Barriers to vaccination decision in north-eastern Nigeria.

Submission date 18/02/2019	Recruitment status No longer recruiting	 Prospectively registered Protocol
Registration date 19/02/2019	Overall study status Completed	 [] Statistical analysis plan [X] Results
Last Edited 17/12/2020	Condition category Infections and Infestations	Individual participant data

Plain English summary of protocol

Background and study aims

Despite the huge benefits of preventing diseases at low cost, the persistent low vaccine take-up remains hard to explain. The relevance of psychological factors as barriers to vaccination has been commonly documented in Africa, without rigorous evidence. This study conducts a field experiment explicitly designed to evaluate psychic and monetary costs as potential barriers to tetanus vaccine take-up among women of childbearing age in 80 villages in Adamawa state, in rural Nigeria.

Who can participate?

Women aged 15 to 35 and had not received a tetanus vaccine less than six months prior to the baseline survey.

What does the study involve?

We have three interventions; 1) condition under which a respondent can receive the cash incentives (clinic visit s. clinic visit + vaccination), 2) amount of cash incentives (low, middle, and high), and 3) priming intervention (control flipcharts vs. " scared-straight" intervention)

What are the possible benefits and risks of participating?

The possible benefits include the tetanus-toxoid vaccination and cash incentives. Through receiving the tetanus-toxoid vaccination, they can be protected against tetanus. If the respondents are pregnant, vaccination can also protect their new-born baby from neonatal tetanus.

There are side effects of the tetanus-toxoid vaccination such as swelling of the body part of the injection, fever, and headache. However, these side effects are expected to be at minimal.

Where is the study run from?

This is a single-site study. We cover 10 health clinics which covers 80 villages in Jada local government areas in Adamawa state, Nigeria. The lead center is Adamawa Primary Healthcare Development Agency based in Yola, the capital city of Adamawa state.

When is the study starting and how long is it expected to run for? March 2013 to August 2013 Who is funding the study?

This project was supported with research grants from the Institute for Research on Women & Gender, the Rackham Graduate School, the Department of Afroamerican and African Studies, the Department of Economics, and the Center for the Education of Women at the University of Michigan; the Japan Society for the Promotion of Science; and Yamada Scholarship Foundation.

Who is the main contact? Ryoko Sato, rsato@hsph.harvard.edu

This study evaluates the relative importance of psychic costs of vaccination compared to monetary costs through a field experiment that randomizes several factors affecting tetanus vaccine take-up among women in rural Nigeria. We conducted our study in 80 villages in Adamawa state, which is in the northeastern region of Nigeria.

To capture monetary costs as potential barriers to vaccination, we randomized the amount of cash incentives provided to women whose condition was simply to attend a clinic. To capture psychic costs of vaccination as potential barriers, we gave a group of women their cash incentives with the additional condition of receiving a vaccine at the clinic. Because the only difference between these two conditions is whether or not a woman was is required to receive a vaccine for cash rewards upon arrival at the clinic, the difference in clinic attendance between these two groups captures the psychic costs of vaccination. Furthermore, if those women whose condition for cash provision was clinic attendance refused to take the vaccine after showing up at the clinic, this is directly attributed to the psychic costs of vaccination.

Finally, to examine the effect of priming on vaccination, we randomized a disease message: either a "scared-straight" message, which emphasizes the severity of tetanus, or a control message, which provides the same information on tetanus without emphasis on the severity of the disease.

Contact information

Type(s) Scientific

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number Nil known

Secondary identifying numbers HUM00063832

Study information

Scientific Title Psychic vs. Economic Barriers to Vaccine Take-up: a Field Experiment in Nigeria in Northeastern Nigeria

Study objectives

It is expected that psychological factors are major barriers to vaccination, and that cash incentive and emphasizing the severity of the disease increase vaccine take-up

Ethics approval required Old ethics approval format

Ethics approval(s)

Approved 09/11/2012, University of Michigan Health Sciences and Behavioral Sciences Institutional Review Board (2800 Plymouth Road, Bldg. 520, Rm. 1169, Ann Arbor, MI 48109-2800; +1 (734) 936-0933; irbhsbs@umich.edu), ref: HUM00063832

Study design

Interventional single-centre study randomised controlled trial

Primary study design Interventional

Secondary study design Randomised controlled trial

Study setting(s) Home

Study type(s) Prevention

Participant information sheet None available

Health condition(s) or problem(s) studied We studied the uptake of tetanus-toxoid vaccine.

