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An electronic health registry with interactive checklists and clinical decision support for improving quality of antenatal care

Submission date
28/03/2017

Recruitment status
No longer recruiting

Registration date
06/04/2017

Overall study status
Completed

Last Edited
07/06/2023

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Current plain English summary as of 24/04/2017:

Background and study aims
Healthcare providers need to maintain good quality patient records. At the same time, they should be able to share meaningful health data with colleagues, supervisors and policy makers in an efficient and secure way. An eRegistry is a type of electronic health information system which provides guidance for such collection and management of data. eRegistries can also support healthcare providers to follow best practices during clinical work, leading to improved quality of care for their clients. 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 Palestine.

Who can participate?
All pregnant women attending antenatal care in 133 primary healthcare clinics in five districts in the West Bank, Palestine.

What does the study involve?
Participating clinics are randomly allocated to one of two groups. Clinics in the first group receive an electronic health information system called the MCH eRegistry. Healthcare workers in these clinics use the eRegistry for care of clients throughout their pregnancy. When healthcare workers 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. Clinics in the second group continue to use paper-based files and receive the MCH eRegistry after the study is over. Data to measure quality of care and data on birth outcomes of enrolled pregnant women is routinely extracted every month during the study period for clinics in both groups in order to assess the effectiveness of the eRegistry in comparison to paper-based filing.

Substudy eRegTime: The time spent by the care providers in managing health information during their working day, in clinics with and without the eRegistry will be measured.

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, and because this is part of a national deployment of the MCH eRegistry, no alternative health information system is provided.

Where is the study run from?
The study is run from the Palestinian National Institute of Public Health, World Health Organization, Ramallah, Palestine and takes place in 133 Primary Healthcare Clinics (Palestine)

When is study starting and how long is it expected to run for?
January 2016 to May 2018

Who is funding the study?
1. European Research Council (European Union)
2. Norwegian Research Council (Norway)
3. Center for Intervention Science in Maternal and Child Health (Norway)
4. Norwegian Institute of Public Health (Norway)
5. Palestinian National Institute of Public Health, World Health Organization (Palestine)

Who is the main contact?
Dr J. Frederik Frøen
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Previous plain English summary:

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Contact information

Type(s)
Public

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
eRegQual: an electronic health registry with interactive checklists and clinical decision support for improving quality of antenatal care – protocol for a cluster-randomized controlled trial

Substudy eRegTime: Efficiency of health information management using an eRegistry for maternal and child health – protocol for a time-motion study in a cluster randomized trial

Acronym
eRegQual; eRegTime

Study objectives
Current study hypothesis as of 24/04/2018:
eRegQual hypotheses:
1. Interactive checklists with clinical decision support in antenatal care improve quality of care for pregnant women
2. Interactive checklists with clinical decision support in antenatal care prevent women from entering into labor with an unknown or unidentified risk of an important condition during pregnancy

eRegTime hypothesis:
Interactive checklists with clinical decision support in antenatal care does not increase the time spent on information management

Previous study hypothesis
1. Interactive checklists with clinical decision support in antenatal care improves quality of care for pregnant women
2. Interactive checklists with clinical decision support in antenatal care prevents women from entering into labor with an unknown or unidentified risk important condition during pregnancy

Ethics approval required
Old ethics approval format

Ethics approval(s)
Current ethics approval as of 24/04/2018:
1. Regional Committee for Health Research Ethics (REK) - Section South East B, Norway (REK), 02/03/2016, 2016/264 B (eRegQual), 19/04/2017 (date added 22/05/2018), 2017/400 (eRegTime)
2. Palestinian Health Research Council, 07/04/2014 (renewed 25/06/2016), PHRC/HC/04/14 (eRegQual), 03/04/2017 (date added 22/05/2018), PHRC/HC/208/17 (eRegTime)

Previous ethics approval:
1. Regional Committee for Health Research Ethics (REK) - Section South East B, Norway (REK), 02/03/2016, ref: 2016/264 B
2. Palestinian Health Research Council, 07/04/2014 (renewed 25/06/2016), ref: PHRC/HC/04/14

Study design
Cluster randomized controlled trial

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Antenatal care

Interventions
Primary healthcare clinics are randomized to one of two groups, stratified by district and constrained on the following characteristics:
1. Number of new enrollments of pregnancies per year
2. Laboratory availability
3. Proportion of new enrollments above 40 years of age
4. Proportion of primiparous women

Intervention arm: The primary healthcare clinics in the intervention arm receive the intervention - eRegistry's interactive checklists with clinical decision support for antenatal care. The eRegistry allows for seamless incorporation of clinical workflow and guideline support in addition to reminders of daily clinical procedures and referrals. All intervention primary healthcare clinics are provided with desktop computers to be used by care providers in the consultation rooms. Each user has a unique username and password identifying their authorized access to the eRegistry. Clinics in the intervention arm use the eRegistry for an average of 20 weeks prior to start of recruitment.

