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

Submission date
24/10/2018

Recruitment status
No longer recruiting

Registration date
06/12/2018

Overall study status
Completed

Last Edited
18/01/2023

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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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Contact information

Type(s)
Public

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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

Study type(s)
Other

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(s)
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.

Key secondary outcome(s))
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.

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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

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, The 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, University of Bergen, Norway, Universitas Bergensis, UiB

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Norway

Results and Publications

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 will all personal identifiers removed will be made available.

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	qualitative results	20/04/2021	22/04/2021	Yes	No
Results article	results	28/09/2021	29/09/2021	Yes	No
Protocol article		06/07/2021	14/07/2021	Yes	No
Other publications		31/12/2022	18/01/2023	Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes