

The evolving threat of antimicrobial resistance

Options for action

Executive Summary



World Health
Organization

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Foreword



Antimicrobial resistance (AMR) is not a recent phenomenon, but it is a critical health issue today. Over several decades, to varying degrees, bacteria causing common infections have developed resistance to each new antibiotic, and AMR has evolved to become a worldwide health threat. With a dearth of new antibiotics coming to market, the need for action to avert a developing global crisis in health care is increasingly urgent.

In addition to a substantial financial burden that national health-care budgets can ill afford, AMR has economic consequences far beyond the health sector, such as damaging repercussions on international travel and trade resulting from the cross-border spread of resistant infections. The cost of *not* acting against AMR needs to be considered when deciding resource allocation and assessing interventions.

We know how and why AMR develops, what factors favour its emergence and spread, and what measures can be taken to limit it. Why then are we now facing an impending crisis in the treatment of many infections? The book “The evolving threat of antimicrobial resistance – Options for action”, of which this is the executive summary, describes the context of the problem, some of the progress made in recent years to tackle it, and what more should be done. Without question, more information and new tools are needed, but available strategies and interventions can go a long way towards minimizing the scale and impact of AMR, and maximizing the effective lifespan of existing antibiotics. Much more could be achieved by better and more widespread application of these measures, and there are many promising opportunities for innovation in this area.

Infections which are increasingly resistant to antibiotics together account for a heavy disease burden, often affecting developing countries disproportionately. The use of vast quantities of

antibiotics in food-producing animals adds another dimension to a complex situation. Several sectors and services are involved and each, from public health to animal husbandry, has an important role to play in counteracting AMR. Responsibility needs to be shared, and coordination of the separate necessary inputs requires determined leadership, additional resources, and solid commitment at many levels.

The World Health Organization (WHO) has long recognized AMR as a growing global health threat, and the World Health Assembly, through several resolutions over two decades, has called upon Member States and the international community to take measures to curtail the emergence and spread of AMR. The WHO Global Strategy for Containment of Antimicrobial Resistance, published in 2001, set out a comprehensive set of recommendations for AMR control which remain valid today. This book examines the experiences with implementing some of those recommendations ten years on, the lessons learnt along the way and the remaining gaps. On World Health Day 2011, WHO again highlighted AMR, and urged countries to commit to a comprehensive financed national plan to combat AMR, engaging all principal stakeholders including civil society.

I am pleased to present this book during the campaign year chosen by WHO for special emphasis on the importance of AMR. It testifies to the Organization’s commitment to promoting and facilitating global action to contain AMR and ensuring that effective antibiotics will be available worldwide in the future.

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Options for action

The evolving public health threat of antimicrobial resistance (AMR) is driven both by the appropriate and inappropriate use of anti-infective medicines for human and animal health and food production, together with inadequate measures to control the spread of infections. Recognizing this public health crisis, several nations, international agencies, and many other organizations worldwide have taken action to counteract it through strategies applied in the relevant sectors. Several World Health Assembly resolutions have called for action on specific health aspects related to AMR, and the World Health Organization (WHO) published its global strategy for containment of antimicrobial resistance in 2001, and on World Health Day (WHD) 2011 called on countries in a six-point policy package to (1) commit to a comprehensive and financed national plan with accountability and civil society engagement, (2) strengthen the surveillance and laboratory capacity, (3) ensure uninterrupted access to essential medicines of assured quality, (4) regulate and promote the rational use of medicines in animal husbandry and to ensure proper patient care, (5) enhance infection prevention and control, and (6) foster innovations and the research and development of new tools.

The WHO book “The evolving threat of antimicrobial resistance - Options for action”¹ describes examples of policy activities and experiences of interventions that have addressed AMR in different parts of the world. It also describes some of the progress made since the publication of the 2001 WHO strategy. It draws attention to areas where knowledge is lacking and where urgent action is still needed. The aim of the book is to raise awareness about AMR and stimulate further efforts to meet

the recommendations outlined in the 2001 strategy and in the 2011 WHD policy package.