Control arm: The primary healthcare clinics in the control arm continue to use the current system of paper files during antenatal care.

The eRegistry's interactive checklists and the current paper records contain the same datapoints. The period of enrollment is 8 months, followed by another 8 months of follow-up for clinics in both arms.

Added 24/04/2018:
Substudy eRegTime: the clinics included in the data collection were selected using a stratified random sampling. The data collection for the eRegTime study will be conducted April to June 2018.

Intervention Type
Other

Primary outcome(s)
1. Adverse pregnancy outcomes are masured using data from hospitals in the eRegistry, registered continuously at point-of-care and exported monthly. This is a composite outcome that includes the following adverse pregnancy outcomes:
1.1. Moderate or severe anemia at admission for labor
1.2. Severe hypertension at admission for labor
1.3. Malpresentation at delivery undetected during pregnancy
1.4. Large for gestational age baby at delivery
1.5. Small-for-gestational age baby at delivery undetected during pregnancy
2. Process (adherence) outcomes are measured using data from primary healthcare clinics in the eRegistry, registered continuously at point-of-care and exported monthly. These include timely and appropriate screening and management of:
2.1. Anemia during pregnancy

2.2. Hypertension in pregnancy
2.3. Diabetes in pregnancy
2.4. Abnormal fetal growth

Key secondary outcome(s))
Current secondary outcome measures as of 24/04/2018:

eRegQual:
1. Timely ANC visit rate is measured using data from primary healthcare clinics in the eRegistry, registered continuously at point-of-care into the eRegistry and exported monthly
2. Timely and appropriate screening and management of malpresentation ≥ 36 weeks rate is measured using data from primary healthcare clinics in the eRegistry, registered continuously at point-of-care into the eRegistry and exported monthly
3. Stillbirth rate is measured using data from primary healthcare clinics in the eRegistry, registered continuously at point-of-care into the eRegistry and exported monthly

eRegTime:
4. Time spent on health information management per antenatal consultation, measured using data collected by time-motion observations of care providers' entire work days in the primary healthcare clinics. Health information management is defined as time spent by care providers on accessing, documenting and reporting health information.

Previous secondary outcome measures:
1. Timely ANC visit rate is measured using data from primary healthcare clinics in the eRegistry, registered continuously at point-of-care into the eRegistry and exported monthly
2. Timely and appropriate screening and management of malpresentation ≥ 36 weeks rate is measured using data from primary healthcare clinics in the eRegistry, registered continuously at point-of-care into the eRegistry and exported monthly
3. Stillbirth rate is measured using data from primary healthcare clinics in the eRegistry, registered continuously at point-of-care into the eRegistry and exported monthly

Completion date
15/05/2018

Eligibility

Key inclusion criteria
Current participant inclusion criteria as of 24/04/2018:
eRegQual - Clinics:
1. Clinics run by the Ministry of Health, Palestine
2. Clinics located in the 5 districts: Bethlehem, Nablus, Jenin, Ramallah/ Al-Bireh, Salfit
3. Clinics run by non-governmental organizations but still reporting to the Ministry of Health, Palestine

eRegTime - Clinics:
4. Clinics that have one nurse or one midwife providing antenatal care services on a given workday
5. Clinics that have, on average, at least one booking visit per workday

Patients:
There are no eligibility criteria based on individual patient characteristics.

Previous participant inclusion criteria:
Clinics:
1. Clinics run by the Ministry of Health, Palestine
2. Clinics located in the 5 districts: Bethlehem, Nablus, Jenin, Ramallah/ Al-Bireh, Salfit
3. Clinics run by non-governmental organizations but still reporting to the Ministry of Health, Palestine

Patients:
There are no eligibility criteria based on individual patient characteristics.

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
Other

Sex
Female

Total final enrolment
6367

Key exclusion criteria
Clinics:
1. Primary healthcare clinics that are defined as level 1
2. Primary healthcare clinics with no pregnant women enrolled in 2013
3. Primary healthcare clinics providing high-risk management
4. Primary healthcare clinics participating in another health systems study addressing the quality of antenatal care

Date of first enrolment
15/01/2017

Date of final enrolment
15/09/2017

Locations

Countries of recruitment
Palestine, State of

Study participating centre
Palestinian National Institute of Public Health, World Health Organization
Ministry of Health Building, 1st Floor
Qadora Street

Ramallah/ Al-Bireh
Palestine, State of
PO Box 4284

Sponsor information

Organisation
Norwegian Institute of Public Health

ROR
https://ror.org/046nvst19

Organisation
Palestinian National Institute of Public Health, World Health Organization

Funder(s)

Funder type
Government

Funder Name
European Research Council

Alternative Name(s)
The European Research Council, ERC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

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
Center for Intervention Science in Maternal and Child Health

Results and Publications

Individual participant data (IPD) sharing plan
The current data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		31/01/2022	31/01/2022	Yes	No
Results article	eRegTime sub-study results	13/05/2022	07/06/2023	Yes	No
Protocol article	protocol	22/01/2018		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes