

Regional strategy
on
prevention and containment of
antimicrobial resistance

2010-2015

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Regional strategy on antimicrobial resistance

1. Background

Communicable diseases continue to be a major public health problem in Member countries of the South-East Asia (SEA) Region of WHO. Each year, of 14 million deaths that occur in the SEA Region, 6 million (40%) are due to communicable diseases, contributing to 42% of the total DALYs lost¹. The continuous interplay between complex socio-economic, environmental, and behavioural factors, as well as population movements in an inter-connected world provides a milieu conducive to persistence and spread of communicable diseases² both within and across borders, thereby threatening international health security.

Emerging diseases continue to challenge public health as never before. An estimated 3.5 million people currently living with HIV/AIDS, the Region's HIV/AIDS burden is next only to sub-Saharan Africa. The generic anti-retroviral (ART) drugs produced by the pharmaceutical industry in the Region are contributing greatly to improve survival of patients worldwide and in rendering HIV as a chronic manageable condition. Although response to ART is excellent when delivered at health facilities³, emergence of resistance in HIV can destroy the hopes of survival for millions of people living with HIV.

The Region also suffers disproportionately from the global burden of tuberculosis; 34% of all TB patients are in this Region⁴. The level of multi-drug-resistant TB however remains low-- below 3% reflecting good quality of

TB programmes. Need for preserving the efficacy of first line antituberculous drugs has been widely felt since drugs used in the management of MDR-TB cases are not only expensive but also toxic. Resistant malaria has already become a major issue for a population of 400 million living in areas with high risk of contracting it⁵.

In spite of these challenges, the Region has witnessed significant achievements over the past decade towards combating old diseases as well as new and emerging ones, and in health outcomes. During the past decade leprosy has been eliminated from all countries except one and elimination of yaws achieved in India. The Region has now targeted selected neglected tropical diseases for elimination namely leprosy, lymphatic filariasis, visceral leishmaniasis (kala-azar) and yaws due to unique epidemiological, technological, and historical factors⁶. One of the most critical factors that will facilitate elimination of these diseases is availability of effective antimicrobial agents against the causative agents of these diseases.

2. Emergence of resistance and factors influencing it

Resistance against antimicrobial agents has now become a huge problem. Though during past seven decades, antimicrobial agents have saved millions of lives, substantially reduced the burden of diseases that were previously widespread and improved quality and longevity of life, in recent past, emergence and spread of resistance in several microorganisms has rendered management of many infectious diseases difficult using the common anti-infective drugs. According to European Centre for Diseases Control (ECDC) *antimicrobial resistance is possibly the single biggest threat facing world in the area of infectious diseases.*

Resistance to antimicrobials is a natural consequence of exposure to antimicrobials and is not a new phenomenon. Even with appropriate antimicrobial use, the rates of emergence of resistance can increase⁷. The progress is more rapid when there is inappropriate use. Several reports have shown association between heavy use of antimicrobials and drug resistance

because of selection pressure exerted by these agents⁸. The selection pressure is utmost when antimicrobials are used irrationally in health and veterinary sectors.

The emergence and spread of antimicrobial resistance are complex problems fuelled by the knowledge, expectations, and interactions of prescribers and patients, and regulatory environment⁹. Patient compliance with recommended treatment is another major problem. Easy access of antimicrobials in developing countries and myths amongst communities about its use exert equally important influence on emergence of resistance.

While resistance can and does appear in any setting but hospitals, with combination of highly susceptible patients, intensive and prolonged antimicrobial use, and cross-infection have become a hot spot for highly resistant bacterial pathogens. Veterinary prescription of antimicrobials also contributes to the problem of resistance. The largest quantities are used as regular supplements for prophylaxis or growth promotion, thus exposing a large number of animals, irrespective of their health status, to frequently sub-therapeutic concentrations of antimicrobials.

Resistance in microorganisms costs money, livelihood and lives and threatens to undermine the effectiveness of health delivery programmes. The WHO strategies of all major disease control programmes (HIV, TB, malaria, influenza) do advocate monitoring of drug resistance and suggest appropriate activities. The international movement of resistant strains especially when these are multi- or extensively resistant can be considered as public health event of international concern (PHEIC) as per IHR (2005).

Unfortunately combating antimicrobial resistance has not been accorded priority and attention it deserves in Member countries in spite of several resolutions (WHA37.33, WHA51.17, WHA54.11 and WHA58.27) that have been endorsed by World Health Assembly (WHA) on rational use of drugs and prevention of antimicrobial resistance.