While much of what is summarized here is well known to the scientific community, awareness at the political level, although essential, is often lacking. A specific objective is therefore to encourage policy decision-makers and the global community to commit to intensified action against AMR.

The book focuses on five of the most important areas for the control of antibiotic resistance as recognized in the WHO 2001 strategy, which are: surveillance, rational use in humans, rational use in animals, infection prevention and control, and innovations. Political commitment is highlighted as an indispensable and overarching prerequisite for action in the five focus areas of this book.

AMR as a public health concern

Many patients around the world suffer harm due to AMR because infections are no longer susceptible to the common medicines previously used to treat them. Data from around the world confirm that AMR, including multidrug resistance, is increasing among many pathogens responsible for infections in health-care facilities and in the community.

Many of the medical advances of recent years, such as chemotherapy for cancer treatment and organ transplantation, are dependent on the availability of anti-infective drugs. The predictable consequence of resistance is increased morbidity, prolonged illness, a greater risk of complications, and higher mortality rates. The economic burden includes loss of productivity (loss of income, diminished worker productivity, time spent by family) and increased cost of

1. http://whqlibdoc.who.int/publications/2012/9789241503181_eng.pdf



diagnostics and treatment (consultation, infrastructure, screening, cost of equipment, drugs).

Estimates from Europe of the health and economic burdens resulting from resistant infections indicate that the excess mortality due to resistant bacterial hospital infections exceeds 25 000 annually. Apart from additional patient morbidity/mortality, the attributable health-care costs and productivity losses are estimated to be at least €1.5 billion each year. For community-acquired infections the effect of AMR on the overall disease burden is less clear. Another consequence of AMR in health-care facilities and community-associated infections is the need to change prescribing practices to newer, more costly medicines – some of which are also associated with higher rates of adverse reactions.

AMR threatens practices in both high-income countries and in countries with limited resources – from complex therapeutic procedures to the routine control of common infectious diseases. Once resistance has emerged, the resistant bacteria can spread in hospitals and in communities.

The evolution of AMR is coupled with a dearth of new antibiotics in the development pipeline. This raises the possibility that untreatable multi-drug resistant (MDR) infections will become more and more common. It is particularly worrisome that once it develops, AMR is either irreversible or very slow to reverse, despite the introduction of AMR containment and stewardship programmes. Consequently, an early implementation of interventions to avoid the initial development and/or spread of AMR can be considered as a key public health policy.

Surveillance of antimicrobial resistance and use

Effective surveillance is the cornerstone of national and international efforts to control antimicrobial resistance (AMR). Tracking antibiotic use, and the emergence and spread of resistant strains of bacteria provides the information and tools needed to guide policy and evaluate measures taken to promote appropriate antimicrobial use at all levels, from local to global. Consequences, if actions are delayed, can also be understood from such data.

There are wide variations between regions and countries, and even within countries, in their capacity to carry out AMR surveillance. Many countries have made considerable progress in setting up AMR surveillance mechanisms and successfully using the data to bring about changes in national policies and practice, leading to reductions in antimicrobial use, with a subsequent reduction in AMR in some cases. However, there is a long way to go before effective antimicrobial use and resistance surveillance is established worldwide. In resource-poor countries with comparatively weak health systems, there are constraints related to infrastructure, trained personnel, networking, and coordination. In countries with effective surveillance, political support and strong health systems appear to be critical for success.

The methods for obtaining data are often problematic, especially regarding collecting data on antimicrobial use. Small-scale, well-designed studies and surveys, such as indicator surveys in different settings, can be effective in providing insight into the general situation and in identifying priority areas for intervention: Trends may be determined through repetition of these surveys at specific intervals. Data on the burden of AMR, such as treatment

failures or extra costs, are scarce, especially in community settings. Hospital-based data from high-income countries show that these costs can be considerable.

