

Strengthening reproductive, maternal, newborn and child health services in Bangladesh with an electronic health registry

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| Submission date 24/10/2018 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol |
| Registration date 06/12/2018 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 18/01/2023 | Condition category Pregnancy and Childbirth | <input type="checkbox"/> Individual participant data |

Plain English summary of protocol

Background and study aims

Healthcare providers need quality patient records to be able to provide quality care. They should also be able to easily use and share health data in efficient and secure ways. An eRegistry is a type of electronic health information system which collects, manages and shares this data with clients, colleagues, supervisors and policy makers. Actions include supporting healthcare providers to follow best practice during clinical work, leading to improved quality of care for their clients, presenting providers' own information back to themselves for quality improvement, and sending appointment reminders to clients based on their own health information. The aim of this study is to assess whether such an eRegistry can improve quality of care and health of pregnant women and their babies in Bangladesh as compared with entering data into an electronic system, but not making that data available for use or sharing.

Who can participate?

Public primary care clinics in Matlab North and Matlab South in Bangladesh

What does the study involve?

Participating clinics are randomly assigned to one of two groups. Clinics in the first group receive an electronic health information system called the Matlab MNCH eRegistry. Healthcare workers in these clinics use the eRegistry for care of clients throughout their pregnancy. When providers enter the client information at the point-of-care into eRegistry, it provides specific actionable advice and recommendations (using interactive checklists with clinical decision support) for the workers and shares this information with other users as needed. Clinics in the second group also enter the data at the point-of-care, but they do not receive any additional support to help improve their quality of care.

Additionally, community health workers throughout the community get a simpler system to link community work with the work of the clinics. All women enrolled in the trial will have a household visit between 7 and 14 days after birth. At this visit, the child will be weighed and the mother's anemia status will be identified.

What are the possible benefits and risks of participating?

Pregnant women may benefit from better quality of healthcare that may lead to improved health outcomes for them and their babies. There are no known risks associated with taking part in the study.

Where is the study run from?

International Center for Diarrheal Disease Research, Dhaka, Bangladesh, in collaboration with the Norwegian Institute for Public Health, Oslo, Norway

When is study starting and how long is it expected to run for?

June 2016 to October 2020

Who is funding the study?

1. Norwegian Research Council (Norway)
2. Center for Intervention Science in Maternal and Child Health (Norway)
3. Norwegian Institute of Public Health (Norway)

Who is the main contact?

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Study website

<http://eregistries.org/>

Contact information

Type(s)

Public

Contact name

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ORCID ID

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Strengthening the extension of reproductive, maternal, newborn and child health services in Bangladesh with an electronic health registry: a cluster randomized controlled trial

Acronym

eReg-Mat

Study objectives

In a rural population of women and children in Bangladesh, the use of an eRegistry (with data entry, decision support, feedback dashboards, data sharing) by health care providers at community health clinics and family welfare centers, and by their supervisors will improve the quality and quantity of health care services delivered, and ultimately, health outcomes for mother and child.

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. Regional Committee for Health Research Ethics (REK) - Section South East B, Norway (REK), 27/06/2017, ref: 2017/1028 (full trial)
2. Regional Committee for Health Research Ethics (REK) - Section South East D, Norway (REK), 13/02/2017, ref: 2016/2251 (formative research)
3. Regional Committee for Health Research Ethics (REK) - Section South East C, Norway (REK), 05/01/2018, ref: 2017/2468 C (palm-scan extension)
4. Ethical Review Committee, International Center for Diarrheal Disease Research, Bangladesh, 27/12/2016 (amendment approved 16/08/2018), ref: PR-16054

Study design

Interventional two-armed cluster randomised controlled trial

Primary study design

Interventional

Secondary study design

Cluster randomised trial

Study setting(s)

Other

Study type(s)

Other

Participant information sheet

No participant information sheet available

Health condition(s) or problem(s) studied

Antenatal care

Interventions

In this cluster randomized trial, primary care clinics are randomised 1:1 to either the intervention arm or the control arm. Randomisation was stratified based upon the qualifications of the primary staff member (community skilled birth attendant or not) and the type of clinic (Community Clinic or Family Welfare Clinic). Women then designate their appropriate clinic at enrollment (if enrolled outside of a clinic setting).