The World Health Assembly Resolution in 1998¹⁰ had urged Member States to develop measures to encourage appropriate and cost-effective use of antimicrobials; prohibit the dispensing of antimicrobials without the prescription of a qualified health care professional; improve practices to prevent the spread of infection and thereby the spread of resistant pathogens; strengthen legislation to prevent the manufacture, sale and distribution of counterfeit antimicrobials and the sale of antimicrobials on the informal market and reduce the use of antimicrobials in food-animal production. This message was reinforced in WHA58.27 in 2005¹¹ wherein Member states were encouraged to ensure the development of a coherent, comprehensive and integrated national approach to implementing the strategies for containment of antimicrobial resistance and to monitor regularly the use of antimicrobial agents and the level of antimicrobial resistance in all relevant sectors.

The South-East Asia Regional Strategy for Prevention and Containment of Antimicrobial Resistance is based on essentials enunciated in WHA Resolutions.

3. Overview of status in the Region and consequences of resistance

No systematic studies have been done in the Region to understand the status of resistance, trends and consumption of antimicrobial agents. While multi-drug resistance in *Mycobacterium tuberculosis*, because of well performing national TB control programmes in the Region is still at an acceptable low level of <3%, amongst several other bacteria this figure is very high. Outbreaks of resistant salmonellae causing typhoid fever and shigellosis causing bacillary dysenterie have been reported from the Region. Resistance to *Vibrio cholerae*, *Escherichia coli*, *Neisseria gonorrhoeae*, and *Streptococcus pneumoniae* has been on an increase^{12,13,14,15}. More than 50% of isolates of *Staphylococcus aureus* in hospital settings are now methicillin resistant¹⁶. The emergence of community acquired methicillin resistant *Staphylococcus aureus* (CA-MRSA) as an increasingly frequent cause of skin and soft tissue infections or invasive infections is further compounding this problem. Multiresistant klebsiellae and *Acinetobacter species* have given new

dimensions to the problem of hospital associated infections. Around 400 million people live in areas which are at risk of resistant malaria. With rapid means of travel, international movement of resistant bacteria occurs frequently¹⁷. In Canada and the USA several outbreaks of resistant strains have been reported with strains originating from SEA region. Studies have also been conducted on international spread of drug-resistant gonorrhoea. *Neisseria gonorrhoeae* resistant to penicillin, tetracycline, and multiple other drugs, detected in Southeast Asia during 1960s and 1970s, has been an emerging public health issue in the United States of America¹⁸

3a. Consequences of resistance

The consequences of resistance are severe and several. Infections caused by resistant microbes fail to respond to standard treatment, resulting in prolonged illness and greater risk of death. Treatment of infections with resistant strains may require use of expensive and potentially toxic second line of drugs. Treatment failures also lead to longer periods of infectivity, which increase the numbers of infected people moving in the community and thus expose the general population to the risk of contracting a resistant strain of infection. It is also a threat to patient safety due to the rapidly growing pandemic of antimicrobial resistance^{19,20}.

4. Rationale for a strategy and major issues

Resistance is a biological, behavioural, technical, economic, regulatory and educational problem and requires a comprehensive response. Antimicrobial resistance has been an unrecognized and neglected problem which is not only cross cutting but also has far reaching implications as an emerging public health problem with huge risk to international health security. Newer drugs are being discovered very slowly. Efforts need to be made to slow down or delay the resistance thus preserving the available antimicrobials. Several success stories of reversing resistance through rational use of

antimicrobials are available from SEA Region which need to be scaled up to combat this problem comprehensively.

It is hence essential to develop a regional strategy that is acceptable to multiple stakeholders, is simple and practical, can be adapted by Member countries and acts as a powerful tool to prevent negation of progress made in the field of communicable diseases. The regional strategy aims to give particular attention to interventions involving the introduction of legislation and policies governing the use of antimicrobial agents, establish laboratory-based networks for the surveillance of resistance and assuring rational use of these drugs at all levels of health care settings.

Antimicrobial resistance is a cross-cutting issue which is influenced by several factors. Accordingly it requires ownership and active participation by several stakeholders. Some of which are: MoH, MoAnimal Husbandry, MoEducation, national regulatory authority, medical and veterinary professional bodies, medical and veterinary councils, national medical and veterinary research councils, health facilities in public, private and other sectors, international agencies, NGOs, laboratory professionals, mass media and community champions.

The regional strategy shall address following issues which continue to plague prevention and containment of antimicrobial resistance and preserve the efficacy of these drugs to maintain their “wonder” status. Some of these are:

- Neglected problem with profound impact on health and economy
- Inadequate visibility at decision making level in spite of WHA Resolutions
- Absence of a national approach/direction to combat emerging problem of antimicrobial resistance
- Lack of education amongst prescribers and users
- Weak collaboration between stakeholders
- Poor or no systematic surveillance of resistance and consumption of antimicrobial agents
- Ineffective regulatory mechanism

- Lack of economic potential/incentives for pharmaceuticals to invest in development of new drugs
- Abysmal infection control practices

5. The Strategy

The strategy shall have following guiding principles:

5.1 Guiding Principles

- Understand emergence and spread of resistance
- Rationalize the use of available antimicrobial agents
- Prevent emergence of resistance by reducing selection pressure by appropriate control measures
- Bring about a change in behaviour of prescribers of antimicrobial agents and communities to ensure their rational use
- Combat antimicrobial resistance by promoting discovery, development and delivery of new drugs/tools
- Combat antimicrobial resistance through nationally coordinated efforts with defined functions by different sectors/programmes

5.2 Goal

“To minimize the morbidity and mortality due to antimicrobial resistant infection and to preserve the effectiveness of antimicrobial agents in the treatment and prevention of microbial infections”.

5.3 Objectives

- To establish a national alliance for prevention and control of antimicrobial resistance
- To institute a surveillance system that captures emergence of resistance, trends in its spread and utilization of antimicrobial agents in different settings

- To promote rational use of antimicrobial agents at all levels of health-care and veterinary settings
- To strengthen infection control measures to reduce disease burden
- To support research to develop &/or improve use of antimicrobial agents

6. Key strategic elements and major activities

Objective 1: *To establish a national alliance for prevention and control of antimicrobial resistance*

Concerted and nationally coordinated efforts are needed to bring together various stakeholders and harness the expertise and resources available within the country in different sectors. Key elements and major activities that will accomplish Objective 1 are:

1.a **Establish national alliance against antimicrobial resistance**

- Establish a cell in MoH preferably within the unit dealing with Emerging Infectious Diseases or implementation of IHR (2005) for coordinating national activities and sharing information with other countries in the Region.
- Designate national focal point for coordinating antimicrobial resistance related activities
- Forge national alliance of relevant programmes, stakeholders from both public and private sectors
- Constitute inter-sectoral steering committee under the chairpersonship of high level policy maker
- Establish national expert advisory committees
- Develop a national strategic approach towards antimicrobial resistance with consensus of all stakeholders about their specific roles
- Strengthen national regulatory mechanism
- Allocate adequate resources to implement strategy for prevention and containment of antimicrobial resistance

- Provide adequate representation to private sector in steering committee and advisory committees

1.b Strengthen national networks

- Augment existing networks to fulfil Objective 2
- Incorporate standards in national regulatory framework
- Establish/strengthen accreditation mechanism for hospitals which articulates rational use of antimicrobials as an integral requirement
- Enhance capacity and authority of regulatory authority to implement national standards in use of antimicrobials
- Involve networks under IHR and WAPS

1.c Collaborate with stakeholders

- Develop linkages with stakeholders (potential stakeholders at Annex 1)
- Promote regular and formal interactions
- Encourage NGOs role in community awareness and targeted education

Objective 2: *To institute a surveillance system that captures emergence of resistance, trends in its spread and utilization of antimicrobial agents in different settings*

Several networks may be operational in the country that generate and collate data on resistance in microorganisms and consumption of antimicrobial agents. These should be activated to support national efforts towards containment of antimicrobial resistance. If such networks are not functional, these must be established. Key elements and major activities that will accomplish Objective 2 are:

2.a Monitor resistance in microorganisms

- Quantify resistance in micro-organisms through networks of laboratories with capacity built to perform quality assured antimicrobial susceptibility testing

- Ascertain trends in emergence & spread of resistance
- Detect and report new events
- Assess effect of interventions on resistance
- Communicate data to users and national focal point
- Advocate establishment of surveillance networks in veterinary sector and develop linkages between human and veterinary networks

