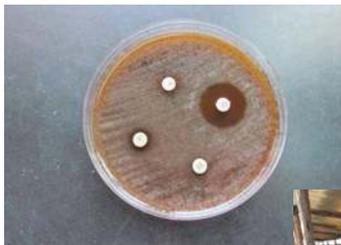


SITUATION ANALYSIS AND RECOMMENDATIONS

Antibiotic Use and Resistance in Mozambique

Executive Summary



The GARP-Mozambique Working Group

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Foreword

Antibiotic resistance impairs our ability to treat common bacterial infections and is a major threat to public health, especially in developing countries where the burden of infectious diseases is enormous. Excessive use of the few available antibiotics adds to the antibiotic resistance problem, increasing morbidity and increasing costs to the National Health Service of treating resistant infections.

Although the problem of antibiotic resistance is global, and has been recognized in the scientific community and by many international organizations, there is still a lack of political commitment from most national governments, which have the primary responsibility for developing and implementing policies and action plans to mitigate antibiotic resistance.

In Mozambique the government is currently making a great effort to consolidate the pharmaceutical sector, with a focus on ensuring access to quality healthcare, strengthening regulation and inspection, and taking into account the challenge of significant growth in medicine imports, particularly antibiotics.

Increasing importation and easy access to medicines increases the pressure on government to improve management and inspection systems to protect human health. Counterfeit and substandard medicines, whether dispensed by a physician or purchased by a mother in an informal market, can put health at risk and must be factored into government programs.

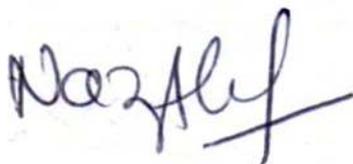
In order to ascertain the extent of antibiotic resistance and use in the country, the Ministry of Health joined with a multidisciplinary working group, GARP-Mozambique, in August of 2012 to begin the hard task of developing national policy to protect Mozambique's citizens against the ravages of antibiotic resistance.

GARP-Mozambique objectives are:

1. To assess the current status of antibiotic use, quality and resistance levels in the country;
2. To review relevant research in order to identify and fill research gaps, as well as to obtain reliable data; and
3. Finally, to recommend national policies for the rational use of antibiotics and to prevent the emergence of antibiotic-resistant bacteria.

GARP-Mozambique was established in partnership with the Center for Disease Dynamics, Economics & Policy (CDDEP), based in the United States and India.

Today we have the honor and privilege of presenting this report, the Situation Analysis and Recommendations on Antibiotic Use and Resistance, produced by the GARP-Mozambique Working Group. This report is an important contribution to the country and the world, and will be instrumental in the development of strategies to strengthen the national health system and to ensure the rational use of antibiotics and the preservation their power.

A handwritten signature in blue ink, appearing to read 'Nazira', with a long horizontal stroke extending to the right.

NAZIRA KARIMO VALI ABDULA, MD

Minister of Health, Mozambique

Executive Summary

The discovery of antibiotics in the twentieth century has transformed the treatment of infectious diseases and the world's population structure by vanquishing deaths from common illnesses, especially in childhood. However, acute respiratory infections and diarrheal disease remain the leading causes of death for children under five worldwide because the benefit of antibiotics has not been shared universally. Antibiotic treatment can prevent most of these needless deaths, but only if antibiotics remain broadly effective. The potential for the growth of resistance to antibiotics has been known since Alexander Fleming first discovered penicillin in the 1920s.

Increased use of antibiotics in humans and animals has led to the development of resistance, reducing the effectiveness of drugs against common bacterial infections. Each time an antibiotic is used—both appropriately and inappropriately—resistance increases. When antibiotics are prescribed by health workers without a confirmed diagnosis or are purchased by patients without a prescription for an illness that does not require antibiotics, they can further increase the resistance burden without providing any benefit. The World Health Organization recently declared that the world is headed towards a post-antibiotic era, and the issue is now a major concern worldwide and for Mozambique.

