Promoting the Rational Medicine Use of ARVs, Anti-TB, and Other Medicines and Preventing the Development of Antimicrobial Resistance in Namibia: Workshop and Stakeholders Forum

David Mabirizi
Dan Kibuule
Mathias Adorka
Tim Rennie
Evans Sagwa
Victor Sumbi
Kennedy Kambyambya
Harriet R. Kagoya
Francis Kalemeera

August 2013

Republic of Namibia

Ministry of Health and Social Services

University of Namibia

USAID FROM THE AMERICAN PEOPLE

SIAPS Systems for Improved Access to Pharmaceuticals and Services

This report is made possible by the generous support of the American people through the US Agency for International Development (USAID), under the terms of cooperative agreement number AID-OAA-A-11-00021. The contents are the responsibility of Management Sciences for Health and do not necessarily reflect the views of USAID or the United States Government.

About the University of Namibia (UNAM)

The University of Namibia (UNAM) is a leading public higher education institution with a student population of close to 13,000 students each year. Academic programs at UNAM emanate from eight faculties and two schools: the Faculty of Agriculture and Natural Resources; Faculty of Economics and Management Science; Faculty of Education; Faculty of Engineering and Information Technology; Faculty of Humanities and Social Sciences; Faculty of Law; Faculty of Health Sciences, consisting of the School of Nursing and Public Health and the School of Medicine; and the Faculty of Science.

In 2006, UNAM was rated as the best higher education institution in Namibia by the Professional Management Review of South Africa and won a Golden Arrow Award. The previous year, the Geneva-based Foundation for Excellence in Business Practice nominated UNAM to receive its Gold Medal for Excellence in Business Practice. UNAM has graduated over 17,000 students who are serving the country in various sectors of the economy, with most occupying prominent positions in government and the private sector.

About SIAPS

The goal of the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program is to assure the availability of quality pharmaceutical products and effective pharmaceutical services to achieve desired health outcomes. Toward this end, the SIAPS result areas include improving governance, building capacity for pharmaceutical management and services, addressing information needed for decision-making in the pharmaceutical sector, strengthening financing strategies and mechanisms to improve access to medicines, and increasing quality pharmaceutical services.

Recommended Citation

Mabirizi, D, Kibuule D, Adorka M, et al. *Promoting the Rational Medicine Use of ARVs, Anti-TB, and Other Medicines and Preventing the Development of Antimicrobial Resistance in Namibia: Workshop and Stakeholders Forum.* Developed in collaboration with the University of Namibia-School of Pharmacy and Ministry of Health and Social Services, Division of Pharmaceutical Services. Submitted to USAID by the SIAPS Program. Arlington, VA: Management Sciences for Health, 2013.

Key Words

Antimicrobial resistance, antiretroviral, drug resistance, HIV/AIDS, Namibia, tuberculosis, rational medicine use

University of Namibia
School of Pharmacy
Private Bag 13301, 340 Mandume Ndemufayo Ave, Pionierspark,
Windhoek, NAMIBIA http://www.unam.na

Systems for Improved Access to Pharmaceuticals and Services
Center for Pharmaceutical Management
Management Sciences for Health
4301 North Fairfax Drive, Suite 400
Arlington, VA 22203 USA
Telephone: 703.524.6575
Fax: 703.524.7898
E-mail: siaps@msh.org
Web: www.siapsprogram.org

CONTENTS

List of Tables

List of Figures

ACRONYMS AND ABBREVIATIONS

AIDS	acquired immunodeficiency syndrome
AMR	antimicrobial resistance
ART	antiretroviral therapy
ARV	antiretroviral
CDC	US Centers for Disease Control and Prevention
CMS	Central Medical Stores
DR	drug resistance
DSP	Directorate of Special Programmes
Div. PhS	Division of Pharmaceutical Services
EDT	Electronic Dispensing Tool
EML	Essential Medicines List
EWI	early warning indicator
HCW	health care worker
HIV	human immunodeficiency virus
HOD	Head of Department
HPCNA	Health Professions Council of Namibia
MDR	multidrug resistance
MoHSS	Ministry of Health and Social Services
MSH	Management Sciences for Health
MUE	medicine use evaluation
NAAR	Namibians Against Antimicrobial Resistance
NGO	nongovernmental organisation
NHTC	National Health Training Centre
NIP	Namibia Institute of Pathology
NMRC	Namibia Medicines Regulatory Council
PA	pharmacist's assistant
PLWHIV	people living with HIV
PSN	Pharmaceutical Society of Namibia
RMU	rational medicine use
SIAPS	Systems for Improved Access to Pharmaceuticals and Services
SOP	School of Pharmacy
STG	standard treatment guideline
TAC	Treatment Advisory Committee
TB	tuberculosis
TC	Therapeutics Committee(s)
UNAIDS	United Nations Programme on HIV/AIDS
UNAM	University of Namibia
USAID	US Agency for International Development
WCH	Windhoek Central Hospital
WHO	World Health Organization

ACKNOWLEDGMENTS

The workshop organizers and the authors of this report thank the US Agency for International Development (USAID)-funded Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program for supporting the workshop and stakeholders' forum on containing antimicrobial resistance and promoting rational medicine use in Namibia. The team is equally grateful to the University of Namibia, School of Pharmacy and the Ministry of Health and Social Services Division of Pharmaceutical Services (Div. PhS) for the efforts put into preparations that ensured success of the workshop and forum. Thanks also to the UNAM and SIAPS administrative staff for their contribution to the success of the workshop. We also acknowledge all participants for the enthusiasm and active participation in the workshop.

EXECUTIVE SUMMARY

Rational medicine use (RMU) and prevention of antimicrobial resistance (AMR) are vital components of ensuring efficient, safe, and cost-effective health service delivery. In Namibia, the role of the university and academia in general in ensuring availability of medicine-related research is pivotal in supporting the Ministry of Health and Social Services (MoHSS) to implement interventions based on evidence.

This activity included a workshop and a stakeholders' forum to raise awareness of RMU, develop action plans to combat the emergence of resistance against antimicrobials, and mobilize consensus through a call to action. The specific objectives were to:

- Enhance awareness
- Mobilize stakeholders for a common goal
- Increase availability of evidence
- Agree on a call-to-action on RMU and prevention of AMR in Namibia

The University of Namibia (UNAM) School of Pharmacy (SOP) did an excellent job of coordinating the training. The key achievements of this activity included training and raising the awareness of more than 60 students, health workers, and allied health professionals and mobilizing key stakeholders. As a result of these efforts, the course was accredited by the Health Professionals Council of Namibia. Therefore, academicians and health workers from UMAN, MoHSS, and the private sector have been engaged in improving RMU and preventing AMR in Namibia.

The call to action and action plan developed and agreed upon by stakeholders will serve as key documents in the implementation of activities to improve RMU in Namibia. Through these achievements, UNAM is in a good position to continue coordinating RMU and AMR activities and to develop activities that will enhance operational research on antibiotics and antivirals in health facilities in Namibia.

UNAM and other stakeholders have agreed upon their roles and responsibilities, and with continued support from UNAM and MoHSS, the call to action will be disseminated and activities implemented as proposed in the action plan.

BACKGROUND

Namibia has adopted the public health approach to scaling up antiretroviral therapy (ART) that involves the use of standardized and simplified treatment regimens. Drug resistance (DR) to antiretroviral (ARVs) medications is inevitable in populations on life-long ART. Namibia is one of the three countries in Africa (in addition to Botswana and Rwanda) that has reached 80 percent coverage for ART[1] (Joint United Nations Programme on HIV/AIDS - UNAIDS, 2011). By June 2013, 100,000[2] public sector patients were on ART in Namibia and this number continues to grow. MoHSS continues to increase access to ART by decentralization and adoption of the 2013 WHO guidelines on the management and treatment of people living with HIV (PLWHIV). Namibians continue to have access to medicines for managing a variety of conditions including tuberculosis (TB) and other communicable and non-communicable diseases. In ensuring availability and access to these safe, efficacious, and cost-effective antibiotics and antivirals for a large population of patients, it is important to improve rational use medicines to prevent and minimize the risk of AMR.

To minimize the development of HIV DR, the focus should be on early detection factors associated with increasing the risk of DR (e.g., associated with prescription patterns, adherence to ARVs) and implementation effective interventions to minimize the impact of these factors. The challenges of HIV and AIDS management are not unique to Namibia, but are similar to the management of other health issues and medicines including—

- Insufficient capacity to coordinate and support RMU activities, particularly the lack of capacity to generate evidence (through operational research) on the burden and risk of AMR
- Limited local evidence on evaluation of practices and interventions that increase awareness or advocate for prevention of AMR
- Limited advocacy for and coalitions on RMU and AMR, thereby limiting opportunities for discussions and for enhancing awareness and training
- High prevalence of multidrug resistant (MDR) and extensively resistant TB in Namibia

In recognition of the challenges, MoHSS and its partners have put in place a number of interventions including—

- Development and implementation of the HIV/AIDS early warning system to detect and prevent HIV DR
- Formation and use of a multidisciplinary coalition of professionals to strengthen advocacy (Namibians Against Antimicrobial Resistance [NAAR])
- Optimisation of the partnership with UNAM, which provides a great opportunity to enhance operational research and availability of evidence for decision making

[1] Joint United Nations Programme on HIV/AIDS - UNAIDS. (2011). World AIDS Day Report. Geneva: UNAIDS.
[2] Mugala-Mukungu, F. (2012). Antiretroviral Therapy in Namibia. SA HIV/AIDS Conference. 25-28 November 2012

- Strengthening the analysis and use of antimicrobial sensitivity data for decision making

- Establishment of the Therapeutics Information and Pharmacovigilance Centre (TIPC) to enhance awareness and facilitate the generation and use of medicine-related evidence

Purpose of this Activity

Containing AMR is a key focus of the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program in Namibia. SIAPS proposes to work with UNAM SOP, MoHSS, and other stakeholders to strengthen local initiatives and networks to help prevent the development and spread of resistance to ARV, anti-TB, and other antimicrobial agents.

In view of the challenges and measures put in place by MoHSS and partners to minimize DR in Namibia, SIAPS has supported UNAM SOP in two key activities to:

- Organize and conduct a national workshop on promoting rational use of ARVs and other medicines

- Establish an International Network for Rational Use of Drugs Namibia chapter at UNAM SOP and engage key stakeholders in developing and implementing an effective strategy to reduce the risk of AMR in Namibia

The overall objectives are to build institutional capacity for UNAM to deliver this training and other pharmaceutical trainings and for UNAM SOP to become a pivotal resource for conducting, analyzing, disseminating, and coordinating operational research activities on RMU and AMR. This activity and subsequent interventions all lead to RMU and AMR-related operational research activities by UNAM SOP and other stakeholders.

Key opportunities—

- Develop a platform for advocacy and technical assistance to establish a coalition of interested stakeholders that are committed to discussing and implementing an array of interventions to reduce the negative impact of irrational use of medicines in Namibia

- Develop and adapt SIAPS in-service AMR curriculum and related training materials for a pre-service training module in the UNAM SOP

Expected Results of this Activity

- Increase in the number of health care workers (HCWs) who successfully complete an in-service training on strategic information (monitoring and evaluation, surveys, surveillance, evaluations, health information systems)

- Holding of the stakeholders forum

- RMU and AMR training accredited by the Health Professionals Council

- Incorporation of RMU and AMR training in the pre-service curriculum of the bachelor of pharmacy program

To prepare and facilitate the workshop, the following activities were carried out—

- Training materials for a workshop and stakeholders' forum were revised and adapted.

- The UNAM SOP team was oriented and guided on the purpose and opportunities of training and the stakeholders' forum. The SOP team was also supported on how best to accomplish their role as the lead in conducting the workshop and stakeholders' forum. Key RMU and AMR stakeholders in Namibia were identified and mobilized to effectively participate in the discussions.

- Provide structured follow-up of the action plan activities.

SCOPE OF WORK FOR THE WORKSHOP AND FORUM

SIAPS/Namibia FY13 Work Plan Activity

This activity is in SIAPS Namibia's approved work plan and focuses on providing technical assistance to increase UNAM's and the National Health Training Centre's (NHTC) capacity to conduct pharmaceutical-related operational research. (NHTC is a MOHSS pharmacists' assistants' training institute network.) This research will enhance availability of locally generated evidence that will guide decision making on the rational use of ARVs and other medicines and the use of metrics to monitor the performance of the pharmaceutical sector in the delivery of services in Namibia.

This activity is to build capacity of UNAM SOP to coordinate and support RMU activities in Namibia. The activities include generating evidence through operational research on the burden and risk of AMR, evaluating the results of AMR interventions, assessing clinician compliance to treatment guidelines, advocacy, coalition building and providing training in RMU/AMR, and the effective management of therapeutics committees. Additionally, UNAM's increased capacity will support MoHSS in routine indicator monitoring of the quality of pharmaceutical services, such as—

- How many patients report being satisfied with the information they received about their medications
- How many patients know correct information about their medications
- How many treatment sites implement good standards for dispensing medicines
- How many prescriptions are in compliance with current standard treatment guidelines (STGs)
- How many patient encounters result in an antibiotic being prescribed

Specific Tasks

This training focused on promoting the rational use of ARVs and adherence to ARVs/anti-TB medicines. The overall goal is to establish research capacity at UNAM to provide ongoing performance monitoring of the pharmaceutical service delivery. SIAPS facilitated this workshop using the principles of developing a national forum and agenda for addressing RMU issues and investigating medicine use problems. These principles include identification and mobilization of stakeholders, identification of a national champion to facilitate this process, development and agreement on a call to action and drafting of an action plan. The specific tasks included—

- Supporting UNAM SOP to organize and conduct a national workshop on promoting RMU that covered—
    - Appropriate antimicrobial (including ARVs) use and prevention of AMR
    - Proper techniques on investigating problems related with the use of ARVs and other medicines

  - HIV DR early warning indicators (EWIs)
  - Strategies for remedying the identified medicine use problems
  - Strengthening therapeutic committees in control of the use of antimicrobials, strengthening patient adherence to prescribed ARVs and other medications, and promoting clinicians' compliance with treatment guidelines

- Providing a platform for advocacy and technical assistance in establishing the International Network for Rational Use of Drugs Namibia chapter at UNAM SOP, including engaging with key stakeholders such as relevant MoHSS divisions, the pharmaceutical and medical professional bodies, Namibia Institute of Pathology, and NAAR

- Developing and adapting SIAPS in-service AMR curriculum and related training materials for a pre-service training module at UNAM SOP, School of Medicine, School of Nursing, and NHTC

Deliverables or Products to be Developed

- Technical report and an action plan to combat AMR in Namibia
- Draft module for pre-service training on RMU/AMR

GOALS, OBJECTIVES, AND SUMMARY OF THE WORKSHOP AND FORUM

Workshop Theme: Advocacy and Containment of AMR in Namibia

Goal

This workshop was to raise awareness of RMU, develop action plans to combat the emergence of resistance against antimicrobials, and mobilize consensus through a call to action.

Specific Objectives

- Enhance awareness of rational use and AMR to antibiotics and ARVs
- Mobilize stakeholders for a common goal of reducing the risk of AMR in Namibia
- Increase availability of evidence on AMR and rational use and enhance use of this evidence in decision making
- Agree on a call to action and developing an action plan or agenda for preventing and building momentum for AMR activities in Namibia

Workshop and Forum Proceedings Summary

Several collaborative preparatory meetings were held for the workshop and stakeholders' forum. Key stakeholders involved included UNAM SOP, MoHSS Div. PhS, and NAAR. The workshop and forum were held at UNAM SOP. A total of 66 individuals attended, including academicians (lecturers) from UNAM, administrators from MoHSS, and HCWs from public and private facilities. The workshop participants were physicians, pharmacists, nurses, and other allied professionals critical in the prevention of AMR (for agenda and content of the workshop, refer to annex C).

SUMMARY OF SESSIONS

The workshop was officially opened by Prof. Peter Nyarang'o, Dean, Faculty of Health Sciences, and Founding Dean, School of Medicine, University of Namibia. In his remarks entitled "Guilty as Charged," he emphasized the fact that as much as health workers save lives, they are guilty of misusing medicines, which results in AMR and increases the risk of morbidity. Health workers should therefore take the responsibility to put in place measures to minimize the risk of AMR and enhance the achievement of health outcomes of reduced morbidity and mortality. He called on participants to change individual practices and improve health care delivery, saying that, "We need multiple approaches— technical, professional behavior, and political action."

Table 1. Session Summaries

Session title	Objectives	Summary of the session
Day 1		
Global Challenge of Irrational Use of Medicines	• Provide an overview of the extent and nature of inappropriate use of medicines • Discuss irrationalities pertaining to the use of antimicrobials, including those used in the treatment of HIV/AIDS and TB • Understand the adverse impact of inappropriate use of medicines • Identify factors underlying the irrational use of medicines	The presentation showed that the problem of irrational use of medicines, particularly antimicrobials—including but not limited to anti-TB and ARV medicines—is a challenge in a number of countries. It was shown that AMR is one of the major effects of irrational use of antimicrobials. The presenter also showed that irrational use of medicines emanates from problems with medicine supply, poor quality of medicines, and health system problems, such as failure to implement STGs. What the audience learned from this presentation: • Irrational use of ART and TB medicines is not expected as their management involves only a limited number of medicines, but it has been observed. • Namibia has data that can be analyzed to generate recommendations for policy makers and prescribers, but it is not being analyzed. • The consequences of irrational drug use are far reaching, for example, in the area of increased cost of medicines for management of drug-resistant TB. • EWIs are essential for the monitoring of outcomes of ART programs.
Understanding Medicine Use Problems	• Describe the process of identifying and changing medicine use problems • Identify and evaluation sources of quantitative and qualitative data • Understand the importance of studying provider and patient motivations • Introduce qualitative research methods	The presenter explained the components of the drug use system, understanding these components exposes the areas where medicine use interventions can be targeted. He presented the systematic implementation of medicine use evaluations (MUEs) with detailed discussion in the following areas: measurement of existing practices, identifying the specific problems and causes, designing and implementing intervention; and assessing change in outcomes. Furthermore, he explained quantitative and qualitative methods in MUEs. He stressed that qualitative methods are crucial as they answer the question “why.” In response to questions: • **On MUEs for antibiotics:** it was advised that 30 prescriptions of antibiotics provide a sample that can be analyzed, as long as the selection of prescriptions is not biased. • **On which source to depend for selection of antibiotics:** he shared that MoHSS has produced STGs, which have medicines that are in tandem with the Essential Medicines List (EML). But he also emphasized that laboratory results on sensitivity of organisms affecting the patient should be a guiding factor. • **On the life-span for the EML:** the discussion highlighted the need for evidence that will be used to design the EML and the lifespan of the EML varies from two to five years depending on the number of changes in the global and local guidelines.

Session title	Objectives	Summary of the session
Interventions to Change Medicine Use Problems	• Provide an overview of the strategies and interventions that can be utilized to address medicine use problems • Discuss education, managerial and regulatory methods to improve use of medicines • Discuss strategies to encourage RMU in the treatment of HIV/AIDS and TB	The presenter highlighted the need for a multipronged approach as a means for realizing strategies to combat AMR. Particularly, he emphasized each of the four strategies that were designed by Management Sciences for Health (MSH) and WHO, including education, managerial, economic, and regulatory. He suggested that for TB and HIV the following interventions are necessary: update ART guidelines, advocate for newer and better ARVs and formulations; use of fixed-dose combinations, rationalization of regimens, minimization of variability on medicines due to supplier differences in the medicines provided, and promotion of treatment literacy.
Day 2		
Evaluating Changes in Medicine Use Practice and Medicine Use Related Outcomes	• Provide detailed information on the concepts and process of conducting a medicine use evaluation • Describe MUE as a mechanism that contributes to quality assurance and continuous quality improvement	The presenter emphasized that the key to successful initiation of an MUE is to have buy-in from management and to have the MUE sanctioned by the TC. The presenter also pointed out that MUEs are audits of medicine use practices, and because they are a kind of audit, if they are not carefully planned and implemented, they have potential to cause unnecessary anxiety. It was emphasized that the MUE is not a fault finding activity, but rather a quality improvement process. Thus the interventions target a system. On the other hand, it was noted that the interventions may target an individual. The bottom line of the presentation was to emphasize that the MUEs should be implemented in a stepwise approach, should be consultative and should avoid unnecessary anxiety.
Overview of AMR and Interventions Recommended to Contain AMR	• Provide an overview of AMR, including its causes and impact, around the world and in Africa, • Give an overview of the problem of drug resistance in HIV and TB • Provide the key interventions recommended for containment of AMR in the 2011 World Health Day AMR Policy Package • Provide a brief overview of interventions recommended to contain HIV and TB DR	The presenter talked about how resistance to antimicrobials develops. He pointed out that the major cause for AMR is human practice, especially in countries where medicine regulation is absent or poorly implemented.
Using Indicators to Monitor HIV DR	• Sharing successful implementation of the early warning indicators of HIV DR in Namibia	

Key Stakeholders and Roles in RMU and AMR Prevention and Containment

Through group work, participants enlisted stakeholders and the roles that they should play in the prevention/containment of AMR in Namibia and promotion of RMU (table 2).

