CHX cord application, further implementation research to explore how register design, filling and use can improve data quality is required. Such research should include assessment of health worker training and support. In addition to assessment of data flow and data quality for this indicator's inclusion in national routine HMIS, evidence of feasibility and cost effectiveness are also required [34]. For home births in high mortality contexts, validation of survey questions regarding women's report of CHX application on day of birth and afterwards is necessary. These studies could also explore use of visual prompts as used by DHS, such as a picture of the commodity packaging most commonly used in that context.

Conclusions

Routine register data performed better than exit survey-report for measurement of CHX coverage in hospitals. Routine registers are a promising source of data where there is a national policy for facility-based CHX application. Further research should assess the opportunity costs in time for health workers to record, as well as utility of the data if coverage is already extremely high. Attention to home births is essential to ensure the poorest and most at-risk families are not omitted from coverage measurement.

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s12884-020-03338-4.

Additional file 1. Chlorhexidine question wording compared with DHS/MICS. DHS: Demographic and Health Surveys; MICS: Multiple Indicator Cluster Surveys.

Additional file 2. EN-BIRTH cord care survey questionnaire used to collect information about cord care and Chlorhexidine cord cleansing.

Additional file 3. EN-BIRTH study data collection dates by site and time elapsed between birth and exit survey. Sample size was calculated to observe at least 106 observations per intervention per country, based on estimated coverage of intervention during formative research.

Additional file 4. Ethical approval of local institutional review boards for EN-BIRTH study Voluntary informed 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 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 approached for recruitment and consent. No health worker refused participation and all maintained the right to withdraw throughout the study. 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 5. STROBE statement—checklist of items that should be included in reports of observational studies. *Give information separately for cases and controls in case-control studies and, if applicable, for exposed 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 article (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.

Additional file 6. Individual-level validation in exit-survey report of umbilical cord care practices, EN-BIRTH study (n = 12,379) n = 12,379 observed livebirths, n = 11,827 livebirths with survey. Red colour: cell count is < 5 in 2 × 2 table; blank (**) indicates cell could not construct as 2 × 2 table; Green colour: cell count is ≥5 but < 10 in 2 × 2 table.

Additional file 7. Exit-survey reported health-worker communication of Chlorhexidine application, EN-BIRTH study (n = 11,639 live births). *Total includes vaginal and caesarean. n = Number; % = Percentage; CHX: Chlorhexidine

Additional file 8. Validation register-recorded umbilical cord care practices, EN-BIRTH study (n = 10,772). Red colour: cell count is < 5 in 2 × 2 table; blank (**) indicates cell could not construct as 2 × 2 table; Green colour: cell count is ≥5 but < 10 in 2 × 2 table.

Additional file 9. Descriptive data for observer-assessed, register-recorded, and survey-reported Chlorhexidine cord application, EN-BIRTH study (n = 12,379 live births).

Abbreviations

BD: Bangladesh; CEmONC: Comprehensive emergency obstetric and newborn care; CHX: 7.1% Chlorhexidine application to the umbilical cord; CIFF: Children's Investment Fund Foundation; DHS: Demographic Health Surveys Program; EN-BIRTH: *Every Newborn*-Birth Indicators Research Tracking in Hospitals study; HMIS: Health Management Information System; icddr,b: International Centre for Diarrheal Disease Research, Bangladesh; LMIC: Low- and Middle- Income Countries; LSHTM: London School of Hygiene & Tropical Medicine; MCHTI: Maternal and Child Health Training Institute, Azimpur, Bangladesh; MICS: Multiple Indicator Cluster Survey; NP: Nepal; PRISM: Performance of Routine Information System Management; UNICEF: United Nations International Children's Emergency Fund; WHO: World Health Organisation

