

# Technical Report of the Regional Pharmaceutical Forum and Antimicrobial Resistance Meeting, Kampala, Uganda: April 28–30, 2008

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**ECSA HC**



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## **About SPS**

The Strengthening Pharmaceutical Systems (SPS) Program strives to build capacity within developing countries to effectively manage all aspects of pharmaceutical systems and services. SPS focuses on improving governance in the pharmaceutical sector, strengthening pharmaceutical management systems and financing mechanisms, containing antimicrobial resistance, and enhancing access to and appropriate use of medicines.

## **About ECSA HC and the RPF**

The East, Central and Southern African Health Community (ECSA HC), formerly called the Commonwealth Regional Health Community Secretariat (CRHCS), was established as an intergovernmental organization in 1974. The aim of ECSA HC is to foster regional cooperation to promote and strengthen health services in the ECSA Region. In 2003 the ECSA HC created the Regional Pharmaceutical Forum (RPF) to help strengthen pharmaceutical management in the member countries.

## **Abstract**

Many first-line antimicrobials for infectious diseases of public health importance—including those for malaria, tuberculosis, and HIV/AIDS—are becoming ineffective due to the rapidly rising global problem of antimicrobial resistance (AMR). Urgent and concerted efforts are needed to contain this problem and prolong the useful life of antimicrobials that are still effective. The Regional Pharmaceutical Forum (RPF) of East, Central, and Southern Africa Health Community (ECSA HC) and the USAID-supported Strengthening Pharmaceutical Systems (SPS) Program of Management Sciences for Health collaborated to organize and implement a three-day meeting in April 2008 in Kampala to strategize on how to integrate an AMR advocacy and containment initiative at regional-level in ECSA. Recognizing AMR as a global public health emergency, the participants of the meeting committed themselves to join hands to address this emergency. They developed a Call-To-Action document and plan to expand stakeholder coalition in the region to generate advocacy and feasible interventions to fight AMR. This technical report describes the presentations, group activities, discussions and outputs of the meeting. Additionally, the report presents the approach the RPF has adapted to build support for tackling AMR in the region learning from the existing country-level AMR containment efforts in Zambia and Ethiopia.

## **Key Words**

antimicrobial resistance, drug resistance, antibiotic resistance, advocacy, antimicrobial resistance containment, call-to-action, RPF, ECSA Health Community, SPS Program, MSH

## **Recommended Citation**

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## ACRONYMS

ACT	Artemisinin Combination Therapy
ADR	Adverse Drug Reaction
AMR	Antimicrobial Resistance
AMRAC	Antimicrobial Resistance Advisory Committee (Ethiopia)
APUA	Alliance for the Prudent Use of Antibiotics
ARI	Acute Respiratory Infection
ARV	Anti-Retroviral
CDC	Center for Disease Control
CHAZ	Churches Health Association of Zambia
CIB	Coordinated Informed Buying
CRHCS	Commonwealth Regional Health Community Secretariat
DACA	Drug Administration and Control Authority (Ethiopia)
DJCC	Directors (of Health) Joint Consultative Committee
DTC	Drug and Therapeutics Committee
DUE	Drug Use Evaluation
ECSA HC	East, Central, and Southern Africa Health Community
ESBL	Extended-Spectrum Beta-Lactamase
HIV/AIDS	Human Immunodeficiency Virus/Acquired Immunodeficiency Syndrome
ICAT	Infection Control Assessment Tool
M&E	Monitoring and Evaluation
IDs	Infectious Diseases
IEC	Information, Education, Communication
MDR	Multi-Drug Resistant
MOH	Ministry of Health
MRSA	Methicillin-Resistant <i>Staphylococcus aureus</i>
MSH	Management Sciences for Health
NGO	Non-governmental Organization
NISIR	National Institute for Scientific and Industrial Research (Zambia)
NMTCs	National Medicines and Therapeutics Committees
PRA	Pharmaceutical Regulatory Authority (Zambia)
PRDU	Promoting Rational Drug Use
QA	Quality Assurance
RHMC	Regional Health Ministers' Conference
RPF	Regional Pharmaceutical Forum
SPS	Strengthening Pharmaceutical Systems
STGs	Standard Treatment Guidelines
STIs	Sexually Transmitted Infections
TB	Tuberculosis
TWGs	Technical Working Groups
USAID	U.S. Agency for International Development
USAID/EA	USAID East Africa
VRE	Vancomycin-Resistant Enterococcus

VRSA  
WHO  
XDR TB

Vancomycin-Resistant *Staphylococcus aureus*  
World Health Organization  
Extensively Drug Resistant Tuberculosis



## INTRODUCTION

Infectious diseases (IDs) were a major cause of illness and death all over the world when there were no antimicrobials. However, many antimicrobials and vaccines became available during the second half of the 20<sup>th</sup> century. This, along with highly improved sanitation, greatly reduced the prevalence of infections and the associated morbidity and mortality, particularly in industrialized countries. Despite advances, IDs still continue to remain a leading cause of morbidity and mortality in most resource-constrained countries.

An added challenge to this infectious disease burden is the increasing emergence and spread of antimicrobial resistant pathogens. Many infections that were thought to be well under control some decades ago are now re-emerging as serious problems. Diseases such as tuberculosis, malaria, sexually transmitted infections (STIs), bacterial dysentery, typhoid, and pneumonia are no longer as readily manageable with available first-line antimicrobial agents as they were only a few decades ago. Even for HIV/AIDS treatment, antimicrobial resistance (AMR) is already a major concern. Many of the infections are now caused by multi-drug resistant microbes that are very difficult and expensive to manage.

AMR has become a global issue and is a complex, multifactorial problem. While all countries are being affected, the impact is greatest in resource-constrained countries due to the financial, technical and management challenges involved in responding to such a complex problem.

The AMR problem has recently received increased attention in many industrialized countries, but it still remains on the back burner in most resource-constrained countries. Advocacy and awareness of the issue is generally very low in these settings. Efforts towards AMR advocacy and awareness are urgently required, especially in the context of the recent huge increases in the supply and use of antimicrobials for HIV/AIDS, malaria and TB through multiple global health initiatives in countries with weak pharmaceutical management capacity. Adequate and timely efforts are needed to preserve the effectiveness of the life-saving antimicrobials for these big three diseases and for other IDs of public health importance.

Unless urgent, concerted and sustained containment efforts are made, AMR will soon reverse the gains achieved so far and throw us back into a pre-antibiotic era. The Report of the United Kingdom House of Lords that came out a decade back, in 1998, clearly articulated this situation, "...Antibiotic resistance threatens mankind with the prospect of a return to the pre-antibiotic era. This will not, of course, happen overnight. It is a relatively slow but inexorable process, patchy in its effects but already under way. The options available for the treatment of infections have everywhere become constrained. In some locations, the organisms causing several life-threatening infections are now resistant to all available antibiotics, so that for patients suffering these illnesses the antibiotic era has already ended...."<sup>1</sup>

In the past, a common strategy for countering drug resistance was to switch to alternative drugs once first-line therapy became ineffective. However, this is not a long-term solution because:

- Drugs are losing effectiveness more quickly than new drugs can be developed;

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<sup>1</sup> House of Lords. 1998. Science and Technology Seventh Report. UK.  
<http://www.parliament.the-stationery-office.co.uk/pa/ld199798/ldselect/ldsctech/081vii/st0703.htm>

- The cost of new drugs and combination drugs is significantly higher than first-line drugs; and
- This increased cost, and in some cases the increased complexity, length, and/or toxicity of new treatment regimens has a negative impact on patient compliance, which in turn increases the risk of developing drug resistance.

The key emphasis should therefore be on preventing the development of AMR and preserving the effectiveness of the existing antimicrobials. More recently, an increasing number of stakeholders, including development partners, are emphasizing these strategies to combat AMR.

## **ECSA HC AND MSH/SPS PARTNER TO INITIATE AMR ADVOCACY AND CONTAINMENT**

Over the last several years the U.S. Agency for International Development (USAID) has made significant investments to address the problem of resistance. The Agency's continued priority to address this area is evidenced by the inclusion of a dedicated AMR-related intermediate result (IR3) in the new Strengthening Pharmaceutical Systems (SPS) award made to Management Sciences for Health (MSH) in 2007. SPS is a follow-on to MSH's Rational Pharmaceutical Management Plus (RPM Plus) Program and will thus benefit from a strong foundation and experience base created through several years of multiple AMR-related activities under RPM Plus. Summary information of the key AMR activities of RPM Plus can be found at the AMR section of the MSH/RPM Plus website.<sup>2</sup>

One of SPS's core strategies to contain AMR focuses on AMR advocacy and containment at the regional and country level. SPS and the East, Central, and Southern Africa Health Community (ECSA HC) are working together via ECSA's Regional Pharmaceutical Forum (RPF) to initiate AMR activities in the region.

The ECSA HC was established as an intergovernmental organization in 1974. It was formerly called the Commonwealth Regional Health Community Secretariat (CRHCS). The aim of ECSA HC is to foster regional cooperation to promote and strengthen health services in the East, Central, and Southern African Region. The member countries are Kenya, Lesotho, Malawi, Mauritius, Seychelles, Swaziland, Tanzania, Uganda, Zambia, and Zimbabwe and other collaborating countries are Mozambique, South Africa, Rwanda, Burundi, Ethiopia and Democratic Republic of Congo.

In 2003 the ECSA HC established the *Regional Pharmaceutical Forum (RPF)* to help strengthen pharmaceutical management in the member countries. The RPF was established with technical assistance from the USAID-supported RPM Plus program. RPF is an advisory body whose objectives are to:

- Coordinate with member states to strengthen national pharmaceutical policies, legislation, and regulations
- Establish a mechanism to research regional collaboration on procurement of pharmaceuticals and commodities

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<sup>2</sup> <http://www.msh.org/projects/rpmplus/WhatWeDo/Antimicrobial-Resistance/index.cfm>

- Promote the regional harmonization of standard treatment guidelines and essential medicines lists and facilitate the development of a regional pharmaceutical formulary
- Help strengthen regional and in-country mechanisms for pharmaceutical management, including selection, procurement, storage, distribution, quality assurance and rational use

ECSA HC's Directors (of Health) Joint Consultative Committee (DJCC) is the foremost technical committee to guide RPF actions. The DJCC has different Expert Committees on specific subjects including one for the RPF. The RPF Expert Committee lays strategies for the RPF, monitors Workplan progress and receives progress reports for upward transmission to the DJCC and the Regional Health Ministers' Conference (RHMC). The DJCC meets annually to shape the agenda for the RHMC at which ECSA HC decisions and resolutions are made.

RPF members are drawn from government bodies, teaching hospitals, universities, research organizations, and practitioners. RPF's work is implemented by four Technical Working Groups (TWGs):

- Policy, Legal Framework and Management Support TWG
- Procurement and Distribution TWG
- Promoting Rational Use of Pharmaceuticals TWG
- HIV/AIDS-related Pharmaceutical Management TWG

Each TWG is composed of experts from various disciplines. The purpose of each TWG is to plan and carry out regional initiatives focused in its respective topical area.

RPF has already done much that supports AMR containment. Accomplishments such as developing a generic National Medicines Policy, developing harmonized standard treatment guidelines (STGs) for HIV/AIDS, TB and malaria and a harmonized formulary for member states, and supporting drug and therapeutics committee (DTC) all address AMR-related issues. However, until recently there was little or no direct focus on AMR in the RPF initiative. To preserve the effectiveness of antimicrobial medicines AMR issues must be tackled *proactively* and mainstreamed within the existing plans and activities. Positioning AMR issues in such a proactive manner as value-added would greatly complement the RPF's overall goal toward improving pharmaceutical management in the region.

In this context, SPS and RPF collaborated to organize an RPF-AMR meeting in April 2008 to jump start the process of incorporating AMR advocacy and containment in RPF work.<sup>3</sup> The meeting was supported by USAID core and USAID East Africa (USAID/EA) funds. To minimize cost, this AMR meeting was tagged on to a routine meeting to discuss regular RPF business. The meeting dates were April 28 to 30, 2008 and the venue Kampala, Uganda. A total of 18 RPF representatives from 10 countries participated in the meeting along with USAID/East Africa (USAID/EA) and SPS staff. Table 1 lists the participants along with their country and workplace.

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<sup>3</sup> Nelson N., Kirika R., Joshi M., and Goredema W. 2008. *Antimicrobial Resistance Meeting for the East, Central and Southern Africa Health Community (ECSA HC) Regional Pharmaceutical Forum April 28-30, 2008: Trip Report*. Submitted to the U.S. Agency for International Development by the Strengthening Pharmaceutical Systems (SPS) Program. Arlington, VA: Management Sciences for Health.

Table 1. Participants of the April 2008 RPF-AMR Meeting in Kampala.

<b>Name</b>	<b>Workplace/Country</b>
Ms. Carol M Yeta	Director, Pharmaceutical Regulatory Authority Zambia
Thuli Sibiya	Chief Pharmacist, Ministry of Health & Social welfare Swaziland
Margareth Ndomondo-Sigonda	Director General, Tanzania Food & Drugs Authority (TFDA) Tanzania
Martin Olowo Oteba	Principal Pharmacist Ministry of Health Uganda
Ms. Mercy Kimaro	Ministry of Health & Social Welfare Tanzania
Dr. Hizero Lievin	DPMLI Minisante Burundi
Mr. Viateur Mutanguha	Minisante Rwanda
Dr. Samuel Gitau K.	MOH-NLTP Ministry of Health Kenya
Dr Albert Mwango	Ministry of health Zambia
Dr. Enoch Omonge	Kenyatta National Hospital Kenya
Dr. G. Ombuya	Kenyatta National Hospital Kenya
Davison Vuragu	Parirenyatwa Group of Hospitals Zimbabwe
Thato Nkuebe	Ministry of Health & Social Welfare Lesotho
Mr. A. Chafulumira	Ministry of Health Malawi
Dr. Benefentule Bryarugaba	Mulago Hospital Uganda
Mr. Bosco Okello	Mulago Hospital Uganda
Dr. Sigsbert Mkude	National Malaria Control Program Tanzania
Dr. Mark Bura	ECSA Health Community Arusha, Tanzania

Name	Workplace/Country
Moses Mukuna	USAID/East Africa Kenya
Mohan P. Joshi	MSH/SPS Arlington, USA
Rosalind Kirika	MSH/SPS Kenya
Nick Nelson	MSH/SPS Arlington, USA
Wonder Goredema	MSH/SPS Arlington, USA
Fregenet Getachew Desta	MSH - Ethiopia

## **BRIEF PROCEEDINGS OF THE AMR COMPONENT OF THE MEETING**

The overall objective of the AMR portion of the meeting was to produce a scope and mandate of AMR activities for RPF. The specific objectives were to:

- Discuss the public health threat posed by AMR and share global, regional and country examples of resistance patterns and treatment failures, including those in AIDS, malaria and tuberculosis
- Discuss the problem of AMR in ECSA countries
- Discuss past and current RPF activities and identify how AMR will fit into the overall scheme of RPF objectives and scope of action
- Get views and buy in of the RPF participants to take leadership in initiating a coalition for addressing this common threat in the ECSA Region
- Discuss country-level AMR advocacy and containment experiences and what lessons RPF can draw from these initiatives for its own actions
- Appraise the participants on AMR-related tools/materials developed by and available through MSH/RPM Plus/SPS
- Obtain consensus on an appropriate approach and the way forward for RPF stakeholders

*Annex 1* gives the meeting Agenda. The meeting included presentations, group tasks, and plenary discussions.

### *Presentations*

A total of 8 presentations were made, each of which was followed by plenary discussion. The following are the salient topics covered during the different presentations:

- RPF structure and its technical working groups; RPF goals, objectives and achievements so far; objectives and expected outputs of the April 28–30 RPF/AMR meeting (*Annex 2*)
- The problem of irrational use of medicines; consequences of irrational use; strategies and core interventions to promote rational use of medicines (*Annex 3*)
- Current global threat and examples of AMR; rising trends of AMR; impact of AMR; key factors contributing to AMR; reasons for added urgency to address AMR (*Annex 4*)
- AMR in the ECSA countries; rising AMR trends in the region (*Annex 5*)

- Limited operationalization of the 2001 WHO Global Strategy for Containment of Antimicrobial Resistance; RPF's role in AMR advocacy and containment in the region (*Annex 6*)
- Experiences so far in implementing country-level AMR advocacy and containment activities in Zambia (*Annex 7*) and in Ethiopia (*Annex 8*)
- Description of the key tools/guidance documents developed by MSH/RPM Plus/SPS (*Annex 9*)

#### *Group Work and plenary discussions*

The meeting identified three key areas/topics for break-out work, which led to the division of the participants into three groups to address the following three tasks:

- Draft an RPF's AMR Call-To-Action Document (Group 1)
- Revise the Promoting Rational Use of Pharmaceuticals TWG's Section of the Regional Pharmaceutical Strategy (2008–2012) by identifying and including relevant AMR components (Group 2)
- Identify the immediate next steps for RPF to expand AMR advocacy (Group 3)

Each of the three break-out groups reported their work in the plenary which was then discussed and finalized by consensus. *Annex 10* includes the finalized Call-To-Action Document and *Annex 11* the revised Regional Pharmaceutical Strategy (2008–2012) that incorporates AMR components. Planning and effort to secure a highly visible coverage of AMR issues during the upcoming ECSA HC's DJCC Meeting was identified and agreed as a key next step.

*Annex 12* contains a group photo of the participants at the RPF-AMR meeting.

