"It is like a doctor present near us. We can rely on this book" – A qualitative study assessing the feasibility of implementing antibiotic use guidelines among informal human and animal healthcare providers.

MSc One Health: ecosystems, humans and animals Project Report

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Abstract

Antibiotic use guidelines aim to promote stewardship by supporting and facilitating appropriate antibiotic practices. In India, informal animal and human health providers are critical care givers and a key source of antibiotics, particularly in rural populations where public health resources are insufficient. Despite this, informal providers are typically excluded from antibiotic stewardship policies.

This research qualitatively analysed secondary data, through reflexive thematic analysis, to investigate the perspectives of informal providers who applied antibiotic use guidelines in a feasibility study. The analysis generated five themes which represent patterns of meaning across the data. The themes broadly relate to two categories: the role of providers within the community and pressures of the external environment. Three themes represent enablers to guideline use: guidelines empower informal provider capacity, long term community benefits exceed short term loss and informal providers have strong community influence. Two themes act as barriers to guideline implementation: uncertain pharmaceutical market relationships and all or nothing.

The results demonstrate that the guidelines enhance the capacity of informal providers to practice systematically and build their treatment confidence. Providers possess strong relationships with the communities they serve, this enables them to influence societal perception and develop guideline acceptance. However, providers are influenced by complex factors beyond their control, including their position in the community, their access to pharmaceuticals and strong competition between healthcare providers. These factors can hinder their ability to follow the guidelines. Promotion of greater cohesion across healthcare sectors in India and critical investigation into the influence of the pharmaceutical industry is essential to ease the implementation of the guidelines across rural communities.

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Glossary:

Antimicrobial Consumption: The quantity of antimicrobials imported and manufactured by a country.

Antimicrobial Use: The quantity of antimicrobials taken at the patient level.

Antimicrobial Resistance: Where disease-causing microbial organisms (including bacteria, fungi, viruses, and parasites) are able to survive treatment with antimicrobial medicines (including antibacterials, antifungals, antivirals and antiparasitics).

Antimicrobial Stewardship: The responsible and appropriate use of antimicrobials to limit the emergence of resistance.

Informal Providers: Healthcare providers who do not possess a formal medical/veterinary degree or diploma, who provide consultation services and dispense/prescribe biomedical drugs.

Medical Representatives: Individuals who work on behalf of the pharmaceutical industry to distribute medicines.

Para-Veterinarians: Informal veterinary providers trained in insemination and vaccination, who do not possess full veterinary qualifications. Known by different terms across India including Pranibandhu and Pranimitra.

Rural Healthcare Providers: Informal medical providers who do not possess full medical qualifications.

Acronyms and Abbreviations:

ABU: Antibiotic Use

AMC: Antimicrobial Consumption

AMR: Antimicrobial Resistance

AMS: Antimicrobial Stewardship

AMU: Antimicrobial Use

CD: Community Development

IDIs: In-Depth Interviews

IPs: Informal Providers

LMICs: Low- and Middle-Income Countries

LSHTM: London School of Hygiene and Tropical Medicine

Med Reps: Medical representatives

Para-Vets: Para-Veterinarians

RHPs: Rural Healthcare Providers

RTA: Reflexive Thematic Analysis

WB: West Bengal

Part 1: Literature review

1.1. An Introduction to Antimicrobial Resistance

Antimicrobial Resistance (AMR) occurs when disease-causing microbial organisms acquire the ability to survive treatment with antimicrobial medicines (WHO, 2023). AMR occurs as a natural phenomenon: resistance emerges as an evolutionary response to exposure to antimicrobials. However, extensive use of antimicrobials in healthcare, agriculture and environmental contamination is driving the emergence of AMR at an accelerated rate (Holmes, *et al.*, 2016). Beyond these direct drivers structural factors influence the development and transmission of resistant organisms, including health system stability, food security and healthcare access (Khan, *et al.,* 2019*;* Ahmad *et al.,* 2019).

1.2. AMR Poses a Significant Global Health Threat

AMR threatens our ability to treat microbial infection in humans and animals. AMR is predicted to directly result in 10 million human deaths annually by 2050, with an associated production loss equating to 100 trillion USD (O'Neill, 2016). Microbial organisms are not restricted by international borders; resistant organisms can be transported through movements of people, animals, water and food (DHSC, 2019). Co-ordinated interventions must be implemented universally to provide long-term global protection. The effects of AMR will be disproportionately severe in Low- and Middle-Income Countries (LMICs) due to high prevalence of microbial infection. These countries experience the highest burdens of infectious disease, due to a combination of high population densities, poor healthcare access and infrastructure, environmental, social and economic factors (Baker, *et al.,* 2022).

1.3. Access to Appropriate Antibiotics is Insufficient in India

In India, the mortality rate from infectious disease is one of the highest in the world: 417 per 100,000 individuals (GOI, 2017). Infectious disease is also highly problematic in the animal sector, it is estimated that 70% of mortality in dairy herds is due to infectious disease (Mutua, *et al.,* 2020). The extreme prevalence of infectious disease means that antibiotics are heavily relied upon to treat infection and reduce the high level of mortality. Accordingly, the rate of Antimicrobial Consumption (AMC) for human health is the highest in the world and the fourth highest for animal health (Fazaludeen Koya, *et al.*,

2022). LMICs have often been criticised in health discourse for excessively high Antimicrobial Use (AMU). However, AMC is calculated using nationwide antimicrobial import and manufacturing data, this creates an incomplete picture of individual use (Thamlikitkul, *et al.*, 2020). Reports have shown per capita AMU is lower in LMICs than in High-Income Countries (CDDEP, 2015). Accordingly, when considering the population size of India, use is only 10.7 units per person, less than half of the US rate of 22 units per person (Laxminarayan, and Chaudhury, 2016). Demonstrating that although overall consumption rates are high, on an individual level people lack access to sufficient, essential antimicrobials. Limited availability of medicines contributes to the use of short, suboptimal courses which further facilitates the development of resistance.

Overreliance on low resolution data can obscure highly relevant regional and context-specific factors. Specific data on animal and human patient level AMU and resistance profiles are distinctly lacking in low-income rural areas (Schar, *et al.,* 2018). Nationally, India possesses one of the world's highest rates of AMR in both humans and animals (Rousham, Unicomb, and Islam, 2018). However, the majority of resistance studies are based on urban areas and hospitals. There is a critical lack of research in rural regions from small-holder farms and community settings, where an estimated 80% of antibiotic use occurs (Dhayal, *et al.,* 2024; CDDEP, 2015). The reality is that in rural areas, lack of access to antibiotics continues to kill more people than drug resistance (Taneja and Sharma, 2019; Laxminarayan, *et al.,* 2016). Future research efforts must focus on understanding the factors influencing antibiotic availability and use practices at the community level, considering local perspectives. This allows the development of AMR interventions which account for the health resources available, ensuring that access to essential antimicrobials is maintained.

1.4. Antibiotics Support Healthcare Structures in LMICs

It is necessary to contextualise human and animal antibiotic use in LMICs within structural and societal circumstances. Due to lack of regulatory enforcement, antibiotics in India can often be purchased over the counter as first-line treatments without diagnosis or prescriptions (Singh, *et al.,* 2024). Purchasing medicines from local sources provides the most direct access to antibiotics for people and their animals. These choices are often described in public health discourse as 'demanding' and

'inappropriate' individual-level behaviours. However, this negative terminology fails to acknowledge the context in which these practices are used. In reality, factors across individuals, communities and health systems influence antibiotic use in rural settings. These include, but are not limited to, the role of peers, community kinship, physical access to medicines and personal motivations (Gautham, *et al.,* 2024). Social research has explored the use of antibiotics in LMICs and proposes that antibiotics have become infrastructural (Willis and Chandler, 2019). Antibiotics are often the preferred treatment as they are perceived to offer the fastest and most effective option for humans and animals when living in settings that demand rapid recovery. In countries with high rates of productivity, a day of work absenteeism or loss of livestock represents a significant threat to livelihood. In these circumstances antibiotics become essential to support broader structural instability. This demonstrates that interventions cannot simply target individual behaviour change. AMR interventions in rural regions must use community-wide, participatory approaches to gain insights into the factors beyond individual-level awareness and behaviour. Alongside localised interventions, national healthcare reform is necessary to ensure access to suitable preventative and curative health resources.

1.5. AMR Epitomises a One Health Challenge

AMR represents a health systems challenge, characterised by complex interactions across health sectors and closely intertwined with structural problems as discussed above. There is cross-over use of critical medicines, with the same antimicrobials being used to treat animal and human infection (Myers, *et al.,* 2022). Furthermore, the mechanisms of resistance acquired by pathogens are indistinguishable between animal and human isolates (Holmes., *et al.*, 2016). Once resistance has emerged, it is well established that organisms can transmit between animals and humans (Bhatia, 2023).

The environment acts as a critical source for the emergence and spread of antimicrobial resistant organisms. In particular, contamination of the environment with pharmaceutical waste generates a pressure for the emergence of resistance in the soil and water (Biswas, *et al.*, 2022). AMR is not restricted to a single species or environment: complex, multidirectional interactions facilitate the spread of AMR across health sectors **(Figure 1)**.

Addressing resistance and ensuring the continued provision of effective antimicrobials requires a One Health approach. One Health promotes collaboration across human, animal, and ecosystem health sectors to ensure co-ordinated interventions across disciplines. This study initially concentrates on antimicrobial use within informal human and animal health sectors. Given the role of the environment as a reservoir for resistance, further research will be necessary to understand broader relationships between these informal health sectors, agriculture and the wider ecosystem.

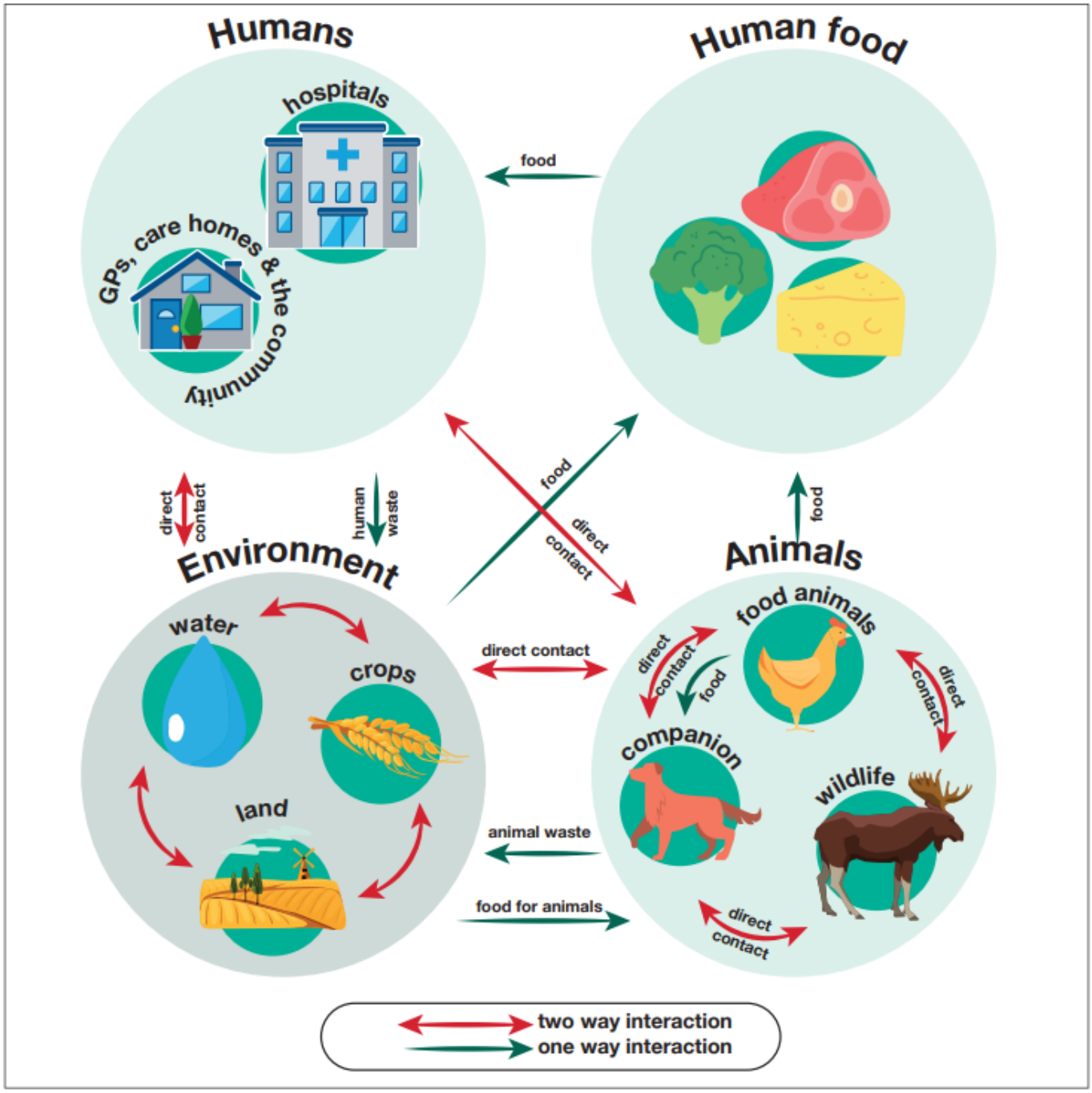


Figure 1. *The interactions between humans, human food, the environment and animals which permit the transfer of antimicrobial resistant organisms. Figure from DHSC, 2024.*

1.6. Global Health Terminology is Problematic in Nature

According to Gross National Income (GNI), India is classified as a LMIC and hence the term is used throughout this research. However, it is important to acknowledge the limitations of such terminology. The vocabulary of global health and development originates in racism and colonialism, with terms implying hierarchies of countries (Khan, *et al.*, 2022). Currently, 137 countries are categorised as 'LMICs' – using umbrella classifications ignores extreme heterogeneity between and within countries. Countries have varying rates of development across sectors and whilst they may be financially limited, they are rich in other resources (for example culture and expertise). Aggregate terminology does not provide insight into which specific resources are limited or the reasons why this may be (Zyl, *et al.*, 2021). The following section endeavours to explore the specific healthcare resource challenges faced in rural regions of India.

1.7. Public Health and Veterinary Resources in Rural India are Inadequate

India possesses a pluralistic healthcare system, which is characterised by a huge diversity of public, private, formal and informal healthcare workers (Chaturvedi, *et al.*, 2023). The majority of care is private and informal; a study showed 86% of human health providers in rural areas are private and only 8% of all providers have a MBBS degree (official medical degree) (Das, *et al.*, 2022). The formal, public healthcare sector is insufficient to provide care to India's rural population. Accordingly, 68% of care is provided by Informal Providers (IPs). IPs are defined as individuals who provide consultation services and biomedical drugs without possession of a formal medical or veterinary degree (Debsarma, 2022). Rural Healthcare Providers (RHPs) is a term used to describe IPs of the human health sector in community areas. The insufficiencies of the formal human health sector are mirrored in the animal health sector, which has only 34,500 trained veterinarians against a required 75,000 (Mutua, *et al.*, 2020). Animal healthcare IPs again offer essential services; para-veterinarians (para-vets) who are trained in insemination and vaccination provide veterinary treatment to animals.

Whilst IPs are not legally allowed to provide allopathic treatment, poor regulatory enforcement enables them to bridge this critical gap in healthcare provision, particularly in rural areas where access to adequate health resources is restricted (George and Iyer, 2013; Gautham, *et al.,* 2014). However, the informal healthcare system is associated

with inappropriate antimicrobial use (Kumar, and Gupta, 2018; Nair, *et al*., 2019). Methods of antibiotic selection and dosing are inconsistent: treatment is often determined by cost rather than clinical signs, with sub-optimal dosing durations being provided to meet the economic needs of the patient (Gautham, *et al*., 2021).

1.8. Antimicrobial Stewardship Interventions Need to be Developed for IPs in India

Antimicrobial Stewardship (AMS) refers to the responsible and appropriate use of antimicrobials to limit the emergence of resistance. Promotion of AMS is essential to addressing the AMR crisis. AMS strategies must account for local circumstances to be sustainable: considering healthcare resources, medicine accessibility, patient requirements and availability of providers. Given the importance of IPs in supplying antimicrobials to rural Indian communities, promotion of stewardship within IP practice is fundamental. However, the majority of current interventions are not designed for IPs as they are not acknowledged as a legal, legitimate source of healthcare provision (Bloom, *et al*., 2015; Sujatha, 2023).

The One Health Antibiotic Stewardship in Society (OASIS) study group is a consortium of public health and veterinary researchers in India and the UK. OASIS used a multistakeholder approach to promote AMS practices by IPs in rural India (OASIS, 2022). Antibiotic Use (ABU) guidelines were co-designed for IPs by task forces of medical, veterinary, pharmaceutical and governmental representatives. These guidelines aimed to empower informal health providers to deliver the most suitable care to patients, considering the medicines and health resources available to them. Integration of diverse perspectives incorporated context-specific insights, supporting the guidelines to be suitable and sustainable for use within the practice setting. AMU guidelines for similar cadres of informally trained community healthcare providers have never been designed, implemented and assessed anywhere in the world. The guidelines were used by RHPs and para-vets in rural regions of West Bengal, interviews were conducted to discuss provider perceptions of the guidelines. This project uses qualitative analysis of interview data to assess the feasibility of implementing the guidelines in rural healthcare settings. Assessing the feasibility of the guidelines aims to understand if they are perceived to be appropriate and acceptable within the specific context setting. This ensures that

interventions can address AMR whilst continuing to meet the health and social care requirements of the local communities.

1.9. Conclusion

AMR represents a global health challenge of increasing importance, international efforts must be made with a focus on regions of highest risk. The drivers of antimicrobial use in these high risk areas, particularly low-income rural regions, extend beyond individual-level behaviours. Strategies to address AMR in LMICs must be tailored to the specific available resources, prioritising access to necessary medicines. Community-wide interventions, which consider structural factors across health sectors are essential to ensure sustained and effective outcomes. The development of intervention strategies which recognise the informal health market and incorporate IPs are critical to supporting responsible antibiotic use in rural communities.

Part 1 word count: 1,998

2. Introduction

2.1. Infectious Disease and Antimicrobial Resistance in India

In India, the mortality rate from infectious disease is one of the highest in the world, antibiotics are heavily relied upon to treat the high frequency of bacterial infection (GOI, 2017). Lack of access to sufficient, quality and appropriate antimicrobials poses a significant threat to overcoming this healthcare burden (Taneja and Sharma, 2019; Laxminarayan, *et al.,* 2016). AMR compounds this issue by reducing the efficacy of medicines used to treat infectious disease, resulting in significant human and animal morbidity and mortality (O'Neill, 2016). Efforts to reduce antimicrobial usage and address AMR must be balanced against the essential requirement for antimicrobials in this setting.

2.2. The Challenges of Addressing AMR in India

In India's healthcare system, there are insufficient accessible, affordable and professionally trained individuals to provide care to the entire human and animal population. Informal providers of animal healthcare, para-vets, and human healthcare, RHPs, provide consultation services and biomedical drugs without possession of a formal veterinary or medical degree (Debsarma, 2022). IPs are fundamental to the animal and human health system throughout India, particularly in rural areas where access to formal treatment is extremely limited (Gautham, *et al*., 2014). However, the informal health system in India is associated with inappropriate use of antimicrobials, including sub-optimal dosing and unsuitable antibiotic selection methods (Nair, *et al*., 2019; Gautham, *et al.,* 2021). Strategies to improve antimicrobial practices by IPs are restricted due to legal barriers: they are not acknowledged as a legal, legitimate source of healthcare provision.

2.3. Addressing AMR Requires a One Health Approach

AMR represents a health systems problem, arising from and interacting with a range of health sectors and disciplines; addressing AMR must take a holistic perspective (Ahmad, *et al*. 2019). A One Health approach is required to integrate action across human, animal, formal and informal sectors to provide the most sustainable solution (Bera, *et al.,* 2024).

Stewardship practices, which promote the responsible use of antimicrobials, must therefore be practiced within all constituents of the system. However, IPs are currently not included in stewardship promotion strategies, this reflects a failure to acknowledge their critical role in primary healthcare provision to humans and animals.

2.4. The OASIS Study Group

The OASIS study group is a consortium of public health and veterinary researchers in India and the UK. The OASIS study group used a multistakeholder approach to co-design interventions to promote antimicrobial stewardship in rural locations in India with healthcare providers, communities, professionals and policymakers (OASIS, 2022). A key component of these interventions was the development of antibiotic usage guidelines for RHPs and para-vets by medical and veterinary task forces. AMU guidelines for similar cadres of informally trained community healthcare providers have never been designed, implemented and assessed anywhere in the world. Alongside orientation and training sessions, these guidelines were provided to a small group of RHPs and para-vets in West Bengal in a feasibility study. These IPs were subsequently interviewed to discuss their perceptions of implementing the guidelines within their practice. This current project aims to use qualitative analysis of secondary data to assess the comparative feasibility of using these guidelines in informal healthcare settings, considering their acceptability and appropriateness.

3. Aims and Objectives

3.1. Aims

This study aims to understand the comparative feasibility of implementing antibiotic usage guidelines among Rural Healthcare Providers and Para-Veterinarians in West Bengal, India. Qualitative analysis is conducted to explore the narrative underlying the interview data, with a central focus on understanding the perspectives and experiences of the participants. Meaning is co-created by the researcher and data through a process of reflexive thematic analysis.

3.2. Objectives

1: To explore the extent to which the antibiotic usage guidelines are perceived to be appropriate, understanding their compatibility within the given practice setting, how they are used and their perceived impact on treatment practices.

2: To explore the acceptability of the antibiotic usage guidelines, characterising attitudes and opinions regarding their use, effectiveness, agreeability and suitability.

3: To locate key barriers and enablers which influence the adoption and long term implementation of the guidelines by providers, considering recommendations which could alleviate such barriers.

4. Methodology

4.1. Study Sites and Participants

The original data for this study was collected during August – December 2023 as part of the OASIS study in West Bengal (WB) State in India. Study sites were determined by working with the reputed medical institution, the All India Institute of Medical Sciences, Kalyani (AIIMSK) to identify priority areas for development programmes. Human and animal health IPs, including RHPs and para-vets, were selected alongside consultation with relevant stakeholders, including RHP associations and local medical and veterinary system staff. Research with RHPs was conducted in Chakdah Community Development (CD) block in Nadia District. Research with para-vets was conducted in Basirhat Animal Hospital in Basirhat-1 CD block in North 24 Parganas district.

4.2. Primary Data Collection

This current study is a secondary analysis of transcript data from investigations conducted by the OASIS group (OASIS, 2022). ABU guidelines, for human and animal IPs, have been developed by OASIS as part of a research initiative to transform AMS practices in rural regions of India. Following orientation sessions with medical doctors and veterinarians, these guidelines were provided to nine RHPs and nine para-vets in a feasibility study. Providers used the guidelines for 7-10 days before In-Depth Interviews (IDIs) were conducted. Interviews were recorded, transcribed and translated by bilingual researchers.

4.3. Study Design and Conceptual Framework

This secondary analysis draws on transcript data from the IDIs conducted with RHPs and para-vets. This study aimed to qualitatively analyse the data to assess the comparative feasibility of implementing the guidelines in rural settings. Feasibility analysis addresses a critical gap towards providing appropriate and accepted ABU guidance to optimise the antibiotic usage of RHPs and para-vets and promote stewardship. Analysis was supported by a conceptual feasibility framework designed to explore the perceived acceptability and appropriateness of the guidelines **(Figure 2)**. Acceptability is the extent to which the guidelines are considered agreeable and suitable (Sekhon, Cartwright, and

Francis, 2017). Appropriateness is the perceived relevance, compatibility and impact of the guidelines within the practice setting (Mettert, *et al*. 2020).

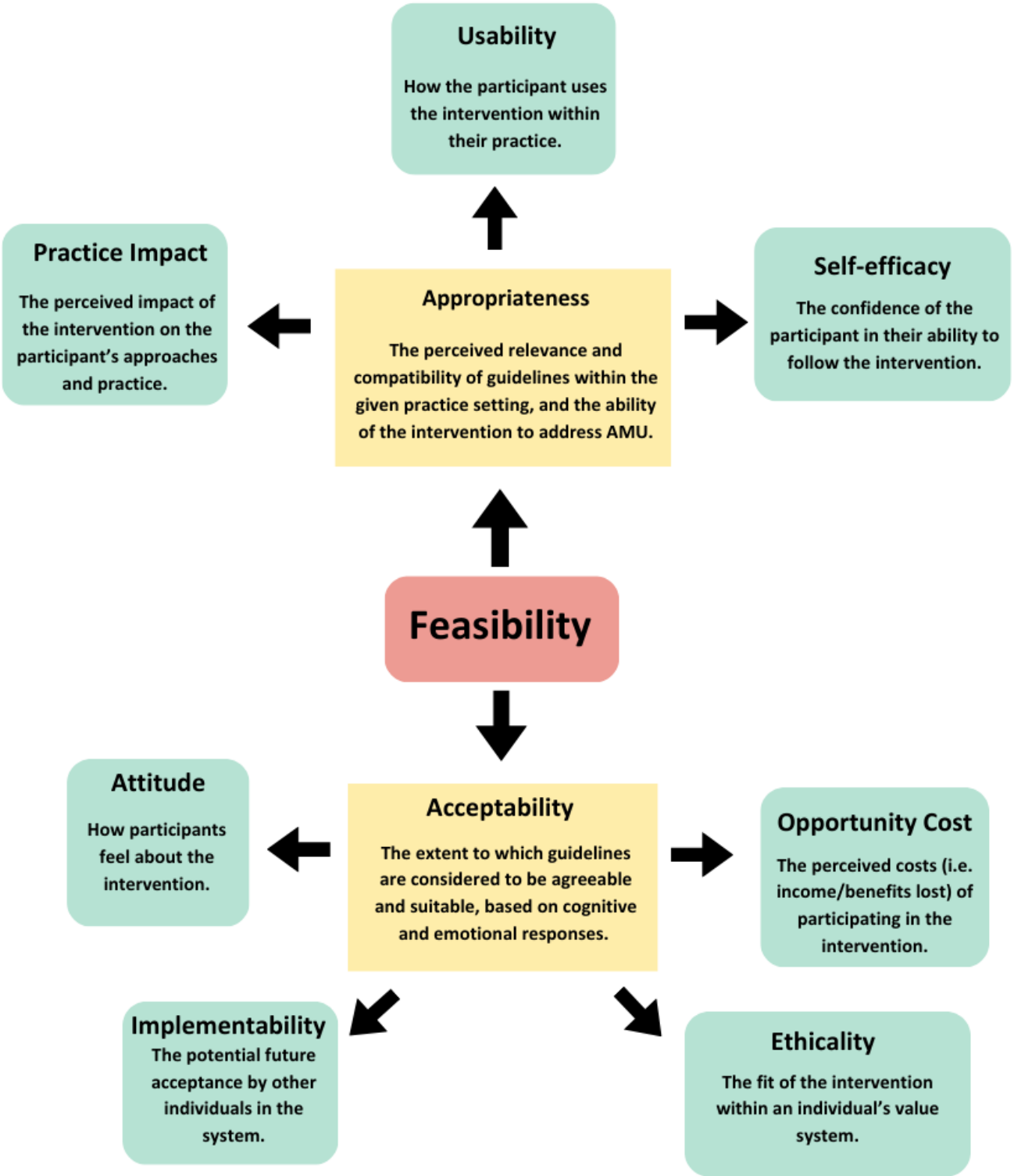


Figure 2. *A conceptual feasibility framework used to outline the key concepts of acceptability and appropriateness to be considered within the study. Adapted from the 'Theoretical Framework of Acceptability' of Sekhon, et al., (2017).*

4.4. Data Analysis

Reflexive Thematic Analysis (RTA) was conducted on the transcript data, following guidance from Braun and Clarke (2006, 2022). RTA facilitates the development and analysis of patterns of themes across the data set, to understand the complex narrative underlying the data. RTA is theoretically flexible and can be conducted using different frameworks and orientations to data, this ensures the analysis aligns to the specific research aims. An experiential qualitative framework was applied to the analysis to understand the perspectives of the participants. What individuals said they think, feel and do was taken as reality, with appreciation of their thoughts and feelings as a reflection of personal states. This approach was most appropriate for the present study as it aligns with the objectives which seek to understand the perspectives of the participants.

In this analysis, the meaning of the data is created through a 'Big Q' qualitative paradigm approach. This approach was supported by concrete practices of reflexivity throughout the project. Reflexivity refers to a set of continuous practices through which researchers evaluate and critique how their own subjectivity influences the process of research. The practices of reflexivity used, including journalling and voice memos, were supported by guiding literature (Olmos-Vega, et al., 2022; Wilkinson, 1998). A reflexive approach was particularly essential for this secondary data analysis as it allowed critical engagement with the data despite not having been involved in data collection. In the analysis subjectivity was valued. The subjectivity of the participants and researcher was considered to be an integral part of data generation, this helped to understand reality as it was experienced by participants.

RTA is an iterative process and the following stages were not necessarily followed in a linear fashion, but rather were repeated and revised throughout the analysis. Data familiarisation was performed by reading and re-reading the transcripts. Data was coded to highlight and label meaningful pieces of information, coding was conducted using QRS international Nvivo 14 (Lumivero, 2023). Coding followed a deductive orientation, the development of codes was guided by the components of the conceptual feasibility framework (**Figure 1**). Throughout data coding, RHP and para-vet transcripts were considered separately such that differences could be identified and isolated. Codes were

then combined and grouped together to generate candidate themes which share a central organising concept across transcripts. Themes were reviewed and revised in reference to the individual interviews and data set as a whole. Whilst the overall patterns presented in themes refer to all informal providers, nuanced differences between human and animal providers are described and discussed as themes are presented.

4.5. Consent, Confidentiality and Data Storage

The lead researcher of the study (who spoke the local language) explained the purpose of the interview and the informed consent form to the study participants. Written consent was taken from the participants for the study. The interviews were audio recorded; the recordings were anonymised and transcribed verbatim by bilingual interviewing researchers.

The transcripts are stored as MS word files in a password protected LSHTM (London School of Hygiene and Tropical Medicine) server space. The identifier information has been separated from the detailed transcripts and stored in a separate log sheet. At the end of the study and after publications are completed, data will be curated and deposited in the LSHTM Compass repository and UK Data Service repositories.

4.6. Ethics

Ethical approval for the present study was obtained through the LSHTM's Research Ethics Committee (reference code: 30367).

Ethical approval was gained for collection of the original data from LSHTM's Research Ethics Committee (reference code: 17484) and from Indian Ethics Committees: Indian Institute of Liver and Digestive Sciences (reference code: IILDS/IECHR/01/2019), Public Health Foundation of India Institutional Review Board (reference code: TRC-IEC 448/20, extension approval reference code: TRC-IEC 448.1/20) and West Bengal University of Animal and Fishery Sciences (reference code: IAEC/190(XVII)/B).

5. Results

Interviews were conducted with nine RHPs who provide human healthcare services and nine para-vets who provide animal healthcare services. Participant ID, type of provider and their stated training is given in **table 1** for reference. IPs were defined as individuals who do not posses a formal medical or veterinary degree, who provide consultation services and biomedical drugs. Within this study, the term 'IPs' refers to both medical (RHPs) and veterinary (para-vets) providers. Providers mostly described gaining their knowledge through working experience with other IPs or formal doctors. However, some have participated in training schemes, such as training from the Rural Medical Practitioner Association. The term 'patients' is used to refer both to people treated by RHPs and animals treated by para-vets.

Table 1. *Provider ID, the health sector in which they work, type of provider and training for each participant within the data set.*

Provider ID	Health sector	Type of provider	Training stated
RHP 1	Human	Rural Healthcare Provider	Training from Chakdah hospital on TB
RHP 2	Human	Rural Healthcare Provider	Learnt from working experience with another IP and medical doctor
RHP 3	Human	Rural Healthcare Provider	Training from Kalyani Jawaharlal hospital and WHO course
RHP 4	Human	Rural Healthcare Provider	Learnt from working experience with another IP
RHP 5	Human	Rural Healthcare Provider	Learnt from working experience with a medical doctor
RHP 6	Human	Rural Healthcare Provider	Training in a medical college from a medical doctor
RHP 7	Human	Rural Healthcare Provider	Training from other IPs at Rural Medical Practitioner Association
RHP 8	Human	Rural Healthcare Provider	Completed unspecified degree
RHP 9	Human	Rural Healthcare Provider	Learnt from working experience with other IPs
PB 1	Animal	Para-veterinarian, Pranibandhu	Attended unspecified training courses
PB 2	Animal	Para-veterinarian, Pranibandhu	Learnt from working experience with a veterinary doctor
PB 3	Animal	Para-veterinarian, Pranibandhu	Not specified
PM 4	Animal	Para-veterinarian, Pranimitra	Not specified
PM 5	Animal	Para-veterinarian, Pranimitra	Not specified
PM 6	Animal	Para-veterinarian, Pranimitra	Trainings from a veterinary doctor in Bashirhat
PM 7	Animal	Para-veterinarian, Pranimitra	Learnt from working experience with veterinary doctor
PM 8	Animal	Para-veterinarian, Pranimitra	Learnt from working experience with a veterinary doctor
PB 9	Animal	Para-veterinarian, Pranibandhu	Not specified

5.1. How Providers Applied the Guidelines in Practice

Firstly, it is important to outline how providers described their use of the guidelines in practice. Almost all providers acknowledged the guidelines were clear and easy to understand in regard to the language used, structure, font and flow. Providers demonstrated the usability of the guidelines, often stating that they followed them in a step-by-step manner during everyday clinics. For example, one provider described first recognising the symptoms of their patients, referring to the appropriate guideline and then following the outlined practice of diagnosis and provision of medicine. Using the guidelines provided reassurance in their practice to ensure they do not make errors.

> *"I have read and hung the guidelines on the wall…when a patient comes with any symptom which I found in the guideline then I read the related content once and practice accordingly. To avoid any mistake in identifying the disease, prescribing or dispensing the medicine."* **- RHP 7**

Providers were able to recount occasions where they have applied the guidelines for specific conditions. Para-vets most frequently stated that they used the guidelines for fever, diarrhoea and mastitis. They followed these to understand the severity of the disease and therefore the appropriate treatment.

> *"Like in diarrhoea, how will I identify that the diarrhoea is in the initial stage…when it will be recovered normally in calves…in which condition medicine should be given to the calf…in which condition antibiotics should be given…in which condition will we refer…we are understanding all these from the guidelines…"* **– PM 4**

RHPs also described using the guidelines during treatment of diarrhoea and fever, and additionally for urinary tract infections and skin conditions, including carbuncles. One provider explained how they now delay the use of antibiotics when treating a fever.

> *"Before receiving them, for example, when I treated a patient with fever, I used to prescribe antibiotics like Azithromycin when I saw that they had fever. Now I am giving paracetamol only. After 2 to 3 days if they are coming back with fever then I am giving antibiotic."* **– RHP 5**

The analysis, guided by the conceptual framework, generated several distinct but interrelated themes which demonstrate the appropriateness and acceptability of the guidelines. Overall, these themes influence the feasibility of using the guidelines in the community in the future.

5.2. Guidelines Empower IP Capacity

The first theme of meaning across the data illustrates how the guidelines were used to influence the treatment and practice capacity of IPs, this theme relates to the perceived appropriateness of the guidelines and acts as an enabler to guideline use. IPs expressed self-efficacy, with a confidence in their ability to follow and use the guidelines and they perceived an impact on their treatment practices.

Participants, both RHPs and para-vets, perceived that they already possessed some knowledge regarding AMR and appropriate treatment practices. They explained that their previous knowledge was gained through working experience with other practitioners and some training programmes. A deeper examination during the interviews revealed that providers had an awareness of what treatments were effective, however, their understanding of diagnosing disease and why certain medicines were necessary or not necessary was limited. Although knowledge was present, it was superficial in nature, medicines and treatment were given casually, based on what was known previously, or *"more or less"* as was described by one participant. The guidelines provided a comprehensive explanation and understanding of the underlying reasoning behind treatment. This enhanced insight enabled providers to demonstrate self-efficacy, and they expressed a confidence in their ability to understand and follow the guidelines.

> *"Previously, we used to give the medicine according to our perception… We used to prescribe antibiotics and medicines like that more or less…after visiting there, we are able to understand the proper system…"* **- RHP 1**

The guidelines facilitated practicing in a more structured manner, moving from symptoms to diagnosis to treatment and explained what to do in severe cases. This enhanced self-confidence when treating; providers identified an improved understanding of their capacity and understood what to do when this was exceeded. The clear, structured

approach to treatment outlined in the guidelines had a notable practice impact, they were used and applied to enable providers to practice more systematically.

> *"How to identify the illness is the best functionality of these guidelines…I like this feature of the guideline… It shows medicine can be given later… First, identifying the illness is important…like understanding the symptoms of the patient fast after that we have to give the medicine… That's why I like the feature."* **- RHP 4**

> *"If the patient is not recovering then we have to refer the patient to the hospital… […] from this, we have gained confidence to do the treatment… We have understood that if we don't understand anything, we have to refer to the hospital…"* **- RHP 1**

RHPs in particular consistently stated that they would refer a case as soon as they realised it was beyond their control. However, both RHPs and para-vets recognised the value in the guidelines enabling them to practice independently. This demonstrates guideline usability, they can be used to support providers' first level treatment without having to consult outside sources for every patient. This was more strongly expressed by para-vets, who indicated an eagerness to increase their knowledge and expand their capacity to treat more conditions independently.

> *"So we can see the guidelines when we forget something. It is so much helpful. It is like a doctor present near us. We can rely on this book."* **- PM 6**

> *"If we get that training then we will have more knowledge and we can practice more and more."* **- PM 8**

IPs expressed a positive attitude towards their improved capacity; providers perceived value in practicing more systematically and expressed a drive to treat in accordance with the guidelines. In this way guidelines were viewed as appropriate within the practice setting and this acted as an enabler to their long term implementation.

5.3. Long Term Community Benefits Exceed Short Term Loss

Another theme that was generated related to providers acknowledging the long term benefits to the community of reducing antibiotic use. Providers expressed positive attitudes towards the use of the guidelines and the ethical values they represented; this acceptance of and agreement with these values acted as an enabler to guideline implementation.

