



Summary report:of INDEPTH-ReAct workshop on Antibiotic Resistance

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Hosted by: Vadu Rural Health Programme, KEM Hospital and I²IT, Pune, India
Organized by: INDEPTH and ReAct

1. Background

The emergence and spread of antibiotic resistance is one of the greatest public health threats of the 21st century. Antibiotics are a unique class of drugs since they have effects on both the individual and society. Use and misuse of antibiotics by individuals' leads to selection of antibiotic resistance in bacteria that may spread to others and thus curtail effective treatment also for other members of society. The prevalence of antibiotic resistance, especially multidrug resistance, continues to increase globally leading to mounting health-care costs, failed treatments, and deaths. Severe clinical consequences of multidrug resistance make it imperative that the problem be addressed and the frequency of resistance curtailed and reversed. The global problem of antimicrobial resistance is particularly pressing in low-income countries, where the infectious disease burden is high and cost constraints prevent the widespread application of newer, more expensive agents. Gastrointestinal, respiratory, sexually transmitted, and health care associated infections are leading causes of disease and death especially in low-income countries, and management of all these conditions has been critically compromised by the emergence and rapid spread of resistance.

In high- and middle-income countries the most important cause of antibiotic resistance development is over-consumption, with important consequences for individual patients and public health. Available data, however, suggest that also in low-income countries resistance has reached unacceptably high levels in common human pathogens and that trends show further increases. The agents most affected are inexpensive, older antibiotics, which in many situations are all that are available or affordable. In these settings, availability of antibiotics and cost of therapy are critical constraints which will drive irrational use. Respiratory tract infections are a frequent cause of medical consultations. Although the majority (>80 %) of such infections are viral in aetiology – and thus not requiring antibiotic treatment, they account for three-quarters of all human antibiotic consumption. The resulting widespread use of antibiotics is a primary factor that drives the emergence of antibiotic resistance at both the local and regional levels. Recent surveys suggest that the proportion of patients with influenza-like illness who receive antibiotics is at least double the actual incidence of the infections for which the treatment is intended. Moreover, diarrhoeas (that also are most often viral in aetiology) are often incorrectly treated with antibiotics.

There are a number of barriers to rational use of antibiotics including:

- Lack of knowledge about the causes and consequences of irrational use of antibiotics
- Lack of precise and rapid diagnostic tools as well as underutilization of and/or insufficient access to those that exist

17 November 2009

- Lack of surveillance data of antibiotic susceptibility patterns
- Lack of treatment guidelines or ineffective implementation of guidelines
- Limited access to effective antibiotics
- Non-functioning regulatory systems
- Lack of political understanding of the problem and /or commitment to address it
- Cost constraints in resource poor settings and unethical financial incentives which promote inappropriate use

Both the problem description and the potential solutions are context-specific; no country can simply copy the model of another and implement it without modification. However, despite the complexity of the problem there are good examples of how antibiotic use has been improved and new strategies to contain antibiotic resistance have been developed. These examples are valuable templates for building country-specific programs to manage resistance.

2. Proceedings

The meeting was opened by Andreas Hedding who outlined the global situation of emerging antibiotic resistance as an important public health threat, and discussed some of the main causes and possible solutions.

Then the Executive Director of INDEPTH - Osman Sankoh made a presentation of INDEPTH to describe how INDEPTH is organized, how the network was initiated and some of the unique features of population based, longitudinal surveillance in low- and middle income countries. INDEPTH is a network currently comprising of 37 Health Demographic Surveillance System Sites (HDSS) in 20 countries that was established in 1998. The network has nodes in Africa, Asia and Oceania. The purpose is to provide a better, empirical understanding of health and social issues and to apply this understanding to alleviate the most severe health and social challenges.

