

A multi-stakeholder approach towards operationalising antibiotic stewardship in India's mixed health system community settings

(OASIS study)

Stakeholder consultation with pharmaceutical leaders

17 August, 2021

2.00pm – 4.00 pm

Introduction

The OASIS study takes a One Health approach towards understanding antibiotic use and its drivers in human and animal health, and to use the study findings to co-design an antibiotic stewardship intervention through multi-stakeholder engagement. The study consortium includes a multidisciplinary research team of five partner organisations in India and the United Kingdom.

The overall vision of this project is to a) generate a holistic understanding of the social, economic, structural and policy related drivers of antibiotic misuse and overuse in community settings, and b) develop an inclusive approach to address the key drivers; this will include achieving shifts in people's thinking and addressing policy barriers. The OASIS consortium is conducting a series of consultations with various stakeholders within the health system, including medical and veterinary practitioners (private and public), policymakers, pharmaceutical industry leaders, health and regulatory departments, academics and researchers, NGOs, health-workers and communities.

This consultation on 17th August, 2021 with pharmaceutical leaders was the third; the first two involved veterinary providers, academics and medical practitioners from the public and private health sectors.

The consultations are being co-organised with the Federation of Indian Chambers of Commerce and Industry (FICCI).

Key questions posed to stakeholders during this consultation were:

1. What can be done to address the challenges of antibiotic misuse in rural and peri-urban community settings? How can a balance be achieved between the sales of antibiotics and the need to reduce their misuse?
2. Are you currently involved in any strategy for managing antibiotic misuse that you would like to share with us?
3. How can the industry work with other stakeholders (e.g. researchers, health providers, other supply chain stakeholders, government) in reducing antibiotic misuse in rural and peri-urban community settings?

Participants: There were 14 participants representing the pharmaceutical sector, 3 participants from FICCI and 10 OASIS study team members (list of participants attached).

Agenda: The session began with a welcome address by Dr. Priya Balasubramanian, a short presentation on FICCI's AMR perspective by Ms. Swati Aggarwal and a presentation on the study findings by Dr. Meenakshi Gautham. This was followed by breakout group discussions on the key questions. The interventions proposed in the breakouts were summarised, prioritised and detailed further in the final session.

Summary of the discussions

While diverse challenges and interventions emerged during the discussions across rooms, there was unanimous agreement on the need to build context-specific multipronged efforts involving multiple stakeholders targeted at the local levels. Discussions reflected the pharmaceutical industry's awareness and keen understanding of the threat of antimicrobial resistance, the complex nature of community health networks that influence its emergence, and the industry's role and responsibilities in this challenging ecosystem

Key challenges identified by participants, for improving antibiotic practices in community settings

Policies and guidelines

- Lack of appropriate policies/guidelines for informal and formal prescribers and pharmacists related to antibiotics sales and dispensing (currently a wide variety of antibiotics across the ACCESS, WATCH and RESERVE classes are used)
- Lack of surveillance data (including continuous data) from outpatient settings in different locations to develop contextually relevant guidelines (with an improved and more nuanced contextual application of the ACCESS and WATCH categorisations-e.g: depending on local data, the restricted ones may actually need to be more accessible); reaching continuous surveillance data to prescribers

Regulatory

- Regulatory barriers for the pharmaceutical sector to develop proper training programmes for IPs
- Challenges in implementation/enforcement of regulations by the government

Diagnostics

- Poor diagnostics capacity; large scale clinical/empiric use of antibiotics
- Practitioners often rely on their clinical judgement to prescribe antibiotics, however, the evidence around drugs often lies with microbiologists. This disconnect between microbiologists and prescribing physicians in hospitals is a further hindrance to appropriate antibiotic use.

Educational

- Limited awareness/education across the healthcare spectrum ranging from formal and informal providers to super specialists and communities, acute lack of educational programmes for IPs and paravets.
- While IPs are keen to develop a deeper understanding of antimicrobial resistance, the science around AMR is often complex and difficult to understand. There is a need for context-sensitive simplification of existing literature and guidelines for each level.
- No QIDP (quality infectious disease physician) type certification for doctors.

Pharmaceutical code of conduct

- Lack of antibiotic related guidance in the OPPI and the UCPMP codes of conduct for pharmaceuticals.
- Competition within the industry: national vs multinational companies, fragmented, collective responsibility may be a challenge.

