BMC Digital Health

RESEARCH

Open Access

eRegMat – a digital registry for improved quality of antenatal care: a cluster-randomized trial in a rural area in Bangladesh

Mahima Venkateswaran[1,2†], Jesmin Pervin[1,3*†], Akuba Dolphyne[2], Ingrid K. Friberg[4], Ingvild Fjeldheim[2], J. Frederik Frøen[1,2], Fatema Khatun[3], Brian O'Donnell[5], Monjur Rahman[3], A. M. Quaiyum Rahman[3], U Tin Nu[3], Christopher James Rose[6,7], Bidhan Krishna Sarker[3] and Anisur Rahman[3]

Abstract

Introduction Longitudinal client tracking systems with digital health interventions are recommended for implementation in resource-limited settings but lack evidence of benefits, harms, and implementation. In the eRegMat cluster-randomized controlled trial, we aimed to assess the effectiveness of an eRegistry versus an unshared digital client record.

Methods Fifty-nine primary health care facilities in Matlab, Bangladesh were randomized with a 1:1 allocation ratio to receive an eRegistry (intervention, 30 health facilities) with decision support, feedback dashboards and targeted client communication, or an unshared digital client record without digital health interventions (control, 29 health facilities). We assessed timely antenatal care attendance, quality of care, and health outcomes. Outcome data were captured in the eRegistry, or unshared digital client record used by health workers, and through a postpartum household survey. We estimated adjusted relative risks (ARRs) following the intention-to-treat principle and adjusted for cluster randomization.

Results From October 2018 to June 2020, 3023 pregnant women were enrolled in the intervention and 2746 in the control groups through community and facility registrations. Intervention and control groups did not differ for the primary outcomes: timely attendance at eligible antenatal care visits (42.5% vs. 40.3%, ARR 0.96, 95% CI 0.89–1.05, *p*-value 0.4) and hypertension screening and management (95.1% vs. 94.7%, ARR 1.00, 95% CI 0.96–1.03, *p*-value 0.8). The secondary outcome of perinatal mortality and severe perinatal morbidities was lower in the intervention (14.6%) compared to the control group (15%) (ARR 0.74, 95% CI 0.58–0.96, *p*-value 0.02), with the change mostly attributed to morbidity outcomes.

Conclusion Due to technical and implementation challenges we were unable to estimate the effect of the intervention with sufficient precision. Challenges included delays in rollout of the digital health interventions and outcome

[†]Mahima Venkateswaran and Jesmin Pervin contributed equally and joint first authorship.

*Correspondence:
Jesmin Pervin
jpervin@icddrb.org
Full list of author information is available at the end of the article

data collection, existence of parallel documentation systems on paper and digital and the COVID-19 pandemic. Given these methodological constraints, we are unable to draw definitive interpretations of trial results.

Trial registration ISRCTN Registry ISRCTN69491836; https://www.isrctn.com/ISRCTN69491836. Date of registration 06.12.2018.

Keywords Antenatal care, Bangladesh, Digital health interventions, Longitudinal client tracking, Health information systems

Background

Despite considerable progress in child and maternal survival in the last two decades, challenges persist in healthcare delivery and utilization in many low- and-middle-income countries (LMICs), including Bangladesh [1, 2]. Health care services provided during pregnancy, childbirth, and postpartum periods help early identification and management of risk factors to prevent maternal and newborn morbidity and mortality. Utilization alone, however, is insufficient to improve health and outcomes, and the quality of care is recognized as an important determinant of better health outcomes [3]. In many LMICs, the quality of care is poor due to a combination of factors, such as a lack of infrastructure, manpower, and supplies in the health facilities, and sub-optimal guideline adherence among health workers [4]. A robust monitoring system, even in resource-limited settings, is an effective tool for ensuring increased utilization and improved quality of health care services. To monitor maternal and child health effectively, a health system should have an accessible pathway of information from ground-level health workers to policy makers on essential health indicators [5] based on a range of data such as pregnancy identification and registrations, antenatal care coverage, pregnancy losses, births, and deaths [6, 7]. Health systems in LMICs largely rely on two sources of data: health information systems and household surveys. In a typical health information system, large amounts of granular or individual-level data are recorded by health workers in a structured paper register, and reporting is limited to a set of simple aggregated count-based indicators. Subsequently, information on diagnoses and risk factors for individuals is not easily accessible to health workers or health systems managers. Digital Health Interventions (DHIs) provide opportunities to tackle several of the barriers to effective data capture and use and to optimize healthcare service delivery [8, 9]. The World Health Organization (WHO) in 2019 recommended a set of prioritized DHIs for health system strengthening [8]. Based on the comprehensive evidence mapping conducted during the guideline development process, the WHO has highlighted the need for more rigorous, high-quality, and adequately powered experimental studies of DHIs to better inform implementations [8, 10].

Maternal and child health is a priority area in the health system of Bangladesh, and different interventions have been implemented that are continuing to improve key service indicators nationwide. About 47% of women receive four or more antenatal care (ANC) visits, and 51% deliver in health facilities [11]. Quality of ANC has been reported to be poor, with studies showing that less than half of women attending ANC receive essential interventions during their visits [12]. Digital health is one of the strategies promoted by the government for improving health and care services [13]. In the last decade, mobile phone ownership, internet connectivity, and information and communication technology use in public services have proliferated in Bangladesh [14]. Several DHIs have been piloted in different parts of the country in response to the rise in technology use, but often as single interventions.

Implementation of multiple DHIs can strengthen the health system and improve health outcomes, with potentially multiplicative effects compared to stand-alone DHIs [8]. Such implementations are only feasible by setting up integrated DHIs within the health information system. eRegistries are digital registries designed to support longitudinal tracking of clients' health status and care services. An eRegistry can support several DHIs such as clinical decision support, feedback dashboards, and targeted client communication, among others [6]. A maternal and child health eRegistry has been implemented in primary healthcare in Palestine. The accompanying cluster-randomized controlled trial in Palestine of the eRegistry versus paper-based records showed effects on quality of care but not on health outcomes [15]. Our aim was to evaluate the effect of an eRegistry compared to unshared digital client records in two rural sub-districts in Bangladesh.

Methods

Study design

We conducted a two-arm cluster-randomized controlled trial in primary care health facilities (Community Clinics and Union Health & Family Welfare Centers) offering routine ANC services in Matlab North and South sub-districts in Bangladesh. The full study protocol describing the context and methods has been published [16]. Our

study was implemented among public maternal, newborn, and child health (MCH) service providers at health facilities and community level. Within the public health system in Bangladesh, MNCH services are provided by the Ministry of Health and Family Welfare (MOH&FW) through two Directorates: The Directorate General of Family Planning (DGFP) and the Directorate General of Health Services (DGHS). Under the DGFP, Family Welfare Visitors (FWV) provide maternal and child health services at Union Health & Family Welfare Centers (FWC) and Family Welfare Assistants (FWA) provide community outreach services. Under the DGHS, Community Health Care Providers (CHCP) offer maternal and child healthcare as well as general healthcare services from Community Clinics (CC), and Health Assistants (HA) provide vaccination services and community outreach services. Both community and facility-based health workers register pregnancies and encourage clients to seek further MCH services, including ANC [16].