While little information is available on resistance rates in Mozambique, the few studies that have been conducted have revealed high levels of resistance to the common drugs used to treat serious bacterial illnesses. To address the growing resistance burden, the Global Antibiotic Resistance Partnership (GARP)-Mozambique aims to improve knowledge on the current state of antibiotic use and resistance and to develop sustainable and actionable policies to reduce resistance rates. To achieve these goals, access to antibiotics must be increased while their inappropriate use is curbed, in order to ensure that these life-saving drugs maintain their ability to reduce human morbidity and mortality.

About GARP:

The Global Antibiotic Resistance Partnership (GARP) is a project of the Center for Disease Dynamics, Economics & Policy (CDDEP) that facilitates the development of actionable policy proposals on antibiotic resistance by and for low- and middle-income countries (LMICs). With a grant from the Bill & Melinda Gates Foundation (BMGF), GARP supports the creation of multi-sectoral national-level working groups whose mandate is to stimulate specific research and develop evidence-based proposals to encourage the introduction of measures to preserve antibiotic effectiveness, slow the spread of antibiotic resistance and improve antibiotic access.

The first phase of GARP took place from 2009 to 2011 and involved four countries: India, Kenya, South Africa and Vietnam. Phase one culminated in the First Global Forum on Bacterial Infections, held in October 2011 in New Delhi, India. In 2012, phase two of GARP was initiated with the addition of working groups in Mozambique, Tanzania, Nepal and Uganda.

The GARP-Mozambique working group is the first multi-disciplinary, multi-sectoral group in the country to consider the problem of antibiotic resistance and to prioritize recommendations for public health policies.

National Burden of Disease and Resistance Rates

Mozambique has experienced strong economic growth in recent years, accompanied by a drop in maternal and under-five mortality rates. However, life expectancy at birth remains low, in part due to the large burden of infectious diseases. The under-five mortality rate is largely driven by malaria, acute respiratory infections (ARIs), meningitis, sepsis and HIV/AIDS, several of which can be successfully treated with antibiotics.

Major contributors to the burden of disease include acute lower respiratory infections such as pneumonia; meningitis; bacteremia; and enteric infections such as *Escherichia coli*, non-typhoidal *Salmonella*, *Shigella* and *Vibrio cholerae*. The true burden of these diseases and their resistance rates remains largely unknown, but the available evidence points to high rates of resistance for all these diseases to first line treatments. Improving surveillance and diagnostics for these diseases

would help to provide an improved evidence base for the development of policies addressing resistance. The following section presents an outline of the research on antibiotic resistance that has been conducted in Mozambique. Complete details can be found in the full report.

Respiratory Tract Infections and Invasive Bacterial Diseases

Bacterial infections are a leading cause of death in young children in Mozambique. Among neonates, severe infections such as pneumonia, sepsis and diarrheal diseases are among the leading causes of death, and pneumonia is the third-largest cause of death of children under five. Common invasive bacterial diseases include bacteremia, pneumonia, meningitis and sepsis.

Many respiratory tract infections are caused by viral diseases and are resolved without any type of medical treatment. Pneumonia is a serious and often fatal lower respiratory tract infection that can be caused by many pathogens, including viruses and bacteria. Bacterial pneumonia is appropriately treated with antibiotics.

Studies have found high levels of resistance of bacterial pneumonia pathogens to penicillin and cotrimoxazole, the most commonly used first-line antibiotics for these infections. In published studies, resistance ranged from 37 to 89 percent for cotrimoxazole and from fully susceptible to more than 50 percent resistant for penicillin. The widespread use of cotrimoxazole as a first-line treatment for acute respiratory infections as well as to prevent opportunistic infections in people with HIV/AIDS also contributes to high rates of resistance.

Bloodstream infections, where bacteria enter the blood, include bacteremia and sepsis. These conditions are major contributors to the under-five mortality burden. The main pathogens responsible for bloodstream infections are *Haemophilus influenzae type b* (Hib) and *Streptococcus pneumoniae*, though vaccines for these diseases have been recently introduced.

Community-acquired bacteremia is a major contributor to the neonatal health burden, and studies have revealed increasing rates of resistance of various bacteria to chloramphenicol, the first-line treatment, between 2001 and 2006, reaching 92 percent of *E. coli* isolates and 94 percent of *H. influenzae* isolates. High rates of multi-drug resistance were also observed in many pathogens, ranging from 5 to 92 percent.

Bacterial meningitis is another major contributor to under-five mortality in Mozambique. Bacterial meningitis is treatable with antibiotics such as chloramphenicol and penicillin G with gentamicin, but high rates of resistance have been reported to all these drugs. Resistance ranged from 39 percent to chloramphenicol to 52 percent to ampicillin or penicillin. A study focusing on *H. influenzae* isolates found that resistance had increased to both chloramphenicol and ampicillin between 2001 and 2005, and that resistance to cotrimoxazole was also high during this period. Mortality rates were much higher for those with resistant compared to susceptible strains.

Enteric Infections

Diarrheal diseases are the second leading cause of death in children under five worldwide. They are caused by a variety of pathogens, including bacteria, and detecting the source of the infection requires good diagnostic facilities. While most diarrheal diseases can be treated with simple oral rehydration therapy, severe infections can be fatal and require antibiotic treatment. The primary bacterial infectious agents in Mozambique include *E. coli*, non-typhoidal *Salmonella*, *Shigella* spp. and *V. cholerae*. Non-typhoidal *Salmonella* is highly prevalent in children presenting with bacteremia.

Resistance of all these pathogens to first line antibiotics, including chloramphenicol and ampicillin, was found to be high across all studies. Multi-drug resistance was also detected in a high percentage of isolates.

In one study, 96 percent of *E. coli* isolates were resistant to ampicillin. Non-typhoidal *Salmonella* showed high rates of resistance to chloramphenicol and ampicillin. Similarly, *Shigella* spp. showed resistance of over 50 percent to both ampicillin and chloramphenicol, with a high level of multi-drug resistance. Resistance rates of *V. cholerae* isolates to chloramphenicol, cotrimoxazole and tetracycline ranged from 58 to 97 percent in one study.

Overall, quinolones, third generation cephalosporins and fluoroquinolones were found to be effective against most pathogens, but these drugs are more expensive and may not be an accessible treatment option for all patients.

Antibiotic Use and Resistance in Animals

Very limited information is available on the use of antibiotics and related resistance patterns in animals in Mozambique. Antibiotics for food-producing animals are generally used for disease prevention and treatment, in addition to growth promotion, particularly in chickens. A variety of antibiotics is available for use in animals but no pharmacovigilance is currently conducted. A National Veterinary Council is being established to regulate the Vet Act, and a draft regulation governing the registration of veterinary medical products was recently submitted to the Ministry of Health (MoH). Use of antibiotics in aquaculture is regulated by the Ministry of Fisheries and the National Plan for the Control of Veterinary Antibiotic Residues and Environmental Contaminants.

Strategies to Reduce Antibiotic Resistance

Reducing resistance requires limiting antibiotic use while ensuring access for those who need treatment. The six primary strategies to improve antibiotic use at the national level are:

1. Reduce the need for antibiotics through public health measures;
2. Improve hospital infection control and antibiotic stewardship;
3. Rationalize antibiotic use in the community;
4. Reduce antibiotic use in agriculture;
5. Educate health professionals, policy makers and the public on sustainable antibiotic use; and
6. Ensure political commitment to meet the threat of antibiotic resistance.

At the global level, the development of new antibiotics, alternatives to antibiotics and new diagnostics for bacterial and other infectious diseases is an important aspect of curbing antibiotic resistance, and these efforts should be increased.

Reduce the need for antibiotics through public health measures

Reducing the burden of disease can reduce the need for antibiotics. Every episode of infection averted equals a savings of antibiotic treatment. Decreasing both the viral and the bacterial disease burden can have an impact, as many viral diseases are mistakenly treated with antibiotics and some, especially influenza, predispose to secondary bacterial infections. Increasing immunization coverage and improving access to clean water, food, nutrition and sanitation are the most obvious routes to disease reduction.