Table 2. Stakeholders and Their Roles in Containing AMR in Namibia

Intervention areas	AMR to antibiotics in general	HIV DR	TB DR	RMU in general
Stakeholders				
	MoHSS, National Medicines Regulatory Council (NMRC), UNAM, HPCNA, NAAR, medical associations, Pharmaceutical Society of Namibia, veterinary services, National Institute of Pathology (NIP), PathCare, private sector, Ministry of Defence, USAID,CDC, WHO, development partners, MSH, medical aid companies	CDC, USAID, Catholic AIDS Action (CAA), Church Alliance for Orphans (CAFO), Development Aid from People to People (DAPP), MoHSS, Global Fund, UNAM, NIP, private practitioners	MoHSS, UNAM, HCWs, KNCV TB Foundation-Netherlands, community TB implementing partners, HPCNA, NIP, Central Medical Stores (CMS), media, HIV-Technical Advisory Committee (TAC), Namibian Alliance for Improved Nutrition	PathCare, NIP, nongovernmental organizations (NGOs), prescribers, UNAM, NHTC, media, dispensers (pharmacists, physician assistants, and nurses), MoHSS (CMS), private suppliers, community, medical representatives
Roles of Stakeholders				
Educational	• UNAM–through research, continuing professional development (CPD)/ training • Development partners–providing funds to support strategies including training • MoHSS/NHTC–training • MoHSS TIPC–disseminate information	• Evidence: pharmacy – research to generate evidence, NIP, UNAM • Operations: MoHSS, Red Cross, UNAM (training HCWs)	• UNAM–capacity building • HCWs–RMU, diagnosis, and infection control	• Training institutions • Prescribers and dispensers through patient education • Research–education takes place during research (sharing information)
Managerial	• MoHSS—publication of guidelines • Private sector		• NTLP–policy development, training, mobilisation of funding, case tracing • MoHSS–providing infrastructure and human resources • CMS–procuring medicines	• Making guidelines available and ensuring that the users understand the guidelines (guidelines should be user friendly). • Availability of medicines in accordance with the guidelines
Regulatory	• HPCNA • NMRC • SIAPS–providing technical support to NMRC • Medical aid funds • Development partners–providing technical assistance to MoHSS		• HPCNA–policy enforcement • NMRC–regulation, registration	• EML and STGs to guide on medicine selection • Enforcing adherence to guidelines • On-going supervision and monitoring and evaluation • Recruiting qualified professionals

Intervention areas	AMR to antibiotics in general	HIV DR	TB DR	RMU in general
Economic	• Development partners–funding and technical assistance • MoHSS–funding • Private sector			
Advocacy	• NAAR • Medical associations • Interest groups (clients)	• CDC (e.g., on DR and operational research), NGOs, MoHSS (surveillance)		
Support services	• NIP–providing laboratory data on sensitivity patterns of microbes from patient samples			
Future Plans				
Research and education	• Research: determine the current status of sensitivity patterns • Collaboration of all stakeholders	• Operational research on factors associated with DR • Prevalence of HIV DR (evidence) • WHO on monitoring and implementing resistance containment strategies (evidence) • Evidence for adherence to guidelines (operations)	• Reduce new infection—through research and providing infrastructure; intensive case finding; and IPT • Community education	• Opinion leaders: important for educating the community • Media–through sending out messages on drug use to patients • CPD through regulatory bodies
Managerial	• Production of antibiotic guidelines (one already designed) • Production of Namibian formulary	• Implementation of new HIV guidelines (operations)	• Strengthen direct observed therapy	• Involve politicians/parliamentarians • Put operational research evidence into practice • Check laboratory analysis data for correctness and to ensure quick turnaround of results to clinicians • Provide incentives to the best performing hospitals in terms of containing AMR
Advocacy		• Funding for operational research (advocacy) • Awareness of guidelines and resistance patterns (advocacy)		

NAMIBIA AMR/RMU ACTION PLAN

Participants were randomly divided into four groups and assigned questions to guide discussions towards developing action plans. The group discussions were followed by reporting back in plenary (table 3).

Table 3. The AMR/RMU Activities Action Plan

Intervention area	Activity	Institution responsible	Timeline (month and date, if possible)	Key contact for follow up
Managerial	Increase availability of Namibia STGs to prescribers (with the option of putting them on sale, e.g., at the Health Professionals Council)	MoHSS/Div. PhS, SIAPS	December 2013	Kennedy Kambyambya (MOHSS), Evans Sagwa (SIAPS)
	Antibiotic guidelines: disseminate to all facilities	NAAR	August 2013	NAAR
	Conduct orientation/ training on the guidelines	NAAR (with support from SIAPS)	March 2014	
	Update the antibiotic guidelines as necessary	NAAR	Ongoing	
	Develop Namibia anti-biogram	NIP, UNAM (faculty of health sciences), MoH, Div. PhS, development partners	March 2014	Dr. M. Adorka (UNAM), Emmanuel Ugburo
	Develop national formulary	NMRC; representation from district, regional TCs; NIP; development partners, e.g., USAID	January 4, 2014, to March 3, 2015	Rauma Shitaleni
Advocacy/ communication strategies	Form a coalition to regularly review and coordinate RMU and AMR-related issues; coalition should: • Organize regular (quarterly?) meetings of stakeholders • Coordinate AMR-related activities at health facilities	UNAM	In progress—first workshop July 2013	Dean, SOP
	Generate evidence for advocacy in engaging medical aid funds and Namibia Medical Aid Funds (NAMAF) in developing measures to support appropriate usage of medicines	NAAR, UNAM	October 2013–June 2014	NAAR
	Hold a stakeholders' forum focusing on private sector and use of antimicrobials		October 2013	

Intervention area	Activity	Institution responsible	Timeline (month and date, if possible)	Key contact for follow up
	Design and implement effective communication on AMR and RMU targeting the public—media involvement	NAAR, UNAM		NAAR
	Use existing forums—doctors and dentists – to promote a call to action for AMR advocacy and containment.			UNAM, NAAR, MoHSS
	Involve and engage patients and community, consumer organizations (patient groups: PLWHIV, diabetic association, cancer patient groups) to advocate for RMU in community and home settings	UNAM, MoHSS, SIAPS	October 2013 to March 2014	Positive Vibes, Namibia Business Coalition, Namibia Network of AIDS Support Organisations, and other PLWHIV groups to be identified
Quality improvement evaluations	Enhance RMU and AMR-related operational research	TCs		Div. PhS MoHSS
	Promote MUEs at health facilities (target is 4 in a year) focusing on referral and other hospitals which are already working on MUEs	UNAM	Ongoing in 2014	UNAM, MoHSS
	• Conduct a baseline assessment of compliance to medicines prescribed for inpatients in the Medical Wards at Katatura Intermediate Hospital; implement suitable interventions based on findings	MoHSS	September 2013 to December 2013	Dr. Yana, Katatura Hospital, with support from UNAM/SIAPS
	• Conduct baseline assessment on RMU at Katutura Hospital			Nobesuthu Sibanda, Katatura Hospital, with support from UNAM/ SIAPS
	• Conduct a baseline assessment on rational use of antimicrobials in gynaecology ward at Windhoek Central Hospital (WCH); implement suitable interventions based on findings			Sr. Kanana (WCH) with support from UNAM/ SIAPS
	AMR data from NIP should be requested and available to the coalition (through UNAM) for analysis and dissemination of results to all stakeholders so that feasible interventions can be developed	NIP, UNAM		UNAM, MOHSS
	Disseminate findings on performance in RMU-related indicators in pharmaceutical management information system	MoHSS/Div. PhS	Ongoing	Kennedy Kambyambya (MOHSS)
HIV/DR monitoring (analyze and disseminate)	• HIV DR monitoring and containment • Disseminate results of HIV DR surveys and EWI data abstraction to stakeholders and support targeted interventions	MoHSS/DSP, Response Monitoring and Evaluation (RM&E), Div. PhS, SIAPS	September 2013	Anna Jonas (MOHSS), Victor Sumbi (SIAPS)

Intervention area	Activity	Institution responsible	Timeline (month and date, if possible)	Key contact for follow up
Education (training)	Incorporate/review the current curriculum content (topics, teaching materials) to incorporate AMR/RMU of ARVs, anti-TB, and other medicines; facilitate training of RMU courses in SOP and other schools at UNAM including Schools of Medicine and Nursing and CPD course for practitioners	UNAM, HPCNA	December 2013	Dr. Tim Rennie, Associate Dean, SOP
	• In-service training on AMR/RMU for health care workers at regional level • Target: public and private practitioners	MoHSS (Div. PhS) with partner support, HPCNA	November 2013	Mr. Indongo Lazarus, Deputy Director, Div. PhS (MoHSS)
	Reactivate and retrain TCs on MUE		February 2014	Mr. Indongo Lazarus, Deputy Director, Div. PhS (MoHSS), with chief medical officer
	In-service training on infection control retraining (innovative interventions to promote good infection control practices)	NAAR, UNAM	March 2014	

STAKEHOLDERS' MEETING, JULY 24, 2013

The stakeholders who participated in this forum included the deputy permanent secretary – MoHSS, the dean of the faculty of Health Sciences, lecturers from the School of Medicine and the School of Pharmacy, staff from the MoHSS Div. PhSs and Division Tertiary Health Care and Clinical Support Services, MoHSS Division Primary Health Care, HCWs from tertiary hospitals in Windhoek, regional pharmacists, and representatives from the Pharmaceutical Society of Namibia and Health Professionals Council of Namibia.

Opening Remarks

Prof. Peter M. Nyarang'o, Dean, Faculty of Health Sciences and Founding Dean, School of Medicine – Reasons for resistance are associated with the practice of professionals, poverty, and increased access of medicines where medicines regulation is poorly implemented or is absent. The medical school welcomes the AMR forum so that the students are trained into understanding that as much as they can save lives, through their irrational practices they can destroy lives and they need to conform and maintain standards of care so as to avoid AMR.

Dr. Norbert Forster, Deputy Permanent Secretary, MoHSS – The Ministry was very happy about the forum. The Ministry is much aware of the problem of DR and is aware of the devastation that is caused by the lack of effective interventions to detect and prevent the irrational use of medicines and AMR. Irrational use of medicines has a serious negative impact on HCWs, families, and communities. Therefore, the armamentarium against resistance needs to be sustained. There is an urgent need to raise awareness of RMU and AMR and the need to stay ahead of the organisms to contain the emergence of AMR.

Panel Discussion

The panelists included Prof. Nyarang'o; Dr. Sinyinza Fredrick, lecturer, School of Medicine, Pediatrics Department, UNAM; and Dr. Steven Hong, Assistant Professor of Medicine, Tufts University School of Medicine. Dr. David Mabirizi moderated the session.

- Dr. Hong discussed his experiences in implementing EWIs in Namibia and other low-resource settings, the challenges met, and the way forward. With technical assistance from Dr. Hong, MoHSS started work related to EWIs in 2009. Dr. Hong led a pilot study for EWIs at nine sites in Namibia. Namibia has a good record system for maintaining medical records on delivery of HIV and AIDS services. They abstracted EWI data, analysis of which revealed a positive public health effect of monitoring EWIs and implementing targeted interventions to minimize the risk of DR. The information generated was published and used by WHO in designing the new EWIs.

  When asked about the challenges observed in the implementation of EWIs, Dr. Hong said that there were no issues seen in terms of prescription and dispensing practices for first-line ARVs, and that the dispensing practices were generally good. The problem area that was identified was the loss to follow up—the unknown outcomes of ART. These are considered problems as these patients have a high risk of developing resistance. Therefore, it is necessary to intensify efforts to trace patients lost and lost to follow-up to

get them restarted on treatment. Sites were encouraged to optimize use of their data. Increasing facilities' access to the national database is essential as the facilities will be able to identify patients who are still in care but at different facilities.

- **Dr. Sinyinza Fredrick** discussed his experience in using electronic tools used in MoHSS facilities, such as the Electronic Data Tool, and the Electronic Patient Management System (ePMS) and what should be done to improve these electronic information systems. Namibia like other countries in sub-Saharan Africa has enrolled a large number of patients into the ART program. Introducing these electronic tools in Namibia has enabled the MoHSS to identify the number of patients enrolled and to follow up the patients who could be "lost to follow-up." However, there has been a problem with data entry—some data clerks have not been trained or have limited experience on entering data. Also, some data-related problems led to overestimates of enrolled patients, such as those on second-line ART. These errors need to be corrected through first, data validation exercises and secondly, improved sharing of results of the ART patterns. These ART patterns should be shared with health facilities so that health workers can appreciate the importance of accurate and timely data in decision making to improvise service delivery.

- **Prof. Nyarang'o** led a home-based care intervention in Kenya. The university that implemented this activity created a modern laboratory at the medical school. The laboratory was able to provide results and advanced studies with a short turn-around time, which encouraged the use of laboratory results in the management of patients and one of the first home-based care ART programs. The laboratory needs to be public health oriented. While NIP is effective in terms of providing laboratory results, it is not public health oriented an aspect that needs attention.

Discussion

What is the association between EWIs and HIV DR? Can this model be used for TB and other antimicrobials?

- **Dr. Hong**: there is a guidance document from the 2012 meeting in Geneva that looks at the relationship between the EWIs and DR that has resulted in a justified focus on dispensing practices as a cornerstone for the detection and prevention of HIV DR. Key indicators include prescription/dispensing practices; retention into care; on-time pill pickup; and availability/ stock outs of ARVs.

- **Dr. Sinyinza**: distance from facility and congestion at the facility were some of the reasons why patients missed appointments. Outreaches were created by the MoHSS to enable patients to attend clinics that near to their homes. They agreed and there was improvement in terms of reduction in loss to follow-up. However, the major problem was lack of highly qualified health care workers at the facilities. Getting a patient from the private sector was challenging. Patients moved to the south of Namibia to work on vineyards. Patients would be given medicine for 6 months to cover the time they spend in the south. They used NGOs to trace patients in the community—total control of epidemic (TCE) funded by USAID.

- **Dr. Basenero** informed the forum that the HIV Qual programme developed a curriculum and trained HCWs to identify challenges and to design interventions to improve the

quality of ART services. Every six months regions come together and share challenges. Some facilities struggling with loss to follow up have come up with interventions to reduce the number of patients lost to follow up.

Final Comments from Panelists

- **Dr. Hong:** Namibia has successfully rolled out ART, with the most eligible people being treated. The challenge is to continue to deliver ART without drug resistance. WHO has provided good guidance. The current approach to monitoring EWIs requires nationally representative data on drug resistance and that is the direction Namibia is taking.

- **Dr. Sinyinza:** A patient with TB and HIV, found it difficult to attend to both clinics. An intervention helped patients with TB and HIV to attend both clinics on the same day which reduced the need for patients coming to the clinic on separate visits to access medicines for the two conditions. This intervention contributed to a reduction in the loss to follow-up.

- **Prof. Nyarango'o:** The home-based care initiative in Kenya has progressed to include non-communicable diseases in the home-based care program, providing primary health care. These models should be revisited and reviewed to identify opportunities for applying these strategies in Namibia.

- **Moderator (David):** The gaps seen have focused on adults; pediatric patients should be included in all our discussions and interventions to reduce the risk of AMR.

THE CALL TO ACTION

The Namibia AMR/RMU Call to Action – July 2013

Republic of Namibia

Ministry of Health and Social

Call-to-Action for Antimicrobial Resistance Advocacy and Containment in Namibia

July 2013

Infectious diseases kill 11 million people around the world every year, 95 percent of whom live in resource-constrained settings. The major life-saving intervention for infectious diseases is antimicrobial treatment; however the problem of antimicrobial resistance (AMR) is rapidly reducing the effectiveness of these life-saving medicines. AMR is a steadily increasing global public health threat that impacts all public health diseases of major significance, including HIV, TB, and malaria. When compared to drug-susceptible infections, drug-resistant infections result in a 1.3 to 2-fold increase in morbidity, mortality, and cost[3]. Other related consequences include prolonged infectiousness, increased risk of transmission of resistant pathogens, extended hospital stay, use of more expensive second- or third-line medicines, reduced productivity, and financial hardships.

Resistance to antimicrobials often develops as a result of poor prescribing and dispensing practices, inappropriate use by patients, and poor medicine quality. Furthermore, weak systems for pharmaceutical management, poor infection prevention and control practices, and inadequate regulation contribute to AMR.

Enhanced availability and use of evidence generated through research, effective advocacy through coalition-building at various levels, and implementation of prioritized containment interventions are vital for an organized, coordinated, and sustained response to the challenge of AMR. AMR is a complex, multi-faceted problem that necessitates a multi-faceted approach. Much is already known about AMR and a number of interventions and tools are available to address and correct factors contributing to AMR, as outlined in the *World Health Organization Global Strategy for the Containment of Antimicrobial Resistance*[4]. Several activities that support AMR containment have been implemented in Namibia: however several gaps remain but at the same time various opportunities also exist to strengthen and enhance a more integrated approach to AMR containment. We must communicate to share expertise, experience, lessons learned, best practices, and resources.

We, the participants of this *workshop on antimicrobial resistance and promoting the rational use of ARVs, anti-TB and other medicines in Namibia* (held at the University of Namibia School of Pharmacy in Windhoek from July 22 to 24, 2013), represent various institutions and stakeholder groups involved in health care in Namibia. We recognize and commend the actions by various local, national and international players in the fight against AMR and view AMR containment as our collective

[3] Cosgrove SE and Y Cameli. 2003. The impact of AMR on health and economic outcomes. *Clinical Infectious Diseases*. 36:1433-1437

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

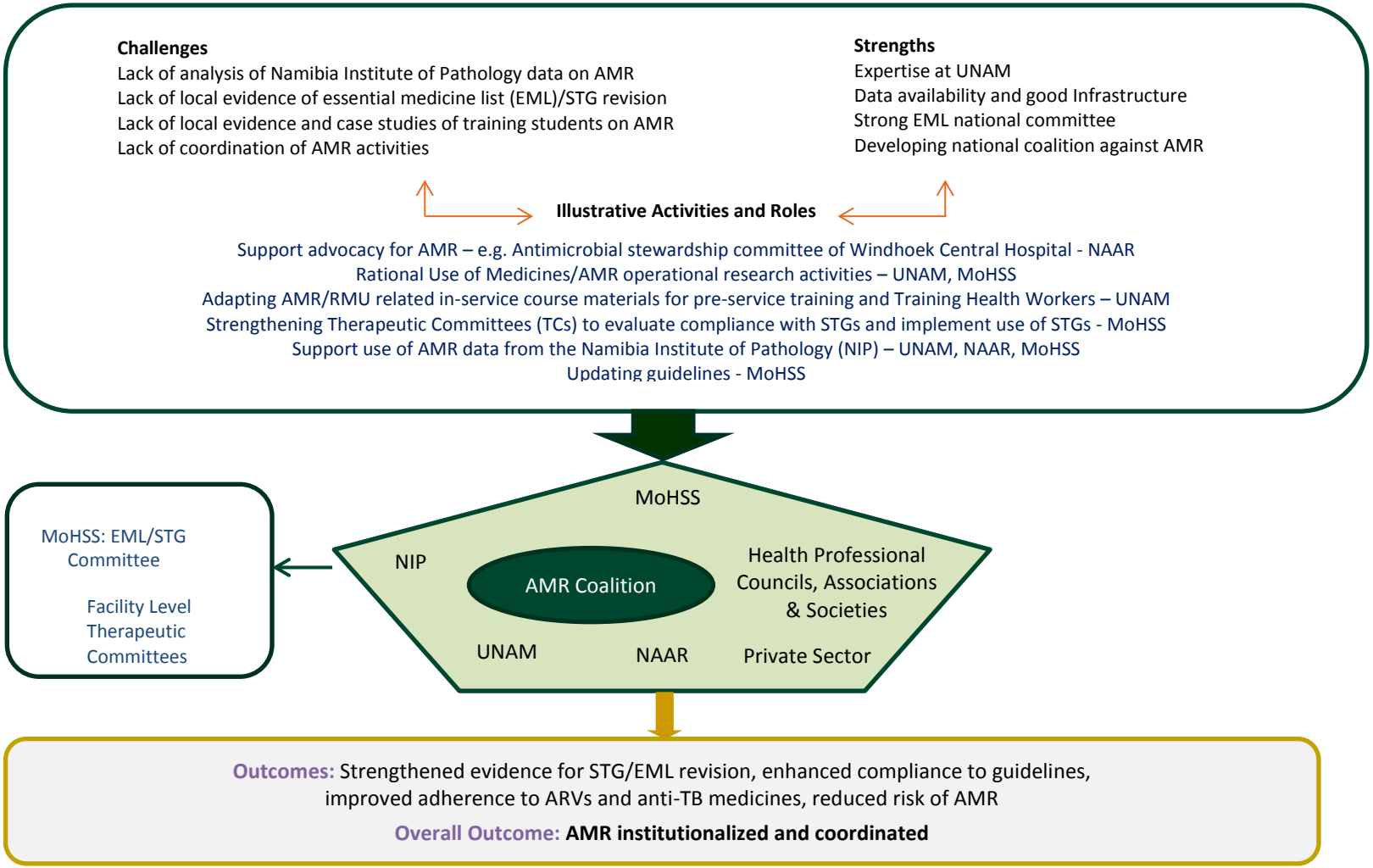
responsibility. We hereby call for action from all stakeholders, including government, academia, regulatory authorities, professional associations, donor agencies, civil society, media personnel, and industry to forge strong alliances to minimize the risk of AMR in Namibia.
We commit ourselves to –

- ✓ *Creating a national movement to enhance capacity, increase evidence on antimicrobial use, raise awareness about AMR, and support implementation of effective interventions*
- ✓ *Enhancing the engagement of patients and caregivers in making informed choices on adherence to treatment plans through treatment literacy and other interventions*
- ✓ *Supporting ongoing efforts to reduce the risk of HIV drug resistance in Namibia, including implementation of HIV drug resistance early warning indicators, treatment guidelines, and treatment adherence*
- ✓ Broadening the focus *to include antimicrobials for TB, opportunistic infections, and antibiotics in general-use*
- ✓ *Increasing private sector engagement* and collaboration with the public sector on Rational Use of Medicines/Antimicrobial resistance
- ✓ *Strengthening collaboration between medicines use interventions and laboratory services*
- ✓ *Increasing support for community based interventions on appropriate use of medicines*

If we do not act now to preserve the effectiveness of antimicrobial medicines, the health and prosperity of current and future generations will suffer. We make this call-to-action to all the players to join hands against this common threat and collectively work to engage new partners, strengthen collaboration with existing partners, and advocate for AMR as a local and national priority in Namibia.