Our study area was comprised of 72 public primary health facilities. A digital data capture tool (eRegistry or unshared digital client record) was implemented in all 72 health facilities in June 2018 (refer section on Procedures for more information), following a phase of co-design with stakeholders including national and sub-national clinical experts, district supervisors and sample of target health workers [16]. The overall goal of the implementation was to digitize and support longitudinal tracking of clients' pregnancy-related information and maternal and child health services received across different wings of the public health system. Subsequently, all cadres of community- and facility-based health workers providing ANC were trained to enter clinical information in digital client health records (see Procedures section for more information).

Randomization

All 72 health facilities were assessed (Community Clinics or Union Health & Family Welfare Centers) in the two sub-districts considered for inclusion in the trial. Thirteen were excluded due to unavailability of full-time health care providers or provision of limited ANC services (less than five ANC visits in a month). After initial exclusion, 59 health facilities (Community Clinics or Union Health & Family Welfare Centers) were randomized with a 1:1 allocation ratio to intervention (eRegistry) or control (unshared digital client record) groups. The randomization was stratified by type of health facility (Union Health & Family Welfare Centers and Community Clinics), and constrained on the following characteristics: 1) allocation of the health facility as intervention or control in a preceding project in the study area to strengthen MCH services through increased coverage of four ANC visits and facility deliveries [17]; 2) technological capabilities of staff, based on prior experience using technology (using a phone for SMS or internet, and comfort with technology); 3) average number of new pregnancies per month; and 4) average number of ANC visits per month. All women with a confirmed pregnancy that were registered in the eRegistry, or unshared digital client record were enrolled in the trial between October 2018 and June 2020. No selection criteria were applied to individual women.

Procedures

The intervention was an eRegistry with three DHIs: health worker clinical decision support, feedback dashboards with action items, and targeted client communication via SMS [16, 18]. Health worker clinical decision support was based on the recommended national guidelines for ANC in the public health system and consisted of referral guidance, medication alerts, and flags for risk conditions during pregnancy. Feedback dashboards were customized for each cadre of health workers, with indicators of ANC attendance, and screening and management of hypertension, diabetes, and anemia during pregnancy. Reminders of routine ANC visits, referral reminders for certain high-risk conditions, and facility delivery reminders for those at risk, were implemented as part of targeted client communication via SMS [18]. The DHIs were triggered by data entered into the eRegistry by the health workers. Health workers in the intervention group could access shared digital client records across different cadres and different facilities. This was to support continuity of care for individuals throughout ANC, including in other geographic areas across the sub-districts.

The control arm received a digital data entry tool with unshared digital client records without any DHIs. Health workers in the control arm had no access to client records entered by other users. This was to simulate their paper register system where the health workers would not have access to records entered in the paper registers of other facilities. The 13 health facilities that were not included in the randomization were provided with unshared digital client records, like the control group.

The eRegistry and unshared digital client records were configured in the free and open-source District Health Information Software 2 (DHIS2) Tracker Capture App and accessed through the DHIS2 Tracker Capture App on Android Tablets (community-based health workers) or a browser on Chromebook (facility-based health workers) [19]. Client identification in both arms was facilitated through a separate palm-based biometric application, which generated a unique identifier for each client based on her palm print [20]. The DHIS2 Tracker

Capture App also generated a unique identifier at registration of each pregnancy.

All health workers in the study area (intervention, control, and non-randomized groups) were trained at the start of the implementation in April 2018, and at regular intervals of 3–6 months throughout the trial period. Full details of intervention characteristics can be found in the published trial protocol [16]. Recruitment for the trial started in October 2018 following a "run-in" period of 6 months. The DHIs in the intervention arm were gradually introduced over the course of the trial: Health worker clinical decision support was introduced in October 2018 at the trial start, appointment reminders for the first ANC visit (for clients registered in the community), facility delivery reminders and referral reminders, and feedback dashboards were implemented in July 2019; and appointment reminders for all ANC visits were implemented in December 2019.

At pregnancy identification and registration, women were asked for written informed consent to 1) receive SMS from the study and 2) a home visit 8–14 days after childbirth [16]. For home pregnancy registrations, women were asked about their preferred public health facility for ANC, and this determined allocation to intervention or control groups based on the allocation status of that health facility. If identified as pregnant in a health facility, women were automatically assigned to intervention or control groups, similarly based on the allocation status of that health facility.

The project data manager developed a data dashboard showing the number of pregnant women enrolled by each care provider, which the research team monitored regularly. The research team also attended monthly meetings at the Upazilla (district) level where all the public health care providers with their respective supervisors were available. In these meetings the team discussed issues related to the use of the eRegistry (intervention group) or unshared digital client record (control group).

Outcomes

The primary outcomes were timely attendance at eligible ANC visits according to the national ANC guidelines, and hypertension screening and management (Table 1). The secondary outcomes were timely first ANC visit, high-risk women successfully referred to a skilled provider for additional care, facility delivery, perinatal mortality and severe perinatal morbidities, and severe postpartum anemia (Table 1). Trial outcomes were selected to capture the potential impacts of specific DHIs and in consultation with stakeholders.

The unit of assessment for the primary outcomes was ANC visits, defined based on the national recommendation for ANC in the health system (Table 1). Timely attendance was calculated among those who had an opportunity to attend a given ANC visit by having pregnancy identification done before the visit (Table 1). Hypertension screening and management were assessed at each of the recommended ANC visits. Screening and management were defined by the clinical guidelines in the health system. We allowed for a window of flexibility in terms of gestational age for the definition of timely ANC visit, except for the recommended five-week range for the second ANC visit (24–28 weeks). For example, a 16-week ANC visit was considered to have happened if women attended any time before gestational age of 17 weeks and 6 days. Gestational age at the ANC visit was calculated using the last menstrual period date.

The unit of assessment for the secondary outcomes was women, and we included those eligible for the outcome based on a priori definitions (Table 1). The outcome perinatal mortality and severe perinatal morbidities was defined as a composite outcome of stillbirth, early neonatal death, very preterm births, very low birthweight, severe illness (delayed crying after birth, difficulty in breathing, and convulsion) or hospitalization in the first week of life. This secondary outcome was assessed among all pregnancies enrolled in the trial, and specifically among those with an identified and documented risk factor during ANC (Table 1).

Data collection and blinding

We obtained outcome data from two sources, the digital data capture tool used by health workers in the intervention (eRegistry) and control groups (unshared digital client records), and a postpartum household survey conducted by a separate group of trained data collectors. The postpartum household survey started in July 2019, and all pregnancies enrolled in the trial that were 28–35 weeks of gestation as of July 2019 were included. Data collectors made biweekly phone calls to clients until 35 weeks and weekly thereafter to ascertain pregnancy status. Data collectors subsequently visited the household at 8–14 days of childbirth, when they used a questionnaire to collect data on birth outcomes, ANC utilization as per the woman's handheld ANC cards, and referral care-seeking. The infant's weight was measured, and the woman's finger-prick blood was taken to measure hemoglobin. Participant responses were first recorded on paper and then transferred to an electronic database.

Two field supervisors who resided at the study site were in-charge of monitoring the performance of the data collectors and ensuring quality control throughout the data collection period. Field supervisors conducted random in-person checks of post-partum interviews and reviewed the postpartum survey data for completeness and consistency. If needed, interviews were repeated.