The guidelines and associated training enabled providers to recognise the long term benefits of treating without antibiotics, they acknowledged that treating in accordance with the guidelines was the right thing to do. A number of providers expressed a lack of interest in 'quick fix' solutions, stating that antibiotics result in patient 'weakness'. There was an expression of blame on other providers, particularly formal doctors, who they said continued to use practices which were not in accordance with the guidelines as this may have a negative impact on patients in the future.

> *"Those doctors give them steroids or antibiotics for speedy recovery… I have told my patients that these medicines can help them recover quickly but it will affect them in the future…"* **- RHP 1**

Following on from this, using the guidelines enabled providers to recognise that reducing antibiotic use limited the emergence of resistance. One provider explained that they previously gave antibiotics because it was profitable for them, however, through using the guidelines they have understood that this will increase resistance and create challenges for the future. They recognised that they must make difficult decisions now to ensure the next generation can be treated successfully. The guidelines appeared aligned with the ethical values and altruistic nature of these providers who were embedded within the communities they served. They expressed a respect for the inherent value of using the guidelines in their practice to support their communities into the future.

> *"It is true that if I give fewer antibiotics, it will create economic difficulty for us but that is to some extent and not to a great extent. I look at the good side of giving fewer antibiotics which is good for all. I cannot think only about my gain only. If my patients become antibiotic resistant, it is our loss. If 10 patients become resistant today, 100 will be resistant tomorrow…antibiotics will not work on them. It is dangerous for us. Keeping in mind the steady earning in future, I have to accept this temporary income loss."* **- RHP 7**

This theme was more consistent throughout interviews with RHPs, than para-vets, as RHPs focused strongly on moral obligation and their duty to their patients. However, both RHPs and para-vets expressed a positive attitude towards the long term community benefits of using the guidelines, which aligned with their personal value systems. This sense of social responsibility enabled the implementation of the guidelines as they were viewed as the appropriate system to follow. For both RHPs and para-vets it was evident

that the community acted as a vital part of IP practice and local relationships were highly influential.

5.4. IPs Have Strong Community Influence

This theme explored how IPs were integrated in the communities in which they practiced and had influence over individuals in the community. Many providers perceived that they could easily encourage acceptance of the guidelines, by their local patients, enabling them to use and implement them freely.

Providers recognised that duration of practice, reputation and experience established trust, it was perceived that IP treatment was accepted more easily if they have been practicing in the community for a long time.

> *"They have trust in me…even if I change the treatment process, […] I have been treating them for a long time and they believe I can cure them. So a change in treatment process is not going to affect them that they will leave me. They will not go to other doctors. Using guidelines is not reducing my number of patients."*
>
> **- RHP 5**

The strong bonds created with the communities enabled providers to alter the practices they use whilst still retaining trust. This means that providers were able to practice in accordance with the guidelines without facing challenge from patients. Many IPs were positive in their attitude and perceived that they will be able to convince patients to follow the new treatments. This demonstrates that providers feel it will be possible to implement the guidelines more broadly, once they have explained the new practice to patients they will not be challenged.

> *"When I say all these things to them, patients usually listen to me… these patients are not very rude, they are good patients in this village area…"* **- RHP 4**

Providers identified that patients preferred to receive treatment from community providers rather than formally trained or hospital doctors. There was a sense of distrust between the healthcare systems, with providers stating that patients could not be honest with formal doctors as there was a lack of mutual respect. It was perceived that because the community respects IPs, it would be easier to use the guidelines and implement them

within these settings rather than with formal doctors who were believed to be untrustworthy.

> *"You people have taken the proper way to do it because you are working with the doctors like us… People who live in the villages really respect doctors like us… if they visit an MBBS doctor or MD doctor, they are unable to speak freely with them… they can express themselves properly to us… As they express everything and speak with us without hesitation, it is helpful for us as well to do the treatment properly…"* **RHP 3**

These community relationships are critically important to IP practice, mutual respect is essential for their maintenance. Strong community relationships enable providers to act with autonomy, influence their patients and gain acceptance of the guidelines.

5.5. Uncertain Pharmaceutical Market Relationships

Whilst strong, trusting community relationships can empower IPs to act with autonomy, this theme explored how healthcare market relationships can restrict treatment practices. Individuals from the pharmaceutical industry were identified as influencing the purchasing practices of para-vets, this would reduce the usability of the guidelines, and limit the impact on treatment practice. These relationships act as a potential barrier to implementation as the guidelines may not appropriately align with the pharmaceutical market. Para-vets commonly cited receiving medical guidance from medical representatives (med reps) and pressure to purchase antibiotics.

> *"They (med reps) explain us in detail which antibiotic will cure which disease and always try to insist selling higher antibiotics…"* **- PB 1**

Para-vets recognised that if they follow the guidelines and do not use antibiotics then the med reps will be negatively impacted. One participant explained that they may use business tactics to encourage the purchasing of certain medications, currently they receive subsidies, or discounts, for purchasing medicines but these could be taken away. In this instance following the guidelines may damage economic relationships between providers and med reps and this could make the treatments provided by IPs more expensive. This would restrict providers self-efficacy to follow the guidelines and purchase the necessary medicines, acting as a barrier to their use.

> *"I get medicine at a good price with subsidy. They (med reps) may not give that."* **– PM 5**

Interestingly, one para-vet started describing how med reps use gifts to encourage sales of certain medications but then expressed hesitancy to discuss the topic further, PM4 stated: 'Maybe I should not say this…' and then clarified with the interviewer 'Should I say this?'. This indicated a concern regarding what was appropriate information to share.

Contrastingly to para-vets, RHPs stated that med reps did not influence them to purchase medications. One RHP noted that if they did not purchase antibiotics then the med reps may be negatively impacted, however, they stated that with time they would adapt. They maintained full autonomy to purchase the medicines that best suited their treatment practices. This would enable RHPs to freely use the guidelines in practice, purchasing and prescribing any medication necessary, in this instance, med reps do not act as a barrier to guideline implementation.

> *"No. They (med reps) are selling all kinds of medicines. Whatever we purchase, they will earn money so they will be happy. They are not forcing me to purchase antibiotics."* **- RHP 4**

Whilst contradictory responses were provided by RHPs and para-vets, the results indicate that at least some IPs were influenced by med reps. This means that they may be restricted in their ability to purchase and prescribe the most suitable medicines in accordance with the guidelines. This would restrict their usability and impact on practice, reducing the overall appropriateness of their use within the informal health system.

5.6. All or Nothing

The following theme 'All or Nothing' is split into two sub-themes: competition between healthcare providers is intense and co-operation is essential. These relate to both the appropriateness and acceptability of the guidelines, considering how the guidelines can create an opportunity cost through loss of business and how providers perceived this can be overcome.

5.6.1. Competition Between Healthcare Providers is Intense

Participants often spoke of a high level of competition between healthcare providers. It was stated that a variety of treatment practices were used across providers and there was

little consistency in the care a patient received. They described that patients could easily access treatment from other sources if they were not happy with the care provided. Due to this, providers expressed some hesitation to use the guidelines, as they feared that they may lose business to other providers who were still prescribing antibiotics. As such the guidelines could create an opportunity cost to providers, reducing patient number. This creates a pressure to comply with the wishes of patients, acting outside of the guidelines, to protect their future livelihoods.

> *"Now I am giving different medicine and it is taking more time to recover…the market is competitive…if after 2 to 3 days the animal is not cured they will call another doctor (paravet) and I will lose patient and my income will fall…"* **- PB 2**

Furthermore, providers stated that for patients, recovery time is their top priority, people are under extreme pressure to recover themselves or their animals quickly and this pressure was then transferred to IPs. As patients are driven to recover as quickly as possible, they will seek other sources of care if they are not recovering rapidly enough. This was particularly intense for para-vets who commonly recounted that owners did not want to delay treatment for their animals as regaining their productivity was essential to their livelihoods.

> *"Yes there are challenges in using them…as in the guidelines it is mentioned that no antibiotic for mild cases or in some cases first use paracetamol or enzymes…but it is not possible in rural area…owners will not accept…when they will see that the animal is getting better in 1 or 2 days then they will give call to another doctor (paravet)…"* **- PB 3**

In order to prevent losing their patients to competitors, IPs were often compelled to provide the most fast acting treatment rather than the most appropriate. If patients create pressure for providers to give medicines with the fastest recovery time, this restricts the usability of the guidelines and limits the impact on provider practice.

5.6.2. Co-operation is Essential

IPs recognised the importance of all providers within the community co-operating, using the same treatment practices and following the guidelines. IPs expressed concern that if others continue to use antibiotics and their patients recover faster, this will result in the reputation of those following the guidelines being comparatively damaged. Other providers may talk negatively about the practices of those using the guidelines to secure

their own business, this acts as a barrier to the implementation of the guidelines. IPs perceived that if all providers followed and used the guidelines the care provided to patients will be more consistent and they will not seek alternative sources. This would help to reduce the opportunity cost through lost services, maintain reputation and accelerate recognition from patients.

> *"So if the rest are not getting guidelines and training they will play opposite role and the use of guidelines will not be successful…they will act as barrier to take the patient from us…"* **- PB 1**

> *"Also following of guidelines should be started by all the village doctors…if that happens then patients will understand that not only this doctor (him)…everyone is following the same…then it is possible to overcome this challenge related to acceptance among patients."* **- RHP 7**

The perception that providers must co-operate and accept the guidelines together to allow their successful implementation was a strong pattern across RHP and para-vet data. It was recognised that protecting the IPs business and preventing loss of patients hinged on the guidelines being accepted across the whole community.

5.7. Relationships Between Themes and Future Directions

This analysis generated five distinct but interrelated themes which depict the patterns of meaning across the data. The themes which were generated broadly relate to two categories: the role of providers within the community and pressures of the external environment. Connections between themes and their relationship to the project aims are shown in a thematic map (**Figure 3**). A summary of each theme and its relationship to the conceptual feasibility framework is demonstrated in **table 2**. Providers perceived that the guidelines could be used to structure their treatment and enable them to practice more systematically. However, in order to implement them effectively and enable acceptance by the community, the influence of outside factors must be considered, including pharmaceutical representatives and other healthcare providers. IPs recommended that to enhance acceptance of the guidelines they should be used by all providers within the community. In terms of practicality, providers also suggested that the guidelines should be developed in a book and PDF format with additional photos. They expressed that this would increase the efficiency of use and movability, enabling them to use the guidelines

in all practice settings and increase the ease with which they can be distributed to other providers.

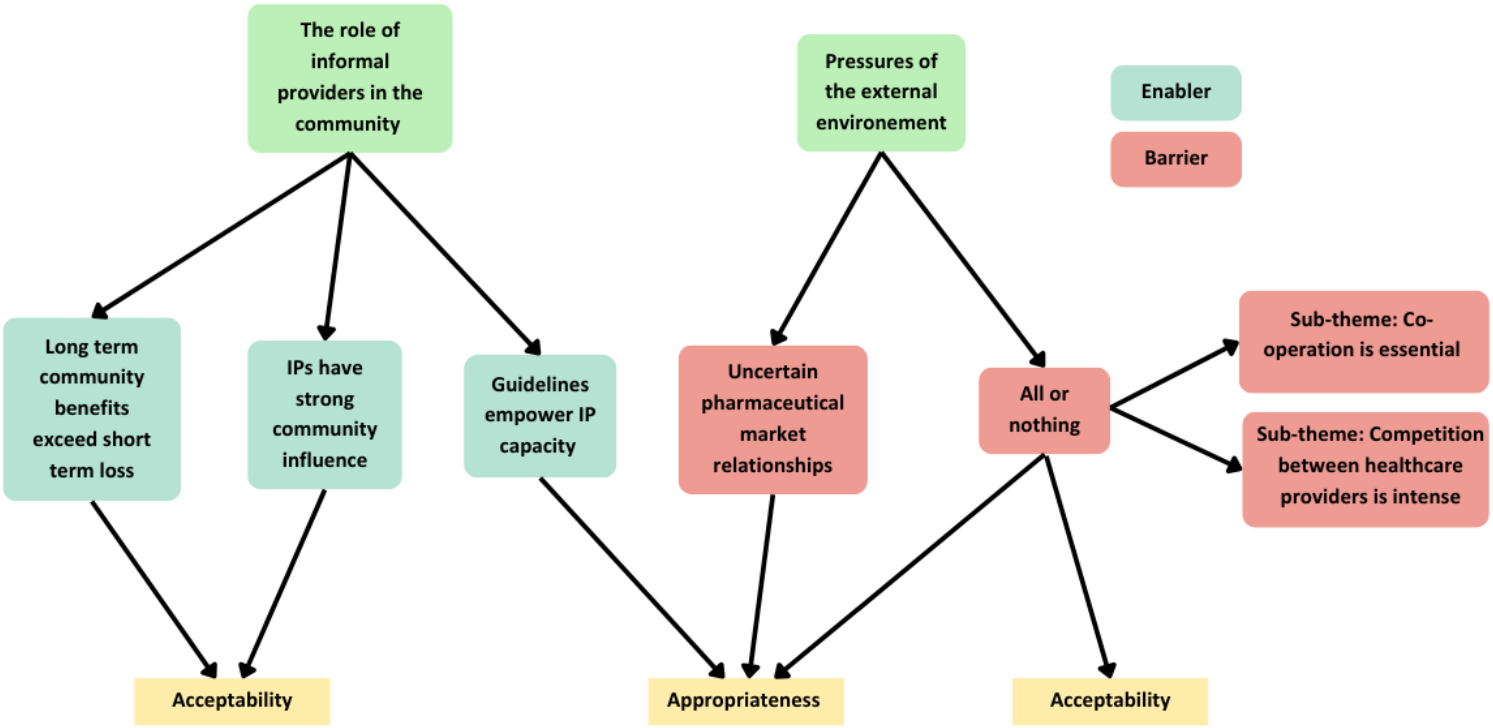


Figure 3. *A thematic map to demonstrate the relationships between themes and their relevance to the project objectives: acceptability and appropriateness.*

Table 2. *A summary table to show the themes discussed, provide a description of their meaning and demonstrate their relationship to the conceptual feasibility framework.*

Themes	Description	Relation to conceptual feasibility framework
Guidelines empower IP capacity	The guidelines provided further understanding of AMR and treatment structure which allowed them to practice more systematically. Confidence has been built in IP practice capacity, IPs have an increased awareness of their limits, can practice independently and know what to do with cases outside of their capacity.	**Appropriateness** Practice impact, self-efficacy & usability Theme acts as an **enabler** to guideline implementation
Long term community benefits exceed short term loss	The guidelines enabled IPs to recognise that the long term negative impact of AMR exceeds any benefits that might be received by using antibiotics in the short term. There is a moral sense to alter treatment practice now to avoid this in the future.	**Acceptability** Attitude, implementability & ethicality Theme acts as an **enabler** to guideline implementation
IPs have strong community influence	IPs are fully integrated within the community, they have built trusting relationships with patients over years of working experience. Their relationships enable them to influence and advise patients. There is reluctance to trust formal doctors who are not perceived to be honest or acting in their best interests.	**Acceptability** Attitude & implementability Theme acts as an **enabler** to guideline implementation
Uncertain pharmaceutical market relationships	The treatment practices provided by para-vets are restricted by the economic relationships they have with medical providers. They may be influenced to purchase certain medicines outside of the guideline recommendations. **However,** RHPs do not express any pressure from medical representatives.	**Appropriateness** Practice impact, usability & self-efficacy Theme acts as a potential **barrier** to guideline implementation
All or nothing		**Appropriateness & Acceptability**
Competition between healthcare providers is intense	There is strong competition and use of contradictory practices between medical providers, both informal and formal. Patients can easily access care from other sources if they are unhappy and do not feel they are recovering fast enough.	Practice impact, opportunity cost & implementability
Co-operation is essential	If others continue to practice outside of the guidelines then the reputation of IPs in the study will be damaged. If all practice the same way then the community acceptance of the guidelines will accelerate.	Theme acts as a **barrier** to guideline implementation

6. Discussion

This study aimed to investigate the feasibility of implementing antibiotic guidelines for use by informal animal and human healthcare providers. Providers were able to apply and follow the guidelines in a step-by-step manner to diagnose conditions based on symptoms and treat accordingly. Participants had a limited underlying awareness of AMR and appropriate practice, however the guidelines enhanced this awareness, empowering IPs to understand the reasoning behind certain practices and treat more systematically. IPs acknowledged the long term benefits of providing treatment without antibiotics. However, providers recognised that there were external influences beyond their control which may hinder their abilities to use the guidelines in practice. Within this discussion, focus will be placed on how providers apply the guidelines within their practice, relationships with other healthcare providers and the pharmaceutical industry influence. How these topics relate to the current body of literature and how they act as enablers or barriers to the implementation of the guidelines will be explored.

6.1. Building and Enabling Provider Capacity

In the present study, providers perceived that they possessed an awareness of AMR and appropriate treatment practices, however this knowledge was limited and inconsistent. This finding has also been recorded by previous investigations (Gautham, *et al.,* 2014; Dhayal, *et al.*, 2024). The guidelines built provider confidence and understanding by presenting the stages of treatment in an in-depth, comprehensive manner. This enabled more structured practice and increased provider capacity to follow the correct protocol, with an improved understanding of why procedures were necessary. This demonstrates that training IPs can enhance their capacity through more systematic practice, as such the guidelines offer an appropriate intervention for use by informal healthcare providers and it is feasible to implement them within this setting. This reflects the finding of Das, *et al.,* (2016), who quantified the impact of training IPs and identified a 14.2% increase in correct case management. This counters the concern of the Indian Medical Association, that training IPs threatens the legitimacy of medical standards and encourages them to violate rules (Sujatha, 2023). Interestingly however, Das showed that training IPs had no impact on the use of unnecessary antibiotics. Despite this and regardless of training, IPs prescribed 28.2% fewer unnecessary antibiotics than formally trained public doctors.

This demonstrates that formal education and knowledge of AMR is not necessarily sufficient to ensure correct prescribing practice. This finding was also identified in the present study, providers were not always able to choose correct prescribing practice, despite having an enhanced awareness of AMR. Das proposed that this is due to the revenue model employed by health providers, implying that overprescription is expected when diagnosis is tied to profit.

However, it should be contended that whilst profit may partly explain prescription choices, the decision to use antibiotics ought not to be attributed to a single economic driver. Increasingly it has been demonstrated that the 'illegal' actions of IPs cannot be reduced to individual behaviour choices (Cross and MacGregor, 2010; Pearson and Chandler, 2019). Participants in the present study explained that whilst the guidelines helped them to appreciate the importance of not giving unnecessary antibiotics, often the 'demands' of patients restricted their autonomy. It has been shown that antibiotics are often perceived by patients as the 'gold standard' treatment, capable of rapidly treating all infectious diseases (Gautham, *et al.,* 2024). For patients, rapid recovery is often their top priority, in a highly competitive healthcare market they may select the fastest recovery treatment. In these circumstances patients are equally constrained, they are not freely choosing to insist on fast recovery, rather it is essential within the high productivity economic structure in which they live. A day of work absenteeism due to illness represents a threat to livelihood (Gautham, *et al.*, 2021). This pattern of meaning was particularly strong among para-vets, where animal morbidity or mortality represents a direct economic loss to owners. This created an additional dimension of fragility in their relationships as trust in para-vets was built on the basis of providing rapid and effective recovery. Antibiotics are often not chosen due to lack of awareness but rather they are the only option given societal constraints (Willis and Chandler, 2019; George, and Iyer, 2013). In this respect, it is critical to recognise how structural violence influences healthcare; the social structures in which individuals live prevent people from meeting their basic needs and accessing appropriate treatment.

These factors compound to create a barrier to guideline implementation; IPs and patients in rural communities reside in a healthcare structure where they are not always able to make free decisions (Chandra and Bhattacharya, 2019; Cross and MacGregor,

2010; Willis and Chandler, 2019). In this respect, despite being capable and driven to act in accordance with the guidelines, providers cannot always follow the advice due to constraints on their behaviour. OASIS used a multi-stakeholder approach to design the guidelines, considering the perspectives of the veterinary, medical, pharmaceutical and government sectors. The importance and power of this strategy was recognised by providers who avidly encouraged cohesive implementation and recognition of the guidelines across medical sectors. Providers perceived that widespread adoption would reduce the strain of patient demand and competitive nature of the industry, easing the implementation of the guidelines. It was anticipated that this would reduce the intensity of competition and enable providers to practice more freely, without fear of losing patients.

6.2. Harnessing the Social Capital of Community Based Providers

Providers in the present study demonstrated a willingness to ensure their treatments followed the correct procedures and were eager to maintain honest practice. They expressed a positive attitude towards using the guidelines as it enabled them to do what was right by their patients and future generations. Understanding the alignment of the intervention with the community value system is a critical aspect of assessing feasibility, ensuring there is not only a practical but ethical fit (Dillip, *et al.,* 2012; Orsmond, and Cohn, 2015). Providers recognised that they represent localised and trustworthy care for rural populations, they placed exceptional value in respecting and preserving these community networks. Across literature, IPs demonstrably possess social capital, they have influence over the community which can be leveraged to increase the flow of information (Chandra and Bhattacharya, 2019; Cross and MacGregor, 2010). The public acceptance of IPs facilitates the use and implementation of the guidelines within the community as they are trusted to act in their patient's best interests. Utilising the strong community relationships of IPs to improve health outcomes has been successfully demonstrated in previous studies, such as investigations into TB care (Thapa, *et al.,* 2023). Thapa identified that clear policies which recognise the essential role of IPs in healthcare provision and engagement in national programmes are essential to utilising IPs to improve health outcomes.

This goal is challenged by public health discourse which often aims to ostracise informal providers, using pejorative language to describe their practice as calculated and exploitative of their patients (Cross and MacGregor, 2010; Sujatha, 2023). In contrast, in this study, IPs criticised the practices of formal doctors and blamed them for using antibiotics to gain profit without consideration of the long term impact. Providers made a point of distinguishing themselves from formal doctors, who were perceived to be untrustworthy by patients and providers. This reiterates findings that the hierarchical nature of healthcare providers in India positions formal doctors as not only physically but socially distant from patients, whereas IPs are much more accessible (Gautham, *et al.*, 2024; Broom and Doron, 2020). Whilst it has been shown that relationships between informal and formal providers can be beneficial (George and Iyer, 2013). Evidently, there are challenges and tensions between them, often accompanied by a culture of blame. Presently, there remains a lack of trust across healthcare sectors and an absence of structural cohesion (Broom and Doron, 2020; Chaturvedi, *et al.,* 2023; Bloom, *et al.,* 2015; Das and Guha, 2024). This disconnectedness creates challenges for the implementation and use of the guidelines as providers may act against each other to protect their own reputation and business. Initiatives must co-operate with political stakeholders to promote recognition and integration of IPs within the health system, generating a more unified, supportive structure.

6.3. The Role of the Pharmaceutical Industry

Another key external player discussed by para-vets was med reps, who work on behalf of the pharmaceutical industry to distribute medicines. Para-vets stated that med reps encouraged them to purchase certain medicines, especially antibiotics, in some instances reporting the use of incentives. This would act as a barrier to the implementation of the guidelines as providers could be influenced to purchase medicines which are not advised. This concept has become increasingly evident throughout literature. Numerous other studies have expressed concern regarding the role of med reps in antibiotic prescribing practices (Davies, *et al.,* 2019; Hennessey, *et al.,* 2023; Gautham, *et al.,* 2022). This body of literature reports that the influence of med reps causes IPs to alter their purchasing choices. However in stark contrast to this, RHPs in this study did not mentioned receiving any pressure from med reps to select specific

medicines. Whilst it was acknowledged that the med reps might be impacted by altered treatment practice, they stated they remained freely able to purchase the medicines requested. This would indicate that med reps do not act as a barrier to guideline use for RHPs.

However, it is appropriate to explore this finding further, given that the results are highly contrasting between this study and previous research. Interestingly, one para-vet expressed concern and hesitancy to discuss the influence, and potential bribery, of med reps. This could indicate that some IPs do not feel comfortable discussing the role of the pharmaceutical industry. The apparent lack of influence from med reps on RHPs could represent a case of non-disclosure. Given the illegal nature of the activity, providers may recognise the negative implications and choose not to reveal this information due to social desirability bias. This refers to a potential for participants to provide responses perceived to be appropriate rather than their honest opinion (Grimm, 2010). Previous studies have demonstrated that IPs can express reluctance to discuss their practice in detail and indicate that strong relationships must be built to ensure participants trust researchers (Sujatha, 2023; Kotwani, *et al.,* 2021). Given the ongoing nature of the OASIS project, it may be possible to reinvestigate this topic once a greater rapport has been built with participants. At present, it is uncertain if the influence of the pharmaceutical industry represents a barrier to guideline implementation. Ensuring and maintaining unrestricted access to necessary, appropriate medicines is essential to enabling the proper use of the guidelines in practice. A country-wide, in-depth and scrutinising investigation into the pressure from pharmaceutical organisations is essential, especially given the power held by such a large and influential industry.

7. Strengths, Limitations and Conclusion

7.1. Strengths and Limitations

A core strength of the current research was the use of reflexive practices throughout the project to actively engage with and critically interrogate the choices made. Reflexivity does not aim to eliminate 'researcher bias'; in RTA researcher subjectivity is viewed as an integral aspect of data generation. Reflexivity recognises the role of the researcher in influencing and creating the analysis. Through reflexivity, initial themes could be explored critically with consideration of other potential avenues of interpretation. Themes were comprehensively reviewed and refined, gaining a deeper understanding of the meaning of the data. For example, this enabled the development of the theme 'All or nothing' into two distinct but interrelated sub-themes to increase the clarity of the analysis.