Rational antimicrobial use and regulation

The emergence of resistance to antimicrobials is a consequence of their use. This relationship is evident both for individual patients and for populations. While antibiotics are essential to cure some infections, significant misuse occurs in most parts of the world, usually in the form of unnecessary overuse, which increases the selective pressure on bacteria to develop resistance.

Many options for action are available to reduce unnecessary use, but putting the measures into practice is often problematic. Political leadership in countries is needed, but commitment to address the issue through policies and regulations may be difficult to obtain. How to implement the interventions is often unclear – and while reducing unnecessary overuse, access to these essential medicines for those who need them most has to be ensured. The 2001 WHO Global Strategy for Containment of AMR provides specific recommendations including education, supporting treatment decisions through improved diagnostic services and treatment guidelines, encouraging restrictions in prescriptions, instituting prescription audits and feedback, and implementing regulations on quality, dispensing and drug promotion.

There are encouraging examples from different parts of the world of action to reduce the excessive use of antimicrobials, with successful outcomes including improved antibiotic use, reduced use and cost savings, and in some cases an impact on

AMR has also been demonstrated. However, the extent to which interventions are implemented and integrated into health systems varies across different countries.

At a global level, AMR does not have the level of political commitment that is warranted by the actual threat, and priorities and capacities of health systems differ between countries. Tackling inappropriate antibiotic use at national level requires a system-wide approach for which governments have the ultimate responsibility. Regulation is needed to ensure the quality of medicines and secure the supply chain, and to control the prescription and dispensing of medicines, but the necessary legal and regulatory framework appears inadequate in many countries. Policy leadership and support for actions at facility level are needed to improve prescribing, and to obtain data to inform local policies. Interventions targeting dispensers and other sellers are being tested and implemented, but need to be scaled up. A bottom-up approach involving communities, patients, and health professionals could prove useful, with education and awareness-raising to engage all stakeholders.

Antimicrobial use in animal husbandry

Antibiotics are used in greater quantities in healthy food-producing animals than in the treatment of disease in human patients. In animal husbandry, antibiotics are used extensively for disease prevention and as growth promoters, involving mass administration to many animals at the same time. This practice constitutes the main difference between the use of antibiotics in animals and in humans. Some of the same antibiotics or classes are in use in food animals and in human medicine, carrying the very real risk of emergence and spread



of resistant bacteria, including those capable of causing infections in both animals and people. The importance of food animals as reservoirs of resistant human pathogens is well documented. The spread of resistance genes from animal bacteria to human bacteria is another potential danger. The problems associated with the use of antibiotics in animal husbandry, including in livestock, poultry and fish farming, are growing worldwide without clear evidence of the need for or benefit from them, leading to increasing recognition that urgent action is needed.

There appear to be major differences in the amounts of antimicrobials used per kilogram of meat produced in high-income countries, which together account for 70% of global meat production. Working groups hosted by WHO, the Food and Agriculture Organization (FAO), and the World Animal Health Organisation (OIE) have proposed options for actions to be taken by national and international authorities. Large-scale interventions are already being instituted in a number of countries, mainly aimed at reducing the use of specific classes of antimicrobial agents used in human clinical practice. The steps to be taken include the introduction and enforcement of regulations, methods to promote the prudent use of antibiotics, and measures to improve animal health so that less antibiotic treatment is needed. Several such interventions have led to a demonstrable reduction in AMR, but this is not always the case.

Important gaps and challenges remain. More information is needed on the prevalence of AMR in bacteria of animal origin and its impact on human health, on the quantity of antibiotics used for different indications and on the classes of antibiotics used. Risk assessments and risk management are impeded by a lack of data and/or inability to access available data. Legislations and regulatory

frameworks for approval of veterinary medicines and for controlling their use need strengthening in many countries. The capacity to implement interventions varies and the potential impact of specific interventions in different settings is still largely unknown.

Infection prevention and control

The hospital environment favours the emergence and spread of resistant bacteria. Infection prevention and control (IPC) measures are designed to prevent the spread of pathogens, including those with AMR, within and between health-care facilities, and from facilities to the community, and also vice versa. Interventions to bring about system change in individual health-care facilities involve organizational structures, human resources, guidelines, protocols and practices, monitoring and evaluation, infrastructure, and linking to public health services. In addition to the standard IPC measures, there are specific recommendations concerning AMR pathogens.

