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Spotlight: AMR policy in South Africa

The South African experience in developing an antimicrobial resistance strategy and implementation plan

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Introduction

South Africa's antimicrobial resistance (AMR) strategy was developed through great political leadership, partnership with clinicians, perseverance and a good dose of serendipity. Many countries are now experiencing the challenges of developing their own multisectoral, multidisciplinary responses to address AMR as they gear up for the World Health Organization May deadline, presenting a great opportunity for South Africa to reflect on how far they have come in the last four years and to share lessons learned with the GARP network.

The development of South Africa's AMR response was the culmination of efforts and interventions by both the National Department of Health (NDOH) and clinicians in the fields of infectious disease, microbiology and infection prevention and control.

In 2011, a situation analysis of AMR in human and animal sectors was undertaken as part of the collaboration between GARP and South African clinicians, chaired by Prof. Adriano Duse and Prof. Olga Perovic (GARP-SA).[1, 2]

The situation analysis and subsequent publications confirmed that South Africa has a quadruple burden of AMR in both the public and private sectors, with multidrug resistant (MDR) bacterial infections, increasing antifungal resistance, multidrug- resistant *Mycobacterium tuberculosis*, and a projected increase in antiretroviral resistance with mass treatment rollout for human immunodeficiency virus (HIV). Very little information was available on AMR in animals and the environment.

In response to increasing outbreaks of MDR-bacteria in South African hospitals, and the adoption of antimicrobial stewardship as an international response, the South African Antibiotic Stewardship Programme (SAASP) was formed in 2012, under the auspices of the Federation of Infectious Diseases Societies of Southern Africa (FIDSSA), co-chaired by Prof. Marc Mendelson and Dr. Adrian Brink. These clinicians approached the Minister of Health, Dr. Aaron Motsoaledi, in 2013 to voice their growing concerns about antibiotic misuse and the threat of AMR. **The SAASP clinicians' advocacy to partner with the Department of Health was a significant step driving the development of South Africa's strategy and action plan.**

The Minister of Health acknowledged the urgency of the issue and committed to gather all stakeholders together to identify a strategy for action. The following series of events helped to increase momentum towards a comprehensive and defined AMR strategy (see Figure 1):

1. A first set of meetings to review the national situation analysis, delineate what stewardship activities were under way in human health, and review the critical components of a national strategy;
2. Consultation meetings with larger stakeholder groups to understand the situation in the livestock and agriculture sectors and to provide a platform for stakeholders to contribute to the development of the national AMR strategy.