The use of qualitative research methods also enables a more in depth exploration of personal experiences of the participants, this generates valuable insights into the perceived factors underlying antibiotic practices. Given the broad variation exhibited by informal healthcare providers across India the results are 'softly' generalisable (Braun and Clarke, 2022). There is relevance beyond the context studied, the data explores wider topics of structural inequalities which are highly supported by studies of other rural Indian regions. However, it should not be assumed that the experiences and perceptions of providers in the communities studied are identical to those of providers in other regions. Critical engagement with the setting and participants in other locations remains essential to ensure action is context-specific.

The greatest limitation of the study is that it was a secondary analysis conducted from an outsider perspective. Involvement in project design and primary data collection could have enabled the research to be more iterative, exploring topics of interest in greater depth. Personally collecting data would also allow greater awareness of the research setting and provide a deeper understanding of the research context. Further, lack of prior experience with qualitative research methods may have altered the interpretation of the data. A researcher who has greater familiarity with RTA may engage differently, producing an alternative analytic perspective.

7.2. Conclusion

This data demonstrates that antibiotic guidelines can be used to enhance IP capacity and confidence, enabling them to practice more systematically; providers possess social capital to influence their communities and encourage guideline acceptance. However, antibiotic use practices are affected by a diversity of external stakeholders, social and economic conditions. Furthermore, as discussed, many of the factors influencing antibiotic practices are structural in nature and have a deep-rooted history. The complexity of connections between elements of the healthcare sector make it impossible to address using a siloed approach. Using a One Health approach, through trans-disciplinary action across all health sectors is essential: formal, informal, private, public, animal and human. Increased cohesion and co-operation across health sectors, including increased integration of IPs, is necessary to begin to address the structural inadequacies of healthcare provision to rural communities in India, in turn enabling the operationalisation of antibiotic stewardship.

The development of these guidelines takes a community-wide perspective, giving value and support to the practices of IPs. However, despite taking a multi-stakeholder approach the influence of outside factors continues to create barriers for the application of the guidelines. Providers felt that further distribution to all healthcare practitioners would assist in community-wide acceptance. Practically, developing a small booklet and PDF version of the guidelines was recommended to improve their usability and portability, enabling widespread distribution across providers and health sectors. Full integration of the guidelines into the community requires long term support, ensuring that the health of individuals and animals is balanced alongside the need to reduce antibiotic use. Ensuring sustained, unrestricted access to essential antibiotics is critical, in order to achieve this further investigation and regulation of the pharmaceutical industry is vital. To effectively counteract external market-related influences, it is imperative to leverage the kinship relationships and social standing of providers within their communities. This approach will empower these providers to adhere to established guidelines and enhance their practices in a sustainable way.

Word count: 7,987

Appendix

8.1. Interview Guide: Informal Providers of Human Health (RHPs)

IN DEPTH INTERVIEW GUIDE: INFORMAL PROVIDERS

A. Acceptability and usability:

1. Are you using the guidelines in your daily practice? How did it change your practice? Share your experience of using these guidelines with examples.

   Probe: based on the answers-

   I) What are the aspects useful from the guidelines? Example with the actual scenario.

   II) What are the challenging aspects while using the guidelines? Give us examples with real scenarios.

   III) What are the recommended changes from your side based on the experience of using these guidelines?

   IV) Do you think it will affect your patient load? To what extent? Explain in detail.

2. Do you think that acceptance building is a continuous process? How long it will take to build acceptance? Explain with your perspectives.

B. Operational Feasibility: Behavioural areas:

3. How do you use these guidelines?

   Probe: Where do you keep it in your clinic? Do you look at the guidelines when a patient comes with these symptoms? Have you memorized these guidelines? If any other technique is used, ask for real-life examples.

4. When exactly do you start consulting these guidelines?

Probe: does consulting with the guidelines create any challenges for you? What are they and how are you overcoming these challenges?

1. What changes have you identified in your AB dispensing pattern after starting using these guidelines? Is that affecting your practice? Please give us examples of how these are affecting you.
2. After using the guidelines, how are you assessing the illnesses? Are there any changes in the process of identifying the illnesses?
3. What was the previous process you practised? How is this different after using the guidelines?
4. Are all the medicines suggested in these guidelines available in your clinic? Are all of them accessible? Do you have any suggestions? What are they? What about the quality of these antibiotics suggested in the guidelines in terms of effectiveness, quality and cost?
5. In terms of understanding these guidelines, which parts are easy to understand and which parts are difficult? Please give us some examples.

A. Technical feasibility:

6. Is the terminology used in these guidelines easy to understand? What changes are required to make it better to understand and adopt?
7. What do you think about the design of these guidelines in terms of the font size, layout and colour use?

Ask for example whenever needed.

Social areas:

8. What are the responses from your patients after you use the treatment from the guidelines? Give us real-life examples.

1. If you deny the request of giving antibiotics in the initial stage of illness by patients, what is the response and how are you handling it?

Referral or mentorship:

2. When are you referring your patients and to whom?
3. If they mention the name of a doctor, ask them about where he practices. How does he get to know about this doctor? Does he consult with this MBBS doctor before using these guidelines?

   Probe as needed: Identify the network.

   If they refer to a hospital, ask for the name of the hospital. Is there any specific doctor of the hospital he refers to?

   Ask for any examples if he did any referral of patients after using the guidelines. Tell us about the example where trying to identify any network available.

A. Schedule feasibility

4. According to your opinion, how long it will take to effectively operationalize these guidelines given your challenges?
5. How long it will take to get the acceptance among other stakeholders – pharmacist, retailers of antibiotics?
6. Do you think use of these guidelines can be made sustainable?

Future intention to use:

7. Do you have any plan to use the guidelines in your future practice? Ask why that is.
8. What strategies can we adopt to create a long lasting impact about these guidelines?

1. What strategies are to be adopted/ adjustments to be made to make the use sustainable?

A. Economic feasibility:

2. How does your business get affected due to the use of these guidelines? How are you planning to improve your economic loss? Please give us examples to understand the effect.
3. How far the guidelines are helpful to reduce Out Of Pocket Expenditure (OOPE) in healthcare seeking? If OOPE decreases at the community side in seeking care how it will increase patient turnover and help you to earn more? Explain what you think.
4. If economic benefits and health benefits of using these guidelines are explained to the community, how they will behave – what do you think? Explain with example.

B. Legal feasibility:

5. Do you know any laws about antibiotic dispensing? If yes, what is it and why do you think they are not followed? From where you have learnt it? How can we make people follow this law? If not, ask them from where they learn their practice and if there are any rules talk to them about AB .

C. Market feasibility:

6. From where are you purchasing these medicines? Is the use of these guidelines going to impact your relation with the MR and the distributors?

Orientation process:

7. What changes can be made in the orientation of these guidelines, in terms of time, explanation process, etc.
8. Please recommend how these guidelines can be further improved.

8.2. Interview Guide: Informal Providers of Animal Health (Para-vets)

IN DEPTH INTERVIEW GUIDE: PARAVETS

A. Acceptability and usability:

1. Are you using the guidelines in your daily practice? How did it change your practice? Share your experience of using these guidelines with examples.

   Probe: based on the answers-

   I) What are the aspects useful from the guidelines? Example with the actual scenario.

   II) What are the challenging aspects while using the guidelines? Give us examples with real scenarios.

   III) What are the recommended changes from your side based on the experience of using these guidelines?

   IV) Do you think it will affect the number of cases you treat? To what extent? Explain in detail.

2. Do you think that acceptance building is a continuous process? How long it will take to build acceptance? Explain with your perspectives.

B. Operational Feasibility:Behavioural areas:

3. How do you use these guidelines?

   Probe: Do you look at the guidelines when a patient comes with these symptoms? Have you memorized these guidelines? If any other technique is used, ask for real-life examples.

4. When exactly do you start consulting these guidelines?

1. If you deny the request of giving antibiotics in the initial stage of illness by patients, what is the response and how are you handling it?

Referral or mentorship:

2. When are you referring your patients and to whom?
3. If they mention the name of a doctor, ask them about where he practices. How does he get to know about this doctor? Does he consult with this formal Veterinary doctor before using these guidelines?

   Probe as needed: Identify the network.

   Ask for any examples if he did any referral of patients to formal Veterianarianafter using the guidelines. Tell us about the example where trying to identify any network available.

A. Schedule feasibility

4. According to your opinion, how long it will take to effectively operationalize these guidelines given your challenges?
5. How long it will take to get the acceptance among other stakeholders – pharmacist, retailers of antibiotics?
6. Do you think use of these guidelines can be made sustainable?

Future intention to use:

7. Do you have any plan to use the guidelines in your future practice? Ask why that is.
8. What strategies can we adopt to create a long lasting impact about these guidelines?

1. What strategies are to be adopted/ adjustments to be made to make the use sustainable?

A. Economic feasibility:

2. How does your business get affected due to the use of these guidelines? How are you planning to improve your economic loss? Please give us examples to understand the effect.
3. How far the guidelinesare helpful to reduce Out Of Pocket Expenditure (OOPE)in healthcare seeking? If OOPE decreases at the community side in seeking care how it will increase patient turnover and help you to earn more? Explain what you think.
4. If economic benefits and health benefits of using these guidelines are explained to the community, how they will behave – what do you think? Explain with example.

B. Legal feasibility:

5. Do you know any laws about antibiotic dispensing? If yes, what is it and why do you think they are not followed? From where you have learnt it? How can we make people follow this law? If not, ask them from where they learn their practice and if there are any rules talk to them about AB .

C. Market feasibility:

6. From where are you purchasing these medicines? Is the use of these guidelines going to impact your relation with the MR and the distributors?

Orientation process:

7. What changes can be made in the orientation of these guidelines, in terms of time, explanation process, etc.

Probe: does consulting with the guidelines create any challenges for you? What are they and how are you overcoming these challenges?

1. What changes have you identified in your AB dispensing pattern after starting using these guidelines? Is that affecting your practice? Please give us examples of how these are affecting you.
2. After using the guidelines, how are you assessing the illnesses? Are there any changes in the process of identifying the illnesses?
3. What was the previous process you practised? How is this different after using the guidelines?
4. Are all the medicines suggested in these guidelines available in your locality? Are all of them accessible? Do you have any suggestions? What are they? What about the quality of these antibiotics suggested in the guidelines in terms of effectiveness, quality and cost?
5. In terms of understanding these guidelines, which parts are easy to understand and which parts are difficult? Please give us some examples.

A. Technical feasibility:

6. Is the terminology used in these guidelines easy to understand? What changes are required to make it better to understand and adopt?
7. What do you think about the design of these guidelines in terms of the font size, layout and colour use?

Ask for example whenever needed.

Social areas:

8. What are the responses from your patients after you use the treatment from the guidelines? Give us real-life examples.

8.3. Ethical Approval: Current Research Project

8.3.1. LSHTM MSc Research Ethics Committee

London School of Hygiene & Tropical Medicine
Keppel Street, London WC1E 7HT
United Kingdom
Switchboard: +44 (0)20 7636 8636
www.lshtm.ac.uk

MSc Research Ethics Committee

Miss Rhian Davies
MSc Student
One Health
LSHTM

16 May 2024

Dear Rhian,

Study Title: Assessing feasibility of transforming antibiotic usage by informal healthcare providers for humans and animals through the introduction of antibiotic usage guidelines: A comparative analysis.

LSHTM MSc Ethics Ref: 30367

Thank you for your application for the above MSc research project, which has now been considered by the MSc Research Ethics Committee.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application (CARE) form, and supporting documentation, subject to the conditions specified below.

Conditions of the favourable opinion

Approval is contingent on local ethical approval having been received, where relevant. It is the responsibility of the student and their supervisor to ensure appropriate local ethical approval is in place before a study commences (ie if you indicated in the local approval section that local approval is required).

Approved documents

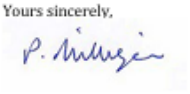
The final list of documents reviewed and approved by the Committee is as follows:

Document Type	File Name	Date	Version
Research Ethics training certificate	Research ethics certificate		
Local Approval	WBAFS Ethics Committee response	19/03/2019	1
Protocol / Proposal	Participant information sheet-antimicrobial providers_original	14/05/2019	1
Consent form	Combined informed consent form_original	14/05/2019	1
Consent form	Participant information sheet-antimicrobial providers_original	14/05/2019	1
Local Approval	ILDS West bengal Ethics Approval	10/08/2019	1
Local Approval	LSHTM ETHICS APPROVAL Letter 4 Sept 2019	04/09/2019	1
Local Approval	PHFI-IEC approval- (1)	04/01/2021	1
Local Approval	PHFI-Amend IEC approval (1)	30/05/2022	1
Protocol / Proposal	IDI Guide Providers _human health	31/05/2022	1
Protocol / Proposal	IDI Guide Providers_paravets	31/05/2022	1
Protocol / Proposal	Participant Information Sheet	31/05/2022	2
Consent form	Informed consent form	31/05/2022	2
Consent form	Participant Information Sheet	31/05/2022	2
Investigator CV	CV - 2024	06/03/2024	1
Protocol / Proposal	Research Project Protocol	28/03/2024	1
Other	Project access	12/04/2024	1
Covering Letter	Cover Letter ethics comittee response	09/05/2024	1

After ethical review

Any subsequent changes to the application **must** be submitted to the Committee via an Amendment form on the ethics online applications website: http://leo.lshtm.ac.uk . Amendments must not be initiated before receipt of written favourable opinion from the committee.