Acknowledgements

Firstly, and most importantly, we thank the women, their families, the health workers and data collectors. We credit the inspiration of the late Godfrey Mbaruku. We thank Claudia DaSilva, Veronica Ulaya, Mohammad Raisul Islam, Susheel Karki, Bhula Rai and Maria Cesay for their administrative support and Sabrina Jabeen, Goutom Banik, Md. Shahidul Alam, Tamatun Islam Tanha and Md. Moshiur Rahman for support during data collectors training.
We acknowledge the following groups for their guidance and support:
National Advisory Groups:
Bangladesh: Mohammad Shahidullah, Khaleda Islam, Md Jahurul Islam.
Nepal: Naresh P KC, Parashu Ram Shrestha, Tara Pokharel, Uwe Ewald.
Tanzania: Muhammad Bakari Kambi, Georgina Msemo, Asia Hussein, Talhiya Yahya, Claud Kumalija, Eliakim Eliud, Mary Azayo, Mary Drake, Onest Kimaro.
EN-BIRTH validation collaborative group:
Bangladesh: Md. Ayub Ali, Bilkish Biswas, Rajib Haider, Md. Abu Hasanuzzaman, Md. Amir Hossain, Ishrat Jahan, Rowshan Hosne Jahan, Jasmin Khan, M A Mannan, Tapas Mazumder, Md. Hafizur Rahman, Md. Ziaul Haque Shaikh, Aysha Siddika, Taslima Akter Sumi, Md. Taqbir Us Samad Talha.
Tanzania: Evelyne Assenga, Claudia Hanson, Edward Kija, Rodrick Kisenge, Karim Manji, Fatuma Manzi, Namala Mkopi, Mwifadhi Mrisho, Andrea Pembe.
Nepal: Jagat Jeevan Ghimire, Regina Gurung, Elisha Joshi, Avinash K Sunny, Naresh P. KC, Nisha Rana, Shree Krishna Shrestha, Dela Singh, Parashu Ram Shrestha, Nishant Thakur,
LSHTM: Hannah Blencowe, Sarah G Moxon.
EN-BIRTH Expert Advisory Group: Agbessi Amouzou, Tariq Azim, Debra Jackson, Theopista John Kabuteni, Matthews Mathai, Jean-Pierre Monet, Allisyn Moran, Pavani Ram, Barbara Rawlins, Jennifer Requejo, Johan Ivar Sæbø, Florina Serbanescu, Lara Vaz.

About this supplement

This article has been published as part of BMC Pregnancy and Childbirth Volume 20 Supplement 1, 2020: Every Newborn BIRTH multi-country study; informing measurement of coverage and quality of maternal and newborn care. The full contents of the supplement are available online at https://

bmcpregnancychildbirth.biomedcentral.com/articles/supplements/volume-20-supplement-1.

Authors' contributions

The EN-BIRTH study was conceived by JEL, who acquired the funding and led the overall design with support from HR. Each of the three country research teams input to design of data collection tools and review processes, data collection and quality management with technical coordination from HR, GGL, and DB. The icddr,b team (notably AER, TT, TH, QSR, SA and SBZ) led the development of the software application, data dashboards and database development with VG and the LSHTM team. IHI (notably DS) coordinated work on barriers and enablers for data collection and use, working closely with LTD. QSR was the main lead for data management working closely with OB, KS and LTD. For this paper, SBZ, ABS and HR led the analyses and first draft of manuscript working closely with JEL and SA. All authors (AKC, KP, SA, NT, QSR, NS, RG, TT, AER, PSC, BR, LTD) revised the manuscript and gave final approval of the version to be published and agree to be accountable for the work. The EN-BIRTH study group authors made contributions to the conception, design, data collection or analysis or interpretation of data. This paper is published with permission from the Directors of Ifakara Health Institute, Muhimbili University of Health and Allied Sciences, icddr,b and Golden Community. The author's views are their own, and not necessarily from any of the institutions they represent.
EN-BIRTH Study Group. **Bangladesh:** Qazi Sadeq-ur Rahman, Ahmed Ehsanur Rahman, Tazeen Tahsina, Sojib Bin Zaman, Shafiqul Ameen, Tanvir Hossain, Abu Bakkar Siddique, Aniqa Tasnim Hossain, Tapas Mazumder, Jasmin Khan, Taqbir Us Samad Talha, Rajib Haider, Md. Hafizur Rahman, Anisuddin Ahmed, Shams Arifeen. **Nepal:** Omkar Basnet, Avinash K Sunny, Nishant Thakur, Regina Jurung, Anjani Kumar Jha, Bijay Jha, Ram Chandra Bastola, Rajendra Paudel, Asmita Paudel, Ashish KC. **Tanzania:** Nahya Salim, Donat Shamba, Josephine Shabani, Kizito Shirima, Menna Narcis Tarimo, Godfrey Mbaruku (deceased), Honorati Masanja. **LSHTM:** Louise T Day, Harriet Ruysen, Kimberly Peven, Vladimir S Gordeev, Georgia R Gore-Langton, Dorothy Boggs, Stefanie Kong, Angela Baschieri, Simon Cousens, Joy E Lawn.

