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Preventing antimicrobial resistance by promoting appropriate prescription of antibiotics, for acute respiratory infections and diarrhoea among adolescents and adults, at rural health centers in Punjab, Pakistan

Submission date 03/09/2024	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 09/09/2024	**Overall study status** Ongoing	
Last Edited 27/10/2026	**Condition category** Infections and Infestations	

Plain English summary of protocol

Backgrounds and study aim
The aim of this trial is to assess the effectiveness of a contextualized intervention, including training and a training manual and desk guide for healthcare staff, to reduce the number of irrational antibiotic prescriptions for upper respiratory tract infections and diarrheal conditions at rural health centers in Punjab, Pakistan.

Who can participate?
Patients aged 12 years and over diagnosed with upper respiratory tract infection or diarrhoea

What does the study involve?
Rural health centers are randomly allocated to the control group or the intervention group.
In the control group the treatment of acute upper respiratory tract infection and diarrhoea will be continued as per routine.
However, to ensure comparability, both in the intervention and control groups, the doctors and allied healthcare staff will be trained to diagnose the patients coming with URTI or diarrhoea according to the case definitions used in the trial. The staff will also be trained in routine patient record-keeping. Patients with symptoms of URTI or diarrhoea will get a WhatsApp number to report the occurrence of significant medical conditions with the help of simplified coding.
The intervention group will be strengthened with a contextualized care package for URTI and diarrhoea which will include a desk guide for the doctors, training modules for doctors and allied staff and a digital application to support patient engagement.
Data will be collected at two distinct time points: firstly, at baseline (February 2025), and subsequently at the end line (March 2026).

What are the possible benefits and risks of participating?
Though there are no immediate benefits for those people participating in the project, it is

expected that this work will reduce the practices of inappropriate antibiotic prescriptions amongst healthcare providers and promote responsible consumption within the community. There are no potential risks or disadvantages to participating in the study.

Where is the study run from?
Association for Social Development (Pakistan)

When is the study starting and how long is it expected to run for?
September 2024 to December 2026

Who is funding the study?
International Centre for Antimicrobial Resistance Solutions (Denmark)

Who is the main contact?
Muhammad Amir Khan, ccp@asd.com.pk

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Protocol serial number
100023

Study information

Scientific Title
A cluster randomized controlled trial to promote appropriate antibiotic prescriptions at rural health centers in Punjab, Pakistan

Study objectives
The contextual intervention at the Rural Health Centers of Punjab will be effective in reducing inappropriate antibiotic prescriptions by 15%.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. Approved 03/09/2024, Association For Social Development (House 12, street 48, F-7/4, Islamabad, 04409, Pakistan; +92 (0)3005191866; irb@asd.com.pk), ref: ASD-EAG-24-002

2. Approved 29/01/2025, Research Ethics Committee for School of Medicine (Governance and Compliance, 11-14 Blenheim Terrace, University of Leeds, Leeds, LS2 9HZ, United Kingdom; +44 (0)113 2431751; FMHUniEthics@leeds.ac.uk), ref: 2247

Primary study design
Interventional

Study design
Cluster randomized controlled trial

Study type(s)
Other

Health condition(s) or problem(s) studied
Diarrhea and upper respiratory tract infections

Interventions
In the control arm the treatment of acute upper respiratory tract infection and diarrhoea will be continued as per routine.

However, to ensure comparability, both in intervention and control arms, the doctors and allied healthcare staff will be trained to diagnose the patients coming with URTI or diarrhoea according to the case definitions used in the trial. The staff will also be trained in routine patient record-keeping.

The patient with symptoms of URTI or diarrhoea will get a WhatsApp number to report the occurrence of significant medical conditions with the help of simplified coding.

The intervention arm will be strengthened with a contextualized care package for URTI and diarrhoea which will include a desk guide for the doctors, training modules for doctors and allied staff and a digital application (i.e., Engage ALL-AMR) to support patient engagement.

Randomization:
The study will recruit and randomize the required sample size of 30 rural health centers (RHCs) in three districts of rural Punjab, i.e., Jhang, Muzaffargarh and Sargodha. All ten RHCs in each district will be allocated into intervention and control at a 1:1 ratio using the randomizeR package in R software.

Intervention Type
Other

Primary outcome(s)
The effectiveness of the intervention measured by calculating the proportion of upper respiratory tract infection (URTI)/diarrhea patients getting inappropriate antibiotic prescriptions in the intervention and control arms. This will be a binary outcome variable stating whether the antibiotic prescription is appropriate or inappropriate. This outcome measure will actually be presented as a proportion and percentage change in the appropriate antibiotic prescription

among intervention and control arms. The outcome will be assessed exactly 1 year after the intervention, which is known as endline assessment.

Key secondary outcome(s)
Current key secondary outcome(s) as of 27/10/2026:

We have one secondary outcome that is only collected for the subgroup of eligible patients who are prescribed any antibiotics: a binary indicator of whether an eligible patient visit resulting in a prescription for any antibiotics includes more than one antibiotic versus just one antibiotic.

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Previous key secondary outcome(s):

The subgroups of diarrhea and URTI patients getting inappropriate antibiotic prescription in the intervention and control arms. Upon collecting all the data, the researchers will stratify the dataset into two subgroups: patients diagnosed with upper respiratory tract infections and/or those diagnosed with diarrhea. The effectiveness of the intervention will be evaluated within both subgroups. The assessment is planned for the first quarter of 2026 (January to March).

Completion date
31/12/2026

Eligibility

Key inclusion criteria
Current key inclusion criteria as of 27/10/2026:

At the cluster level, to maximise generalisability, any functioning RHC, defined as an RHC with regular staff in place, with regular patient flow, and that has basic medicines and diagnostic tests /equipment in place, will be eligible for inclusion in the trial.
At the patient level, any consenting patient aged 12 years or older who presents with upper respiratory tract infections and/or acute diarrhoea, as defined by the clinical case definitions used in their training, and who lacks any severe conditions requiring inpatient hospital care, will be eligible for inclusion in the trial.

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Previous key inclusion criteria:

Cluster level:
1. The top 10 rural health centers per district with the best annual OPD attendance will be included in this study

Patient level:
1. 12 or more years of age
2. Upper respiratory tract infections and/or acute diarrhea based on clinical case definitions
3. Voluntarily accepts the study’s informed consent and age-appropriate parental consent form

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
12 Years

Upper age limit
100 Years

Sex
All

Total final enrolment
612

Key exclusion criteria
1. Chronic diarrheal disease
2. Diagnosed as any other lung condition except URTI
3. Severe conditions requiring (inpatient) hospital attention
4. Failure to provide consent

Date of first enrolment
01/07/2025

Date of final enrolment
30/06/2026

Locations

Countries of recruitment
Pakistan

Study participating centre
Rural health centers of Punjab
House 12, street 48, F-7/4
Islamabad
Pakistan
04409

Sponsor information

Organisation

International Centre for Antimicrobial Resistance Solutions (ICARS)

Funder(s)

Funder type
Research organisation

Funder Name
International Centre for Antimicrobial Resistance Solutions (ICARS)

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publicly available repository; Research Data Leeds Repository (https://archive.researchdata.leeds.ac.uk/)

IPD sharing plan summary
Stored in non-publicly available repository