Yours sincerely,



Professor Paul Milligan
Chair

MScEthics@lshtm.ac.uk
http://www.lshtm.ac.uk/ethics

Improving health worldwide

8.4. Ethical Approval: Primary Data Collection

8.4.1. LSHTM

London School of Hygiene & Tropical Medicine
Keppel Street, London WC1E 7HT
United Kingdom
Switchboard: +44 (0)20 7636 8636

www.lshtm.ac.uk

LONDON SCHOOL of HYGIENE &TROPICAL MEDICINE

Observational / Interventions Research Ethics Committee

Dr Meenakshi Gautham
LSHTM

4 September 2019

Dear Meenakshi

Study Title: A multi-stakeholder approach towards operationalising antibiotic stewardship in India's pluralistic rural health system

LSHTM Ethics Ref: 17484

Thank you for responding to the Observational Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Conditions of the favourable opinion

Approval is dependent on local ethical approval having been received, where relevant.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document Type	File Name	Date	Version
Local Approval	WBAFS_Ethics Committee response	19/03/2019	1
Investigator CV	India AMS Study_CVs and publications	09/05/2019	1
Protocol / Proposal	Interview Guide Antibiotic Providers_v2	14/05/2019	1
Protocol / Proposal	Interview Guide Household Livestock Owners_v2	14/05/2019	1
Protocol / Proposal	Interview Guide Key Informants for animal ABU_v2	14/05/2019	1
Protocol / Proposal	study protocol	14/05/2019	1
Information Sheet	Combined informed consent form_v2	14/05/2019	1
Information Sheet	Participant information- key informants animal abu_v2	14/05/2019	1
Information Sheet	Participant information sheet- antimicrobial providers_v2	14/05/2019	1
Information Sheet	Participant information sheet-Household Livestock keepers_v2	14/05/2019	1
Protocol / Proposal	Copy of Extraction_Spreadsheet_LOCAL AMR DATA	14/05/2019	1
Information Sheet	Participant Information Sheet- IDI and FGD and observation	14/05/2019	1
Information Sheet	Participant information Sheet- AMR Prevalence Data	14/05/2019	1
Information Sheet	Information sheet for key informants idi _mapping the chain	14/05/2019	1
Information Sheet	Information sheet for stakeholder idi_mapping the chain	14/05/2019	1
Information Sheet	Participant Information sheet for formal doctor and vets kii_v2	14/05/2019	1
Information Sheet	Participant Information sheet for govt stakeholders	14/05/2019	1
Protocol / Proposal	FGD Guide for community members_v2	14/05/2019	1
Protocol / Proposal	KII For Community CHW_v2	14/05/2019	1
Protocol / Proposal	KII for community leaders_v2	14/05/2019	1
Protocol / Proposal	Observation Checklist for community meetings_v2	14/05/2019	1
Protocol / Proposal	Interview Guide - Key Informants - mapping the chain_v3	14/05/2019	1
Protocol / Proposal	Interview Guide - stakeholder - mapping the chain_v3	14/05/2019	1

Protocol / Proposal	Govt stakeholders_KII guide	14/05/2019	1
Protocol / Proposal	IDI guide_formal doctors and vets_v2	14/05/2019	1
Local Approval	ILDS West bengal Ethics Approval	10/08/2019	1
Covering Letter	Gautham response_20 Aug 2019	20/08/2019	1

After ethical review

The Chief Investigator (CI) or delegate is responsible for informing the ethics committee of any subsequent changes to the application. These must be submitted to the Committee for review using an Amendment form. Amendments must not be initiated before receipt of written favourable opinion from the committee.

The CI or delegate is also required to notify the ethics committee of any protocol violations and/or Suspected Unexpected Serious Adverse Reactions (SUSARs) which occur during the project by submitting a Serious Adverse Event form.

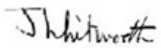
An annual report should be submitted to the committee using an Annual Report form on the anniversary of the approval of the study during the lifetime of the study.

At the end of the study, the CI or delegate must notify the committee using an End of Study form.

All aforementioned forms are available on the ethics online applications website and can only be submitted to the committee via the website at: http://leo.lshtm.ac.uk

Additional information is available at: www.lshtm.ac.uk/ethics

Yours sincerely,



Professor Jimmy Whitworth
Chair

ethics@lshtm.ac.uk
http://www.lshtm.ac.uk/ethics/

Improving health worldwide

8.4.2 Local Ethical Approval: Indian Institute of Liver and Digestive Sciences

Indian Institute of Liver and Digestive Sciences
(A Unit of Liver Foundation, West Bengal)
Sitala East, Malipukuria, Jagadishpur, P.S: Sonarpur, 24 Parganas (South) Pin : 700150

Institutional Ethics Committee for Human Research

Memo No. IILDS/IECHR/01/2019 Dated 10th August, 2019

To
Dr. Abhijit Chowdhury
Principal Investigator &
Secretary, Liver Foundation, West Bengal.

A meeting of the Institutional Ethics Committee of IILDS, Sonarpur was held on 9th August, 2019 at 3pm at the Seminar room of SDLD building, at SSKM Hospital. The following members were present :

Sl. No	Name	Sex	Status	Affiliation/Designation
1	Prof.(Dr) Pradip Kumar Mitra	M	Chairman	Ex-DME and presently as OSD (Research), in the rank of DME, Health and Family Welfare Dept. Govt. of WB.
2	Dr. G. K. Dhali	M	Member Secretary	Prof. & Head Gastroenterology Dept. School of Digestive & Liver Disease, IPGME&R, Kolkata.
3	Dr. Simanti Datta	F	Member	Asstt. Professor Centre for Liver Research School of Digestive & Liver Disease, IPGME&R, Kolkata.
4	Dr. Jayati Chakraborty	F	Member	Professor and Social Activist.
5	Mr. Sumitendranath Saha	M	Member	Ex-Senior Manager of United Bank of India as lay person.

The following project proposal submitted with other relevant documents were discussed:

"A multi-stakeholder approach towards operationalising antibiotic stewardship in India's pluralistic rural health system"

☎ 033 2428 0190 / 033 2434 2300 helpdesk@iilds.in | www.iilds.in

Indian Institute of Liver and Digestive Sciences
(A Unit of Liver Foundation, West Bengal)
Sitala East, Malipukuria, Jagadishpur, P.S: Sonarpur, 24 Parganas (South) Pin : 700150

List of other documents:

1. Forwarding Letter.
2. Patient Information Forms – English, Bengali, Hindi.
3. Patient Consent Forms and Interview guides – English, Bengali, Hindi.
4. Budget of the study.

After detailed deliberation and review, the following decision was taken:

☑ Approved.

☐ Disapproved.

☐ Resubmit after modification as detailed below.

☐ Approved earlier but approval withdrawn now for reasons detailed below.

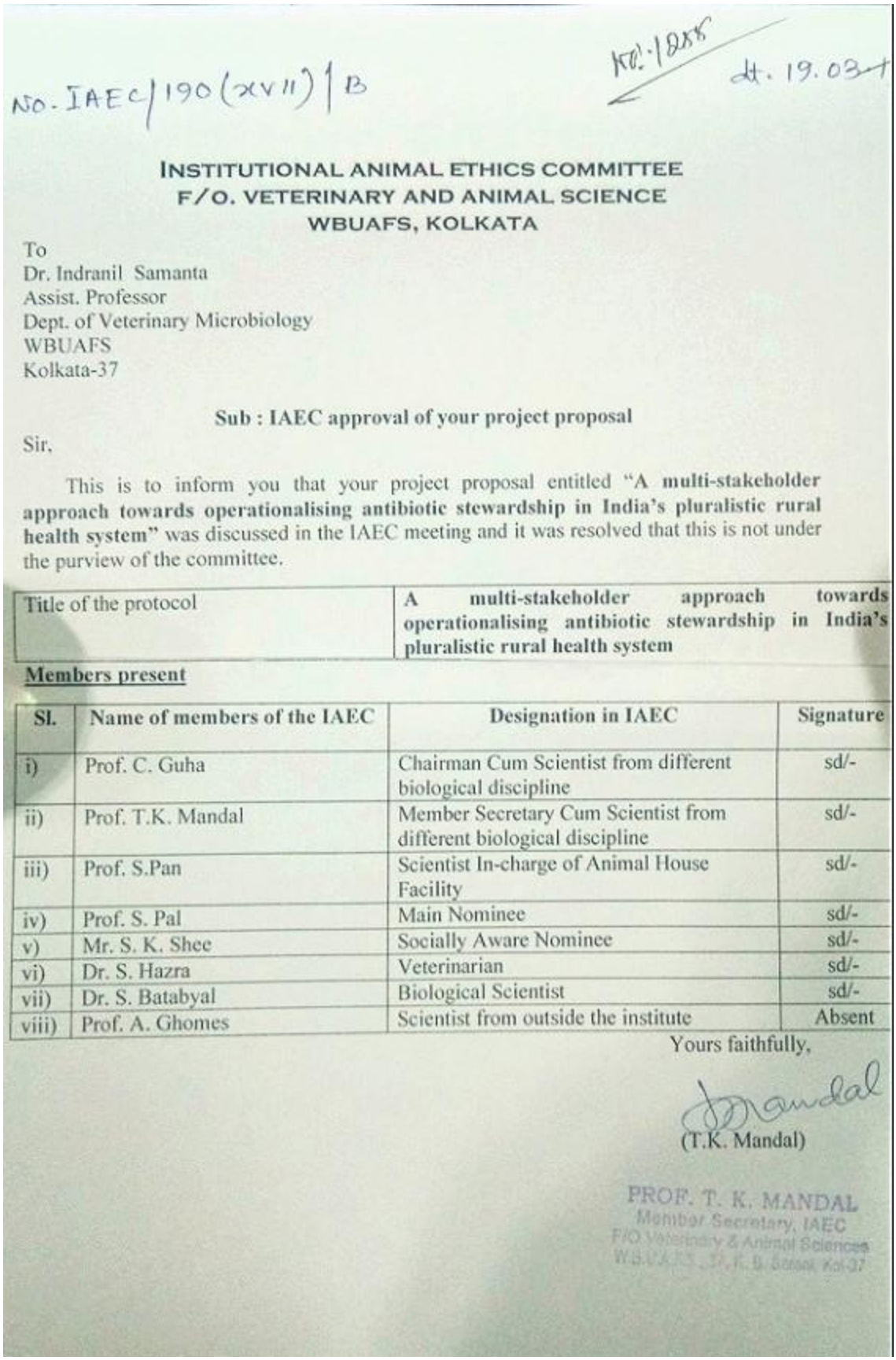
☐ Reasons for disapproval ☐ Modifications suggested ☐ Reasons for withdrawing approval

10/08/19

Member- Secretary
Institutional Ethics Committee for Human Research
Indian Institute of Liver and Digestive Sciences, Sonarpur

☎ 033 2428 0190 / 033 2434 2300 helpdesk@iilds.in | www.iilds.in

8.4.3. Local Ethical Approval: West University of Animal and Fishery Sciences' Ethics Committee



No. IAEC/190(xvii)/B

Dt. 19.03

INSTITUTIONAL ANIMAL ETHICS COMMITTEE
F/O. VETERINARY AND ANIMAL SCIENCE
WBUAFS, KOLKATA

To
Dr. Indranil Samanta
Assist. Professor
Dept. of Veterinary Microbiology
WBUAFS
Kolkata-37

Sub : IAEC approval of your project proposal

Sir,

This is to inform you that your project proposal entitled "**A multi-stakeholder approach towards operationalising antibiotic stewardship in India's pluralistic rural health system**" was discussed in the IAEC meeting and it was resolved that this is not under the purview of the committee.

