

# An infection control intervention study: Using infection control as an entry point for improving the quality of delivery care and strengthening health systems in developing countries

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<b>Registration date</b> 25/11/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 10/09/2014	<b>Condition category</b> Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

N/A

## **Study information**

### **Scientific Title**

An infection control intervention study incorporating an interrupted time series with control:  
Using infection control as an entry point for improving the quality of delivery care and strengthening health systems in developing countries

### **Study objectives**

The multifaceted strategy infection control package will result in the formulation and implementation of locally achievable and sustainable action to reduce rates of wound, bloodstream and reproductive tract infections after childbirth.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Prof Rajeev Sharma, Convenor of the Ethics committee, Indian Institute of Management, Ahmadabad, 23/09/2010

### **Study design**

Interrupted time series with control

### **Primary study design**

Interventional

### **Secondary study design**

Cohort study

### **Study setting(s)**

Hospital

### **Study type(s)**

Prevention

### **Participant information sheet**

Not available in web format, please use contact details below to request a patient information sheet [in Gujarati and/or Hindi]

### **Health condition(s) or problem(s) studied**

Maternal infections during childbirth

### **Interventions**

Our intervention will have four core infection control elements, and a fifth element of appreciative inquiry as indicated below.

1. Improvement of surveillance systems for infection control

2. Operationalisation of infection control committees
3. Use of an audit, feedback, and problem solving mechanism
4. Development of locally relevant, standardised guidelines and protocols
5. Appreciative inquiry

Appreciative inquiry (AI) is a fairly new concept in infection control, and is the fundamental basis for our intervention. Appreciative inquiry hence brings together groups of people to identify problems and develop solutions, using self-reflective analysis and learning within a supportive environment. Sessions are held to include health facility personnel with diverse roles such as hospital cleaners, ambulance drivers, water engineer, nurses, doctors, administrators etc. Critical events are used in discussions which are non-threatening and non-punitive. Successes and problem-solving are the focus of discussions. In maternal health, it has been implemented at small scale to improve quality of emergency obstetric care in countries such as Bangladesh, India and Nepal. Although its effects were not evaluated formally in these settings, existing evidence suggest benefits of the approach.

We are planning to have 6 study sites of about 1000 deliveries per site, all in Gujarat state. They are a mix of government and private non profit health facilities. We hope to have 2 government and one PNP in each arm, control and intervention. The control facility will implement routine government procedures for infection control and will not receive the intensive surveillance-infection control committee-appreciative enquiry inputs.

The duration of the intervention and follow up will be 6 months.

### **Intervention Type**

Other

### **Phase**

Not Applicable

### **Primary outcome measure**

1. Puerperal infections in women who deliver in study health facilities including
  - 1.1. Bloodstream
  - 1.2. Reproductive tract
  - 1.3. Wound infections

### **Secondary outcome measures**

1. Antibiotic use
2. Duration of hospital stay

### **Overall study start date**

01/01/2011

### **Completion date**

01/09/2012

## **Eligibility**

### **Key inclusion criteria**

1. Women who delivered in the intervention and control hospitals (Gujarat state), who subsequently contract (puerperal) infection of the genital tract

2. Women in whom infections of the genital tract are identified after delivery, up to 42 days post partum
3. Puerperal infections are defined as those specified in ICD-10 codes 085 and 086 (see annex 1):
  - 3.1. Puerperal sepsis
  - 3.2. Other puerperal infections
  - 3.3. Infection of obstetric surgical wound
  - 3.4. Other infection of genital tract following delivery
  - 3.5. Urinary tract infection following delivery
  - 3.6. Other genital tract infection following delivery
  - 3.7. Pyrexia of unknown origin following delivery
  - 3.8. Other specified puerperal infections
4. Any woman over 28 weeks gestation who delivers a baby (live or stillborn) in any of the control or intervention hospitals
5. Any woman over 28 weeks gestation who has delivered a baby (in any location be it in the community, a study site or a non-study hospital) who is admitted with the placenta undelivered

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Female

**Target number of participants**

6000

**Key exclusion criteria**

1. Any woman who delivers a baby (live or stillborn) less than 28 weeks gestation.
2. Miscarriage and abortion cases

Note: Often, these cases are seen in out-patients or admitted in a different ward and are classified as 'gynaecologic' cases and not 'obstetric' cases

3. Any woman admitted to the study site after delivery of the placenta

**Date of first enrolment**

01/01/2011

**Date of final enrolment**

01/09/2012

**Locations****Countries of recruitment**

India

Scotland

United Kingdom

**Study participating centre****Impact**

Aberdeen

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## Sponsor information

**Organisation**

John D and Catherine T MacArthur Foundation (USA)

**Sponsor details**

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**Sponsor type**

Charity

**Website**

<http://www.macfound.org/>

**ROR**

<https://ror.org/00dxczh48>

## Funder(s)

**Funder type**

Charity

**Funder Name**

John D and Catherine T MacArthur Foundation (USA) (Grant number GSS 09-94513-000)

**Alternative Name(s)**

MacArthur Foundation, John D. & Catherine T. MacArthur Foundation, JDCTMF

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Trusts, charities, foundations (both public and private)

**Location**

United States of America

## Results and Publications

**Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date****Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	30/01/2014		Yes	No