Funding

The Children's Investment Fund Foundation (CIFF) are the main funder of the EN-BIRTH Study and funding is administered via The London School of Hygiene & Tropical Medicine. The Swedish Research Council specifically funded the Nepal site through Lifeline Nepal and Golden Community. Publication of this manuscript has been funded by CIFF. CIFF attended the study design workshop but had no role in data collection, analysis, data interpretation, report writing or decision to submit for publication. The corresponding author had full access to study data and final responsibility for publication submission decision.

Availability of data and materials

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

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 4).
Voluntary informed written consent was obtained from all observed participants, their families for newborns, and respondents for the qualitative interviews. Participants 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. EN-BIRTH is study number 4833, registered at https://www.researchregistry.com

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

Author details

[1]Maternal and Child Health Division, International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b), 68 Shahid Tajuddin Ahmed Sarani, Mohakhali, Dhaka, Bangladesh. [2]The Maternal, Adolescent, Reproductive, & Child, Health (MARCH) Centre, London School of Hygiene & Tropical Medicine, London WC1E 7HT, UK. [3]Department of Women's and Children's Health, Uppsala University, Uppsala, Sweden. [4]Florence Nightingale Faculty of Nursing, Midwifery & Palliative Care, King's College London, London, UK. [5]Research Division, Golden Community, Lalitpur, Nepal. [6]Department of Paediatrics and Child Health, Muhimbili University of Health and Allied Sciences, Dar es Salaam, Tanzania. [7]Department of Health Systems, Impact Evaluation and Policy, Ifakara Health Institute, Dar es Salaam, Tanzania. [8]PATH, Seattle, WA, USA. [9]Maternal and Child Survival Program, jhpiego, Baltimore, MD, USA.

References

1. Blencowe H, Cousens S. Addressing the challenge of neonatal mortality. Tropical Med Int Health. 2013;18(3):303–12.
2. UNICEF. The state of the World's children 2019. Children, food and nutrition: growing well in a changing world. New York: UNICEF; 2019. [https://www.unicef.org/reports/state-of-worlds-children-2019]. Accessed 29 Sep 2020.
3. Liu L, Johnson HL, Cousens S, Perin J, Scott S, Lawn JE, Rudan I, Campbell H, Cibulskis R, Li M. Global, regional, and national causes of child mortality: an updated systematic analysis for 2010 with time trends since 2000. Lancet. 2012;379(9832):2151–61.
4. Moran AC, Kerber K, Sitrin D, Guenther T, Morrissey CS, Newby H, Fishel J, Yoder PS, Hill Z, Lawn JE. Measuring coverage in MNCH: indicators for global tracking of newborn care. PLoS Med. 2013;10(5):e1001415.
5. Mullany LC, Darmstadt GL, Tielsch JM. Role of antimicrobial applications to the umbilical cord in neonates to prevent bacterial colonization and infection: a review of the evidence. Pediatr Infect Dis J. 2003;22(11):996.
6. World Health Organisation: Recommendations on Postnatal care of the mother and newborn. 2014 WHO library cataloguing- Oct 2013. [https://www.who.int/maternal_child_adolescent/documents/postnatal-care-recommendations/en/]. Accessed 29 Sep 2020.
7. PATH: From research to use: saving newborn lives with chlorhexidine for umbilical cord care. 2017. [https://path.azureedge.net/media/documents/DT_CHX_story_rpt.pdf]. Accessed 29 Sep 2020.
8. El Arifeen S, Mullany LC, Shah R, Mannan I, Rahman SM, Talukder MRR, Begum N, Al-Kabir A, Darmstadt GL, Santosham M. The effect of cord cleansing with chlorhexidine on neonatal mortality in rural Bangladesh: a community-based, cluster-randomised trial. Lancet. 2012;379(9820):1022–8.
9. Mullany LC, Darmstadt GL, Khatry SK, Katz J, LeClerq SC, Shrestha S, Adhikari R, Tielsch JM. Topical applications of chlorhexidine to the umbilical cord for prevention of omphalitis and neonatal mortality in southern Nepal: a community-based, cluster-randomised trial. Lancet. 2006;367(9514):910–8.
10. McClure EM, Goldenberg RL, Brandes N, Darmstadt GL, Wright LL, Group CW. The use of chlorhexidine to reduce maternal and neonatal mortality and morbidity in low-resource settings. Int J Gynecol Obstet. 2007;97(2):89–94.
11. Imdad A, Bautista RMM, Senen KAA, Uy MEV, Mantaring JB III, Bhutta ZA. Umbilical cord antiseptics for preventing sepsis and death among newborns. Cochrane Database Syst Rev. 2013;(5).
12. Soofi S, Cousens S, Imdad A, Bhutto N, Ali N, Bhutta ZA. Topical application of chlorhexidine to neonatal umbilical cords for prevention of omphalitis and neonatal mortality in a rural district of Pakistan: a community-based, cluster-randomised trial. Lancet. 2012;379(9820):1029–36.
13. Mullany LC, Shah R, El Arifeen S, Mannan I, Winch PJ, Hill A, Darmstadt GL, Baqui AH. Chlorhexidine cleansing of the umbilical cord and separation time: a cluster-randomized trial. Pediatrics. 2013;131(4):708–15.
14. Mullany LC, Darmstadt GL, Khatry SK, LeClerq SC, Katz J, Tielsch JM. Impact of umbilical cord cleansing with 4.0% chlorhexidine on time to cord separation among newborns in southern Nepal: a cluster-randomized, community-based trial. Pediatrics. 2006;118(5):1864–71.
15. World Health Organisation. WHO Recommendations on newborn health: guidelines approved by the WHO guidelines review committee. Geneva: WHO; 2017. [https://apps.who.int/iris/handle/10665/259269]. Accessed 29 Sep 2020.
16. Sazawal S, Dhingra U, Ali SM, Dutta A, Deb S, Ame SM, Mkasha MH, Yadav A, Black RE. Efficacy of chlorhexidine application to umbilical cord on