Many facilities and countries have progressed well in implementing recommendations on IPC and there have also been several welcome recent innovations in the field of IPC. WHO has led and coordinated the development of guidance on core components of IPC, based on evidence-based principles. However, there are considerable differences within and between countries in the extent to which IPC measures are actually implemented. Health-care facilities in some countries lack even the basic elements of IPC. Situation analyses at national and facility levels would help to define the current status, to set realistic goals for the local context, and to develop strategies for progressive improvement.

The gaps and challenges include: lack of data related to healthcare-associated infections and inadequate laboratory capacity in many parts of the world; lack of uniform standards, data collection methods and definitions; insufficient information on the effectiveness of specific interventions and the resources needed for effective and sustained implementation.

Fostering innovations

Innovative strategies and technologies are needed to alleviate the dearth of new antibiotics and other products for limiting AMR, ranging from scientific to financial and regulatory aspects. Various innovative approaches are being pursued but more are needed. Innovation flourishes in an enabling environment.

While antimicrobial medicines are the mainstay of treatment for bacterial infections, diagnostics and vaccines play important complementary roles by promoting the rational use of such medicines and preventing infections that would require antimicrobial treatment. New products coming to the market have not kept pace with the increasing need for improvements in antimicrobial treatment. Setting priorities for research and development (R&D) involves making strategic choices and identifying complementary technologies.

Both scientific and financial aspects pose challenges for R&D. Strengthening infrastructure, from specimen banks for diagnostics to broader compound library access for drugs, as well as human resources, has facilitated collaborative research. Carefully weighed financing mechanisms—*push* and *pull* incentives— are being used to spur greater R&D into new technologies. Push incentives

that de-link the return on investment from volume-based sales, such as the public funding of clinical trials and providing services that help bring promising compounds to trials, are being explored in some countries. Such incentives could also reduce the inappropriate use of antibiotics by preventing the need to sell large volumes to improve the return on investment. Strategies such as pooled procurement and Advanced Market Commitments can help to create markets that reassure the private sector of returns on investment. Target Product Profiles are being increasingly used to help align public health goals with economic incentives, especially in pharmaceutical R&D, to facilitate public sector return on investment. Innovations such as the pooling of building blocks of knowledge and open access repositories show promise.

Regulatory requirements have an important role in directing R&D and there is a need for clear guidance to the industry. Strategic and judicious use of intellectual property rights can either be an incentive or an obstacle. New opportunities could result from supporting a greater participation of developing countries in R&D, including small biotechnology firms and academic institutions. To meet the twin challenges of enhanced innovation and affordable end-products, there is a need to pilot alternative approaches to pharmaceutical R&D, and for concerted action by a broad range of stakeholders.

The way forward : Political commitment to enable options for action

The development of resistance by a growing number of pathogens to a growing number of antibiotics is a public health problem which has been steadily increasing for several decades. It has now reached a scale and distribution which has led WHO to



recognize AMR as a global public health crisis. AMR is both a medical and an economic problem, with consequences felt worldwide, including in lower-income countries where the burden of infectious diseases is generally greater and the availability, accessibility and affordability of medicines generally more limited. The importance of governments in creating the enabling environment necessary to implement effective actions is very clear. Looking ahead, the overriding message from past experience is that AMR can be contained, if not totally prevented, and that only a concerted effort will ensure that it does not constitute a significant public health threat in the long term.

The urgency of the AMR situation is now well recognized by most policy makers, scientists, and professionals in relevant domains, and by civil society, including patients' advocacy groups. By setting out the main facets of the AMR situation – what drives it, what can be done about it – illustrated by practical experiences from around the world, this book seeks to encourage greater national and international efforts and further initiatives to counter AMR.