Osman also pointed to some of the key challenges:

- Identifying and leading new cross-site research opportunities
- Strengthening the capacities of local scientists to analyze the data
- Need for more training opportunities in the relevant fields: M.Sc./Ph.D.
- Funding from developing-country institutions

17 November 2009

- Core support to INDEPTH and sites
- Site selection for cross-site projects and the need for objective criteria

Otto Cars, Executive Director of ReAct presented ReAct – Action on Antibiotic Resistance and described some of the previous activities and achievements of the network. ReAct (www.reactgroup.org) is a network that links a wide range of individuals, organizations and networks around the world taking concerted action to respond to antibiotic resistance. The ReAct Secretariat is based in Uppsala, Sweden and has 5 networking nodes around the globe. ReAct has network activities in Europe, the US, Latin America, Asia and Africa. ReAct is not a grant-making body but works to facilitate research activities or sometimes undertakes research studies in the field of antibiotic resistance. Through the network, a large number of scientists, physicians, pharmacists and policy makers are connected and provides a resource and knowledge base to be drawn upon.

During the workshop presentations were made from 14 INDEPTH sites and 5 non-INDEPTH sites including the Indian Initiative for Management of Antibiotic Resistance (IIMAR). In total, experiences from 12 different countries (Kenya, Tanzania, Ghana, Burkina Faso, Uganda, Vietnam, India, Malaysia, Mozambique, Bangladesh, Thailand and Nepal) plus the EU were shared. Presentations brought up different aspects in relation to antibiotic resistance ranging from surveillance of microbiological data and data on antibiotic use to complex health system interventions and efforts to influence national health policies.

Available data suggest that resistance among bacteria towards common antibiotics has reached unacceptable levels in many low- and middle income countries and that trends show further increases. Resistance appears to have emerged and spread rapidly in many areas, with important consequences for individual patients and public health. The agents most affected are the inexpensive, older antimicrobials, which in many cases are all that are available or affordable.

2.1. Experiences from African sites

There were 7 presentations from sites that are part of the Malaria Clinical Trials Alliance (MCTA; www.indepth-network.net/mcta/mctaindex.htm) which is a large multi-site project funded by the Bill and Melinda Gates Foundation. The MCTA aims to strengthen and prepare African institutions to undertake clinical trials of novel malaria vaccines and drugs. For the second phase of this project the scope will also allow studies of other diseases and health problems to be undertaken. Many of the MCTA sites have recently established facilities for microbiology and susceptibility testing. Some MCTA sites are about to initiate work on TB but many have also done limited work on antibiotic resistance in common pathogens, such as *Streptococcus pneumoniae*, *Hemophilus influenza* and other respiratory bacteria. Some sites have also looked at enteric pathogens e.g. *salmonella*.

17 November 2009

During the workshop presentations were made from the following INDEPTH sites:

1. Nanoro (IRSS), Burkina Faso
2. Kintampo Health Research Centre, Kintampo, Ghana
3. Kumasi Centre for Collaborative Research (KCCR), Agogo, Ghana
4. KEMRI CGMRC Kilifi, Kenya
5. CDC/KEMRI DSS, Kisumu, Kenya
6. Centro De Investigaçao em Saude de Manhiça- Maputo, Mozambique
7. Bagamoyo/Ifakara Health Research and Development Centre, Tanzania
8. Iganga/Mayuge HDSS, Uganda

For example work in Manhiça, Mozambique showed that levels of antibiotic resistance are high for most available antibiotics for *Shigella* and *Salmonella*.

Researchers at Kilifi in Kenya have been doing comprehensive sampling on every child admitted to hospital since 1998 and have since then collected data on invasive bacterial infection: 45,000 cultures; 2,500 (6%) positive for pathogens with *pneumococci* (26%), *staph aureus* (10%) and non-typhi *salmonella* (11%) being the commonest isolates. Since 2007 data from adult patients have also been collected.

Iganga/Mayuge HDSS in Uganda has also studied pneumococcal disease and found that 30-40% of children who had been sick in last 2 weeks had used antibiotics and that 99% of colonizing *pneumococci* were resistant to trimetoprim-sulfametoxazol; and that 81% showed intermediate resistance to penicillin.

