

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

(OASIS study)

High level stakeholder consultation

5 October, 2021

2.30pm – 4.00 pm

Introduction

The OASIS study takes a One Health approach towards understanding antibiotic use and its drivers in human and animal health, with the ultimate goal of using 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 and veterinary systems, including medical and veterinary practitioners (private and public), policymakers, pharmaceutical industry leaders, health and regulatory departments, academics and researchers, NGOs, health-workers and communities.

The high-level consultation on 5th October, 2021 with government policymakers, senior pharmaceutical leaders and medical experts was the fourth; the first three involved veterinary providers, academics and medical practitioners from the public and private health sectors, and senior executives from the pharmaceutical sector. The consultations were co-organised with the Federation of Indian Chambers of Commerce and Industry (FICCI).

Key questions posed to stakeholders during this consultation were:

1. How can we create rational antibiotic use guidelines for informal providers, paravets, retail chemists/pharmacies?
2. What will be the barriers/challenges to these? How can these be overcome? Who should be involved in this process?
3. Where can we pilot a multipronged intervention to optimise antibiotic use? Who should be involved and how can we involve them?

4. Which existing policies will support this intervention so it has relevance for national AMR strategy? How can we link this work with existing policies for AMR, e.g with Niti Ayog's AMR plan and the Indian national action plan for AMR.

Participants: There were thirteen participants representing the government sector (Niti Ayog, Department of Pharmaceuticals, State Drug Controller's Office in Haryana Government, Department of Health of the Government of West Bengal, Planning Department of the Government of Uttar Pradesh), pharmaceutical sector (Indian Pharmaceutical Alliance and Organisation of Pharmaceutical Producers of India), medical sector (Indian Medical Association) and FICCI. There were thirteen OASIS study team members also present.

Agenda: The session began with a welcome address by Dr. Priya Balasubramanian, introductions 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 and detailed further in the final session.

Summary of the discussion

There was consensus amongst all participants that the threat of antimicrobial resistance (AMR) was a grave public health issue and there was a need for a multi-stakeholder, multisectoral interventions to address AMR in India

Building on and corroborating the OASIS study findings, participants further identified the following **key challenges** to improving antibiotic practices in community settings and by different levels of health providers:

- Inadequate regulations and guidelines for veterinary drug use, in particular for livestock owning households and for animal feed
- Lack of tier wise prescription guidelines and policies, including at the level of OTC sales
- the challenge of balancing excessive use of antibiotics with ensuring people have access to essential antibiotics; and also to ensure that those who have access do not use antibiotics excessively
- The unclear legitimacy of informal healthcare providers despite their widespread presence and popularity (govt of West Bengal is trying to address this through training and integrating these providers)
- Lack of pricing policy support for older generation ACCESS category antibiotics (pricing policies are against rational drug use)
- Lack of AMR awareness across the board – amongst health providers, users, supply chain actors, policymakers and political leaders
- Lack of appropriate penal backing for violating prescription/dispensing guidelines
- Lack of AMR surveillance and antibiotic sensitivity data at the national level (this needs to be made publicly available)

Recommendations for interventions

The following broad range of interventions were presented during the discussions

○ Guidelines

Develop primary, secondary and tertiary level tiered prescribing guidelines for antibiotics, using WHO's classification, and restricting the upper levels, i.e. WATCH and RESERVE antibiotics.

Treatment guidelines encouraging use of ACCESS and very limited WATCH antibiotics as first line treatment to be developed and publicized by the pharmaceutical industry, medical associations and political leadership.

While guidance for addressing AMR is available in the form of the National Policy for Containment of AMR, formulated in 2011, and the National Action Plan on AMR, adopted in 2017, there is little implementation at the state level. As health is a state subject, the onus of implementation is on the state. It is therefore recommended a Joint Secretary at the Union Health Ministry is made responsible for implementation of the national AMR action plan who can work closely with state health secretaries to facilitate implementation at the state level.

○ Awareness

Sustainable awareness programs aimed at all stakeholders, including informal providers, pharmacies, retailers, doctors, and associations are needed to illuminate the harmful effects of antimicrobial resistance. *Such programs must address existing knowledge gaps in mechanism of action of antibiotics, appropriate dosage and duration of treatment, existing prescription guidelines, national and international drugs classification and laws about sale and use of antibiotics.*

Leverage existing programs such as AMR awareness week (18 Nov-24 Nov) for community sensitization, introducing AMR in educational curriculum and using local area networks to involve key stakeholders locally i.e. pharmacies, doctors, informal providers and community leaders.

Different stakeholder groups have different incentives to change behaviour and/or be involved in antimicrobial stewardship efforts. Identify their incentives and tailor language to the particular audience when communicating about AMR. If society at large does not understand and appreciate the problem of AMR, implementation of policies will still be lacking.

○ Regulation

Leverage recent telemedicine practice guidelines issued by the Ministry of Health and Family Welfare, Government of India and identify how antibiotic policy can be embedded in digital health. Since prescriptions are shared via the same portal, there is optimism that the practice of telemedicine may curtail over the counter sale of antibiotics in the long run and reduce drug abuse. Additionally, while the opportunity to improve access to quality healthcare through telemedicine is recognised and supported

through the National Digital Health Mission, regulation for telemedicine and e-pharmacies is lacking, specifically limiting dispensation of Schedule H1 drugs or high risk antibiotics through e-pharmacies.

Introduce prescription validity period, for eg. one month from the prescription date, to limit abuse and misuse of antibiotics.

A Code of Ethics and Etiquettes 2002 under Indian Medical council ACT 1956, must be given penal backing for violation.

Review the pricing policy on ACCESS, WATCH and RESERVE categories to incentivise production and wider availability of ACCESS antibiotics, especially the older ones like tetracycline and gentamycin and exempt low priced antibiotics from price control to make them profitable for pharmaceutical companies and therefore more easily accessible.

- **Prevention and alternatives to antibiotics**

Non-standardised antibiotic use, by even qualified doctors, has been attributed to (but is not limited to) lack of diagnostic facilities in rural areas. Setting up essential diagnostic labs for point of care testing and scaling up diagnostic stewardship in health facilities may facilitate better antibiotic prescription by health care providers.

Prevention efforts, including vaccination and adopting an integrative approach to include AYUSH treatments and yoga may reduce the current over reliance on antibiotics

Surveillance

AMR surveillance at different tiers of the health system is needed to understand patterns of resistance to develop evidence-based, tierwise guidelines.

A national database should be made available in the public domain to annually publish data on resistance and sensitivity patterns.

Adapt WHO's antimicrobial stewardship tool kit to the community level; monitor use of antibiotics and audit prescribing patterns present in the community.

- **Education and training**

Harness existing relationships between formally and informally trained providers; provide training on appropriate antibiotic use and repercussions of misuse possibly through a cascade model of training to reach maximum providers in a short span of time.

Train providers on existing guidelines and classifications of drugs, both Schedule H and H1 as well as WHO's ACCESS, WATCH and RESERVE classification. Covid-19 has illuminated that protocol driven treatment is possible, therefore regular training buttressed by development of standard treatment guidelines will encourage adherence to the same.

- **Other One Health issues:**

In the context of a One Health Approach, participants reflected on the Ministry of Environment, Forests and Climate Change's (MoEFCC) decision to drop specification of limits for antibiotic residues/effluents in

its latest set of rules. The withdrawal may be due to a lack of standard validation of AMR residue, i.e. how to assess it, and it is yet to be determined if this is a temporary withdrawal or not. Consideration of smaller pharmaceutical companies, particularly the cost of compliance with such regulatory standards, was highlighted.

A six member expert committee from the invited stakeholders will be established to revisit the exemption of use of animal feed from Schedule K jurisdiction as part of the Drugs and Cosmetics ACT of 1945 and allow for a regulatory pathway to curb AMR within the veterinary sector. The Harayna state government dignitary urged the group to provide their recommendations to this Committee.

Next steps:

- OASIS team is currently developing concept to share with industry bodies and State Governments for a **multi-pronged locally driven intervention** to optimise antibiotic use in the primary care setting for human and animal health. This could be integrated with ongoing state level programmes such as the West Bengal's training programme for informal providers and the national digital health mission's telemedicine programme linking primary and tertiary healthcare providers and facilities.
- Have research organizations and industry bodies collaborate as intermediaries with state and central government to work on innovative One Health guidelines for AMR across the human and veterinary health sectors in selected state .