2.b Monitor use of antimicrobials

- Evaluate prescription policies in health-care settings in public and private sectors and utilization of antimicrobial agents at various levels
- Assess therapeutic and non-therapeutic use in animals
- Appraise impact of pharmaceuticals promotion
- Collate data and communicate to stakeholders

2.c Monitor disease & economic burden due to resistant organisms

- Correlate data on utilization of antimicrobials and resistance
- Determine impact of non-pharmaceutical factors on emergence of resistance
- Calculate economic losses due to resistance
- Utilize data generated for policy formulation and programme development/improvement

Objective 3: *To promote rational use of antimicrobial agents at all levels of health-care and veterinary settings*

This is the most complex and yet critical objective since it involves strengthening of technical and regulatory requirements along with bringing about a change in the behaviour of prescribers and users. Key elements and major activities that will accomplish Objective 3 are:

3.a Promote optimal prescription

- Develop standard national/local treatment guidelines (STG) advocating evidence based monotherapy or combination therapy
- Train professionals in use of these STG
- Assure use of STGs through Hospital Committees
- Provide effective curriculum on rational prescription of antimicrobial agents in undergraduate and postgraduate teaching of medical, dental, veterinary and pharmacy students

3.b Make available quality laboratory data in real time

- Ensure quality assured lab determination of resistance
- Utilize locally generated data for immediate use as well as for developing/modifying use of antibiotics guidelines
- Build capacity of health care providers to utilize the resistance data efficiently

3.c Rationalize use in veterinary sector

- Ban non therapeutic use of antimicrobial agents using IHR Framework
- Develop Standard treatment guidelines
- Train professionals in use of STG

3 d. Promote compliance and proper public use

- Educate communities on proper compliance and non-self-medication
- Prevent over-the-counter availability of antimicrobial drugs
- Provide continuous education to pharmacists/chemists in appropriate use of antimicrobial agents

Objective 4: *To strengthen infection prevention and control measures to reduce disease burden*

Since all the factors that promote or influence communicable diseases also facilitate resistance, efforts made to reduce disease burden are bound to mitigate extent of resistance. Key elements and major activities that will accomplish Objective 4 are:

4.a Strengthen disease control programmes

- Develop standard treatment guidelines and assure implementation
- Train professionals in use of STG
- Support activities at community level to assure adherence
- Monitor resistance and effect of interventions
- Promote PPP

4.b Augment infection control practices in hospitals® (Include WHO Doc)

- Establish infection control practices especially universal/standard precautions and provide enabling environment
- Ensure availability of adequate number of trained health care staff
- Provide PPE and other infrastructural support
- Institute and empower Hospital Infection Control Committees

4.c: Promote infection control practices in communities

- Launch comprehensive health education campaigns
- Promote hygiene in school curriculum
- Collaborate with NGOs and local champions

4d. Promote and strengthen disease prevention interventions

- Strengthen immunization programmes
- Educational campaigns of hygiene and non-pharmaceutical practices
- Strengthening of disease prevention measures
- Collaborate with mass media in creating awareness

Objective 5: *To promote research in area of antimicrobial resistance*

5a. Encourage basic research

- Ascertain dynamics of spread and drivers of resistance
- Understand mechanism of resistance
- Evaluate impact of use of antimicrobials in agriculture and fishery on human health

5b. Support operational research

- Develop optimum doses and duration of various drugs as monotherapy or in combinations
- Understand impact of resistance on illness and economy
- Develop rapid diagnostic tools
- Determine factors that influence prescription habits
- Elucidate behavioural aspects about self-medication and adherence and develop interventions to bring about change

5.c Support development of new antimicrobial agents and vaccines

Development of new antimicrobial agents or alternatives thereof requires support from government and industry supported research through

- research grants, PPP, public contribution to research funding and R&D tax credits;
- pay for outputs from R&D process including advanced purchase commitments or patent buyouts and also through
- reducing time to market entry through fast track mechanisms of regulatory approvals.

