

Household cost-benefit equations and equity in immunisation: a randomised cluster controlled trial of knowledge translation for sustainable universal childhood immunisation in south Pakistan

Submission date

09/03/2005

Recruitment status

No longer recruiting

☐ Prospectively registered

☒ Protocol

Registration date

18/04/2005

Overall study status

Completed

☐ Statistical analysis plan

☒ Results

Last Edited

25/02/2021

Condition category

Infections and Infestations

☐ 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

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

T-0581-100-19

Study information

Scientific Title

Household cost-benefit equations and equity in immunisation: a randomised cluster controlled trial of knowledge translation for sustainable universal childhood immunisation in south Pakistan

Study objectives

The hypothesis is that this dynamic equation can be influenced by a multi-directional knowledge transfer (KT) and, based on this culture-appropriate exchange, that people will adjust their household cost-benefit equations and their uptake of immunisation.

A corollary of the household cost-benefit equation is accessible to planners and health service managers: cost-gains. By deriving this from the same data used by communities for their cost-benefit equations, a common language can be identified for interaction between health services and communities. Parallel to the community-based knowledge transfer (KT) intervention, the team will work with the district authorities in Lasbela. We will build capacity to improve immunisation rates in the selected district, reaching health care workers, community leaders and policy makers. Research teams will be trained in community-based research, enhancing the capacity for ongoing monitoring of immunisation and other health interventions.

This project hopes to address two main areas:

1. In the Lasbela district, what cost-benefit calculations are used to make decisions about immunisation and how do they change over the four year period?
2. Does the intervention-sharing of information in focus groups and the feedback loop- influence the household cost-benefit calculation? If so, how?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Two review panels, one at the University of Ottawa and a panel in the south of Pakistan registered with the US Government's Office of Human Research Protections, deliberated the ethical issues and approved the study.

Study design

Randomized controlled trial

Primary study design

Interventional

Study type(s)

Quality of life

Health condition(s) or problem(s) studied

Immunisation

Interventions

We propose to test the importance of this household cost-benefit equation that decision-makers for children derive from their knowledge, attitudes, social norms, intentions, sense of agency and degree of socialisation about immunisation.

Step 1: Two communities will be chosen as the locations for piloting the cost-benefit survey. Piloting involves development of the instrument and making changes through collaboration with the communities.

Step 2: The communities in which the pilot was performed will be excluded from the randomisation.

Step 3: All households in both the intervention and control communities will respond to the household questionnaire. In the case of the intervention communities the information gathered in the household questionnaire will be brought back to the communities in focus groups (one focus group of 6 - 10 people in each of the 10 intervention locations).

Step 4: Step 3 will be repeated 3 additional times over the four year period in order to assess any changes in household cost-benefit calculations. The use of a control group permits us to see whether observed changes are the result of the focus group feedback loop or caused by factors external to the project.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Survey content:

In addition to baseline data about the coverage with and obstacles to immunisation, the standard Knowledge, Attitudes, and Practices (KAP) approach will be enriched by a modification: steps to behaviour change model developed by Community Information and Epidemiological Technology (CIET) to measure youth responses to risk. CIETs beyond-KAP approach, "cascade", refers to knowledge about:

1. Immunisation and its side effects
2. Attitudes to childhood immunisation
3. Social norms (what neighbours do) and positive or negative deviation from those norms
4. Intentions to vaccinate in the future
5. Agency (self-efficacy expectancy about immunisation) and degree of socialisation or discussion about immunisation, its benefits and side effects

The outcome of this "cascade" is immunisation, which will be documented in detail. Attention will be paid to perceived or real costs of immunisation and non-immunisation, and the weigh up costs and benefits.

Gender and poverty affect the household cost-benefit equation. The poor, who typically have less access to services and less information about services, will almost certainly weigh up the cost and benefit in a different way than will the rich. Some diseases like measles and pertussis

may be an inconvenience for the well nourished but, for the malnourished, they are a question of life or death. Costs of not vaccinating (disease burden, care and funerals) are borne disproportionately by the poor and, in a single epidemic; they can wipe out household economies.

Key secondary outcome(s)

No secondary outcome measures

Completion date

31/07/2008

Eligibility

Key inclusion criteria

This project is a randomised controlled trial; randomisation will be computer generated. There will be 2000 participating households (1000 intervention; 1000 control); 20 locations are to be chosen and randomised by computer (10 intervention; 10 control) and interviewers will interview 100 households with parents of children less than 5 years or parents planning on having children in the next year in each of these locations.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Total final enrolment

958

Key exclusion criteria

Does not comply with the above inclusion criteria

Date of first enrolment

01/07/2004

Date of final enrolment

31/07/2008

Locations

Countries of recruitment

Canada

Pakistan

Study participating centre

CIET Canada

Ottawa

Canada

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Sponsor information

Organisation

International Development Research Centre (Canada)

ROR

<https://ror.org/0445x0472>

Funder(s)

Funder type

Research organisation

Funder Name

International Development Research Centre (Canada)

Alternative Name(s)

Centre de recherches pour le développement international, IDRC.CRDI, le Centre de recherches pour le développement international (CRDI), el Centro Internacional de Investigaciones para el Desarrollo (IDRC), International Development Research Centre: IDRC, El Centro Internacional de Investigaciones para el Desarrollo, IDRC, CRDI

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Canada

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	14/10/2009	25/02/2021	Yes	No
Protocol article	protocol	28/06/2005		Yes	No