

Mozambique Drug and Therapeutics Committee Workshop and Field Activities: Technical Report

August 2014



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Mozambique Drug and Therapeutics Committee Workshop and Field Activities: Technical Report

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August 2014



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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.

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Key Words

Drug and Therapeutics Committee, rational medicine use, antimicrobial resistance, standard treatment guidelines, and medicine use evaluation

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ACRONYMS

DFH	Departamento de Farmacia Hospitalar (Department of Hospital Pharmacy)
DNAM	Direcção Nacional de Assistência Médica (National Directorate of Medical Assistance)
DTC	Drug and Therapeutics Committee
MISAU	Ministério da Saúde (Ministry of Health - Mozambique)
MUE	medicine use evaluation
OPD	outpatient department
SIAPS	Systems for Improved Access to Pharmaceuticals and Services [Program]
STG	standard treatment guideline
TOR	terms of reference
WHO	World Health Organization

INTRODUCTION

The irrational use of medicines is a pervasive problem that threatens healthcare systems and quality of patient care in countries worldwide. The World Health Organization (WHO) estimates that 50% of patients receive unnecessary medicines and half of patients take their medicines incorrectly.

Irrational use behaviors include polypharmacy (the use of too many medicines per patient); the use of incorrect medicine(s) for a particular indication; the use of medicines with uncertain or unproven efficacy; inappropriate self-medication, particularly with prescription-only medicines; and taking medicines in incorrect dosages or for an improper duration. The inappropriate use of medicines has a number of consequences for public health, including:

- Increased mortality and morbidity
- Higher numbers of adverse medicine events
- Rising rates of antimicrobial resistance
- Rising health care costs

To counter the problems of irrational use, Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program and Ministério da Saúde (MISAU) (Ministry of Health) are working together in Mozambique to improve medicine management and use. SIAPS is seeking to create sustainable Drug and Therapeutics Committees (DTCs) to monitor and identify medicine use problems and to implement interventions to improve medicine use at the local health-facility level. SIAPS will also support the revision of the National Essential Medicines List (NEML) and development of new standard treatment guidelines (STGs) to complement those that are currently available.

This technical report provides information on the DTC workshop conducted on August 4-5, 2014, and on field visits to two hospitals in the Maputo area: Maputo Central Hospital and Matola Provincial Hospital. These field visits were designed to meet with hospital officials and DTCs, as well as to develop specific DTC activities to address medicine use problems.

BACKGROUND

SIAPS works with partners in the pharmaceutical sector and priority health programs to improve pharmaceutical services so that pharmaceutical products are not only available at service delivery points, but are also prescribed and dispensed appropriately, used correctly by patients, and monitored for safety and efficacy with the aim of achieving desired health outcomes. SIAPS provides technical support for the implementation of the national pharmacovigilance system to improve medicine safety; the creation of DTCs at hospitals to improve medicine use; the collection and analysis of medicine use information for decision-making; and the implementation of integrated supportive supervision and other supportive materials (e.g., guidelines, SOPs, training materials, and job aids) to improve the quality of pharmaceutical management and services according to established standards. Opportunities to improve patient adherence will also be identified and implemented in collaboration with partners. These interventions will be integrated and coordinated as appropriate to reinforce each other and improve the overall efficiency, cost-effectiveness, and quality of pharmaceutical services. It is expected that measurable improvements in pharmaceutical services will lead to measurable improvements in health outcomes.

A DTC orientation/training session was conducted in August 2013. This aimed to help establish DTCs, identify problems with—and solutions to improve—medicine use, and save funds and resources. Several DTCs were established after this orientation, and existing DTCs were able to strengthen their programs. A structure for DTCs, including multidisciplinary membership, terms of reference (TOR), action plans, and regular meetings, has also been established. They have also carried out basic prescribing indicator studies of medicine use and facilitated the monitoring of medicine availability and antibiotic use.

The Department of Hospital Pharmacy (DFH) at Direção Nacional de Assistência Médica (DNAM) (National Directorate of Medical Assistance) has identified the establishment of DTCs at hospitals as a priority intervention to improve the rational use of medicines at the hospital level. SIAPS collaborated with DFH to review and define the TOR and membership profile for the committees, as well as to identify hospitals that have already established DTCs.

Between August 2013 and July 2014, two pilot hospitals in Maputo City were established and supported. Additionally, four DTCs in Maputo Province were established, and personnel were trained. SIAPS worked with related stakeholders at two central hospital DTCs within both Maputo City and Maputo Province to identify challenges related to STGs or other rational medicine use issues and consider specific interventions to address these problems. MISAU and SIAPS will help to establish two additional pilot DTCs in hospitals in the Maputo area.

All DTCs were invited to attend a national DTC workshop, sponsored by SIAPS, to share their experiences, and to determine which interventions should be implemented to encourage rational medicine use.

Drug and Therapeutics Committee Workshop

A two-day DTC workshop was developed and held to provide an overview of the role, main functions, and responsibilities of DTCs, as well as to hear from DTC participants about their experiences and accomplishments. The 49 attendees included physicians, pharmacists, and other health professionals from hospital DTCs and MISAU (annexes A and B).

Between July 23 and July 27, preparations for the DTC workshop took place. These included setting objectives and an agenda for the workshop, and developing PowerPoint presentation slides and relevant handouts. Standardized DTC training materials were used for the workshop with modifications making them specific to Mozambique.

Key topics for the workshop include:

- Participant presentations on their hospital DTCs, covering current activities, identified problems with – and barriers to – rational medicine use, future challenges, and DTC impact
- Medicine use overview
- Developing and implementing DTCs
- Interventions to improve medicine use and STGs
- Updating the revision process and encouraging better use of the National Essential Medicines List (NEML)
- Medicine Use Evaluation (MUE)– Improving medicine use through a MUE process, Recommendations and next steps

Day 1

At the opening session, the Minister of Health, Alexandre Manguale, welcomed all attendees and expressed his intention to improve the operations of DTCs and encourage rational medicine use in Mozambique. He explained that the workshop would evaluate the functions of the DTCs established in the provinces, representing a major step towards improving the use of medicines in health facilities. MISAU has been making efforts to improve pharmaceutical services in general, particularly at the hospital level. MISAU hopes to increase the number of staff members and available financial resources, expand availability of medicines and medical information, improve the management of the entire supply chain, and encourage rational medicines use and appropriate prescribing practices within the country's hospitals.

The 11 hospital DTCs represented at the workshop each gave a presentation. Though many DTCs have only been recently formed, they have been able to identify the challenges facing rational medicine use and the changes they would like to implement. Key activities included the

monitoring of prescriptions for appropriate format (patient name, signatures, legible writing, dosing), basic medicine use studies (including evaluation of health facility prescribing indicators), and monitoring of the NEML.

The first day of the workshop concluded with an overview of international medicine use problems. DTCs worked in groups to identify the specific medicine use problems they face and identify possible solutions (annex C).

Day 2

On Day 2, participants took part in a number of workshops. These included sessions on:

- Developing and implementing DTCs, in which participants reviewed DTC structure and functions, with a special emphasis on establishing new DTCs.
- Interventions to improve medicine use and establish STGs, where participants discussed the importance of STGs in improving medicine use and considered case studies of successful STG implementation.
- NEML, in which participants reviewed the importance of having an NEML and the process of developing and monitoring the use of the list.

An additional session on conducting an MUE had been arranged, but MISAU representatives requested to skip this session due to time constraints, saying they wanted to spend more time discussing recommendations and next steps.

Recommendations and Next Steps

The SIAPS team prepared the recommendations for next steps and presented them to the Head of DFM, Tania Sitoie, for review. After approving the recommendations, she presented them to the participants. A key recommendation involves a study of the STGs in place at health facilities, including those for HIV/AIDS, malaria, and hypertension. This study will determine the existence of—and assess compliance with—STGs at health facilities, and will determine factors that contribute to their use or disuse of STGs. A detailed protocol for conducting the study will be developed by SIAPS and presented to MISAU for review and approval (annexes D and E).

Workshop Evaluation

Participants evaluated the workshop just before closing remarks. Evaluations showed a high level of approval of the presentations and outcomes (annex F).

FIELD ACTIVITIES

SIAPS worked with related stakeholders at two pilot hospital DTCs within both Maputo City and Maputo Province to identify specific challenges related to STGs and other rational medicine use issues, as well as to propose specific interventions for addressing these challenges.

Thursday, August 7, 9:00 a.m.: José Macamo General Hospital

Alda Mariano, Neusa Bay, and Terry Green traveled to the hospital, but the appointment was cancelled by the hospital's Pharmacy Department due to an issue with visit approval.

Friday, August 8, 9:00 a.m.: Matola Provincial Hospital

The appointment was cancelled, again due to a lack of approval.

Tuesday, August 12, 1:00 p.m.: Maputo Central Hospital

Appointment was changed to Wednesday at 1:00 pm as the clinical director was not available at the original date and time.

Wednesday, August 13, 8:00-9:30 a.m.: Matola Provincial Hospital

Present at the meeting were Dr. Lisa Malombe, general-director of the hospital; Dr. José Sousa, clinical director; Dra. Durate Ibraimo, M.D.; and Randes Natussa, head of pharmaceutical services. This was an enthusiastic group of health professionals who expressed strong interest in receiving more support to develop a DTC and improve medicine availability and use.

José Sousa explained that medicine use problems are mainly related to the fact that this is a new hospital. A DTC has yet to be created at this hospital and would be very helpful in managing some of the medicine use problems that remain.

While there was very limited time to work with this hospital, we did develop recommendations for capacity-building activities and rational medicine use studies and interventions (annex G).

Wednesday, August 13, 2:30-3:30 p.m.: Maputo Central Hospital

This meeting was attended by Dr. Domingos Dias Diogo, the clinical director of the hospital and chair of the DTC, and Dr. Artur Luis, deputy chair of the DTC.

This hospital has an active DTC that is involved with many aspects of medicine use. For the clinical director, the main problems are compliance with STGs. They have only the HIV/AIDS and hypertension STGs available because he was working within the National committee responsible to develop these STGs. For the STGs discussed, hospital staff is trained, but they don't have enough copies of the STGs. They have an internal STG on the use of antibiotics, particularly the use of 3rd generation cephalosporins, elaborated by the Antibiotics Committee.

Dr. Diogo specifically requested that a comprehensive study of antibiotic use be conducted to better understand the current situation in this 1,500 bed hospital. He wants to ensure rational use of antibiotics throughout the hospital.

Limited time was available to work with Maputo Central hospital. From this brief meeting, recommendations for the DTC were provided – see Annex H.

ANNEX A. AGENDA AND OBJECTIVES



REPÚBLICA DE MOÇAMBIQUE

MINISTÉRIO DA SAÚDE
DIRECÇÃO NACIONAL DE ASSISTÊNCIA MÉDICA
Departamento de Farmácia Hospitalar

II National Workshop of Hospital Medicine Therapeutic Committees (CHTFs)

**Hospital Medicine Therapeutic Committees ensuring the
Rational Use of Medicines in Mozambique**

4 and 5 of August 2014 | Maputo, Mozambique

Objectives

- 1.** Describe the process of implementation of CHTFs in Mozambique
- 2.** Introduce the experience of CHTFs in the identification of the main problems of the use of medicines and their solutions.
- 3.** Discuss the involvement of CHTFs in monthly requisition of medicines and prescribing habits
- 4.** Describe the methods for monitoring and improving the use of medicines in hospitals.
- 5.** Discuss the next steps for the CHTFs of Mozambique – projections for the future

Day 1 | August 4, 2014

Time	Activity/Theme	Moderator
07:30-08:00	Arrival and registration of participants	Protocol
08:00-08:30	Opening ceremony	
	National Anthem	
	Intervention of the Head of the Department of Hospital Pharmacy	Dr. Tania Sitoie
	Opening of the seminar	HE The Minister of Health- Dr. Alexandre Manguela
08:30-08:45	Presentation of participants	
08:45-09:45	Presentation of the activities of the Hospital Medicine Therapeutic Committees –CHTFs (Provinces of Niassa, Cabo Delgado, Nampula, Zambézia)	Hospital Pharmacy and Therapeutics committees (CHTFs)
09:45-10:00	Coffee Break	Protocol
10:00-12:00	Presentation of the activities of the Hospital Medicine Therapeutic Committees-CHTFs (Tete, Manica, Sofala, Inhambane, Gaza, Maputo City)	CHTFs
12:00-13:00	Lunch	Protocol
13:00-13:45	Evaluation of the habits of prescriptions-results of studies conducted in six hospitals	Hélio Gemo (DFH)
13:45-16:00	Improving use of medicines – what needs to be improved and how?	Terry Green Alda Mariano
	<input type="checkbox"/> Overview of the use of medicines	
	<input type="checkbox"/> Group project	CHTFs
16:00-16:15	Coffee Break	Protocol
16:15-17:00	Improving use of medicines – what needs to be improved and how?	CHTFs
	<input type="checkbox"/> Presentation the group project	

Day 2 | August 5, 2014

Time	Activity/Theme	Moderator
08:00-09:00	Development and implementation of Hospital Medicine Therapeutic Committees (CHTFs) - key steps to make them effective	Terry Green Alda Mariano
09:00-10:30	Key activities of CHTFs: finding solutions for the medicine use problems through the use of therapeutic protocols (STGs)	Alda Mariano Terry Green
10:30-11:00	Coffee Break	Protocol
11:00-12:30	Key activities of the CHTFs, finding solutions for the medicine use problems through the list of essential medicines (EML)	Alda Mariano Terry Green Merana Mussá
12:30-13:30	Lunch	Protocol
13:30-14:30	Evaluation of the use of medicines	Alda Mariano Terry Green
14:30-15:30	Recommendations and next steps to be followed by CHTFs	Dr. Tania Sitoie Terry Green Alda Mariano
15:30-16:00	Coffee Break	Protocol
16:00-16:30	Closing of the Seminar	Dr. Ussene Isse, National Directorate of Medical Assistance

**ANNEX B. LISTA DOS PARTICIPANTES QUE ASSINARAM A LISTA DE
PRESENÇA**



REPÚBLICA DE MOÇAMBIQUE

MINISTÉRIO DA SAÚDE

DIRECÇÃO NACIONAL DE ASSISTÊNCIA MÉDICA

Departamento de Farmácia Hospitalar

**II Seminário Nacional dos Comitês Hospitalares de
Terapêutica e Farmácia (CHTFs)**

**Comitês Hospitalares de Terapêutica e Farmácia assegurando o Uso Racional de
Medicamentos em Moçambique**

4 e 5 de Agosto de 2014, Maputo, Moçambique



No.	Nome do participante	Província_Instituição	Categoria
1	Abdel Raouf Quawwas	SIAPS/MSH_Maputo	Director do Projecto no País
2	Aisha Issufo	Direcção Nacional de Assistência Médica_Maputo	Técnica superior N1 Acção Hospitalar
3	Albertina Bizuekue	Hospital Provincial de Xai-Xai_Gaza	Técnica de Farmácia
4	Alda Mariano	SIAPS/MSH_Maputo	Consultora
5	Alfa António Jamisse	Hospital Provincial de Inhambane_Inhambane	Farmacêutico
6	Ambari Anastácio Ambari	Hospital Provincial de Manica_Manica	Farmacêutico
7	Aminofro Langa	Departamento de Farmácia Hospitalar/DNAM/MISAU_Maputo	Técnico de Farmácia
8	Ana Cala	Direcção Nacional de Assistência Médica_Maputo	Médica
9	Ana Cristina Fernandes	Organização Mundial da Saúde_Maputo	National Program Officer – Essential Drug & Medicine

10	Armando Gobeia	Hospital Central da Beira _Sofala	Médico, DTC Vice- Presidente
11	Armando Meque	Hospital Provincial de Pemba _Cabo Delgado	Director Clínico
12	Artur Luis	Hospital Central de Maputo_Maputo	Farmacêutico
13	Avone Chuquela	Direcção Nacional de Assistência Médica_Maputo	Médica
14	Benedito Chaúque	USAID_Maputo	
15	Camila Breyer	SIAPS/MSH_Maputo	Consultora
16	Delto Jose Meneses	Hospital Provincial de Tete_Tete	Farmacêutico
17	Didon Olavo Cacheta	Hospital Provincial de Quelimane_Zambézia	Farmacêutico
18	Dr. Ussene Isse	Direcção Nacional de Assistência Médica_Maputo	Médico
19	Elenia Azarias Macamo	Hospital Central de Nampula_Nampula	Director Clínico
20	Eugenia Munguambe	Hospital Central de Nampula_Nampula	Farmacêutico
21	Feliciano Cumaquela	Hospital Central de Maputo_Maputo	Farmacêutico
22	Fonseca Júlio Domingos	Hospital Central da Beira _Sofala	Farmacêutico
23	Gregorio Ernesto Gale	Hospital Provincial de Inhambane_Inhambane	Clínico
24	Helder Nhocuané	Hospital Provincial de Lichinga _Niassa	Director Clínico
25	Hélio Gemo	Departamento de Farmácia Hospitalar/DNAM/MISAU_Maputo	Farmacêutico
26	Horácio Lupanheque	Hospital Provincial de Lichinga _Niassa	Farmacêutico
27	Isabel Dinis Pinto	Direcção Nacional de Assistência Médica_Maputo	Bióloga
28	Jorge Aleluia Vicente	Hospital Provincial de Manica _Manica	Médico Cirurgião, Presidente do CHTF de Manica
29	Vânia Manhique	Hospital Provincial da Matola_Maputo	Médica
30	Júlio Langa	ICAP Inhambane_Inhambane	Assessor para a Área de Farmácia
31	Lidia Cunha	Hospital Provincial de Tete_Tete	Directora Clínica
32	Maria Helena Costa	Hospital Geral de Mavalane_Maputo	Director Clínico
33	Paula Tocha	Direcção Nacional de Assistência Médica_Maputo	Médica Dentista
34	Merana Mussá	Departamento Farmacêutico_Maputo	Departamento Farmacêutico/Farmacovigilância
35	Narciso Cumbana	Hospital Geral de Mavalane_Maputo	Farmacêutico
36	Natacha Mbeve	Departamento de Farmácia	Assessora Técnica

		Hospitalar/DNAM/MISAU_Maputo	Sénior_Farmacêutica
37	Neusa Bay	SIAPS/MSH_Maputo	Assessora Técnica do SIAPS
38	Nuro Ali	Hospital Geral Jose Macamo_Maputo	Farmacêutico
39	Olga Novela	Direcção Nacional de Assistência Médica_Maputo	Médica
40	Paula Denise Pinto	Hospital Geral José Macamo_Maputo	Medica –DTC Vice-president
41	Paulo Carlos Vilanculos	Hospital Provincial de Pemba_Cabo Delgado	Farmacêutico
42	Randes Nafussa	Hospital Provincial da Matola_Maputo	Farmacêutico
43	Rafique Edson J. Bualani	Hospital Distrital de Mocuba_Zambézia – Mocuba	Farmacêutico
44	Sureia Hassamo	Global Fund/MISAU_Maputo	Assessora Técnica Sénior
45	Tânia Sitoi	Departamento de Farmácia Hospitalar/DNAM/MISAU_Maputo	Chefe do DFH
46	Tatiana Fonseca	Centro de Colaboração em Saúde (CCS)_Maputo	Assessora para a Área de Farmácia
47	Terry Green	SIAPS/MSH_Maputo	Consultor
48	Vicente Garcia	Hospital Distrital de Mocuba_Zambézia – Mocuba	Tecnico de Medicina
49	Virginia Albino	Hospital Provincial de Quelimane_Zambézia	Medica
50	Yolanda Cachomba	Hospital Provincial de Xai-Xai_Gaza	Director Clínico
51	Carmina Biquiza	Central de Medicamentos e Artigos Médicos_Maputo	Farmacêutica
52	Sergio Seni	Central de Medicamentos e Artigos Médicos_Maputo	Farmacêutico
53	Alginane I. Mussagy	Direcção Nacional da Assistência Médica_Protocolo	
54	Mayra Rodrigues	Direcção Nacional da Assistência Médica_Protocolo	
55	Juan Rumero	Direcção Nacional da Assistência Médica_Protocolo	Assessor
56	Maria dos Anjos	Hospital Geral Polana Caniço	Directora Clínica

ANNEX C. PARTICIPANT PRESENTATIONS

1. Niassa Provincial Hospital CHTF-Lichinga

Findings

- The three most prescribed medicines are: antibiotics, analgesics and anti-malarial.
- Conducted a study on medical prescriptions in the outpatient pharmacy. The main problems encountered at the level of requirements were:
 - Prescriptions without the patient's age
 - Prescriptions with antibiotic association
 - Prescriptions with antimalarial and NSAIDS

Impact:

- Assist the services in the management of pharmaceutical medicines
- Ensure the rational use of medicines through the analysis of requirements and cardexes.

2. Cabo Delgado-Pemba Provincial hospital CHTF

Findings:

- The most prescribed medicines at the hospital level are: antibiotics, NSAID and Anti-malarias

Study

Conducted a study of evaluation of medical instructions

Results:

- 35% of prescriptions without patient's age
- 33% of prescriptions with antibiotic association
- 6% of prescriptions without code number of National Drug Formulary

Impact of the activities of the Committee

- Advise on support the pharmaceutical services in acquisition of medicines
- Ensure the rational use of medicines through the analysis of instructions and cardexes.

Existence of weak medicine rotation for: propranolol, digoxin, haloperidol, etc.

3. Nampula-Nampula Provincial Hospital CHTF

Study

Evaluated prescription indicators.

Results:

900 Prescriptions without National Drug Formulary code, age of patient, name of the Health Facilities and duration of treatment.

The 3 most prescribed medicines are analgesics, anti-inflammatories, antibiotics followed by anti- malarial.

Impact of the activities of the committee:

- Reducing the risks of diseases
- Reduction of the admission period or time (duration of admission)
- Reduction of dispensing prescription with more than 2 antibiotics
- Reduction of dispensing prescriptions without signature and stamp of prescriber

4. Zambézia-Quelimane CHTF Provincial Hospital

Study

The DTC conducted a study of hospital indicators on the use of antimicrobials in the outpatient and inpatient department.

Results:

- Improvement in the satisfaction level of services of orthopedics, surgery, pediatrics and medicine wards
- The medicines are prescribed by international non-proprietary name
- Decrease the exposure time of the antimicrobial patients
- Medicines of weak rotation: calcium gluconate, pyridoxine and heparin, etc.

5. Zambézia-CHTF of Mocuba Rural Hospital

Findings:

- There are medicines with low rotation such as thioridazine, fluphenazine, haloperidol, oral antidiabetic medicines, etc.
- Lack of National Drug Formulary in hospitals
- The acquisition of medicines is made according to the EML prepared at the level of the hospital

Impact of the activities of the Committee in the management of medicines

- Improvement on prescription medicines
- Improvement in the management of medicines on medical wards
- Clinical cases of malaria reduction (reduction of people treated with antimalarial without positive malaria rapid test or smear)

6. Tete-Tete Provincial Hospital CHTF

Findings:

- Conducted a study of prescriptions
- Weak involvement of the directors of the services
- Lack of National Medicines Formulary on the level of the consultations

Impact of the activities of the Committee in the management of medications:

- Improvement in the management of medicines at hospital level
- Strengthening of the supervisory activities of the wards
- Increased number of Adverse Drug Reactions reported
- Creating groups to provide technical assistance to the wards

There are low rotation medicines such as: vitamin A, allopurinol, cycloserine, etc.

7. Manica-CHTF of Chimoio Provincial Hospital

Study

- A study of prescriptions with the following results:
- 19.69% of prescriptions without Number of Patient Identification (NID), 16.12% of prescriptions without pharmaceutical form, 15.59% without dosage of medicine and 14.69% without age of patient.
- Improvement in the reporting of adverse drug reactions.

Impact of the activities of the Committee in the management of medicines

- Improvement in the management of medicines.
- Improvement in communication between clinicians, pharmacy staff and patients.

Other issues

- Lack of prescriptions forms at hospital level, use of khaki paper to write prescriptions
- Lack of STGs
- Lack of nutritionists at hospital level
- Need to work with national Pharmacovigilance programs to implement a comprehensive programs at the DTC
- Need for a nutritionists at the DTC
- Laboratories with weak responsiveness in the diagnosis of pathologies.
- There are medicines of weak rotation such as: simvastatin, heparin, ethionamide, etc.
- Need for integration of pharmacy staff on the medical wards

8. Sofala-CHTF Provincial Hospital of Beira

Findings

- Lack of orientation guide of hospital pharmacy and a hospital medicines policy
- Lack of specific training on rational medicine use for committee members
- Lack of pharmacologist in the DTC
- There are medicines of weak rotation: sulfadiazine, propranolol, maprotiline, etc.
- Therapeutic protocols or STGs developed at the level of hospitals are sent to central level for uniformity

9. Inhambane Provincial Hospital CHTF Inhambane

Impact of the activities carried out by the committee in the management of medicines

According to the committee, it is premature to assess the impact of the activity on the management component of medicines and medical supplies since the activity is still on-going

There are medicines of weak rotation such as omeprazole injectable, ferrous sulfate, tetracycline capsules, etc.

10. Gaza-CHTF Provincial Hospital of Xai-Xai

Impact of the activities of the Committee in the management of medicines

- Good coordination of pharmacy with clinicians and DPM
- Reducing stock-outs of essential medicines

There are medicines of weak rotation such as: cefixime, nifedipine, atenolol, etc.

Results of the study of medical prescriptions

- Reduction in prescribing antibiotics associated with anti-malarial and reduction of prescriptions containing more than 3 medicines

11. Maputo Mavalane General Hospital- Mavalane

Study

Achievements of study on quality of prescription:

- The study concluded that prescriptions have lack of information about the health facility, no stamp of the prescriber and signature of pharmacist.
- 29.5% of prescriptions were not legible
- 31.5% of prescription did not present the duration of the treatment.

General Recommendations

1. It is important that all committees carry out studies of medicine use and management. In the next national meeting of CHTFs they should present the results of the studies carried out in the hospitals.
2. It is important to standardize the techniques for improvement of diagnostic results.
3. Improve communication between the committees.
4. Adopt a mechanism of control of medicines in pharmacies.
5. Change the tendency of hospital prescription habits.
6. The Committee should make strict monitoring of activities in health facilities for the smooth running of the same.
7. It is important to review the prescription levels in order to correct current practices taking into account the current situation of lack of human resources.
8. Each hospital should have a list of essential needs in terms of medicines according to the level of its health facility (primary, secondary, tertiary and quaternary).
9. Inclusion of nutritionists and laboratory technicians in the committee and send the list of members to DFH.
10. All therapeutic protocols developed by clinicians at provincial level should be sent to the Department of Hospital Pharmacy for uniformity and subsequent approval. Note: all authors will appear in the list of authors.
11. Improve communication between the provinces through the central level to improve the management of medicine of low rotation.
12. Improve the distribution and allocation of the Pharmacy staff at provincial level in order to answer the needs of Health Facilities.
13. Carry out activities to train pharmacy professionals in clinical pharmacy.

Recommendations (Manica)

Proposes to create mechanisms for interaction or communication between hospitals to make a return of medicines with low turnover in order to improve the management of these medicines.

Equip the laboratories in order to make the rapid diagnosis and improve the use of antibiotics.

SYNTHESIS of DAY 2 – August 5, 2014

Presentations of the group work on medicine use problems and potential solutions.

Group I

Problems identified	Solutions
Irregular distribution of medicines	
Poor quality of material (prescriptions forms, etc)	
Failure in the supply of medicines	
Lack of communication among professionals	
Lack of pharmaceutical attention	
Lack of consumer data submission	
Bad planning of infrastructures	

Group II

Problems identified	Solutions
Unavailability of essential medicines	Periodic review of National Formulary, where various experts must participate
Non-updated therapeutic protocols	Improving the system of periodic review/information of standard treatment protocols
Lack of harmonization of different programs	Improve communication between the managers of the different programs
Prescription of medicines without proper diagnosis	Improve the use of diagnostic tests
Prescription with unreadable handwriting, missing elements in the prescription	Awareness of prescribers to change their prescription behavior
Use of trade names	Correction by the Directorate
Low quality of pharmaceutical care to the patient	Improve academic training
Poor treatment adherence Self-medication Poor conservation of medicines	Sensitization of the patient

Group III

Problem	Solution
Irregular availability of Medicines Difficulties in management	Definition of essential medicines to the NHS Review the cost of the medicine Improve the management of medicines Training on the job.
Irregular and inappropriate self-medicine administration (Adherence to the treatment)	Improve patient communication at all levels
Habit of prescribing the same medicine Poor writing or unreadable medicine Greater waiting time	Training in work (medical education) Allocate quality human resources
Misinterpretation of the prescription Lack of accountability of the recipe Greater waiting time	Human resources allocation Opening more pharmacies

Group IV

Problems identified	Solutions
Poor communication between professionals in the central deposits with suppliers and quality control Dispensing of medicines with short expiration date Lack of satisfaction in dispensing	Review and update stock and shipping to the province
Poor communication between doctor and patients Use of commercial names in the prescriptions Ineligibility of prescription	Continuous training, access rules for prescribing and improve readability on medical prescription
Lack of communication with the patient The absence of pharmaceutical care	Training in new procedures in management, training continues and training of dispensers in the area of pharmaceutical care.
Lack of human resources	Education for health in the communities, information about the disease to

Discussion

- Non-participation of pharmacy professionals in co-management committees meetings and humanization communities
- Lack of attention to dosage in the moment of dispensing medicines to patients
- Lack of training continues
- Lack Pharmaceutical Directorate services at the hospital level
- Lack a list containing the name and signature of all prescribers in pharmacy

Recommendation

- Include Pharmacy professionals in quality and humanization committees.
- Creating a list of prescribers to outpatient level as well as the inpatient level. This list should be available in pharmacies.
- The committees are responsible for the identification of problems and its resolution. Improvement on the advice of the medicines to patients.
- The committees should invite other key members in some areas (tuberculosis, HIV, maternal and child health, immunization program) to participate in their meetings to discuss some activities.
- The committees can improve the relationship between the different health professionals for its multidisciplinary character.
- The National Drug Formulary should be reviewed.
- There must be a greater communication with the Central level (DFH).
- Experts should be included in the development of essential medicine list.

Functions and key activities of the committees

- Development of EML
- Assessment criteria of use of medicines
- Identify the problems of medicines s, making indicators studies, evaluation of use of medicines etc.
- Monitoring and evaluation of the Committee performance to improve the efficiency in the activities undertaken.
- Monitor the Adverse Drug Reactions at health facilities

ANNEX D. RECOMMENDATIONS AND NEXT STEPS

Each DTC will work on the following activities over the next year (with support from MISAU and SIAPS)

DTC Structure and functions

- All DTCs must have approvals from Hospital Director
- Implement TOR at each facility (available from MISAU)
- Develop action plans and objectives for the year
- Ensure DTC has appropriate members, ones that will empower the DTC to achieve its objectives of improving medicine use at all levels of the healthcare system

STGs

- Obtain all approved MISAU Guidelines for hospitals and health facility and make sure they are readily available for the health care staff. Need 1 copy to each provider
- Provide training on use of STGs, especially new staff
- Study and monitor 1 or 2 important medical conditions (e.g., HIV, Malaria, Hypertension) for compliance to guidelines. Include a baseline of current practices. SIAPS will support the implementation of these studies

EML

- Study and monitor medicine use against the approved EML, determine % of prescriptions in accordance with approved EML
- Provide feedback to providers on compliance
- When revised EML becomes available – implement ASAP
- Need current national formulary and essential medicines list to be provided to health facilities

Medicine Use Evaluation (MUE)

- Potential MUE depending local circumstances
 - Surgical prophylaxis (C-section)
 - High profile medicine (e.g., Antiretroviral, gentamicin, ceftriaxone)

Other Possible Activities

Address Supply Management issues - work with MISAU, warehouse, and DTC to improve the supply management at the hospital or clinic

Medicine use study (*if time and staff available*)

- Conduct WHO Health facility indicator study, specifically % of antibiotics, % generic name, average number drugs / prescription.
- Conduct MSH Hospital Antimicrobial indicator studies for selected hospitals.

ANNEX E. STANDARD TREATMENT GUIDELINE MEDICINE USE EVALUATION PROTOCOL

Medicine Use Evaluation Mozambique Standard Treatment Guidelines

August 25, 2014

Background

Standard Treatment Guidelines (STGs) are one of the key World Health Organization (WHO) recommendations to rationalize the use of medicines. The use in healthcare settings worldwide produce benefits for health system, health professionals, and patients.

Health Systems

- Provides information for forecasting and ordering
- Provides effective therapy in terms of quality
- Provides a system for controlling costs
- Provides information for practitioners to give to patients concerning the institution's standards of care
- Serves to integrate special programs (HIV/AIDS, diarrhea disease control, TB) at the primary health care center with a single set of guidelines

Health Professionals

- Provides standardized and approved guidance to practitioners.
- Promotes high quality care by directing practitioners to the most appropriate medicines for specific conditions
- practitioners can concentrate on diagnosis knowing that the appropriate medicines are listed and available, evidenced-based treatments have been established
- Provides assistance to all practitioners, especially to those with lower skill levels

Patients

- Patients receive optimal pharmaceutical therapy and the highest quality of care
- Enables consistent and predictable treatment and access to effective medicines and best treatment available
- Provides a basis for evaluating quality of care provided by health care professionals

MISAU has produced significant effort to improve the use medicines in Mozambique, one of the key activities is the development of STGs for a limited set of diseases. STGs exist for infectious diseases of HIV/AIDS, Malaria, Tuberculosis, STI, and some chronic diseases including hypertension and diabetes. MISAU is in progress of developing other STGs for prevalent diseases and these should be completed in the near future.

For this STG medicine use evaluation, the highly prevalent diseases of HIV/AIDS, malaria, and hypertension were selected to review for appropriate compliance to the approved STGs. These diseases and STGs were selected because they have high impact on adults and children quality of care. Rationale includes:

- HIV/AIDS and related diseases are a major cause of mortality among children in Mozambique. In 2010, it is estimated that 19,000 children under the age of 15 will die as a result of the disease (Source: UNICEF Mozambique).
- In Mozambique, malaria is a major cause of morbidity and mortality especially among children. The disease represents around 45% of all cases in outpatient visits, approximately 56% of inpatient at pediatric clinics and around 26% of all hospital deaths. According to the [Demographic Health Survey 2011](#), the prevalence of malaria among children under five years is 46.3% in rural areas compared to 16.8% in urban areas. The relatively high prevalence in many parts of the country puts the entire population at risk and poses a challenge for malaria elimination efforts nationally and in neighboring countries.
- Cardiovascular diseases are the 4th leading cause of death in Mozambique. One in every three Mozambicans' has hypertension – a major risk factor for stroke. In Maputo City alone, 2-3 strokes occur every day with a mortality rate of 40% (source: WHO 2014)

Having a STG doesn't mean there is automatic improvement in medicine use. Many factors can influence the use of STGs and lead to misuse. The availability of the guideline, training on use of the guideline, and actual use in day to day practice can all vary from one location to another. Taking this into account, it is important to know how they are used in the health facilities and what factors contribute to their use. Without consistent use, the STGs are of little value.

Purpose

To assess the use of STGs in three diseases; HIV/AIDS, malaria, and hypertension and ensure appropriate availability and high compliance with the guideline.

Objectives of the Assessment

1. To determine the degree of compliance with the Mozambique STGs for 3 medical conditions: HIV/AIDS, malaria, and hypertension.
2. To explore factors influencing compliance and availability of the STGs in selected hospitals.
3. To determine the need for specific interventions to improve compliance to STGs.
4. To intervene with appropriate intervention and ensure compliance with the guidelines at a level of 90% or higher.

Methodology

A retrospective review will be conducted at four hospitals in Maputo and 3 additional sites in outlying provinces. The data collection will be carried out by local DTC members under the supervision of MISAU (Hospital Pharmacy Department) and Systems for Improved Access to Pharmaceuticals and Services (SIAPS). The specific hospitals were chosen, based on:

- location - Maputo and provinces representing a northern province, a central province, and a southern province
- need to confirm compliance with standards
- availability of a local DTC to manage:
 - the data collection
 - follow-up monitoring
 - actions including introductions of medicine use interventions to strengthen the compliance on STG if needed.

Facilities to be reviewed:

Maputo

- Maputo Central Hospital
- Jose Macamo General Hospital
- Mavalane General Hospital
- Matola Provincial hospital

Provincial Health Facilities

- Inhambane Provincial Hospital (Inhambane Province)
- Quelimane Provincial Hospital (Zambézia Province)
- Nampula Provincial Hospital (Nampula Province)

Initially, one health facility will be selected to start this MUE. After initial assessment, introduction of interventions and the establishment of improvement and reaching targets, other hospitals will be added.

Data collectors will review medical records, registries and prescription to obtain the necessary quantitative data for the review (see Annex A). A second survey instrument, interview of physicians and pharmacists, will document the reasons for using or not using the STGs. A third instrument, health director/clinical director interview form (annex C) will be used to determine health facility participation in the use of STGs.

The sample size will consist of 30 medical records (randomly selected from records over the past 12 months for malaria and hypertension diseases. For HIV/AIDS, the previous 4 months will be used because the HIV/AIDS protocol was recently revised and disseminated in May 2014.

Prescriptions for the selected disease conditions will be reviewed from the patient medical records or registries. Information will be recorded on data collection tool (annex A) and will be analyzed for compliance with the STG exactly as written in these approved STGs.

Data Collection Procedure

Data will be collected over a two day period for each disease state, after confirming approval for the activity from the hospital director, data collectors will review necessary medical records and registries and collect the necessary information on data collection instrument (See Annex D for details of procedure). For some of the hospitals, interviews of providers and health officials will take place in the week before the review by members of the hospital DTC.

Data Collection Team(s)

To build capacity in the regions, data collection will be conducted by hospital DTCs and supervised by MISAU and SIAPS.

Data Collection Tools

Annex A contains a data collection tool used to record information from the patients' health record. The instrument enables the treatment prescribed to be compared against treatment recommended by the current STGs for each of the tracer disease conditions selected.

Annex B is the tool used to collect qualitative data from prescribers. The prescribers interviewed were selected from among prescribers in the outpatient department at the same health facilities from which the data on prescriptions were obtained.

Annex C – has an instrument to interview hospital and primary health officials on the availability and use of STGs.

Selection Criteria for Prescriptions

Inclusion

Only prescriptions generated between October 2013 to September 2014 by prescribers at the health facilities with the diagnosis of HIV/AIDS, malaria, or hypertension were included in the assessment. If there were two or more prescriptions for the same condition in the medical record, *any one* of the eligible prescriptions written during the study period will be selected. Prescriptions were attributed to the person who signed the prescription on the date of treatment, e.g., if it was a repeat prescription prepared by a nurse for a prescription that was originally written by a doctor, it was attributed to the nurse.

Exclusion

The following exclusion criteria were applied to the prescriptions during the data collection process:

- Prescriptions without a diagnosis or with an unclear diagnosis.
- Prescriptions with an unclear prescriber, i.e., where it was not clear whether the prescriber was a doctor, nurse, etc.
- Prescriptions prepared outside the study period

Outcome Measures

The outcome measures for the assessment were developed in line with the assessment objectives

1. % of medicines prescribed in accordance with STG
2. % of medicines prescribed by generic name
3. % of prescriptions with unnecessary medicines
4. % of health facilities with a copy of the guideline in treatment area and readily available for practitioners
5. % of health professionals with a personal copy of the guideline
6. % of qualified prescribers for each medical condition reviewed

Overall outcome: Pharmaceutical Services improved.

Data Entry and Analysis

Data will be recorded on data collection instruments (annex A) and this information will be transferred to Excel spreadsheet designed to record data collection and calculate the indicators. All data recorded will be exactly as written in the medical record and analysis will compare exactly as written in the MISAU approved standard treatment guidelines.

A spreadsheet designed this activity will be utilized to document results of the survey, analyze results, and calculate indicators. SIAPS and MISAU will be responsible for data cleaning and final data analysis and reporting. Results will be report to DTCs and MISAU.

Follow-up and implementation of Interventions

Depending on the results, specific interventions will be introduced at each hospital to improve compliance including the use of education (in-service training, face to face education), managerial (supervision, order sheets, job aids) as necessary. Interventions will be introduced and monitoring of the use of the STG will take place on a continuous basis until targets are reached, e.g., 90% compliance.

Technical review of protocol

This protocol for collecting and analyzing data and the entire assessment process will be reviewed by SIAPS technical staff in Arlington, VA, senior technical staff and hospital pharmacy department, MISAU.

References:

WHO, How to Investigate Drug Use in Health Facilities: Selected Indicators, 1993 World Health Organization

Namibia Standard Treatment Guideline Assessment - Akpabio, E., Sagwa, E., Mazibuko, G., Kagoya, H.R., Niaz, Q, and Mibirizi, D. 2014. *Assessment of Compliance of Outpatient Prescribing with the Namibia Standard Treatment Guidelines in Public Sector Health Facilities*. Submitted to the US Agency for International Development by the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program. Arlington, VA: Management Sciences for Health.

(STG Protocol - Annex A. Data Collection Instrument)

Medical record #						Date of data collection					
Data Collector						Date of prescription					
Health Facility Name											
Health Facility Region											
Position of prescriber											
Physician Nurse Other											
Patient's weight						Patient's birthday -					
Primary diagnosis indicated on medical record						Other diagnosis recorded					
Signs and symptoms listed in medical record											
Laboratory tests done											
Treatment Prescribed (exactly as prescriber has written)											
#	Medicine (1)	Dose and Frequency (2)	Duration (3)	Generic (4) Y-1 N- 0	Antibiotic (5) Y-1 N-2	Compliance with STG (exactly as written) (if No, indicate which parameter with STG)					
						Yes (Y-1)	1	2	3	4	5
1											
2											
3											
4											
5											
6											
7											
8											
Other comments/observations for this patient's treatment											
<i>Adapted from Akpabio, E, et al</i>											

(STG protocol -Annex B Questionnaire for providers)

Health Facility		Comments
Location		
Practitioner Interviewed - Number only		
Position		
Interviewer		

Introduction and Consent

Hello, I am, part of the data collection team from MISAU and your DTC team to assess the implementation of the Standard Treatment Guidelines in public facilities (HIV/AIDS, malaria, and hypertension). This assessment is being carried in 7 hospitals in Mozambique. The findings of this assessment will help to improve the quality of medicine use and health care in Mozambique.

As a prescriber in this facility, you are highly regarded as a key respondent for this assessment. You are kindly requested to give honest information for purposes of genuine and accurate results.

Procedures and Confidentiality

Your participation is absolutely voluntary and there is no penalty for refusing to take part. All information that I record will be kept strictly confidential; your name will not be used and you will not be identified in any way.

Risks/discomfort and Benefits:

There is no serious risk to you if you agree to participate in this activity. Your honest opinion will help in developing interventions to improve use of STG to improve patient care in Mozambique.

Consent to participate

I have read (or someone has read to me) and I have understood the information given above and what will be required of me if I choose to take part in the assessment. I therefore agree to take part in this study

..... Signature of respondent Date

Interviewer Name:

Thank you for accepting to take part in this assessment.

Questionnaire

Have you ever seen a copy of the Mozambique Standard Treatment Guidelines (HIV, Malaria, Hypertension)?

(1) YES (2) NO List the ones seen-

Have you ever received a *personal* copy of the STG?

(1) YES (2) NO List ones that they have a personal copy

Do you currently have access to a copy of the STG when you need it?

(1) YES (2) NO

How often do you make reference to the guidelines (STGs)?

(1) Daily (2) Once in a week (3) Once in a month (4) Once in 6 months (5) rarely

(6) Never (7) Other (*state explicitly*) _____

Could you explain more what makes you use the STG on the frequency you have stated?

In your experience is the current STGs helpful in your prescribing practices?

(1) YES (2) NO

Could you explain more what makes it **helpful/not helpful** in your prescribing practices?

How do you rate the quality of the current STGs in the following parameters?

Comprehensiveness in conditions covered

Very poor Poor Fair Good Very good Don't know

Quality of design and layout

Very poor Poor Fair Good Very good Don't know

Very poor Poor Fair Good Very good Don't know

User friendliness

Very poor Poor Fair Good Very good Don't know

Do you think the current Mozambique STG is up to date?

(1) YES (2) NO

Do you think the current Mozambique STG needs improvement?

(1) YES (2) NO

If YES above, what do you think should be done to improve on the current STGs?

- | | | | |
|--|----------------------------------|---------------------------------|-------|
| <input type="checkbox"/> In-service training on STGs | (1) <input type="checkbox"/> YES | (2) <input type="checkbox"/> NO | |
| <input type="checkbox"/> Monitoring on use of the new STGs | (1) <input type="checkbox"/> YES | (2) <input type="checkbox"/> NO | |
| <input type="checkbox"/> Facility level medicine use evaluations | (1) <input type="checkbox"/> YES | (2) <input type="checkbox"/> NO | |
| <input type="checkbox"/> Awareness creation on STGs | (1) <input type="checkbox"/> YES | (2) <input type="checkbox"/> NO | Other |

intervention since the launch (*Specify*): _____

NO INTERVENTION

Have you participated in any of the following interventions related to STGs since the launch in 2011? (*Tick all options that apply*)

- | | | |
|--|----------------------------------|---------------------------------|
| <input type="checkbox"/> In-service training on STGs | (1) <input type="checkbox"/> YES | (2) <input type="checkbox"/> NO |
| <input type="checkbox"/> Monitoring on use of the new STGs | (1) <input type="checkbox"/> YES | (2) <input type="checkbox"/> NO |
| <input type="checkbox"/> Facility level medicine use evaluations | (1) <input type="checkbox"/> YES | (2) <input type="checkbox"/> NO |
| <input type="checkbox"/> Awareness creation on STGs | (1) <input type="checkbox"/> YES | (2) <input type="checkbox"/> NO |

Other intervention since the launch (*Specify*): _____ Not participated in any intervention

Adapted from Akpabio, E, et al

(STG Protocol, Annex C. Interview form for Health Officials at Hospitals and Clinics)

Interview form for health officials at Hospitals and Clinics

Health Facility		Comments
Location		
Health Official Interviewed		
Position		
Interviewer		

Introduction and Consent

Hello, I am, part of the data collection team from MISAU and your DTC team to assess the implementation of the Standard Treatment Guidelines in public facilities (HIV/AIDS, malaria, and hypertension). This assessment is being carried in 7 hospitals in Mozambique. The findings of this assessment will help to improve the quality of medicine use and health care in Mozambique.

As a prescriber in this facility, you are highly regarded as a key respondent for this assessment. You are kindly requested to give honest information for purposes of genuine and accurate results.

Procedures and Confidentiality

Your participation is absolutely voluntary and there is no penalty for refusing to take part. All information that I record will be kept strictly confidential; your name will not be used and you will not be identified in any way.

Risks/discomfort and Benefits:

There is no serious risk to you if you agree to participate in this activity. Your honest opinion will help in developing interventions to improve use of STG to improve patient care in Mozambique.

Consent to participate

I have read (or someone has read to me) and I have understood the information given above and what will be required of me if I choose to take part in the assessment. I therefore agree to take part in this study

..... Signature of respondent Date

Interviewer Name:

Thank you for accepting to take part in this assessment.

Questionnaire

Have you ever seen a copy of the HIV/AIDS, Malaria, or Hypertension Standard Treatment Guidelines ((STG)?

- (1) YES (2) NO List ones you have seen

Did your receive copies of the STGs for *each health facility* in your region/ district since they were made available?

- (1) YES (2) NO

What interventions have been conducted by this health facility since the launch of the

STGs to ensure its availability and use by prescribers? (Tick all options that apply)

Name of intervention	Carried Out (Y/N)	How Often Carried Out	114. Any documentation available? (Y/N)
1. Distribution of STG to all health facilities			
2. In-service training on STGs			
3. Monitoring on use of the new STGs			
4. Facility level medicine use evaluations			
5. Awareness creation on STGs			
6. Other intervention since the launch (Specify):			

Do you think all prescribers have access to the STGs in your District?

Yes No

If no, could you explain why this is so?

Do you think the current Mozambique STGs are up to date? (1) YES (2) NO

What do you think should be done to improve on the current STG?

a) Increase number of health conditions covered (1) YES (2) NO (3) Don't Know

b) Reduce number of health conditions covered (1) YES (2) NO (3) Don't Know

c) Develop new sections (1) YES (2) NO (3) Don't Know

d) Improve quality of paper (1) YES (2) NO (3) Don't Know

e) Improve design (1) YES (2) NO (3) Don't Know

f) Improve graphics and charts (1) YES (2) NO (3) Don't Know

g) Other suggestions:

h) No improvement needed(1)

Yes

What do you think are the barriers to the use of the Standard Treatment Guidelines by prescribers? *Please advise on how to overcome them*

Barrier	Suggestions to overcome
1.	
2.	
3.	
4.	
5.	

Adapted from Akpabio, E, et al

(STG Protocol, Annex D – Procedures for Data Collection)

- 1) **Formation of the data Collection Team(s):** Data collection will be led and coordinated by MISAU, Department of Hospital Pharmacy, SIAPS, and assisted by members of each hospital DTC in the respective health facilities. The team will attend a one day meeting in Maputo to review the data collection tools and logistics.
- 2) **Time frame for collection:** The data collection period will be for a period of 2 days for each health facility.
- 3) **Data Collection tools:** For each facility, data collectors will be provided with Instrument A, Data collection form, and 1 each of Instruments B and C for structured interviews.

4) Data collection: Appendix A- Prescribing Practices

Patient medical records (or outpatient registers in PHC Clinics) will be used to collect data onto the survey tool (Appendix A) for all the conditions.

In PHC Clinics the outpatient registers may be used as alternative or additional source of treatment data where the patient passports are not available for review.

Patients' medical records will first be reviewed for any diagnosis for the 3 selected conditions; only prescriptions with dates in the first period August 2013 to September 1, 2014, will be selected. For HIV/AIDS, the time period will be from June 1, 2014 to September 30, 2014.

30 prescriptions should be randomly selected for each of the 3 conditions.

Information from the prescription will be transcribed from the medical records or register onto the survey tool (Appendix A)

If there are two or more prescriptions for the same condition in the record, *any one* of the eligible prescriptions falling in the study period will be selected. As much as possible, only one prescribing encounter per medical record will be used i.e. if a record contains prescribing encounters for three of the conditions to be assessed, just one of the conditions will be selected and data will be abstracted for that condition onto the data collection tool.

Prescriptions will be attributed to the person who signed the prescription on the date of treatment, e.g. if it is a repeat prescription by a nurse for a prescription that was originally done by a doctor, it will be attributed to the nurse.

5) Data collection: Appendix B- Prescriber Interviews

The prescriber interviews will be done after completion of data collection for Appendix A.

Appointments will be made with the respective prescribers to be interviewed

All the information collected will be entered into the questionnaire as required.

10 prescribers will be interviewed from each health facility

6) Data collection: Appendix C- Key Informant Interviews

Hospital directors and/or clinical directors will be interviewed to ensure access and use of the STGs by the prescribers since the STGs were made available.

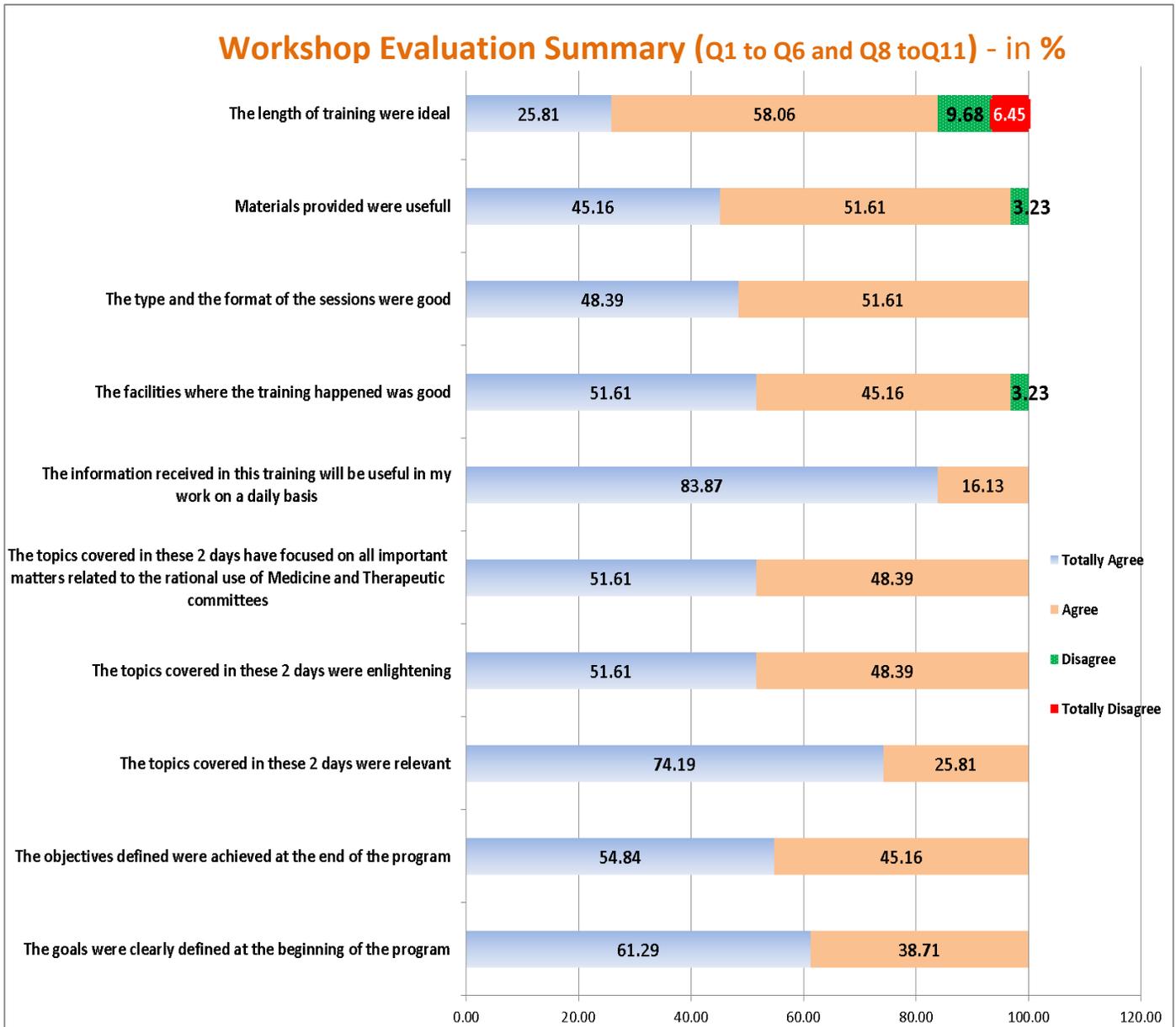
7) Data entry procedures

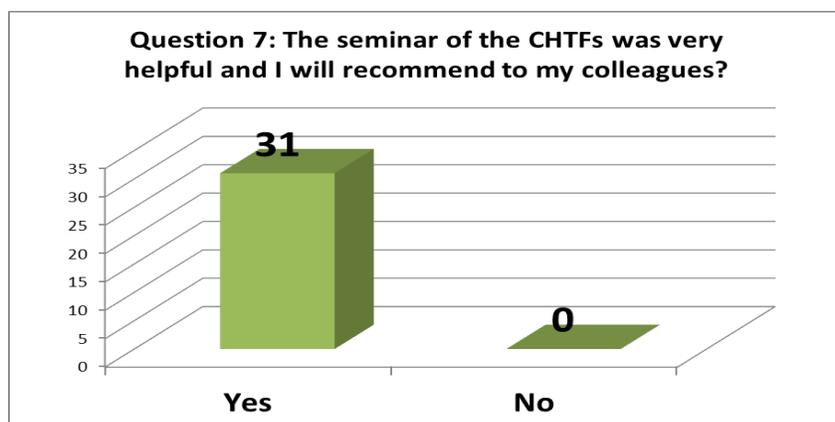
Data will be entered into Instrument A exactly as it appears on the medical records or registry.

Data from Instrument A will subsequently be entered into spreadsheet specifically designed for recording information about the STG and for analyzing and calculating indicators.

Adapted Akpabio, E, et al.

ANNEX F. DTC WORKSHOP EVALUATION





Workshop Evaluation Participant Comments

	Q12 - Please give us your recommendations to improve the program in the upcoming opportunities :	Q13 – What other subjects or aspects should be addressed?	Q14 - Additional comments
1	The Seminar should take 3-4 days	Evaluate problems related the use of medicines used in specialties.	
2	Create recommendations for the provincial superiors to give more power to the CHTF/DTCs	The Pharmacy staff should prepare for clinicians presentation regarding the slow rotation medicines to revitalize its use.	Reinforce the management of medicines on the economic politics
3	DNAM must press the Clinical Directors to reinforce the participation of the Clinical Directors in the DTC meetings.		Improve the time that the participants will stay in Maputo and congratulate the team that organized the seminar
4			Improve subsistence allowances for participants
5	Presentations in English with interpreters are tiring and participants lose concentration		Learned a lot and will try to implement in the field
6	Can't understand		
7	The Seminar was excellent. Keep supporting the provinces		More attention should be given to pharmacoeconomics and the presentations should be more clear

8			Congratulations to the organizers, improve the disclosure of the seminar, propose to do the seminar out of the Maputo City
9	The seminar was excellent		Keep the seminar annually
10			Always remember that food and medicine use the same path and the DTC trainings should have the compound of Nutrition. Mozambican population needs to improve their caloric intake, especially on the metabolic pathologies and the pharmacists should be aware of this.
11	Involvement of other members of the DTC in the national workshop and send the invitation letter with enough time	Create a study and evaluate risk of the final destination of the medicines kept at home by the patients	The workshop should have more time for discussions
12	Improve communications between the members of the DTC and between the DTCs and DNAM	The themes in the program of the workshop are the more important ones	
13	Improve communications between the DTCs and the programs	Improve communications between the DTC and the other committees in all the country	
14	Include one Laboratory staff to be represented in the DTC		There should be more visits to the DTCs at their local of work.
15		The seminar was very good, with a lot of interaction, very important to all	
16	There should be more days for the Workshop to allow DTCs to present fully the activities of the committee	In RDU, should discuss the influence of the cycle of medicinedistribution in the country	Thanks for the sessions and wish all the success to DNAM
17			Congratulate the initiative. This type of event should happened more frequently to harmonize the medicine management system from Rovuma to Maputo.