7. Implementation Mechanism

Resistance to antimicrobial agents is a cross-cutting problem, a problem which needs to be tackled by a well-coordinated action. This Regional

strategy recognises the need for a wide range of activities which are required to support the control of antimicrobial resistance and the need for commitment from a wide variety of players. It needs to be endorsed by all countries of the SEA Region and will lead to sustained action to combat this problem. Microbes are dynamic organisms and so should be our approach to tackling their resistance to antimicrobial agents. The strategy also recognises the need for action across a wide range of interests and by many organisations and individuals. Since microorganisms do not recognise geographical boundaries and are increasingly spread through international travel and commerce, it also recognises the need for the SEARO to play its part by providing appropriate technical support in step-wise implementation of strategy at national and local level with following steps:

1. Obtaining national commitment towards prevention and containment of antimicrobial resistance
2. Constitution of an inter-sectoral steering committee with all stakeholders from public and private sectors represented and chaired by a senior policy maker
3. Establishment of a cell and focal point in MoH within unit responsible for emerging infectious diseases or International Health Regulations (2005) to coordinate national alliance (comprising mainly of existing programmes) and empowered to provide evidence-based directives for rational use of antimicrobial agents and disease prevention and control interventions
4. Constitution of a national expert advisory committee
5. Designation of subgroups in specialized areas
6. Development of public information campaigns
7. Establishment of national surveillance system with mandatory reporting system through efficient and quality lab networks and existing surveillance systems

8. Development and making available various national standards, guidelines for surveillance and treatment and strengthening regulatory support for their implementation
9. Organize continuing education for professional and all HCW etc. through medical and health-related institutions, and professional bodies
10. Invoking IHR and other national measures to reduce or ban use of antimicrobials as growth promoters in animals
11. Collation of research findings for conversion into actions
12. Establishment of national forum of multidisciplinary professionals (health, veterinary, agriculture, fishery etc) to share information to promote understanding the impact of use of antimicrobial agents on human health
13. Collaborate with international agencies for technical support and obtaining information from other countries/sectors. WHO to coordinate information exchange in SEA Region.
14. Regular meetings to review, assess and modify the action plans

7a. Indicators and Targets

Following are suggested as Regional indicators

- Number of countries with national intersectoral steering committee for AMR

Target : all countries by 2012

- Number of countries with national alliances for prevention and control of antimicrobial resistance

Target : all countries by 2013

- Number of countries with national networks for surveillance of antimicrobial resistance through quality laboratory services

Target: all countries by 2015

- Number of countries with legislation banning over the counter sale of selected antimicrobial agents

Target: all countries by 2015

- Number of countries with ban on non-therapeutic use of antimicrobial agents in animals

Target: all countries by 2015

- Number of antimicrobial agents for which resistance against nationally identified microorganism has stabilized or decreased

Target: At least five drugs for which resistance has stabilized or decreased by 2015

- Number of antimicrobial agents of which the annual use has declined by 25% as indicated by DDD by 1000 patient days

Target: at least five antimicrobial agents with annual utilization reduced by 25% as indicated by DDD by 2013

- Percent of hospitals that show decrease in rate of hospital associated infections (HAI)

Target: More than 25% of hospitals in at least five countries demonstrate decrease in rate of HAI by 2015

- Percent of hospitals in public and private sector in a country with policy for rational use of antimicrobials

Target: At least 75% of hospitals in public and private sector in at least five countries with policy for rational use of antimicrobials by 2015

Indicator: Number of countries with national Hospital Accreditation schemes with rational use of antimicrobials as an essential requirement for accreditation

Target: All countries by 2015

8. Monitoring & Evaluation

A strong component of monitoring and evaluation mechanism through alliance utilizing the aforementioned indicators and targets shall be established. National baseline data should be established. The national steering committee shall regularly review the data generated for this purpose and provide guidance for changes, if any, required to achieve the targets.

Regional annual reviews should be undertaken through WHO intercountry coordination mechanism and assessment made during mid-term of the strategy plan period.

9. Mainstreaming the national response

Given the cross cutting nature of the problem and complexity of the response, it is essential that every stakeholder has clarity about its role in combating this menace, both within its own mandate as well as for those issues which have a bearing upon activities of other sectors. An ownership of the strategy by all stakeholders is critical for its moving forward and yielding desired results.

Antimicrobial drug failure may occur for many reasons but it impacts not only patient care and safety but also threatens effective management of public health infectious diseases globally. A strategic approach is urgently needed to combat this emerging threat.

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Annex 1

Suggested stakeholders

- MoH, MoAnimal Husbandry, MoEducation
- National Regulatory Agency
- Medical & Veterinary and Pharmacy Professional Bodies
- Medical & Veterinary Councils
- National Medical & Veterinary Research Organizations
- International agencies
- Corporate hospitals
- NGOs
- Community champions
- Mass media
- Pharmaceutical industry