

# The role of information in the uptake of preventative healthcare

<b>Submission date</b> 10/02/2015	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 17/02/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 06/03/2024	<b>Condition category</b> Other	<input checked="" type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Many families in low- and middle-income countries do not use preventative health services. One potential reason is that they underestimate the health benefits of such services. We will examine whether giving families information designed to improve household perceptions of the benefits of healthcare increases service uptake. The general principle will be tested using the example of the vaccine for diphtheria, pertussis, and tetanus (DPT) for which there is universally accepted evidence on its health benefits. The study takes place in Uttar Pradesh, India.

### Who can participate?

Families with a child aged 0-36 months who has not received the recommended three doses of the DPT vaccine.

### What does the study involve?

One group of families will receive information that describes the symptoms of tetanus, the possible health consequences, the benefits of getting their child vaccinated against tetanus in terms of mortality and morbidity gains, wider community benefits associated with herd immunity (spillovers), and where the family can get the child vaccinated at what cost and up until what age. A second group of families will receive similar information except that the benefits of vaccination will be framed in negative terms. A third group of families will receive no information and thus act as a control. At least nine months later the vaccination rates of children will be compared across the three groups.

### What are the possible benefits and risks of participating?

By taking part in this study there are no risks of physical injury or harm since the research involves no invasive procedures or examinations. Knowledge generated by the study may benefit the health of children in future.

### Where is the study run from?

The study has been set up by the London School of Hygiene and Tropical Medicine (UK), working in collaboration with Sambodhi Research and Communications (India).

When is the study starting and how long is it expected to run for?

It is anticipated that recruitment will start in April 2015. The final data will be collected in April 2016.

Who is funding the study?

Merck Sharp & Dohme Corp (USA) through MSD for Mothers

Who is the main contact?

Dr Timothy Powell-Jackson

Timothy.Powell-Jackson@lshtm.ac.uk

## Contact information

### Type(s)

Scientific

### Contact name

Dr Timothy Powell-Jackson

### ORCID ID

<http://orcid.org/0000-0002-6082-3805>

### Contact details

15-17 Tavistock Place

London

United Kingdom

WC1H 9SH

## Additional identifiers

### EudraCT/CTIS number

Nil known

### IRAS number

### ClinicalTrials.gov number

Nil known

### Secondary identifying numbers

Nil known

## Study information

### Scientific Title

Information and the demand for preventative healthcare: a randomised controlled trial of improving household perceptions on the efficacy of DPT immunisation in Uttar Pradesh, India

### Study objectives

1. Providing households with accurate information on the health benefits of the DPT vaccine will increase uptake of the vaccine.
2. Framing the information as a loss (incurred by not vaccinating the child) will increase uptake of the DPT vaccine more than when the information is framed as a gain (incurred by vaccinating the child).
3. The effect of information is greater amongst those who initially have lower perceptions of the efficacy of DPT vaccine.

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

1. The Intervention Research Ethics Committee of the London School of Hygiene and Tropical Medicine in London, 16/12/2014, ref: 8778
2. The institutional review board of the Public HealthCare Society in New Delhi, 18/08/2014
3. The Intervention Research Ethics Committee of the London School of Hygiene and Tropical Medicine in London, amendment 13/11/2017, ref: 8778-1
4. The institutional review board of the Public HealthCare Society in New Delhi, amendment 24/09/2017

## **Study design**

Randomized controlled trial design

## **Primary study design**

Interventional

## **Secondary study design**

Randomised controlled trial

## **Study setting(s)**

Community

## **Study type(s)**

Prevention

## **Participant information sheet**

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

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

The role of information in influencing household decisions to get their child vaccinated against tetanus

## **Interventions**

Families will be individually randomised into three study arms. Mothers in the first treatment group will be given information on tetanus and benefits of vaccination framed in positive terms. The information script will describe the symptoms of tetanus, possible health consequences, the individual benefit of the combination vaccine in terms of mortality and morbidity gains, wider community benefits associated with herd immunity, and where the family can get the child

vaccinated at what cost and up until what age. A second treatment group will provide essentially the same information on efficacy but framed in negative terms. The third arm acts as a control group with no information given to the mother.