In the intervention arm, providers working at clinics assigned to the intervention will be given an electronic data collection tool to support their work in reporting and recording antenatal care (as well as delivery, postnatal, and newborn care). As part of this data collection tool, they will also have automated and integrated decision and workflow support, audit and feedback dashboards and access to data entered by all other providers within this trial. Women assigned to these clinics will also receive health status tailored SMS reminders to attend antenatal care. All providers are given a tablet to use and/or a Chromebook, depending on their work location and skillset. Each user has a unique username and password identifying their authorized access to the eRegistry. In addition to using name based searching tools, they may use biometric palm-based searching and identification. Providers will typically have used the devices for more than 3 months before enrollment begins.

In the control arm, providers working at clinics assigned to the control arm will have an identical data collection tool, which does not have decision and workflow support, audit and feedback dashboards, and access to data entered at other clinics. Women assigned to these clinics will not get health status tailored SMS reminders to attend antenatal care. Each user has a unique username and password identifying their authorized access to the eRegistry. In addition to using name based searching tools, we will also be using palm-based searching and identification. Providers will typically have used the devices for more than 3 months before enrollment begins. All providers will use the intervention or control systems at every contact with the pregnant woman from pregnancy identification through 28 days after childbirth.

This trial is not blinded to the implementers and providers, but is blinded to the analytic team. The trial will enroll clients for 18 months, or until the required sample size is collected.

Updated 30/06/2020: The trial will enroll clients for 20 months, or until the required sample size is collected.

Intervention Type

Other

Primary outcome measure

The data for the following will be obtained from electronic medical records collected at the point of care when the antenatal care visit occurs:

1. Proportion of women who attend 4 timely antenatal care visits according to national guidelines, prospectively assessed throughout pregnancy and retrospectively between 7 and 14 days after birth.
2. Proportion of women receiving appropriate screening and management for hypertension in pregnancy, according to national guidelines, assessed throughout pregnancy. Screening is defined as measuring and recording blood pressure levels at all timely ANC visits. Management is defined as recording that a referral was done at a visit at which hypertension was identified, according to national guidelines.

Secondary outcome measures

Current secondary outcome measures as of 30/06/2020:

1. Proportion of women with anemia, hypertension or diabetes identified in pregnancy who are successfully referred to a skilled provider for additional care, prospectively collected throughout pregnancy. All data related to referrals will be obtained from electronic medical records collected at the point of care when the antenatal visit occurs. Data on success of the referral will be retrospectively assessed through an interview with the woman 7-14 days after birth.
2. Proportion of women with a facility delivery recommended during an antenatal care visit who deliver in an institution, prospectively collected throughout pregnancy and retrospectively collected 7-14 days after birth. Data on facility delivery recommendations will be obtained from electronic medical records collected at the point of care when the antenatal care visit occurs. Facility delivery status will be retrospectively assessed through an interview with the woman 7-14 days after birth.
3. Proportion of women attending a timely first antenatal care visit, retrospectively collected 7-14 days after birth. Antenatal care visit dates will be retrospectively obtained through an interview with the woman 7-14 days after birth.
4. Mean number of days of hospitalization in the first 7 days of life, retrospectively measured between 7-14 days of life. Hospitalization data will be retrospectively obtained through an interview with the woman 7-14 days after birth.
5. Proportion of births with severe morbidity/mortality (perinatal death plus hospitalization for at least 7 days) among pregnancies with any risk identified, retrospectively measured between 7 and 14 days of life. Survival data will be retrospectively obtained through an interview with the woman 7-14 days after birth.
6. Hemoglobin level, measured using a hemoglobin meter during a home visit 7-14 days after birth.

Previous secondary outcome measures:

1. Proportion of women receiving appropriate screening and management for hypertension in pregnancy, according to national guidelines, prospectively collected throughout pregnancy. All data will be obtained from electronic medical records collected at the point of care when the antenatal visit occurs.
2. Proportion of women with anemia, hypertension or diabetes identified in pregnancy who are successfully referred to a skilled provider for additional care, prospectively collected throughout pregnancy. All data related to referrals will be obtained from electronic medical records collected at the point of care when the antenatal visit occurs. Data on success of the referral will be retrospectively assessed through an interview with the woman between 7-14 days after birth.
3. Proportion of women with a facility delivery recommended during an antenatal care visit who deliver in an institution, prospectively collected throughout pregnancy and retrospectively collected between 7-14 days after birth. Data on facility delivery recommendations will be obtained from electronic medical records collected at the point of care when the antenatal care visit occurs. Facility delivery status will be retrospectively assessed through an interview with the woman between 7-14 days after birth.
4. Proportion of women attending a timely first antenatal care visit, retrospectively collected between 7-14 days after birth. Antenatal care visit dates will be retrospectively obtained through an interview with the woman between 7-14 days after birth.
5. Proportion of women correctly screened and managed for anemia in pregnancy, prospectively collected throughout pregnancy. All data will be obtained from electronic medical records collected at the point of care when the antenatal visit occurs.
6. Average percentage of interventions relating to anemia, diabetes and hypertension correctly delivered to a pregnant woman during each antenatal care visit, prospectively collected throughout pregnancy. All data will be obtained from electronic medical records collected at the point of care when the antenatal visit occurs.
7. Mean number of days of hospitalization in the first 7 days of life, retrospectively measured

between 7-14 days of life. Hospitalization data will be retrospectively obtained through an interview with the woman between 7-14 days after birth

8. Proportion of births with severe morbidity/mortality (perinatal death plus hospitalization for at least 7 days) among pregnancies with any risk identified, retrospectively measured between 7-1414 days of life. Survival data will be retrospectively obtained through an interview with the woman between 7-14 days after birth.

9. Hemoglobin level, measured using a hemoglobin meter during a home visit between 7-14 days after birth.

Overall study start date

17/06/2016

Completion date

30/11/2020

Eligibility

Key inclusion criteria

Clinics:

1. Community Clinics and Family Welfare Clinics situated in Matlab North or Matlab South, and their associated staff
2. Clinics with at least 1 staff member able to provide antenatal, childbirth, or postnatal care services
3. Clinics providing at least 5 antenatal care consultations per month

Participant type(s)

Mixed

Age group

Adult

Sex

Both

Target number of participants

2000

Total final enrolment

3293

Key exclusion criteria

Clinics:

1. Non governmental clinics
2. Family Welfare Centers or Community Clinics located in Upazila Health Complexes.

Women are excluded if their gestational age at enrollment is greater than 17 weeks.

Date of first enrolment

30/10/2018

Date of final enrolment

30/06/2020

Locations

Countries of recruitment

Bangladesh

Study participating centre

International Center for Diarrheal Disease Research, Bangladesh

68, Shaheed Tajuddin Ahmed Sarani, Mohakhali

Dhaka

Bangladesh

1212

Sponsor information

Organisation

Norwegian Institute for Public Health

Sponsor details

PO Box 4404 Nydalen

Oslo

Norway

0403

Sponsor type

Government

Website

www.fhi.no

ROR

<https://ror.org/046nvst19>

Funder(s)

Funder type

Government

Funder Name

Norges Forskningsråd

Alternative Name(s)

Forskningsrådet, Norwegian Research Council, Research Council of Norway

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Norway

Funder Name

Universitetet i Bergen

Alternative Name(s)

University of Bergen, UiB

Funding Body Type

Government organisation

Funding Body Subtype

Local government

Location

Norway

Results and Publications

Publication and dissemination plan

The protocol will be submitted for publication within 3 months of trial registration. Formative research components will be submitted for publication within 6 months of trial registration. Primary outcomes will be submitted for publication within 6 months of locking the dataset. Other publications will be submitted as soon as they are ready.

Intention to publish date

15/02/2021

Individual participant data (IPD) sharing plan

The datasets will be stored in a non-publically available repository, the icddr,b Data repository within the Research Administration division. All data will be stored here 3 months after the protocol has been completed, and will be only available for the primary study team for 3 years. After this period, the data will be made available to researchers for secondary data analyses, upon approval of a Data Licensing Application & Agreement, as laid out in the icddr,b Data Access Policy. All ethics approvals, internal and external, must be completed before data will be made available. Only datasets with all personal identifiers removed will be made available.

IPD sharing plan summary

Stored in repository

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|------------------------------------|------------------------------------|--------------|------------|----------------|-----------------|
| Results article | qualitative results results | 20/04/2021 | 22/04/2021 | Yes | No |
| Protocol article | | 06/07/2021 | 14/07/2021 | Yes | No |
| Results article | | 28/09/2021 | 29/09/2021 | Yes | No |
| Other publications | | 31/12/2022 | 18/01/2023 | Yes | No |