Title of the protocol	**A multi-stakeholder approach towards operationalising antibiotic stewardship in India's pluralistic rural health system**

Members present

Sl.	Name of members of the IAEC	Designation in IAEC	Signature
i)	Prof. C. Guha	Chairman Cum Scientist from different biological discipline	sd/-
ii)	Prof. T.K. Mandal	Member Secretary Cum Scientist from different biological discipline	sd/-
iii)	Prof. S.Pan	Scientist In-charge of Animal House Facility	sd/-
iv)	Prof. S. Pal	Main Nominee	sd/-
v)	Mr. S. K. Shee	Socially Aware Nominee	sd/-
vi)	Dr. S. Hazra	Veterinarian	sd/-
vii)	Dr. S. Batabyal	Biological Scientist	sd/-
viii)	Prof. A. Ghomes	Scientist from outside the institute	Absent

Yours faithfully,

Mandal

(T.K. Mandal)

PROF. T. K. MANDAL
Member Secretary, IAEC
F/O Veterinary & Animal Sciences
W.B.U.A.F.S., 37, K. B. Sarani, Kol-37

8.4.4. Local Ethical Approval: Public Health Foundation of Indi

PUBLIC HEALTH FOUNDATION OF INDIA

Institutional Ethics Committee

Public Health Foundation of India

Delhi NCR, Plot No. 47, Sector 44, Institutional Area, Gurgaon – 122002

Communication of Decision of the IEC[1]
Form II

TRC-IEC No:	**TRC-IEC 448/20**	**Date:**	**January 4, 2021**	
Project Title:	**Assessing the impact of COVID-19 on primary healthcare services and antibiotic provision by rural healthcare providers in India and co-designing a multi-stakeholder intervention**			
Principal Investigator:	**Dr. K. Srinath Reddy**			
Review	**Full review** ☐		**Expedited review** ☒	
Date of review:		**(DD/MM/YYYY)**		
Date of previous review:		***(in case of re-submitted applications)*** **(DD/MM/YYYY)**		
Decision of the IEC:	**Approval** ☒	**Study can begin** ☒	**Resubmission** ☐	
	Conditional Approval ☐		**Study cannot begin** ☐	
Requirements to be fulfilled in case of conditional approval:				
Suggested alterations in case of resubmission:				
In case of approval, ***recommended for a period of :***	**Valid for 1 year from study approval date**			
Comments:	**PI is requested to inform the secretariat of the start and end date of the study.** **Study duration is for 1 year 6 months. IEC approval is granted for ONE year from the approval date. PI is requested to seek annual ethics approval for the study and submit annual progress report.** **PI to inform of any amendments in the study and seek IEC approval for any amendments.** **Closure report must be submitted to the PHFI-IEC after study's completion** Following documents were submitted to IEC: 1. Responses to IEC comments 2. PIS and ICF for PCPs in English (version no. 4 dated 31.12.2020) 3. PIS and ICF for IP in English (version no. 4 dated 31.12.2020) 4. PIS and ICF for IP in Hindi, Telugu, Bengali and its back translations (version no. 4 dated 31.12.2020) 5. MoU between PHFI and LSHTM 6. Survey Too for PCPs in English (version no. 2 dated 28.12.2020) 7. Survey Too for IP in English (version no. 2 dated 28.12.2020) 8. Survey Too for IP in Hindi, Telugu, Bengali and its back translations (version no. 2			

[1] Adapted from the ICMR form: available at http://www.icmr.nic.in/bioethics/Communication%20of%20Decision%20of%20the%20IEC.doc

	dated 28.12.2020) 9. Application form (version no.3 dated 25.12.2020) 10. Project summary (version no. 1 dated 21.10.2020) 11. Proposal (version no. 1 dated 21.10.2020) 12. Ethics approval of LSHTM dated 30.07.2020 13. Cover letters dated 27.11.2020 and 20.10.2020 14. CVs and ethics training certification

Please note: Beginning of the research based on this approval implies acceptance of the following conditions:

1. *PI will inform the Secretariat of the start date of the study.*
2. *The PI will inform the IEC in case of any adverse events.*
3. *The PI will inform the TRC (Technical Review Committee) and IEC in case of any change of study procedure (including- changes in the informed consent form, recruitment procedure, potential research participant information), site and investigator.*
4. *The PI will inform the TRC - IEC Secretariat on termination of the study and submit a final report within 3 months of completion of the study.*
5. *Members of the IEC have the right to monitor the study with prior intimation.*
6. *Progress report to be submitted to the TRC-IEC Secretariat every 6 months from the date of start of study.*
7. *This permission is only for the period mentioned above.*

Dr. Aastha Aggarwal
Name and signature of Member-Secretary

[1] Adapted from the ICMR form: available at http://www.icmr.nic.in/bioethics/Communication%20of%20Decision%20of%20the%20IEC.doc

8.4.5. Local Ethical Approval: Public Health Foundation of India (extension)

PUBLIC HEALTH FOUNDATION OF INDIA

Institutional Ethics Committee

Public Health Foundation of India

Delhi NCR, Plot No. 47, Sector 44, Institutional Area, Gurgaon – 122002

Communication of Decision of the IEC[1]
Form II

TRC-IEC No:	**TRC-IEC 448.1/20**	**Date:**	**May 30, 2022**		
Project Title:	**Assessing the impact of COVID-19 on primary healthcare services and antibiotic provision by rural healthcare providers in India and co-designing a multi-stakeholder intervention – (1st Amendment and renewal)**				
Principal Investigator:	**Dr. K. Srinath Reddy**				
Review	**Full review**	☐	**Expedited review**	☒	
Date of review:		**(DD/MM/YYYY)**			
Date of previous review:		***(in case of re-submitted applications)* (DD/MM/YYYY)**			
Decision of the IEC:	**Approval** ☒	**Study can begin** ☒	**Resubmission**	☐	
	Conditional Approval ☐		**Study cannot begin**	☐	
Requirements to be fulfilled in case of conditional approval:					
Suggested alterations in case of resubmission:					
In case of approval, *recommended for a period of :*	**Valid till December 2022 from study approval date.**				
Comments:	**Study duration is for 1 year 6 months. IEC approval was granted for ONE year on January 4, 2021 under expedited review category and was valid for one year.** **Now the PI has requested for extension of the IEC approval from 05/01/2022 to 30/09/2022 as the project period has extended as there was delay due to pandemic lockdown. PI has shared the no-cost extension letter from LSHTM. PI has shared that there is a change in the Co-PI name. The CO-PI is changed from Dr. Sandeep Bhalla to Dr. Priya Balasubramanium. Dr. Bhalla has resigned PHFI and Dr. Priya has joined the project.** **PI to inform of any amendments in the study and seek IEC approval for any amendments.** **Closure report must be submitted to the PHFI-IEC after study's completion.** Following documents were submitted to IEC: 1. Responses to IEC comments 2. Amendment and renewal application (version no. 2, dated 26.5.2022) 3. Progress report 4. Previous IEC approval letter 5. No cost extension letter from LSHTM dated 1.2.2022				

[1] Adapted from the ICMR form: available at http://www.icmr.nic.in/bioethics/Communication%20of%20Decision%20of%20the%20IEC.doc

	6. Old approved study documents

Please note: Beginning of the research based on this approval implies acceptance of the following conditions:

1. *PI will inform the Secretariat of the start date of the study.*
2. *The PI will inform the IEC in case of any adverse events.*
3. *The PI will inform the TRC (Technical Review Committee) and IEC in case of any change of study procedure (including- changes in the informed consent form, recruitment procedure, potential research participant information), site and investigator.*
4. *The PI will inform the TRC - IEC Secretariat on termination of the study and submit a final report within 3 months of completion of the study.*
5. *Members of the IEC have the right to monitor the study with prior intimation.*
6. *Progress report to be submitted to the TRC-IEC Secretariat every 6 months from the date of start of study.*
7. *This permission is only for the period mentioned above.*

INSTITUTIONAL ETHICS COMMITTEE
APPROVED
CHAIRMAN/MEMBER SECRETARY
PUBLIC HEALTH FOUNDATION OF INDIA

working towards healthier India

Dr. Aastha Aggarwal
Name and signature of Member-Secretary

[1] Adapted from the ICMR form: available at http://www.icmr.nic.in/bioethics/Communication%20of%20Decision%20of%20the%20IEC.doc

8.5. Participant Information Sheet

A multi-stakeholder approach towards operationalising antibiotic stewardship in India's pluralistic rural health system.

Participant Information Sheet For In-Depth Interview (modified version of PIS v2,14.05.2019)

Introduction and study overview

My name is …….. and I'm from the ….. (PHFI / AIIMS-Kalyani). We are conducting academic research with London School of Hygiene and Tropical Medicine, UK for a study on operationalising antibiotic stewardship in India's pluralistic rural health system. The study is funded by the Medical Research Council, UK. Our study policy requires that we share essential information about our study with you and formally ask for your consent to this interview. Please read this information sheet and indicate your willingness by signing the consent form.

Study objectives and its purpose

The focus of this study is on antibiotics use because these are essential medicines that can save lives. However, their misuse also leads to the disease causing bacteria becoming resistant to the antibiotics. We are trying to find out what are the disease patterns here, where and from whom people seek care, what are the antibiotics used, how are these used and why, whether any resistance is being perceived to any antibiotics, and what can be done to rationalise the use of antibiotics among rural communities and providers. This will help the government and the health care providers to understand the situation and to modify the use of medicines, particularly antibiotics. We will use the study findings to work with all of you and the government and the local health care providers to develop strategies that can help everyone use antibiotics properly. This in turn will be of great value to the health of the millions of people. Therefore, your responses and contributions will be highly valuable.

Study processes

In last three years we have carried a detailed process in developing a guideline for aiding the community health providers in appropriate use of antibiotics, which you are currently using. Through this interview we want to understand whether the guideline is suitable to you in diagnosis, referral and administering of antibiotics. We will look for your suggestions in improving this guideline in terms of terminology, ease of use in front of patients and its design. Your views and suggestion will help in refining the guideline so it can be used in larger scale.

Data use and confidentiality

This interview will last about 30- 45 min. We will take notes during the interview, and if you agree we will also digitally make an audio recording of the interview to ensure that we capture all your responses accurately. If you agree, we may use some quotes from your interview anonymously in our report. All information gathered will be treated as confidential. We will not use your name in any of our reports. Each informant will be given a unique identification number and the data spreadsheet will contain only the identification number, so that the data is anonymised. A separate document will link the names with the ID numbers, before the data spreadsheet and the identifier sheet is stored on the PHFi and LSHTM server. The analysis of the quantitative data will be done without reference to personal particulars, such

analysis about 12 months after the study is completed, and requests for data sharing will be reviewed and approved by the study PI and co-I. The data will be stored for 10 years on the PHFI and LSHTM server, and after that the study team will decide whether to delete or continue with the data storage and for how long. There may be no direct benefits to you for participating in this study. However, the collective findings of this study will be of widespread interest to Government and Non-Government stakeholders to improve health for the rural population.

Voluntary participation and right to refuse
Participation in this research is voluntary. You may choose not to participate without anticipating any negative consequences. You can stop participating at any time. You will not have to pay anything to participate in this study and neither will you be paid for your participation

Sharing the findings and Further Engagement
As this will be a three years long project and this study is a part of multi-stakeholder approach to co design an effective intervention, so we may come back to you to share the study findings, ask your feedback on what interventions can be tried so that providers and communities use antibiotics more responsibly as well as to seek your further valuable participation in this program. Please give us your contact number.

If you have any questions, you can ask them at any time. If you wish to ask questions later, you may contact any of the following members of the study:

Study team:

Person 1. Dr. Meenakshi Gautham PI, LSHTM, Phone Number: 9871145571
Person 2. Dr. Paramita Sengupta, Co-I, AMMIS- Kalyani, Phone Number - 9815333725
Person 3. Dr. Sanghita Bhattacharyya, Co I, PHFI, Phone Number:9958797983

8.6. Informed Consent Form

A multi-stakeholder approach towards operationalising antibiotic stewardship in India's pluralistic rural health system.

STUDY CONSENT FORM FOR INTERVIEWEES (modified version of form dated 14.05.2019)

Information

- We are conducting a feasibility study to understand what extent is the guideline developed for rational use of antibiotics is acceptable and usable by informal providers in diagnosis, referral and administering of antibiotics. The finding of the feasibility study will help in revising this guideline and scaling up and integrating it within the existing health system.
- The interview will take only about 30-45 minutes of your time
- You do not need to provide your name and all the information you provide will be kept anonymous and confidential. Only our research team will have access to the interview recording.

Before you proceed further, you are required to read the detailed information about the study and confirm that you have read it and are willing to participate.

The interviewee should tick all boxes that apply:

I have read the study information sheet and/or have been given a clear overview of the study	
I am happy for your research group and other researchers approved by you to write about what I have said during our interview on the understanding that you will not reveal my identify in any study outputs.	
I am happy for the interview to be sound recorded on the understanding that you will not reveal my identify in any study outputs	
I am happy for you to include quotations from this interview on the understanding that you will not reveal my identify in any study outputs	
I am happy to be photographed and consent to my photograph being used in study outputs	
I am willing to be interviewed	

Interviewee (name in BLOCK CAPITALS)	
Signature	Date
Researcher (name in BLOCK CAPITALS)	
Signature	Date

8.7. Declaration

Number of words: Part 1 = 1,998, Part 2 = 7,987

a) I have performed all the experiments and/or analyses described in this project.

YES ☑

NO ☐

If no, please list the procedures/analyses etc described in the project that were performed by research staff in the host laboratory:

b) My supervisor has seen and commented on my project report.

YES ☑

NO ☐

c) I confirm that where applicable I have returned data to my supervisors after completion of my work

YES ☑

NO ☐

d) I confirm that I have sent the final version of the thesis to all my supervisors

YES ☑

NO ☐

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