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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

Registration date
18/04/2005

Overall study status
Completed

Last Edited
25/02/2021

Condition category
Infections and Infestations

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Neil Andersson

Contact details
CIET Canada
1 Stewart Street
Room 319
Ottawa
Canada
K1N 5R2
+1 613 562 5393
neil@ciet.org

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Quality of life

Participant information sheet

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 measure
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.

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/07/2004

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

Age group
Adult

Sex
Both

Target number of participants
2000

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
K1N 5R2

Sponsor information

Organisation
International Development Research Centre (Canada)

Sponsor details
250 Albert Street
Ottawa
Canada
K1P 6M1
+1 613 236 6163
info@idrc.ca

Sponsor type
Research organisation

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

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Canada

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?
Protocol article	protocol	28/06/2005		Yes	No
Results article	results	14/10/2009	25/02/2021	Yes	No