neonatal mortality in Pemba, Tanzania: a community-based randomised controlled trial. Lancet Glob Health. 2016;4(11):e837–44.
17. Semrau KE, Herlihy J, Grogan C, Musokotwane K, Yeboah-Antwi K, Mbewe R, Banda B, Mpamba C, Hamomba F, Pilingana P. Effectiveness of 4% chlorhexidine umbilical cord care on neonatal mortality in Southern Province, Zambia (ZamCAT): a cluster-randomised controlled trial. Lancet Glob Health. 2016;4(11):e827–36.
18. Okomo U, Akpalu EN, Le Doare K, Roca A, Cousens S, Jarde A, Sharland M, Kampmann B, Lawn JE. Aetiology of invasive bacterial infection and antimicrobial resistance in neonates in sub-Saharan Africa: a systematic review and meta-analysis in line with the STROBE-NI reporting guidelines. Lancet Infect Dis. 2019;19(11):1219–34.
19. Mwananyanda L, Pierre C, Mwansa J, Cowden C, Localio AR, Kapasa ML, Machona S, Musyani CL, Chilufya MM, Munanjala G. Preventing bloodstream infections and death in Zambian neonates: impact of a low-cost infection control bundle. Clin Infect Dis. 2019;69(8):1360–7.
20. Nankabirwa V, Tylleskär T, Tumuhamye J, Tumwine JK, Ndeezi G, Martines JC, Sommerfelt H. Efficacy of umbilical cord cleansing with a single application of 4% chlorhexidine for the prevention of newborn infections in Uganda: study protocol for a randomized controlled trial. Trials. 2017;18(1):322.
21. Mullany LC, El Arifeen S, Khatry SK, Katz J, Shah R, Baqui AH, Tielsch JM. Impact of chlorhexidine cord cleansing on mortality, omphalitis, and cord separation time among facility-born babies in Nepal and Bangladesh. Pediatr Infect Dis J. 2017;36(10):1011.
22. Global chlorhexidine scale-up tracker: location of use [https://www.healthynewbornnetwork.org/chlorhexidine-location/]. Accessed 28 Sep 2020.
23. Multiple indicator cluster surveys (MICS)6 tools [http://mics.unicef.org/tools#survey-design]. Accessed 29 Sep 2020.
24. Demographic and Health Surverys (DHS) Model questionnaire - phase 7 [https://dhsprogram.com/publications/publication-dhsq7-dhs-questionnaires-and-manuals.cfm]. Accessed 29 Sep 2020.
25. Bhattacharya AA, Allen E, Umar N, Usman AU, Felix H, Audu A, Schellenberg JR, Marchant T. Monitoring childbirth care in primary health facilities: a validity study in Gombe State, northeastern Nigeria. J Glob Health. 2019;9(2).
26. Hancioglu A, Arnold F. Measuring coverage in MNCH: tracking progress in health for women and children using DHS and MICS household surveys. PLoS Med. 2013;10(5):e1001391.
27. Blanc AK, Diaz C, McCarthy KJ, Berdichevsky K. Measuring progress in maternal and newborn health care in Mexico: validating indicators of health system contact and quality of care. BMC Pregnancy Childbirth. 2016;16(1):255.
28. Blanc AK, Warren C, McCarthy KJ, Kimani J, Ndwiga C, RamaRao S. Assessing the validity of indicators of the quality of maternal and newborn health care in Kenya. J Glob Health. 2016;6(1).
29. McCarthy KJ, Blanc AK, Warren CE, Kimani J, Mdawida B, Ndwidga C. Can surveys of women accurately track indicators of maternal and newborn care? A validity and reliability study in Kenya. J Glob Health. 2016;6(2).
30. Stanton CK, Rawlins B, Drake M, dos Anjos M, Cantor D, Chongo L, Chavane L, da Luz VM, Ricca J. Measuring coverage in MNCH: testing the validity of women's self-report of key maternal and newborn health interventions during the peripartum period in Mozambique. PLoS One. 2013;8(5):e60694.
