

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

<b>Submission date</b> 28/03/2017	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 06/04/2017	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 07/06/2023	<b>Condition category</b> Pregnancy and Childbirth	<input type="checkbox"/> 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  
frederik.froen@fhi.no

Previous plain English summary:

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.

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  
frederik.froen@fhi.no

### **Study website**

[www.fhi.no/en/more/international/eregistries/research/](http://www.fhi.no/en/more/international/eregistries/research/); [www.eregistries.org](http://www.eregistries.org)

## **Contact information**

### **Type(s)**

Public

### **Contact name**

Dr J. Frederik Frøen

### **ORCID ID**

<http://orcid.org/0000-0001-9390-8509>

### **Contact details**

Norwegian Institute of Public Health  
PB 4404 Nydalen  
Oslo  
Norway  
N-0403  
+47 (0)210 78 194  
frederik.froen@fhi.no

## **Additional identifiers**

EudraCT/CTIS number

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

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

## **Secondary study design**

Cluster randomised trial

## **Study setting(s)**

Other

## **Study type(s)**

Other

## **Participant information sheet**

Not available in web format, please use the contact details to request a patient information sheet

## **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 measure**

1. Adverse pregnancy outcomes are measured 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

## **Secondary outcome measures**

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  $\geq 36$  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  $\geq 36$  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

**Overall study start date**

15/01/2016

**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

**Age group**

Other

**Sex**

Female

**Target number of participants**

120 clusters of clinics and approximately 6000 enrolled pregnant women and their newborns

**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

**Sponsor details**

Postboks 4404 Nydalen

Oslo

Norway

0403

+47 (0)210 77 000

eregistries@fhi.no

**Sponsor type**

Government

**Website**

[www.fhi.no](http://www.fhi.no)

**ROR**

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

**Organisation**

Palestinian National Institute of Public Health, World Health Organization

**Sponsor details**

Ministry of Health Building, 1st Floor

Qadora Street

Ramallah/ Al-Bireh

Palestine, State of

PO Box 4284

+970 (0)2 296 6842/7

info.pniph@gmail.com

**Sponsor type**

Government

**Website**

[www.pniph.org](http://www.pniph.org)

**Funder(s)****Funder type**

Government

**Funder Name**

European Research Council

**Alternative Name(s)**

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

**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

**Publication and dissemination plan**

Current publication and dissemination plan as of 24/04/2018:

The following are the tentative titles of the planned publications related to this trial during 2017- 2018:

1. Quality of antenatal care services in Palestine – an indicator based assessment
2. Design of interactive electronic checklists for antenatal, postpartum and newborn care implemented in an electronic registry in primary
3. Implementation of a mother and child health electronic registry in Palestine
4. eRegQual: An electronic health registry with interactive checklists and clinical decision support for improving quality of antenatal care – study protocol for a cluster-randomized controlled trial
5. Substudy eRegTime: Efficiency of health information management using an eRegistry for maternal and child health – study protocol for a time-motion study in a cluster randomized trial
6. eRegQual: An electronic health registry with interactive checklists and clinical decision support for improving quality of antenatal care – a cluster-randomized controlled trial
7. eRegQual: Effect of an electronic health registry with interactive checklists and clinical decision support on equity of antenatal care service delivery
8. Substudy eRegTime: Efficiency of health information management using an eRegistry for maternal and child health – a time-motion study in a cluster randomized trial

Previous publication and dissemination plan:

The following are the tentative titles of the planned publications related to this trial during 2017- 2018:

1. Quality of antenatal care services in Palestine – an indicator based assessment
2. Design of interactive electronic checklists for antenatal, postpartum and newborn care implemented in an electronic registry in primary
3. Implementation of a mother and child health electronic registry in Palestine
4. eRegQual: An electronic health registry with interactive checklists and clinical decision support for improving quality of antenatal care – study protocol for a cluster-randomized controlled trial
5. eRegQual: An electronic health registry with interactive checklists and clinical decision

support for improving quality of antenatal care – a cluster-randomized controlled trial  
6. eRegQual: Effect of an electronic health registry with interactive checklists and clinical decision support on equity of antenatal care service delivery

### Intention to publish date

31/12/2018

### 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?
<a href="#">Protocol article</a>	protocol	22/01/2018		Yes	No
<a href="#">Results article</a>		31/01/2022	31/01/2022	Yes	No
<a href="#">Results article</a>	eRegTime sub-study results	13/05/2022	07/06/2023	Yes	No