Table 1 Definitions of trial outcomes, the corresponding intervention sub-component and the trial period when all sub-components were available

Outcome	Definition	Intervention with direct effect	Implementation period with all sub-components available
Timely attendance at eligible ANC visits	Timely ANC attendance at recommended visits[a]	Targeted Client Communication via SMS: ANC appointment reminders Health worker clinical decision support Feedback dashboard with action items	December 2019 – June 2020
Screening and management of hypertension in pregnancy	Screening with blood pressure measurement at recommended ANC visits[a] and blood pressure within normal range; and appropriate management if hypertension is detected at any time[b]	Health worker clinical decision support Feedback dashboard with action items	October 2018 – June 2020
Timely first antenatal care visit	ANC visit at or before 16 weeks[c]	Targeted client communication via SMS: ANC visit appointment reminder for first ANC visit	July 2019 – June 2020
High risk[d] women successfully referred to a skilled provider for additional care	Additional care received among those referred for severe anemia, hypertension, or diabetes during pregnancy	Health worker clinical decision support Targeted client communication via SMS: Referral reminders, high risk, facility delivery reminders	July 2019 – June 2020
Facility delivery	Health facility delivery among those that should deliver in a health facility according to identified risk factors during pregnancy	Health worker clinical decision support Targeted client communication via SMS: facility delivery reminders	July 2019 – June 2020
Perinatal mortality and severe perinatal morbidities among all and among those with any risk factors identified[d]	Mortality and morbidities in the perinatal period[e] among all enrolled participants and among those with a risk factor identified in the woman during pregnancy	Health worker clinical decision support Feedback dashboard with action items Targeted client communication via SMS: ANC appointment reminders, referral reminders, facility delivery reminders	December 2019 – June 2020
Severe postpartum anemia	Severe anemia in the postpartum period (hemoglobin 7 g/dl)	Health worker clinical decision support Feedback dashboard with action items Targeted client communication via SMS: ANC appointment reminders, Referral reminders, high risk, facility delivery reminders	December 2019 – June 2020

ANC Antenatal care

[a] Recommended antenatal care visits and gestational age windows for analysis: 16 weeks ($\leq 17+^{6}$ weeks), $24+^{0}$ to $28+^{6}$ weeks, 32 weeks ($31+^{0}$ to $33+^{6}$ weeks), and 36 weeks ($35+^{0}$ to $37+^{6}$ weeks)

[b] Defined as systolic blood pressure $\geq$ 140 mm Hg and diastolic blood pressure $\geq$ 90 mm Hg at $\geq$ 20 weeks of gestation, chronic hypertension if detected < 20 weeks

[c] Defined as an ANC visit $\leq 17+^{6}$ weeks

[d] Risk pregnancies were generated automatically in the eRegistry based on the documentation of certain conditions according to the national guidelines in Bangladesh

[e] Defined as having a stillbirth, early neonatal death, very preterm birth, very low birthweight baby, a neonate that was severely ill or hospitalized in the first week of life

Meetings were held with data collectors weekly to discuss issues with data collection and data quality, and how these could be resolved. Household visits were replaced with phone interviews from March 2020 to June 2020, and until the end of follow-up due to the COVID-19 pandemic.

Given that the facility health workers used the eRegistry for data entry and were provided with DHIs such as clinical decision support and feedback dashboards in the intervention arm, it was not possible to blind them to treatment allocation. Community-based health workers registering pregnant women were blinded to the allocation status of women to intervention or control groups. Data collectors that conducted the postpartum survey to gather outcome data and the statistician that ran the final analyses were blinded to treatment allocation.

All data collected in the digital data capture tool were stored in servers belonging to the Government of Bangladesh. An authorized data manager from the study team routinely extracted predefined, anonymous data from the server. Data from the postpartum household survey were stored in the premises of the implementing institution, the international center for diarrhoeal diseases research (icddr,b), with the personal identifiers removed. The data manager provided complete datasets for analysis from the eRegistry and the postpartum survey.

Statistical analysis

We performed sample size calculations and statistical analyses using Stata 16 (StataCorp LLC, College Station, Texas, USA). We powered the study by assuming the following: an average of 77 women for each cluster; an average of 140 antenatal contacts per cluster; 20% coverage of timely ANC (primary outcome 1) and 12% coverage of hypertension screening and management (primary outcome 2) [21]; an intracluster correlation coefficient (ICC) of 0.1 [22]; statistical power 80%; and significance level 95%. We then estimated an enrollment period of 21-months, at which our trial would be able to detect a minimum clinically significant difference of timely ANC (primary outcome 1) from 20 to 33% and hypertension screening and management (primary outcome 2) from 12 to 22%.

We used data from the postpartum household survey to produce background characteristics of women enrolled in the trial. All analyses followed the intention-to-treat principle: all randomized participants were included and were analyzed in the arms to which their clinics were randomized. We used generalized linear mixed-effects models to estimate the relative risk of each outcome [23]. We accounted for clustering within pregnant woman and clinic, as appropriate, using one- or two-level random intercepts. Where possible, we used fixed-effects to adjust for the stratification variable and the variables used in constrained randomization; the variables monthly numbers of clients and of antenatal clinic visits were modelled on the log scale due to their wide ranges.

This trial suffered an intercurrent event [24] that resulted in some pregnant women being enrolled and randomized before the complete set of intervention subcomponents were available. We performed a non-prespecified simulation study to explore analysis options. This showed that failing to account for the intercurrent event in analysis would likely yield a substantially biased effect estimate. Briefly, if the subcomponents have non-zero effect, then an estimate of effect that does not account for the fact that some participants could not have benefitted from all subcomponents would be biased towards the null. Based on the simulation study and before analyzing the trial data or unblinding, we chose to estimate treatment effect as the sum (on the log RR scale) of one coefficient that estimates the effect of being allocated to the intervention arm and another coefficient that estimates the effect of attending a clinic where the DHIs were available. The simulation study showed that, assuming that treatment effect can be decomposed in this way, estimates of treatment effect are likely to be almost unbiased but somewhat less precise than if the intercurrent event had not occurred.

While some of the outcome data were not collected for some of the pregnant women due to the late start of the postpartum household survey, we have no reason to believe this excessively affected one arm, or some types of clinic or pregnant women (10.1% in the intervention arm and 11.9% in the control arm were not included in the postpartum survey). This evaluation was consistent with the results of exploratory Little's tests [25]. We therefore treated data as missing completely at random and did not impute any data.

We performed estimation using maximum likelihood and report 95% confidence intervals and two-sided p-values, except for outcomes with sparse data (e.g., no outcomes in one arm). In these cases, we used Bayesian analyses and report posterior means and equal-tailed 95% credible intervals (see Additional file 1). We used the $p < 0.05$ significance criterion throughout.

Protocol deviations

The three DHIs in the intervention arm were implemented incrementally, not at the start of first enrollment as originally planned. As a result, some participants were not exposed to specific sub-components of the intervention (see Results section). We have dealt with this in the analysis by accounting for lack of exposure of some participants to the intervention (see Statistical analysis).

Outcome data collection through postpartum household survey did not start until July 2019, about 9 months after trial start in October 2018 [16].

Results

Between October 2018 and June 2020, 3023 women were registered for antenatal care in the intervention group ($n=30$ clusters) and 2746 women registered for antenatal care in the control group ($n=29$ clusters). All clusters allocated to the respective arms were included in the analysis (Fig. 1). At home registration, a slightly higher proportion of women chose health facilities that were randomized to the intervention group: in the intervention group, 2083 (70%) pregnancies were registered in the community and in the control group, 1650 (60%) pregnancies were registered in the community.

The three DHIs in the intervention arm were introduced incrementally (Table 1, Fig. 2). From October 2018 to June 2019, 1237 women were enrolled in the intervention arm and 1070 women were enrolled in the control arm. From July 2019 to November 2019, 688 women were enrolled in the intervention arm and 663 women were enrolled in the control arm. From December 2019 to June 2020, 1098 women were enrolled in the intervention arm and 1013 women were enrolled in the control arm (Fig. 2). COVID-19 pandemic-related restrictions on movement were imposed in the study area in March 2020. Between March and June 2020, 84 women were enrolled in the trial. Slightly more were in the intervention group ($n=61$ women, 55 home pregnancy registrations, and 6 facility registrations) than the control group ($n=23$ women, 4 home pregnancy registrations and 19 facility registrations).

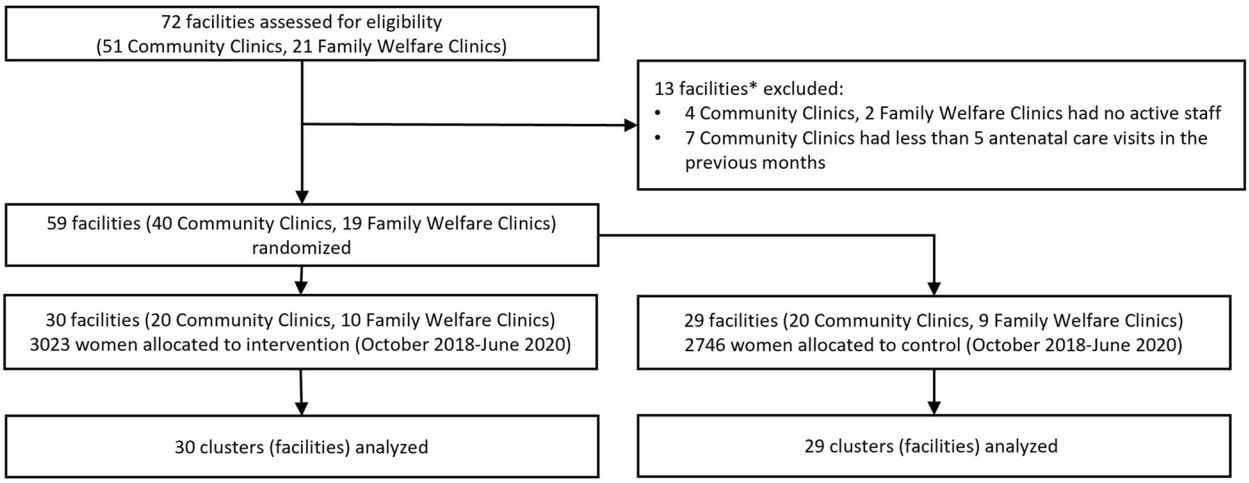

Fig. 1 Participant flow diagram

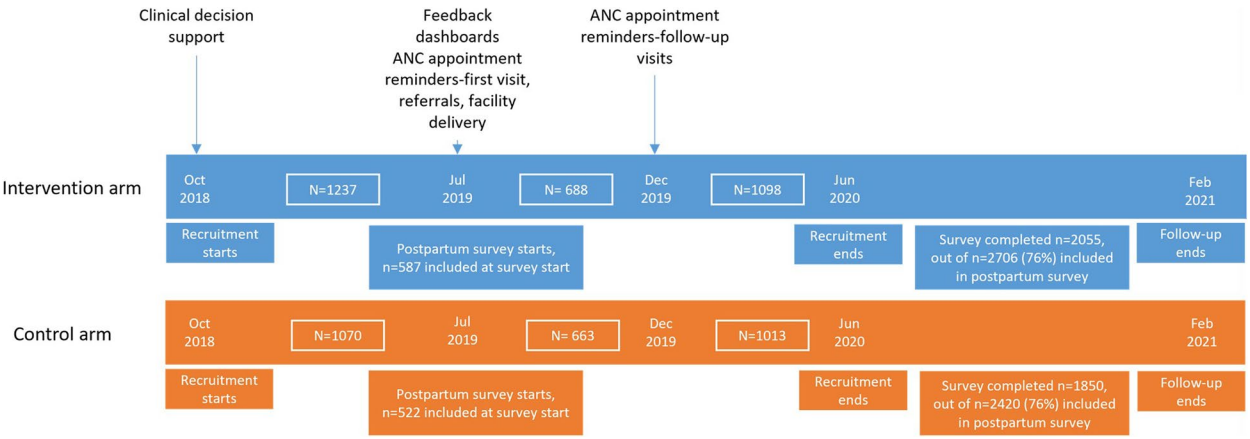

Fig. 2 Trial timeline, implementation of digital health interventions and postpartum survey data collection, and number of pregnant women enrolled

Of all those enrolled in the intervention arm, 2706 women (89.5%) were contacted for the postpartum survey, and 2055 women (75.9%) were surveyed (Fig. 2). In the control arm, 2420 (88.1%) were contacted and 1850 (76.4%) women were surveyed (Fig. 2). Infant weight was measured for 733 women in the intervention group and 652 women in the control group. Hemoglobin measurements were available for only 790 women in the intervention group and 701 women in the control group due to lack of supplies and the inability to do physical household visits due to COVID-19 pandemic restrictions. For hypertension screening and management, all outcome data were derived exclusively from the eRegistry. We assumed that lack of documentation in the eRegistry was lack of provision of care and there was no missing data per se. Data on preferred health facility for ANC were missing for 1112 participants with community registration of pregnancy; they could not be assigned to intervention or control groups. Another 779 women were enrolled in the 13 health facilities that were in the non-randomized group from October 2018 to June 2020.

Intervention and control groups had similar profiles of health workers in terms of gender (27% male in intervention group and 28% in control group) and years of education (67% in intervention group and 68% in control group with more than 12 years of education) (Table 2). Mean age in years was comparable across the two groups (32 years, SD 9.4 in the intervention group and 33 years, SD 9.6 in the control group) (Table 2). Health facilities allocated to the intervention and control groups were similar in terms of volume of clients per month (mean 14.5, interquartile range 10–30 in the intervention group and mean 14, interquartile range 9–24 in the control group). At trial start, 21 of the 30 (70%) health facilities in the intervention group had a good internet connection, while 26 of the 29 (90%) health facilities had a good internet connection in the control group.

The characteristics of pregnant women enrolled in the trial, as derived from the postpartum household survey data, are presented in Table 3. Intervention and control groups were similar in age, parity, socioeconomic status, and years of education. Thirty-eight percent of the women had received their first ANC in private health facilities, and this was similar across intervention ($n=727$, 35%) and control groups ($n=743$, 40%). About a quarter of all participants had attended four ANC visits ($n=511$, 25% in the intervention group and $n=472$, 26% from control group). In total, in the intervention group, 1559 (75.8%) had a facility delivery (vaginal delivery: $n=538$, 35% and caesarean section: $n=1021$, 65%), while 1346 (79.5%) had a facility delivery in the control group (vaginal delivery: $n=421$, 31% and caesarean section: $n=925$, 69%).

Table 2 Characteristics of health workers and health facilities

Characteristic	Control group- N (%)	Intervention group- N (%)
Health worker		
Gender		
Male	8 (28)	9 (30)
Female	21 (72)	21 (70)
Age in years		
20–30	18 (62)	17 (57)
30–50	11 (38)	13 (43)
Years of education/training		
10–12	9 (32)	10 (33)
> 12	20 (69)	20 (67)
Health facility		
Distance (km) to referral unit		
< 5	1 (3)	4 (13)
5 to 10	15 (52)	10 (33)
> 10	13 (45)	16 (54)
Clients per month		
< 10	8 (28)	6 (20)
10 to 24	14 (48)	15 (50)
> 24	7 (24)	9 (30)
Internet connectivity		
Good	26 (90)	21 (70)
Weak/No	3 (10)	9 (30)

Table 4 shows the crude outcome proportions in the intervention group when the different DHIs were available, crude outcome proportions in the control group for the same periods (Fig. 2), and the adjusted relative risks (ARR). Crude outcome proportions through the duration of the trial are presented in Additional file 2.

The primary outcomes were not statistically different between the intervention and control groups. Timely attendance at eligible ANC visits was slightly higher in the intervention group (42.5%) than the control group (40.3%), given the opportunity to attend ANC (Table 4) (ARR 0.96, 95% CI 0.89 to 1.05). Hypertension screening and management was high overall, with 95.1% and 94.7% screened and managed in the intervention and control groups, respectively (Table 4).

The secondary outcomes of the trial are presented in Table 5. Of the 445 women with home pregnancy registration before 16 weeks in the intervention group, 252 had a timely ANC visit at 16 weeks (56.6%) for the period July 2019 – June 2020. In the control group, 188 of 348 women with a home pregnancy registration had a timely ANC visit at 16 weeks (54.0%). The groups were not significantly different (ARR 0.97, 95% CI 0.84 to 1.11) (Table 5).

Table 3 Characteristics of pregnant women enrolled in the trial

Characteristics	Control group ($n=2746$) N (%)	Intervention group ($n=3023$) N (%)
Age in years		
< 20	346 (13)	363 (12)
20–30	1355 (49)	1505 (50)
> 30	149 (5)	187 (6)
Missing	896 (33)	968 (32)
Parity		
1	744 (27)	805 (27)
2	648 (24)	733 (24)
> 2	456 (16)	515 (17)
Missing	898 (33)	970 (32)
Socioeconomic status/household assets		
First (Poorest)	397 (14)	423 (14)
Second (Poor)	350 (13)	401 (13)
Third (Middle)	371 (14)	421 (14)
Fourth (Richer)	388 (14)	383 (13)
Fifth (Richest)	343 (12)	426 (14)
Missing	897 (33)	969 (32)
Women's years of education		
0–5	260 (9)	285 (9)
6–10	1277 (47)	1426 (47)
> 10	313 (11)	344 (11)
Missing	896 (33)	968 (33)

For the outcome of high-risk referral, only 13 women in the intervention group and 10 in the control group had a documented high-risk condition for the period July 2019 – June 2020, with similar proportions of women receiving additional referral care in the two groups (20% in the control group and 23% in the intervention group, ARR 1.27, 95% CI 0.27 to 5.96). Similarly, relatively few women had a documented indication for facility delivery ($N=124$ in the intervention group and $N=77$ in the control group) during July 2019 – June 2020, and 75% and 79.2% of these had a facility delivery in the intervention and control groups respectively (ARR 0.95, 95% CI 0.82 to 1.11).

Intervention (14.6%) and control groups (15%) were significantly different for the composite outcome, perinatal mortality and severe perinatal morbidities (ARR 0.74, 95% CI 0.58 to 0.96). During December 2019 – June 2020, the stillbirth rates (19 per 1000 births in the control group, 23 per 1000 births in the intervention group) and neonatal death rates (≤ 7 days) (14/874, 1.6% in the control group vs. 16/934, 1.7% in the intervention group) were reasonably similar across the two groups. The intervention group had a lower crude proportion of hospitalizations of newborns in the first week of life (96/934, 10.2%) compared to the control group (98/874, 11.2%) (see Additional file 2).

Very few women had any of the risk factors recommended for screening in the national ANC guidelines documented during their ANC ($n=75$ in the intervention group and $n=55$ in the control group). Crude proportions for perinatal mortality and severe perinatal morbidity among those with risk factors were lower in the intervention group (10.7%) compared to the control group (20%), although with a non-significant ARR (0.49, 95% CI 0.23 to 1.09).

The intervention group had 1 case of severe postpartum anemia, while the control group had no cases of severe postpartum anemia during the inclusion period. Given that outcome data were sparse, we applied Bayesian methods for the analysis (see Statistical analysis) (see Additional file 1), which yielded an adjusted risk ratio of 6.31 (95% credible interval 0.09 to 31.20).

The intracluster correlation coefficient (ICC) was relatively small for all outcomes except hypertension screening and management (ICC = 0.207) (Table 4) and perinatal mortality and severe morbidities of newborns among women with risk factors (ICC = 0.096) (Table 5).

Table 4 Primary outcomes of the eRegMat cluster-randomized controlled trial

Outcome	Control group[a]	Intervention group[a]	Adj. RR	95% Interval[b]		*p*	ICC[c]
Timely attendance at eligible ANC visits[d]	1022/2533 (40.3%)	1158/2723 (42.5%)	0.96	[0.89	1.05]	0.404	0.010
Hypertension screening and management[d]	884/933 (94.7%)	789/830 (95.1%)	1.00	[0.96	1.03]	0.846	0.207

[a] Data are n/N (%), aggregate over visit and clinic, and exclude women with missing outcome data. Numerators and denominators exclude pregnant women in the intervention arm who were not exposed to the intervention and exclude pregnant women in the control arm who could not have been exposed to the intervention; had they instead been randomized to the intervention arm

[b] Precision is quantified using 95% confidence intervals

[c] Intraclass correlation coefficients were estimated using mixed effects logistic regression

[d] Adjusted for the variables used for stratified and restricted randomization

Table 5 Secondary outcomes of the eRegMat cluster-randomized controlled trial

Outcome	Control group[a]	Intervention group[a]	Adj. RR	95% Interval[b]		*p*	ICC[c]
Timely first ANC visit[d]	188/348 (54.0%)	252/445 (56.6%)	0.97	[0.84	1.11]	0.639	0.014
High risk women referred[e]	3/13 (23.1%)	2/10 (20.0%)	1.27	[0.27	5.96]	0.765	0.000
Facility delivery[d]	61/77 (79.2%)	93/124 (75.0%)	0.95	[0.82	1.11]	0.532	0.000
Mortality and morbidity (all women)[d]	131/874 (15.0%)	136/934 (14.6%)	0.74	[0.58	0.96]	0.021	0.038
Mortality and morbidity (women with risk factors)[e]	11/55 (20.0%)	8/75 (10.7%)	0.49	[0.23	1.09]	0.079	0.096
Severe postpartum anemia[e]	0/81 (0.0%)	1/68 (1.5%)	6.31	[0.09	31.20]	N/A	

[a] Data are n/N (%), aggregate over visit and clinic, and exclude women with missing outcome data. Numerators and denominators exclude pregnant women in the intervention arm who were not exposed to the intervention and exclude pregnant women in the control arm who could not have been exposed to the intervention; had they instead been randomized to the intervention arm

[b] Precision is quantified using 95% confidence intervals for all outcomes except those for which Bayesian estimation was performed (indicated by N/A in the *p*-value column); precision is quantified for those outcomes using 95% equal-tailed credible intervals

[c] Intraclass correlation coefficients were estimated using mixed effects logistic regression

[d] Adjusted for the variables used for stratified and restricted randomization

[e] Adjusted for clustering within clinic and repeated antenatal care visits (where applicable). All randomized pregnant women with outcome data are included and analyzed in the arms to which their clinics were randomized

Discussion

We conducted a cluster-randomized controlled trial of an eRegistry with DHIs versus unshared digital client records. The intervention did not have a statistically significant effect on the primary outcomes of timely ANC attendance, hypertension screening, and management or on the secondary outcomes of timely first ANC visit, high-risk referrals, and facility delivery. The secondary outcome of perinatal mortality and severe perinatal morbidities was significantly lower in the intervention group compared to the control group.

Our results show no significant effect of the intervention on the ANC attendance outcomes (timely attendance at eligible ANC visits and timely first ANC visit). The summary of evidence accompanying the WHO Guideline Recommendations for Digital Health Interventions (DHIs) suggests that targeted client communication via SMS may be effective in increasing ANC attendance [8]. Of the three DHIs implemented in the intervention group in our trial, TCC via SMS was hypothesized to have the most direct effect on ANC attendance outcomes (timely attendance at eligible ANC visits and timely first ANC visit). While more than 90% of households have mobile connectivity in Bangladesh, only 60% of married women own a mobile phone [14, 26], and phones are likely to be shared by several members of the household. Furthermore, in Bangladesh, mobile phone users often face a significant inundation of SMS advertisements from both private and public sources, creating a situation where crucial messages can easily be overshadowed and disregarded. Only about a third of ($n = 324/898$, 35%) trial participants reported reading the one-week SMS, showing low intervention fidelity. This may, partly, explain the lack of effect of TCC via SMS on ANC attendance outcomes in the study. We did not find any randomized controlled trials of TCC for ANC in Bangladesh, but a cross-sectional study conducted in five districts in the country found no association between TCC through a mobile device and the use of maternal health care services [27].

Data on risk factors during pregnancy were evidently not entered by health workers in the eRegistry or in the unshared digital client record, either because health workers did not use the digital tool or did not perform clinical screening. Less than 1% of pregnancies (see results section) were documented as having severe anemia, or diabetes, or hypertension in pregnancy, an estimate that is far too low compared to expected population prevalence for these conditions [28]. As a result, fewer pregnancies than anticipated were included for analysis of the secondary outcomes of high-risk referrals and facility delivery among those supposed to deliver in facilities. The analysis of differences in the groups for these outcomes was underpowered and renders itself difficult to interpret.

Both intervention delivery and outcome assessment in our trial were conditional on use of the eRegistry or unshared digital client records for all data entry. Our data showed that while health workers enrolled pregnant women in the eRegistry or unshared digital client record, as expected, relatively few subsequent ANC visits data were entered in both the intervention and control groups. For example, for a given public health facility, more ANC visits were recorded in the postpartum survey, compared to data derived from the digital tool used by health workers. Data on risk factors during

pregnancy and test results were also not entered in the eRegistry or unshared digital client record, as mentioned earlier.

Throughout the trial period, health workers continued to maintain all paper-based documentations in the health information system, using the eRegistry or unshared digital client record alongside paper. We repeatedly engaged with the relevant public health officials, both before and during the trial, at all levels of the hierarchy to try and eliminate at least some of the additional reports required of health workers. These attempts were unsuccessful and health workers were mandated to maintain paper registers and reporting, and a separate digital aggregate reporting, in addition to using the digital tools (eRegistry and unshared digital client record) rolled out in our trial. The substantial documentation burden is likely to have hampered fidelity to use of the digital tool by health workers. Parallel documentation systems have been highlighted as an important hindrance to success of DHIS implementations in general [8, 29], including for Bangladesh [30].

Trials of individual DHIs, such as clinical decision support, have demonstrated modest improvements in health outcomes [31, 32]. While our intervention appeared to be effective in reducing the outcome of perinatal mortality and severe perinatal morbidities with an ARR of 0.74 (95% CI 0.58 to 0.96), the finding should be interpreted with caution given the issues that affected the trial. This result seems to be driven by differences between the groups in terms of morbidity rather than mortality outcomes (see Additional file 2).

Implications for research

The trial was affected by an intercurrent event: we were unable to implement the DHIs at the start of first recruitment and the DHIs were implemented incrementally. As a result, some participants randomized to intervention received all the DHIs while others received only some components. We used simulation to select a statistical approach prior to analyzing the trial data or unblinding. For example, this showed that the chosen method is likely to provide estimates that are almost unbiased but less precise than an analysis that simply excludes pregnant women who could not have received the intervention (i.e., a per-protocol analysis).

The DHIs in our trial were co-designed with users; we engaged with health workers to develop clinical decision support and with pregnant women for design of content of SMS [18]. Beyond this, engaging with other stakeholders and policymakers is equally crucial to address practicability of the DHIs, adaptation and integration into the health information system [33].

Feasibility considerations

To ensure feasibility and scale-up, the larger context of the health management information system should be considered. Often in LMICs including Bangladesh, data are entered on paper records and registers. Health workers typically gather count data from these sources for monthly reports and feed them into a paper-based reporting system or a digital reporting system. While an eRegistry can produce automated months reports and support several DHIs, the accuracy and completeness hinges on the near universal use of the digital tool. Such use requires good and steady internet connectivity and a well-trained health workforce, both of which are often lacking in LMICs.

The context of the health system plays a crucial role in supporting and sustaining effective DHIs at scale. The availability of essential supplies, screening tools, and equipment is limited in the area, posing significant challenges to effective healthcare delivery. Additionally, in our study setting, effective referral chains and systems are lacking, leading to problems in accessing specialized care. The landscape is further complicated by the presence of privately-owned facilities that prioritize caesarean sections. [34]. These issues were evenly distributed across intervention and control groups, and do not directly influence trial results or their interpretation. However, they do have implications for the implementation of DHIs in health systems.

Strengths and limitations

To the best of our best knowledge, this is the first cluster-randomized controlled trial of digital longitudinal client tracking with multiple integrated DHIs in Bangladesh. Our trial and implementation covered all cadres of health workers providing ANC-related services in the public health system, to create complete longitudinal clinical records of pregnant women. Outcome measures were chosen to capture potential effects of individual DHIs in a complex health system setting. Another limitation is the late start of the postpartum survey, resulting in missing outcome data and potential bias. The trial was interrupted by the COVID-19 pandemic during the last 4 months of recruitment, and household visits and postpartum survey data collections were replaced with phone interviews. However, all maternal and child health services including ANC were disrupted in Bangladesh [35] and very few women ($n=61$ women in the intervention group and $n=23$ women in the control group) visited health facilities for ANC during the pandemic. As a result, the trial did not achieve the expected sample size and yielded imprecise estimates. This is a limitation for interpretation of trial results.

Conclusions

In this cluster-randomized controlled trial, we assessed the effect of an eRegistry with multiple integrated digital health interventions in Matlab, Bangladesh. This trial could not exclude no effect of the intervention on ANC attendance, hypertension screening and management, high-risk referrals, or facility delivery. The intervention appeared to have an effect in reducing perinatal mortality and severe perinatal morbidities. However, the trial suffered several implementation challenges which precludes high certainty interpretations of the results.

Moving forward, implementation projects for Digital Health Interventions (DHIs) should prioritize the seamless integration of new digital tools into existing health information systems in LMICs. The willingness of health system owners to reduce the documentation burden on health workers is a pivotal factor in the successful implementation and acceptance of DHIs.