18	The invitation letter for the seminar should be sent earlier to allow the participants to prepare properly for the seminar		
19		There should be more discussions about pharmacovigilance	Increase the per diem
20			The per diem doesn't match with Maputo City reality
21	There should be more days for the Workshop		
22	The workshop should have more time for the presentation of studies	Speak more about pharmacovigilance and medicine management at the provincial level	
23	Send the invitation letter for the participants with more time in advance and request their confirmation with enough time in advance	Address the existing resources for the movement of the committee members to monitor the activities of the different areas	
24	The workshop should have more days		
25	Some of the presentation were a repetition from the previous DTC workshop		

ANNEX G. INTERVENTION REPORT FOR PILOT HOSPITALS, Matola Provincial Hospital

Present at the meeting:

Dr. Lisa Malombe - General Director of the Hospital

Dr. José Sousa - Clinical Director of the Hospital

Dra. Durate Ibraimo – Medical doctor at Hospital

Randes Natussa – Head of the Pharmaceutical Services of the Hospital

Dr. Hélio Gemo – Department of Hospital Pharmacy/MISAU

Dr. Aminofro Langa - Department of Hospital Pharmacy/MISAU

Dr. Neusa Bay – SIAPS MSH

Dr. Terry Green – International Consultant

Dr. Alda Mariano – National Consultant

Objective: to determine what assistance is needed for Matola Provincial Hospital to start their DTC and what specific studies and interventions should be addressed.

Discussion

Dr. Helio Gemo presented the Department Hospital Pharmacy team and the objectives of the meeting. Dr José Sousa, clinical director, provided information on this hospital, a 400 bed provincial hospital that was opened in July 2014. They have many medicine use problems, mainly related to the fact that it is a new hospital and the Provincial Warehouse of Medicines is not prepared (and they don't have a plan) to distribute medicines to hospitals. They have experience to distribute medicines to health centers and the mechanism of distribution is different. Now they are trying to obtain permission from MISAU to be supplied directly from the Central Medical Store, but do not know if it will work because policies say that this hospital should be supplied by the provincial warehouse.

This supply management problem is producing significant shortages of essential medicines including ARV and TB medicines, particularly 4DFC (a fixed dose combination containing rifampicin, isoniazid, pyrazinamide and ethambutol), from the warehouse because it is a hospital and the provincial warehouse is to supply only health centers. This hospital has many AIDS and TB patients admitted who have to interrupt their treatment during their admission.

Another crucial supply issue is the lack of oxygen for this new hospital. The hospital has an intensive care unit, recovery rooms, 4 operating rooms that all require oxygen and they have none. Obtaining enough oxygen and having it readily available has delayed the use of surgical department and ICU.

A DTC needs to be created to help manage some of the medicine use problems including the issues of availability. The DTC should be multidisciplinary in its membership as they have many different prescribers from different medical schools and countries.

Prominent diseases and medical conditions at the hospital include HIV with opportunistic infections, TB, gastroenteritis, malaria and stroke secondary to uncontrolled hypertension.

The hospital requested:

1. Help to interact with other DTCs from Mavalane or José Macamo, perhaps to be present in their meetings to have experience on how to start and how to work.
2. Copies of National Drug Formulary and National STGs (malaria, hypertension, AIDS, Diabetes, TB).

They will have a meeting this afternoon where they will talk about the need of DTC and start the process of identifying members for the committee. Neusa will send the TOR established by the MISAU on how the DTC should operate.

Specific activities and intervention recommended for this Hospital:

The hospital is new and no DTC exist. Start by creating a DTC with the assistance of MISAU and SIAPS:

Structure and organization of the DTC

- Obtain hospital management approval, including the director
- Develop multi-disciplinary membership from key stakeholders
- Collaborate with other organizations and committees in the hospital and community
- Develop action plans and objectives for the year
- Terms of Reference (TOR) (as provided by MISAU, Hospital Pharmacy) in place and approved
- Regular meetings, at least quarterly, with distribution of minutes

Identification of medicine use problems

- Discusses medicine use problems at regular meetings (and proposed solutions)
- Conducts medicine use studies when possible (WHO Health Facility Indicator studies, Medicine Use Evaluation (MUE))
- Conducts Prescription Norms Study regularly (studies of prescription format)
- Review of monthly medicines order to determine availability and appropriate quantities of medicines

Implementation of Interventions to improvement medicine use

- EML – monitors for compliance (revised EML)
- STG – ensures availability of all STGs approved by MISAU
 - Participates in STG compliance study for HIV/AIDS, malaria, hypertension
- Education - provides in-service education on important topics at the hospital - STGs, EML, medicine use problems, rational medicine use
- MUE – Conducts MUE (with evidenced-based criteria) on important, problem prone medicines

Pharmacovigilance

- Works with national Pharmacovigilance programs to implement a comprehensive programs at the DTC
- Supports Pharmacovigilance programs with the DTC including the reporting of adverse clinical events

Specific Recommended Activities

Medicine use according to approved standards

Comprehensive national guidelines are not available. There are guidelines for certain diseases (HIV-AIDS, TB, Malaria, STI, and hypertension) but no other national guidelines. The DTC will need do the following for treatment guidelines:

- Obtain all STGS available (those that have been approved by MISAU) including:
 - HIV-AIDS
 - Tuberculosis
 - Malaria
 - Hypertension
 - Sexual Transmitted Infections
- Ensure the guidelines are available in the appropriate sections of the hospital, ambulatory health facility and ER. These should be available in full form and as posters and wall charts. Practitioners throughout the hospital and health facilities must have immediate access to all approved guidelines.
- DTC provide training at hospital (in conjunction with national programs) on the use of STGs and where they are located in the health facility.
- Monitor the use of the guidelines by reviewing medical records periodically to determine compliance with the approved guideline, e.g., percentage of patients treated who are in compliance with approved STGs.
- Participate in the monitoring and use of guidelines - SIAPS/MISAU STG compliance MUE. This involves reviewing the medical records at the hospital, ambulatory clinic, and ER to determine if they follow the approved guidelines for HIV/AIDS, malaria, and hypertension. SIAPS will work directly with the DTC to conduct this MUE. **See protocol in Annex E.**

Medicine Availability

- Using the Mozambique EML and National Formulary determine if medicines are available from local warehouse. These documents will be made available by SIAPS.
- Ensure all prescribing is according to these approved lists.
- Work directly with local and national warehouse to ensure medicines are available, especially those for HIV-Aids, TB, and Malaria.

ANNEX H: MAPUTO CENTRAL HOSPITAL

Maputo Central Hospital

Present at the meeting:

Dr. Domingos Dias Diogo - Clinical Director of the hospital and chair of the DTC

Dr. Artur Luis - Deputy of the DTC

Dr. Hélio Gemo – Department of Hospital Pharmacy/MISAU

Dr. Aminofro Langa - Department of Hospital Pharmacy/MISAU

Dr. Neusa Bay – SIAPS MSH

Dr. Terry Green – International Consultant

Dr. Alda Mariano – National Consultant

Objective: to understand how the committee is working and progressing and how SIAPS and MISAU can provide assistance to improve their performance.

The hospital has approximately 1,500 beds. They have a DTC working and many other committees, for example: antibiotics, maternal, HIV/AIDS, oncology, and others. Dr. Diogo belongs to many committees and is the chair of several.

Dr. Diogo explained that a significant problem for the DTC and rational medicine use at this hospital is the poor availability of standards and the lack of compliance with those that exist. They have only the HIV/AIDS and hypertension STGs available because he was working within the national committee responsible to develop these STGs. These two STGs are available and staff has been trained on their use, but not enough copies are available in the hospital and clinics.

They have an internal STG on the use of antibiotics, particularly the use of 3rd generation cephalosporins, elaborated by the Antibiotics Committee. The use of this antibiotic is authorized exclusively by the clinical director, based on the evidence, diagnostic and sensitivity laboratory tests that should be attached to the request form filled by the prescriber.

Achievements of the DTC:

1. They discussed the structure of DTC, duties, TOR, etc.
2. They have a pharmacovigilance focal point at the DTC. MISAU has introduced pharmacovigilance to the committee and some activity has started.
3. They have legal authorization from MISAU to buy medicines for the hospital and they do not depend solely on Central Medical Stores. They have developed a list of medicines (local formulary) mainly with medicines to use at this hospital (4th Level). The Central Medical Store provides basic medicines like paracetamol, ibuprofen, and amoxicillin. Streptokinase has been problematic - they have months without the medicine and suddenly they receive a large distribution. Because of a low rotation for this medicine, they expire and they have to be destroyed (wasting a significant amount of money). The list (or formulary) was developed involving specialists from different areas and is considered to be a consensus list.

4. They developed another list for chronic conditions for example hypertension, diabetes, epilepsy and also medicines for psychiatric conditions. TB and AIDS medicines were excluded as well as oncology drugs.
5. They also have permission to use the money from a special clinic (where physicians attend private patients within the hospital). The money reverts to the hospital and this money is used to buy medicines for the intensive care unit like streptokinase (if it is not available from central medical stores) and other medicines for emergencies.
6. They are doing a study of the bacteriology and antibiotic sensitivities in the hospital and have found the main organism identified is staphylococcus aureus.
7. The hospital is working to develop a protocol to treat cardiac failure.

Maputo Central Hospital staff asked SIPAS and MISAU for the following:

- Take part in their meetings and develop minutes to help them to improve the performance of the DTC. In the next meeting they will draw up a work plan for the next six months.
- Provide a tool to evaluate the use of antibiotics in the hospital
- Extend the use of STGs and to supply enough copies of the STGs to each of the Departments of the Central Hospital of Maputo and provide training on how to use the guidelines.

Recommended hospital and SIAPS activities:

- Work with this hospital as requested by attending meetings and help to produce agenda and minutes.
- Obtain all approved STGs and distribute to hospital to make readily available in hospital units, ER, and OPD clinics.
- Train staff on use of STGs (this will be done by DTC in the hospital)
- Participate in the STG compliance MUE (HIV/AIDS, Malaria, hypertension). **See protocol in Annex E.** SIAPS will work directly with the hospital to conduct this MUE
- Conduct a study of antibiotic use in the hospital using the SIAPS manual: How to Investigate Antimicrobial Use in Hospitals: Selected Indicators. Some of these indicators include:
 - a. Existence of standard treatment guidelines (STGs) for infectious diseases
 - b. Existence of an approved hospital formulary list or essential medicines list (EML)
 - c. Availability of a set of key antimicrobials in the hospital stores on the day of the study

- d. Average number of days that a set of key antimicrobials is out of stock
- e. Percentage of hospitalizations with one or more antimicrobials prescribed
- f. Average number of antimicrobials prescribed per hospitalization in which antimicrobials were prescribed
- g. Percentage of antimicrobials prescribed consistent with the hospital formulary list
- h. average duration of prescribed antimicrobial treatment
- i. Percentage of patients who receive surgical antimicrobial prophylaxis for cesarean section in accordance with hospital guideline
- j. average number of doses of surgical antimicrobial prophylaxis prescribed for cesarean section procedures
- k. Percentage of antimicrobials prescribed by generic name
- l. Average duration of hospital stay of patients who receive antimicrobials

SIAPS will assist in conducting this study with a special emphasis on indicators I and J, cesarean section antibiotic prophylaxis. From this study, SIAPS can then work with this hospital to develop a protocol for cesarean section antibiotic prophylaxis using a single dose of a first generation cephalosporin, 1 hour before surgery. This protocol and subsequent compliance will lead to rationalizing antibiotic use in the hospital for surgical antibiotic prophylaxis.

ANNEX I. POWERPOINT SLIDES FOR WORKSHOP



Medicine Use Overview

Terry Green
Aida Mariano
Raouf Qawwas
Neusa Amad

August 4-5, 2014
Maputo, Mozambique

USAID
SIAPS
Systems for Improved Access to Pharmaceuticals and Services

Objectives

- Define appropriate use of medicines.
- Understand the problems of inappropriate use
- Illustrate factors contributing to inappropriate medicine use.
- Explain the consequences of inappropriate medicine use on individual patient outcomes, public health, and the healthcare system.

USAID SIAPS

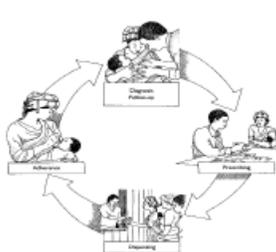
Outline

- Defining appropriate medicine use
- Problems and determinants of inappropriate use
- Consequences of inappropriate use
- Process for addressing problems in medicine use

USAID SIAPS

What is Medicine Use?

Medicine use is the result of behaviors or practices occurring during the interactions of health care providers (medicine prescribers, dispensers and sellers) and end users of the medicine (patients, consumers).



These behaviors or practices relate to the process of diagnosing the condition, prescribing medicines, labeling, packaging and dispensing the product, and taking the medicine as instructed. (MDS-3 Chapter 27)

USAID SIAPS

Improving Use of Products and Services

Health Facilities | Laboratories | Pharmacies | Drug Shops | Communities | Households



Medicine use encounters occur in many environments: public and private settings, at health care facilities, laboratories, private pharmacies or drug shops, as well as at the level of the household

USAID SIAPS

When is Use Appropriate?

Expanding on this WHO definition, appropriate use implies that:

- The medication has been prescribed based on sound medical judgment for the condition
- The medicine is of proven efficacy and safety
- The medicine is suitability for the individual patient needs, based on age, gender, special coexisting conditions and minimum likelihood of adverse reactions
- The medicines is properly administered in adequate dosage and for the length of time indicated
- Correct dispensing, labeling and packaging ensuring provision of needed information to the patient
- Patient or caregiver adheres to instructions and completes treatment regimen

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

WHO, Conference of Experts on Rational Use of Drugs, 1985

USAID SIAPS

Problems of Inappropriate Use –

Inappropriate use is very common and the consequences are substantial to patients and the healthcare system.

