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Evaluation of diarrhoea measurement

Submission date	Recruitment status	[X] Prospectively registered
05/03/2019	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
20/03/2019	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
25/04/2022	Infections and Infestations	

Plain English summary of protocol

Background and study aims
This study aims to evaluate different methods of measuring infant diarrhoea prevalence in refugee camps and slums. Currently, the accepted method of doing this is by asking parents if their child has had two or more loose or watery stools in the past two weeks. However, this measurement can lead to an incorrect result due to problems with memory, not answering truthfully, or not understanding the question. As an alternative, in this study this method will be tested against more in depth questions and sampling of stool to test for causes of diarrhoea.

Who can participate?
Household with at least one adult over the age of 18 and children under the age of five in the Cox's bazar refugee camp

What does the study involve?
The study involves selection of 400 households by house to house surveying, recruiting consenting households who have a child under the age of five. Consenting households are initially given a survey on their demographics, health status, and access to care, toilets, and water. Households are then randomly allocated to receive either the enhanced survey or the standard survey. 20 households from each survey who report diarrhoea, and 20 surveys from each survey who don't report diarrhoea, are also asked to provide stool samples. Stool samples are collected, visually inspected by a researcher for presence of diarrhoea, and sent for laboratory analysis. Households are first surveyed in April, a time with low diarrhoea prevalence; and again in June/July, a time with high diarrhoea prevalence.

What are the possible benefits and risks of participating?
There are no benefits to participating, with no compensation. However, if a participant gives an answer indicating that the child requires medical care, or if stool samples indicate that medical care is required, the carer will be notified. Risks include discomfort with questions being asked, and discomfort collecting stool. Households will be instructed that they are free to stop the survey and withdraw at any time. A small amount of risk results in data being traceable back to participants, however, all measures have been taken to mitigate this – including storing identifiers and data separately; and encryption of all data on a secure server.

Where is the study run from?
University of Warwick (UK) and International Center for Diarrhoeal Disease Research (Bangladesh)

When is the study starting and how long is it expected to run for?
November 2018 to August 2019

Who is funding the study?
University of Warwick (UK)

Who is the main contact?
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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
REGO-2019-2345

Study information

Scientific Title

Comparison of traditional diarrhoea measurement methods with microbiological indicators

Acronym
DiarrhoeaMeasurement

Study objectives
The researchers hypothesise that traditional methods of measuring diarrhoea prevalence in infants (asking questions on loose stools in the past two weeks) are plagued by several issues, including recall bias, social desirability, and ascertainment bias. To evaluate this, the researchers are comparing traditional diarrhoea measurement questions against two alternatives: an enhanced questionnaire using pictorial representation, and stool sampling for visual inspection and microbiological analysis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 27/02/2019 by the Warwick Biomedical & Scientific Research Ethics Committee in the UK, Contact: Emily Dight, Research Support Officer- Governance & Ethics, University House, University of Warwick, Coventry, CV4 7AL, UK, Tel: +44 (0)24 765 73961, Email: E.C. Dight@warwick.ac.uk, ref: REGO-2019-2345
2. This study has also been submitted to the ICDDR,B Ethics Research Committee in Bangladesh

Study design
Observational longitudinal cohort study

Primary study design
Observational

Study type(s)
Screening

Health condition(s) or problem(s) studied
Diarrhoea/enteric infection

Interventions
Initially 400 households will be randomly selected, of which 200 will be randomised by block randomisation to receive the standard survey (standard diarrhoea measurement questions), and 200 to receive the enhanced survey (with pictorial representation). From each arm, 20 households reporting diarrhoea and 20 not reporting diarrhoea will be chosen for stool sampling.

The study will collect baseline data in April 2019, with follow-up in June/July 2019. The study will be taking place in Camp 18 (Balukhali) of the Cox's Bazar refugee camp in Bangladesh.

Intervention Type
Other

Primary outcome(s)
Diarrhoea prevalence measured through standard survey or enhanced survey at baseline (April 2019) and endline (June/July 2019)

Key secondary outcome(s))
Pathogenic profile measured by microbiological analysis of stool at baseline (April 2019) and endline (June/July 2019)

Completion date
01/08/2019

Eligibility

Key inclusion criteria
1. Household has at least one child under the age of five
2. Household has at least one adult over the age of 18
3. Household consents to study

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

Total final enrolment
800

Key exclusion criteria
Household is expecting to relocate/resettle/repatriate in the next 6 months

Date of first enrolment
20/03/2019

Date of final enrolment
10/04/2019

Locations

Countries of recruitment
Bangladesh

Study participating centre
ICDDR,B
68, Shaheed Tajuddin Ahmed Sarani

Dhaka
Bangladesh
1212

Sponsor information

Organisation
University of Warwick

ROR
https://ror.org/01a77tt86

Funder(s)

Funder type
University/education

Funder Name
University of Warwick

Alternative Name(s)
The University of Warwick, Warwick

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/12/2021	25/04/2022	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version V2.3		01/04/2019	No	No