Added 08/03/2018:

The trialists are doing a longer term follow-up study of the same study participants. A household survey will be administered at 30 months follow-up.

### **Intervention Type**

Behavioural

### **Primary outcome measure**

Proportion of study children with three doses of DPT vaccine at endline as verified by the vaccination card or reported by the mother

Added 08/03/2018:

1. Proportion of (index) children with three doses of DPT vaccine at 30 months follow-up as verified by vaccination card or reported by the mother
2. Proportion of other children in the household under five years with three doses of DPT vaccine at 30 months follow-up as verified by vaccination card or reported by the mother

### **Secondary outcome measures**

1. The proportion of children fully vaccinated (against tuberculosis, diphtheria, pertussis, tetanus, polio and measles)
2. An index of the mother's knowledge of tetanus symptoms
3. An index of the mother's perception of the efficacy of tetanus vaccination

Added 08/03/2018:

1. Proportion of children fully vaccinated at 30 months follow-up (against tuberculosis, diphtheria, pertussis, tetanus, and measles)
2. Proportion of other children in the household under five years fully vaccinated at 30 months follow-up (against tuberculosis, diphtheria, pertussis, tetanus, and measles)
3. Proportion of children vaccinated with measles vaccine at 30 months follow-up
4. Proportion of other children in the household under five years vaccinated with measles vaccine at 30 months follow-up
5. Proportion of children with suspected diarrhoea in the last four weeks at 30 months follow-up
6. Proportion of children with suspected pneumonia in the last four weeks at 30 months follow-up
7. Proportion of children with suspected diarrhoea in the last four weeks and correctly treated at 30 months follow-up
8. Proportion of children with suspected pneumonia in the last four weeks and correctly treated at 30 months follow-up
9. Mother's knowledge of any symptom of tetanus at 30 months follow-up
10. Mother's knowledge of any cause of tetanus at 30 months follow-up
11. Mother's knowledge of any tetanus prevention method at 30 months follow-up
12. Mother's perception of the efficacy of tetanus vaccination at 30 months follow-up

### **Overall study start date**

01/10/2014

### **Completion date**

15/05/2018

## Eligibility

### Key inclusion criteria

1. Mother with a child aged 0-36 months living in the same household
2. Child has not received three doses of DPT vaccine
3. Mother gives consent to participate in the study
4. Mother intends to remain in the study area for the six months

### Participant type(s)

Healthy volunteer

### Age group

Adult

### Sex

Female

### Target number of participants

900

### Total final enrolment

722

### Key exclusion criteria

1. Child of mother is not aged 0-36 months
2. Child of mother is not living in the same household
3. Child has received three doses of DPT vaccine
4. Mother does not give consent to participate in the study
5. Mother due to emigrate from the study area in the six months

### Date of first enrolment

10/07/2015

### Date of final enrolment

01/08/2015

## Locations

### Countries of recruitment

India

### Study participating centre

**Sambodhi Research and Communications Limited**

O-2, 2nd Floor

Lajpat Nagar-II

New Delhi

India  
110024

## Sponsor information

### Organisation

London School of Hygiene and Tropical Medicine

### Sponsor details

Keppel Street  
London  
United Kingdom  
WC1E 7HT

### Sponsor type

Research organisation

### Website

<http://www.lshtm.ac.uk/>

### ROR

<https://ror.org/00a0jsq62>

## Funder(s)

### Funder type

Industry

### Funder Name

Merck Sharp & Dohme Corp (USA) through MSD for Mothers

## Results and Publications

### Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal around 1 year after the trial end date

### Intention to publish date

15/05/2019

### Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in the LSHTM repository (DataCompass). The data used in the analysis (not the raw complete dataset) are available off the PLOS Med website alongside the paper.

### IPD sharing plan summary

Published as a supplement to the results publication, Stored in repository

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	06/03/2018		Yes	No
<a href="#">Protocol file</a>			24/08/2022	No	No
<a href="#">Dataset</a>		06/03/2018	06/03/2024	No	No