Abbreviations

LMICs	Low- and middle-income countries
DHIs	Digital Health Interventions
WHO	World Health Organization
ANC	Antenatal care
MCH	Maternal, newborn and child health
MOH&FW	Ministry of Health and Family Welfare
DGFP	Directorate General of Family Planning
DGHS	Directorate General of Health Services
FWV	Family Welfare Visitor
FWC	Union Health & Family Welfare Center
FWA	Family Welfare Assistants
CHCP	Community Health Care Providers
CC	Community Clinics
HA	Health Assistants

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s44247-023-00059-4.

Additional file 1. Details of Bayesian analysis for the outcome severe postpartum anemia.

Additional file 2. Trial outcomes and crude proportions.

Acknowledgements

This trial was part of the portfolio of the Centre for Intervention Science in Maternal and Child Health (CISMAC), University of Bergen. Jose Martinez from CISMAC monitored the trial. We thank the District Health Information Software 2 (DHIS2) team at the University of Oslo for their role in software development and customization. We acknowledge the contributions of Hannan Khan, Health Information Systems Programme (HISP) Bangladesh, towards software upgrades and maintenance. We thank the users of the eRegistry, the health workers and supervisors, for their time and cooperation. We are grateful to the data collectors for their efforts.

Authors' contributions

IKF, JFF and AR conceptualized the study. MV, JP, IKF, JFF, FK, UTN, BKS and AR contributed to defining study objectives and designing the methodology. AD, BO, IF and MR contributed to intervention design and customized the software. MV and JP were responsible for data curation and writing the original draft of the manuscript. JP, UTN, MR and AMQR were in-charge of data curation. AR and IKF were responsible for overall project supervision. MV, JP, FK, MR, AMQR, UTN, BKS and AR were part of the project administration team and were responsible for the implementation of the intervention and outcome data collection. IKF and JFF acquired funding. CJR performed the statistical analyses. All authors reviewed and edited the manuscript and approved of the final version.

Funding

This research was funded by the Research Council of Norway (project number 248073/H10) under the title "Strengthening the extension of Reproductive, Maternal, Newborn, and Child Health services in Bangladesh with an electronic health registry: A cluster randomized controlled trial" and by CISMAC, University of Bergen (project number 223269). In addition to financial support, CISMAC also contributed intellectual input to the study design and conducted trial monitoring. The funders had no role in the design of the trial, analysis, or publication of the results.

Availability of data and materials

The eRegistry data, used in the analysis, consists of all datapoints gathered during clinical care and therefore has data beyond what was needed for the outcomes of this trial. The dataset supporting the findings of this trial is available from the first author, JP and the corresponding author, AR upon reasonable request.

Declarations

Ethics approval and consent to participate

This study received approval from the Research Review Committee and Ethical Review Committee of icddr,b (Ref: PR-16054) in Bangladesh, and the Regional Committee for Health Research Ethics–Southeast B Section (Ref: 2017/1028 C) in Norway. While informed consent is typically not required for health systems research using anonymous health data like our trial, we obtained informed consent from women to: 1) perform urine pregnancy tests due to the unavailability of test kits in the health system, 2) receive targeted client communication via SMS text messages with the option to opt out at any time, 3) be interviewed by data collectors at postpartum home visits 8–14 days after childbirth. The urine sample for the pregnancy test did not leave the home and women were free to refuse the test. For illiterate participants, all sections of the informed consent form were read out loud by the study staff and the woman's thumbprint was obtained if she agreed to participate. For enrolment during a household visit or at a health facility, a family member acted as a witness to the informed consent process and his/her signature was obtained on the consent form. For enrolment at health facilities of women not accompanied by a family member, a randomly chosen pregnant woman attending ANC acted as a witness to the informed consent process. If this was not possible, the hospital assistant (health facility staff not involved in care provision) acted as a witness. Study procedures were performed in accordance with the ethical principles summarized in the Declaration of Helsinki – ethical principles for medical research involving human subjects [36].

The MOH&FW notified all health workers and supervisors in the study site about their participation in the trial. No financial incentives were provided to the involved facilities or care providers for use of the digital tools. An incentive of 100 taka (approximately US $1) was given to women that voluntarily notified the study team of the completion of their pregnancy.

The eRegistry data were owned by the Ministry of Health and Family Welfare in Bangladesh, with access limited to one authorized person. Researchers did not have access to identifiable data. The postpartum household questionnaire database followed standard protocols set by icddr, b.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

Author details

[1]Centre for Intervention Science in Maternal and Child Health (CISMAC), University of Bergen, Bergen, Norway. [2]Global Health Cluster, Division for Health Services, Norwegian Institute of Public Health, Oslo, Norway. [3]Maternal and Child Health Division, International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b), 68 Shaheed Tajuddin Ahmed Sarani,

Mohakhali, Dhaka 1212, Bangladesh. [4]Tacoma-Pierce County Health Department, Tacoma, WA, USA. [5]Health Information Systems Programme, Department of Informatics, University of Oslo, Oslo, Norway. [6]Center for Epidemic Interventions Research, Division for Health Services, Norwegian Institute of Public Health, Oslo, Norway. [7]Reviews and Health Technology Assessments, Division for Health Services, Norwegian Institute of Public Health, Oslo, Norway.

Received: 2 August 2023 Accepted: 5 December 2023
Published online: 16 January 2024