## **MOVING FROM COUNTRY TO REGIONAL LEVEL WITH RPF LEADERSHIP**

In 2001, the WHO published a comprehensive global document, *The Global Strategy for the Containment of Antimicrobial Resistance*,<sup>4</sup> which contains a detailed framework and a comprehensive set of recommended interventions to contain AMR. However, the actual operationalization of this document and its recommendations has so far been limited in resource-constrained countries. Therefore, with USAID support RPM Plus and partners developed an “approach” to help local stakeholders kick start a process of coalition-building to mount country-level AMR advocacy and containment actions based on local realities and circumstances.

Zambia and Ethiopia have implemented this approach (*Annex 7 and 8*). RPM Plus recently finalized and published a guidance document called *Building Local Coalitions for Containing Drug Resistance: A Guide*.<sup>5</sup> The guide outlines the approach, describes some of the key

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<sup>4</sup> WHO. 2001. *The Global Strategy for the Containment of Antimicrobial Resistance*. Geneva, WHO. Downloadable from [http://www.who.int/csr/resources/publications/drugresist/en/EGlobal\\_Strat.pdf](http://www.who.int/csr/resources/publications/drugresist/en/EGlobal_Strat.pdf)

<sup>5</sup> Management Sciences for Health. 2008. *Building Local Coalitions for Containing Drug Resistance: A Guide*. Submitted to the U.S. Agency for International Development by the Rational Pharmaceutical Management Plus Program. Arlington, VA: Management Sciences for Health.

Downloadable from [http://www1.msh.org/projects/rpmpplus/loader.cfm?url=/commonspot/security/getfile.cfm&pageid=24155\\_2.pdf](http://www1.msh.org/projects/rpmpplus/loader.cfm?url=/commonspot/security/getfile.cfm&pageid=24155_2.pdf)

implementation steps and experiences in Zambia and Ethiopia, and gives a number of tools and forms to assist other countries interested in starting such an initiative.

The approach emphasizes on quick mapping of the already available AMR-related information and stakeholders and facilitating the establishment of a local champion group (AMR working group) that catalyzes the process of building and expanding local coalition for AMR advocacy leading to identification and implementation of a package of locally relevant and feasible interventions. Important stakeholder groups to engage in the process include national governments, the public and private sectors, healthcare professionals and societies, academics, consumers, non-governmental organizations (NGOs), the pharmaceutical industry, the media, donors and international agencies. Figure 1 below shows the main elements of the approach.

RPM Plus also finalized a complementary AMR field guide that describes a set of institution-based interventions that support AMR containment.<sup>6</sup> Although targeted to the USAID missions in countries as the primary audience, the field guide contains information that can be useful for health facilities, ministries of health and other AMR stakeholders. Drawing lessons from the Zambia and Ethiopia experiences, MSH/SPS is now supporting the expansion of the approach to a regional level.

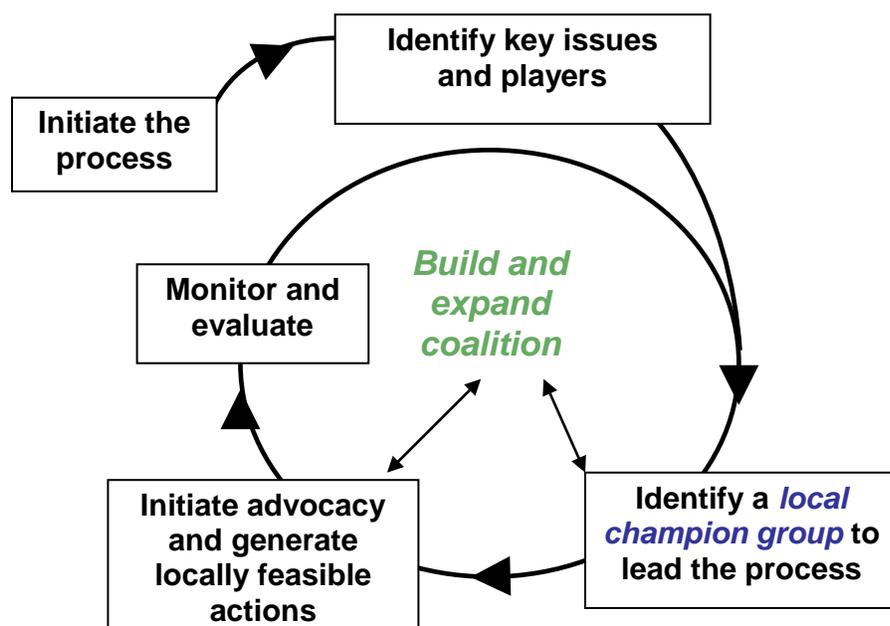


Figure 1: The AMR Coalition Building Approach

<sup>6</sup> Management Sciences for Health. 2008. Containing Antimicrobial Resistance: Guide for USAID Missions to Promote Institution-Based Interventions. Submitted to the U.S. Agency for International Development by the Rational Pharmaceutical Management Plus Program. Arlington, VA: Management Sciences for health.

Downloadable from

[http://www1.msh.org/projects/rpmpplus/loader.cfm?url=/commonspot/security/getfile.cfm&pageid=24161\\_2.pdf](http://www1.msh.org/projects/rpmpplus/loader.cfm?url=/commonspot/security/getfile.cfm&pageid=24161_2.pdf)

Such a “regional approach” can build a multi-country platform to:

- recognize and address the common problem of AMR
- create and expand advocacy and coalition
- share expertise, experience, lessons learned, best practices, and resources
- disseminate available AMR data and improve networking of existing surveillance
- motivate each other and strengthen overall South-South collaboration

RPF is well positioned to promote and push such a regional initiative to fight the shared problem of AMR. Existing organizational structure, presence of representatives from member countries, experience with workplan development, experience working at the regional level, acknowledgement of the importance of advocacy, and experience with wide dissemination of key documents are just some of RPF’s strengths that enable it to shoulder the task of facilitating regional-level activities relating to AMR.

Additionally, during the AMR meeting, the RPF members acknowledged that much is already known about AMR containment. They viewed the existence of AMR containment initiatives in Zambia and Ethiopia and the “approach” they have used as valuable resources they can tap into for information and thus avoid reinventing the wheel.

The approach shown above, although designed initially for country-level implementation, has shown itself to be readily adaptable to the regional context. The first element of *initiating the approach* at the regional level completed with the April meeting. The planning and implementation of the meeting also involved a quick desk review to *gather available information* on AMR in the ECSA region. During the meeting RPF articulated AMR as a global public health emergency and saw it as an issue of major concern in the ECSA region as well. The participants agreed that already available information can be used to spark immediate advocacy and containment actions but also expressed that more information can be gathered where appropriate. They also decided that RPF should take the role of a *regional champion group* to lead the process and catalyze such actions.

Since AMR containment and rational use of pharmaceuticals are closely related, the RPF identified that it would be a natural fit for the Promoting Rational Use of Pharmaceuticals TWG to function as the focal group (AMR working group) to advance RPF’s AMR-related actions in the region. The Forum, however, also noted that AMR impacts on the objectives of the remaining three TWGs as well. So it would be value-added for these working groups also to include AMR actions as opportunities arise in their on-going and future activities.

The other element of the approach is *generating advocacy and locally feasible actions*. The meeting itself acted as a powerful advocacy forum that sensitized the member country representatives and generated their motivation, support and commitment for the cause. The participants worked together to create and accept by consensus an RPF Call-To-Action 1-pager document (*Annex 10*) that will act as a short but powerful advocacy piece to communicate with and mobilize support of additional stakeholders, including potential donors. Soon after the meeting the Call-To-Action statement was posted on the ECSA HC website.<sup>7</sup>

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<sup>7</sup> <http://www.crhcs.or.tz/>

The planned immediate step to continue and scale up advocacy is to make AMR presentations at the upcoming DJCC meeting in Arusa, Tanzania. Along with the presentations, a package of advocacy materials will be distributed to the DJCC participants that will include, among other things, a detailed review of AMR situation in the ECSA region. A major advocacy goal after the DJCC meeting will be to achieve a resolution on AMR through the Regional Health Ministers' Conference (RHMC). RPF will also work with its country members to identify additional AMR stakeholders in each member country and communicate with them with the Call-To-Action and other appropriate documents to expand AMR awareness and enlarge the coalition base.

While advocacy is important it is not an end in itself. It builds coalition and raises the much-needed awareness, but specific interventions will also be required to support AMR containment. In this context, the meeting participants added AMR orientation in the rational medicines use-related activities already identified in the 2008-2012 Regional Pharmaceutical Strategy—drug and therapeutics committees; pharmacovigilance; drug information service; and information, education, and communication (IEC) (*Annex 11*).

The RPF representatives further pointed out the need for *monitoring and evaluation* to monitor progress as a key part of AMR advocacy and containment activities.

The RPF-AMR Meeting was a critical first step in establishing AMR as a priority issue in the ECSA region. Further advocacy should and can be built on the foundation laid at this meeting to raise awareness of this critical issue among additional stakeholders and to operationalize priority AMR containment interventions. RPF is uniquely suited and has committed to continue to spearhead this regional task.

## ANNEX 1. APRIL 2008 RPF-AMR MEETING AGENDA

### East, Central and Southern Africa (ECSA) Health Community Regional Pharmaceutical Forum Antimicrobial Resistance Meeting

**28<sup>th</sup> – 30<sup>th</sup> April, 2008**  
**Kampala, Uganda**

<b>DAY 1: Monday, 28<sup>th</sup> April, 2008</b>		
<b>Time</b>	<b>Session</b>	<b>Speaker/Facilitator</b>
8:15-8:45	<b>Registration</b>	
8:45 – 9:15am	<b>Opening Ceremonies</b> Welcome & Announcements	<i>Master of ceremony</i> <i>MSH/SPS Team</i>
	<b>Opening Remarks -</b>  - ECSA HC -USAID /EA -USAID/Uganda	<i>Director, Community &amp; Clinical Health Services, MOH, Uganda</i>  <i>Mark Bura</i> <i>Moses Mukuna</i>
9:15 -9:30 am	<b>Purpose of Meeting:</b> ▶ Purpose & Objectives of the Meeting ▶ Program of Work ▶ Expected Outputs	<i>Session Chair: (Uganda)</i>  <i>ECSA HC, MSH/SPS</i>
9:30 – 10:30 am	▶ Feedback - 4 <sup>th</sup> RPF ▶ Feedback from 46 <sup>th</sup> RHMC ▶ Discussions	<i>Mark Bura, Rosalind Kirika</i>
10:30-11:00 am	<b>TEA BREAK</b>	
11:00-12:00 pm	▶ Feedback from TWGs: ○ Policy & Legal Framework ○ Quality Assurance ○ Procurement - CIB ○ PRDU ○ Discussion	<i>Session Chair: (Zambia)</i>  <i>Martin Oteba</i> <i>Margareth Ndomondo</i> <i>Mark Bura</i> <i>Caroline Yeta</i>
12:00 – 1:00 pm	▶ Finalization of the Regional	<i>Mark Bura, Rosalind Kirika</i>

	Pharmaceutical Strategy -2008 – 2012.	
1:00-2:00 pm	<b>LUNCH</b>	
2:00 – 2:20 pm	<ul style="list-style-type: none"> <li>▶ Overview of Promoting Rational Drug Use (PRDU) Issues</li> </ul>	<u>Session Chair:</u> (Kenya) Mohan Joshi
2:20 – 5:00 pm	<ul style="list-style-type: none"> <li>▶ Group Work on Implementation of the 2008–2012 Strategy</li> </ul>	All Participants

<b>DAY 2: Tuesday 29<sup>th</sup> April, 2008</b>		
<b>Time</b>	<b>Session</b>	<b>Speaker/Facilitator</b>
8.30-9.30am	Introduction/Objective of the AMR part of the meeting  AMR situation and impact: global overview	<u>Session Chair:</u> (Swaziland)  Mohan Joshi  Nick Nelson, Wonder Goredema, Mohan Joshi
9:30-10.00am	AMR in the ECSA Region	Enoch Omonge
10.00-10.30am	Q&A/discussion	
10.30-11.00am	<b>Tea Break</b>	
11.00am-12.00noon	RPF's role in AMR advocacy and containment	Mohan Joshi
12.00pm-12.30pm	Q&A/discussion	
12.30-1.30pm	<b>LUNCH</b>	
1.30-2.00pm	Zambia AMR experience	<u>Session Chair:</u> (Tanzania) Jennifer Chisanga
2.00-2.15pm	Ethiopia AMR experience	Fregenet Getachew
2.15-2.30pm	Q&A/Discussion	
2.30-3.30pm	Discussion on the way forward for AMR issues + group division for small group work	Facilitated by: Mark Bura, Mohan Joshi, Rosalind Kirika

3.30-4.00pm	<b>Tea Break</b>	
4.00-5.00pm	Group work on RPF and AMR	All Participants

<b>DAY 3: Wednesday 30<sup>th</sup> April, 2008</b>		
Time	Session	Speaker
8.30-8.50am	Recap and day's objectives and overview and distribution of MSH/RPM Plus/SPS Tools	<u>Session Chair:</u> (Rwanda) Wonder Goredema, Nick Nelson
8.50-9.45am	Group work on RPF and AMR (continued)	All Participants
9.45-10.30 am	Preparation of report by each group for plenary presentation	Each Group
10.30-11.00am	<b>Tea Break</b>	
11am-12:00pm	Plenary reporting back from the groups	Group Reporters  (Facilitated by: Mark Bura, Mohan Joshi, and Rosalind Kirika)
12.00-1.00pm	Discussion, consolidation and consensus on AMR group reports	Facilitated by: Mark Bura, Mohan Joshi, and Rosalind Kirika
1.00-2.00pm	<b>LUNCH</b>	
2.00-4.00pm	Final Discussion on Implementing the RPF 2008-2012 Strategy (integration of the agreed AMR action plans) ➤ Policy TWG ➤ PRDU TWG	<u>Session Chair:</u> (Zimbabwe) ECSA HC, MSH/SPS
4.00-4.30pm	Closing Remarks	ECSA HC, USAID/EA, MSH/SPS

## ANNEX 2. PRESENTATION ON THE BACKGROUND OF RPF AND OBJECTIVES OF THE AMR MEETING

### 5<sup>th</sup> Regional Pharmaceutical Forum & Antimicrobial Resistance Containment Meeting

Rosalind Kirika, Mark Bura, Mohan Joshi  
April 28<sup>th</sup> –30<sup>th</sup>, 2008  
Kampala, Uganda



1

### Presentation Outline

- Background to the RPF
- This Meeting
  - o Purpose
  - o Objectives
  - o Program of Work
  - o Output

2

### Definition:

- The RPF is a collaborative intervention mechanism to scale-up Best Practices in pharmaceutical management in ECSA Member States.
- AMR containment refers to efforts employed in “preserving the effectiveness” of antimicrobial medicines.



3

## Why RPF?

- Access to pharmaceuticals in the ECSCA ms is still poor despite the efforts made so far by governments & funding agencies;
- There are observed, felt and perceived inefficiencies and inadequacies in pharmaceutical management;
- To facilitate assessment of the impact of Policy and strategic investments in the pharmaceutical sector;
- Recent/on-going huge increase in commodities and funding for the pharmaceutical sector arising from international initiatives.

4

## Goal of the RPF

To provide **technical leadership and support** to ECSCA countries in order to increase access to high quality pharmaceuticals and other health commodities and to promote their appropriate use by the people of the Region.

5

## RPF – Specific Objectives

- To Explore and apply regional mechanisms for improving access to pharmaceuticals
- To Coordinate pharmaceutical and commodity management activities to maximize resource use
- To Establish a mechanism for collaboration on procurement of medicines and other health commodities.

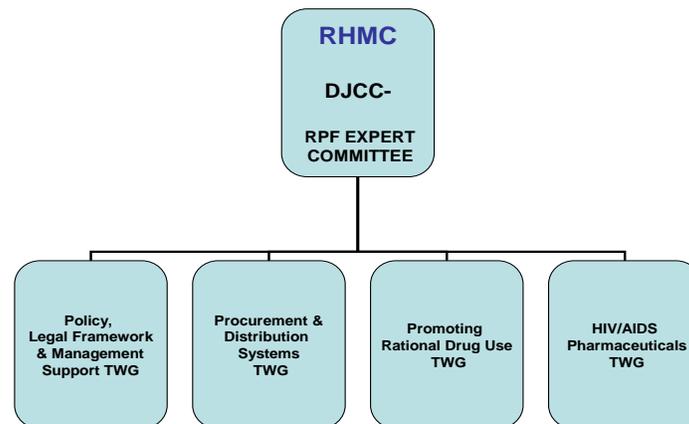
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## RPF - an Intervention Mechanism

- Established in 2003 as an advisory network for ECSA HC, with technical expertise from MSH/RPM Plus and funding from USAID/REDSO .
- Activities implemented through 4 TWGs:
  - Policy, Legal Framework and Management Support
  - Procurement and Distribution Systems
  - Promoting Rational Drug Use (PRDU)
  - HIV/AIDS-related Pharmaceuticals

7

## ORGANIZATIONAL CHART - 2003



8

## Targeted Users of RPF Strategies

- Countries: to prioritize and focus interventions.
- National Policymakers to:
  - o synchronize health inputs with economic policies;
  - o assess overall improvement of health provision by monitoring progress in drug policy implementation;
  - o Present performance of pharmaceutical sector to donors and other government agencies.
- Funding Partners to assess capacity of countries
  - o When developing new programs,
  - o To track:
    - progress and achievements of on-going projects
    - impact of financial and technical support.

9

## Achievements - 1

- Development of the Regional Pharmaceutical Strategy 2004 – 2007 October, 2004
- Performance Assessment Tool for Pharmaceutical Management Systems in ECSA member states developed - 2004
- Performance Assessment Tool applied in 8 countries 2005-2006.
- A Pre-service Curriculum for Pharmaceutical Management in Support of Antiretroviral Therapy developed in 2005 and implemented

10

## Achievements - 2

- A webpage for Coordinated Informed Buying CIB ([www.ecsamedicines.com](http://www.ecsamedicines.com)) set-up - 2006.
- Harmonized STG for clinical management of HIV/AIDS, TB, Malaria in ECSA countries -2006 and updated in 2007.
- Medicines Formulary for ECSA countries – (2006 and updated in 2007)
- Generic Medicines Policy for ECSA countries developed - 2006/2007
- Generic Medicines Policy Implementation Plan drafted - 2007/8

11

## 5<sup>th</sup> Regional Pharmaceutical Forum & Antimicrobial Resistance Containment Meeting

Rosalind Kirika, Mark Bura, Mohan Joshi  
April 28<sup>th</sup> –30<sup>th</sup>, 2008  
Kampala, Uganda



12

## Purpose of Meeting

To strategize on the implementation of the 2<sup>nd</sup> Regional Pharmaceutical Strategy (2008 – 2012) and explore approaches for mainstreaming AMR containment activities to preserve effectiveness of essential medicines for infectious diseases.

13

## Program of Work

- Day 1:
  - Largely devoted to strategizing and updates on the RPF.
  - Review of elements of promoting rational medicine use.
- Day 2:
  - Understanding AMR at global, regional and country level.
  - Contextualizing AMR in the RPF.
- Day 3:
  - Finalizing RPF implementation plans with integrated AMR interventions.
  - Drafting of an AMR Strategy.
  - Charting the way forward.

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## Specific Objectives 1

- Finalize the Regional Pharmaceutical Strategy 2008 – 2012;
- Respond (proactively) to the establishment of a pharmaceutical program at ECSA HC;
- Draft Action plans for the TWGs on Policy and PRDU;
- Discuss the public health threat posed by AMR with an aim to mainstream it in the RPF;
- Share global, regional and country examples of resistance patterns and treatment failures, including those in AIDS, malaria and tuberculosis;

15

## Specific Objectives - 2

- Position the RPF to take leadership towards promoting regional collaboration and co-ordination to address AMR;
- Strategize on an appropriate approach to AMR by the PRDU TWG of the RPF;
- Select 3-4 Medicine and Therapeutics Committees (MTCs) of member countries to start implementing AMR activities.

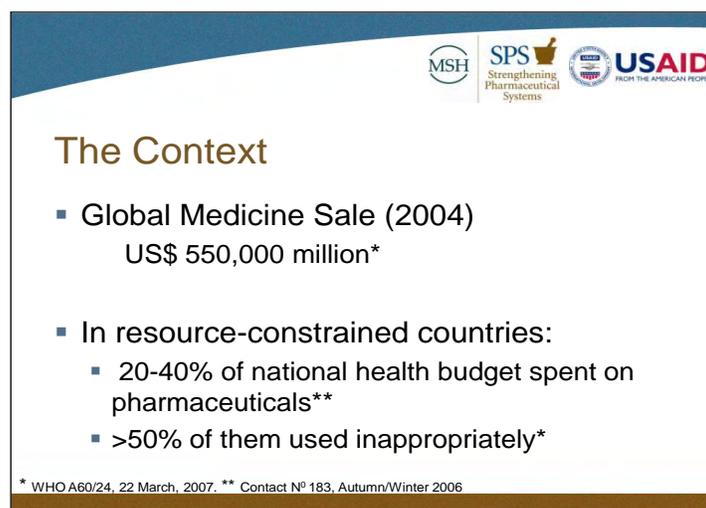
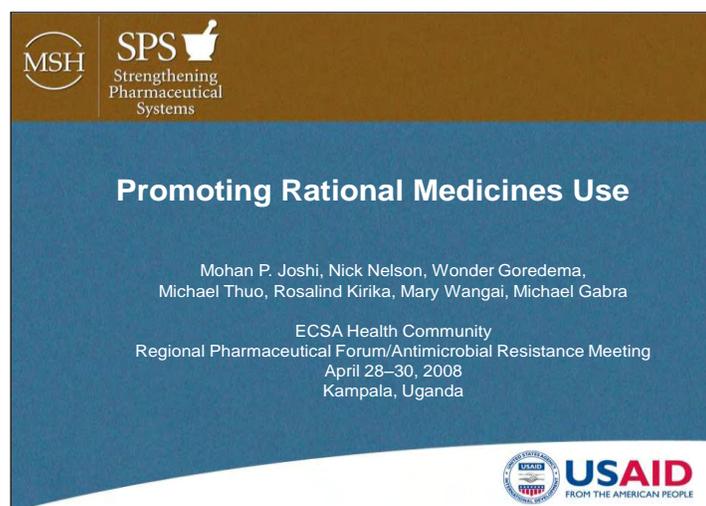
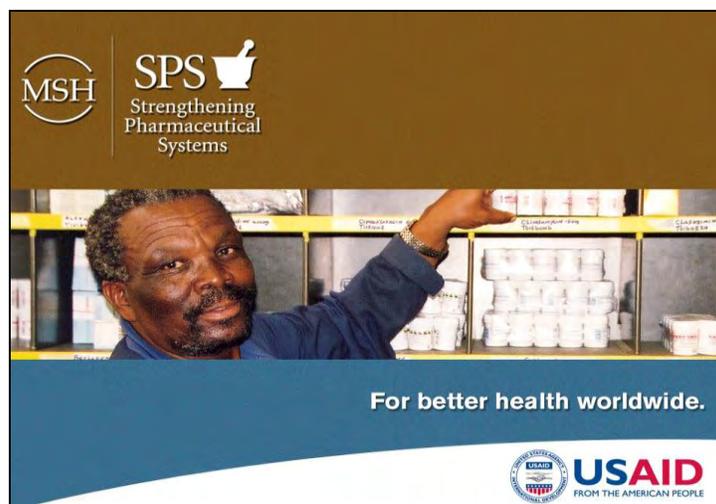
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## Expected Key Outputs

- 2<sup>nd</sup> Regional Pharmaceutical Strategy (2008–2012).
- PRDU TWG Operation Plan.
- Policy TWG Operation Plan.
- Regional AMR advocacy and containment strategy and operational plan drafted.
- An RPF “AMR Working Group” identified.
- Immediate next steps for the Group drafted

17

## ANNEX 3. PRESENTATION ON PROMOTING RATIONAL MEDICINES USE

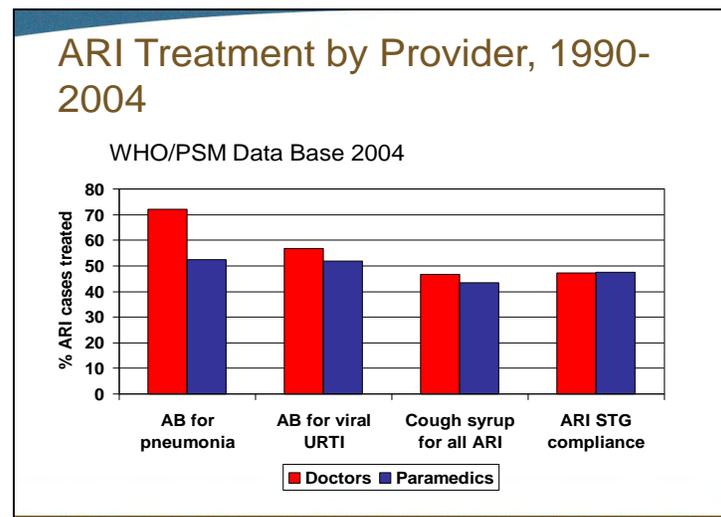
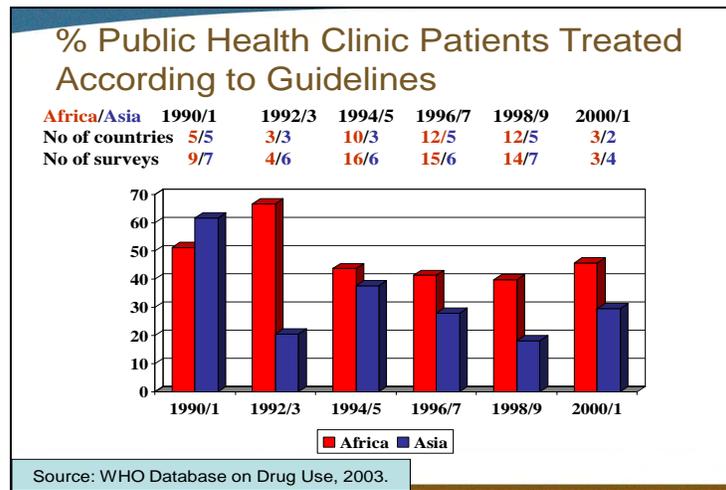


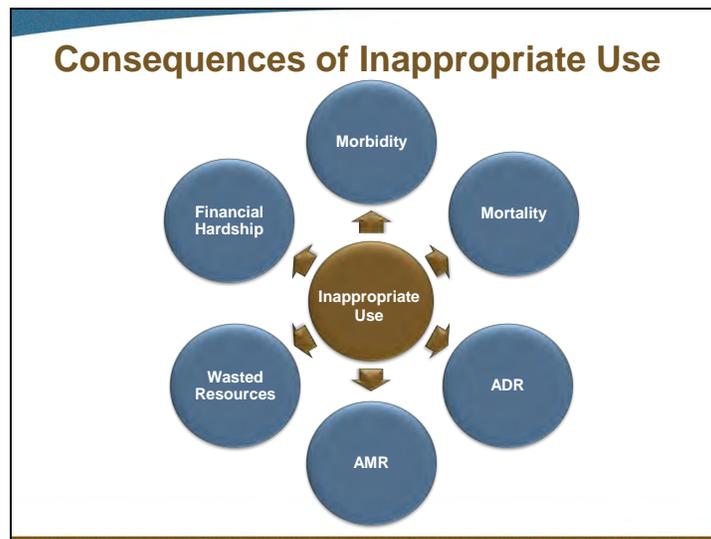
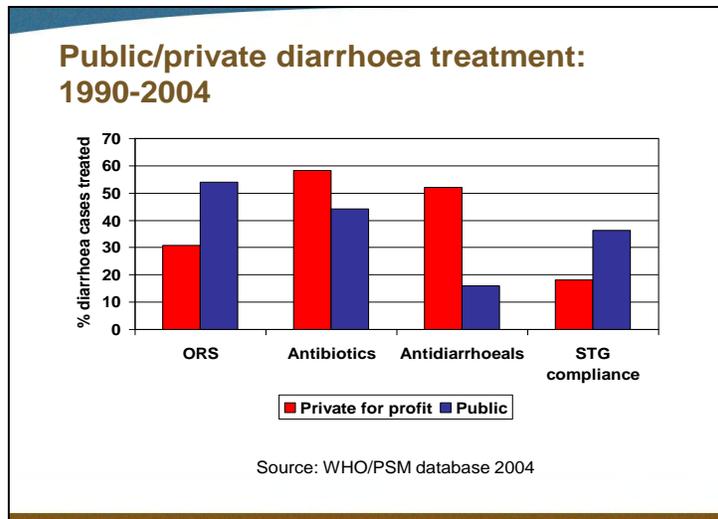
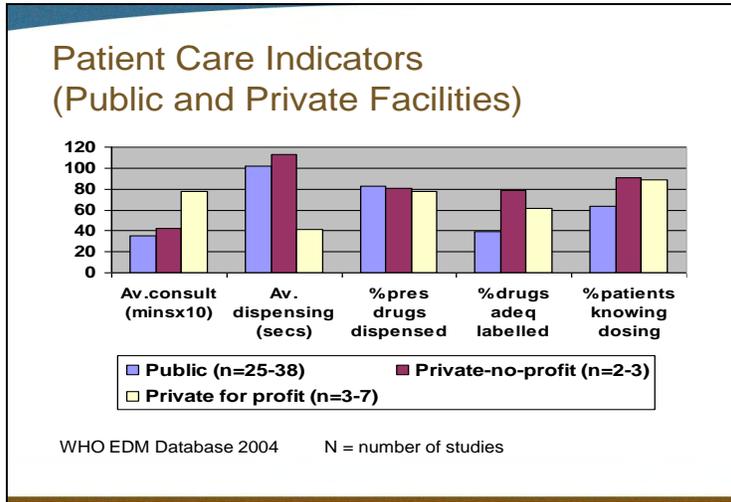


## Examples of Inappropriate Use\*

- 25-75% antibiotics in teaching hospitals are inappropriate
- over 2/3 of antibiotics without prescription in many countries
- 90% of consumers buy 3-days supply of antibiotics or less
- Private providers in India use 80 different TB regimens
- 50% of people worldwide fail to take medicines correctly
- 15 billion injections/year; half with unsterile needle/syringe

\* Hogerzeil HV. Promoting Rational Use of Medicines: a Global Perspective, WHO/PSM



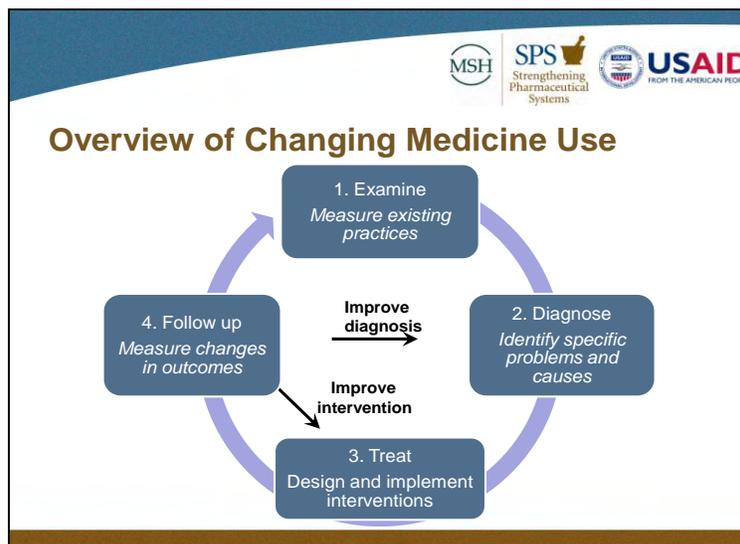


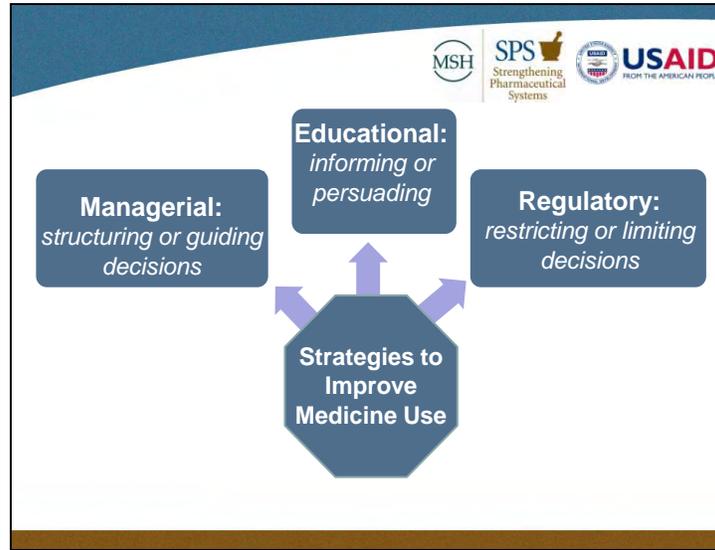


The rational use of drugs requires that patients receive medications appropriate to their clinical needs, in doses that meet their own individual requirements for an adequate period of time, and at the lowest cost to them and their community.

WHO conference of experts Nairobi 1985

- ➔ Right Drug
- ➔ Right Dose
- ➔ Right Duration
- ➔ Affordable



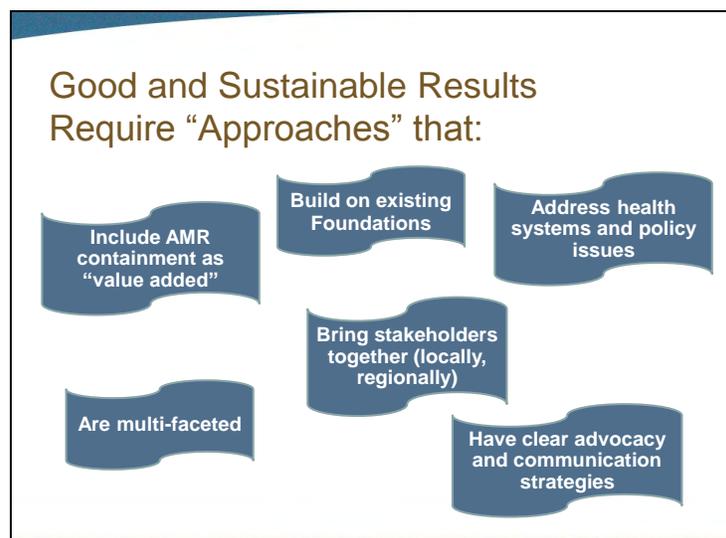
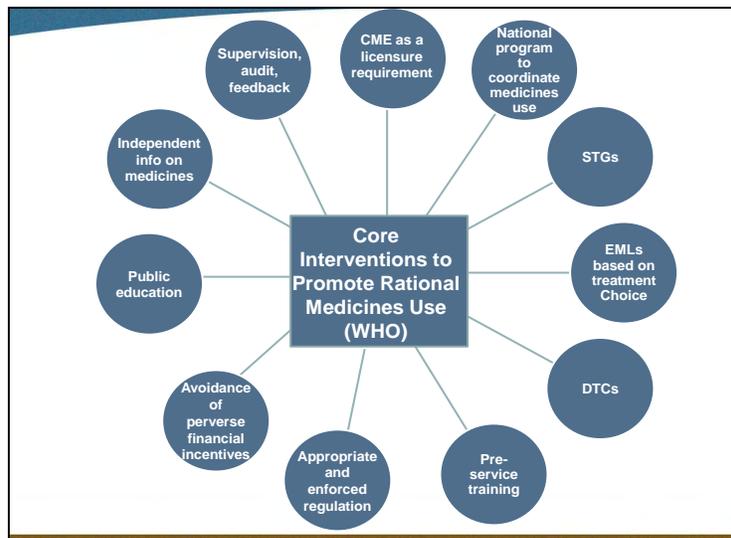
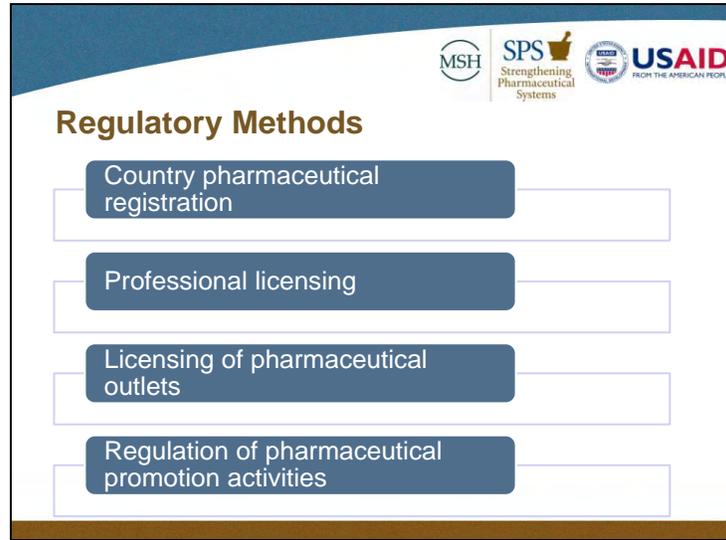


This slide features the same logos as the first slide. The title "Educational Methods" is in bold brown text. Below it are two blue rounded rectangles, each followed by a white box containing a list of items.

- Printed materials and Electronic Resources**
  - Pharmaceutical bulletins and newsletters
  - Formulary manuals and STGs
  - Internet-based: website, emails
- Face-to-face activities**
  - Group: in-service education, workshops, seminars
  - Individual: face-to-face (academic detailing)

This slide features the same logos as the first slide. The title "Managerial Methods" is in bold brown text. Below it are four blue rounded rectangles, each followed by a white box.

- STGs
- DUEs
- Clinical pharmacy programs
- Medicine restrictions and control





### ***RPF is Well-positioned***

***to promote such “core interventions” and “approaches” because of its strengths:***

- An already established multi-country network focusing on pharmaceutical management
- Multi-sectoral membership (teaching hospitals, universities, research organizations, and practitioners)
- Technical and organizational strength with presence of TWGs and upward link to DJCC and RHMC
- Experience in developing and implementing workplans

## ANNEX 4. OVERVIEW OF ANTIMICROBIAL RESISTANCE



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Systems



For better health worldwide.



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### Antimicrobial Resistance

A Growing Threat to Public Health Programs

Nick Nelson, Mohan P. Joshi, Wonder Goredema,  
Rosalind Kirika, Michael Thuo, Mary Wangai, Michael Gabra

ECSA Health Community  
Regional Pharmaceutical Forum/Antimicrobial Resistance Meeting  
April 28–30, 2008  
Kampala, Uganda



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### Objectives

- Define antimicrobial resistance (AMR)
- Describe the current global situation of AMR
- Describe the impact of AMR
- Review the main contributing factors to AMR

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Strengthening Pharmaceutical Systems FROM THE AMERICAN PEOPLE

## The Global Threat of Antimicrobial Resistance (1)

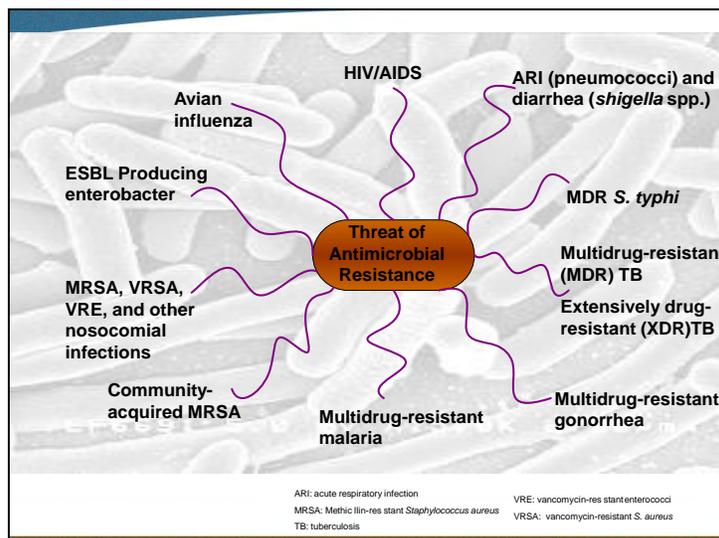
- Infectious diseases kill 11 million people annually, 95% of whom live in resource-constrained countries
- The major life-saving intervention for infectious diseases is *antimicrobial treatment*
- But AMR is rapidly reducing the effectiveness of antimicrobials

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Strengthening Pharmaceutical Systems FROM THE AMERICAN PEOPLE

## The Global Threat of Antimicrobial Resistance (2)

AMR is

- A steadily increasing global public health threat
- Widespread in both the hospital and community
- Rapidly making many 1<sup>st</sup> line treatments ineffective
- Impacting all infectious diseases, including HIV/AIDS, TB and malaria



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## What is AMR?

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### Definition

“Ability of a parasite [microbe] strain to survive and/or multiply despite the administration and absorption of a drug given in doses equal to or higher than those usually recommended but within tolerance of the subject.” (WHO, 1973)

Translation: the recommended antimicrobial medicine is no longer effective for treating an infectious disease

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### Selection Pressure

Level of resistance to an antimicrobial varies between individual microbes in a population

Antimicrobial use, particularly inappropriate use, leaves resistant microbes behind

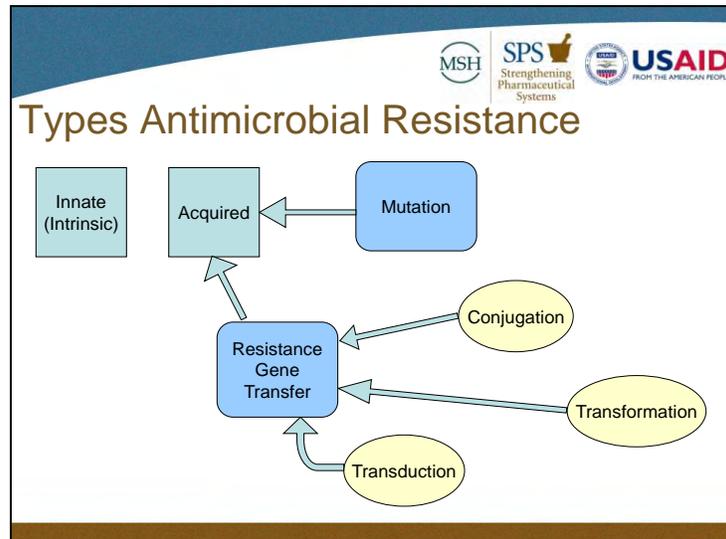
Without competition resistant microbes grow uninhibited

Original Population

After Antimicrobial Treatment

Final Population

Resistance Level  
low high



How serious is AMR?

- ### Global Examples of AMR- HIV/AIDS
- Resistance to any ARV
    - Africa- 5.5%
    - East Asia- 7.4%
    - S.E. Asia- 5.7%
    - Latin America- 6.4%
    - N. America- 11.4%
    - Europe- 10.6%
- From WATCH reports, cited in: Maglione, M, et al. 2007. *Antiretroviral (ARV) Drug Resistance in the Developing World. Evidence Report/Technology Assessment No. 156.* AHRQ Publication No. 07-E014. Rockville, MD: Agency for Healthcare Research and Quality.



## Global Examples of AMR- TB

- 400,000 cases of MDR-TB emerging every year
- A 2006 global study found 20% of TB isolates were MDR and 2% XDR<sup>1</sup>
- XDR-TB identified in every region of the world<sup>2</sup>

1. Emergence of Mycobacterium tuberculosis with extensive resistance to second-line drugs-worldwide, 200-2004. *Morbidity and Mortality Weekly Report*, 2006, 55(11):301-305

2. WHO. 2007. The Global MDR-TB and XDR-TB Response Plan 2007-2008. Geneva, WHO.



## Global Examples of AMR- Malaria

- Resistance to Chloroquine and SP are highly prevalent in most malaria-endemic areas<sup>1</sup>
- ACT remains the *last option* for treatment in many areas
- Resistance to even ACTs has been reported in South East Asia<sup>2</sup>

1. Boland, P.B. 2001. *Drug Resistance in Malaria*. Geneva, WHO.

2. SEARO and WRPO. 2007. Containment of Malaria Multi-drug Resistance on the Cambodia-Thailand Border: Report of an Informal Consultation, Phnom Penh, Cambodia, 29-30 January, 2007. Geneva, WHO.



## Global Example of AMR: *S. pneumoniae*

Prevalence not susceptible to any three drug classes (including penicillin), Alexander Project 1998—2000

- Italy (22.4%)
- Saudi Arabia (23.5%)
- US (25.8%)
- Mexico (31.1%)
- Spain (32.9%)
- South Africa (33.5%)
- Singapore (39.9%)
- France (49.1%)
- Japan (63.1%)
- Hong Kong (79.3%)

*Adapted from:* Jacobs and Others 2003. *Quoted in:* Laxminarayan and colleagues. Drug resistance (Chapter 55, Pages 1031-1051) In: *Disease Control Priorities in Developing Countries*, 2006.

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## Global Examples of AMR: Sexually Transmitted Infections

- Current range of penicillin resistant gonorrhoea—9-90% in Asia and more than 35% in Sub-Saharan Africa and the Caribbean<sup>1</sup>
- *N. gonorrhoeae* isolates in Guangzhou in China during a 6-year period from 1996 to 2001—from 57.2% to 81.8% for penicillin G and from 17.6% to 72.7% for ciprofloxacin<sup>2</sup>

1. Okeke et al. *Lancet Infect Dis* 2005; 5: 481-93  
2. Zheng et al. *Sex Transm Infect* 2003; 79(5): 399-402

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## Global Examples of AMR: Shigella

Resistance of *Shigella* strains isolated from children under 5 with acute diarrhea in Chile over a 4-year period

Antibiotic	Resistance Percentage
ampicillin	82%
chloramphenicol	49%
cotrimoxazole	65%
tetracycline	53%
multi-drug resistance	51%

Fulla N et al. *Am J Trop Med Hyg* 2005; 72(6): 851-854

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## Is AMR Getting Worse?





## AMR on the Rise (1)

1981-1999 Surveillance data on nosocomial infections at National Taiwan University Hospital showed a great increase in the incidence of some drug resistant pathogens

Pathogen	Incidence in 1981-1986	Incidence in 1993-1998
Methicillin-resistant <i>Staphylococcus aureus</i>	4.3%	58.9%
Cefotaxime-resistant <i>Escherichia coli</i>	0%	6.1%
Cefotaxime-resistant <i>Klebsiella pneumoniae</i>	4%	25.8%

Source: Hsueh et al. *Emerg Infect Dis* 2002; 8(1): 63-8





## AMR on the Rise (2)

Trends in MRSA in European countries between 2000 and 2005.

Country	2000	2001	2002	2003	2004	2005
Germany	10	12	15	18	20	22
Hungary	4	6	8	12	15	18
Slovakia	5	7	10	12	15	18
Czech Republic	3	4	5	6	8	10

European Antimicrobial Resistance Surveillance System (EARSS). 2005. EARSS Annual Report:2005. Bilthoven, The Netherlands: EARSS.





## AMR on the Rise (3)

### Resistant Strains Spread Rapidly

Source: Centers for Disease Control and Prevention

MRSA = Methicillin-resistant *Staphylococcus Aureus*  
 VRE = Vancomycin-resistant Enterococci  
 FQRP = Fluoroquinolone-resistant *Pseudomonas aeruginosa*



## What is the Impact of AMR?



## Impact of AMR

Huge individual as well as public health consequences in terms of

- Prolonged illness
- Increased mortality
- Prolonged periods of infectiousness with increased risk of transmission of resistant pathogens to others
- Indirect costs (prolonged absence from work, etc)
- Increased direct cost (longer hospital stay, use of more expensive 2<sup>nd</sup> or 3<sup>rd</sup> line drugs)



## Impact of AMR: Cost implications (1)

Disease	Avg. First-Line Cost (USD)	Avg. Second-Line Cost (USD)	Increase
HIV/AIDS <sup>1</sup>	482/patient/year	6,700/patient/year	6,218/patient/year (~14x more)
TB <sup>2</sup>	20/course	3,500/course	3,480/course (~175x more)
Malaria <sup>3</sup>	0.10---0.20/adult course (Chloroquine/sulfa doxine-pyrimethamine)	1.20–3.50/adult course (artemisinin-based combination therapy)	1-2.20/adult course (~6–35x more)

1. Revenga, A. et al. 2006. *The Economics of Effective AIDS Treatment: Evaluating Policy Options for Thailand*. Washington, DC: The World Bank.  
 2. [http://www.upmc-cbn.org/report\\_archive/2006/11\\_November\\_2006/cbnreport\\_111006.html](http://www.upmc-cbn.org/report_archive/2006/11_November_2006/cbnreport_111006.html)  
 3. Yeung, S. et al. 2004. *Am J Trop Med Hyg.*71(Suppl. 2): 179-86.





## Impact of AMR: Cost Implications (2)

Primary blood stream infections due to nosocomial MRSA caused about 3-fold increase in cost and hospital stay when compared with infections due to MSSA

Pathogen	Median hospital stay (days)	Median total cost (US\$)
Methicillin-sensitive <i>Staphylococcus aureus</i>	4	9,661
Methicillin-resistant <i>Staphylococcus aureus</i>	12	27,083 ← 3 x more

Source: Abramson and Sexton. *Infect Control Hosp Epidemiol* 1999; 20(6): 408-11





## Impact of AMR: Cost Implications (3)

Because of failing treatment with chloroquine or SP, most malaria-affected African countries have changed to ACT-based regimen, which has significant cost implications

Drug	Cost for an adult treatment course (US\$) <sup>1</sup>
Artemether-lumefantrine (Coartem)	2.4 ← 18 x more
Chloroquine	0.13
Sulfadoxine-pyrimethamine (SP)	0.14

Source: 1. Omari et al. *Tropical Medicine and International Health* 2004; 9(2): 192-199





## Impact of AMR: Reduced Effectiveness of Medical Technology

- Antimicrobials compliment many other medical technologies which require the drugs to ward off infection such as-
  - Transplants
  - Chemotherapy
  - Surgery
- Ineffectiveness of antimicrobials has indirect costs by limiting the value of these technologies.

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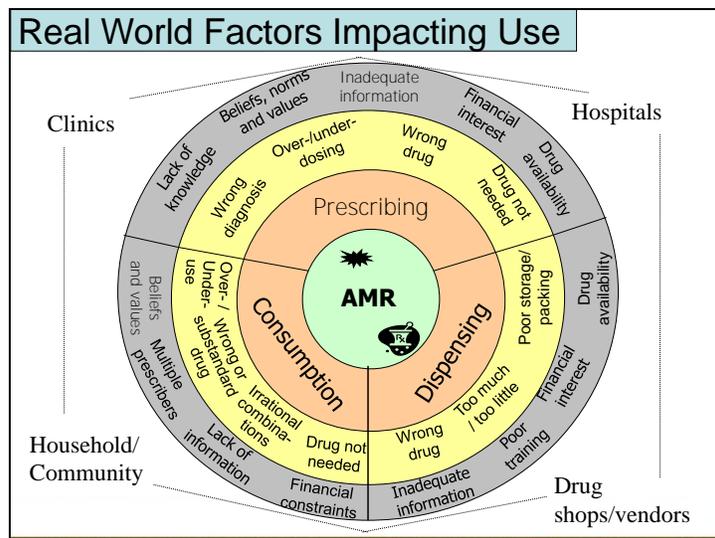
## What are the Key Factors Contributing to AMR?

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## Inappropriate Use of Antimicrobials

- Antimicrobials are one of the most widely used and misused agents
- 20–50% of human use UNNECESSARY
- Inappropriate use includes the prescriber, dispenser and patient/consumer

Wise et al. *British Medical Journal* 1998; 317(7159): 609–10.