Availability of antibiotics

- Low pricing including of some Reserve antibiotics making them more easily accessible
- Easy availability of irrational fixed dose combinations in the market
- Lack of incentives for pharmaceuticals to invest in new antibiotics

One Health issues

- Crossover/injudicious antibiotic use in animals for economic reasons and lack of clear data comparing antibiotic use in animals with that used in humans

The following range of interventions were presented during the discussions.

Priority ones that can be implemented over the next 2-3 years:

Policies and guidelines:

- Development of contextually relevant guidelines (using the ACCESS/WATCH/RESERVE categorisations) for informal and formal providers based on local epidemiological data (along with setting up continuous surveillance platforms like the work initiated by Pfizer with ICMR).
- There is a strong need for greater support and clear communication from the government going out to everyone, including healthcare providers, pharmacists and industry regarding the appropriate use of different types of antibiotics.
- Simplified approach to managing antibiotics using the ACCESS/WATCH/RESERVE classification.
- Include the Ministry of AYUSH – to suggest alternative therapies to antibiotics.

What the pharmaceutical industry can do:

- **Develop a voluntary code of conduct for pharmaceutical marketing**

Expand the guidance provided in the Uniform Code of Pharmaceutical Marketing Practices. Sign up to the revised guidelines for antibiotic use by different levels and types of providers.

Protect the WATCH and RSERVE category antibiotics. The pricing of some of the RESERVE category drugs like colistin could be moderated to make them less easily accessible.

- **Support surveillance efforts**

Continuous surveillance efforts at both national and local levels were proposed to generate area specific susceptibility data and also inform guidelines for antibiotic use. These can be conducted through the industry themselves, as in the case of Pfizer's ATLAS program that monitors changing bacterial resistance patterns and makes data available to participating centers, or in partnership with the ICMR.

- **Harness knowledge pathways for appropriate antibiotic use:**

The importance of continuous and regular education around AMR prevention and awareness was stressed for all health system actors. This includes formal training for informal providers aimed at simplifying the science of antimicrobial resistance and affecting well-informed prescribing behaviour. Spreading awareness around AMR will require leveraging influencers within rural communities to educate the general public, i.e. consumers, on the benefits of antibiotics and their appropriate use was also recommended. Building on existing education programs, especially those that have been in wide circulation during these times such as handwashing, and organising public awareness campaigns under the aegis of ICMR was also proposed. The range of health workers in rural India also necessitates extending education and awareness programs to include non-clinical workers.

- **Collaborate in intervention pilots – implementation and evaluation**

Participants also discussed the execution of AMR surveillance pilot programmes in rural regions, which will be of relevance to government entities interested in assisting in the development of a large-scale AMR stewardship programme. Regular monitoring and assessment of these initiatives may also assist in establishing a tight requirement for AMR stewardship, hence reducing irrational antibiotic use. Pilot a multipronged effort to determine how different stakeholders can affect antibiotic stewardship at a local level using a range of interventions in education guidelines, prevention and awareness. Leverage relationships between formal practitioners (use them as hubs) and IPs.

Participants expressed support for an antibiotic stewardship pilot intervention in one region, in collaboration with intermediary organisations like FICCI and PHFI, and regional government bodies involved in AMR action plans. The success of a small pilot would pave the way for a larger national level programme.

Next steps:

1. Identifying which interventions are short-term and which are long-term. Short term interventions will include setting up a pharmaceutical collaborative committed to a voluntary code of conduct, developing provider and context appropriate guidelines, community awareness and HCP education programs that can be delivered digitally, and harnessing existing knowledge pathways between informal and formal providers and the industry. Longer term interventions will include gathering surveillance data and aligning antibiotic guidelines with local sensitivity patterns, sharing the data on an ongoing basis with healthcare providers to inform their antibiotic practices, improved diagnostics support and improved tracking of antibiotic consumption across the human and veterinary sectors.
2. Establishment of a multi-sectoral consortium for AMR prevention in India in partnership with the pharmaceutical industry, practitioners, and veterinary sector actors -with FICCI, LSHTM and PHFI -to develop a pilot; specifically, a multipronged approach that involves the range of stakeholders who constitute the complex health system and influence antibiotic practices.