Furthermore, few studies regarding antibiotic use in the HDSS setting have been undertaken hitherto, although the opportunities for investigating this are excellent given the setting and existing well-developed tools (verbal and social autopsy methodology).

2.1.1. Constraints

- Lack microbiology facilities particularly in rural areas
- Financial support & adequately trained human resources
 - There is a need for trained microbiologists to undertake microbiological surveillance work and also for health systems researchers to conduct studies at the health system- and community level to better map current use and structural barriers to rational use of antibiotics.
- Lack of national policies on antibiotic use

17 November 2009

- In many cases there are no guidelines for antibiotic use - or if there are they are not implemented - which of course impacts consumption.
- Lack of access to effective antibiotics, this encompasses several aspects including:
 - Adequately trained human resources
 - Health care facilities to prescribe and dispense drugs of known quality in a safe and effective way
 - Surveillance of resistance levels in bacteria locally to aid in the choice of drug for treatment of patients in the local setting.
 - Affordable antibiotics in a form that encourages adherence and safe use by patients
- Counterfeit and substandard drugs
 - Substandard drugs are genuine drug products which do not meet quality specifications set for them, whereas counterfeit drugs are pharmaceutical products which are produced and sold with the intent to deceptively represent their origin, authenticity or effectiveness. Both are common problems, particularly in low and middle income countries and negatively impact the efficacy and effectiveness of antibiotics. Most countries have legislative frameworks that prohibit and ban counterfeit drug manufacture and selling, however, legal enforcement is often weak and incomplete, leading to widespread circulation of both substandard and counterfeit drugs.

2.1.2. Opportunities and ideas for future work

- Evaluation of antibiotic use
- Studies of consumers attitudes and behavior
- Conduct extended microbiological studies of bacterial susceptibility and prevalence of different resistance phenotypes
- Studies of carriage of resistant bacteria in the community
- Assessment of antibiotic quality
- Cost-benefit analyses of pre-packaged antibiotics for children

- 3-day vs. 5-day treatment with Amoxicillin

2.2. Experiences from Asian sites

The situation in many Asian countries differs compared to the African setting and antibiotic overconsumption is more widespread. This is due to greater availability, and in many cases strong financial incentives for irrational drug use on the prescriber/dispenser side and – in some countries - possibly stronger public demands for poly-pharmacy. Several of the Asian INDEPTH sites have already conducted extensive work in the field and examples include:

- Drug use & health seeking behavior in both hospital and community settings
- Health-care providers' knowledge, practical competence & reported practice
- Microbiological surveillance and susceptibility testing in hospital and community settings
- Interventions to increase knowledge amongst prescribers and consumers

At icddr,b in Bangladesh, detailed studies of susceptibility patterns of enteric pathogens have been carried out as well as behavioral studies of village doctors and interventions to promote rational use. Data from icddr,b show the effects of antibiotic cycling where resistance to tetracycline in *V. cholera* decreased significantly during an 11-year period of when that antibiotic was not used (1993-2004). When tetracycline was introduced again the levels of resistance rose again.

Work done at non-INDEPTH sites illustrated a number of different strategies for mobilizing attention and action to the problems in hospitals, amongst health professionals and the community and to stimulate national policy action. These presentations highlighted the underlying difficulty of adequate accurate data to support and monitor system change. A presentation from Nepal showed the challenge of beginning data collection, developing and implementing treatment guidelines and creating policy within health institutions and government. Presentations from Thailand and Malaysia showed a broad array of activities in various fields including:

- Surveillance of antibiotic resistance patterns at national level through networks of hospitals
- Studies of prescribing behavior amongst clinicians
- Mapping of antibiotic use and resistance in the agricultural sector
- Media campaigns to increase public awareness and promote rational use on the consumer side

17 November 2009

- University Sains in Malaysia also has several ongoing projects to study different aspects of antibiotic resistance in the Middle-East (Yemen, Libya and Sudan)

A presentation from the Indian Initiative for Management of Antibiotic Resistance (IIMAR) showed the kind of sustained communication and support for advocacy needed to many target groups – again highlighting the challenge of creating adequate data sets, especially in low-income countries.