While vaccination coverage for many childhood diseases is relatively high in Mozambique, at 74 percent, one-fourth of the population is still not receiving protection against preventable infections. Recently, both Hib and pneumococcal vaccines have been introduced but national coverage rates are still below 80 percent. Increasing vaccine coverage should reduce the disease burden, particularly for children under five. Rotavirus vaccination to prevent diarrhea is scheduled to start in 2015.

GARP-Mozambique will not specifically target the important public health improvements in water, food, nutrition and sanitation that are critical for better health, because they have their own constituencies and programs. They are, however, high priorities.

Improve hospital infection control and antibiotic stewardship

Hospitals are notoriously dangerous places for the spread of infections, including multi-drug resistant infections. Often these infections are transmitted inadvertently through health care providers as they move from patient to patient. Infection prevention and control (IPC) programs in hospitals can decrease transmission through simple interventions such as promoting hand washing with soap or the use of alcohol hand sanitizer between patients. Creating antibiotic stewardship programs in hospitals can also improve practices. Finally, the establishment of sentinel surveillance or point prevalence systems for antibiotic resistance can provide data to guide clinical decisions and policies at the hospital level.

The MoH currently has an IPC program in place in several hospitals but the program lacks consistency in quality between sites.

Antibiotic stewardship programs (ASPs) in hospitals aim to improve the correct treatment of bacterial infections with appropriate antibiotics, improving patient outcomes and reducing overall antibiotic use. ASPs also have the potential to

reduce rates of antibiotic resistance. The components of ASPs vary, including the use of formularies, prescription reviews, pharmacist consultations and others. An additional measure to improve rational antibiotic use in hospitals is the development of prescribing guidelines for common bacterial diseases, taking local resistance patterns into account.

Increased surveillance of antibiotic use and resistance in hospitals is needed to inform interventions and policies at the hospital and higher levels. The implementation of surveillance systems will require increased microbiological lab capacity and facilities as well as standardized lab methods and procedures.

The establishment of point prevalence surveillance in some hospitals is planned, and Maputo Central Hospital is currently working with WHONET to begin monitoring resistance in their laboratory.

Rationalize antibiotic use in the community

Unnecessary antibiotic use can be defined as the administration of antibiotics for viral or other non-bacterial infections. Antibiotics may be unnecessarily prescribed by health care providers or unnecessarily purchased directly by consumers. Studies in Mozambique have shown that health practitioners are liable to misuse their status to profit from antibiotic prescription sales. Informal sales of antibiotics overall are estimated to be quite high, in part because antibiotics are not subsidized the way other medications are. Another study found that 14 percent of university students had purchased antibiotics without a prescription.

The recognition of infectious diseases as a public health problem by the MoH and subsequent government subsidization of antibiotics would lower costs and reduce incentives for resale. In addition, conducting regular reviews of prescriptions written by health care providers at the district and provincial levels and assessing the clinical and laboratory basis of those prescriptions would help provide feedback to reduce irrational prescribing in communities.

Although the levels of antibiotic use at the community level are likely to be high, there is limited information on resistance patterns in communities. While surveillance has been initiated at the hospital level, this should eventually be expanded to communities. Studies to assess the magnitude of antibiotic consumption at the

community level and to understand health-seeking behavior are urgently needed to guide community interventions to improve the rational use of antibiotics. These strategies would ultimately reduce the sale of antibiotics without a prescription and reduce the self-administration or healthcare provider prescription of antibiotics for most acute respiratory illnesses and diarrhea.

Reduce antibiotic use in agriculture

Because so little is currently known about antibiotic use in animals in Mozambique, it will be important to quantify the amount of antibiotics currently in use to fully understand the situation. The establishment of studies and sentinel veterinary surveillance systems to document the current disease burden, levels of antibiotic use and resistance levels is an important first step in deciding on policies to limit the impact of drug use in animals. There is also a need to update and enforce current regulations and policies relating to antibiotic use in animals and to raise awareness about the issue in all sectors.