AMR INTERVENTION MODEL FOR NAMIBIA

Figure 1. Proposed approach for advocacy and containment of AMR in Namibia – July 2013



WORKSHOP EVALUATION, KEY COMMENTS, AND RECOMMENDATIONS

Table 4. Participants' Evaluation of the Workshop

Level of satisfaction	
Parameter	**%**
The information in this course will be helpful in my work	86
The objectives were clearly defined at the beginning of the training course	93
The amount of material covered in 2 days was appropriate	86
The defined objectives were achieved by the end of the workshop	92
The depth of coverage of the material in the workshop was appropriate	82
Overall, I would say the quality of the instruction was good	89
Overall, the workshop met my expectations	82
Communication of information to the participants before the workshop	71
Running of the workshop	86
Overall satisfaction with the workshop materials and visual aids	96
Overall satisfaction with the length of the workshop	86
Overall satisfaction with the pace of the workshop	82
Overall satisfaction with the style and format of the sessions	89
Overall satisfaction with the workshop facilities	100
Meals	93
Average	88

A. The three sessions that the participants rated as most relevant to their work or in medical and pharmaceutical education and practice were—

- The global challenge of irrational use of medicines
- Overview of the problem of AMR and the interventions recommended to contain AMR
- Understanding medicine use problems

B. Topics suggested for addition to AMR/RMU related workshops included—

- Overview of AMR
- A global case study and more practice sessions on M&E studies

C. Other suggestions/recommendations

- Greater collaboration with stakeholders including academic personnel and public and private partners to achieve goals
- Include AMR/RMU in the curriculum (e.g., medicine and nursing curricula)
- Invite more prescribers to such workshops
- Organize a forum that focuses specifically on the private sector
- Regular training on AMR, spread to regional levels

D. General comments

Participants stated that the workshop was excellent in terms of content and organisation, and look forward to similar workshops in the future.

Comments from Attendees

In one or two sentences, what is your comment on the AMR/RMU workshop?

"…an eye opener… excellent presentations, clear explanations. Need to look in other categories and organize similar workshops" (*Augustine, infection prevention/control nurse, MoHSS)*

Schedule another ASAP and re-invite those that did not attend... *(Nobesuthu Sibanda, Pharmacist, Katutura Hospital).*

"I think the workshop was very interesting and very important [we now need to work to resolve the problems] and reduce the irrational use medicine. I am very happy I participated in this event. Thanks…" (*Liliam Acosta Amaya, Pharmacist, Intermediate Hospital Katutura).*

"Very well organized… In private practice we do not have a say regarding use of medication. Private GPs and specialists do as they think good while medicine reps play a role [in prescription patterns and rational or irrational use of medicines]. It will be difficult to change [the] behaviours. But the government should get involved put rules in place for both private and public sector. Too few private sector involved in this workshop to make a difference…" *Nurse*

"Highlight the research projects already done as part of presentations. Material well arranged…" (*Doctor, MoHSS)*

"It is very informative. It has made me reflect on my prescribing habits and patterns and I have realized that some practices have to change…" (*Baluti, medical practitioner, Katutura Intermediate Hospital)*

"It is educative, eye opening workshop, which assists health workers to reduce the impact of drug resistance to the patient, themselves, families and community at large. It will also strengthen the roles of the health workers to monitor and evaluate the rational use of medicine. This kind of workshop needs to be done to most health care workers as they are the focal people in reducing the irrational use of medicine…" (*Anna E. Ilanani – Nurse, WCH)*

"The workshop was well organized, the presentation style was simple and interesting, and left me engaged the whole time. Great facilitators with great skills. Information on AMR/RMU concise and clear the handouts and explanations were so much more comprehensive. Thorough discussions of topic with real life examples and experiences made it more real. Thank you so much on the eye opening workshop. I wish the SOM good success in its future endeavors…" (*Hulda Nowases, Nurse, Paramount Hospital)*

"Informative and thought provoking; it is good for students, especially to be exposed to RMU/AMR in practice context, instead of theoretically only" (*UNAM 3rd year pharmacy student)*

"The workshop was very educating. The workshop pointed out the effect of irrational use of medicines and ideas on how to combat this problem." (*UNAM 3rd year pharmacy student)*
"Thought provoking as it made us aware of different points where irrational use of medication can arise" (*UNAM 3rd year Pharmacy Student)*

"Very educative and informative." (*UNAM 3rd year pharmacy student)*

"It was awesome" (*UNAM 3rd year pharmacy student)*

"The workshop was educative, really learned a lot. More of such events should be organized and students, should be allowed to attend" (*UNAM 3rd year pharmacy student)*

"The workshop was very informative and up to date. Provided me as a student with a very specific insight into the AMR/RMU problem we face." (*Louis, UNAM 3rd year pharmacy student)*

"It was educative and a good experience. Learnt new things about AMR/RMU." (*UNAM 3rd year pharmacy student)*

"[It was] very informative and educative." (*UNAM 3rd year pharmacy student)*

"The workshop has been excellent"
"Excellent workshop, nicely paced, very informative"
"Very productive workshop in my opinion"
"Speakers were interesting and highly knowledgeable; the use of experiences and examples made it more real. I cannot wait to attend another one of your workshops

Achievements

- The course was effectively coordinated by the UNAM SOP
- The RMU/AMR modules were accredited by the HPCNa
- Academicians and health workers from UNAM, MoHSS, and the private sector were trained on RMU and AMR—increased awareness
- The stakeholders forum was held and resulted in a call to action which was agreed upon and approved as a key component of the advocacy and future activities
- An action plan for 2013/2014 was developed

Next Steps

- Disseminate the call to action"
- Disseminate the workshop report
- Implement the action plan

ANNEX A. ATTENDANCE LIST

Workshop Facilitators

Name	Designation	Affiliated institution
David Mabirizi	Principal Technical Advisor	SIAPS
Evans Sagwa	Acting Country Director	SIAPS
Dan Kibuule	Head of Department and Lecturer, School of Pharmacy	UNAM
Mathias Adorka	Head of Department and Senior Lecturer, Pharmacology	UNAM
Victor Sumbi	Senior Technical Advisor	SIAPS

Participants of the workshop and stakeholders forum

Participant			Organization/office
Ms.	Anna	Kanana	WCH
Mr.	Anthony	Ishola	UNAM
Dr.	Apollo	Basenero	QA Division
Mr.	Ashton	Nyawo	UNAM
Dr.	Assegid	Mengistu	MoHSS/NMRC
Mr.	Augustine	Kastherody	Intermediate Hospital Katutura (IHK-MoHSS)
Mr.	Benjamin	Ongeri	SCMS
Ms.	Bridget	Kadungure	MoHSS
Ms.	Cherizaan	Willemse	MSH/BLC
Dr.	Dawit	Tsegaye	USAID
Mr.	Emmanuel	Ugburo	MoHSS/Phs
Mr.	Emmanuel	Nepolo	UNAM
Mr.	Emmanuel	Tom	UNAM
Mr.	Evans	Sagwa	MSH
Ms.	Fabiola	Vahekeni	WCH
Mr.	Francis	Kalameera	MoHSS
Dr.	Fredrick	Singinza	UNAM School of Medicine; Paediatrics Department
Mrs.	Harriet	Kagoya	MSH
Mrs.	Hulda	Nawases	Paramount HCC
Prof.	Hunter	Christian	UNAM School of Medicine
Mr.	Immanuel	Naukushu	UNAM
Dr.	Jacob	Sheehama	UNAM
Dr.	Julius	Ojulong	UNAM School of Medicine
Dr.	Julius	Ojulong	UNAM
Dr.	Kani	Herve	MoHSS
Dr.	Kazuvire	Veii	UNAM
Dr.	Kongo	Baluti	MoHSS
Ms.	Liliam	Acosta	IHK
Prof.	Louis	Small	UNAM School of Nursing and Public Health
Dr.	Louis	Theron	UNAM
Prof.	Lyaku	Robert	UNAM Veterinary Campus
Dr.	Lydia	Kabango	
Ms.	Maano	Mika	UNAM
Ms.	Marita	Mann	UOF Washington
Dr.	Matthias	Adorka	UNAM School of Pharmacy
Ms.	Megan	Kassick	TUHS
Dr.	Milly	Morkel	UNAM School of Medicine
Ms.	Mpeza	Kantumoya	UNAM
Mrs.	Nadia	Coetzee	Pharmacy Council

Participant			Organization/office
Ms.	Natu	Mango	UNAM
Ms.	Nobesuthu	Sibanda	Katutura Hospital
Dr.	Norbert	Forster	MoHSS/Deputy PS
Mr.	Paulus	Shindunge	UNAM
Prof.	Peter	Nyarang'o	(Dean) UNAM Faculty of Health Sciences
Ms.	Pia	Simeon	UNAM
Ms.	Pipi	Mataranyika	UNAM
Mr.	Qamar	Niaz	MoHSS/Phs
Ms.	Rahorekau	Kuzatjike	WCH
Ms.	Rauna	Shitaleni	(Regional Pharmacist) Oshikoto
Ms.	Rumbidzayi	Nyaswiswo	UNAM
Mr.	Seth	Nowaseb	UNAM School of Pharmacy
Dr.	Steven	Hong	Tufts University School of Medicine, Massachusetts, USA
Ms.	Tehillah	Mangiza	UNAM
Dr.	Timothy	Rennie	UNAM School of Pharmacy
Dr.	Timothy	Rennie	UNAM
Ms.	Tracy	Schickerling	Paramount
Ms.	Trish	Toga	UNAM
Mr.	Tuli	Nakanyala	MoHSS
Dr.	Vetja	Haakuria	UNAM
Mr.	Victor	Sumbi	MSH
Ms.	Vulika	Nangombe	UNAM
Dr.	Yana	Lyeshchuk	MoHSS
Dr.	Zeko	Sikota	MoHSS

Key project stakeholders met during this meeting

- Mr. Andrew Ndishishi, Permanent Secretary, MoHSS
- Dr. Nobert Foster, Deputy Permanent Secretary, MoHSS
- Ms. Melissa Jones, Director, Health and HIV and AIDS office, USAID Namibia
- Ms. Pauline Nghipandulwa, Director, Tertiary Health Care and Clinical Support Services, MoHSS
- Prof. Peter Nyarang'o, Dean, Faculty of Health Sciences, University of Namibia
- Mr. Qamar Niaz, Acting. Deputy Director Pharmaceutical Services, MoHSS
- Mr. Johanses Gaeseb, Deputy Director, Narcotics and Controlled Substances

ANNEX B. SELECTED PHOTOGRAPHS FROM THE WORKSHOP AND FORUM

Group photo of AMR/RMU workshop participants at UNAM, July 22, 2013.

Photo by SIAPS/Namibia staff

(L-R) Prof. Peter Nyarang'o – Dean Faculty of Health sciences UNAM ; Dr. Norbert Foster – Deputy Permanent Secretary MoHSS and Dr. David Mabirizi, Principal Technical Advisor MSH at the opening of the AMR/RMU stakeholders' forum at UNAM on 24 July 2013.

Photo by SIAPS/Namibia staff

Group photo (AMR/RMU forum participants) and call to action celebration. July 24, 2013.

Photo by SIAPS/Namibia staff

Facilitators and organizers: (L-R) Dr. Assegid Mengistu (MoHSS), Dan Kibuule, and Dr. Tim Rennie (UNAM). July 2013.

Photo by SIAPS/Namibia staff

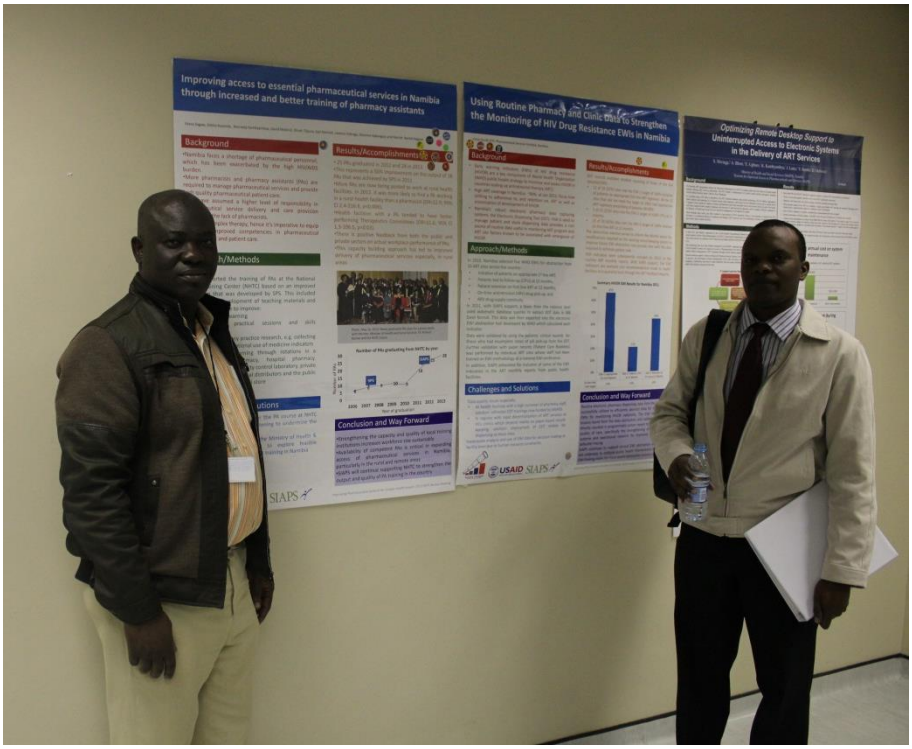
Some of the participants in a session at the RMU/AMR Workshop in Windhoek, Namibia. July 2013.
Photo by SIAPS/Namibia staff

Panel discussion (L-R) Dr. David Mabirizi – Moderator; Dr. Steven Hong, Dr. Frederick Sinyinza, and Prof. Peter Nyarang'o. July 2013.

Photo by SIAPS/Namibia staff

Facilitators and organizers of the AMR workshop – staff (L-R) Evans Sagwa, David Mabirizi, and Harriet Kagoya. July 2013.

Photo by SIAPS/Namibia staff



Organisers and facilitators Mr. Emmanuel Ugburo (left, MoHSS) and Mr. Victor Sumbi (SIAPS) at the posters area of the AMR/ RMU workshop at UNAM. July 2013.

Photo by SIAPS/Namibia staff

ANNEX C. WORKSHOP PROGRAM

Republic of Namibia

Ministry of Health and Social Services

Programme: Workshop on antimicrobial resistance and promoting the rational use of ARVs, anti-TB and other medicines in Namibia

Venue: UNAM School of Pharmacy, Windhoek **Date: 22-23 July 2013**

Invited: Health policy makers, health system managers, health program managers, health practitioners

Day 1	**Monday, 22-July-2013**
08:30 – 08:45	Arrival and registration of participants – Gisella and Cherizaan (MSH)
08:45 – 08:50	Welcoming remarks by the associate dean of the School of Pharmacy Dr. Timothy Rennie
08:50 – 09:00	Official opening by the Dean: School of Medicine Professor Peter Nyarang'o
09:00 – 10:30	**Module 1: The Global challenge of Irrational Use of Medicines** Dr. David Mabirizi, Principal Technical Advisor, HIV & AIDS -SIAPS
10:30 – 11:00	**Tea/ coffee break (group photo)**
11:00 – 12:45	**Module 2: Understanding Medicine Use Problems** Mr. Evans Sagwa, Acting Country Director: SIAPS/SCMS Namibia
12:45 – 14:00	**Lunch break**
14:00 – 15:00	**Module 3: Interventions to Change Medicine Use Problems** Mr. Dan Kibuule, Lecturer, UNAM School of Pharmacy
15:00 – 15:15	**Tea/ Coffee break**
15:30 – 17:00	**Group work and poster session** Dr. Matthias Adorka

USAID FROM THE AMERICAN PEOPLE

SIAPS Systems for Improved Access to Pharmaceuticals and Services

Day 2	**Tuesday, 23 July 2013**
08:30 – 08:45	**Recap of day 1** Mr. Dan Kibuule
08:45 – 09:45	**Module 4: Evaluating changes in medicine use practice and medicine use-related outcomes** Mr. Kennedy Kambyambya: Chief Pharmacist, National Medicines Policy Coordination, MoHSS
09:45 – 10:30	**Group exercise** Evans Sagwa
10:30 – 11:00	**Tea/ coffee break**
11:00 – 12:45	**Module 5: Overview of the problem of antimicrobial resistance (AMR) and the interventions recommended to contain AMR** Dr. Matthias Adorka, Senior Lecturer, UNAM School of Pharmacy
12:45 – 14:00	**Lunch break**
14:00 – 15:30	**Module 6: Using indicators to monitor HIV Drug Resistance** Dr. David Mabirizi, Principal Technical Advisor- HIV & AIDS (SIAPS); Ms. Anna Jonas, Subdivision: Response, Monitoring & Evaluation (MoHSS); Mr. Victor Sumbi, Senior Technical Advisor- SIAPS
15:30 – 15:45	**Tea/coffee break**
15:45 – 17:00	**Developing action plans** Mr. Dan Kibuule

ANNEX D. AMR/RMU STAKEHOLDERS FORUM PROGRAM

Republic of Namibia

Ministry of Health and Social Services

Stakeholders meeting on antimicrobial resistance and promoting the rational use of ARVs, anti-TB and other medicines

Venue: UNAM School of Pharmacy, Windhoek, 24 July 2013

Invited: Health policy makers, health system managers, health program managers, health practitioners