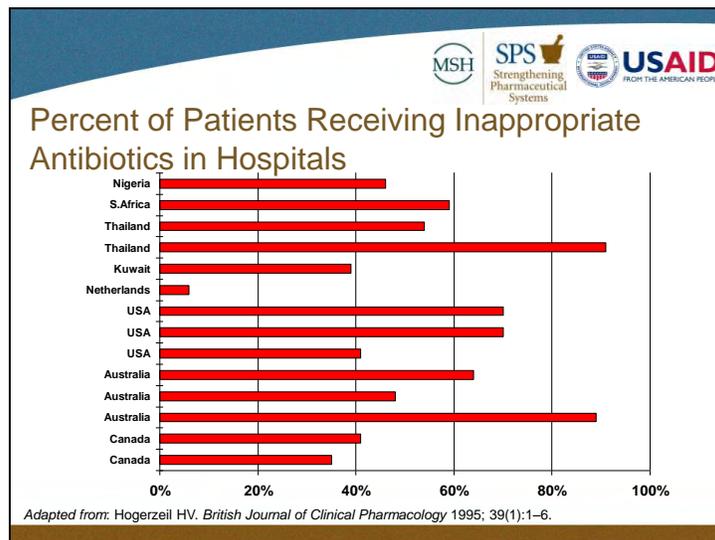
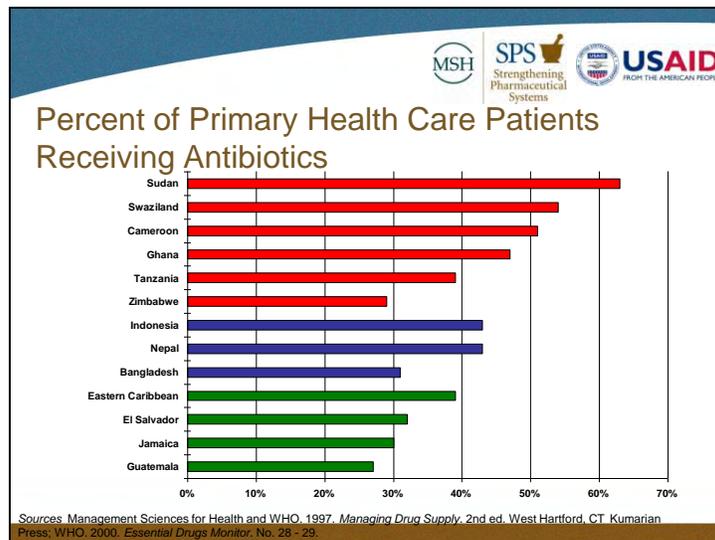






## Antimicrobial Use in Hospitals and Primary Healthcare

- Every 2nd patient in acute care hospitals receives antibiotics
- 30–60% patients given antibiotics in primary health care. This is perhaps twice that is clinically needed
- Up to 10% of admitted patients get hospital-acquired infections
  - 60% of hospital-acquired infections are drug-resistant





## Antimicrobial Use in Animals

- 50% of use in developing countries is in animals (large proportion of which is for growth promotion)
- 40–80% of animal use HIGHLY QUESTIONABLE \*
- Irrational use in animals can contribute to resistance in human pathogens

\* Wise et al. *British Medical Journal* 1998; 317(7159): 609–10.



## Poor Infection Prevention and Control

- Common modes of transmission include hands and medical devices (catheters, ventilators, etc).
- Lack of or poor adherence to effective infection control protocols
- Fewer infections in a hospital setting means less need for antimicrobial use and therefore a lower selective pressure for infectious agents to develop resistance.



## Poor Regulation and Enforcement

- Control of supply, distribution and sales
  - Antimicrobials sold through unofficial retail outlets or street vendors.
  - Antimicrobials sold without requiring a prescription (“over the counter”) or in incomplete doses.



## Poor Quality Antimicrobial Products

- Counterfeit and substandard Drugs
  - Lack the stated active ingredient, contain the wrong active ingredient, or have an insufficient level of active ingredient
  - The US FDA estimates that 10% of drugs worldwide are counterfeit and in some countries more than 50% of the drug supply is fake
- Sub-therapeutic levels of a drug in the patient results in treatment failure and growth of resistant strains



## Inadequate Surveillance in Resource-Constrained Countries

- Inadequate data to guide policy, use, and impact measurement
- Quality and dependability of data can be of concern even where available
- Lack of standardization & reporting process so comparison & recommendations not easy



## Weak Pharmaceutical Management

Deficiencies in pharmaceutical management manifest in such ways as

- Inappropriate selection and use  
(due to lack of policies and guidelines such as STGs, EMLs, and inadequate pre and in-service trainings)
- Undependable supply (stock-outs, etc)
- Poor storage practices



## Drug Advertising and Promotion

- Direct-to-consumer Ads
  - Markets medicines directly to the public
  - Stimulated demand for the “latest” medicine
- Pharmaceutical Promotion
  - Target prescribers
  - Use of a host of “incentives”- gifts, free samples, speaking engagements, etc



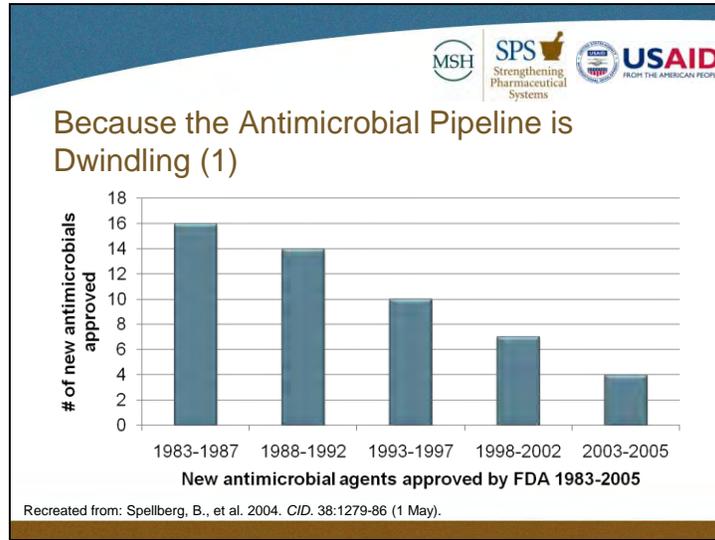
## Why Is It More Acutely Urgent Now To “Preserve the Effectiveness of Currently Available Antimicrobials”?



## Because First-line Treatments are Failing

Infectious Disease	AMR Global Prevalence Rates
Malaria	Chloroquine resistance in 81/92 countries
Tuberculosis	Up to 17% primary multi-drug resistance
HIV/AIDS	Up to 25% primary resistance to at least one antiretroviral agents
Gonorrhea	5-98% penicillin resistance and 1-50% fluoroquinolone resistance in <i>Neisseria gonorrhoeae</i>
Pneumonia and bacterial meningitis	Up to 70% penicillin resistance, 6-43 % ampicillin resistance, and 11-72% Macrolide resistance in <i>Streptococcus pneumoniae</i>
Diarrhea: shigellosis	10-90% ampicillin resistance 5-95% cotrimoxazole resistance
Hospital infections	Up to 70% resistance of <i>Staphylococcus aureus</i> to all penicillins and cephalosporins

Source: WHO country data, 2000-03 and APUA.2005. Global Advisory on Antibiotic Resistance DATA (GAARD Report). Boston, APUA.



**Because the Antimicrobial Pipeline is Dwindling (2)**  
New antimicrobial agents approved between 1998-2003

Drug	Year Approved	Novel Mechanism
Rifapentine	1998	No
Quinupristin/dalfopristin	1999	No
Moxifloxacin	1999	No
Gatifloxacin	1999	No
Linezolid	2000	Yes
Cefditoren pivoxil	2001	No
Ertapenem	2001	No
Gemifloxacin	2003	No
Daptomycin	2003	Yes

Recreated from: Spellberg, B., et al. 2004. *C/D*. 38:1279-86 (1 May).

- 
- Because the Flow of Medicines is Substantially Increasing**
- Multifold increase in supply of medicines through recent global health initiatives (GFATM, US Presidential Initiatives, GDF, etc)
  - Resistance likely to escalate rapidly if strategies to strengthen pharmaceutical management and contain AMR not implemented

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## What Can “Superbugs” Do?

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### Simon’s Story: The Real Impact of AMR on a Family



- Simon, a 15-month old child recovering from a cold, awoke with a high fever on the morning of April 16, 2004.
- His parents took him to the ER where the standard tests (chest X-ray, oxygen-level test), were run.
- It was speculated that he could be asthmatic. He was discharged at 1:30 PM.
- Once home, Simon began vomiting, became cold to the touch, his lips turned blue and he was breathing very heavily. He was rushed to the hospital again and sent to the ICU where he soon fell into a septic coma.
- The doctors could not diagnose Simon’s infection, and **all of the treatments they tried failed**. On April 17, 2004, Simon was pronounced dead at 12:45 p.m.

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### Simon’s Story...

Two months later

- The autopsy confirmed that Simon died from **methicillin-resistant *Staphylococcus aureus* (MRSA)**,
- Most likely the “community-acquired” strain rather than the hospital-based one.

Adapted from *My Son, My Sun—A Mother’s Story of Tragedy in the Face of MRSA*  
Posted: 3/1/06  
[http://www.idsociety.org/Content/NavigationMenu/News\\_Room1/Bad\\_Bugs\\_Need\\_Drugs/My\\_Son\\_My\\_SunandNum8212;A\\_Mother%E2%80%99s\\_Story\\_of\\_Tragedy\\_in\\_the\\_Face\\_of\\_MRSA.h](http://www.idsociety.org/Content/NavigationMenu/News_Room1/Bad_Bugs_Need_Drugs/My_Son_My_SunandNum8212;A_Mother%E2%80%99s_Story_of_Tragedy_in_the_Face_of_MRSA.h)



## A Glimpse of the Past

**Case 1 Policeman, aged 43.**

- The patient was discharging pus on his face, scalp and both eyes, which had started from a sore at the corner of his mouth a month earlier. The primary infection was Staph. aureus; the secondary Strep. pyogenes.
- Sulphapyridine was given to him from December 12 to 19 with no improvement, and he developed a drug-rash. On January 19, incisions were made on multiple abscesses on his face and scalp, and resulted in arm abscess that gave Staph. aureus pus. A general infection of the left eye developed and the cornea perforated. The eye was removed.
- On February 12, all of his incisions were producing pus, in scalp, face, both eyes, and right arm. The lungs became involved, filling with pus containing both the pyogenic cocci.
- As a last resort, doctors tried penicillin and noted "striking improvement" after 24 hours. The scalp discharge stopped, and the pus formation in the right-eye was reduced. On February 16, he was much improved, with the right eye being almost normal. By February 17, the patient felt much better with no fever, improved appetite, and resolution of infections in the face, scalp, and right eye.

Adapted from Abraham, Chain et al. 1941. *The Lancet*. Found in Laxminarayan, R., et al. 2007. *Extending the Cure*. Washington, DC. Resources for the Future.



## A Glimpse of the Past

**Case 2 Canadian Boy- 17**

- A previously healthy high school student was taken to the ER with fever, shortness of breath and a dry cough that had started 2 days earlier. He had temperatures up to 39.5°C and extensive bilateral lung infiltrates. He developed respiratory distress and became hypotensive.
- Within 12 hours of ICU admission, he required ventilation to help him breathe. He needed significant inotropic support. A bronchoscopy was performed, which revealed patches of dead tissue suggestive of a necrotizing pneumonia.
- The patient was treated with **numerous antimicrobial medicines** during the first 24 hours, including azithromycin, ceftazidime, ciprofloxacin, clindamycin, cloxacillin, and vancomycin. **Despite this aggressive care, the patient's status continued to deteriorate, and he died** on the fifth day after admission.
- Cultures yielded both MRSA and influenza A virus.

Adapted from Adam, H. et al. 2006. Fatal case of post-influenza, community-associated MRSA pneumonia in an Ontario teenager with subsequent familial transmission. *Canadian Communicable Disease Report*. Vol 33.No. 4.



## A Glimpse of the Past

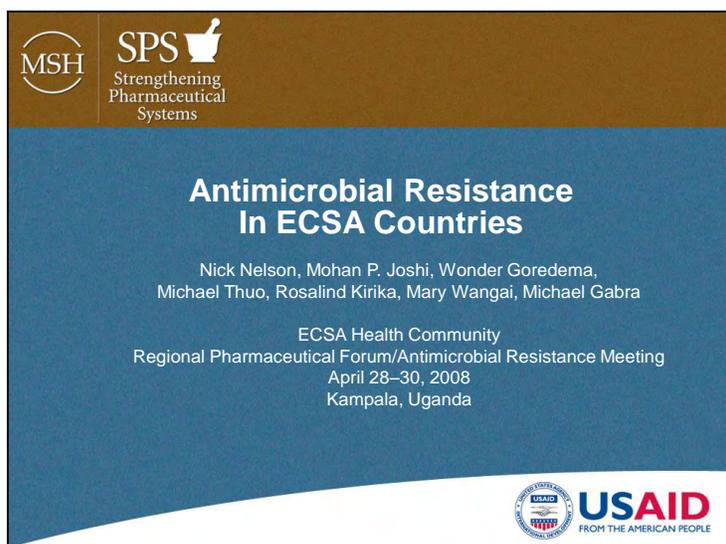
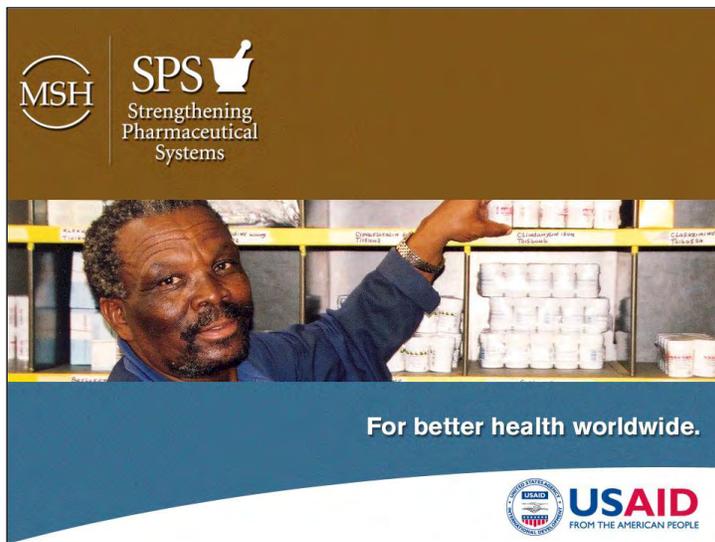
- Both cases describe *S. aureus* infection
- Case 1- Policeman: from 1941 at the dawn of the antibiotic era.
- Case 2- Canadian boy: from 2006 in the twilight of the antimicrobial era?



**We Act Now or We Lose**

- 60 years ago we were in a **PRE-antimicrobial** era
- We are in impending danger of going into a **POST-antimicrobial** era
- So we must **act NOW** to “preserve the effectiveness of antimicrobials that work

## ANNEX 5. PRESENTATION ON THE PROBLEM OF AMR IN ECSA COUNTRIES



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## AMR in ECOSA Region

- AMR has emerged and spread in every region and country in the world
- The ECOSA Region is no exception
  - Resistant strains are present for all diseases of major public health importance
  - Their rates are rising rapidly

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## AMR in ECOSA Countries: *V. cholerae* in East Africa

- 85% of *V. cholerae* isolates from Kenya and Somalia were *sensitive* to chloramphenicol and cotrimoxazole in 1994
- **Less than 10%** were found to be sensitive by 1996.

Materu, SF. et al. *East Afr Med J.* 1997; 74(3): 193-7.

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## AMR in ECOSA Countries: Malaria

Median percentage of clinical failure for Chloroquine

Country	% Clinical Failure*
Ethiopia	~70
Kenya	~65
Tanzania	~45
TZ (Zanzibar)	~60
Uganda	~30
Zambia	~35

\*Represents the median of the rates indicated by different studies  
Source: Roll Back Malaria. 2005 World Malaria Report. Website: <http://www.rbm.who.int/wmr2005/>





## AMR in ECSA Countries: *South Africa*

- Extensively drug resistant TB (XDR-TB) cases—cases that are resistant to 3 of the 6 classes of second-line drugs—carry a very high mortality rate and are increasing
- An XDR-TB strain in South Africa killed 52 of 53 identified cases in 2006 causing widespread concern in the public health community<sup>1</sup>

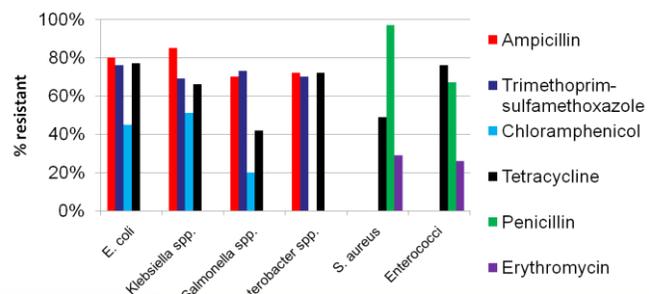
<sup>1</sup> Singh et al. *PLoS Med* 2007; 4 (1):e50.





## AMR in ECSA Countries: *Tanzania*

*Percentage of bacterial isolates resistant to several antimicrobial agents at a tertiary hospital in Tanzania*



Bacterial Species	Ampicillin (%)	Trimethoprim-sulfamethoxazole (%)	Chloramphenicol (%)	Tetracycline (%)	Penicillin (%)	Erythromycin (%)
<i>E. coli</i>	80	75	45	75	75	75
<i>Klebsiella spp.</i>	85	70	55	65	65	65
<i>Salmonella spp.</i>	70	70	20	40	70	70
<i>Enterobacter spp.</i>	70	70	70	70	70	70
<i>S. aureus</i>	45	45	45	45	95	30
<i>Enterococci</i>	75	75	75	75	75	25

Blomberg, B. et al. *BMC Public Health*. 2004; 4: 45.





## AMR in ECSA Countries: *Kenya*

- 51% of diarrheal pathogens (*Shigella*, *Campylobacter*, *Vibrio cholerae*, and *Salmonella*) isolated were not susceptible to the antimicrobial treatment given
- 76% of children in the study received >1 antibiotic

Shapiro, R.L. *J. Inf. Dis.* 2001;183:1701-4



## AMR in ECSA Countries: *Ethiopia* (1)

- **Malaria** in Ethiopia—very high chloroquine resistance (65% treatment failure)<sup>1</sup> and high sulfadoxine-pyrimethamine resistance (32% parasitological failure)<sup>1,2</sup>
- A study in Gondar College of Medical Sciences Teaching and Referral Hospital showed that >68% of **urinary pathogens** isolated were resistant to two or more antimicrobials<sup>3</sup>
- In a study done at Gondar Health Center, only 7.7% of the **gonococcal isolates** were sensitive to cotrimoxazole and 87.5% were multi-drug resistant. One strain was resistant to as many as 8 antibiotics, including ceftriaxone.<sup>4</sup>

1 – Jimma et al. *East African Med. J.* 2005; 82(8): 391-5  
2 – Kassa et al. *Ethiop. Med. J.* 2005; 43(3): 181-7  
3 – Moges, et al. *East African Med. J.* 2002; 79(8): 415-19  
4 – Tadasse et al. *East African Med J.* 2001; 78(5): 259-61



## AMR in ECSA Countries: *Ethiopia* (2)

- 16.4 % of the surgical patients admitted to a hospital in Addis Ababa between April 1983 and January 1984 developed a nosocomial infection.
- 90% of these pathogens were gram-negative bacteria (84% Enterobacteriaceae), which were mostly resistant to the commonly used antibiotics.

Habte-Gabr, et al. *Am J Infect. Control.* 1988; 16(1): 7-13.



## AMR In ECSA Countries: *Zimbabwe*

- Pneumococci was isolated from blood and CSF cultures at a Hospital in Harare and it was found that
  - 35% were resistant to penicillin
  - 50% resistant to TMP-SMX<sup>1</sup>
- Gonococci isolated from different patient groups in Harare
  - Over 90% were resistant to TMP/SMX
  - 16% were resistant to tetracycline
  - 10% of isolates from sex workers were multi-drug resistant (penicillin, TMP/SMX, tetracycline and kanamycin)<sup>2</sup>

1. Gwanzura, L. et al. *International J of antimicrobial agents.* 2003; 21(6): 557-561  
2. Mason, P.R. et al. *International J of antimicrobial agents.* 1998; 9(3):175-179





## AMR In ECSCA Countries: *Mauritius*

- Enterobacteriaceae in urine showed high rates of resistance to
  - ampicillin (80%)
  - co-trimoxazole (50%)
  - nalidixic acid (34%)
  - ciprofloxacin (26%)

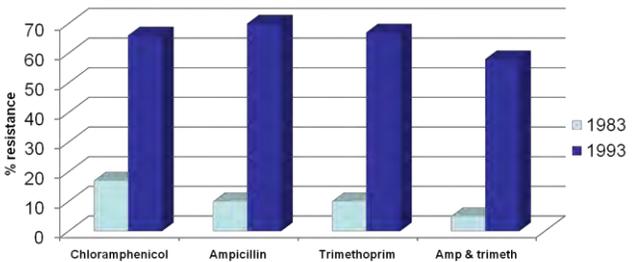
Issack, M.I. *Journal of Chemotherapy*. 2007; 19: 222-225.





## AMR on the Rise: *Rwanda*

Trends in resistance of *Shigella* to several antibiotics over a 10-year period



Antibiotic	1983 (%)	1993 (%)
Chloramphenicol	~20	~70
Ampicillin	~15	~75
Trimethoprim	~15	~70
Amp & trimeth	~10	~65

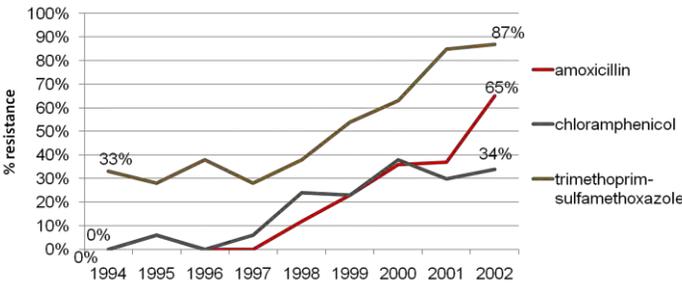
Bogaerts, J., et al. 1997. *Diagn. Microbiol. Infect. Dis.* Aug;28(4):165-71.





## AMR on the Rise: *Kenya*

Trends in resistance of *Haemophilus influenzae* to several antibiotics from a hospital in Kilifi



Year	amoxicillin (%)	chloramphenicol (%)	trimethoprim-sulfamethoxazole (%)
1994	0%	0%	33%
1995	0%	~5%	~30%
1996	0%	~5%	~35%
1997	0%	~5%	~30%
1998	~10%	~25%	~40%
1999	~20%	~25%	~55%
2000	~35%	~35%	~65%
2001	~35%	~30%	~85%
2002	65%	34%	87%

Scott, J.A.G., et al. *Antimicrobial Agents and Chemotherapy*. 2005 July. Pg. 3021-3024.





## Impact of AMR: Cost implications

**MDR-TB** (resistant to at least isoniazid and rifampicin)

- Treatment over 100 times more expensive. Treatment duration much longer, cure rate much lower even in the best centers

Susceptible TB	MDR-TB
Rand 215 (US\$ 35) <sup>1</sup>	Rand 26,354 (US\$ 4300)
Kenyan Sh 20,000 <sup>2</sup>	Kenyan Sh 2 million

1. Hensher M. 1999. Budget Planning Assistance for North West Province: TB and HIV/AIDS/STD Programs - Final Report, 23rd September 1999. *Quoted in: Okeke et al. Lancet Infect Dis* 2005; 5: 481-93.  
 2. Gachenge, B. Kenya: Cost of Treating TB Up As Drug-Resistant Strain Spreads. *Business Daily (Nairobi)* March 28, 2008.





## Impact of AMR: Cost Implications

### Antiretrovirals

- Second-line ARVs can cost between 2 and 9 times as much as first-line drugs and few generic versions are available.
- The WHO has estimated that without price reductions, by 2012 as much as 90 percent of the funds for providing ARV treatment will be spent on second-line drugs.

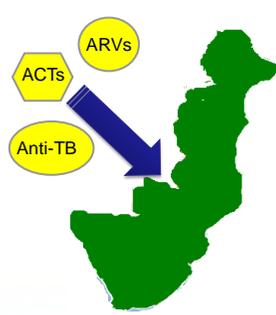
Plus News. *WHO narrows down second-line ARV options.* 7 February 2008.  
<http://www.plusnews.org/Report.aspx?ReportId=76633>





## Increased Drug Flow and Risk of AMR

- Recent global health initiatives like GFATM, The President's Emergency Plan, GDF, and others have led to a multifold increase in supply of HIV/AIDS, TB and malaria medicines to ECSA countries
- Adequate attention is required to strengthen pharmaceutical management capacity, and ensure proper use.
- Otherwise AMR may escalate quickly



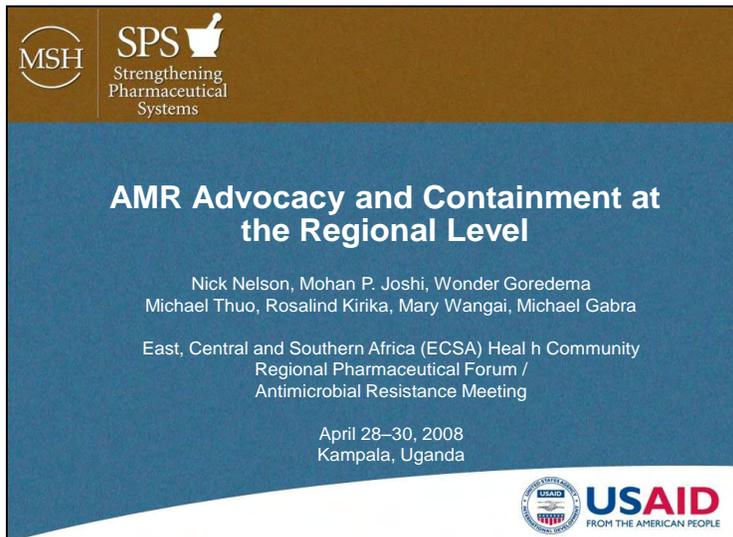
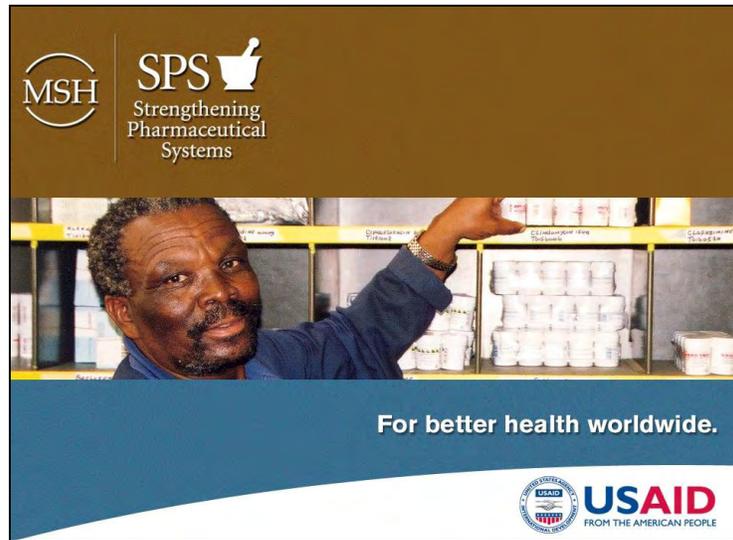


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## AMR in the ECSCA Region

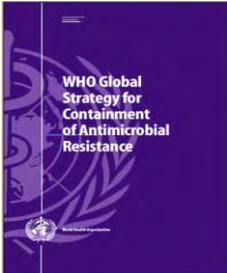
- Just as in several other regions, AMR issues currently receive inadequate priority and advocacy in ECSCA
- The RPF has the challenge and the opportunity to mobilize AMR actions through advocacy and prioritized containment interventions

## ANNEX 6. PRESENTATION ON RPF'S ROLE IN AMR ADVOCACY AND CONTAINMENT IN THE ECSA REGION





## WHO Global Strategy for Containment of AMR



- A **framework of interventions** to slow the emergence and reduce the spread of antimicrobial resistance
- **Essential information** on factors responsible for increasing resistance
- **Assessment of issues** around appropriate antimicrobial use and specific interventions needed to contain resistance
- **Practical guide** to implementation in line with national realities

WHO Global Strategy for Containment of Antimicrobial Resistance. Geneva: WHO, 2001



## WHO Global Strategy

<h3>Framework</h3> <ul style="list-style-type: none"> <li>▪ Reduce disease burden and spread of infection</li> <li>▪ Improve access</li> <li>▪ Improve antimicrobial use</li> <li>▪ Strengthen health systems and their surveillance capacity</li> <li>▪ Enforce regulation and legislation</li> <li>▪ Encourage new drugs and vaccines development</li> </ul>	<h3>Multifaceted approach</h3> <ul style="list-style-type: none"> <li>▪ Patients/ general community</li> <li>▪ Prescribers and dispensers</li> <li>▪ Hospitals</li> <li>▪ Use in food-producing animals</li> <li>▪ National governments and health systems</li> <li>▪ Vaccines &amp; drug development</li> <li>▪ Pharmaceutical promotion</li> <li>▪ International aspects of containing AMR</li> </ul>
--	---

Source: WHO Global Strategy for Containment of Antimicrobial Resistance. Geneva: WHO, 2001



## Implementing the Global Strategy (1)

- Success of the Global Strategy lies in implementation in the “field” at the country and regional levels
- However, such country and regional implementation have so far been limited



## Implementation of the Global Strategy (2)

The 58<sup>th</sup> World Health Assembly Resolution on Antimicrobial Resistance (2005) states:

“...despite some progress, the strategy for containment of antimicrobial resistance has not been widely implemented.”<sup>1</sup>

The 60<sup>th</sup> World Health Assembly Resolution on Progress in the Rational Use of Medicines (2007) acknowledges that:

“successful implementation of previous resolutions on antimicrobial resistance cannot be achieved without addressing the global problem of irrational use of medicines.”<sup>2</sup>

1-WHA58.27  
2- WHA60.16



## Regional collaboration is important to

- Recognize and address the common problem of AMR
- Create and expand advocacy and coalition
- Share expertise, experience, lessons learned, best practices, and resources
- Disseminate available AMR data and improve networking of existing surveillance
- Motivate each other and strengthen overall South-South collaboration



## How to move forward at regional and country levels

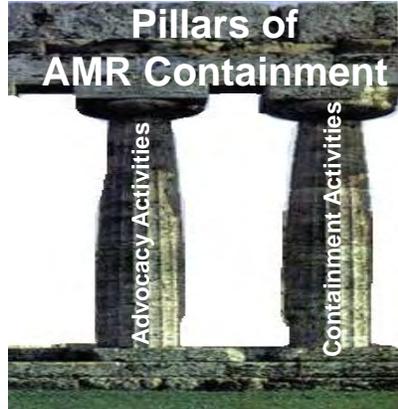
- Build on existing efforts to support AMR containment
- Use existing information or build the evidence base for an AMR strategy
- Reframe current interventions to consider implications for AMR
- Integrate AMR interventions into program planning
- Develop and use AMR-related indicators to monitor progress

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## Guiding Principles

- Generally, much is already known about the causes of AMR and what can be done to contain and prevent it; there is no need to wait for more information **to act immediately**
- Action must focus on **realistic regional and local strategies** that **capitalize on existing initiatives and resources**
- **Mobilizing local stakeholders** around the common issue of drug resistance is important for coordinated and collaborative action
- The initiative **must be seen as adding value** to existing health programs rather than as a separate, vertical and competing activity

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## Pillars of AMR Containment

Advocacy Activities

Containment Activities

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## Why is Advocacy for AMR Important

- “Preserving the effectiveness of antimicrobials” is foundational for the sustained success of all infectious disease programs
- While much attention is usually focused on improving *access* to antimicrobials, not much is being done to *preserve their effectiveness*
- Advocacy is thus important to bring the issue to the forefront



### Advocacy:

#### Key initial steps for mobilization

- Identify representatives in member states who can function as AMR focal persons
- Identify AMR stakeholders and involve them
- Facilitate cross communications and transfer of information on AMR
- Capitalize opportunities to provide an AMR perspective in the existing networks and initiatives
- Create voice to sensitize donors and mobilize funding for AMR initiatives
- Work with “the media” as an ally for large scale awareness and advocacy



### Advocacy to Containment

- AMR advocacy is central to success but it should not be viewed as an end in itself
- Rather it should be utilized as a strategic step that ultimately leads to packages of interventions identified and prioritized by local stakeholders.