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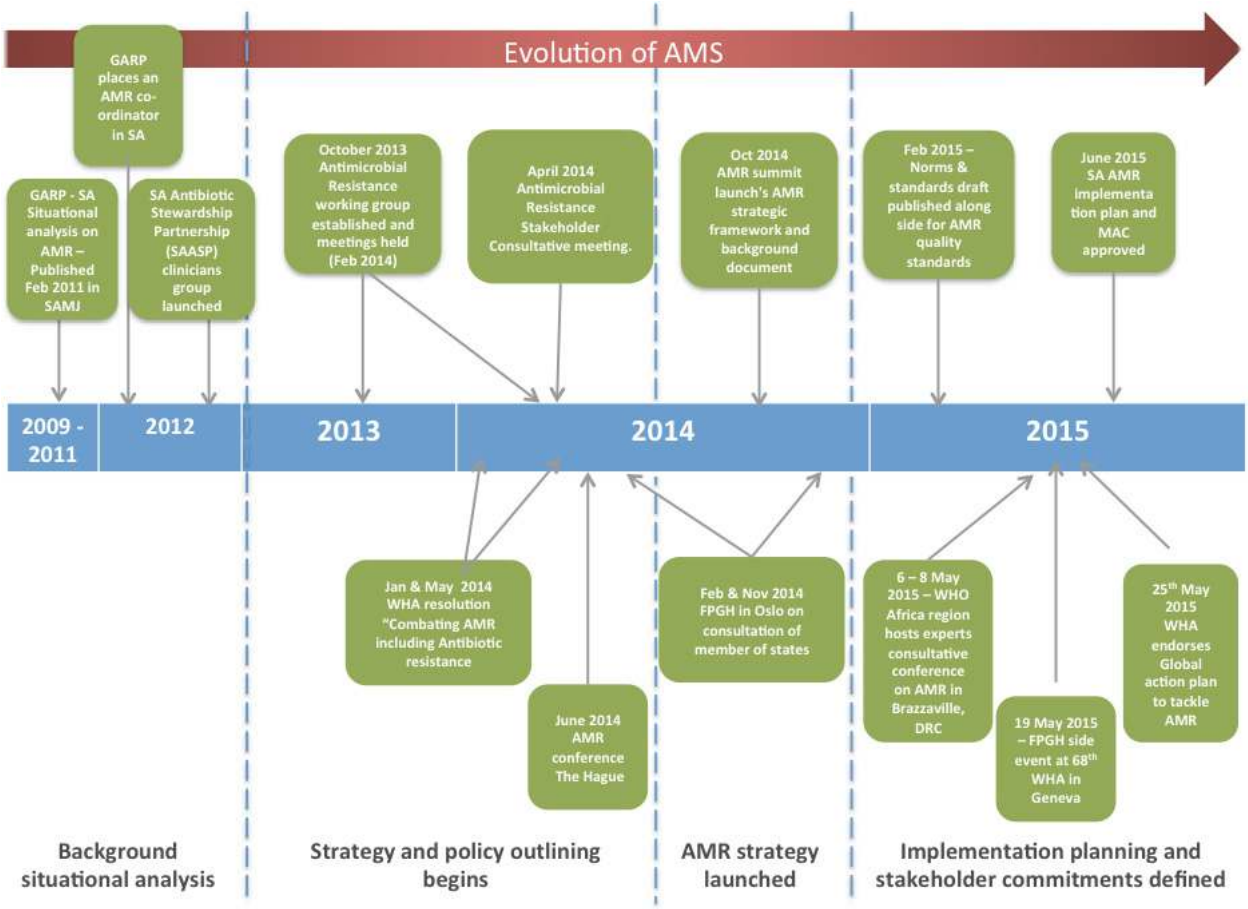
1 The situation analysis was published as a series of articles in a special issue of the South African Medical Journal. *(August 2011, Vol. 101, No. 8, pages 549 – 596).*

2 The situation analysis was a collaboration between public and private sector microbiologists, academics and laboratories to data mine existing information available on antimicrobial resistance and was supported by the Center for Disease Dynamics, Economics & Policy (CDDEP is based in the USA and India) who run GARP.

In October 2014, an AMR Summit was convened where the Minister of Health launched the AMR Strategy Framework.[3] The Summit brought together all relevant South African government departments such as Agriculture, Fisheries and Forestry (DAFF), Science & Technology (DST), as well as clinicians, academia, health professional councils, regulatory bodies, professional societies, research institutes, and civil society groups whose roles will shape efforts to contain AMR. **The stakeholders committed in writing (figures 2 & 3) to work collaboratively to invest relevant resources and to implement sound strategies and interventions in order to preserve the effectiveness of antimicrobials for future generations. This was a significant step and has been valuable in engaging stakeholders to follow through with their commitments.**

Figure 1.
Timeline of events in South Africa



3 Antimicrobial Resistance National Strategy Framework for South Africa 2014 – 2024

Figure 2. The Director General of the NDOH, Ms. Precious Matsoso, and the Representative for WHO for Africa, Dr. W. Nkhoma, with the commitments poster from the AMR Summit