Agenda

09:00 – 09:15	Arrival and registration of participants
09:15 – 09:20	Welcoming remarks by the Dean: School of Medicine Professor Peter Nyarang'o
09:20 – 09:30	Remarks by the Deputy Permanent Secretary, Ministry of Health & Social Services, Dr. Norbert Forster
09:30 – 10:30	***An overview of the extent and nature of inappropriate use of medicines and antimicrobial resistance*** Dr. David Mabirizi, Principal Technical Advisor, HIV & AIDS -SIAPS ***An overview of Early Warning Indicators (EWIs) of HIV DR and the status of EWI implementation in Namibia*** Ms. Ana Jonas (RM&E - MoHSS) and Mr. Victor Sumbi (MSH – SIAPS) Brief presentation by Namibians Against Antimicrobial Resistance (NAAR) Dr. Gordon Cupido
10:30 – 11:00	**Tea/ Coffee break**
11:00 – 11:45	Panel discussion - ***The problem of drug resistance in HIV/AIDS and TB in Namibia – experience from practice.*** Panelists:- Dr. Ishmael Katjitae; Dr. Gram Mutandi; Dr. Farai Mavhunga; Dr. Flavia Mugala
11:45 – 12:30	Group work: develop a call to action and action plan to combat AMR in Namibia
12:30 – 13:00	Plenary feedback and wrap-up

ANNEX E. WORKSHOP EVALUATION FORM

Workshop and stakeholders' forum on AMR and promoting the rational use of ARVs, anti-TB, and other medicines, 22-24 July 2013, UNAM SOP, Windhoek, Namibia

Rating of the workshop based on various parameters:

1. Please indicate your agreement with the following statements:

Parameter	Response / Rating (circle one option)			
	Strongly Agree	Agree	Disagree	Strongly Disagree
1. The information in this course will be helpful in my work	4	3	2	1
2. The objectives were clearly defined at the beginning of the training course	4	3	2	1
3. The amount of material covered in 2 days was appropriate	4	3	2	1
4. The defined objectives were achieved by the end of the workshop	4	3	2	1
5. The depth of coverage of the material in the workshop was appropriate	4	3	2	1
6. Overall, I would say the quality of the instruction was good	4	3	2	1
7. Overall, the workshop met my expectations	4	3	2	1

2. Rate each of the following areas of the meeting on a scale of 1-4:

Parameter	Very good	Good	Satisfactory	Poor
1. Organisation of the workshop	4	3	2	1
2. Communication of information to the participants before the workshop	4	3	2	1
3. Running of the workshop	4	3	2	1
4. Overall satisfaction with the workshop materials and visual aids	4	3	2	1
5. Overall satisfaction with the length of the workshop	4	3	2	1
6. Overall satisfaction with the pace of the workshop	4	3	2	1
7. Overall satisfaction with the style and format of the sessions	4	3	2	1
8. Overall satisfaction with the workshop facilities	4	3	2	1
9. Meals	4	3	2	1

3. Which 3 sessions did find most relevant to your work or in medical and pharmaceutical education and practice?

   a) _____

   b) _____

   c) _____

4. Which 3 sessions in the workshop did you find least relevant for medical and pharmaceutical education and practice?

   a) _____

   b) _____

   c) _____

5. What topics would you like to see added to AMR/RMU related workshops?

   a) _____

   b) _____

   c) _____

6. Recommendations for improving similar workshops

   a) _____

   b) _____

   c) _____

7. General comments

   a) _____

   b) _____

   c) _____

Thanks for your feedback

ANNEX F. PRESENTATIONS

Session 1. The Global Challenge of Irrational Use of Medicines

The Global Challenge of Irrational Use of Medicines

David Mabirizi, Mohan P. Joshi, Malaika Schiller

Workshop on antimicrobial resistance and promoting the rational use of ARVs, anti-TB and other medicines in Namibia
UNAM School of Pharmacy, Windhoek
22-24 July 2013

Acknowledgements

This presentation is based on:

- Management Sciences for Health. 2011. *MDS-3: Managing Access to Medicines and Health Technologies (Chapter 27).* Sterling, Va.: Kumarian Press.

Session objectives

- Provide an overview of the extent and nature of inappropriate use of medicines
- Discuss irrationalities pertaining to the use of antimicrobials, including those used in the treatment of HIV/AIDS and TB
- Understand the adverse impacts of inappropriate use of medicines
- Identify factors underlying the irrational use of medicines

Rational medicine use

Rational medicine use - requires that patients receive appropriate medications for their clinical needs, in doses meeting individual requirements, for an adequate period, and at the lowest cost to them and their community.

RIGHT DRUG
RIGHT DOSE
RIGHT DURATION
AFFORDABLE

Irrational medicine use occurs when one or more of these conditions are not met

The global challenge of irrational use of medicines

- Globally, more than 50% of medicines are prescribed, dispensed, or sold inappropriately and 50% of all patients do not take their medicines correctly*
- In primary care in developing and transitional countries** –
  - <50% of the patients are treated according to clinical guidelines for common diseases
  - >50% of all cases of upper respiratory tract infections are treated with antibiotics
  - <60% of pneumonia cases are treated with an appropriate antibiotic
  - <60% of children with diarrhea are given oral rehydration therapy, >40% receive antibiotics, mostly unnecessarily
  - Only 50% of malaria cases receive an appropriate antimalarial agent

The global challenge of irrational use of medicines (2)

- Higher levels of medicine use problems occur in the private sector than in the public sector
  - e.g. treatment of acute childhood diarrhea was according to clinical guidelines in the public sector in about 40% of the cases, but less than 20% in the private-for-profit sector
- Patient care indicators are suboptimal
  - Consultation time – only 4 minutes (average of studies in 10 countries)
  - Dispensing time – only 105 seconds (7 countries)
  - % of drugs dispensed – only 89% (12 countries)
  - % adequately labeled – only 54% (8 countries)
  - % patients with correct knowledge of dosage – only 71.4% (16 countries)

WHO World Medicine Situation Report
http://apps.who.int/medicinedocs/en/m/abstract/Js18064en/

The global challenge of irrational use of medicines (3)

- About 2/3 of global antibiotic sales occur without any prescription*
- 15 billion injections are given per year, and ½ of them are with unsterile needles or syringes.** Up to 90% of the injections given are estimated to be unnecessary.[1]
- 1.3 to 2.1 billion people in the world do not have access to essential medicines*
- 2 in every 6 WHO member states have no or very little drug regulatory capacity*
- 20 to 50% of antimicrobial use in *humans* is unnecessary, and 40 to 80% of their use in *animals* is highly questionable***
- Approximately 10% of all patients admitted to hospitals acquire an infection during their stay (nosocomial infection)****

* The World Medicines Situation, WHO, 2004.
** Holloway K. Slide presentation on promoting rational use of medicines in developing countries, WHO, 2007.
*** Wise et al. British Medical Journal 1998;317(7159):609-10.
**** Brown N. Preventing and preventing hospital-acquired infection. 2004. Emerging Infectious Diseases. Accessed July 31, 2009.

USAID FROM THE AMERICAN PEOPLE SIAPS

Evidence of continuing gaps in RUM solutions

- Less than half of countries have an up-to-date policy framework that actively encourages appropriate use of medicines such as –
  - regular monitoring of medicine use
  - regular updates to clinical guidelines
  - regular medicine updates for prescribers (medicines information center)
  - effective drug and therapeutics committees in hospitals (health facilities) or regions
- In some countries, the policy exists but is inadequately implemented

RUM = Rational use of medicines

USAID FROM THE AMERICAN PEOPLE SIAPS

Evidence of continuing gaps in RUM solutions (2)

- <40% of countries updated STGs in the last 2 years and
- Only about 50% of countries updated EMLs in the last 2 years
- Only about 40% of countries have a drug information center for prescribers
- Only about 50% of countries have DTCs in most referral hospitals
- Only about 40% of countries have conducted a drug use audit in the last 2 years
- <50% of countries enforce obligatory CME for doctors and nurses
- <50% of countries promote public education on antibiotic use
- In only less then 40% of countries are antibiotics not available OTC
- Only about 20% of countries have a national strategy to contain AMR

OTC = over the counter

Source: Holloway K. Slide presentation on promoting rational use of medicines in developing countries, WHO, 2007.

USAID FROM THE AMERICAN PEOPLE SIAPS

The challenge and risks to irrational use in Namibia

- Adherence survey 2012
- Early warning indicators (EWI) study
- Pharmaceutical Management Information System (PMIS) reports
- Therapeutics Committees' activity reports
- Limited research into rational use of medicines in Namibia

USAID FROM THE AMERICAN PEOPLE SIAPS

Examples of irrational use of medicines

Polypharmacy	Medicine used when not needed	Wrong medicines
Ineffective medicines and medicines with doubtful efficacy	Unsafe medicines	Underuse of available effective medicines
	Incorrect use of medicines	

USAID FROM THE AMERICAN PEOPLE SIAPS

Polypharmacy

- Occurs when patients use more medicines than are necessary
  - e.g., a patient with an upper respiratory infection receives prescriptions for antibiotics, cough remedies, analgesics, and multivitamins
- May be associated with –
  - inadequate in- or pre-service training
  - inadequately skilled prescriber, especially in this era of task shifting
  - prescriber not knowing when to refer
  - financial incentives

USAID FROM THE AMERICAN PEOPLE SIAPS

No medicine needed

- Many times, medications may be used unnecessarily
- Use of medicines when none is needed involves many non-therapeutic uses
- In many countries, the majority of children suffering from minor upper respiratory infections are treated with antibiotics, which are not needed

Wrong medicines prescribed

- For various reasons, the wrong medicine may be prescribed and dispensed
- In some countries, many children with acute diarrhea are indiscriminately prescribed and dispensed unnecessary and ineffective antimicrobials or antidiarrheal medicines, instead of the recommended oral rehydration therapy
- As a result of the emergence of AMR, a medicine that was once efficacious may now be the wrong treatment choice

Ineffective medicines and medicines with doubtful efficacy

- Medicines that are ineffective are sometimes given to patients because of common practice or because the patient thinks that the more medicines prescribed, the better
- Excessive and unnecessary use of multivitamin preparations or tonics is an example of this prescribing pattern

Unsafe medicines

- The likelihood of adverse reactions outweighs the therapeutic effects when unsafe medicines are prescribed
- A common example is the use of anabolic steroids for growth or appetite stimulation in children or athletes

Underuse of available effective medicines

- Several studies show that underuse of effective oral rehydration therapy for acute diarrhea in children still occurs in many countries
- A large WHO multi-country survey found that many people with serious mental disorders were not receiving any treatment, despite the availability of effective medicines*
  - 35.5% to 50.3% of serious cases in developed countries and 76.3% to 85.4% in less-developed countries received no treatment

A mentally ill man shackled in Ivory Coast **

Incorrect use of medicines

- Giving a patient only one or two days' supply of antibiotics rather than the full course of therapy
- A patient taking only as much medicine as needed to feel better, and saving the rest for a future illness
- Self-medicating using antibiotics or other prescription-only medicines bought from untrained drug sellers in retail drug outlets
- Overusing injectable preparations when in fact using oral preparations would be easier and safer (stems from belief among prescribers and patients that injections are more efficacious than pills)

Irrational use of antiretroviral agents

- Insufficient compliance to ART guidelines, drug shortages in health facilities, poor patient adherence, drug quality assurance issues, and inadequate laboratory support all contribute to irrational use of ARVs
- Based on an autopsy study in Uganda, at least 8 of the 10 patients on ART died of HIV-related conditions, 50% died of disseminated TB, 20% of disseminated *Cryptococcus neoformans* infection, and 10% of disseminated KS*

ART = antiretroviral therapy
ARV = antiretroviral medicine

Early warning indicators of HIV drug resistance

Indicator	Proportion of clinics reaching target
100% prescription of WHO first-line recommended regimens	86%
< 20% loss to follow-up	43%
>70% retention on appropriate first-line regimen	42%
>90% of patients picking up prescribed ARVs on time	17%
>80% of clinic appointments attended as scheduled	55%
100% of drugs available at pharmacy at all times	42%

Namibia example 1: *Patients who picked up their medicines on time*

EDT Facility Reports 4.01 for

From: 01/01/2013 18 — To: 31/01/2013 All — No Regimens

18 Patients late for appointment +

	On Time	1-3 days	4-10 days	11-19 days	20-29 days	> 29 days	Total
Adult:	2016	456	236	74	217	514	3513
Paediatric:	200	38	20	6	23	36	323
Total:	2216	494	256	80	240	550	3836

DaysLate Unknown:	33
Grand Total:	3869

Patients who collected medicine in the date range, but who were late for the appointment by number of days. Patients who did not collect medicines are excluded

EDT Ver 4.01

Namibia example 2: *Patients with more than 75% adherence by pill count/patient adherence*

EDT Facility Reports 4.01 for

From: 01/01/2013 21 — To: 31/01/2013 All — No Regimens

21 Patient Adherence +

Percentage Adherence	Pediatrics (i) PM	PF	PT	Adults AM	AF	AT	Totals TM	TF	GT
>95% to 100%	7	6	13	55	104	159	62	110	172
75% to 95%	21	23	44	70	122	192	91	145	236
< 75%	48	30	78	211	372	583	259	403	662
Others (>100%) -ii-	73	66	139	641	1254	1895	714	1320	2034
Adherence not calculated -iii-	28	22	50	264	453	717	292	475	767
TOTAL NUMBER OF PATIENTS	177	147	324	1241	2305	3546	1418	2453	3871
MEAN FACILITY ADHERENCE -iv-	53	61.7	56.8	59.4	59.6	59.5	58.2	59.8	59.2

Patient adherence over the period selected, based on pill counts:
(i) Paediatric patients on solid dosage forms
(ii)-Patients dumped some (or did not come with all) of their remaining pills
-Patients left all their remaining pills at home but claimed they had no pills remaining
-Patients shared pills with others; -Patients lost their pills.
(iii)New or Active Patients without a previous pill count on last visit(pill count not done)
(iv)Mean Facility Adherence is only calculated for the first three categories of patients

EDT Ver 4.01

Namibia example 3: *Patients lost to follow up at 12 months after initiating ART*

EDT Facility Reports 4.01 for

From: 01/11/2012 08 — To: 30/11/2012 All — VIEW: Numerator — No Regimens

08 Lost to Follow Up at 12 Months (EWI02) *

Adult % 25.0%; Paediatric % 33.0%

	Pediatrics PM	PF	PT	Adults AM	AF	AT	Totals TM	TF	GT
AZT/3TC/NVP	0	1	1	1	0	1	1	1	2
D4T/3TC/EFV	0	0	0	1	0	1	1	0	1
D4T/3TC/LPV/r	0	1	1	0	0	0	0	1	1
D4T/3TC/NVP	1	0	1	0	0	0	1	0	1
TDF/3TC/EFV	0	0	0	2	1	3	2	1	3
TDF/3TC/NVP	0	0	0	15	10	25	15	10	25
Grand Totals:	1	2	3	19	11	30	20	13	33

EWI02: Number of patients initiating therapy 12 months ago who have not been seen at pharmacy for 90 days or more since date of last visit

EDT Ver 4.01

Namibia example 4: *Patients retained on therapy 12 months after initiating ART*

EDT Facility Reports 4.01 for

From: 01/11/2012 09 — To: 30/11/2012 All — VIEW: Numerator — No Regimens

09 Patients Retained on Therapy at 12 months

Adult % 74.0%; Paediatric % 100.0%

	Pediatrics PM	PF	PT	Adults AM	AF	AT	Totals TM	TF	GT
AZT/3TC/NVP	2	2	4	1	6	7	3	8	11
D4T/3TC/EFV	0	0	0	0	1	1	0	1	1
D4T/3TC/NVP	4	1	5	1	1	2	5	2	7
TDF/3TC/EFV	0	0	0	2	3	5	2	3	5
TDF/3TC/NVP	0	0	0	25	49	74	25	49	74
Grand Totals:	6	3	9	29	60	89	35	63	98

EWI 03 : Patients retained on ART 12 months after initiating on an appropriate first line regimen

EDT Ver 4.01

Irrational use of anti-TB treatment

- Every year, nearly 3 million people affected by TB are neither diagnosed nor treated according to international guidelines*
- Nearly 450,000 new cases of MDR-TB emerge every year due to inadequate treatment and subsequent transmission**
- Inappropriate TB treatment regimen increases 27-fold the risk of developing MDR-TB compared with patients who received an appropriate treatment regimen***
- Insufficient knowledge of TB guidelines, unregulated availability of TB drugs, drug shortages in health facilities, poor patient adherence, drug quality assurance issues, inadequate laboratory support, and poor infection control practices also contribute to irrational use

Irrational use of anti-TB treatment (2)

"… India is spending about 45% of its TB budget on 3 to 4% of the patients and this is just not sustainable. That is driven by cost of second line drugs, because of a more expensive product and a broken market. …"

Adverse impacts of irrational medicine use

AMR = Antimicrobial resistance
ADR = Adverse drug reaction

Adverse impacts of irrational medicine use: *AMR*

- AMR is rapidly growing worldwide, causing significant morbidity and mortality
- Overuse of antibiotics increases AMR, as well as the number of medicines that are no longer effective against diseases
- Up to 70 to 90% AMR to original first line antibiotics for dysentery, pneumonia, gonorrhea, and hospital-acquired infections has been noted*
- Compared to susceptible infections, resistant infections lead to a 1.3- to 2-fold increase in morbidity, mortality, and cost**

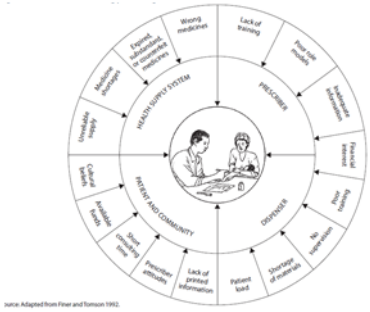
Adverse impacts of irrational use of medicine: *ADRs and medication errors*

- Harmful reactions to medicines caused by wrong use, or allergic reactions to medicines, can lead to increased illness, suffering, and death*
- In countries where data are available, it is estimated that ADRs are the 4th to 6th leading cause of death in hospitalized patients.** Over 70 percent of these ADRs are either possibly or definitely avoidable.***
- ADRs have been estimated to cost millions of dollars each year

Adverse impacts of irrational medicine use: *Wasted resources*

- Between 10 to 40% of national health budgets are spent on medicines
- Out-of-pocket purchases of medicines can cause severe financial hardship to individuals and families

Factors underlying the irrational use of medicines



Many **interrelated** factors influence medicine use

The **health supply system, prescriber, dispenser, patient, and community** are all involved in the therapeutic process, and can all contribute to irrational use in a variety of ways

Factors underlying the irrational use of medicines: *Health supply system*

- Unreliable supply
- Medicine shortages
- Expired medicines
- Availability of inappropriate medicines, including substandard and counterfeit products
- Systemic inefficiencies, which negatively affect prescriber and patient confidence in the system
- Health systems that fail to implement policies on STGs, EMLs, and medicine formularies are missing out on well-proven methods to increase the rational use of medicines

Factors underlying the irrational use of medicines: *Prescriber*

- Inadequate pre- or in-service training
- Poor supervisory system
- Imitating the behavior of prescribing role models who may not prescribe rationally
- Insufficient objective information on medicines
- Limited personal experience
- Heavy patient load and pressure to prescribe from peers, patients, and pharmaceutical company representatives
- Profit

Factors underlying the irrational use of medicines: *Dispenser*

- Inadequate training, supervision and medicine information available
- Shortage of dispensing materials
- Short dispensing time due to heavy patient load
- Financial incentive, especially among private drug sellers
- Inadequate training and little to no structure for monitoring or supervision of drug sellers in retail outlets
- Low status of dispensers affects the quality of dispensing

Factors underlying the irrational use of medicines: *The patient and community*

- Cultural beliefs
- Communication skills and attitudes of the prescriber and dispenser
- Limited time available for consulting
- Shortage of printed information
- Affordability of treatment
- Community beliefs about the efficacy of certain medicines or routes of administration

Combating irrational medicine use

Major steps –

- Monitoring and measuring the use of medicines
- Identifying the determinants of inappropriate use
- Developing, implementing and evaluating the impact of interventions to improve the use of medicines, while taking into account the factors underlying inappropriate use
- Working towards an enabling policy framework that encourages appropriate use
- Developing a national strategy for containing AMR

Combating irrational medicine use (2)

There is increasing global awareness of the need for –

- health systems strengthening
- national coordination to combat irrational medicine use
- coordination of international aid to developing countries to ensure it contributes to combating irrational use of medicines

The major challenge moving forward will be to institutionalize the fight against inappropriate medicine use

Savings with Rational Use

About 8% of total healthcare expenditure, or about 500Bn USD per year globally, can be avoided through better responsible medicine use

Session 2. Understanding Medicine Use Problems

Understanding Medicine Use Problems

Presented by Evans Sagwa

Workshop on antimicrobial resistance and promoting the rational use of ARVs, anti-TB and other medicines in Namibia
UNAM School of Pharmacy, Windhoek
22-24 July 2013

Acknowledgments

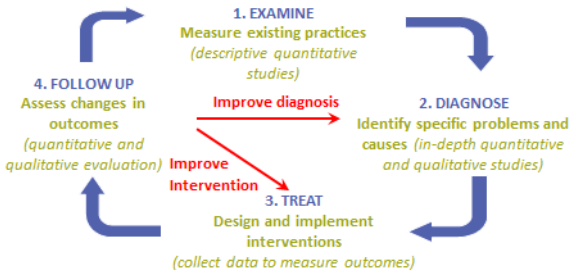
- This presentation is based on:
  - MSH/RPM Plus and WHO. Drug and Therapeutics Committee Training Course—Understanding the Problems Associated with Medicine Use: Qualitative Methods
  - WHO and INRUD. Promoting Rational Drug Use (PRDU) Course—Learning about a drug use problem.