International and national actions to address AMR have shown what can be done, often with good results, but these efforts have usually been limited in scope and lacking real coordination. The reasons behind the lack of general worldwide determination to tackle AMR perhaps include a widespread assumption that scientific advancement will eventually resolve the problem by bringing in an endless supply of new and potent anti-infective medicines. The reality, however, is that there are only very few new antibiotics on the horizon, and research in this area is not a priority for pharmaceutical companies.

There is broad international consensus on the key areas for action and the specific measures that urgently need to be taken. Political commitment to lead and support concerted action in all relevant domains has been highlighted as a prerequisite for a comprehensive and coordinated multi-stakeholder effort against AMR. Decisions on interventions have to balance the need to provide effective antimicrobial therapy to patients today with the need to preserve the usefulness of medicines for future generations.

A number of strategies and measures have been implemented successfully, and not only in the wealthier countries. All of those require some level of leadership and support from the political level. Sustaining and building upon these gains requires assured financial and human resources, and infrastructure capabilities, as is true for most health programmes in many countries. A range of interventions are needed, but not all of them are necessary or relevant in all countries or all settings. As local circumstances and current AMR status differ widely between and within countries, a country-focused situation analysis would be a logical initial step towards setting up a comprehensive anti-AMR programme. Prioritizing national strategies, measures and resources is essential and to this end, partnerships and closer collaboration could be fostered between policy-makers, academia, and appropriate professionals, managers, and interest groups. More collaboration is also needed between disciplines within sectors. In the health sector, for example, between those involved in promoting the rational use of medicines and those in infection prevention and control. WHO seeks to stimulate thinking and policy action in this direction, by discussing the range of key issues and actions within one book, probably for the first time, to assist policy decision-makers, and raise awareness among all stakeholders concerned by AMR.

Interventions, such as those focussing on hospitals, pharmacies, medical and veterinary practices, are ongoing in many countries, but very few countries have nationally funded and coordinated comprehensive activities. These are mostly high-income countries with stronger management and infrastructure capabilities. But where commitment, including from the political level, exists, some less wealthy countries are also making important progress and showing the way for others. Strengthening health systems is an issue for most public health initiatives and would enable countries to participate in, and benefit fully, from global efforts to deal with the problem. The commitment of policy decision-makers will be essential to ensure leadership and support for these efforts.

Although most of the large-scale actions described here required a 'top down' approach instated with government support, there are other successful examples where activities were initiated by a few motivated individuals and groups, and which have later been developed stepwise to a nationwide scale. This is probably a useful model to follow, particularly where resources for large-scale national actions are lacking at the outset. It requires leadership and support from the political level fostering multi-stakeholder engagement and empowerment for action. To fill knowledge gaps regarding implementation, it is important to incorporate mechanisms to monitor and evaluate the impact, resource requirements and sustainability of the measures taken.

The role of WHO is to facilitate action worldwide through stimulating political commitment, advocating for action, shaping collaborations between different stakeholders, facilitating development of evidence-based guidance, norms and standards, and tools for countries to implement specific interventions

and evaluations. WHO support is critical for strengthening global surveillance strategies and networks, and in defining an AMR research agenda.

Although there is more to be learnt about the impact of AMR on individuals, societies and countries, the need for additional information should not delay national or international anti-AMR initiatives, of which there are plenty of successful examples. Many more opportunities for innovation could be exploited in areas spanning the spectrum from scientific discovery, R&D for new products, financing mechanisms, regulatory aspects, to marketing and service provision.

Because AMR is a complex problem with many diverse contributing factors, tackling it effectively has to involve many individuals and groups in society. This may be perceived as a discouraging reality that could lead to apathy and inaction, with people feeling that their own individual effort is not worth making. On the contrary, efforts at all levels are essential and advocacy is needed to convince and encourage people, from patients to policy-makers, to make their special contribution, and to be part of the solution rather than part of the problem. Leadership by governments is crucial to motivate, support and sustain these efforts if the way forward is to be a way towards the long-term availability of effective antimicrobial medicines.

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