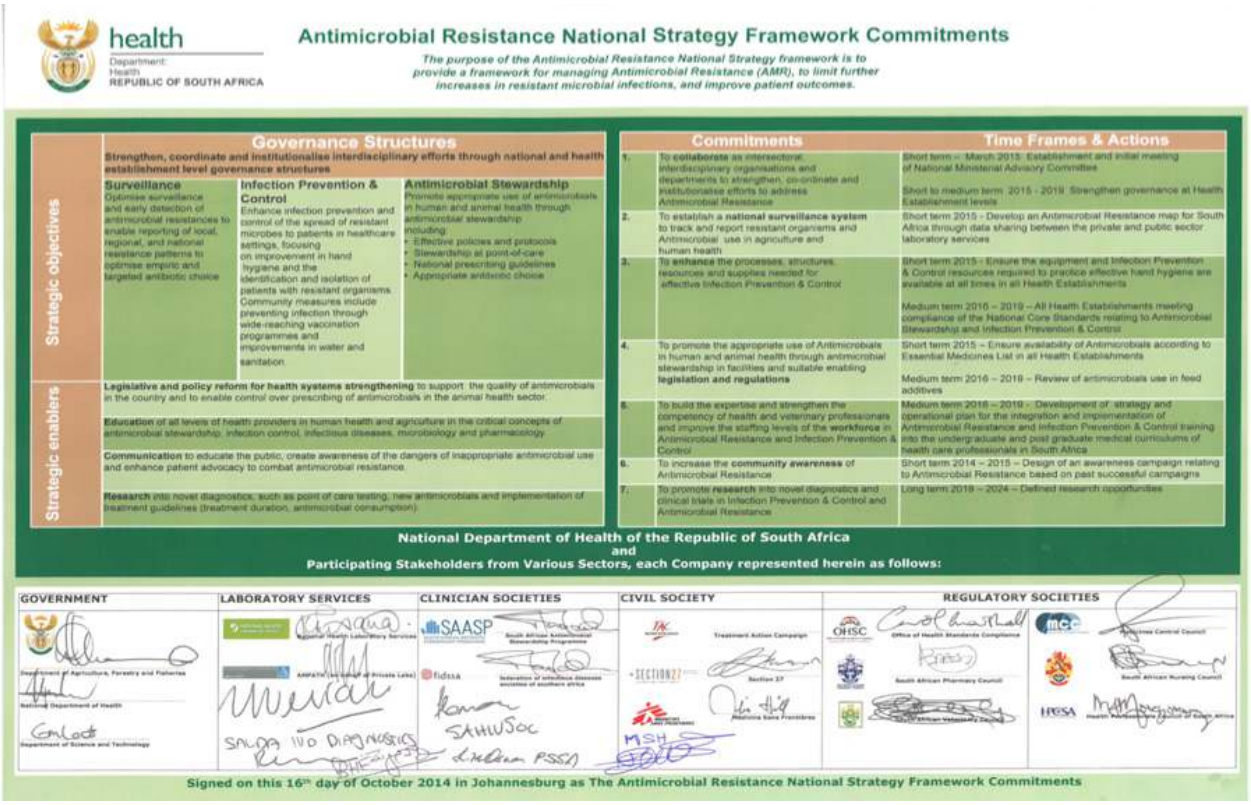
An incidental and fortuitous driver of change occurred around the same time as AMR issues were being highlighted by the Department of Health. The Office of Health Standards Compliance (OHSC) developed Norms and Standards for Quality Care as part of a new regulatory process to improve patient safety in all health facilities. This process included the development of specific standards of care that all health facilities must comply with to be certified and to access future funding through the National Health Insurance scheme. An opportunity existed to link the AMR strategy with Norms and Standards for key activities in facilities around monitoring rates of infection, antimicrobial resistance and use, guiding appropriate prescribing and use of antibiotics and improving education and awareness of staff on good prescribing practices.

All health facilities in South Africa are now required to comply with legally enforceable standards for AMR and infection prevention and control (IPC) as well as the national AMR strategy, a dual process that will give more traction to the AMR activities and accelerate implementation efforts.

What regulations were already in place before the AMR Strategy was developed?

South Africa has strong regulatory control of medicines that affects the incentives and disincentives for appropriate antimicrobial use. These regulatory controls include:

Figure 3.
Signed commitments poster from the AMR Summit



- Two sets of regulations to ensure that medicines are safe, efficacious and of good quality:[4]
    - Act 101 is administered by the NDOH, which regulates human and veterinary medicines and houses the Medicines Control Council (MCC), responsible for registering and relicensing medicines, ensuring that quality-assured medicines enter the market and are produced under good manufacturing practice (GMP);
    - Act 36 is administered by the DAFF and governs the use of veterinary medicines for growth promotion, prophylaxis/metaphylaxis and the purchase of antimicrobials over the counter by the lay public (chiefly farmers). DAFF is responsible for ensuring that farmers have access to veterinary drugs for disease control and improved food production, and for safeguarding human health by monitoring residues (including antibiotics) in products of food-producing animals, preventing zoonoses and controlling notifiable diseases.

