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Does community engagement improve understanding of appropriate practices to prevent antimicrobial resistance in rural Bangladesh?

Submission date
16/12/2021

Recruitment status
No longer recruiting

Registration date
17/12/2021

Overall study status
Completed

Last Edited
07/01/2026

Condition category
Other

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol
Background and study aims
Antimicrobial resistance (AMR) is a global threat to human health, healthcare provision and socio-economic development. AMR is also a global threat to animal health, and therefore to food sustainability and security. Many factors influence the risk that antimicrobial-resistant infections will develop in individuals, animals and the environment, including the inappropriate use of antimicrobials for human and animal health issues, as well as inappropriate practices around water use (e.g. for drinking and cooking), sanitation and hygiene that increase the risk of infections. Such factors are particularly problematic in low- and middle-income countries (LMICs), especially among rural communities, where levels of awareness about these issues and understanding around appropriate practices to prevent AMR are typically low, while the risks of antimicrobial-resistant infections occurring are high.
Although there are many other factors affecting the risk of AMR in such contexts, such as access and regulation of antimicrobials, one area that is emphasised in global guidance is the importance of raising public awareness on the issue. One promising and well-used approach to raising awareness, particularly in LMICs, is through community engagement approaches. However, to the best of our knowledge, community engagement approaches to address AMR have not been evaluated anywhere in the world. In order to address this gap, a world-leading research group has been established that builds partnerships between six research organisations and project partners in Bangladesh and the United Kingdom.
The aim of this study is to test the effectiveness of a particular, well-developed, community engagement approach, known as the Community Dialogues Approach (CDA). Specifically, the researchers aim to test whether the CDA will improve levels of correct knowledge among community members about antimicrobials and about preventing antimicrobial resistance through knowledge about appropriate use of antimicrobials (both for human and animal health) and appropriate practices around water, sanitation and hygiene issues.

Who can participate?
Any community members aged 18-49 who have been living within the community for the past 12

months without having lived outside the community during that period for more than a total of 1 month.

What does the study involve?
A set of rural communities in Cumilla district, Bangladesh will receive the community dialogues educational process. The researchers will then compare how community members' levels of knowledge about the issues discussed change compared to community members from another set of randomly chosen communities that will not receive the educational process or any inputs from the study team.
The researchers will compare how the CDA, delivered by (voluntary) members of the community through short lectures and facilitated discussions, affects community members' levels of correct and appropriate knowledge about antimicrobials, antimicrobial resistance and how to prevent antimicrobial resistance via appropriate practices around antimicrobial use in humans and animals, as well as appropriate practices around health issues related to water, sanitation and hygiene issues. The researchers will compare the levels of correct and appropriate knowledge about these issues in community members who live in communities where the intervention is delivered to community members from other communities where no such intervention is delivered.

What are the possible benefits and risks of participating?
The possible benefits are improved knowledge about antimicrobials, antimicrobial resistance, and around the appropriate use of antimicrobials in humans and animals, as well as improved knowledge about water, sanitation and hygiene issues in rural Bangladeshi communities. The main risk is inappropriate risky practices relating to antimicrobial use or water, sanitation and hygiene practices due to misunderstanding of the educational information provided, but the researchers aim to mitigate this risk through clearly emphasising what is appropriate and not appropriate practices.

Where is the study run from?
1. University of Leeds (UK)
2. NGO ARK Foundation (Bangladesh)

When is the study starting and how long is it expected to run for?
January 2019 to July 2023

Who is funding the study?
The Medical Research Council (UK)

Who is the main contact?
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Study information

Scientific Title
Evaluating the effectiveness of community engagement at improving understanding of appropriate practices to prevent antimicrobial resistance in rural Bangladesh: a cluster randomised controlled trial