Interventions

To capture monetary costs as potential barriers to vaccination, we randomly chose the amount of cash incentives provided to women whose condition was simply to attend a clinic. To capture psychic costs of vaccination as potential barriers, we gave another group of women their cash incentives with the additional requirement of receiving a vaccine at the clinic. As the only difference between these two conditions is whether or not a woman was is required to receive a vaccine for cash rewards upon arrival at the clinic, the difference in clinic attendance between these two groups captures the psychic costs of vaccination. Furthermore, if those women whose condition for cash provision was clinic attendance refused to take the vaccine after showing up at the clinic, this is directly attributed to the psychic costs of vaccination.

Finally, to examine the effect of priming on vaccination, we randomized a disease message: either a "scared-straight" message, which emphasizes the severity of tetanus, or a control message, which provides the same information on tetanus without emphasis on the severity of the disease.

There were 9 groups in the study:

group 1) clinic visit condition + control flipcharts + 5 naira group 2) clinic visit condition + control flipcharts + 300 naira group 3) clinic visit condition + control flipcharts + 800 naira group 4) vaccination condition + control flipcharts + 5 naira group 5) vaccination condition + control flipcharts + 300 naira group 6) vaccination condition + control flipcharts + 800 naira group 7) vaccination condition + scared-straight flipcharts + 5 naira group 8) vaccination condition + scared-straight flipcharts + 300 naira group 9) vaccination condition + scared-straight flipcharts + 800 naira

Participants were randomised into groups upon enrollment. Baseline survey forms contained randomisation information in the middle page: interviewers randomly picked one of the baseline survey forms (without looking at the middle page) and initiated the baseline interview.

Intervention Type

Behavioural

Primary outcome measure

The primary outcome is the take-up of the tetanus-toxoid vaccination measured by observation at health clinics.

Secondary outcome measures

The risk perception is measured by interview at baseline and at follow-up survey (right after the intervention).

Overall study start date 01/01/2012

Completion date 31/07/2013

Eligibility

Key inclusion criteria Female, between the ages of 15 and 35 **Participant type(s)** Healthy volunteer

Age group Adult

Sex Female

Target number of participants 2500

Total final enrolment 1660

Key exclusion criteria Received the tetanus-toxoid vaccine within 6 months prior to the study

Date of first enrolment 01/03/2013

Date of final enrolment 31/03/2013

Locations

Countries of recruitment Nigeria

Study participating centre Adamawa State Primary Health Care Development Agency Wuro Jabbe Jimeta Nigeria NA

Sponsor information

Organisation University of Michigan

Sponsor details 540 East Liberty Street, Suite 202 Ann Arbor United States of America 48104 +1 734 9360933 irbhsbs@umich.edu

Sponsor type University/education

ROR https://ror.org/00jmfr291

Funder(s)

Funder type Research organisation

Funder Name Japan Society for the Promotion of Science

Alternative Name(s) KAKENHI, , Gakushin, JSPS KAKEN, JSPS Grants-in-Aid for Scientific Research, JSPS

Funding Body Type Government organisation

Funding Body Subtype National government

Location Japan

Funder Name Department of Afroamerican and African Studies, University of Michigan

Alternative Name(s)

Department of Afroamerican and African Studies, UM Department of Afroamerican and African Studies, U-M Department of Afroamerican and African Studies, DAAS, DAAS, UM

Funding Body Type Government organisation

Funding Body Subtype Universities (academic only)

Location

United States of America

Funder Name Institute for Research on Women and Gender, University of Michigan

Alternative Name(s)

Institute for Research on Women and Gender, Institute for Research on Women & Gender, University of Michigan, IRWG

Funding Body Type Government organisation

Funding Body Subtype Universities (academic only)

Location United States of America

Funder Name Horace H. Rackham School of Graduate Studies, University of Michigan

Alternative Name(s) Rackham Graduate School, Rackham U-M

Funding Body Type Government organisation

Funding Body Subtype Universities (academic only)

Location United States of America

Funder Name Center for the Education of Women, University of Michigan

Funder Name Yamada Scholarship Foundation

Funder Name

Results and Publications

Publication and dissemination plan

We intend to publish the results of the trial in public health journals, upon completion of the data analysis.

Intention to publish date

01/04/2019

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available due to the sensitive and identifiable nature of the data.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	16/12/2020	17/12/2020	Yes	No