4 The Medicines and Related Substances Act (Act 101 of 1965) and The Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act (Act 36 of 1947)

- Two sets of regulations govern prescribing and dispensing medicines, including antimicrobials, to ensure that they can be purchased only with a doctor's prescription and not over the counter at a pharmacy for humans,[5] and provide for the compounding and or dispensing of any medicine that is prescribed by a veterinarian for use in the treatment of an animal that is under his or her professional care.[6]
- A National Drug Policy developed by the NDOH guides rational medicine use to ensure availability and accessibility of essential drugs to all citizens and promotes rational use by prescribers, dispensers and patients through training, education and information.
- In human health, the Essential Medicines List (EML) forms the foundation of appropriate antibiotic use in the public sector. The EML is an evidence-based list by clinical indication developed with extensive clinical review against the burden of disease in South Africa. Public sector procurement of antibiotics is aligned with the EML and the Standard Treatment Guidelines (STGs) to decrease the overall consumption of antibiotics and to improve their rational use. A similar list of vaccines for the Extended Programme on Immunisaton (EPI) includes standard vaccines for all children plus vaccines to prevent hepatitis B, *Haemophilus influenzae* type B, pneumococcal disease and rotavirus.

How is the National Department of Health moving forward with implementation?

Since the launch of the AMR National Strategy Framework in October 2014, the NDOH has used five major strategies to support implementation of the activities and strategic objectives:

1. **Implementation plan** – An AMR Implementation Plan for the AMR National Strategy Framework 2014-2024 was developed and approved by the highest decision-making body in the NDOH. The Council's approval of the strategic objectives ensures political buy-in and commitment for implementation at national (strategic) and provincial (operational) levels of government, and to align budgets and resources.

2. **Governance and oversight** – An intersectoral multidisciplinary Ministerial Advisory Committee for Antimicrobial Resistance (MAC-AMR) with representation from both human and animal health will advise the Minister of Health. The MAC-AMR will coordinate efforts, provide advocacy and awareness, and monitor and evaluate the implementation of the Strategy Framework. It

5 Pharmacy Act 1974 (Act 53 of 1974)

6 The Veterinary And Para-Veterinary Professions Act (Act 19 of 1982)

will link to other national advisory committees, such as the National Essential Medicines List Committee (NEMLAC), the HIV & TB Drug Resistance Committees, and the National Communicable Diseases and Notifiable Medical Conditions Advisory Committee.

3. **Working groups** – Following a One Health approach (human, animal, and environmental health), a working group was established to deal with the emergence of colistin resistance, a threat to the effectiveness of this last resort antibiotic in humans. A critical intervention was to restrict its use in food-producing animals, unless justified by a veterinarian. Feed mills and compounding pharmacies may obtain colistin only through a prescription from a veterinarian with the necessary sensitivity tests. These steps have effectively eliminated colistin from veterinary use, under an existing regulation.

4. **Standardized surveillance** – Building on the existing national surveillance system to track and report resistant organisms, which was first published as part of CDDEP's ResistanceMap in 2015, further work has been completed to standardize and combine public and private sector AMR data for human health. New sources of antimicrobial use data in humans are being identified and work is ongoing to establish similar systems for animal health. Once the national surveillance system is complete, it will support the development of appropriate treatment guidelines for both sectors.

5. **Guidelines** – Guidelines are being developed to improve appropriate use of antimicrobials at the prescriber level in health facilities through effective AMS programs in all hospitals and districts supporting primary health clinics.

Critical Success Factors

- Clinician-led advocacy to partner with the Department of Health and contribute to developing and implementing the strategic framework;
- Strong committed leadership from the Department of Health, supporting a Directorate to translate the strategy into operational plans;
- Strong regulatory environment for medicine registration, quality control, prescribing and dispensing;
- Sufficient reliable data on AMR from public and private sectors, reported publicly for clinicians' use;
- External technical and financial support and facilitation by technical advisors sponsored by GARP/CDDEP and MSH.

