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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

Submission date 22/10/2010	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 25/11/2010	**Overall study status** Completed	
Last Edited 10/09/2014	**Condition category** Pregnancy and Childbirth	

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
Immpact
Aberdeen
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AB25 2ZD

Sponsor information

Organisation
John D and Catherine T MacArthur Foundation (USA)

Sponsor details
140 S. Dearborn Street,
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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?
Results article	results	30/01/2014		Yes	No