For disease prevention, the Direção Nacional de Serviços de Veterinária (DNSV) runs a vaccination program that includes the strategic compulsory immunization of animals, including the bacterial diseases bovine brucellosis, anthrax and blackleg. Other compulsory immunizations are administered against viral diseases including Newcastle disease in poultry, foot and mouth disease in cattle and rabies in dogs and cats. Immunization of animals against vector-borne diseases such the Rift Valley fever, African horse sickness and lumpy skin disease is also recommended by the DNSV.

Improving regulation and registration of veterinary products is a much-needed first step in reducing antibiotic use. The importation, commercialization, distribution and use of antibiotics in animals and aquaculture are currently controlled through policies and regulations that are obsolete and poorly enforced. The DNSV has drafted regulations for veterinary medicines and a Veterinary Council is to be established to implement a Vet Act that may facilitate the incorporation of new policies and regulations for antibiotic use in animals. Finally, eliminating the use of antibiotics as growth promoters in food-producing animals and reducing their use for disease prevention would have a significant impact on the levels of antibiotics being used.

Educate health professionals, policy makers and the public on sustainable antibiotic use

In spite of the seriousness of the issue, antibiotic resistance is still not widely recognized as a problem, even within the health community. Raising awareness about resistance and educating health professionals, policy makers and the public on the diverse roots of resistance will support efforts to improve practices and build policies that improve rational antibiotic use.

Health professionals can be targeted through updates to curricula and treatment guidelines, as well as through the implementation of hospital antibiotic stewardship programs, as mentioned previously. Policy makers can be engaged through the dissemination of relevant research and by fostering dialogue at national and regional meetings. Finally, the public can be educated through awareness campaigns and events coinciding with international activities. Effective education should have an impact on many other areas, including improving rational use at the hospital and community level, reducing use in agriculture and building political commitment for the issue.

Current educational activities targeting healthcare workers include a yearly course on rational drug use given to doctors at Eduardo Mondlane University. It will be important to review and revise curricula and training materials on antibiotic prescribing practices for all levels of health care workers, including clinicians, nurses, pharmacists, community health workers, veterinarians and other allied health sciences.

Ensure political commitment to meet the threat of antibiotic resistance

GARP-Mozambique is the first multi-sectoral group working on antibiotic resistance in the country, and has engaged with key stakeholders from human, animal and environmental health. Further efforts to raise awareness and build cooperation between experts have the potential to improve antibiotic use as they engage in advocacy and take action in their respective sectors. In addition, increasing collaborative research will strengthen the knowledge base on which policies can be built. Creating national policies and action plans to guide antibiotic use is the most sustainable way to ensure that changes are implemented and maintained. At present, though there are laws that guide drug purchasing, distribution and use, and a national formulary that outlines essential medicines and the type of health providers that may prescribe them, no national policies are in place to guide antibiotic use.

Ensuring Access to Effective Antibiotics

Improving access to drugs for those who need them will be another important component of policies aiming to rationalize the use of antibiotics. Only half the population of Mozambique currently has access to a primary health care facility, and shortages of doctors and drugs are common in the health facilities that do exist. The government is currently seeking to expand access to health workers and pharmacies outside of the capital.

Ensuring that the antibiotics being accessed are effective requires strong supply chains and quality assurance measures at the hospital and community level. Antibiotics may be substandard as manufactured, or may degrade during transport and storage—a particular risk for drugs sold in informal markets. Quality assurance methods include conducting spot checks for drug quality on imports and at the point of sale, which need to be carried out on a consistent basis. Currently the Pharmaceutical Department of the MoH is responsible for monitoring drug quality. An analysis of the current supply chain is needed to identify factors contributing to stock outs of antibiotics and to address them.

Recommendations

This situation analysis aims to provide a solid scientific basis for future interventions to improve the sustainable use of antibiotics in Mozambique, presenting all the available information and highlighting research and policy gaps. Based on the findings of this analysis and the urgent global need to confront the threat of antibiotic resistance, GARP-Mozambique recommends the following priority action:

The development and implementation of a national strategic plan for antibiotic resistance, preserving the effectiveness of antibiotics while ensuring their effective use against disease.