31. Strachan M, Drake M, Rawlins B, Dwivedi V, Levine B, Ly M, Ishola G: Strengthening health management information systems for maternal and child health: documenting MCHIP's Contributions. Baltimore: Jhpiego , 17:2014.
32. Jolivet RR, Moran AC, O'Connor M, Chou D, Bhardwaj N, Newby H, Requejo J, Schaaf M, Say L, Langer A. Ending preventable maternal mortality: phase II of a multi-step process to develop a monitoring framework, 2016–2030. BMC Pregnancy Childbirth. 2018;18(1):258.
33. World Health Organisation, UNICEF. Every newborn; an action plan to end preventable deaths. Geneva: WHO; 2014. [https://www.who.int/maternal_child_adolescent/newborns/every-newborn/en/]. Accessed 29 Sep 2020.
34. Day LT, Ruysen H, Gordeev VS, Gore-Langton GR, Boggs D, Cousens S, Moxon SG, Blencowe H, Baschieri A, Rahman AE, et al. "Every Newborn-BIRTH" protocol: observational study validating indicators for coverage and quality of maternal and newborn health care in Bangladesh, Nepal and Tanzania. J Glob Health. 2019;9(1).
35. Day LT, Rahman Q, Rahman A, Salim N, KC A, Ruysen H, Tahsina T, Masanja H, Basnet O, Gordeev V, et al. Every newborn-BIRTH observational study to test validity of newborn and maternal coverage measurement in routine systems and surveys. Lancet Glob Health. [In Press].
36. World Health Organisation. Data quality review: a toolkit for facility data quality assessment. Module 2: desk review of data quality. Geneva: World Health Organisation; 2017. [https://apps.who.int/iris/handle/10665/259225]. Accessed 28 Sep 2020.
37. Shamba D, Day LT, Zaman SB, Khan J, Talha T, Rahman M, Kayastha A, Thakur N, Tarimo M, Singh N et al: Barriers and enablers to routine data collection and use: EN-BIRTH multi-country study informing routine measurement of coverage and quality BMC Pregnancy Childbirth [In press].
38. Performance of Routine Information System Management (PRISM) [https://www.measureevaluation.org/our-work/routine-health-information-systems/performance-of-routine-information-system-management-prism.]. Accessed 29 Sep 2020.
39. Tahsina T, Hossain AT, Ruysen H, Rahman AE, Day LT, Peven K, Rahman QS-U, Khan J, Shabani J, KC A, et al. Immediate newborn care and breastfeeding practices: EN-BIRTH multi-country study informing routine measurement of coverage and quality. BMC Pregnancy Childbirth. 2019; In press.
40. Khan J, Vesel L, Bahl R, Martines JC. Timing of breastfeeding initiation and exclusivity of breastfeeding during the first month of life: effects on neonatal mortality and morbidity—a systematic review and meta-analysis. Matern Child Health J. 2015;19(3):468–79.
41. NEOVITA Study Group. Timing of initiation, patterns of breastfeeding, and infant survival: prospective analysis of pooled data from three randomised trials. Lancet Glob Health. 2016;4(4):e266–75.
42. Debes AK, Kohli A, Walker N, Edmond K, Mullany LC. Time to initiation of breastfeeding and neonatal mortality and morbidity: a systematic review. BMC Public Health. 2013;13(3):S19.
43. Campbell JP, Maxey VA, Watson WA. Hawthorne effect: implications for prehospital research. Ann Emerg Med. 1995;26(5):590–4.

Publisher's Note