Up to 50% of medicines used for humans is unnecessary and 50% patients fail to take medicines correctly

Inappropriate use includes:

- use of drugs when no drug therapy is needed
- Incorrect medicine for a particular indication
- Use of medicines of uncertain or unproven efficacy
- Use of medicines of uncertain safety
- Failure to prescribe available, safe and effective medicines
- Incorrect administration, dosages or duration



Problems of Inappropriate Use- Prescribing Practices

Prescribers

- Overuse of antibiotics
 - Use antibiotics for viral or other conditions not needed an antibiotic
- Overuse of injections when other dosage forms work as well or better
- Polypharmacy – multiple prescriptions
- Overuse of vitamins and “tonics”
- Underuse of essential medicines, i.e., antihypertensives
- Prescribing for every patient symptom
- Prescribing highly promoted medicines with questionable efficacy.



Problems of Inappropriate Use -

Dispensers

- Incorrect interpretation of prescriptions
- Dispensing the wrong medication
- Inadequate labeling
- Inadequate counselling

Patients

- Did not obtain (or take) medicines
- Sharing medicines with other persons
- Poor adherence to prescribed medicines



Determinants of Inappropriate Use- Health Systems

Medicine supply

- Inefficient management (example: procurement and distribution are ineffective leading to delays in receiving medicines)
- Non-availability of required medicines (example: lack of funds, pilferage, health professions using first, contribute to non-availability)
- Availability of inappropriate medicines including substandard and counterfeit products (example: procurement of non-essential)

Regulation

- Availability of non-essential medicines (example: lack of regulations and enforcement of policies including EML)
- Informal prescribers (example: lack of regulations and enforcement concerning use of medicines)
- Lack of specific policies and guidelines that address medicine use and supply (Example: laws governing medicine use are not available or not enforced)



Determinants of Inappropriate Use- Prescribers

Internal Factors

- **Lack of education (pre-service and in-service)** (example: does not know recommended antibiotic timing, frequency, or dosing for treatment of pneumonia)
- **Lack of experience** (example: does not know the latest treatment and referral procedures acute psychotic illness)
- **Lack of unbiased medicine Information** (example, no drug literature or treatment guidelines)
- **Misleading beliefs about efficacy and Safety** (example, believes that inj. is preferable route of admin, believes every one needs and antibiotic)

External Factors

- **Workload** (example: too many pt. encounters, obtaining history and providing advice is very limited)
- **Pressure from peers to prescribe** (example: doctors follow what others are prescribing for TB)
- **Pressure from patients to prescribe** (patients believe they need medicines for every symptoms. More is better)
- **Financial incentives** (manufacturers and suppliers are providing financial or in-kind services in return for using their medicines)



Determinants of Inappropriate Use- Dispensers

Internal

- **Lack of education** (lack of pre-service and post service education leading to lack of knowledge on medicines and treatment options)
- **Lack of experience** (lack of experience to know what is actually needed at the service delivery point to dispense and counsel effectively)
- **Lack of unbiased medicine information** (medical/pharmacy texts and information sources, drug information center, treatment guidelines)
- **Misleading beliefs about efficacy and safety of medicines** (example: unbiased information is not available leading non- evidence based decisions and beliefs)

External

- **Lack of supervision** (example, poor supervision can lead to Poor performance)
- **Workload** (heavy workload leaves little time to education oneself, provide the necessary time to review prescriptions accurately and to counsel patients)
- **Shortage of dispensing material** (example: Dispensing materials not available)
- **Financial incentives to dispense inappropriately** (manufacturers, suppliers and others may influence dispensers to dispense related medicines in return for incentives)
- **Low status in healthcare system**



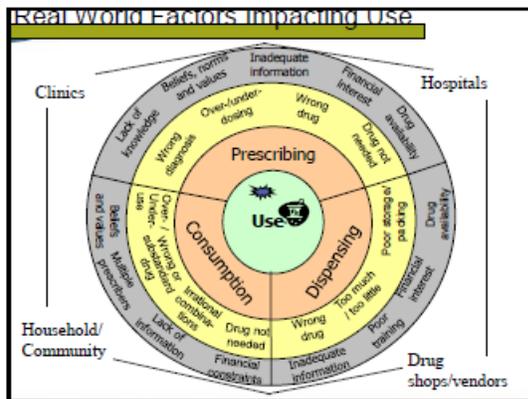
Determinants of Inappropriate Use- Patients and Community

<p>Patients</p> <ul style="list-style-type: none"> Cultural beliefs Communication skills unable to understand directions and counselling provided) Limited time available for counselling (example: waiting times for consultations and to obtain medicines are long and leaves little time for counselling) Inadequate unbiased medicine information (example: unbiased information is not readily available and consequently optimal treatment is not provided. 	<p>Community</p> <ul style="list-style-type: none"> Community beliefs about the efficacy of certain medicines and methods of administration (Example: (1) community feels that treatment of many diseases can best be done with local (herbal) remedies and there is only western medicine is used only intermittently (2) believes that injections are superior even when they are not necessary)
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Determinants of Inappropriate Use- Industry

<ul style="list-style-type: none"> Biased promotion of manufacturers products (example: manufacturers provide information that support their product. Detailing is discrete and effective) Misleading claims (example: biased articles, poorly written articles provided that provide misleading information to support their products) 	<p>Financial gain</p> <p>(example: sizable financial gains are the result of providing many excellent medicines but also for ineffective, unsafe and low quality Products. Financial gain can lead to significant inappropriate use)</p>
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Consequences of Inappropriate Use – Increased Mortality and Morbidity

Example:

- Oral rehydration solution is proven to be effective and safer to treat simple diarrhea in children – unnecessary exposure to unsafe use of needles for intravenous fluids may bring unnecessary exposure to infections

Consequences of Inappropriate Use – Increase Adverse Medicine Events

Examples

- An overdosage of gentamicin can lead to permanent hearing loss.
- Prescribing antibiotics for viral conditions leads to an increase in the number of allergic reactions.



Consequences of Inappropriate Use – Antimicrobial Resistance

- Infectious diseases kill 12-15 million people annually, 95% of whom live in resource-constrained countries
- The major life-saving intervention for infectious diseases is **antimicrobial treatment**
- But when antimicrobial medicines are used unnecessarily, or in doses that are inadequate, these pathogens develop resistance to these medicines at higher speed reducing their effectiveness against infections.



Consequences of Inappropriate Use – Psychosocial

Psychosocial –

- Unnecessary prescribing encourages patients to believe that they need medications for any and all conditions, even trivial ones
- Previous overuse of injections led physicians to considered them the best treatment, when in fact they are rarely needed.
- Studies have shown that increased patient expectations of the benefit of medicines, and the increased demand for prescriptions tend to lead prescribers to provide unnecessary antibiotics for viral infections



What Do We Mean by Improving Use?

Improving use requires a change in actions and behavior of health systems, health professionals and patients to ensure the safe, appropriate use of medicines. There is a need to understand:

- Nature of medicine use including social, cultural and economic context
- A standardized approach to measuring medicine use problems
- Efficient and effective use of interventions and strategies to address the medicine use problem



How Do We Go About Addressing the Problems of Medicine Use?

- Improving use requires a change in behaviors and practices of all actors involved in the process of medicine use.
- MSH, WHO and the International Network for the Rational Use of Drugs proposed a process for changing medicine use behavior. This process follows a pathway similar to the way physicians make a diagnosis and decide on treatment (which explains the terms used)
 - Examine – the current situation is observed and measurements of the problems in medicine use are conducted
 - Diagnose – the underlying reasons determining or influencing the problem behavior are thoroughly investigated by a variety of qualitative and quantitative methods

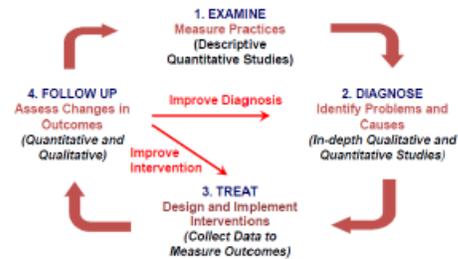


How Do We Go About Addressing the Problems of Medicine Use? (2)

- Treat – interventions to address the factors or underlying causes of the inappropriate practice or behavior and that have been proven to modify the problem behavior or practice, are proposed. After analyzing that resources are available and the interventions are feasible, they are implemented – usually in pilot sites.
- Follow-up – intended and unintended changes in behavior are monitored throughout the period of intervention. Intervention may be modified if needed. Outcomes are measured, and decisions are made on whether the initial diagnosis of the causes of the problem was correct.



An Overview of the Process of Improving Medicine Use



Another way of depicting this process can be seen in Figure 29-6 of MDS-3, Managing Access to Medicines and Health Services



The DTC and Appropriate Medicine Use

- Medicine use problems are complex, widespread, costly and affects quality of care at all levels of the health system
- Identifying the problems, understanding why they occur, and implementing interventions to improve or resolve requires a multifaceted approach by a highly skilled team of professionals
- The DTC provides the organization, skilled professionals, and the mandate to address the many problems of medicine use and ensure use is rational



Summary

- Appropriate medicine use is essential to ensuring good patient health outcomes
- Inappropriate use contributes to increased morbidity/mortality, development of antimicrobial resistance, and substantial increases in health care costs.
- Improving a medicine use problem or practice requires a methodology that will identify what the problem is and why it exist and a standardized approach to change the practice or behavior.





Medicine Use Evaluation (MUE)

Terry Green
Alda Mariano
Raouf Qawwas
Neusa Amad

August 4-5, 2014
Maputo, Mozambique



Objectives

- Understand basic concepts of conducting a Medicine Use Evaluation
 - Describe the steps to implement a MUE
 - Describe the case study using MUE in surgical prophylaxis
 - Understand how MUE can be used in Mozambique to address a medicine use problem
- 

Outline

- Introduction and objectives of a MUE
 - Stepwise Approach to Implementing a MUE
 - Case Study Using an MUE in a surgical prophylaxis medicine use problem
 - Summary
- 

Medicine Use Evaluation (MUE) – Introduction

- Ongoing, systematic, criteria-based program of medicine evaluations that will ensure appropriate medicine use. Interventions are necessary when inappropriate therapy is identified.
 - A MUE will—
 - Define appropriate medicine use (by establishing criteria)
 - 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
- 

Objectives of a 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

1. Establish responsibility.
 2. Develop scope of activities.
 3. Establish criteria.
 4. Define and establish thresholds.
 5. Collect data and organize results.
 6. Analyze data.
 7. Develop recommendations and plan of action.
 8. Conduct MUE follow-up.
- 

Step 1. Establish Responsibility

- Drug and Therapeutics Committee (DTC) is logical choice
 - Multidisciplinary committee dealing with all facets of medicine therapy—has the necessary expertise
- Subcommittee of the DTC
 - Must include representation of practitioners whose medicine prescribing 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 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

Criteria to define correct medicine use (using evidence-based medicine)—

- Appropriate medicine for medical condition
- Correct dose and 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 (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 3rd generation cephalosporins are for predefined serious infections).



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 versus computerized systems
 - Needs minimum of 50–75 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 3rd generation cephalosporins were given it for predefined criteria—20% short of threshold
- Determine why thresholds (benchmarks) 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.



MUE Case Study—Antibiotic Prophylaxis in Cesarean Section, Jordan

Study setting

- A retrospective study was conducted over 1 months in 4 hospitals in Jordan.
- Antimicrobial surgical prophylaxis for C-Section was shown to use multiple antibiotics in multiple doses over extended periods of time. Predominant use of high cost 2nd and 3rd generation cephalosporin antibiotics. First dose administration was incorrect in most patients (after the surgical procedure)

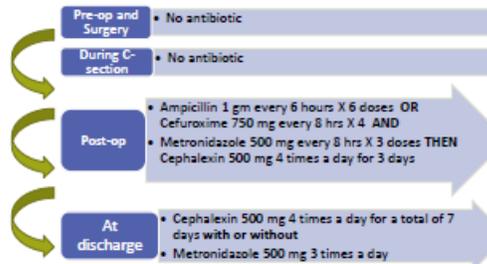
Interventions

- Cesarean Section antimicrobial prophylaxis protocol was developed to include a single dose of a single antibiotic within 1 hour of surgery, e.g., cefazolin.
- Education provided to physicians and protocol approved by the DTC

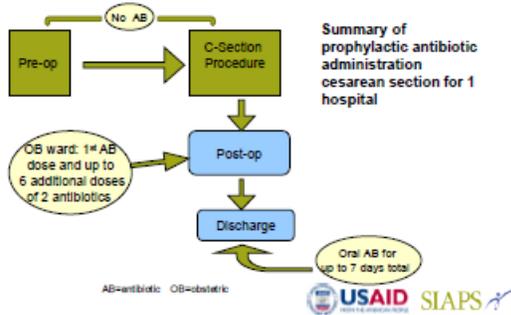


Measuring the Existing Situation, Baseline analysis

Example of a C-section antibiotic prophylaxis regimen at 1 hospital



Measuring the Existing Practice, (baseline analysis)



Establish Criteria (Guideline)

Initially, developed evidenced-based recommendations on antibiotic prophylaxis for CS. This comprehensive search of the literature provided ample evidence (from systematic review, RCT, and other high level evidence) that a single antibiotic given in a single dose within one hour before the surgical procedure was sufficient for prophylaxis. Available local studies or references were also included.

Baseline profiling done prior to the workshop had shown that the local practices at the participating hospitals did not match with the current best international evidence and recommendations in terms of the choice of antibiotic and dose, timing of administration, and duration of prophylaxis.



Establish Criteria (Guidelines) for Antibiotic Prophylaxis and Interventions

Based on initial assessment of current practices, stakeholder interviews and surgical prophylaxis evidenced-based review, the interventions and intervention profile is as follows:

- Development of clinical practice guidelines or protocols to enhance effective, safe, and cost-effective use of medicine. A participatory, transparent, and evidence-based development process will be used that engages key stakeholders in this development
- Development of specific policies and procedures at the hospital and national level to incorporate the protocols and make them a policy.
- Education and training at the hospital level on key concept of evidenced-based antibiotic prophylaxis for cesarean section and CQI concepts to implement the protocols



Establish Criteria (Guidelines) for Antibiotic Prophylaxis

Protocol and Procedures for Antibiotic Prophylaxis in CS	
Prophylactic Antibiotic	Cefazolin
Dose	Single dose -1 gm for < 80kg, 2 gm for > 80kg
Route	Injected direct IV over 3-5 minutes after skin sensitivity allergy testing
Time of administration	15-60 minutes prior to skin incision
Criteria for additional doses	Blood loss >1500ml and/or presence of full adhesions – give 2 nd dose 3-5 hr after 1 st dose Ruptured membranes (>12hrs) with no symptoms of infection – give 2 doses total at 8 hr intervals
Beta-lactam Allergy	Clindamycin 600mg single IV dose and gentamycin 1.5mg/kg single IV dose immediately after cord clamping



Establish Criteria (Guidelines) for Antibiotic Prophylaxis

- All four hospitals were able to complete the protocol developed.
- Although each hospital drafted its own P&P individually without the participation of other hospitals, the resulting hospital-specific protocols and procedures were in fact very similar. When armed with the latest international medical evidence, the teams from each hospital opted to adhere to the evidence, and the resulting protocols therefore contained many similarities.