Study objectives

The community engagement intervention will increase understanding and correct knowledge among community members about antimicrobials and about preventing antimicrobial resistance via appropriate use of antimicrobials (both for human and animal health) and appropriate practices around water, sanitation and hygiene issues.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 21/01/2021, School of Medicine Research Ethics (SOMREC) Committee (University of Leeds, Woodhouse, Leeds LS2 9JT, UK; +44 113 34 31642; fmhuniethics@leeds.ac.uk), ref: MREC 20-034
2. Approved 10/10/2021, Bangladesh Medical Research Council (BMRC Bhaban Mohakhall Dhaka 1212 Bangladesh; +88 (0)2 9848396; info@bmrcbd.org), ref: BMRC/NREC/2019-2022/427, 396 14 03 2021

Study design
Cluster-randomized parallel-arm controlled trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Public understanding of appropriate and safe use of antibiotics and antimicrobials in humans and animals, public understanding of antibiotic and antimicrobial resistance, and public understanding of appropriate and safe water, sanitation and hygiene practices, in rural Bangladesh.

Interventions
The study will use a cluster-randomised, parallel-arm, controlled trial design, with one baseline and one follow-up data collection period. Clusters are defined as the population catchment areas of community clinics, which are basic, primary-care health facilities, located within a village but typically providing basic health services cover to around 6,000 individuals living in typically several villages surrounding the village they are located in. The researchers will randomly and simultaneously allocate all clusters to each arm in a 1:1 ratio following baseline data collection, and all eligible individuals within trial clusters allocated to the intervention will be potentially exposed to the intervention. The researchers will use a repeated cross-sectional sampling trial design, collecting data from two separate groups of participants at baseline and follow-up respectively.

Due to the nature of the intervention (community engagement and education) it will not be possible to mask participants, intervention providers or data collectors to the treatment allocation of clusters or participants. The control clusters will receive no community engagement, educational or any other activities as part of the study, and the only study inputs in their communities will be the two data collection rounds.

The complex intervention consists of the use of the Community Dialogues Approach (CDA), combined with a participatory video (PV) component. The CDA was adapted from the Integrated Model of Communication for Social Change. The model assumes a stimulus is required to trigger dialogue among community members about issues that are of concern for the community. Dialogue is understood as a dynamic, iterative process that results in collective decision making to resolve those issues. This process results in social change through increasing individual and collective self-efficacy, strengthening community ownership and shaping social norms. In the CDA, the stimulus is both external (provision of training and tools) and internal to the community (selection of volunteers, volunteers mobilise participants to attend Community Dialogues [CDs]). While volunteers are given the flexibility to tailor each CD to the specific needs and requirements of the community, the sessions are designed to be highly participatory, giving all participants the opportunity to share experiences and voice concerns. Each CD concludes with participants committing to a course of action. Participants are also encouraged to spread information through word of mouth, set a positive example among family, friends and neighbours and hold each other to account for applying decisions reached during the CD.

Members of this team have previously adapted and piloted the CDA to address the misuse of antibiotics in humans in Bangladesh, based on best-practice information and messages taken from appropriate international health organisations such as the WHO (see https://pubmed.ncbi.nlm.nih.gov/32552687/ for details). A strength of the pilot was the emphasis given to ensuring that it was properly embedded within the existing health system and community infrastructure. The findings from the evaluation of the pilot indicate that individuals who have been exposed to the CDA have identified and are implementing actions that will contribute to better stewardship of antibiotics, and that the approach is feasible and acceptable by the stakeholders involved in its delivery. Outputs from the pilot included a set of contextualised intervention materials, which have a primary emphasis on the health sector and the use of antimicrobials by humans.

Participatory video (PV) is a community-focussed communications tool. It was first developed to support the isolated inhabitants of Fogo Island, Newfoundland in the 1960s. Facilitators taught community members to make short films about their lives and supported the circulation of the films around the island. This helped the islanders to understand the collective economic and social pressures they faced at the time, to create a sense of common cause and to advocate for more effective support from the Canadian government. Since then, PV has been used for grassroots advocacy around the world.