Session Objectives

- Describe the process of identifying and changing drug use problems
- Identify and evaluate sources of quantitative and qualitative data
- Understand the importance of studying provider and patient motivations
- Introduce qualitative research methods

Components of the drug use system

Changing drug use: An overview of the process



Changing drug use problems

- Before attempting to change medicine use –
  - assess and quantify the scale of the problem
  - investigate the underlying reasons for the problem behavior using quantitative and qualitative methods

Changing drug use problems: *Examine*

- Identify drug use issue of interest
  - Highest clinical risk?
  - Widely used or expensive drugs?
  - Easiest to correct?
- Collect data to describe practices
  - In all subgroups of interest
  - Most important prescribers?
  - High-risk patients?

Changing drug use problems: *Diagnose*

- Describe problem in detail
  - Specific problem or behavior
  - Define key players – providers or patients
- Identify determinants of the problem
  - Knowledge and beliefs
  - Cultural factors or peer practices
  - Patient demand and expectations
- Identify constraints to change
  - Attitudes/comfort zones/difficulty to change
  - Economic constraints
  - Guideline limitations/drug supply
  - Work environment

Changing drug use problems: *Treat*

- Select target and design intervention
  - Which medicine or medicines to target?
  - Which behavior can be changed?
  - Feasible interventions?
  - Cost-effectiveness?
  - Who to target? Nurses, doctors, pharmacists, patients
  - Personnel required?
- Pilot test
  - Acceptability
  - Effectiveness
- Implement in stages
  - Collect process and outcome data
  - Evaluate impacts

Changing drug use problems: *Follow-up*

- Evaluate success in relation to intended outcomes
  - Was the intervention implemented as planned?
  - What changes occurred?
  - Was the intervention cost-effective? Transferrable?
- Consider unintended negative and positive outcomes
- Feedback results
  - To managers and policymakers
  - To staff
  - To providers and consumers
- Use results to plan future activities

Drug use encounter

- Defined as the interaction between provider and patient when decisions are made about which drugs to recommend or use
- *Where the pill meets the patient*
- Sites of drug encounters
  - hospital
  - private practice
  - pharmacy
  - home
  - health center
  - traditional healer
  - drug seller

Who is a prescriber? Whose behavior do we change?

- Physicians
- Paramedics
- Pharmacists
- Injectionists
- Patients
- Clinical officers
- Clinical attendants
- Dispensers
- Drug sellers
- Relatives/friends

How to collect data

Quantitative Methods

- Answer *What? How much?*
- Counts
- Rates
- Classifications

Qualitative Methods

- Answer *Why? How strong?*
- Opinions
- Descriptions
- Observations

Selecting methods to study drug use

Method selection depends on –

- nature of the problem
- objectives of data collection
- resource availability
- time available

Quantitative Methods

Sources of quantitative data

- Routine data
  - Drug supply or consumption data
  - Morbidity and mortality reports
- Record systems
  - Medical records
  - Pharmacy records
- Sample surveys
  - Drug use encounters
  - Provider interviews
  - Patient and community interviews

Types of quantitative data

- *Time:* retrospective vs. prospective
- *Level:* aggregate vs. patient-specific
- *Diagnosis information:* known vs. unknown
- *Drug data:* detailed (name, dose, amount, duration) vs. non-detailed (name only, if injection, etc.)

Where can we find useful quantitative data?

- Administrative offices, medical stores
- Clinical treatment areas and medical record departments
- Health facility pharmacies
- Private pharmacies and retail outlets
- Households

Qualitative Methods

Qualitative methods

- Provide insight to reasons for behavior
- Require trained data collectors
- Data analysis is difficult, but results can be very useful

Methods include:

- *in-depth interviews*
- *Focus group discussion*
- *Structured observations*
- *Simulated purchase visits*

In-depth interviews

- *An extended discussion between a respondent and a trained interviewer based on a brief interview guide that usually covers 10-30 topics*
- Open-ended questions
- Data collector can target key informants, opinion leaders, or others in special position
- 5-10 interviews may be enough to get a feel for important issues
- If target group is diverse, 5-10 interviews are held with each important subgroup

In-depth interviews (2)

Strengths

- *Unexpected insights or new ideas*
- *Helps create trust between interviewer and respondent*
- *Less intrusive than a questionnaire*
- *Useful with illiterate respondents*

Weaknesses

- *Time-consuming compared to structured questionnaire*
- *Data analysis can be difficult*
- *Bias toward socially acceptable or expected responses*
- *Requires well-trained interviewers*

Focus group discussions

- A *short discussion (1.5 to 2 hours) led by a moderator in which a small group of respondents (6-10) talk in depth about a defined list of topics of interest*
- Small group promotes equal participation
- Participants share common characteristics (e.g., age, gender, type of work)
- Skilled, trained moderator keeps discussion focused
- Free interaction, open sharing of ideas
- Notes recorded by an assistant
- Analysis completed at a later time

Focus group discussions (2)

Strengths

Elicits the beliefs and opinions of a group

Provides richness and depth

Easy and inexpensive to organize

Weaknesses

Success depends on the skill of the moderator

Group may not represent larger population

Do beliefs and opinions represent true feelings?

Potential bias in analysis

Sampling in focus group studies

- Identify key dimensions of target group along which responses may vary
- Sample within subgroups until a consistent pattern of responses emerges, for example –

	Trained in last 10 years	Trained > 10 years ago
Generalists	2-3 groups	2-3 groups
Specialists	2-3 groups	2-3 groups

Structured observations

- *Systematic observations by trained observers of a series of encounters between health providers and patients*
- To prepare for the study, the observer should provide a non-threatening explanation and spend enough time "blending in"
- At least 30 encounters should be observed to calculate the frequency of behaviors
- Observing a few cases in 5-6 settings may be enough to understand typical features
- Data can be recorded as –
  - coded indicators and scales
  - lists of behaviors and events
  - diary of observer's impressions

Structured observations (2)

Strengths

Best way to study complex provider-patient interactions

Can learn about provider behavior in its natural setting

Best way to learn about patient demand, quality of communication

Collect data on actual, rather than reported, behavior

Weaknesses

Behavior may not be natural because of observer's presence

Requires skilled, patient observers

Not useful for infrequent behaviors

Structured questionnaires

- A *fixed set of questions asked to a large sample of respondents (at least 50-75 from each target group) who are randomly selected according to strict rules to represent a larger population*
- Questions are posed in a standardized way, can be fixed or open-ended
- Useful for assessing attitudes, opinions, beliefs, facts
- Sample size depends on target population, type of sampling, desired accuracy, and available resources

Structured questionnaires (2)

Strengths

Best to study strength and frequency of knowledge, attitudes, population characteristics

Familiar to managers and respondents

Required skills are often locally available

Weaknesses

Attitudes often difficult to quantify

Respondents often answer a direct question even if they have no true opinion

Results are sensitive to the way questions are phrased

Large surveys are expensive

Simulated purchase visits

- *When a research assistant, prepared in advance to present a standard complaint, visits providers seeking treatment in order to determine their practices*
- Usually sample 30+ providers
- Collect data on various aspects of practice, e.g. history-taking, examination, treatment, and advice
- Frequently used to examine practices in private pharmacies
- Can vary scenario (e.g. watery vs. bloody diarrhea)

Simulated purchase visits (2)

Strengths

Can compare knowledge and reported practice with actual practice

Relatively quick and easy to conduct

Data are simple to analyze

Weaknesses

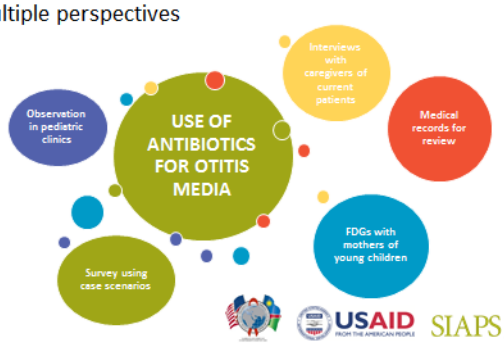
Response may be specific to the scenario presented

Research assistants can vary widely in reliability

Unethical?

Triangulation

Use different methods to look at the same issue from multiple perspectives



Which method to use?

The best method depends on –

- the nature of the problem
- the objectives of collecting data
- available resources and time
- local capacity and experience

Use multiple methods

- Quantitative and qualitative
- "Triangulate" findings
- Each method can look at different aspects of a problem

Session 3. Interventions to Change Medicine Use Problems

Interventions to Change Medicine Use Problems

Presented by Dan Kibuule

Workshop on antimicrobial resistance and promoting the rational use of ARVs, anti-TB and other medicines in Namibia
UNAM School of Pharmacy, Windhoek
22-24 July 2013

Acknowledgments

- The majority of this presentation is based on:
  - MSH/RPM Plus and WHO, Drug and Therapeutics Committee Training Course—Strategies to Improve Medicine Use: Overview
  - Management Sciences for Health. 2011. *MDS-3: Managing Access to Medicines and Health Technologies (Chapter 27).* Sterling, Va.: Kumarian Press.

Session outline

- **PART 1:** Overview on strategies and interventions
  - *Utilized to address medicine use problem(s)*
- **PART 2:** Methods used to implement strategies
  - *Educational, managerial, economic, and regulatory*
- **PART 3:** Strategies for RUM in special conditions
  - *HIV/AIDS and TB treatment*

1

Overview on Strategies & Interventions

DEVELOPING A STRATEGY:
To promote rational medicine use

Step 1. Identify problem and recognize need for action

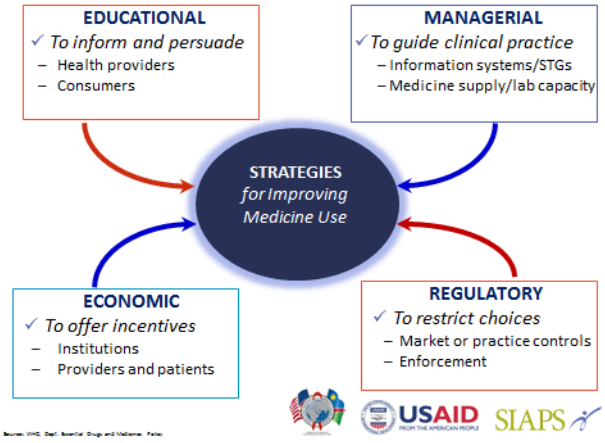
Step 2. Identify underlying causes and motivating factors

Step 3. List possible interventions

Step 4. Assess resources available for action

Step 5. Choose an intervention or interventions to test

Step 6. Monitor impact and restructure interventions

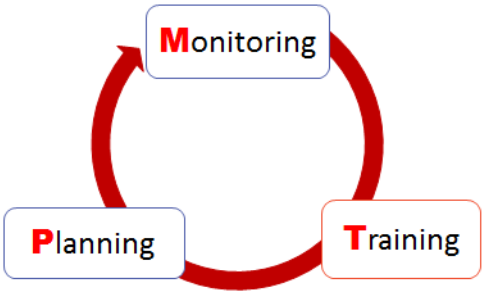


INTERVENTION:
Choosing an Effective Intervention

Regardless of the strategy, the most effective interventions –

- identify key factors that influence practices
- target individuals or facilities with the poorest practices
- use credible information sources and communication channels
- use personal contact whenever possible
- limit the number of messages
- repeat key messages using a variety of methods
- provide better medicine use alternatives

IMLEMENTATION:
Implementing an Intervention



Choosing an intervention

- Factors to consider –
  - The effectiveness with which the intervention addresses the underlying causes of the problem
  - Previous success rate in similar situations, areas, or countries
  - Cost
  - Whether the intervention can be sustained with available resources
- Test intervention before widespread implementation
- A strategy that combines a mix of interventions will be more effective and sustainable

2

Methods for implementing Strategies

EDUCATIONAL METHODS:
(a) Prescriber training

- Formal education (pre-service)
- Continuing education (in-service)
- Supervisory visits
- Group lectures, seminars, and workshops

EDUCATIONAL METHODS:
(b) Printed materials

Clinical Literature & News letters

- *Evidence based (Referenced)*
- *Reason for prescribing behaviour*
- *Concise up-to-date*
- *Attractive graphics*
- *Action & decision oriented messages*
- *Limited & repeated key messages*

Illustrated Materials

- *Flyers , Leaflets, Posters*
- *Key messages*
- *Attractive graphics*
- *Evidence based*

EDUCATIONAL METHODS:
(b) Printed materials

FORMULARY
(Hospital, National)

- *Information on available medicines*
  - *Classes & clinical indications*
  - *Therapeutic information*
  - *Formulations & Price of medicine*
- *Educational & Training material for ALL Health care providers*

GUIDELINES
(Standardize treatment)

- *List the preferred Treatment*
- *Reference for Education*
- *Reference for prescribing audit*

EDUCATIONAL METHODS:
(c) Face-to-face approaches

- **(i) IN-SERVICE EDUCATION:** *Workshops, seminars*
  - Focuses on information of local relevance *(needs based)*
  - Kept BRIEF , SIMPLE and CLEAR
    - Messages are few and clear
    - Descriptions of what to do are concise
  - Repetitive information is needed for individuals to learn
  - Presenter should have in-depth knowledge and an effective teaching style

EDUCATIONAL METHODS:
(c) Face-to-face approaches

- **(ii) PERSON-TO-PERSON EDUCATION** *(academic detailing)*
  - Most effective form of education
  - Focuses on specific problems and targets the prescribers
  - Addresses the underlying causes of prescribing errors, such as inadequate knowledge
  - Allows for interactive discussion with targeted audience
  - Uses concise and authoritative materials to enhance presentations
  - Gives sufficient attention to solving practical problems encountered by prescribers in real settings

EDUCATIONAL METHODS:
(c) Face-to-face approaches

- **(iii) INFLUENCING OPINION LEADERS**
  - Chiefs of service
  - Dominant and experienced physicians in community settings
  - University professors
  - Important and respected traditional healers
- **(iv) PATIENT EDUCATION**
  - Must be provided by persons of authority (e.g., physicians, pharmacists, nurses) in an organized, systematic manner
  - Provides fewer demands for medicines
  - Shows improved compliance to pharmaceutical therapy
  - Improves quality of care and outcomes

MANAGERIAL METHODS:
(a) Monitoring, supervising, and feedback

- Hospital drug and therapeutics committees
- District health teams
- Government inspectorate
- Professional organizations
- Self-assessment

MANAGERIAL METHODS:
(b) Selection, procurement, and distribution

- Limited procurement lists
- Ongoing, systematic, criteria-based drug use review and feedback
- Hospital and regional drug committees
- Cost information

MANAGERIAL METHODS:
Prescribing and dispensing approaches

- Structured medicine order forms
- Standard diagnostic and treatment guidelines
- Medicine use evaluations
- Course-of-therapy packaging

MANAGERIAL METHODS:
(c) Controlling pharmaceutical promotion

- All promotional claims concerning medicines should be reliable, accurate, truthful, informative, balanced, capable of substantiation, and in good taste
- Control access of medical representatives to prescribers in the hospital during working hours

MANAGERIAL METHODS:
(d) Avoiding perverse economic incentives

- Separate prescribing and dispensing functions
- Avoid flat prescription fees that encourage polypharmacy
- Avoid percentage dispensing fees that encourage the sale of more expensive medicines
- Avoid practice where prescribers earn part of their income from the sale of medicines (including the use of expensive medicines where cheaper one would be just as good)

REGULATORY METHODS

- Medicines registration
- Limited medicines lists
- Prescribing restrictions
  - Professional licensing – employ only licensed staff for the level of prescribing required
- Dispensing restrictions
- Regulation of pharmaceutical promotion activities

ECONOMIC METHOD

- Price setting
- Capitation-based budgeting
- Reimbursement and user fees
- Insurance

3

Interventions for TB & HIV/AIDS treatment

Strategies to encourage rational use of HIV/AIDS medicines

- Update ART guidelines
  - Regular treatment updates (e.g., via HIV Clinicians Society)
- Advocate for newer and better ARVs and formulations
- Use fixed-dose combinations
  - easy to prescribe, better compliance
- Rationalize regimens, such that few regimens are used for the majority of patients
- Minimize supplier differences in the medicines provided
  - tendering preferred
- Promote treatment literacy

Strategies to encourage rational use of anti-TB medicines

- Make STGs readily available to prescribers
- Train prescribers on how to use STGs
- Counsel patients on which drugs and doses to take and inform them of the consequences of interrupted treatment
- Use blister packs, fixed-dose combinations, and pill boxes to facilitate logistics and pill-taking
- Practice good dispensing/administration – right drug, right patient, and direct observation while patient takes drugs
- Encourage drug use feedback to national TB program staff
- Reform curriculum – train doctors, nurses, and pharmacists on modern treatment techniques and expectations for TB control

Session 4. Evaluating Changes in Medicine Use Practice and Medicine Use-Related Outcomes

Evaluating Changes in Medicine Use Practice and Medicine Use-Related Outcomes

Presented by Kennedy Kambyambya

Workshop on antimicrobial resistance and promoting the rational use of ARVs, anti-TB and other medicines in Namibia
UNAM School of Pharmacy, Windhoek
22-24 July 2013

Acknowledgments

- This presentation is based on:
  - MSH/RPM Plus and WHO. Drug and Therapeutics Committee Training Course—Drug Use Evaluation

Session objectives

- Provide detailed information on the concepts and processes of conducting a medicine use evaluation (MUE)
- Describe MUE as a mechanism that contributes to quality assurance and continuous quality improvement

What is a MUE?

- A quality assurance intervention that, in a step-by-step manner, identifies and remedies problems related to medicine use by collecting, analyzing, and interpreting data through organized, ongoing, systematic, and criteria-based reviews
- A MUE will –
  - *Define* appropriate medicine use
  - *Audit* criteria against what is being prescribed
  - *Give feedback* to prescribers on all identified problems
  - *Monitor* to see if criteria are followed and prescribing is improved

What is a MUE? (2)

When a problem is identified, the timely dissemination of results, coupled with the implementation of an improvement plan, should–

- detect and minimize irrational medicine use, adverse drug reactions, harmful drug interactions, and drug resistance
- improve treatment outcomes
- reduce treatment costs, in some cases

Indicators suggesting a need for a MUE

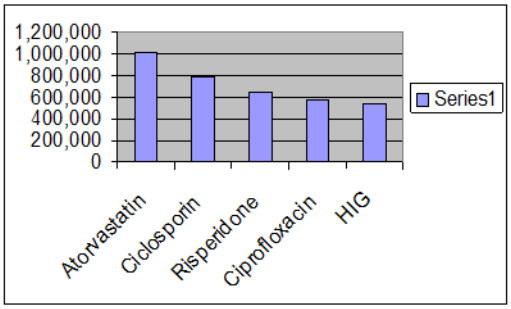
Focus only on those few selected aspects of treatment or medicine use that *indicate* a problem, for example –

- Overuse or underuse of medications
  - *ABC analysis and morbidity studies*
- Problems indicated from WHO/MSH indicator studies
- High number of adverse drug reactions and interactions
  - *Pharmacovigilance is needed*
- Signs of treatment failure
  - *Pharmacovigilance is needed*
- Excessive use of non-formulary medications
- Use of high-cost medicines where less expensive alternatives exist
  - *ABC analysis*
- Excessive number of medicines within a therapeutic category

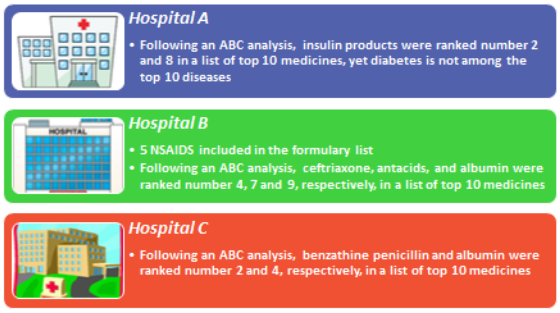
Examples of the need for a MUE

- Extensive use of insulin products in Uganda, where diabetes was not among the most common diagnoses
- Inappropriate use of non-formulary medicines in Malaysia
- Excessive use of antipsychotics in a general hospital in South Africa - first and third medicines by value were haloperidol and fluphenazine
- High use of expensive statins (atorvastatin and simvastatin) in Malaysia
- Excessive number of antihypertensives (38) in Malaysia
- Ciprofloxacin among the top 10 medicines by value in Nepal
- Nine different NSAIDs in Nepal

The need for MUE in Malaysia: Top 5 medicines in Malaysian hospitals



The need for MUE in India



Objectives of MUE

- ✓ Ensure that pharmaceutical therapy meets current standards
- ✓ Promote optimal medication therapy
- ✓ Prevent medication-related problems
- ✓ Identify areas in which further evaluation is needed
- ✓ Create criteria for appropriate medicine use
- ✓ Define thresholds for quality of medicine use below which corrective action will be undertaken
- ✓ Enhance accountability in medicine use
- ✓ Control pharmaceutical costs

Stepwise approach to MUE

Step 1: Establish responsibility

- Therapeutics Committee (TC) is a logical choice
  - multidisciplinary
  - deals with all facets of medicine therapy
  - has the necessary expertise
- Subcommittee of the TC
  - must include representation from practitioners whose prescribing behavior will be assessed

Step 2: Develop scope of activities

- Identify medicine therapy problems to be addressed using ABC/VEN analysis, ADR reports, AMR reports
- Concentrate on medicines with the highest potential for problems
  - High volume
  - Low therapeutic index
  - High ADR rate
  - Expensive medicines
  - Critically important medicines
  - Antimicrobials
  - Injections
  - Medicines undergoing evaluation for addition to the formulary
  - Medicines used for off-label indications
  - Medicines used for high-risk patients

Step 3: Establish criteria

Using evidence-based medicine, establish criteria to define correct medicine use –

- Appropriate medicine for medical condition
- Correct dose
- Quantity dispensed
- Preparation for administration
- Monitoring is appropriate (e.g., laboratory test)
- Contraindications
- Medicine interactions
- Medicine administration (especially for injections)
- Patient education (written and oral instructions)
- Patient outcomes (e.g., blood glucose, glycosylated hemoglobin)
- Pharmacy administrative indicators (e.g., correct cost, billing)

Step 4: Define and establish thresholds

- Define and establish thresholds, or benchmarks, for quality of medicine use below which corrective action will be undertaken
- Thresholds define the expectations or goals for complying with the criteria (e.g., 90% of prescriptions for third generation cephalosporins are for predefined serious infections)

Ciprofloxacin MUE criteria and thresholds

Criteria	Threshold
• Complicated, chronic, or relapsing Gonorrhea • Resistant respiratory tract infections • Bone and joint infections • Prostatitis • GI infections	90%
Dose • Complicated or recurring infections: 500 -750 mg bid • GI infections: 500 mg bid • Gonorrhea: 250 mg in 1 dose • Renal disease – decrease as follows: Creatinine clearance 30-50 ml/min: 250 – 500 q 12 h 5-29 ml/min: 250-500 q 18 h Hemodialysis: 500 mg q 24 h	95%

Ciprofloxacin MUE criteria and thresholds (2)

Criteria	Threshold
Duration • Complicated UTI: 10-21 days • Respiratory: 7-14 days • Osteomyelitis: 4-6 weeks	95%
Contraindications • Pregnancy • Children < 18 years old	100%
Medicine interactions • Theophylline, antacids, iron, sucralfate, probenecid • Food: decreased absorption with milk	90%
Outcome • Negative cultures • Improved symptomatology	90%

Step 5: Collect data and organize results

- Prospective evaluation
  - Done as medicine is prepared or dispensed to the patient
  - Pharmacist can intervene at the time the medicine is dispensed
- Retrospective evaluation
  - Requires access to medical records
- Data sources
  - Patient charts, medical records, prescriptions, laboratory files
  - Manual systems vs. computerized systems
  - Needs minimum 50 to 75 records

Step 6: Analyze data

- Tabulate results for each indicator
- Analyze to see what percentage of prescribing episodes comply with the criteria and whether the threshold is met
  - For example, 70% of patients prescribed third generation cephalosporins were given it for predefined criteria—20% short of threshold
- Determine why thresholds are not met
- Analyze data quarterly, or more frequently

Step 7: Develop recommendations and plan of action

- Recommendations to address
  - Inappropriate medicine use
  - Unacceptable patient outcomes
  - Interventions to resolve any medicine use problems
- Methods to resolve medicine use problems
  - Education
  - Medicine order forms
  - Prescribing restrictions
  - Formulary manual changes
  - STG changes

Step 8: Conduct MUE follow-up

- Check to see that recommendations have been implemented
- Re-evaluate MUE to see if problems with pharmaceutical therapy have been resolved

When MUEs go wrong

- Lack of authority
- Poor prioritization of medicine use problems
- Poor documentation of findings
- Inadequate follow-up
- Overly intrusive data collection and evaluation
- Failure to obtain "buy in" from medical staff

Quality assurance

- The quality assurance process applies broadly to an entire cycle of assessment which extends beyond problem identification to –
  - verification of the problem
  - identification of what is correctable
  - initiation of interventions
  - continual review to assure that identified problems have been adequately corrected and that no further problems have been engendered in the process

Quality assurance programs have two main components:

- *Continuous quality assessment*
- *Continuous quality improvement*

Quality assurance

- MUE is a specific method that supports quality assurance and continuous quality improvement in the realm of pharmaceutical management and rational medicine use
- By its very design and iterative nature, MUE programs help in gradually and incrementally tracking results, thus contributing to *assessing changes in outcomes*

Institutionalization of ongoing MUE program

- Better ***service delivery*** achieved as a result of review and improvement in practices (efficacious, safe and cost-effective treatment)
- Capacity-building of the ***human resources*** involved in treatment as a result of their involvement in the design, implementation, interpretation and dissemination of the MUE programs
- Improved ***information management systems*** as a result of generation, reporting and use of medicine and treatment data; and
- Enhanced ***stewardship and governance*** as a result of audit and feedback, transparency in the patterns of drug use practice, and coordination and collaboration between the various stakeholders

MUE will help improve medicine use by –

- ✓ Ensuring that pharmaceutical therapy meets current standards
- ✓ Promoting optimal medication therapy
- ✓ Preventing medication-related problems
- ✓ Identifying areas in which further evaluation is needed
- ✓ Creating criteria for medicine use
- ✓ Defining thresholds for quality of medicine use below which corrective action will be undertaken
- ✓ Enhancing accountability in medicine use
- ✓ Controlling medicine costs

Group Exercise: MUE Criteria & Thresholds (1)

- The Therapeutics Committee (TC) in your facility is concerned about the current antibiotics use and the increasing rate of resistance. The TC observed that Amoxiclav, Azithromycin and Ceftriaxone are the most prescribed antibiotics with a higher risk of abuse and want to check the appropriateness of the prescribing practice in your facility.
- Develop medicine use evaluation criteria and thresholds for these 3 antibiotics

Group Exercise: MUE Criteria & Thresholds (2)

Develop criteria and thresholds for assessing use of one of the following

- **Amoxicillin + Clavulanic acid (Group 1)**
- **Azithromycin (Group 2)**
- **Ceftriaxone (Group 3)**

Session 5. Overview of Antimicrobial Resistance (AMR) and Interventions Recommended to Contain AMR

Overview of Antimicrobial Resistance (AMR) and Interventions Recommended to Contain AMR

Matthias Adorka, David Mabirizi, Malaika Schiller, Mohan P. Joshi, Evans Sagwa, Victor Sumbi

Workshop on antimicrobial resistance and promoting the rational use of ARVs, anti-TB and other medicines in Namibia
UNAM School of Pharmacy, Windhoek
22-24 July 2013

Acknowledgements

This presentation is based on:

- Management Sciences for Health. 2011. *MDS-3: Managing Access to Medicines and Health Technologies (Chapter 27).* Sterling, Va.: Kumarian Press.

Antimicrobial Resistance
The Problem, the Do's, the Don'ts and the Strategies to contain it

Session objectives: Where do we stand? Are the "super bug generals" really winning the war??

- Provide an overview of AMR around the world and in Africa, including its causes and impact
- Give an overview of the problem of drug resistance in HIV and TB
- Provide the key interventions recommended to contain AMR in the 2001 WHO Global Strategy for Containment of AMR and the 2011 World Health Day AMR Policy Package
- Provide a brief overview of interventions recommended to contain HIV and TB drug resistance

An overview of AMR around the world and in Africa

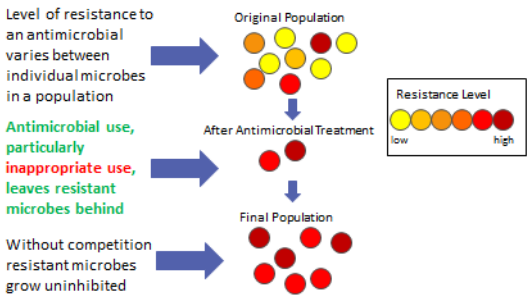
The global threat of AMR

- 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
- AMR is –
  - a steadily increasing global public health threat
  - widespread in both the hospital and community
  - rapidly rendering many first-line treatments ineffective
  - impacting all infectious diseases, including HIV/AIDS, TB and malaria

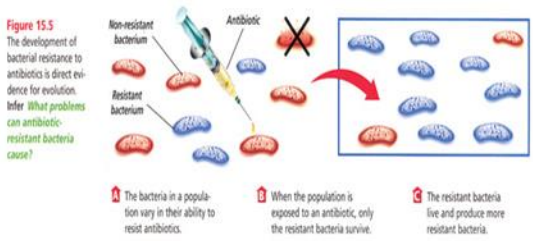
AMR: *Definition*

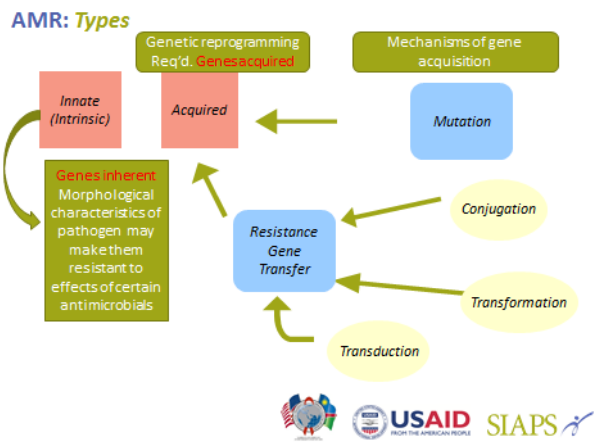
- Resistance of a microorganism to an antimicrobial medicine to which it was originally sensitive
- A natural biological phenomenon that can be amplified by a variety of factors, including human practices
- Resistant organisms (e.g., bacteria, fungi, viruses and some parasites) are able to withstand attack by antimicrobial medicines (e.g., antibiotics, antifungals, antivirals, antimalarials) so that **standard treatments become ineffective and infections persist increasing risk of spread to others**

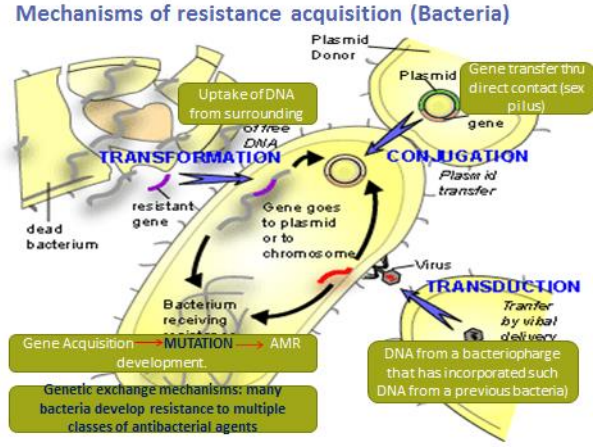
AMR: *Selection Pressure*



In other words:







Development of drug resistant –TB: mechanisms

- *M.tb* has the ability to undergo spontaneous mutation that produces bacilli progeny resistant to any of the known anti-TB medicines.
- Probabilities of producing spontaneous mutants resistant to individual anti-TB medicines recorded as:
  - Isoniazid: 1 in every 1,000,000 cell divisions
  - Rifampicin: 1 in every 1,000,000,000 cell divisions
  - Streptomycin: 1 in every 1,000,000 cell divisions
  - Ethambutol: 1 in every 100,000 cell divisions
  - Pyrazinamide: 1 in every 10,000 cell divisions

USAID SIAPS

- Spontaneous development of MDR-TB strains rather extremely rare
- Occurs once in every 1015 cell divisions (the product of the two probabilities of isoniazid and rifampicin mutation).
- Probability of the presence of resistant mutants in a person, largely depends on the number of M.tb bacilli in a person's body
- The lower the bacillary load, the lower the probability of harbouring naturally resistant mutants.
- Explains why:
  - Preventive therapy with only one anti-TB medicine is effective and does not create drug-resistance in a person with latent TB infection
  - Monotherapy almost invariably leads to resistance against this one medicine in a person with TB
    - A person with TB has many millions of *M.tb* bacilli.

USAID SIAPS

ARV Drug Resistance: Mechanisms

- Necessary for understanding the epidemiology and various treatment choices related to HIV drug resistance
- Rapid mutation during replication primary mechanisms of HIV drug resistance development
- Different strains of virus produced as viral particles replicate from form one CD4+ cell to another
- Strains differ from one another by random mutations in their genetic structures.
- Major mutations involve combinations of amino acid substitutions, deletions, or insertions.
  - Account for ARV drug resistance development.

USAID SIAPS

- Beneficial mutations
  - Help virus to escape pressure of the immune system
    - Survival advantage
- Harmful mutations
  - Produce changes in proteins essential for replication
  - Viruses with such changes disappear as they become overgrown by strains that have better replicative capacity.
- With time constant diversification of HIV occurs.

USAID SIAPS

ARV drug resistance: How does it occur?

- Start of **single** ARV drug therapy:
  - Rx may effectively reduce dominant strains (wild type")
  - A viral strain harbouring a mutation that confers some survival advantage in the presence of the particular ARV drug may however be existing in the population.
  - This variant strain continues to diversify and produce some progeny that accumulate additional mutations conferring greater resistance to the ARV drug
  - A variant harbouring enough key mutations to fully resist the agent eventually emerges
    - **Uncontested dominant strain**
- 2nd agent started:
  - Process repeats itself.

ARV Drug resistance: How long does it take to occur?

- Slow process usually
- Numerous rounds of replication and competition among diversified HIV strains req'd to render one variant with the strong survival advantage needed in the presence of the ARV agent .
- Case of protease inhibitors (PIs) and Nucleoside analogues (NRTIs)
- In the case of some ARVs high level resistance can develop within days or weeks when their monotherapy is initiated
  - Non-Nucleoside reverse transcriptase inhibitors(NNRTIs) and Lamivudine typical examples.
- Secret of the applauded success of HAART in ARV therapy

Global examples of AMR: *S. pneumoniae*

Alexander Project 1998-2000 : Investigated *S. pneumoniae* resistance to 23 commonly used antimicrobial agents in 26 countries

Country	Prevalence of resistance to any three drug classes (including penicillin)
Hong Kong (China)	79.3%
Japan	63.1%
France	49.1%
Singapore	39.9%
South Africa	33.5%
Spain	32.9%
Mexico	31.1%
United States	25.8%
Saudi Arabia	23.5%
Italy	22.4%

Global examples of AMR: *Sexually transmitted infections*

- Current range of penicillin resistant gonorrhea runs from 9 to 90% in Asia, and more than 35% in Sub-Saharan Africa and the Caribbean*
- Resistance of *N. gonorrhoeae* isolates in Guangzhou, China increased from 57.2% to 81.8% for penicillin G and from 17.6% to 72.7% for ciprofloxacin between 1996 and 2001**

An overview of drug resistance in HIV and TB

Types of HIV Drug Resistance

- Basically 2 types
- Transmitted
  - Occurs when previously uninfected individuals are infected with a drug-resistant virus
- Acquired
  - Occurs when resistance mutations emerge because of drug-selective pressure in individuals receiving ART

Source: WHO HIV Drug Resistance Report 2012.

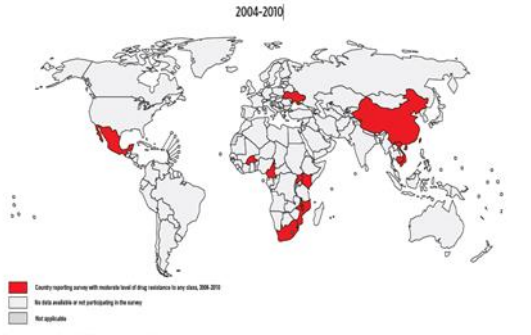
Drug resistance trends in HIV: *Transmitted drug resistance*

- Increasing prevalence of transmitted HIV drug resistance among recently infected populations, not at the high levels some had predicted due to the rapid ART scale-up
- A cautious GOOD NEWs one may say but did it last?
- 6.6% prevalence in select low- and middle-income countries in 2009
- 28% of WHO surveys (n=75) conducted between 2004 and 2010 were classified as having moderate (between 5 to 15%) levels of transmitted drug resistance
- Proportion of surveyed areas reporting moderate levels of transmitted drug resistance increased from 18% in 2004-2006 to 32% in 2007-2010

NNRTI = non-nucleoside reverse transcriptase inhibitors

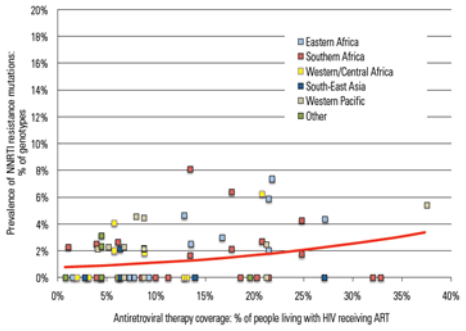
Source: WHO HIV Drug Resistance Report 2012.

Figure 1 Geographical distribution of WHO surveys with moderate (between 5% and 15%) levels of drug resistance to any drug class[a]



Source: WHO HIV Drug Resistance Report 2012.

Figure 2 Relationship between transmitted resistance to NNRTI drugs and antiretroviral therapy coverage



P-value adjusted for region= 0.039; Odds-ratio per 10% increase in ART coverage= 1.49 (95% CI: 1.07 - 2.08)

Source: WHO HIV Drug Resistance Report 2012.

Drug resistance in HIV: *Acquired drug resistance*

- Prevalence of HIV drug resistance to any drug in people starting ART in 12 low- and middle-income countries ranged from 4.8% in 2007 to 6.8% in 2010
- Among people with virological failure in areas surveyed by WHO, 72% had resistance, mostly to NRTI and NNRTI drugs
- True prevalence of HIV drug resistance may be considerably higher than the levels detected in the surveys

NRTI = nucleoside reverse transcriptase inhibitors

Source: WHO HIV Drug Resistance Report 2012.

Way forward?

- Crucial need for –
  - active defaulter tracing
  - improved patient monitoring
  - adherence counseling and monitoring

Resistance to ARVs around the world

Region	% Resistance to any ARV
North America	11.4%
Europe	10.6%
East Asia	7.4%
Latin America	6.4%
Southeast Asia	5.7%
Africa	5.5%

And Namibia? Where lies the resistance gauge?