### RPF and AMR Containment (1)

- Key achievements of RPF that support AMR Containment
  - Developed a generic Medicines Policy for the Region
  - Harmonized STGs for HIV/AIDS, TB and malaria
  - Developed a formulary for HIV/AIDS, TB and malaria
  - Provided TA for 2 DTCs in Kenya



## RPF and AMR Containment (2)

- AMR Activities are a natural fit to RPF objectives, particularly to those of the PRDU TWG
- AMR orientation will support and complement activities already identified by this TWG in its 2008-2012 Strategy
  - Drug and Therapeutics Committees
  - Pharmacovigilance
  - Drug Information Service
  - Information, Education, and Communication



## Drug and Therapeutics Committees (DTCs)

- Antimicrobial misuse and mismanagement is a major driving factor in the emergence and spread of AMR
- DTCs are a key factor in any strategy to contain AMR at the facility level
- Several facility-based AMR containment interventions can be implemented via DTCs



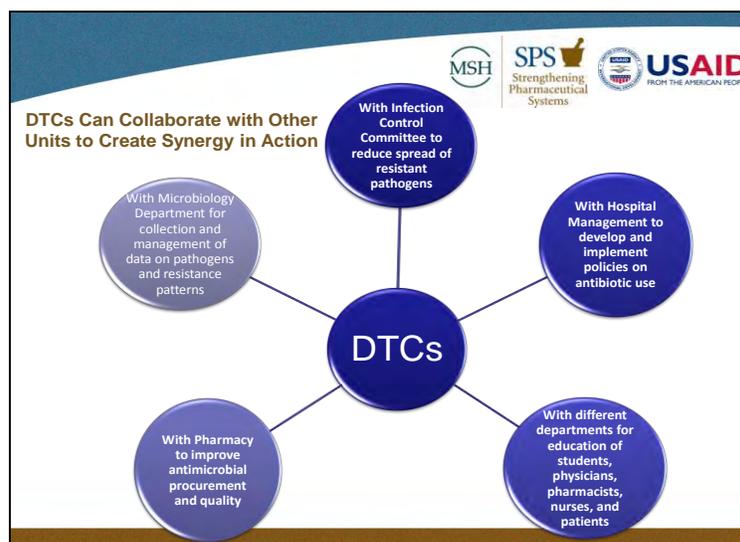
## DTCs Can Help Preserve Effectiveness of Existing Antimicrobials by (1)—

- Updating and managing antimicrobial formulary
- Updating and improving compliance to antibiotic guidelines
- Developing policies (reserve antibiotics, levels of prescribing, automatic stop orders)
- Providing pre-service and in-service training on rational use and AMR

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## DTCs Can Help Preserve Effectiveness of Existing Antimicrobials by (2)—

- Evaluating antibiotic use based on pre-established criteria of appropriateness (DUE) and applying remedial measures
- Contributing to collection and management of antibiotic surveillance and resistance data for coordinated action
- Supporting pharmacovigilance activities for antimicrobials



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## Pharmacovigilance (PV)

- The scope of PV, earlier limited to detection of new safety signals, now increasingly includes aspects of medicines safety like
  - Medication errors
  - Poor quality and counterfeit products
  - Therapeutic ineffectiveness (due to factors such as AMR non-adherence, drug interactions, etc)
- PV issues now require even greater attention as countries are increasingly using “new essential medicines” (ACTs for malaria and ARVs for AIDS) and second-line TB drugs



### Drug Information Service

- Lack of unbiased up-to-date drug and therapeutics information is a chronic problem in many resource constrained settings
- Independent drug information service can effectively address this gap by providing current and correct information on medicines, including antimicrobials



### Information Education Communication (IEC)

Appropriately designed and implemented IEC strategies can:

- Raise awareness about AMR and rational antimicrobial use
- Promote positive behavior change with regard to drug seeking and self medication practices



### Examples of AMR Advocacy and Containment from ECSA countries

- Zambia and Ethiopia are two examples of countries which have initiated AMR advocacy and containment activities in a systematic and organized manner
- The experiences from these countries will be described in later presentations

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## Possible Steps RPF Can Take Using the Existing Mechanisms

- Re-position AMR in the regional strategy
- Identify and network with Key Stakeholders
  - Disseminate a Call to Action document
  - Create an AMR section in the existing ECSA HC website
- Advocate for a Resolution on AMR through the Commonwealth Ministers Meeting

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## Re-position AMR (1)

- AMR must be dealt with **proactively**

Reactive	Proactive
	
	

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## Re-position AMR (2)

- Incorporate AMR statement of importance and focus into RPF's RDU strategy
- Incorporate AMR component as value-added in existing activities
- Emphasize AMR advocacy, especially during initial stages

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## Identify and Network with Stakeholders

- Identify all AMR stakeholders at the country and regional level
- Advocate with a “Call to Action” and promote coalition against the common threat of AMR
- Regularly update and maintain motivation through continuous communication

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## Advocate for a Resolution on AMR

Towards the Goal:  
A Resolution on AMR

- Regional Rapid Assessment/Info Gathering
- Create Advocacy Set for DJCC

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## In summary...

- **AMR is a global threat** but the specific risk factors that contribute to the emergence of AMR in any given context may be different
- **Regional approaches** and **local actions** can be taken to contain AMR
- **RPF** has the opportunity to **catalyze** this process in the ECSA region

## ANNEX 7. OVERVIEW OF COUNTRY-LEVEL AMR INITIATIVE IN ZAMBIA



Antimicrobial Resistance Advocacy and Containment  
The Zambian Experience

Chifumbe Chintu, Jennifer Chisanga, Oliver Hazemba  
Nick Nelson, Mohan Joshi, Wonder Goredema

ECSA Health Community  
Regional Pharmaceutical Forum/Antimicrobial Resistance Meeting  
April 28–30, 2008  
Kampala, Uganda

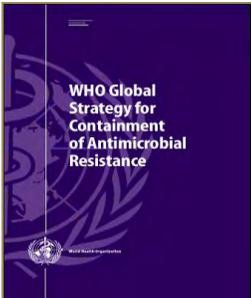


### Objectives

- Describe the establishment of the AMR/AWG Working Group
- Review progress to date
- Explain advocacy process used to mobilize action for AMR containment
- Discuss the lessons learned from the experience and current issues



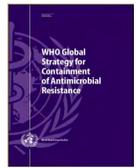
### WHO Global Strategy



- In 2001, WHO released a global strategy to contain AMR
- It recommends an organized **country-level** approach to its implementation



## AMR Country-level Advocacy and Containment

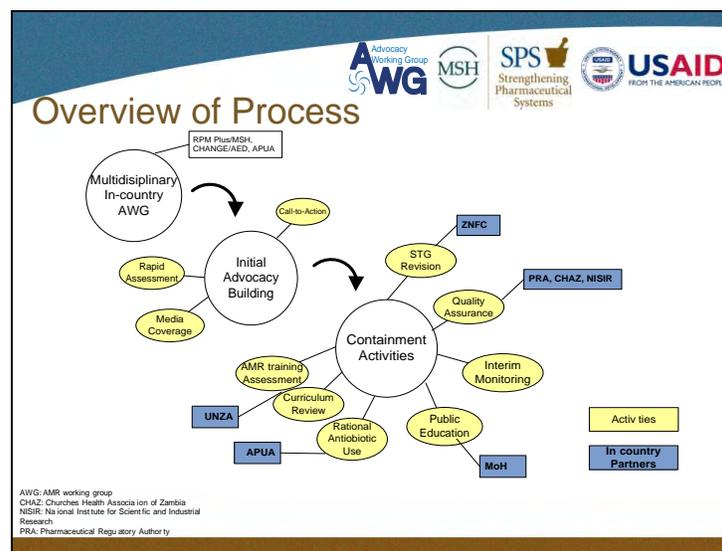
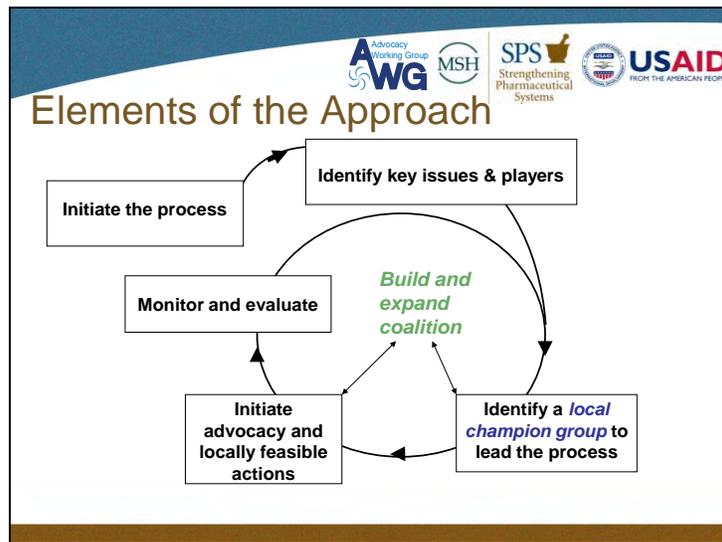


**From Global Strategy  
to Country Implementation**



Zambia 2004

**The approach —**  
focuses on catalyzing a response by local stakeholders to build and coordinate realistic strategies to contain AMR



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## Formation of AMR advocacy working group

- Formed in March 2004
- Independent body working on a *voluntary* basis and endorsed by Ministry of Health's Central Board of Health (CBoH) responsible for service delivery (at the time).
- 10 member group with representation of experts and concerned citizens
  - CBoH, regulatory authority, surveillance laboratories, academia, disease control programs, professional societies, NGOs, private sector

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## Building Advocacy

Rapid Assessment

Call to Action Meeting

Wide Spread Media Coverage

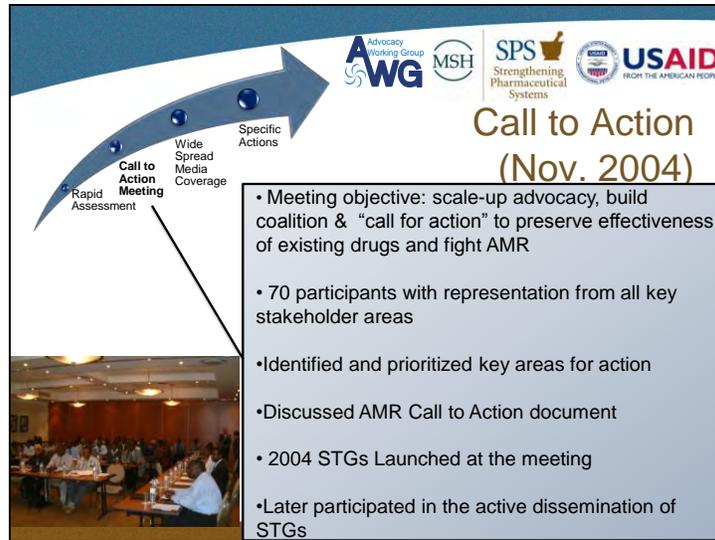
Specific Actions

AWG MSH SPS USAID

## Rapid Assessment

Main action areas identified by AWG after rapid assessment:

- Prescribing and dispensing (pre- and in-service trainings; DTCs; dissemination of STGs)
- Self-medication (public education through media, and other CBO activities; drug vendor adherence to regulations)
- Drug quality (establish national drug quality control lab and pharmacovigilance system; educate public about risks with poor quality drugs)
- Surveillance and collection/management of info (collect & disseminate AMR info; report treatment failures; develop network & feedback system; strengthen existing lab capacities)



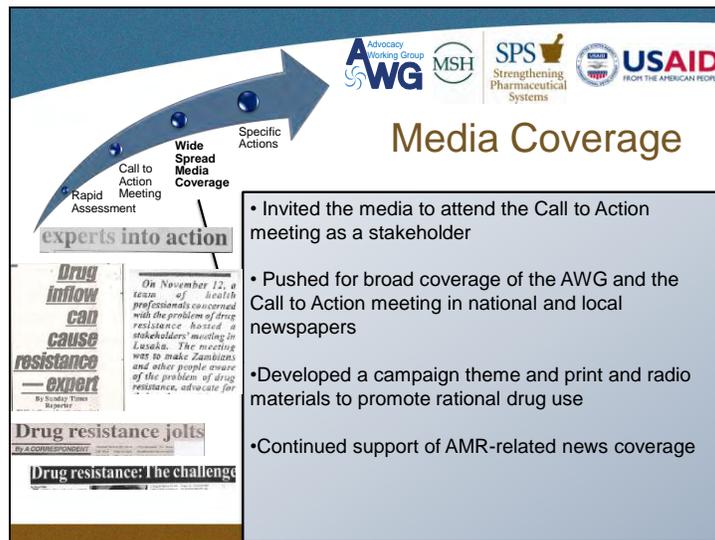
**Call to Action (Nov. 2004)**

Logos: AWG (Advocacy Working Group), MSH, SPS (Strengthening Pharmaceutical Systems), USAID (FROM THE AMERICAN PEOPLE)

Process flow: Rapid Meeting Assessment → Call to Action Meeting → Wide Spread Media Coverage → Specific Actions

**Call to Action Meeting**

- Meeting objective: scale-up advocacy, build coalition & “call for action” to preserve effectiveness of existing drugs and fight AMR
- 70 participants with representation from all key stakeholder areas
- Identified and prioritized key areas for action
- Discussed AMR Call to Action document
- 2004 STGs Launched at the meeting
- Later participated in the active dissemination of STGs

**Media Coverage**

Logos: AWG (Advocacy Working Group), MSH, SPS (Strengthening Pharmaceutical Systems), USAID (FROM THE AMERICAN PEOPLE)

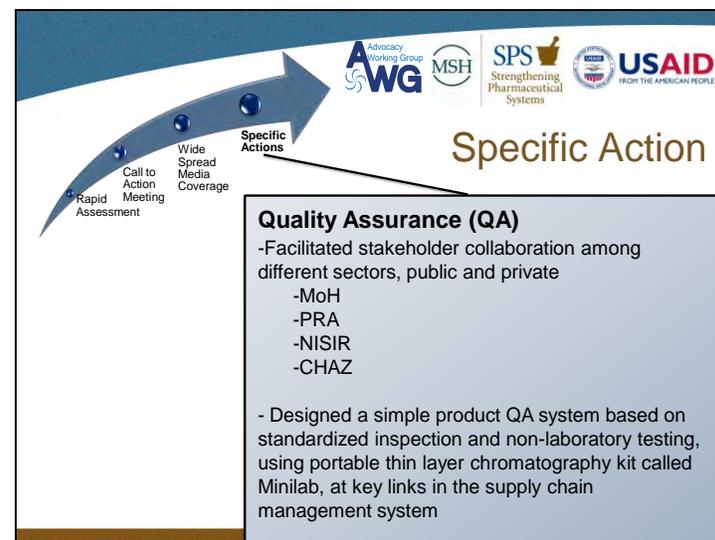
Process flow: Rapid Meeting Assessment → Call to Action Meeting → Wide Spread Media Coverage → Specific Actions

**Wide Spread Media Coverage**

- Invited the media to attend the Call to Action meeting as a stakeholder
- Pushed for broad coverage of the AWG and the Call to Action meeting in national and local newspapers
- Developed a campaign theme and print and radio materials to promote rational drug use
- Continued support of AMR-related news coverage



Clippings include: "Drug inflow can cause resistance — expert", "Drug resistance jolts", "Drug resistance: The challenge"



**Specific Action**

Logos: AWG (Advocacy Working Group), MSH, SPS (Strengthening Pharmaceutical Systems), USAID (FROM THE AMERICAN PEOPLE)

Process flow: Rapid Meeting Assessment → Call to Action Meeting → Wide Spread Media Coverage → Specific Actions

**Specific Actions**

**Quality Assurance (QA)**

- Facilitated stakeholder collaboration among different sectors, public and private
  - MoH
  - PRA
  - NISIR
  - CHAZ
- Designed a simple product QA system based on standardized inspection and non-laboratory testing, using portable thin layer chromatography kit called Minilab, at key links in the supply chain management system

**Specific Action**

**Standard Treatment Guidelines**

- Facilitated a workshop for physicians on implementing and using STGs
- Collaborated and supported MoH and ZNFC in revising STGs and in implementation

**Specific Action**

**In-service and Pre-service Training**

- Organized local consultants to review for gaps in AMR content in
  - pre-service curriculum for physician, pharmacy and nursing schools
  - in-service training curriculum for healthcare professions
- The AWG facilitated dissemination of the findings of these reviews
- UNZA School of Medicine is now addressing AMR and rational drug use topics in the medical curriculum (currently undergoing revision)

**Specific Actions**

**Alliance for the Prudent Use of Antibiotics (APUA) Country Chapter**

- A partner group promoting rational antimicrobial use
- APUA chair is AWG vice-chair
- Did prescribing pattern study and disseminated results
- Conducted AMR research methodology training

**Specific Actions**

Continued Public Awareness

Collaborated with the MoH to incorporate AMR related content in a program called “Your Health Matters”

Three segments on AMR and rational use of medicine. Developed and broadcast over two months during primetime TV

**“Your Health Matters”**

- Video Clip

**Interim Review and Monitoring**

- Held a Capacity Building Meeting in 2004
  - Reviewed mission, vision and objectives
  - Conducted a SWOT analysis
  - Revised advocacy strategy
- Collaborated with RPM Plus to conduct an interim rapid appraisal with support from Links Media (2005)
  - Reviewed program achievements
  - Identified existing opportunities for activities
  - Identified effective future advocacy strategies



## Lessons Learned (1)

- Focus initial information gathering on identifying key issues and stakeholders to provide the basis for quickly starting the national-level process for AMR containment
- Ensure that the champion group includes respected opinion leaders to legitimize activities and change agents to carry them out
- Ensure that the champion group is representative of all stakeholders, including those often overlooked like the consumers and the media.
- Ensure that the champion group plays the role of a catalyzing body rather than being the “one and only action body”



## Lessons Learned (2)

- Use the term “drug resistance” rather than “antimicrobial resistance,” except among select audiences (In Zambia, use of “preserving drug effectiveness” worked as a unifying concept for ownership of a shared vision by stakeholders)
- Use advocacy as a central strategy but ensure that it supports the objectives rather than being an end in itself
- Clearly define the objectives of the program right from the outset
- Emphasize the continuous nature of the national AMR containment process
- Develop a sustainable resource mobilization mechanism and identify opportunities for leverage to support implementation of activities



## Challenges

- Time limitation of AWG core member
- Expanding a champion group that is voluntary

Despite the Challenges the AWG is still functioning from the time of its inception.

## ANNEX 8. OVERVIEW OF COUNTRY-LEVEL AMR INITIATIVE IN ETHIOPIA



### AMR Activities in Ethiopia

**Fregenet Getachew**  
*(Pharmaceutical Management Associate – AMR coordinator)*  
**Regional Pharmaceutical Forum, Kampala, Uganda**  
**28<sup>th</sup>–30<sup>th</sup> April 2008**

MSH SPS  
Strengthening  
Pharmaceutical  
Systems

### Presentation Outline

- AMR in Ethiopia
- What has been done so far
- Challenges
- Next Steps

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Strengthening  
Pharmaceutical  
Systems

## AMR in Ethiopia

Ethiopia, like the rest of the world is facing the development of AMR.

Although AMR existence in Ethiopia is known, the magnitude of the problem has not yet been studied fully.

Various studies have been performed in different regions indicating resistance is growing. However, we do not have a national picture.



## AMR in Ethiopia

- Infectious diseases are the major cause of morbidity & mortality in Ethiopia. Ethiopia is heavily affected by HIV/AIDS, and has a high burden of TB and Malaria.

**Therefore, the need for immediate action has been deemed vital.**

- Following a request by Drug Administration and Control Authority (DACA), MSH/RPM Plus has been supporting DACA on AMR prevention & containment activities.