Members of this team previously adapted and piloted PV to address the misuse of antibiotics in Nepal. Strengths of the approach were the ability of PV to unpack multiple drivers of AMR within communities, and its power to speak to and influence community leaders and national policymakers. The findings from the evaluation of the pilot indicate that communities are driving action on AMR, and that the approach is feasible and acceptable by the stakeholders involved in its delivery. Outputs from the pilot included a detailed implementation guide and a series of films produced by communities. These films have been curated in multiple ways, including as health education tools within communities, and as advocacy tools at national policy level.

The researchers' experience from the two pilot studies suggests that combining these two approaches will result in a more holistic approach, by allowing us to: 1) unpack multiple drivers of AMR within communities through PV, thus enabling us to expand the CDA content from an emphasis on the use of antimicrobials in humans to incorporating a One Health perspective; 2) implement the embedded CDA with refined content and materials based on this enhanced understanding of AMR in context; and 3) to harness the power of PV to influence policymakers

at national, regional and international level and in doing so increase the visibility of community engagement within, and its impact on, the wider AMR research landscape. Moreover, the film products may also be used as an external stimulus to provoke dialogue within the CDA.

In this trial the researchers will evaluate the effectiveness of the CDA at improving understanding and correct knowledge among community members about antimicrobials and about preventing antimicrobial resistance via appropriate use of antimicrobials (both for human and animal health) and appropriate practices around water, sanitation and hygiene issues. They will do this by implementing the CDA in intervention clusters and allowing the CDA to run for 1 year. They define the clusters as the population catchment areas of community clinics (CCs), which cover around 6,000 individuals, and all such clusters will be eligible. CCs are basic public community health centres present across rural Bangladesh. Although CDs are facilitated by members of the community they are supported by supervisors, who are members of the CC support groups, and the CC healthcare provider, while CCs also provide a base for training and workshops. CCs therefore act as a hub for the CDA and are therefore a natural geographical centre for our clusters. The researchers expect to have around four CD facilitators per cluster who will run around 24 CDs each per cluster across the year-long intervention period (around 96 CDs in total per cluster across the year-long intervention period).

Intervention Type
Behavioural

Primary outcome(s)
Appropriate knowledge about antimicrobials, antimicrobial resistance and appropriate antimicrobial use and practices in relation to human health, based on a knowledge test score at baseline and 12 months

Key secondary outcome(s))
1. Appropriate knowledge about antimicrobial use and practices in relation to animal health, based on a knowledge test score at baseline and 12 months
2. Appropriate knowledge about preventing antimicrobial resistance in relation to appropriate water, sanitation and hygiene practices, based on a knowledge test score at baseline and 12 months

Completion date
01/07/2023

Eligibility

Key inclusion criteria
1. Aged 18-49 years
2. During the last 12 months has not lived outside the cluster for more than one month in total (not necessarily consecutive days)
3. Able to provide informed consent

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
49 years

Sex
All

Total final enrolment
0

Key exclusion criteria
Does not meet the inclusion criteria

Date of first enrolment
01/04/2022

Date of final enrolment
01/07/2023

Locations

Countries of recruitment
Bangladesh

Study participating centre
ARK Foundation
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Sponsor information

Organisation
University of Leeds

ROR
https://ror.org/024mrxd33

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
All participant-level data will be made freely available via a publicly available data-sharing archive alongside the publication of the trial results.
We will make available the quantitative data collected as part of the trial, including participants' socio-demographic characteristics, their outcome values and the trial design variables (e.g. cluster IDs). We will seek informed consent from all participants for their data to be shared, and only share data from those participants agreeing to have their data shared. We will take reasonable steps to ensure the data are anonymous by excluding any personally identifying data (e.g. names, addresses, cluster addresses/locations etc). We will archive the data via the UK Data Service (https://ukdataservice.ac.uk/). Through this repository the data will be made available as "open data", meaning the data "… are made available to any user without the requirement for registration for download/access." The data will be deposited within one-year of the end of the trial.

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	Process evaluation protocol	13/12/2024	30/12/2024	Yes	No
Protocol article		17/12/2025	07/01/2026	Yes	No
Study website		11/11/2025	11/11/2025	No	Yes