MUE follow-up and Outcome Measures (analyze data)

- The key indicators agreed for longitudinal tracking included:
 - Adherence to protocol recommended antibiotic
 - Time of administration of first dose of prophylactic antibiotic
 - Administration of the appropriate number of antibiotic doses
 - Rates of surgical site infection
 - Cost-savings (as compared to baseline studies of cost)

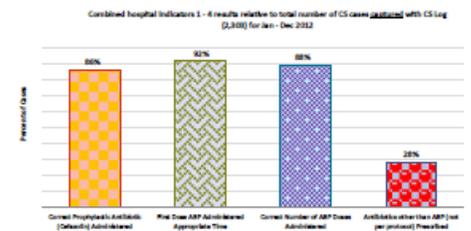


MUE follow-up and Outcome Measures (2)

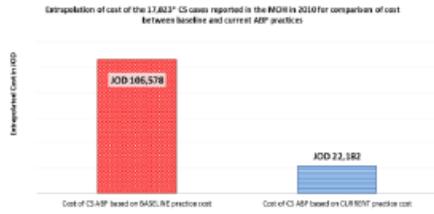
- The attached table combined results for 2012 for all the key program indicators at all the three hospitals. These results indicate good compliance to the protocols and procedures in terms of the use of the antibiotic of choice (cefazolin), use of a single dose (except in cases with pre-identified exceptions), and administration of the antibiotic prior to skin incision (within an hour before skin incision).
- The use of the new protocols also resulted in substantial cost-savings when compared with the cost of antibiotics used during the baseline period. All these results were achieved with a low overall surgical site infection rate of 1.59%.



Indicator Results



Extrapolated Total Annual Cost-saving for all CS Cases



Conclusions of Jordan MUE

- The study showed that irrational antimicrobial use in the surgical prophylaxis field is excessive
- The common problems regarding use of antimicrobials in surgery were—
 - Inappropriate choice of antimicrobial
 - Inappropriate duration
 - Using the new generation of antibiotics which are costly
 - Inappropriate administration times
- The MUE was instrumental in improving use of surgical antibiotics and lower overall cost of medicine treatment



Summary

- MUE is an audit and feedback intervention where medicine use can be reviewed against approved criteria
- Requires establishing criteria and thresholds and then reviewing medicine use to determine if therapy is appropriate
- Feedback to prescribers is necessary to improve prescribing (educational, managerial, regulatory interventions may be required)





Mozambique Essential Medicines List (EML)

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Neusa Amad

August 4-5, 2014
Maputo, Mozambique




Objectives

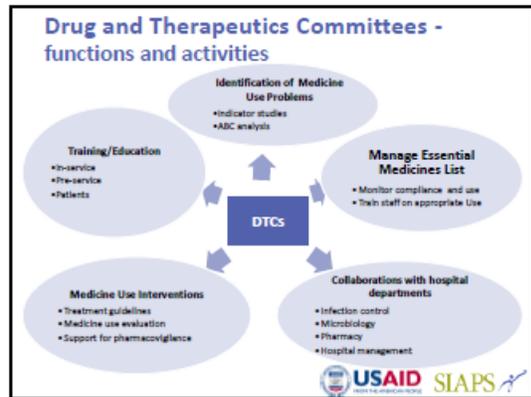
- Understand the WHO essential medicines concept
- Describe the benefits of an essential medicine list and concept
- Describe the process of revising a national essential medicine list
- Understand how to manage an EML at the health facility level




Outline

- Complexities of medicine use
- Essential medicines concept and situation in Mozambique
- National Essential Medicine List revision process
- Managing the EML at the health facility- key DTC activity
- Summary





Complexities of Medicine Use

- Hundreds of thousands of medicine are available worldwide
- Several therapeutic groups and medicines are available to treat any specific disease
- New medicines and new information about existing medicines are emerging




Complexities of Medicine Use (2)

- Developing countries spend up to 40% of their health care budgets on medicines on medicines
- An estimated 70% of medicines are considered duplicative or non-essential
- Lack of access to medicines is a major and chronic issue in resource-constrained settings
- Lack of availability erodes public confidence in the public health system
- In low and middle-income countries, most people pay for their own medicines




Situation in Mozambique

- MISAU has made great strides to improve healthcare to the people of Mozambique
- Challenges remain – only 40-50% of the population have regular access to public health services and more than 75% of the population used traditional medicines primarily to treat health-related problems
- The lack of STGs hinders RMU in the country
- The lack of a updated EML contributes to many medicine use problems and provides the opportunity to prescribe unnecessary and irrational medicines.
- Mozambique EML is under revision this year



Essential Medicines Concept

- Careful selection and implementation of a limited list of essential medicines enhances access and rational use of medicines
- Global and national policy makers and health program managers support the concept of essential medicines
- The essential medicines concept is a key element of national medicines policies
- WHO has promoted this concept for 35 years and regularly publishes a Model List. This important publication was updated in April 2013 and can be used to revise a national EML.



Essential Medicine Concept - WHO Model List of Core and Complementary Medicines

- Adult Model List
- Children Model List
- 18 edition (April 2013)
- 4th edition (April 2013)
- http://www.who.int/medicines/publications/essentialmedicines/18th_EML_Final_web_8Jul13.pdf
- http://www.who.int/medicines/publications/essentialmedicines/4th_EMLc_FINAL_web_8Jul13.pdf



Summary of Benefits of an Effective EML

- **SUPPLY**
 - Easier procurement
 - Lower amount of stocks
 - Improved quality assurance
 - Easier dispensing
- **PATIENT USE**
 - Focused education efforts
 - Better compliance
 - Improved availability
- **PRESCRIBING**
 - Promotes RMU
 - More experience with fewer medicines
 - Irrational alternatives not available
 - Focused medicine information
 - ADRs easier to manage
- **COST**
 - Lower prices, more competition



National Essential Medicines List - Mozambique

- The National Essential Medicines List (NEML) is a vital part of MISAU strategy to provide comprehensive high quality health care in Mozambique
- A revision process has started and a new NEML committee formalized and selected



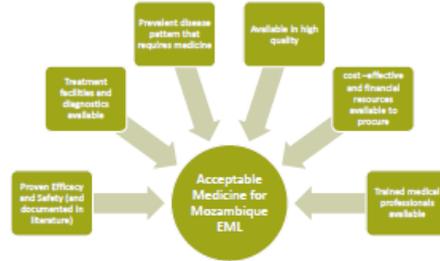
Key steps to produce a revised NEML in Mozambique



NEML Committee Members – a diverse, multi-disciplinary team



Criteria for Evaluating and Selecting Medicines for EML



Managing the EML at the Health Facility – Key DTC activities

- Ensure NEML is available in the health facility
- Monitor prescribing and use of medicines for compliance with the NEML
 - Outcome measures - % of prescriptions in accordance with the EML
- Provide education and training for health care professionals at the health facility concerning use of the NEML
- Request medicines for addition to the NEML, if necessary, using standardized applications and transmit to the national EML committee



Summary

- The essential medicines concept has become an established approach in international public health and is supported by most governments of the world
- The EML provides *extraordinary* benefits for rationalizing medicine prescribing and use, easier and less costly procurement, enhanced inventory management and improved use and acceptance by patients.
- MISAU endorses the essential medicines concept and is in the process of revising the national essential medicines list



Interventions and Strategies to Improve Medicine Use, Standard Treatment Guidelines

Terry Green
Alda Mariano
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Neusa Amad

August 4-5, 2014
Maputo, Mozambique

USAID
SIAPS
Support for Improved Access to Pharmaceuticals and Services

Objectives

- Understand the how treatment guidelines are developed
- Describe the use of treatment guidelines in Mozambique
- Explain how treatment guidelines can be used to improve medicine use

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Outline

- Irrational use of medicines
- Strategies to improve Medicine Use in Developing and Transitional Countries
- Introduction to Treatment Guidelines
- Guidelines available in Mozambique
- Case studies - treatment guideline and improving medicine use
- Summary

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Irrational Use of Medicines

Globally, more than 50% of medicines are prescribed, dispensed, or sold inappropriately

Consequences of Irrational Medicine Use

- Increased morbidity
- Increased mortality
- Increased adverse drug events
- Increased drug resistance
- Increased cost and wasted resources
- Financial hardships

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Irrational Treatment of ARI in Developing and Transitional Countries

Region	% Cases of ARI Treated with Antibiotics	% Prescribed Cases Treated with Recommended Antibiotics	% Treated According to Clinical Guidelines	% ARI Cases Treated with Cough Syrup
Sub-Saharan Africa	~70	~60	~40	~15
East Asia and Pacific	~55	~55	~45	~15
Latin America and Caribbean	~65	~65	~45	~15
Middle East and Central Asia	~60	~60	~45	~15
South Asia	~55	~55	~45	~15

Source: WHO 2009. Medicine Use in Primary Care 1990-2006

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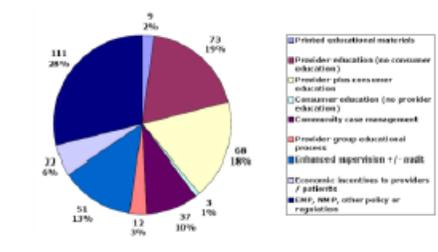
Irrational Prescribing of Antibiotics in Developing and Transitional Countries

Region	% Antibiotics Prescribed Inappropriately	% Patients Prescribed Antibiotics Inappropriately
Sub-Saharan Africa	~65	~50
East Asia and Pacific	~60	~45
Latin America and Caribbean	~60	~45
Middle East and Central Asia	~60	~45
South Asia	~60	~45

Source: WHO 2009. Medicine Use in Primary Care 1990-2006

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Strategies to Improve Medicine Use in Developing and Transitional Countries



Source: WHO 2009. Medicine Use in Primary Care 1990-2005



Interventions to Improve Medicine Use

- Effective interventions to improve use of medicines are generally multi-faceted
 - Provider and consumer education with supervision
 - Peer review and self monitoring (MUE)
 - Community case management
 - Essential Medicines Program
- Printed materials alone have little effect
- The use of guidelines to be effective need to be accompanied by reminders, educational outreach and feedback

Source: WHO 2011. The World Medicines Situation. Rational Use of Medicines



Standard Treatment Guidelines - Introduction

- Treatment of diseases may have many different approaches
- Many practitioners will not remember the best method of treatment
- Applying the most effective treatment benefits both the patient and the health care system
- Formulary management will have only limited impact if the medicines are used incorrectly



Treatment Guidelines—Advantages for Health Care Providers and Patients

- Provides standardized guidance to practitioners
- Promotes high quality of care by directing practitioners to the most appropriate medicines for specific conditions
- Utilizes only formulary or essential medicines, so the health care system needs to provide only the medicines in the STGs
- Provides assistance to all practitioners, especially to those with lower skill levels
- Enables providers to concentrate on making the correct diagnosis
- Patients receive optimal pharmaceutical therapy
- Enables consistent and predictable treatment from all levels of providers and at all locations
- Allows for improved availability of medicines because of consistent and known usage patterns
- Helps provide good outcomes because patients are receiving the best treatment regimen available
- Lowers cost



Advantages to Healthcare Officials and Supply Management

- | | |
|---|--|
| <p>Healthcare Officials</p> <ul style="list-style-type: none"> • Provides a basis for evaluating quality of care provided by health care professionals • Provides effective therapy in terms of quality • Provides a system for controlling costs • Provides information for practitioners to give to patients concerning the institution's standards of care • Serves to integrate special programs (diarrhea disease control, TB) at the primary health care center with a single set of guidelines | <p>Supply Management</p> <ul style="list-style-type: none"> • Utilizes only formulary or essential medicines, so the health care system needs to provide only medicines in the STGs • Provides information for forecasting and ordering • Provides information for purchase of prepackaged medicines |
|---|--|



Disadvantages

- Inaccurate guidelines will provide the wrong information. Often guidelines are based on existing practices rather than evidenced-based medicine.
- Guideline development and maintenance takes much time and effort.
- STGs may give false sense of security and discourage ongoing critical thinking.



Establishing the Guideline

- Important considerations—
 - Create from evidence-based sources
 - Choose cost-effective treatments
 - Use medicines from the national EML
 - Involve respected clinicians and specialists



What Various Studies Are Used to Evaluate ?

- Meta-analysis** • Usually for treatment efficacy and safety
- Randomized controlled trials** • Usually for treatment efficacy or diagnosis
- Cohort study** • Usually for prognosis, harm, etiology, prevention
- Case-control study** • Usually for prognosis, harm, etiology, prevention
- Case study/series** • Usually for harm



Not all Evidence is Equal - Levels of Evidence

Recommendation grades	Level of evidence	Study characteristics to determine efficacy
A	1a	Systematic review (SR) (with homogeneity) of RCTs
	1b	Individual RCT (with narrow confidence interval)
	1c	All or none study
B	2a	BR (with homogeneity) of cohort studies
	2b	Individual cohort studies (including low quality RCT)
	2c	Outcomes research, ecological studies
	3a	BR (with homogeneity) of case-controlled studies
C	3b	Individual case-controlled studies
	4	Case series (and poor quality cohort and case-controlled studies)
D	5	Expert opinion without explicit critical appraisal

Source: Centre for Evidence Based Medicine – University of Oxford

Guidelines Available in Mozambique

- Official MOH Guidelines:
 - HIV, ?
 - TB, ?
 - Malaria, ?
 - Diabetes, 2009
 - Malaria, 2011
 - Mental Health, 2005
 - Hypertension, 2011



Guidelines Available in Mozambique

- Unofficial Guidelines
 - Pediatric medical conditions - several different guidelines and protocols, 2009-2012
 - Others:



Case Study - Use of Standard Treatment guidelines, Namibia

MOH in partnership with SIAPS, conducted an assessment of compliance of prescribers with the Namibia Standard Treatment guideline. The main objective of the assessment was to compare prescribing practices before and after the roll out of STGs that were initially disseminated in 2011.