## Initial Activity

- MSH/RPM Plus with support from HQ carried out a preliminary assessment of AMR in Ethiopia between February & March 2006.
- MSH/RPM Plus team met with DACA as well as potential stakeholders from government & non-government institutes, professional organizations & the education sector.
- Strategies on AMR prevention & containment activities proposed.



## AMRAC

On 2<sup>nd</sup> March 2006 a “champion group”, ***Antimicrobial Resistance Advisory Committee (AMRAC)*** was established to spearhead the AMR advocacy & containment process.



## Current AMRAC members

DACA (*chair*)  
Federal Ministry of Health (FMOH)  
Ethiopian Health and Nutrition Research Institute (EHRNI)  
Federal Ministry of Agriculture (FMOA)  
Addis Ababa University (Medical Faculty & School of Pharmacy)  
Ethiopian Pharmacy Association  
Ethiopian Medical Association  
Ethiopian Public Health Association  
Ethiopian Veterinary Association  
MSH/RPM Plus  
John Hopkins University  
WHO  
USAID  
CDC



## Call to Action Meeting

- In November 2006 a two day workshop was organized by DACA, AMRAC & MSH/RPM Plus.
- 65 participants from government institutes, health care facilities, professional associations, academic & research institutions & mass media were present.
- Aim of the workshop
  - Create awareness on the situation of AMR in Ethiopia
  - Define the role of stakeholders in advocacy & containment of AMR
  - Prioritize the problems & propose national & stakeholder action plans.



### Current AMR work – Following the workshop

- December 2007 AMRAC wheel was restarted with some new members.
- Next steps discussed
- Agreement reached on the need for a baseline assessment to see the extent of AMR in Ethiopia and to obtain a national picture.



### Scope of Baseline Assessment

- Desk top review - Literature, regulatory guidelines & curricula
- Surveys – Provider, facility, patient
- Sensitivity data review



### Status of the Baseline Assessment

- Ready to start the assessment.
- Some assessment tools prepared.
- Waiting for decision on scope, process & budget.



## Challenges

- Delays in decision making.
- Too much emphasis given to the AMRAC on decision making.
- No AMR dedicated person in DACA
- DACA team busy with many other responsibilities



## Other AMR Activities

- In October 2007, technical staff from MSH/RPM Plus, Alliance for the Prudent Use of Antibiotics (APUA) & Links Media provided,
  - A 2 day “Train-The-Trainer” workshop
  - A 3 day training workshop to journalists, spokespersons & advocacy representatives



## Other AMR Trainings

### DTC

- During Drugs & Therapeutics Committee (DTC) establishment training, “The role of DTC in managing AMR” is covered. 63 hospitals, (190 healthcare providers) have received training since January 2008.
- The plan is to provide training to a total of 100 hospitals (320 healthcare providers) by September 2008.

### GCPP

- AMR status & prevention & containment strategies is covered during the Good Community Pharmacist Practice (GCPP) training. Since January 2008, 210 pharmacy personnel have received this training.
- The plan is to train 400 pharmacy personnel by September 2008.



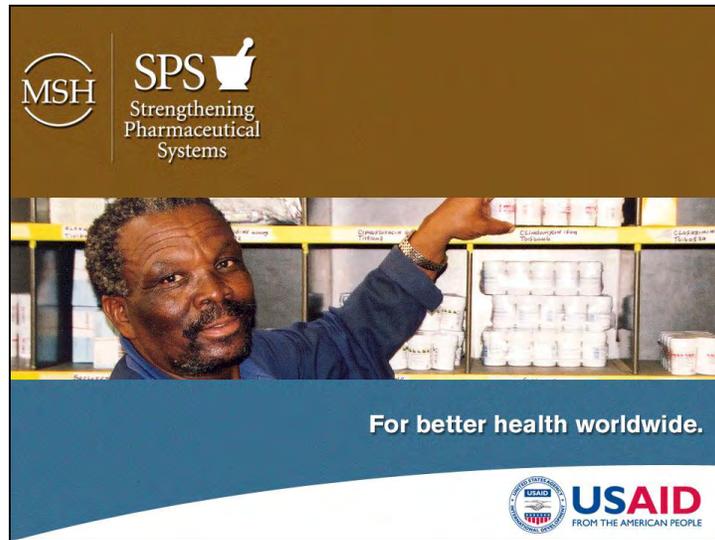
## Next Steps

- Persevere on the baseline assessment.
- Following the assessment findings, organize a dissemination workshop.
- Develop a national action plan
- Media personnel discussion forum & follow up.
- Intervention

**We still have a journey.....and we shall persevere  
with tackling this ever growing worldwide problem!**



## ANNEX 9. OVERVIEW OF KEY AMR-RELATED TOOLS/GUIDANCE DOCUMENTS DEVELOPED BY MSH/RPM PLUS AND SPS





## Drug and Therapeutics Committees

### DTC Training Course

- Development:
  - Developed in 2000 and field tested in Bangkok, Thailand
  - Revised and updated in 2007
  - Added new sessions including those on Training of Trainer's, Antimicrobial Resistance, Getting Started, and Infection Control.



## Drug and Therapeutics Committees

- Features
  - Comprehensive training course that is designed to increase capacity of low-resources country healthcare professions to create and maintain a functional DTC
  - The course materials include presentation slides, detailed participants' guides, and trainers' manual
  - Key topics include DTC overview; formulary and STG management; investigating drug use problems; drug efficacy, safety, cost and quality issues; and strategies to improve drug use
  - Full version is 12 days long, but can be adapted to shorter training periods
  - Follow-up technical assistance activities are provided after the training to assist participants in starting and implementing DTC activities



## Antimicrobial Indicator Manual

*Antimicrobial Indicator Manual, How to Investigate Drug Use in Hospitals: Selected Indicators*

- Development
  - Developed in 2003 and field tested in Ghana
  - Further refinement in 2008 based on Uganda field test.



## Antimicrobial Indicator Manual

- **Features**
  - Manual defines a limited number of indicators that will objectively describe the management and use of antimicrobials in hospitals
  - Provide tools and step-by-step instructions for designing and carrying out an assessment of antibiotic use and management in hospitals.
  - Because these indicators do not need adaptation and can be used in any indicator-based antimicrobial use study, they provide a simple tool for quickly and reliably evaluating critical aspects of antimicrobial use in hospitals.
  - Results of study can be used to improve the use of antimicrobials:
    - Describe antimicrobial drug prescribing practices
    - Compare performance among hospitals or prescribers
    - Monitor performance and orient supervision
    - Assess changes resulting from interventions



## Infection Control Assessment Tool (ICAT)

- MSH/Harvard—self assessment and quality improvement “approach” for strengthening IC programs in hospitals in low-resource countries
- The approach involves assessing existing practices using the ICAT, applying rapid team problem solving methods and monitoring performance using indicators and checklists
- The approach is packaged in a CD set that includes ICAT tools along with accompanying user manual and several other infection control resources



## Infection Control Assessment Tool (ICAT)

- **Implementation Experiences**
  - Established or strengthened multidisciplinary hospital IC teams in several countries
  - Stakeholders embraced the tool and approach as adaptable, useful, and easy to implement, which led to hospital IC teams adapting the tool, taking ownership and promoting an infection-control culture.
  - Developed and implemented low-cost interventions, such as advocacy and awareness campaigns, promotion of policies and procedures, staff training.
  - Improved compliance with hand hygiene and waste management policies and procedures
  - Held 6 provincial TOT workshops with about 140 IC practitioners and coordinators in South Africa.
  - Tool updated to incorporate feedback from the field and is now available to interested countries

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## AMR Coalition Building Guide

*Building Local Coalitions for Containing Drug Resistance: A Guide*

- Builds on the WHO Global Strategy by offering a practical approach to operationalizing the strategy at the local level.
- Based on RPM Plus and other partners' experience supporting AMR advocacy and containment activities in Zambia and Ethiopia
- Contains many practical examples, tools and templates helpful in the coalition building process

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## AMR Coalition Building Guide

**Shows stakeholders how to**

- Mobilize local support around drug resistance
- Gather credible evidence to guide decision making and advocacy
- Build consensus among stakeholders on the nature of the problem and forming a coalition; finding feasible solutions in their context; and then implement their plan

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graph TD; A[Mobilize Support] --> B[Understand the Local Situation]; B --> C[Formulate a Plan]; C --> D[Implement the Action Plan]; D --> E[Monitor and Evaluate]; E --> A;
```

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## AMR Field Guide for USAID Missions

- *Containing Antimicrobial Drug Resistance: Guide for USAID Missions to Institution-Based Interventions*
- Summarizes “nuts and bolts” for 9 key AMR containment interventions
- Menu-like format provide descriptions of time estimates, cost considerations and illustrative M&E indicators

## ANNEX 10. RPF AMR CALL-TO-ACTION DOCUMENT



### **East, Central and Southern Africa (ECSA) Health Community Regional Pharmaceutical Forum Call-To-Action for Antimicrobial Resistance Advocacy and Containment**

Antimicrobial Resistance (AMR), or drug resistance, is a major threat to health around the world. If we don't act now to preserve the effectiveness of antimicrobial medicines, AMR will severely undermine global efforts towards managing infectious diseases and meeting the Millennium Development Goals by 2015. The East, Central, and Southern Africa (ECSA) region is no exception. We have seen chloroquine treatment for malaria become ineffective. If AMR is not addressed urgently, we will lose the benefits attained so far in treating diseases of public health importance including HIV/AIDS, TB and malaria. Access to the essential medicines for these diseases has significantly increased in the ECSA region, but resistance threatens their continued usefulness. Therefore it is of paramount importance that all stakeholders work together to combat this problem.

Collaboration within the region is vital. We must communicate to share expertise, experience, lessons learned, best practices, and resources. No individual country or group can successfully contain AMR alone. Therefore, it is crucial that strategic coalition and partnerships at regional, country, and local levels are established to advance sustained AMR advocacy and containment actions.

Inappropriate use of antimicrobials, poor infection control, poor regulation and enforcement, poor quality antimicrobial products, and weak pharmaceutical management are key factors contributing to the emergence and spread of AMR. A number of interventions and tools are available to address these factors. Comprehensive sets of AMR containment interventions are outlined in the *WHO Global Strategy for the Containment of Antimicrobial Resistance*. Because AMR is a complex and multifaceted problem, interventions need to be multifaceted and coordinated. Activities such as pre-service and in-service trainings; information, education, communication (IEC) strategies to raise awareness; drug and therapeutics committees; standard treatment guidelines and essential medicines lists; infection control; surveillance; and promotion of rational use of medicines have been shown to be effective and must be strengthened by AMR stakeholders.

The Regional Pharmaceutical Forum (RPF) is an established mechanism within the ECSA Health Community to improve pharmaceutical management in the region. Therefore RPF is well placed within the region to champion AMR and rational medicines use issues. RPF has contributed to AMR containment by developing a generic medicines policy; harmonized standard treatment guidelines and formulary for HIV/AIDS, TB, and malaria; and strengthening medicines and therapeutics committees. RPF will continue to work towards AMR containment through sustained advocacy and packages of interventions including those related to medicines and therapeutics committees, pharmacovigilance, drug information service, and IEC.

The RPF acknowledges that many AMR containment activities are being implemented, but are often uncoordinated at the local, national and regional levels. All stakeholders including government, academia, regulatory authorities, professional associations, donor groups, civil society, media personnel, and industry must forge strong alliances and coordinate advocacy and actions for maximum impact and sustainability. AMR containment is our collective responsibility, so we all need to work together. If we neglect action now, future generations will lose out on all the benefits we have enjoyed. Therefore the RPF makes this Call-To-Action to all the players to join hands against this common threat and start immediate advocacy and containment actions.

# **ANNEX 11. 2008–2012 REGIONAL STRATEGY OF THE PROMOTING RATIONAL USE OF PHARMACEUTICALS TECHNICAL WORKING GROUP OF RPF**

## **ECSA HC Regional Pharmaceutical Forum (RPF) The Promoting Rational Drug Use Technical Working Group's 2008-2012 Regional Strategy**

### **Promoting Rational Use of Pharmaceuticals in ECSA Member States- TWG**

#### **1. Background/Problem Statement**

Rational use of pharmaceuticals involves components of the commodity management cycle. This includes selection, procurement, distribution and use. There is diversity of levels and mode of implementation and this makes it necessary to provide guiding principles that are universally acceptable and which if implemented will strengthen the rational use of pharmaceuticals.

#### **TWG Objective**

#### **B. Technical Objectives and Rationale-TWG**

The technical objectives of the group focus on *selection* and *use* of drugs. Other components of the commodity management cycle are addressed elsewhere by a different technical working group. However as an entry point, the main and cross cutting strategies include: advocating for the creation and strengthening of National Medicine and Therapeutics Committees (NMTCs), strengthening sharing of drug information and pharmacovigilance systems and forging stakeholder alliance and expanding advocacy for AMR containment.

#### **Technical Objective 1: To advocate for the implementation and strengthening of National Medicines and Therapeutics Committees and AMR working groups**

There is a lot of intra- and inter-country variation in the establishment, implementation and functioning of National Medicines and Therapeutic Committees (NMTCs) and AMR working groups within the ECSA region. Implementation of these committees/working groups is key to promoting appropriate pharmaceutical management and the containment of AMR .

#### **Planned Activities**

##### **1. Report on functionality of NMTC based on the 2006 performance assessment**

To expedite the implementation of activities under this objective a rapid survey will be used to determine the level of operations of NMTCs in all the ECSA member states. The functionality of these committees will be determined based on a previous country performance assessment conducted in 2006. Countries that were not reflected in the performance assessment will need to be followed up with the country focal person and if required utilising consultants.

2. Follow up and document the status of implementation of NMTCs in ECSA work plans

Based on the preliminary assessment of level of operations a more extensive follow up will be made in specific ECSA countries. A report will then be compiled and disseminated. Proposals based upon the findings in the above survey of MTCs in ECSA countries will be prepared for presentation to the DJCC and the Council of Health Ministers. The aim of this will be to raise awareness among policy makers in the region and show the importance of implementing MTCs in ECSA member states.

Develop generic terms of reference for establishment & functionality of NMTCs & AMR working groups in the ECSA member states

3. Conduct a rapid information gathering/assessment on AMR related issues in the ECSA member states and determine what NMTCs can do on AMR advocacy & containment.

4. Support implementation of Rational Use of Medicine/AMR advocacy and containment activities at country level for selected ECSA member states

Selected countries will be identified and supported in implementing their work plans focusing on rational medicines use & AMR containment issues.

5. Report on functionality of AMR containment working groups and provide technical assistance across the ECSA member states

**Technical Objective 2: To promote the availability, dissemination and use of relevant, unbiased pharmaceutical information, including pharmacovigilance activities**

With the advent of new medicines especially ARVs, antimalarials and anti-TB drugs, there is an increased need to identify credible sources of information and to disseminate this information to the health care workers and public. Strategies should be put into place to ensure that relevant and current information is used by the target groups. Networking within the ECSA member states will go a long way to maximize the use of limited resources within the region. Until recently, post-marketing surveillance has not been a common practice within the ECSA region. With the increased prevalence of treatment resistant malaria, HIV/AIDS, Co-infection with HIV/AIDS and TB, there has been an upsurge in the use of newer medicines whose safety profile is either not well documented or is unknown. As a result of this scenario, the need for pharmacovigilance (including product quality, medication error and therapeutic ineffectiveness issues) can no longer be over emphasised within ECSA member states.

The information obtained from pharmacovigilance, AMR surveillance and medicines use surveys/studies should be used more effectively to guide therapeutic & product safety decisions,

**Planned Activities**

1. Conduct baseline survey on existence and functionality of medicine & therapeutics information services and pharmacovigilance systems in ECSA member states.

A baseline survey will be conducted to establish the status of the information services and pharmacovigilance systems within ECSA member states. The usefulness of data generated through the process of pharmacovigilance can only be maximized through networking both at

national and regional level. This networking will translate into an enlarged and more useful database within the region.

2. Mobilize technical support for establishing or strengthening the medicine & therapeutics information services & pharmacovigilance activities.

Countries within the ECSA region need to be assisted in establishing pharmacovigilance systems and medicines & therapeutic information services (including treatment failure & AMR issues) through development of standard operating procedures and other relevant checklists. Health workers within the region are currently not fully conversant with the concept and operational details of pharmacovigilance. A joint policy and technical meeting will therefore help create an atmosphere that will improve advocacy and the necessary know-how required to develop country specific strategies that can promote understanding and utilisation of pharmacovigilance systems.

3. Strengthen the regional pharmaceutical information sharing mechanism

The existing CIB website for coordinated informed buying of medicinal products should be strengthened. The medicines & therapeutic information services & pharmacovigilance systems of member states need to be brought together through networking of countries, services and systems. Establishing and periodically updating a rational medicines use & AMR section within the ECSA Health Community website will be an additional mechanism for regional sharing & exchange of information.

### **Technical Objective 3: Development of IEC strategies on Rational Use of Medicines and AMR for the providers and the community**

#### **Planned Activity**

1. Provide a coordinated platform for developing themes for preparation of IEC materials

ECSA direction and advocacy has a lot of influence on the policies and practices of ECSA countries. There is need on a year to year basis for common themes on rational medicines use & AMR to guide IEC strategy development and use by member states . This activity will improve awareness and direction in the ECSA communication strategies.

**ANNEX 12. PARTICIPANTS OF THE RPF AMR MEETING,  
KAMPALA, UGANDA, APRIL 28–30, 2008**