- A study carried out on HIV drug resistance in Sentinel Antiretroviral Treatment Sites by Tufts University .
- Study monitored HIVDR emerging in populations on ART from 3 sentinel ART sites (Katutura, Rundu & Oshakati)
- Results showed that ARV resistant rate among patients on:
  - any kind of ARV was 6.8%
  - NNRTI was 6.3%
  - NRTI was 0.3%
  - NRTI + NNRTI was 0%

- By its endpoint classification indicators, the study established in a total 384 patient s entered into the study:
  - HIVDR prevention (VL≤1000 c/ml were achieved in 75%
  - 21% could be possibly drug resistant (VL> 1000c/ml but with no DR mutation detected)
  - 4% were drug resistant (VL> 1000 c/ml and DR mutation detected.
- Prevalence resistance rate lies in the range the WHO established for Africa

Estimated prevalence of mutations in WHO acquired HIVDR surveys at baseline by region and by drug class % (95% confidence intervals), 2007-2010

		Year of Implementation				
	WHO Region	2007	2008	2009	2010	p-value[a]
Any drug class	Africa	4.6 (3.6-5.8)	3.7 (2.8-4.8)	4.6 (2.2-7.8)	6.8 (4.8-9.0)	0.04
	South-East Asia	7.9 (4.0-13.7)	5.4 (2.9-8.6)	--	--	0.34
	Overall	4.8 (3.8-6.0)	3.9 (3.0-4.9)	4.6 (2.2-7.8)	6.8 (4.8-9.0)	0.06
NRTI	Africa	1.1 (0.6-1.7)	1.0 (0.5-1.6)	1.1 (0.3-2.2)	1.0 (0.3-2.0)	0.75
	South-East Asia	3.6 (1.2-8.2)	4.3 (2.0-7.2)	--	--	0.74
	Overall	1.2 (0.7-2.0)	1.3 (0.8-2.0)	1.1 (0.3-2.2)	1.0 (0.3-2.0)	0.70
NNRTI	Africa	3.4 (2.4-4.5)	2.3 (1.4-3.3)	3.3 (1.8-5.0)	5.4 (3.7-7.4)	0.03
	South-East Asia	7.9 (4.0-13.7)	3.0 (1.2-5.6)	--	--	--
	Overall	3.7 (2.5-4.9)	2.4 (1.6-3.3)	3.3 (1.8-5.0)	5.4 (3.7-7.4)	0.06
PI	Africa	0.3 (0.1-0.8)	0.5 (0.1-0.9)	0.5 (0.1-1.7)	0.0 (0.0-0.4)	0.82
	South-East Asia	0.0 (0.0-2.6)	0.0 (0.0-0.7)	--	--	--
	Overall	0.3 (0.0-0.7)	0.4 (0.1-0.8)	0.5 (0.1-1.7)	0.0 (0.0-0.4)	0.97

a Statistical methods are described in Section 9 Annex 1.
-- Data are not available or applicable.

Drug resistance in TB: *MDR-TB*

- WHO estimates 630,000 cases of MDR-TB in the world*
- Globally, 3.7% of new TB cases and 20% of previously treated TB cases are estimated to have multi-drug resistant strains*
- In several high MDR-TB burden countries, 9 to 32% of new cases have MDR-TB and more than 50% of previously treated cases have MDR-TB**

Drug resistance in TB: *XDR-TB*

- 84 countries have reported at least one case of extensively drug-resistant (XDR-TB)*
- The average proportion of MDR-TB cases with XDR-TB is 9% (6.7 to 11.2%)*
- Around 40,000 XDR-TB cases emerge every year**

FIGURE 4.4 **Countries that had notified at least one case of XDR-TB by the end of 2011**

Prevalence of TB drug resistance: Namibia

- Number of notified cases of drug-resistant TB continued to decline in 2011, with a total of 240 cases in 2011 compared to 285 in 2010 and 372 in 2009.
- Of the 2011 total, 192 had multidrug-resistant (MDR) TB while 2 had extensively drug-resistant (XDR) TB
- Majority of Drug resistant cases found in Khomas Okahanja and Ohangwena regions
  - Areas of high population density

Table of TB drug resistance prevalence: Namibia

(Total confirmed DR-TB cases 2007-2011)

Category	2007	2008	2009	2010	2011
Number of cases with MDR-TB (excluding XDR-TB)	116	201	275	214	192
Number of cases with poly-drug resistant TB	7	47	80	63	46
Number of cases with XDR-TB	3	20	17	8	2
Total number of DR-TB cases	126	268	372	285	240

Factors contributing to AMR and impact of AMR

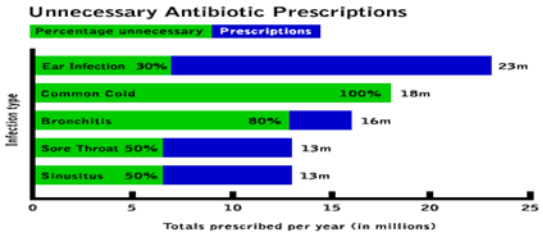
Key factors contributing to AMR

- Inappropriate use of antimicrobials by providers and patients key driver of AMR

20 to 50% of antimicrobial use in humans is unnecessary

40 to 80% of antimicrobial use in animals is highly questionable

Unnecessary and inappropriate usage of antimicrobials e.g. orchestrates the stage for antibiotic resistance development



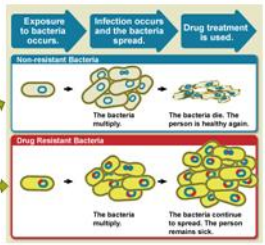
- Source (NPR/US Food and drugs administration)

How?

- Antimicrobial choice

Appropriate
Active against organism
Appropriate dose

Inappropriate
Inactive against organism
Inappropriate dose



Key factors contributing to AMR (2)

The 60th World Health Assembly Resolution on Progress in the Rational Use of Medicines (2007) acknowledged that:

"successful implementation of previous resolutions on antimicrobial resistance cannot be achieved without addressing the global problem of irrational use of medicines."*

Key factors contributing to AMR (3)

- Other factors include:
  - Limited access to antimicrobials
  - Poor quality antimicrobial products
  - Poor infection prevention and control
  - Poor regulation and enforcement
  - Inadequate surveillance in resource-constrained countries
  - Weak pharmaceutical management
  - Inappropriate drug promotion, including direct-to-the-consumer and internet ads

The United States Food and Drug Administration estimates that 10% of medicines worldwide are counterfeit and, in some countries, more than 50% of the medicine supply is fake

Impact of AMR

Significant individual and public health consequences, including –

- Prolonged illness
- Increased mortality
- Prolonged periods of infectiousness with increased risk of transmission of resistant pathogens to others
- Indirect costs (e.g., prolonged absence from work)
- Increased direct costs (e.g., extended hospital stays, use of more expensive second or third line drugs)

Impact of AMR: *Cost*

Disease	Average 1st line cost (USD)	Average 2nd line cost (USD)	Increase
HIV/AIDS*	$482 per patient per year	$6,700 per patient per year	$6,218 per patient per year **OR** 14x more
TB**	$20 per course	$3,500 per course	$3,840 per course **OR** 175x more
Malaria***	$0.10 to $0.20 per adult course (chloroquine/SP)	$1.20 to $3.50 per adult course (ACTs)	$1.00 to $2.20 per adult course **OR** 6-35x more

Impact of AMR: *Cost (2)*

- Estimates from **Europe:**
  - Estimated that excess mortality due to resistant bacterial hospital infections exceeds 25,000 annually
  - Attributable healthcare costs and productivity losses are estimated to be at least €1.5 billion each year

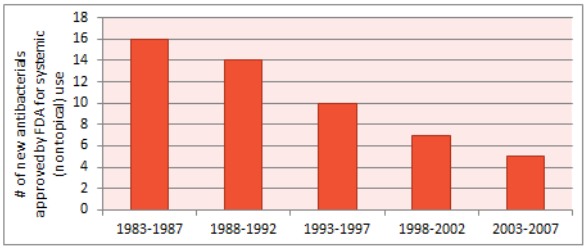
Why must we urgently preserve the effectiveness of currently available antimicrobials?

First-line treatments are failing

Infectious disease	AMR global prevalence rates
Tuberculosis	▪ Up to 17% multi-drug resistance
HIV/AIDS	▪ Up to 25% primary resistance to at least one antiretroviral agents
Gonorrhea	▪ 5 to 98% penicillin resistance and 1 to 50% fluoroquinolone resistance in *Neisseria gonorrhoeae*
Pneumonia and bacterial meningitis	▪ Up to 70% penicillin resistance ▪ 6 to 43 % ampicillin resistance ▪ 11 to 72% Macrolide resistance in *Streptococcus pneumoniae*
Diarrhea (*shigellosis)*	▪ 10 to 90% ampicillin resistance ▪ 5 to 95% cotrimoxazole resistance
Hospital infections	▪ Up to 70% resistance of *Staphylococcus aureus* to all penicillins and cephalosporins

Source: WHO country data, 2000-02 and APUA 2005. Global Advisory on Antibiotic Resistance: GAFA (GAARD Report). Boston, APUA.

The antimicrobial pipeline is dwindling



Source: Spellberg et al. Clinical Infectious Diseases 2008;46:155-64.

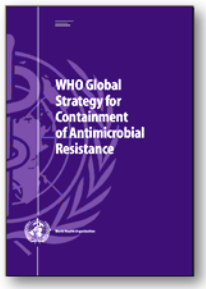
The flow of medicines is substantially increasing

- Multifold increase in supply of HIV/AIDS, TB and malaria medicines through recent global health initiatives (e.g., GFATM, US Presidential Initiatives, Global Drug Facility)
- Resistance likely to escalate rapidly if strategies to strengthen pharmaceutical management and contain AMR are not implemented

2001 WHO Global Strategy for Containment of AMR

2011 World Health Day AMR Policy Package

2001 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

2001 WHO Global Strategy for Containment of AMR (2)

Objectives

- Reduce disease burden and spread of infection
- Improve access
- Improve antimicrobial use
- Strengthen health systems and their surveillance capacity
- Enforce regulation and legislation
- Encourage new drugs and vaccines development

Multifaceted approach

- Patients/ general community
- Prescribers and dispensers
- Hospitals
- Use in food-producing animals
- National governments and health systems
- Vaccines and drug development
- Pharmaceutical promotion
- International aspects of containing AMR

WHO Global Strategy: *Six key points*

- Disease prevention and infection control
- Access to antimicrobials
- Appropriate antimicrobial use
- Legislation and regulation
- Surveillance
- Focused research

World Health Day 2011: Six-point policy package on AMR

- Commit to a comprehensive, financed national plan with accountability and civil society engagement
- Strengthen surveillance and laboratory capacity
- Ensure uninterrupted access to essential medicines of assured quality
- Regulate and promote rational use of medicines, including in animal husbandry, and ensure proper patient care
- Enhance infection prevention and control
- Foster innovations and research and development for new tool

This policy package correlates with the 2001 WHO Global Strategy recommendations discussed on the previous slides

Good and sustainable results require approaches that…

Include AMR containment as "value added"	Build on existing foundations	Address health systems and policy issues
Are multifaceted	Bring stakeholders together (locally, regionally)	Have clear advocacy and communication strategies

Brief overview of interventions to contain drug resistance in HIV and TB

Responding to drug resistance in HIV: *Routine monitoring*

Conduct routine surveillance of transmitted and acquired HIV drug resistance using a minimum set of WHO HIV drug resistance early warning indicators in all treatment sites

The indicators assess:

- How well populations are adherent to therapy
- Whether pharmacies dispense regimens that are likely to promote the emergence of HIV drug resistance
- Whether stock-outs of routinely dispensed ARV medicines occur
- The extent to which people are retained in care at the ARV clinic-level

Responding to drug resistance in HIV: *Routine monitoring (2)*

- WHO surveys of transmitted drug resistance
  - Alert program managers to the existence of drug-resistant HIV among recently infected populations in specific geographical areas
- WHO surveys of acquired HIV drug resistance
  - Estimate prevalence and patterns of resistance at treatment initiation
  - Estimate the proportion of people achieving successful virological suppression at 12 months at sentinel sites
  - Describe drug resistance in populations experiencing treatment failure

Source: WHO HIV Drug Resistance Report 2012.

USAID SIAPS

Responding to drug resistance in HIV: *Routine monitoring (3)*

- Highlights important gaps in the quality of service delivery and program performance, particularly with respect to procurement and supply systems, adherence and patient retention rates
- Optimizes program planning and management
- Informs ART policy in place
  - Provides basis for selecting future first-line treatment regimens
  - Identifies the most effective second-line therapies for patients failing first-line combinations
  - Useful for selecting optimal approaches for PMTCT and pre-and post-exposure prophylaxis

Since 2004, 50 countries have piloted the monitoring of HIV drug resistance early warning indicators at select clinics

Source: WHO HIV Drug Resistance Report 2012.

USAID SIAPS

Responding to drug resistance in TB

- Ultimately the fundamental requirement is **political commitment** and **will** for successful application of all the recommended measures*
- XDR-TB is a reflection of failure to implement all of the measures recommended in the *WHO Stop TB Strategy*. To succeed in our fight against XDR-TB, the scale of our response has to match the scale of the challenge
- The *Global MDR-TB and XDR-TB Response Plan 2007-2008,* a recent WHO/Stop TB Partnership document, details what stakeholders must do to address this problem**
- The Global XDR-TB Taskforce has set a target to *treat 1.6 million MDR-TB patients by 2015*

* Farmer and Kim, BMJ 2007;330:19

** WHO/HTM/TB/2007.387

USAID SIAPS

Responding to drug resistance in TB (2)

Countries must –

- increase awareness, recognition, and commitment to prevent and treat M/XDR-TB
- urgently finalize MDR-TB Plans within national TB and health sector plans, using available tools
- immediately make the necessary policy decisions, at the level of the national TB control program and higher level in the Ministry of Health, to prevent further development of M/XDR-TB
- devise domestic and external resource mobilization strategies and tactics in an era of financial restrictions and ensure their rapid implementation and monitoring

Source: WHO 2009. Ministerial meeting on High MDR-TB Burden countries. Beijing, China.

USAID SIAPS

Responding to MDR/XDR-TB (3)

- Augment DOTS program with:
  - New diagnostics
  - New drugs
  - New vaccines
  - Treatment as prevention – reduction in HIV incidence
  - Advocacy*

* Mathema and Kurepina. Lancet. 2007;370:2030-43

USAID SIAPS

We act now or we lose soon!

act! now!

- 65 years ago, we were in a ***pre-antimicrobial*** era
- Now, we are in impending danger of entering a ***post-antimicrobial*** era, as evidenced by the propagation of XDR-TB
- **If we really want to prevent this disaster, shouldn't our advocacy and interventions be as immediate and as intense as the threat is?**

USAID SIAPS

Session 6. Using Indicators to Monitor HIV Drug Resistance

Using Indicators to Monitor HIV Drug Resistance

Presenter
Victor Sumbi: MSH/ SIAPS

Stakeholders' Meeting on antimicrobial resistance and promoting the rational use of ARVs, anti-TB and other medicines in Namibia
UNAM School of Pharmacy, Windhoek
24 July 2013

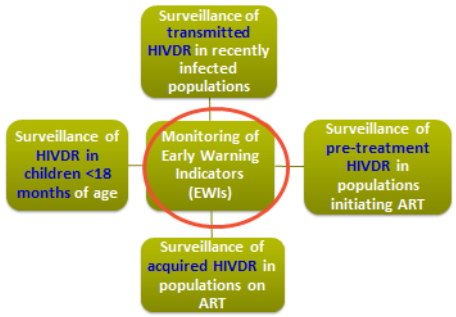
USAID FROM THE AMERICAN PEOPLE
SIAPS Systems for Improved Access to Pharmaceuticals and Services

WHO HIV Drug Resistance (HIVDR) Strategy

- Rapid or uncontrolled emergence and transmission of HIVDR is a widely feared consequence of ART scale-up, which could lead to failure of ART programmes and strategies to prevent HIV transmission, increasing morbidity, mortality and cost
- WHO recommends that countries develop a public health strategy to assess and minimize the emergence and transmission of HIVDR
- WHO has developed global HIVDR strategy designed to be fully integrated into country's routine HIV prevention and monitoring activities

USAID SIAPS

WHO HIVDR Surveillance & Monitoring Strategy



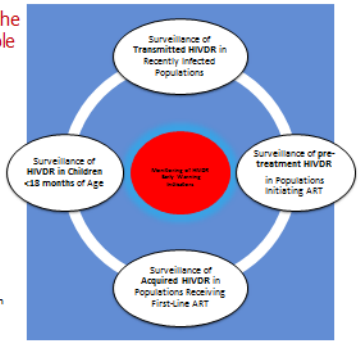
HIV DR EWI = HIV drug resistance early warning indicators

USAID SIAPS

WHO HIV Drug Resistance (HIVDR) Strategy

How are ART clinics and the ART programme as a whole performing in minimizing population-level HIVDR?

1. Prescribing practices
2. Retention in care
3. Adherence
4. ARV stock outs
5. Virologic suppression



The updated WHO strategy recommends national point prevalence with confidence intervals for each type of HIVDR survey, which can be trended over time.

EWIs are the site-specific information from which the surveys of HIVDR can be contextualized and action can be taken.

USAID SIAPS

Early Warning Indicators of HIV Drug Resistance

- WHO EWIs are quality of care indicators which assess factors associated with virological failure and emergence of HIVDR
- Designed to be monitored at all ART sites as part of routine monitoring and evaluation
- Where widely implemented, EWIs provide site-specific information and the necessary programmatic context
  - to interpret results of surveys of HIVDR
  - to offer an opportunity for corrective action to optimize patient care and minimize HIVDR

USAID SIAPS

Namibia Background

- Estimated 18.2% HIV prevalence (ANC) in adults (2012)
- Intensive ART scale-up successful
  - In March 2013, 107,154 patients reported to be on antiretroviral therapy (ART)
  - Coverage estimated at 84% of eligible patients
- Challenge in Namibia is to optimize ART delivery and minimize HIVDR

MoHSS Namibia 2010 & 2011 & 2012; WHO/UNAIDS/UNICEF. Towards Universal Access 2011

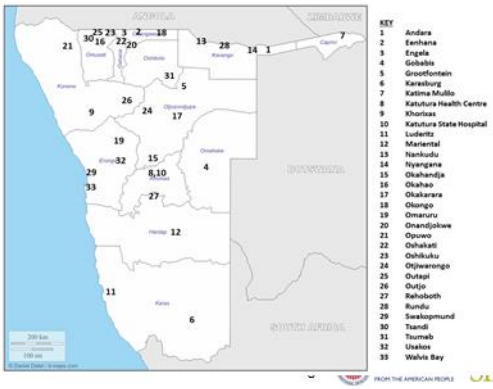
USAID SIAPS

Chosen Early Warning Indicators in Namibia 2010

1. ART prescribing practices; target 100 %
2. Patients lost to follow-up at 12 months; target < 20%
3. Patients switched to second-line ART at 12 months; target = 0%
4. On-time ARV drug pick-up: target; ≥ 90%
6. ARV drug-supply continuity; target 100%

USAID SIAPS

Geographical location of ART sites



USAID SIAPS

Data sources

- Electronic Dispensing Tool (EDT)
- Electronic patient management system (ePMS)
- Patient Care Booklets

USAID SIAPS

National EWI Summary 2010

EWI	EWI Target for all sites (time period)	Number of sites meeting EWI target (% of sites meeting target) N=X ART sites
% appropriate initial ART regimen prescriptions	Target = 100% (1 Jul 2008- 30 Jun 2009)	22 of 33 (67%)
% starting first-line ART lost to follow-up at 12 months	Target ≤ 20% (1 Jul 2008- 30 Jun 2009)	17 of 33 (52%)
% starting first-line ART switched to second-line at 12 months	Target 0% (1 Jul 2008- 30 Jun 2009)	15 of 33 (45%)

USAID SIAPS

Summary of EWI Results-Namibia (1)

- *ART prescribing practices:* 22 of 33 sites (67%) achieved 100% appropriate prescribing of ART starters
  - Although percentage of sites meeting target was low, sites not meeting 100% had very few patients prescribed inappropriate first-line regimen
  - All inappropriate first-line regimens were NOT dual- or mono-therapy and were appropriate PI-based regimens
  - Data suggests successful implementation of national prescribing guidelines and training of ART staff

USAID SIAPS

Summary of EWI Results-Namibia (2)

- *Lost to follow-up at 12-months:* only 17 of 33 (52%) sites achieved the suggested target of ≤20%
  - Data suggests many patients are being lost to follow-up within first 12 months of ART and/or many patients transferring out without informing site
  - This patient population may be at high risk for experiencing treatment interruptions and developing HIVDR
  - Broad range of LTFU rates between sites suggest there may be factors at site-level that are influencing LTFU

USAID SIAPS

Summary of EWI Results-Namibia (3)

- *Patients switched to second-line ART at 12 months:* 15 of 33 (45%) sites achieved the target of 0% of patients on a second-line regimen at 12 months.
  - Although many sites did not meet the target of 0%, in sites not meeting the target very few patients were switched to second-line regimen suggesting appropriate physician prescribing practices and success in managing ARV toxicity and side effects through in-class substitutions.
  - Data suggests patients who were retained in care on ART at 12 months had good clinical outcomes and were not failing therapy

