India: Policies and perspectives on Antimicrobial Resistance

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The problem of antimicrobial resistance: What are the realities and practices in India, and how are they different from those in the developed world?

Points to bear in mind …

- System of health care delivery by Govt is poor
- So is system of insurance coverage for health
- Therefore, health care costs are borne directly by individuals, as and when they become ill: this then becomes a major contributor to their impoverishment
- Generic manufacture of antibiotics in the country have kept their costs low, such that the cost of a course of antibiotic is often less than that for culture-and-sensitivity testing
- > 60% of population lives in rural areas, where physician: population ratio is < 1: 10000

A tragedy of the commons …

- **Patients demand, and medical practitioners prescribe and administer, antibiotics without prior laboratory tests, often irrationally**
- **Antibiotics are sold without prescription by pharmacists, who therefore also act as primary health care providers**
- **Incomplete treatment courses, due to ignorance/economic considerations**
- **Misuse of antibiotics both in veterinary practice, and as growth promoting agents (GPAs) in poultry, livestock and marine products industries leading to antibiotic residues in the environment**
- **Conflicts of interest do exist for manufacturers, physicians, and pharmacists alike in engaging in widespread and unregulated (ab)use of antibiotics**

The new initiatives

- **Policies for antibiotic use**
  - A. Ministry of Health & Family Welfare
  - B. "The Chennai Declaration"
- **Research**
  - A. Department of Health Research (DHR)
  - B. Department of Biotechnology (DBT)

Chennai Declaration: a roadmap by and for stakeholders to tackle the challenge of antimicrobial resistance (Ghafur et al, Ind J Cancer, 2012, 49:71-81)

Theme: "Practical, not perfect"

- Recognizes the need that although a ban on sale of OTC antibiotics without prescription will be the ideal step, it is not practical to implement at present
- Recommends step-by-step regulation, beginning immediately with controls on sales of 3rd and 4th generation antibiotics and anti-TB agents and then gradually expanding the list
- Additional recommendations encompassing accreditation, hospital antibiotic usage policies, veterinary practices, strengthening diagnostic laboratories, education, training, and research
- India needs "An implementable antibiotic policy" and NOT "A perfect policy"

Ministry of Health: new policy measures

- **Proposal to create a national Surveillance system for antibiotic resistance**
- **Initiate studies documenting prescription patterns and to establish a monitoring system for the same**
- **Intervention measures for rational use of antibiotics in hospitals**
- **Develop and implement diagnostic methods pertaining to antimicrobial resistance monitoring**

A policy already implemented: new "Schedule H1"

(in line with one of the recommendations of the Chennai Declaration)

- **"The supply of a drug specified in Schedule H1 shall be recorded in a separate register at the time of the supply giving the name and address of the prescriber, the name of the patient, the name of the drug and the quantity supplied and such records shall be maintained for three years and be open for inspection."**
- **Includes (at present) about 25 antibiotics comprising carbapenems, new-generation cephalosporins and gyrase inhibitors, and all anti-TB agents**
- **Gazette notification issued in August 2013 for rules to come into force six months after publication, ie from 1 March 2013**
- **Pharmacist Associations have expressed strong resistance against implementation, citing impracticality and fears of harassment by regulators**

Research: Proposal under consideration by DBT to fund a National Program on "Antibiotic resistance in microbial pathogens and approaches to their mitigation"

A. Extramural component

- **Encompassing a series of research projects across the country, selected through a call for proposals that will be competitively evaluated and funded**

B. Intramural component (at two Institutes of DBT – CDFD and Natl Inst of Animal Biotech)

- **Three projects:**
  - **Survey of antibiotic usage in a defined geographic area**
  - **Identification of molecular mechanisms of antibiotic resistance in field isolates**
  - **Quantitation of antibiotic residues in environmental samples**

- **Research training program for postgraduate medical and veterinary professionals in molecular microbiology**

Rationale for intramural program and training

- So far, the country has been “dominant-negative” for bacterial genetics
- Principal goal is to expand national capacity and to increase baseline levels of small science in the country
- Develop a cadre of clinician-researchers and public health researchers
- To do so by anchoring the program in one or two institutions

Extramural component: Areas to be covered

(Particular emphasis on network/interdisciplinary projects - the lists below are not exhaustive)

A. Hospital/farm/community-based studies

- **Epidemiologic studies (prevalence of resistance; surveillance studies)**
- **Descriptive and interventional studies on medical/veterinary/community practices that likely affect the emergence and spread of antibiotic resistance**

B. Laboratory studies

- **Molecular mechanisms of antibiotic resistance in microbial pathogens, including horizontal transfer mechanisms**
- **Host-pathogen interactions that affect antibiotic efficacy**
- **Identification and testing of novel antimicrobial agents and/or cognate targets**
- **Design and testing of novel approaches to treat microbial infections**
- **Identification of alternatives to antibiotics for (i) prophylaxis (e.g. growth promoters) and (ii) treatment (such as antivirulence agents)**
- ***VERY IMPORTANT:*** **Inexpensive methods for rapid diagnosis of infections and antibiotic resistance/sensitivity**

Research initiatives: other points

- **Liaison between Dept of Biotech and Dept of Health Reasearch**

- **Indo-Swedish Bilateral Program on Antibiotic Resistance**