To achieve this ambitious goal, GARP-Mozambique will work with a broad range of external stakeholders from relevant sectors. Priority activities will be determined by their potential impact, the feasibility of their implementation, and the costs, expertise and time required for their design and execution. GARP-Mozambique will focus on interventions that are likely to have significant benefits for antibiotic effectiveness but are unlikely to be addressed by other constituencies, with a focus on those outlined in the six strategies to reduce antibiotic resistance presented above.

The realization of a national strategy will be a long and collaborative process, and many of these initiatives can and should be initiated while the process is ongoing. GARP-Mozambique has identified several priority activities, including:

- Improving infection control in hospitals,
- Gathering better information on antibiotic use in the community and formulating interventions to rationalize it,
- Gathering data on antibiotic use in animals and initiating discussions about how to control antibiotic use in food animals, and
- Building political support for a national plan.

With the publication of this situation analysis, GARP-Mozambique is well placed to contribute to the growing knowledge base on antibiotic resistance, inform stakeholders, increase collaboration and initiate change to confront the challenge of antibiotic resistance.



GARP-Mozambique leaders and CDDEP collaborators at the working group launch. (L to R: Antonio Assane, Esperança Sevene, Hellen Gelband, Alix Beith, Betuel Sigaúque). Photo courtesy of Betuel Sigaúque.



Participants at the GARP-Mozambique Working Group launch, including African GARP collaborators and CDDEP colleagues. Photo courtesy of Betuel Sigaúque.

ABOUT CDDEP

The Center for Disease Dynamics, Economics & Policy (CDDEP) was founded with the objective of using research to support better decision-making in health policy. The CDDEP team employs a range of expertise—including economics, epidemiology, disease modeling, risk analysis, and statistics—to produce actionable, policy-oriented studies on malaria, antibiotic resistance, disease control priorities, environmental health, alcohol and tobacco, and various other diseases.

Many CDDEP projects are global in scope, spanning Africa, Asia, and North America. The strength of CDDEP derives from its researchers' experience in addressing country and region-specific health problems, as well as truly global challenges, while recognizing the circumstances in which the answers must fit. The outcomes of individual projects go beyond the usual models to inspire new strategies for analysis, and innovative approaches are shared through publications and presentations focusing specifically on methodology.

Founded in 2009 as a center of Resources for the Future, CDDEP is an independent non-profit organization. With headquarters in Washington D.C. and New Delhi, CDDEP relies on a distinguished team of academics and policy analysts around the world.

ABOUT CISM

The Manhiça Health Research Centre (Centro de Investigação em Saúde de Manhiça, CISM) was established in 1996 to foster and conduct biomedical research in priority health areas. Begun as a collaboration between the governments of Mozambique and Spain, since 2008 CISM has been managed by the non-profit Manhiça Foundation, the Mozambican National Health Institute (INS) and the Fundació Clínic per la Reserca Biomèdica (Spain). Core funding for CISM is provided by the Spanish Agency for International Cooperation & Development (AECID). Dr. Pascoal M. Mucumbi, a former Prime Minister and medical doctor, is the honorary founder.

CISM studies priority health problems, including malaria, HIV/AIDS, tuberculosis, diarrheal diseases, acute respiratory infections and invasive bacterial diseases, including antimicrobial-resistant infections. CISM generates scientific evidence relevant to health policies in Mozambique and the world at large. It has become a leading biomedical research organisation on the African continent, and one of the few rural African research centres. CISM's Training Fellowship Program has contributed to Mozambican scientists completing 15 PhDs and 18 Masters degrees.

CISM participates in a host of international and regional research networks, collaborating with nine national institutions and 40 international organizations in 19 different countries in Africa, Europe, America, Asia and Oceania.

Cover photos courtesy of Molly Miller-Petrie and Christian Macamule

The full report and executive summary are available at
www.cddep.org/GARP