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Health care and health status in the Udaipur district, Rajasthan: demand and supply factors in early childhood immunisation

Submission date	Recruitment status	[_] Prospectively registered
20/07/2008	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
25/07/2008	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
25/05/2010	Infections and Infestations	

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
MIT COUHES protocol: 0503001143

Study information

Scientific Title
Improving immunisation coverage in rural India: A clustered randomised controlled evaluation of immunisation campaigns with and without incentives

Study objectives
1. Regular monthly immunisation can increase immunisation uptake in a low immunisation set-up for children and pregnant women
2. Small incentives can further increase immunisation rate

Ethics approval required
Old ethics approval format

Ethics approval(s)
USA: Massachusetts Institute of Technology Committee on the Use of Humans as Experimental Subjects. Date of approval: 04/14/2005 (Protocol number 0503001143, renewed yearly)
India: Vidya Bhawan Board of Ethics. Date of approval: 04/05/2005 (IRB code: IRB00002646; Federal-wide Assurance code: FWA00003656; Application 04-01)

Study design
Clustered, randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Prevention

Participant information sheet

Health condition(s) or problem(s) studied
Immunisation against tuberculosis, diphtheria, pertussis, tetanus and polio

Interventions
134 villages in rural Udaipur were randomised to one of 3 groups:
1. A once-monthly reliable immunisation camp (intervention A; 30 villages)
2. A once-monthly reliable immunisation camp with small incentives (lentils and metal plates for completed immunization; intervention B; 30 villages)
3. Control (no intervention, 74 villages)

The vaccine package administered in this study is the World Health Organization (WHO)/UNICEF Extended Package of Immunization (EPI), which is the package provided by the Indian government. For children, the EPI includes one dose of BCG vaccine, three doses of DPT vaccine, three doses of OPV, and one dose of measles vaccine. A child should be fully immunised (i.e. have received all the EPI vaccines) by age one year.

Intervention A ("immunisation camps") establishes regular availability of immunisation services. It consists of a mobile immunisation team including a nurse and assistant (both hired by a local NGO, Seva Mandir) who conducts monthly immunisation camps in the villages. The nurse and assistant hold the camp on a fixed date every month at a fixed time (11 AM to 2 PM). The presence of the nurse and assistant is verified by the requirement of timed and dated pictures of them in the villages, and by regular monitoring. In addition, in each village, a social worker is responsible for identifying children, informing mothers about the availability of the immunisation camps, and educating them about the benefits of immunisation.

Intervention B uses the same immunisation camp infrastructure as intervention A, but in addition offered parents one kilogram of lentils per immunisation administered, and a set of thalis (metal plates used for meals) upon completion of a child's full immunisation. The value of the lentils is about Rs 40 (less than one dollar), equivalent to three quarters of one day's wage.

30 households were randomly selected in each study villages, and in 60 neighbouring villages, and all children aged 0 to 7 at the time of endline were surveyed.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Proportion of children receiving part or all of the EPI in intervention A, B and control villages. The main analysis reported in this study focuses on children aged 1- 3 at endline (i.e. eligible and old enough to be fully immunised), and the proportion of pregnant women receiving tetanus immunisation and booster.

Secondary outcome measures
Proportion of children receiving part or all of the EPI in neighbouring villages (hamlets neighbouring intervention A and intervention B camps, differences between these two groups of neighbouring hamlets and the control group, and relative risks). The main analysis reported in this study focuses on children aged 1- 3 at endline (i.e. eligible and old enough to be fully immunised), and the proportion of pregnant women receiving tetanus immunisation and booster, as for the intervention and control villages (see Primary outcome measures).

Overall study start date
05/01/2005

Completion date
05/01/2007

Eligibility

Key inclusion criteria
Participants must:
1. Be children under five years of age
2. Not have already received all of the following vaccinations: tuberculosis (BCG), diphtheria-pertussis-tetanus (DPT1, DPT2, DPT3), oral polio vaccine (OPV1, OPV2, OPV3), measles and measles booster
3. Be brought to an immunisation camp to be immunised by a parent or guardian

OR Participants included in the study must:
1. Be pregnant
2. Not have already received both the tetanus and tetanus booster vaccinations
3. Voluntarily attend an immunisation camp run in the village

Anybody meeting this condition is eligible for immunisation in all intervention villages (regardless of residence) and for incentives in intervention B villages.

Participant type(s)
Patient

Age group
Child

Upper age limit
5 Years

Sex
Both

Target number of participants
At least 9,000 children immunised. 6,000 children surveyed.

Key exclusion criteria
Children older than 5, since immunisation has been shown to be most effective for children under 5

Date of first enrolment
05/01/2005

Date of final enrolment
05/01/2007

Locations

Countries of recruitment
India

United States of America

Study participating centre

Massachusetts Institute of Technology (MIT)
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Sponsor information

Organisation
Abdul Latif Jameel Poverty Action Lab, Massachusetts Institute of Technology (MIT) (USA)

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Sponsor type
University/education

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ROR
https://ror.org/042nb2s44

Funder(s)

Funder type
Charity

Funder Name
Funding for interventions:

Funder Name
Dorabji Tata Trust (http://www.dorabjitatatrust.org) (India) through a grant to Seva Mandir (the implementing non-governmental organisation; http://www.sevamandir.org)

Funder Name
Funding for data collection and analysis:

Funder Name
Data Collection: The John D. and Catherine T. MacArthur Foundation (http://www.macfound.org) (USA) through a grant to the Abdul Latif Jameel Poverty Action Lab, Department of Economics at the Massachusetts Institute of Technology (MIT) (http://www.povertyactionlab.org). Grant ref: 05-84892-000-GS

Funder Name
Abdul Latif Jameel Poverty Action Lab, Department of Economics at the MIT (USA), for data analysis and report writing (self-funding by lead researcher's organisation). MIT Subaward Agreement for this project: #5710001713

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	17/05/2010		Yes	No