2.2.1. Constraints

- In many countries one of the key problems is the lack of national coordination
 - Many countries have institutions that have conducted extensive work in the field over a long period of time, but there are no or few links between e.g. those looking at microbiological data and those who monitor antibiotic consumption or antibiotic use in the agricultural sector.
 - There is not yet strong enough buy-in and ownership from the politicians
- Many countries have national policies and guidelines for antibiotic use but they are not implemented
- Especially in some places; very strong financial incentives for irrational use of antibiotics from the medical profession and pharmacies/dispensers
- Lack of adequate surveillance of drug use and treatment failure data to specify problems, support intervention and policy development and monitor results.

2.2.2. Opportunities and ideas for future work

- Advocate for national antibiotic policy
- In Thailand: Advocate for antibiotic resistance as one agenda item in next National Health Assembly (2010)
- Strengthen and broaden existing networks
- Engage the public and raise awareness

2.3. Experiences from the European Antimicrobial Resistance Surveillance System (EARSS)

EARSS is a European wide network of national surveillance systems, providing reference data on antimicrobial resistance for public health purposes. EARSS is a network of national centers in 33 countries. These national centers systematically collect data from clinical laboratories in their own countries. The national centers send this data to the EARSS Management Team based at the Dutch National Institute for Health and Environment (RIVM) in the Netherlands.

17 November 2009

Since the program began in January 1999 these laboratories have collected antimicrobial resistance data on more than 350,000 invasive isolates. EARSS performs ongoing surveillance of antimicrobial susceptibility of seven indicator bacteria commonly causing infectious in humans.

- *Streptococcus pneumoniae*
- *Staphylococcus aureus*
- *Enterococcus faecalis*
- *Enterococcus faecium*
- *Escherichia coli*
- *Klebsiella pneumonia*
- *Pseudomonas aeruginosa*

The coordinator of EARSS, Dr Hajo Grundmann gave an overview of the EARSS and laid out some ideas regarding the great potential for HDSS to generate data that up till now remain unknown:

- First and foremost to: *Inform our understanding of antibiotic resistance and the appropriate response to its control as a public health problem.*
- Resistance proportions per pathogen per site/region
- Ecological conclusions on causal relationship with consumption
- Burden of Disease estimates attributable to antibiotic resistance

INDEPTH sites could achieve the above by undertaking:

- Point prevalence surveys at HDSS sites
 - Antibiotic consumption using ABC calculator
 - Treatment compliance and failure
 - Microbiological sampling
- Factorising antibiotic use and resistance into verbal autopsy
- Health centre-based surveillance
- Hospital/laboratory based antibiotic resistance surveillance
 - Indicator pathogens and antibiotic classes
 - Health care associated infections

INDEPTH has potential to generate surveillance data at three levels:

1. *Micro level – the pathogen*

Pathogen population dynamics: To type, map and track the geographical and evolutionary trajectories with the aim to explain the reservoirs and origins of emerging virulence, transmissibility, antimicrobial resistance overall fitness and abundance of human pathogens.

2. *Macro level- the patient*

Clinical management of infections: To improve patient treatment by optimisation of empirical anti-infective therapy thereby reducing inappropriate antibiotic administration and critically appraising essential drug availability

3. *Meta level – the society*

Defining the international scale of AMR: To define the dimension of antibiotic resistance with relation to other competing public health threats. This will lead to the public recognition of anti-infective as scarce non-renewable resources, support policy changes and redirect investment into drug development.