USAID SIAPS

Summary of EWI Results-Namibia (4)

- *On-time ARV drug pick-up:* Data were considered not to be a true reflection of population-level adherence in Namibia
  - Existing limitations of EDT data capture
  - Lack of standardization of pharmacy dispensing practices
- *ARV drug-supply continuity:* Using the EDT, all clinics were found to have drug stock outs during 2009
  - Results are very likely to be an overestimation of drug stock outs
  - Because stock data was not routinely entered in real time, it is not possible to assess if sites experienced stock outs which may have been clinically relevant

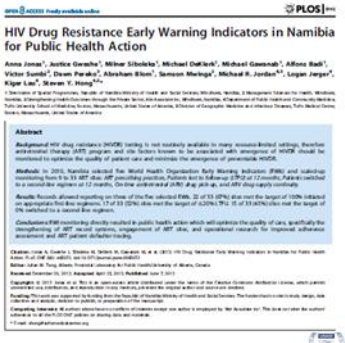
USAID SIAPS

Recommended action plan

- Strengthen record keeping systems (Patient Care Booklet, ePMS, EDT)
- Significant LFTU and treatment interruptions may occur in the highly mobile population
  - Enable clinic staff to access the national EDT patient database which would permit the tracking of patients
  - Investigate predictors and reasons for LTFU and strengthen existing standardized defaulter tracking mechanisms
- Standardize dispensing practices at ART pharmacies and modify definition of 'on-time ARV pick-up' to assess population adherence in future years
- Keep track of stock in the ART dispensing pharmacy in real time and explore other methods of capturing this important EWI

USAID SIAPS

For additional details see:



HIV Drug Resistance Early Warning Indicators in Namibia for Public Health Action

USAID SIAPS

WHO HIVDR EWI 2012 Revisions

- EWIs without strong association with HIVDR were eliminated
- Each EWI retained evaluated
  - Minimize overlap of information
  - Maximize efficiency of data abstraction
  - Harmonize definitions with other reported indicators, whenever possible

http://www.who.int/hiv/topics/drugresistance/en/index.html

USAID SIAPS

Example of EWI target scorecard

Figure 1 Example of EWI target scored card

HIV Drug Resistance Early Warning Indicator Score Card		
Early Warning Indicator	**Status**	**Target**
1. On-time Pill Pick-up		• Red: <80% • Amber 80-90% • Green ≥ 90%
2. Retention in care		• Red < 75% retained after 12 months ART • Amber, 75 - 85% retained after 12 months ART • Green ≥ 85% retained after 12 months ART
3. Pharmacy stock-outs		• Red < 100% of a 12 month period with no stock-outs • Green 100% of a 12 month period with no stock-outs
4. Dispensing practices		• Red > 0% dispensing of mono or dual therapy • Green 0% dispensing of mono or dual therapy
5. Virological Suppression#		• Red < 70% viral load suppression after 12 months of ART • Amber 70 – 85% viral load suppression after 12 months of ART • Green ≥ 85% viral load suppression after 12 months of ART
Explanatory Notes: Red (poor performance, below desired level) Amber (fair performance, not yet at desired level but progressing towards desired level), Green (excellent performance, achieving desired level) Grey (data not available) #Targets for virological suppression in children < 2 years old • Red < 60% viral load suppression after 12 months of ART • Amber 60-69% viral load suppression after 12 months of ART • Green ≥70% viral load suppression after 12 months of ART		

USAID SIAPS

REVISED Early Warning Indicators successfully abstracted in 2012

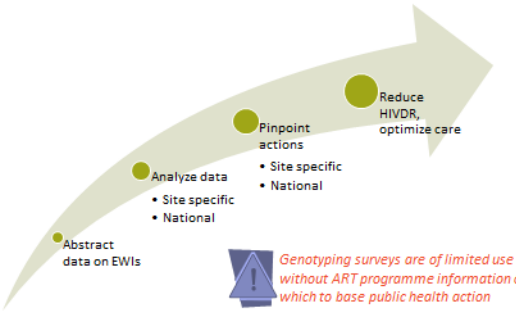
1. On-time Pill Pick-up
2. Retention in care
3. Pharmacy stock-outs
4. Dispensing practices
5. Virological Suppression at 6 months

Paediatric EWIs were also abstracted

USAID SIAPS

20

EWI monitoring Process



USAID SIAPS

Session 7. Building an Effective National-Level Coalition Against Antimicrobial Resistance

Building an Effective National-Level Coalition Against Antimicrobial Resistance

David Mabirizi, Malaika Schiller, Mohan P. Joshi, Evans Sagwa

Workshop on antimicrobial resistance and promoting the rational use of ARVs, anti-TB and other medicines in Namibia
UNAM School of Pharmacy, Windhoek
22-24 July 2013

USAID SIAPS Systems for Improved Access to Pharmaceuticals and Services

Session objectives

- Discuss a country-level approach to identifying and engaging antimicrobial resistance (AMR) stakeholders
- Discuss advocacy and coalition-building guidelines
- Discuss practical implementation tools and templates
- Discuss practical collaboration with stakeholders, including the International Network for the Rational Use of Drugs (INRUD) and Namibians Against Antibiotic Resistance (NAAR)

USAID SIAPS

MSH/SIAPS, SPS, RPM Plus activities

- WHO has provided a Global Strategy on AMR, but few countries are implementing it
- Bridge needed from global strategy to country- and regional-level actions
- USAID-supported SIAPS and its predecessors, SPS and RPM Plus, have helped build country and regional capacity to generate coalitions for AMR advocacy
  - *Country level*: Zambia, Ethiopia
  - *Regional level*: Ecumenical Pharmaceutical Network (EPN), Regional Pharmaceutical Forum (RPF)

SPS = Strengthening Pharmaceutical Systems
RPM Plus = Rational Pharmaceutical Management Plus

USAID SIAPS

AMR advocacy and containment: A country-level approach

WHO. 2001. *WHO Global Strategy for Containment of Antimicrobial Resistance*. WHO/CDS/CSR/DRS/2001.2a. Geneva: WHO.

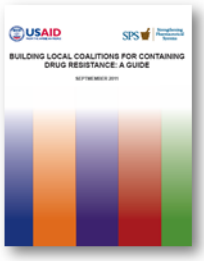
From global strategy...

...to country-level implementation

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

USAID SIAPS

Jump-starting the process with coalition-building



- SPS developed *Building Local Coalitions for Containing Drug Resistance*, a guidebook to help jump-start the AMR advocacy process
- *Key components:*
  - Identifying and engaging AMR stakeholders
  - Advocacy and coalition-building guidelines
  - Examples of practical implementation from country- and regional-level initiatives
  - Practical implementation tools and templates

Who should use this guide?

- Medical, pharmacy, nursing, public health, laboratory professionals, or other health care workers
- Non-governmental organizations (NGOs)
- Disease control programs
- Academic institutions
- Service facilities (e.g., hospitals, clinics)
- Ministries of Health
- Consumer advocacy groups

What does the approach involve?

- Mobilizing support among key stakeholders and creating an AMR working group to lead the coalition
- Understanding the local situation based on existing information
- Formulating a collaborative strategy and plan across all disease areas and levels of the health system
- Implementing an action plan
- Monitoring and evaluating implementation of the plan based on specific indicators for inputs, outputs, and outcomes
- Adapting and expanding the efforts to contain AMR as more information and resources become available

Elements of the country-level approach

Elements of the country-level approach (2)

Step	Description
*1. **Initiate the process***	• Quickly gather available information regarding key AMR-related issues and local players • Bring relevant stakeholders to a common table and facilitate discussion
*2. **Identify a local champion group***	• Develop a new group or expand the role of an existing group • Ensure that the group is multidisciplinary and multisectoral • Empower the champion group to lead the process and catalyze actions
*3. **Gain additional understanding of the local situation***	• Conduct a rapid appraisal

Elements of the country-level approach (2)

Step	Description
*4. **Expand advocacy and initiate interventions***	• Develop a call-to-action or similar advocacy document and disseminate it during the coalition-building process • Organize a call-to-action meeting that brings all stakeholders on board, commits them to action against AMR, and raises the visibility of the initiative • Catalyze and facilitate interventions identified as relevant as feasible, based on the rapid appraisal and call-to-action meeting
*5. **Monitor progress***	• Assess inputs, processes, and outputs associated with specific implementation activities

AMR-related illustrative indicators

- Average number of days that a set of key indicator antimicrobial drugs is out of stock in a 12-month period
- Percentage of treatments that are prescribed in accordance with STGs
- Number of institutions that have established DTCs or improved performance of existing DTCs
- Percentage of hospitals with infection control policies and procedures
- Number of rational antimicrobial use or AMR containment related activities implemented at institutional levels
- Number of IEC messages developed and disseminated on AMR, responsible medicine seeking behavior and appropriate antimicrobial use in the community
- Percentage of patients with knowledge of correct dosage for the antimicrobials prescribed

Relevant tools in the guidebook

Step	Tool
1. Initiate the process *2. Identify a local champion group*	**Form 1.** Stakeholder Identification Worksheet **Form 2.** Stakeholder Contact List **Form 3.** Stakeholder Interview Guide **Form 4.** Sample Invitation for Kick-off Meeting **Form 5.** Sample Agenda for Kick-off Meeting **Annex C.** Global AMR Situation PowerPoint Slides **Country Example 1.** Stakeholder Identification Worksheet: Rwanda **Country Example 6.** Key Stakeholder Characteristics Related to AMR: Zambia **Country Example 3.** Sample Agenda for Kick-off Meeting: Ethiopia

Step	Tool
3. Gain additional understanding of the local situation	***Form 8.*** Questions for Document Review and Interviews to guide collecting information on pharmaceutical management issues that relate to AMR ***Form 9.*** Document Review Guide for Drug Use Behaviors and Underlying Causes ***Form 10.*** AMR Levels and Trends ***Form 11.*** Interview Guide on AMR Surveillance ***Form 12.*** Interview Guide for Reference Laboratories ***Form 13.*** Interview Guide for Microbiology Laboratories ***Form 15.*** Interview Guide for Media Contacts ***Annex G.*** Global AMR Situation PowerPoint Slides ***Annex G.*** Findings from the Pharmaceutical Management Assessment in Zambia, 2004 ***Annex I.*** Summary of AMR surveillance and capacity assessment in Zambia, 2004 ***Annex J.*** Summary of interviews to identify stakeholder perceptions of AMR, Zambia 2004 ***Annex L.*** Extracts of interviews with 10 media members in Zambia ***Country Example 4.*** Methods and Results of a Baseline Assessment of AMR in Ethiopia
4. Expand advocacy and initiate interventions	***Form 16.*** AMR Intervention Prioritization Worksheet ***Form 19.*** Implementation Plan Template ***Annex D.*** AMR Call-to-Action Documents ***Annex M.*** November 20, 2005 article in Times of Zambia after an AMR call-to-action meeting in Lusaka ***Annex N.*** Summary of EPN and member group AMR activities, 2008-2011 ***Country Example 9.*** Stakeholders' Opinions on AMR-Related Issues in Rwanda ***Country Example 10.*** AMR Call-to-Action Meetings in Zambia, Ethiopia, and Rwanda ***Country Example 7.*** Action Plan: Christian Health Association of Nigeria Medi-Pharm ***Country Example 8.*** Examples of Personal Action Commitments
5. Monitor and evaluate	***Country Example 8.*** Hospital Monitoring Plan for Infection Control Activities in Togo

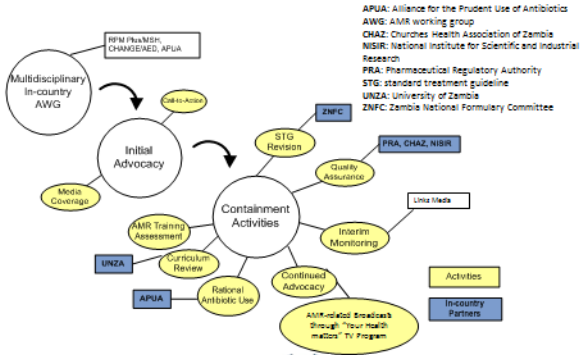
AMR advocacy and containment: Examples

The Zambian and Ethiopian AMR working groups (country level) as well as EPN and RPF (regional level) generated widespread advocacy through their AMR call-to-action meetings and documents

Journalists raise their hands and join in solidarity to support AMR advocacy and containment at the close of a SIAPS-supported workshop organized by the Food, Medicine and Health Care Administration and Control Authority (FMHACA) of Ethiopia in June 2012

EPN = Ecumenical Pharmaceutical Network; RPF = Regional Pharmaceutical Forum

Zambia: A country-level example (2)



EPN: A regional-level example

FIGHT AMR! Save medicines for our children

2007	2008	2009	2008-2010	2013
At a meeting in Lagos, EPN members agreed that AMR was a problem that needed attention	30 health professionals from 16 countries met in Moshi, Tanzania and developed a call-to-action on AMR with SPS support	30 professionals from 7 countries attended a francophone workshop on AMR and infection control in Kigali, Rwanda with SPS support	Advocacy and containment actions by members in different countries and an implementation review meeting at Nairobi with SPS support	3-day training of trainers workshop on AMR and antibiotic use in Zimbabwe with SIAPS support

USAID SIAPS

EPN: A regional-level example (2)

The ***call-for-action document*** was a tool that all EPN members could use to take action to address AMR at multiple levels

- Political leaders
- Ministries of Health
- Health professional associations
- Health care institutions
- Health training institutions
- Health care providers
- Patients
- Public
- Media

USAID SIAPS

Launches of EPN-member AMR campaigns in Uganda, India, Nigeria

USAID SIAPS

Examples of EPN member engagement

Country	Activity
DRC	Sensitization of the catholic women's group on AMR and hospital infection control interventions in Kananga District
Zimbabwe	Presentation of a position paper on AMR at Government Public Health Advisory Committee Meeting
Sierra Leone	Survey of 35 professionals in 9 hospitals on knowledge and attitudes on AMR
Tanzania and Malawi	Re-activation and establishment of Hospital Medicine and Therapeutics Committees
Moldova	Hosting of a roundtable on AMR for the Armenian Orthodox Church

USAID SIAPS

EPN Accomplishments

- Following the EPN-SPS kick-off regional AMR workshop in Moshi, Tanzania in November 2008, EPN members in many countries began advocating for and implementing AMR-related activities.
- Carried out more than 120 activities by June 2011
- Activities included advocacy, research, publication, and containment-related initiatives.

USAID SIAPS

EPN Coalition-building interventions

- Identified stakeholders who could further the cause
- Built the knowledge and understanding of stakeholders
- Produced and disseminated a variety of information, education and communication materials
- Engaged stakeholders
- Implemented practical solutions

USAID SIAPS

Identified and engaged stakeholders

Seminar for health professionals and journalists in Togo (left)

Coalition-building around AMR among front-line health workers in the DRC (right)

USAID SIAPS

Identified and engaged stakeholders (2)

Round table discussion with high level health professionals, policy makers and regulators in Moldova

USAID SIAPS

Identified and engaged stakeholders (3)

Promoting awareness among school children regarding rational antimicrobial use in Moldova (above) and India (right)

USAID SIAPS

Produced and disseminated information

USAID SIAPS

Used diverse formats

- Comic strips
- Skits

USAID SIAPS

Implemented Practical Solutions

Hand hygiene and waste management activities for infection control in Cameroon and the DRC

USAID SIAPS

Lessons learned

- Frame AMR advocacy and containment as ***value added*** **in the context of existing program priorities** rather than presenting as a separate vertical and competing activity
- Focus **initial information gathering on identifying key issues and stakeholders** to provide the basis for quickly starting the national-level process for AMR containment
- Identify and work with a suitable **local champion group** that can lead the in-country process
- Ensure that the champion group includes respected opinion leaders **to legitimize activities and change agents to carry them out**

Source: Management Sciences for Health. 2011. *Building Local Coalitions for Containing Drug Resistance: A Guide.* Submitted to the U.S. Agency for International Development by the Strengthening Pharmaceutical Systems (SPS) Program. Arlington, VA: Management Sciences for Health.

USAID FROM THE AMERICAN PEOPLE SIAPS

Lessons learned (2)

- Ensure that the champion group **clearly articulates its objectives** from the outset
- Ensure that the champion group plays the role of a **catalyzing body** rather than being the "one and only action body"
- **Use advocacy as a central strategy** but ensure that it supports the objectives rather than being an end in itself
- Emphasize the **continuous nature** of the national AMR containment process
- **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

Source: Management Sciences for Health. 2011. *Building Local Coalitions for Containing Drug Resistance: A Guide.* Submitted to the U.S. Agency for International Development by the Strengthening Pharmaceutical Systems (SPS) Program. Arlington, VA: Management Sciences for Health.

USAID FROM THE AMERICAN PEOPLE SIAPS

Namibia: The way forward

USAID FROM THE AMERICAN PEOPLE SIAPS Systems for Improved Access to Pharmaceuticals and Services

SPS/Namibia Strategic Framework for AMR

Strategic Areas for Containment of AMR	MSH/SPS Interventions
Ministry of Health	• Development of SOPs for NMRC • HIVDR monitoring (Early Warning Indicators) • Review of NMP/NPMP, Nemlist • Development & dissemination of National STGs • Support for QSL (risk-based model; TB medicine testing) • Support for TIPC (Medicines Watch bulletin, Call Center, website, ADR reporting) • Improved information systems for monitoring & evidence-based decision-making
Hospital & Regional Management	• Strengthening of Therapeutics Committees • Support for Infection Control Committees • Implementation of STGs, Nemlist • Analysis & use of strategic information on prescribing, dispensing, patient adherence, stock levels • Implementation of NMP/NPMP
Strategic Information Systems	• PMIS • EDT • Rx Solutions • Pharmadex • e-TB Manager • Public Health Evaluations
Prescribers & Dispensers	• Rational Use trainings • Development & implementation of STGs, Nemlist • Pre-service & in-service training • Medicine use studies & feedback • ART SOPs for Pharmacy
Patients & Community	• Treatment Literacy • Resource center at TIPC
Outcomes	Containment of AMR Reduced costs Sustainable health programs

Strategic framework for AMR (2)

- Reflects four of the main strategic areas outlined in the WHO strategy
- General enough to incorporate *future activities* as well as other agencies' activities related to AMR in the health sector
- Addresses AMR at all levels of the health system
- Includes strategic information systems as a cross-cutting feature of AMR containment, as the information generated through these systems is intended to inform the policies, interventions, and research implemented at all levels

USAID FROM THE AMERICAN PEOPLE SIAPS

Gaps and opportunities

- Strengthen HIV AMR activities (HIV DR EWI, treatment guidelines, adherence)
- Broaden focus to include TB, OI and general-use antimicrobials in more activities
- Increase private sector engagement
- Strengthen collaboration with the National Institute of Pathology
- Strengthen link between information on antimicrobial use and resistance and disease surveillance data
- Create a national intersectoral task force to raise awareness about AMR, organize data collection, and coordinate partners

USAID FROM THE AMERICAN PEOPLE SIAPS

A way forward

- Explore opportunities to strengthen, integrate, and enhance approach to AMR containment in Namibia
- Engage new partners and strengthen collaboration with existing partners
  - National Institute of Pathology, Centers for Disease Control, University Research Co LLC, WHO
- Advocate for AMR as a local and national priority
  - AMR working group as a first step towards creating a national coalition
  - INRUD chapter
  - NAAR
  - Information dissemination activities
  - Therapeutics Committees

Policy Implications

- Effective advocacy and coalition-building is vital for catalyzing an organized, coordinated, and sustained response to the AMR challenge
- Only when AMR is identified as an urgent priority can policy level decisions take place related to antibiotic policies, drug regulation, antimicrobial use in animals, and AMR surveillance, education, and research
- Donors, development partners, and key national stakeholders need to support the creation of sustained advocacy efforts and local coalitions around AMR

Future Research

Existing evidence gap for advocacy

- Little data, especially from resource-limited countries, on AMR's effect on morbidity, mortality, and cost increase and diversion
- AMR impact is not obvious to policy makers and even health care providers

Future research need

- More data urgently needed on short- and long-term effects of AMR in resource-constrained countries
- Such data will serve as a powerful advocacy tool to convince policy-makers to give AMR a high priority

Joining Hands for AMR Advocacy

Coalition and collaboration are important to—

- Address AMR as a common problem
- Bring synergy in advocacy and actions
- Share expertise, experience, lessons learned, best practices, and resources
- Disseminate available data and improve networking of existing surveillance
- Motivate each other, facilitate cross-communications, and transfer information
- Create voice to sensitize donors and mobilize funding for AMR initiatives