Country highlights

GARP-Uganda

The Uganda National Academy of Sciences (UNAS), secretariat for GARP-Uganda, hosted a stakeholders' meeting to finalize the content of the AMR National Action Plan on February 21st. Representatives from the WHO, FAO, the Ministry of Health, and CDDEP provided opening remarks, after which GARP Chair Prof. Denis Byarugaba provided an overview of the AMR challenge in Uganda and the NAP contents. The attendees broke into groups to discuss the proposed activities for each of the five focus areas and presented their suggested changes to the document. The stakeholder comments were incorporated into the next version of the NAP, which is now being finalized. The next steps for GARP-Uganda are to create implementation and monitoring and evaluation plans.

The Director General of Health Services, Prof. Mbonye Anthony, opens the NAP stakeholders' workshop in Kampala, Uganda, along with Prof. Denis Byarugaba

GARP-Kenya

Kenya has completed their National Action Plan and accompanying Policy and are awaiting final publication of the documents. GARP-Kenya Coordinator and Ministry of Health AMR focal point Dr. Eveline Wesangula presented the process of AMR policymaking in Kenya at the joint evaluation conducted by WHO and the Global Health Security Agenda (GHSA) on February 27th. The Ministry is also initiating a pilot surveillance program for AMR, and other priorities include establishing a national antimicrobial stewardship program and planning for AMR awareness campaigns in 2017. The GARP-Kenya working group met later that week to discuss the role of GARP in supporting the government in implementation of the NAP. Next steps include finalizing a budget.

Dr. Eveline Wesangula presents on the AMR situation in Kenya at the joint WHO and GHSA evaluation

Zimbabwe workshop participants

GARP-Zimbabwe

The Zimbabwe Antimicrobial Resistance Core Group, supported in part by GARP, the World Health Organization, and the Ministry of Health and Child Care hosted a stakeholders workshop to work on the AMR National Action Plan from March 6th to 10th in Mazowe, Zimbabwe. Dr P. Manangazira, Director, Epidemiology and Disease Control, Ministry of Health and Child Care, opened the meeting. Prior to and following the main meeting, the Core Group met to review and improve the content of the national situation analysis and to create an implementation plan and monitoring and evaluation plan for the NAP. Facilitators from CDDEP and ReAct worked with breakout groups throughout the week. A revised NAP has now been completed, and Zimbabwe hopes to finalize all relevant documents in time for submission to the World Health Assembly by May 2017.

GARP in the news

A major health magazine in Nepal published an article on the One Health approach to AMR in the country, based on an interview with GARP-Nepal Principal Investigator Dr. Sameer Dixit. swasthyakhabar.com/news-details/2776/2017-02-04

The Citizen newspaper in Dar es Salaam publicized the drafting of the National Action Plan on AMR for Tanzania, which had been announced by Chief Medical Officer Mohammed Kambi. GARP-Tanzania Chair Prof. Said Aboud was quoted in the article. http://allafrica.com/stories/201702150047.html

New publications and media

GARP member publication: GARP-Kenya chair Prof. Sam Kariuki published "Prevalence, aetiology and antibiotic sensitivity profile of asymptomatic bacteriuria isolates from pregnant women in selected antenatal clinics from Nairobi, Kenya" in the *Pan African Medical Journal.* http://www.panafrican-med-journal.com/content/article/26/41/full/#.WLVnVZKcpQ0

Strategic and Operational Guidance on Animal and Environmental Aspects of NAPs: The Center for Science and the Environment published an informative and concise guide to incorporating animal and environmental AMR policies into NAPs. www.cseindia.org/userfiles/strategic-and-operational-guidance-final.pdf

Evaluation of antibiotic awareness campaigns: The WHO Collaborating Centre on Patient Safety, Geneva, evaluated 60 AMR awareness campaigns conducted since 2010. http://www.who.int/selection_medicines/committees/expert/21/applications/antibacterials-ccps_rev/en/

GARP activities on the CDDEP blog

Phantoms of the Pharmacy (Feb 16)
http://www.cddep.org/blog/posts/phantoms_pharmacy

ResistanceMap Blog: Successful Public Policy Against MRSA in the United Kingdom (Feb 1)
http://www.cddep.org/blog/posts/successful_public_policy_against_mrsa_united_kingdom

WHO seeking consultants

WHO is seeking consultants to support their work on AMR. More information can be found at this link: http://www.who.int/antimicrobial-resistance/call-for-consultants/en/

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