Apart from issues pertaining to financial resources, legal agreements etc, a key aspect of future cross-site collaboration within the INDEPTH network will be the validity and comparability of data. This will require:

- Agreement on standard protocols
- Defined breakpoints (S,I,R, EUCAST, CLSI)
- Routine internal quality control
- Regular external quality assurance exercises

3. Future prospects for collaborative work and action points

The workshop provided a good starting point for potential future work in the area of antibiotic resistance. This was the first attempt to explore antibiotic resistance as a future strategic area for INDEPTH and to gauge interest from sites. The meeting served to take stock of activities in the area of antibiotic resistance that have been undertaken hitherto, and provided better understanding of the current capacity at the HDSS sites. In addition, the workshop offered new opportunities for collaboration and synergies with partners outside the current INDEPTH networks sites. Various options for collaborative was discussed, from collecting and summarizing data available to conducting multi-sites studies of various kinds.

It was evident from the presentations that there are significant differences between sites in terms of previous experience with microbiological work. Some sites have long-standing experience in conducting routine bacteriological isolation and susceptibility testing whereas other sites have just started or are at present doing only isolation and not susceptibility testing. A prerequisite for comparative cross-site microbiological studies will require a common platform and agreed protocols and breakpoints. This could be through inter-site exchange and formal training of the laboratory staff in order to establish comparable isolation and susceptibility techniques.

During the workshop it became clear that the activities and interests of participants could be categorized into the following areas:

1. *Pharmaco-epidemiology of antibiotic use*

This comprises different studies of antibiotic consumption, including behavioral studies of prescribers and consumers, both in hospital settings and in the community. Further, studies regarding the influence of socioeconomic factors and other determinants of drug utilization belong here as do studies on patterns of drug exposure over time in individual patients and populations. This is an area where data could rapidly be generated by including questions about antibiotic use in the existing surveillance tools.

2. *Surveillance of resistance*

Under this heading we find various methods and approaches for microbiological testing and screening for resistance geno- and phenotypes in bacteria, including sentinel surveillance, antibiograms, surveillance of indicator pathogens both in hospital care and the community; point prevalence as well as longitudinal studies. This area also includes development of standard methodology and laboratory protocols.

3. *Interventions*

This includes interventions at various levels to improve behaviors to promote rational use of antibiotics, educate health care professionals, improvement of diagnostics, new legislation, changes in policy and drug regulation and pricing etc.

4. *Policy/systems*

The problem of antibiotic resistance necessitates a systems view and research needs to be contextualized into the health system, analyzing different components of the national/regional health care infrastructure, looking at hurdles and potential measures to improve the situation from the systems perspective.

5. *Drug quality*

Poor drug quality is a well-known problem in many parts of the world in particular in low- and middle income countries. The situation concerning antibiotic drug quality warrants further studies to better describe and map the current situation in different countries and health care settings.

6. *Burden of antibiotic resistance*

A major barrier in gaining recognition of antibiotic resistance as a serious global public health threat is the lack of comprehensive burden data that illustrates not only the true prevalence of resistant infections and their impact on health outcomes, but also the associated economic costs.

3.1. Potential for collaboration

17 November 2009

Against the background outlines above with different countries having different problems and different HDSS sites having varying degrees of experience and focus on the antibiotic resistance problem it is important to identify where added value can be found within the collaborative framework offered by the INDEPTH network. Some of the ongoing activities at the HDSS sites will continue with or without the network, the challenge is now to identify the areas that are particularly suitable for cross-site collaboration.

INDEPTH with its network of HDSSs is uniquely positioned to take on several of the research questions related to this problem. Issues that could be studied with advantage in the HDSS include:

- Studies of prescription and consumption patterns, costs
- Behavioral aspects and attitudes of consumers and providers
- Prevalence of resistance in defined patient groups, burden data
- Intervention studies with improved diagnostics and rational use
- GIS studies mapping risk factors for resistance such as proximity to animal husbandry and other geo- and demographic data
- Efficacy studies (phase I-II) of combination therapy in selected patient groups
- Studies of access and improved algorithms for presumptive treatment

It was decided that a new meeting will be held in March-April 2010. Before that meeting a short questionnaire regarding interests and available resources will be sent out.

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Appendix 1.

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17 November 2009

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17 November 2009

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17 November 2009

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17 November 2009

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