References

1. The Global Strategy for Women's, Children's and adolescents' health (2016–2030): Survive, Thrive, Transform. New York: Every Woman Every Child. 2015. Available from: https://data.unicef.org/resources/global-strategy-womens-childrens-adolescents-health/. Accessed July 2023.
2. Kuruvilla S, Bustreo F, Kuo T, Mishra CK, Taylor K, Fogstad H, et al. The Global strategy for women's, children's and adolescents' health (2016–2030): a roadmap based on evidence and country experience. Bull World Health Organ. 2016;94(5):398–400.
3. What is Quality of Care and why is it important? Maternal, newborn, child and adolescent health, Topics at a glance, World Health Organization. 2019. Available from: https://www.who.int/maternal_child_adoles2019cent/topics/quality-of-care/definition/en/. Accessed July 2023.
4. Puchalski Ritchie LM, Khan S, Moore JE, Timmings C, van Lettow M, Vogel JP, et al. Low- and middle-income countries face many common barriers to implementation of maternal health evidence products. J Clin Epidemiol. 2016;76:229–37.
5. Agweyu A, Hill K, Diaz T, Jackson D, Hailu BG, Muzigaba M. Regular measurement is essential but insufficient to improve quality of healthcare. BMJ. 2023;380:e073412.
6. Frøen JF, Myhre SL, Frost MJ, Chou D, Mehl G, Say L, et al. eRegistries: Electronic registries for maternal and child health. BMC Pregn Childb. 2016;16(1):11.
7. Flenady V, Wojcieszek AM, Fjeldheim I, Friberg IK, Nankabirwa V, Jani JV, et al. eRegistries: indicators for the WHO Essential Interventions for reproductive, maternal, newborn and child health. BMC Pregn Childb. 2016;16(1):293.
8. WHO guideline: recommendations on digital interventions for health system strengthening. Geneva: World Health Organization; 2019. Licence: CC BY-NC-SA 3.0 IGO. Available from: https://www.who.int/reproductivehealth/publications/digital-interventions-health-system-strengthening/en/. Accessed July 2023. .
9. Global strategy on digital health 2020–2025. Geneva: World Health Organization; 2021. Licence: CC BY-NC-SA 3.0 IGO. Available from: https://www.who.int/docs/default-source/documents/gs4dhdaa2a9f352b0445bafbc79ca799dce4d.pdf. Accessed July 2023.
10. WHO guideline Recommendations on Digital Interventions for Health System Strengthening. Geneva: World Health Organization; 2019. 5, Future research. Available from: https://www.ncbi.nlm.nih.gov/books/NBK541890/. Accessed July 2023.
11. National Institute of Population Research and Training (NIPORT), International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b), and MEASURE Evaluation. (2017). Bangladesh Maternal Mortality and Health Care Survey 2016: Preliminary Report. Dhaka, Bangladesh, and Chapel Hill, NC, USA: NIPORT, icddr,b, and MEASURE Evaluation. Available from: https://www.measureevaluation.org/resources/publications/tr-17-218.html. Accessed July 2023.
12. Islam A, Biswas T. Health system in Bangladesh: challenges and opportunities. Am J Health Res. 2014;2:366.
13. e-Government Master Plan for Digital Bangladesh, ICT Division, Government of Bangladesh. 2019. Available from: https://bcc.portal.gov.bd/sites/default/files/files/bcc.portal.gov.bd/publications/3f9cd471_9905_4122_96ee_ced02b7598a9/2020-05-24-15-54-43f3d2b8b4523b5b62157b069302c4db.pdf. Accessed July 2023. .
14. Rowntree O SM BK, Butler C, Lindsey D, Sibthorpe C. . Connected Women - The Mobile Gender Gap Report 2020, GSMA. Available from: https://www.gsma.com/mobilefordevelopment/wp-content/uploads/2020/05/GSMA-The-Mobile-Gender-Gap-Report-2020.pdf. Accessed July 2023.
15. Venkateswaran M, Ghanem B, Abbas E, Khader KA, Ward IA, Awwad T, et al. A digital health registry with clinical decision support for improving quality of antenatal care in Palestine (eRegQual): a pragmatic, cluster-randomised, controlled, superiority trial. Lancet Digit Health. 2022;4(2):e126–36.
16. Rahman A, Friberg IK, Dolphyne A, Fjeldheim I, Khatun F, O'Donnell B, et al. An electronic registry for improving the quality of antenatal care in rural Bangladesh (eRegMat): protocol for a cluster randomized controlled trial. JMIR Res Protoc. 2021;10(7):e26918.
17. Pervin J, Nu UT, Rahman AMQ, Rahman M, Uddin B, Razzaque A, et al. Level and determinants of birth preparedness and complication readiness among pregnant women: a cross sectional study in a rural area in Bangladesh. PLoS ONE. 2018;13(12):e0209076.
18. Pervin J, Sarker BK, Nu UT, Khatun F, Rahman AMQ, Venkateswaran M, et al. Developing targeted client communication messages to pregnant women in Bangladesh: a qualitative study. BMC Public Health. 2021;21(1):759.
19. District Health Information Software 2 (DHIS 2), Health Information Systems Programme (HISP), University of Oslo. Available from: https://dhis2.org/. Accessed July 2023.
20. Khatun F, Distler R, Rahman M, O'Donnell B, Gachuhi N, Alwani M, et al. Comparison of a palm-based biometric solution with a name-based identification system in rural Bangladesh. Glob Health Action. 2022;15(1):2045769.
21. National Institute of Population Research and Training (NIPORT), Mitra and Associates, and ICF International. 2016. Bangladesh Demographic and Health Survey 2014. Dhaka, Bangladesh, and Rockville, Maryland, USA: NIPORT, Mitra and Associates, and ICF International. Available from: https://dhsprogram.com/pubs/pdf/fr311/fr311.pdf. Accessed July 2023.
22. Pagel C, Prost A, Lewycka S, Das S, Colbourn T, Mahapatra R, et al. Intracluster correlation coefficients and coefficients of variation for perinatal outcomes from five cluster-randomised controlled trials in low and middle-income countries: results and methodological implications. Trials. 2011;12:151.
23. Zou G. A modified poisson regression approach to prospective studies with binary data. Am J Epidemiol. 2004;159(7):702–6.
24. European Medicines Agency. ICH E9 (R1) addendum on estimands and sensitivity analysis in clinical trials to the guideline on statistical principles for clinical trials. EMA/CHMP/ICH/436221/2017. Available from: https://www.ema.europa.eu/en/documents/scientific-guideline/ich-e9-r1-addendum-estimands-sensitivity-analysis-clinical-trials-guideline-statistical-principles_en.pdf. Accessed July 2023.
25. Little RJA. A test of missing completely at random for multivariate data with missing values. J Am Stat Assoc. 1988;83(404):1198–202.
26. National Institute of Population Research and Training (NIPORT), and ICF. 2020. Bangladesh Demographic and Health Survey 2017–18. Dhaka, Bangladesh, and Rockville, Maryland, USA: NIPORT and ICF. Available from: https://dhsprogram.com/pubs/pdf/FR344/FR344.pdf. Accessed July 2023.
27. Alam M, D'Este C, Banwell C, Lokuge K. The impact of mobile phone based messages on maternal and child healthcare behaviour: a retrospective cross-sectional survey in Bangladesh. BMC Health Serv Res. 2017;17(1):434.
28. Sabina Azhar B, Islam MS, Karim MR. Prevalence of anemia and associated risk factors among pregnant women attending antenatal care in Bangladesh: a cross-sectional study. Prim Health Care Res Dev. 2021;22:e61.
29. Rotich JK, Hannan TJ, Smith FE, Bii J, Odero WW, Vu N, et al. Installing and implementing a computer-based patient record system in sub-Saharan Africa: the Mosoriot medical record system. J Am Med Inform Assoc. 2003;10(4):295–303.
30. Tamrat T, Chandir S, Alland K, Pedrana A, Shah MT, Footitt C, et al. Digitalization of routine health information systems: Bangladesh, Indonesia, Pakistan. Bull World Health Organ. 2022;100(10):590–600.
31. Moja L, Kwag KH, Lytras T, Bertizzolo L, Brandt L, Pecoraro V, et al. Effectiveness of computerized decision support systems linked to electronic health records: a systematic review and meta-analysis. Am J Public Health. 2014;104(12):e12-22.
32. Kwan JL, Lo L, Ferguson J, Goldberg H, Diaz-Martinez JP, Tomlinson G, et al. Computerised clinical decision support systems and absolute improvements in care: meta-analysis of controlled clinical trials. BMJ. 2020;370:m3216.

33. Murray E, Hekler EB, Andersson G, Collins LM, Doherty A, Hollis C, et al. Evaluating digital health interventions: key questions and approaches. Am J Prev Med. 2016;51(5):843–51.
34. Pervin J, Venkateswaran M, Nu UT, Rahman M, O'Donnell BF, Friberg IK, et al. Determinants of utilization of antenatal and delivery care at the community level in rural Bangladesh. PLoS ONE. 2021;16(9):e0257782.
35. Mhajabin S, Hossain AT, Nusrat N, Jabeen S, Ameen S, Banik G, et al. Indirect effects of the early phase of the COVID-19 pandemic on the coverage of essential maternal and newborn health services in a rural subdistrict in Bangladesh: results from a cross-sectional household survey. BMJ Open. 2022;12(2):e056951.
36. World Medical Association Declaration of Helsinki. ethical principles for medical research involving human subjects. JAMA. 2013;310(20):2191–4.

Publisher's Note