The assessment also aimed to explore factors associated with compliance and to find out what activities were implemented in health facilities and regions to promote compliance with the STGs.



Case Study - Use of Standard Treatment guidelines, Namibia

- The assessment covered 13 health facilities, including six hospital, four health centers, and 3 clinics.
- A total 1,090 prescriptions were reviewed concerning eleven diseases: Asthma, viral URI, community acquired pneumonia, diarrhea without blood, diabetes mellitus type 2, hypertension, intestinal helminthiasis, HIV/AIDS.



Case Study - Use of Standard Treatment guidelines, Namibia

- Compliance of prescriptions with the STGS was assessed using strict and loose criteria.
 - Strict Criteria – requires that prescriptions to fully comply with the stipulations of the STG
 - Loose criteria – allowed for some deviation in the dose and duration of treatment, non-use of generic name, and use of additional medicines, such as analgesics and multivitamins



Case Study - Use of Standard Treatment guidelines, Namibia

Results:

- The findings show that overall compliance with STGs using strict criteria was 26.2%. Compliance using the loose criteria was 55.1%
- Using strict criteria, the highest disease state with compliance was HIV/AIDS at 63.5%



Case Study - Use of Standard Treatment guidelines, Namibia

Results using Strict Criteria

- HIV/AIDS - 63.5%
- Urethral Discharge – 55.57%
- Diabetes (type 2) – 40.3%
- Intestinal Helminthiasis – 30.6%
- Oral Candidiasis (27.9%)
- Vaginal discharge -26.8%
- Asthma – 22.3%
- Pneumonia – 15.9%
- Hypertension – 14.4%
- Viral URI – 5.7%
- Diarrhea without blood – 0%

Results using Loose Criteria

- HIV/AIDS – 75.8%
- Urethral Discharge- 86.1%
- Diabetes- 74.1
- Intestinal Helminthiasis- 62.1%
- Oral Candidiasis – 54.0%
- Vaginal discharge- 83.0%
- Asthma-60.0%
- Pneumonia-42.4%
- Hypertension-46.4%
- Viral URI-33.3%
- Diarrhea without blood – 13.6%



Case Study - Use of Standard Treatment guidelines, Namibia

Reasons for poor compliance (from interviews and questionnaires)

- Lack of personal STG copies for the prescribers
- Lack of time to read the guidelines
- Lack of adequate copies for the health facilities
- Poor attitude of health workers about STGs
- High patient workload



Case Study - Use of Standard Treatment guidelines, Namibia

To improve compliance, the following was instituted:

- All providers will be provided a copy of the guideline
- Conduct regular refresher training on the guidelines
- Regular updating of the guideline
- Use STGs for continued professional development
- Empower the DTC to supervise prescribers and regularly conduct medicine use evaluations

Source: Namibia SIAPS program - Ebong Alpabio, Evans Sagwa, Greatjoy Mazibuko, Harriet Rachel Kagaya, Qamar Niaz, and David Mabinzi



Case Study 2 – Treatment Guidelines for HIV in South Africa - poor compliance in switching to second line medicines

- The scaling up of ART in South Africa has resulted in a dramatic increase in the number of patients receiving ART. The length of ART treatment may lead to increased need for second line treatment because of therapeutic failures. The cost of this second line therapy is significantly higher than first line treatments.
- In South Africa, SIAPS collaborated with national stakeholders to help conduct a medicine use study in Gauteng Province, which identified that, in 50 percent of patients receiving antiretroviral therapy, the switch from first-line to second-line regimens was not in compliance with treatment guidelines.



Case Study 2 – Treatment Guidelines for HIV in South Africa - poor compliance in switching to second line medicines

The key findings from the study are as follows—

- Low level of compliance with the STGs
- Only 49.4 per cent of the patients were switched to the second-line regimen in compliance with guidelines. This low percentage was partly because of lack of systematic adherence assessment (47.4 per cent). The absence of second viral load (VL) was responsible for 32.1 per cent of the non-compliance, implying switching was done without supporting laboratory evidence.
- Various reasons for switching recorded in medical records
 - Adverse drug reactions (ADRs) and pregnancy were among some of the recorded reasons for switching, which is not in line with the recommended national guidelines. Forty-five medical records had no stated reasons for switching. Among the patients switched for regimen failure, only 46.7%per cent were switched in compliance with the guidelines; hence, regimen failure was recorded as a reason for switching without supporting evidence.



Case Study 2 – Treatment Guidelines for HIV in South Africa - poor compliance in switching to second line medicines

- Key findings, continued
 - Based on the current (2013) government contract prices, 50.6 per cent non-compliance with the guidelines cost an extra R 8.79 million per year per 10,000 patients on second-line ART.

As the programme ages and the number of patients put on treatment increases dramatically, it is crucial to ensure that only patients with confirmed virological failure and a good record of adherence are switched to second line.

Source: South Africa SIAPS Program, Dr. Stephanie Berrada,



Conclusions

- Evidenced-based treatment guidelines will help ensure rational medicine use
- The first step is to have the approved national guidelines readily available in the health facility
- Guidelines must be used with appropriate provider education and monitoring/provider feedback in order to be effective
- Monitor the use of important guidelines and determine compliance and outcomes





Developing and Implementing Drug and Therapeutics Committees in Mozambique

Terry Green
Alda Mariano
Abdel Raouf Qawwas
Neusa Amad

August 4-5, 2014
Maputo, Mozambique



Objectives

- Understand why a DTC is important in Mozambique
- Describe the major functions and activities of a DTC to improve medicine management and use
- Describe how a DTC performance is monitored and impact measured
- Understand the DTC implementation process



Outline

- Why DTCs are Important
- Activities and Functions of the DTC
- Monitoring DTC and Intervention performance
- Implementing the DTC – Getting Started
- Summary



Why DTCs are Important

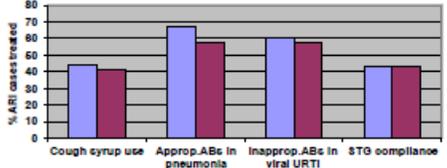
Globally, more than 50% of medicines are prescribed, dispensed, or sold inappropriately

Consequences of Irrational Medicine Use

- Increased morbidity
- Increased mortality
- Increased adverse drug events
- Increased drug resistance
- Increased cost and wasted resources
- Financial hardships



Why DTCs are Important - Providers prescribe inappropriate treatments frequently



Category	Doctor (n=20,18,40,12)	Paramedic/nurse (n=13,04,60,61)
Cough syrup use	~55%	~45%
Approp. ABs in pneumonia	~70%	~65%
Inapprop. ABs in viral URTI	~65%	~60%
STG compliance	~45%	~40%

ABs – antibiotics URTI – upper respiratory tract infections STG – standard treatment guideline

Source: WHO PQSM Database on Medicines Use in Primary Health Care in Developing Countries, 2007.



Why DTCs are Important – Adverse Clinical Events occur frequently and must be managed and prevented

Medication Errors

Adverse Drug Reactions

ADVERSE CLINICAL EVENTS

Poor Quality Medicines

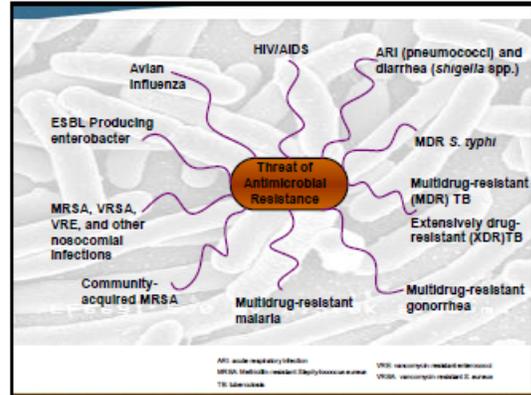
Counterfeit Medicines



Why DTCs are Important - The Global Threat of Antimicrobial Resistance

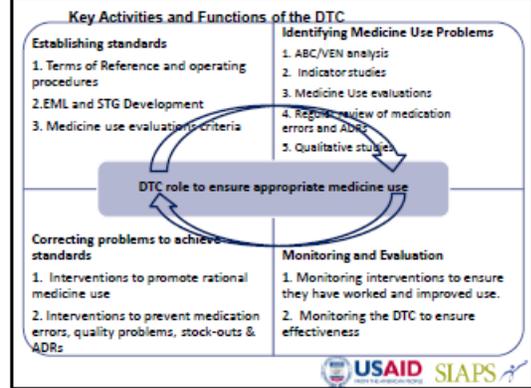
AMR is

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



How do DTCs Improve Medicine Use?

- DTC is the cornerstone for managing the medicine use process
 - Uses skilled local health professionals at hospitals and clinics to review, monitor and manage medicine use
- Ensures medicines prescribed are according to established standards
- Ensures medicines are safe, effective and are of high quality and are cost-effective



Key Activities and Functions of the DTC - Interventions to Improve Medicine Use

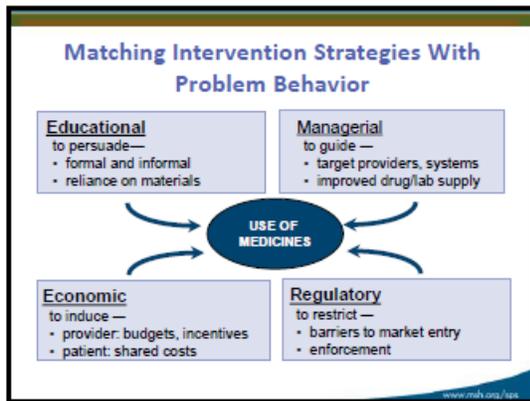
- Educational programs
 - Pharmaceutical bulletins and newsletters
 - In-service education
 - Face to Face education (in-service, workshops)
- Managerial programs
 - Adoption and use of national standard treatment guidelines (use of national level STGs and limited development of local protocols)
 - MUE
- Regulatory programs
 - Pharmaceutical registration
 - Professional licensing
 - Licensing of outlets



Key Activities and Functions of the DTC - Managing Adverse Clinical Events

- DTC needs to monitor and report Adverse Clinical Events including:
 - Adverse Drug reactions
 - Medication errors
 - Poor quality medicines
 - Counterfeit medicines
- Work directly with national Pharmacovigilance Program

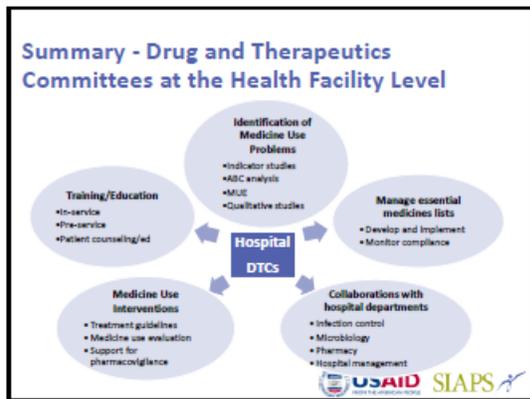




- ### Monitoring DTC Performance: Process Indicators
- Is there a DTC document that indicates its terms of reference including goals, objectives, functions, and membership?
 - What percentage of DTC members attend more than half of meetings?
 - How many DTC meetings are held per year?
 - Have STGs been developed, adapted, adopted, and implemented?
 - How many education programs were presented in the last year?
 - Have EML or hospital formulary been developed, adapted, adopted, and implemented?
 - How many education programs were presented in the last year?
 - How many intervention studies to improve medicine use been conducted?
 - How many MUEs have been undertaken?
 - Is there any documented policy for controlling access of pharmaceutical representatives and promotional literature to hospital staff?
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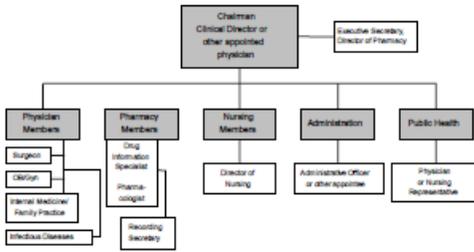
- ### Monitoring DTC Performance— Impact and Outcome Indicators
- **Medicine selection**
 - Number of medicines in the hospital EML
 - % prescribed drugs belonging to the hospital EML
 - **Prescribing quality**
 - % of prescriptions with and antibiotic prescribed
 - % of patients treated in accordance with STGs
 - % of pharmaceutical treatments meeting agreed criteria of MUE
 - **Patient care**
 - % of patients with adequate knowledge of medicine dosage
 - **Drug safety**
 - Number Adverse Medicine Events documented and reported
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- ### DTCs—Guiding Principles
- **Transparent and unbiased decision making**
 - Explicit criteria and process
 - Documentation
 - Absence of conflict of interest including pharmaceutical manufacturers and suppliers
 - Development and enforcement of a strict ethics policy for all activities of the committee
 - **Objectivity**—Evidence-based approach and levels of evidence
 - **Consistency**—Uniformity between formulary and STGs and between regional and national health care programs
 - **Impact orientation**—Indicators of process, impact, and outcome
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- ### Implementing the DTC - Getting Started
- **First Steps**
 - Get approval and buy-in from Ministry of Health, hospital administration and senior physicians
 - Develop terms of reference (TOR) – available from MOH
 - Develop Policies and procedures
 - Develop Objectives for the committee
 - **Select members**
 - Representing key stakeholders from hospital administration, medical, pharmacy, and nursing
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Implementing the DTC— Structure and Organization, example



Implementing the DTC – DTC Structure and Organization

- Plan for regular meetings and regular attendance with documented and circulated agenda and minutes
- Documented goals, terms of reference, policies, AND ALL decisions of the committee



Implementing the DTC

- The way to get started will depend on local circumstances, including the health care system and hospital
- DTCs have to deal with many issues but cannot do everything all at once – so concentrate on only 1-2 issues at a time especially in the beginning
- The first step is for YOU to realize there is a problem and that the DTC can provide a framework for solutions
- Thereafter, you must convince others of the need to address the problem and work with them on solutions



Implementing the DTC

Build evidence for advocacy by determining –

- Whether data on medicine use problems is available. If so, collect it.
- Whether senior health staff think medicine use problems exist. If so—
 - What kind of problems?
 - How serious are they?
 - How can the most serious problems be addressed?
 - Document what they say.



Implementing the DTC

Measure Your Medicine Use Problem

- Involve senior staff in these important activities—
 - VEN analysis
 - ABC analysis
 - Medicine use indicator studies (health facility and hospital indicators)
 - Qualitative studies to determine why a problem occurs



Implementing the DTC

Present Findings, and Plan the Next Steps with your Stakeholders

- Analyze potential medicines use problems and obtain consensus on how to solve them
- If causes are well understood, then solutions can be found by stakeholders. If causes are unknown, then qualitative studies should be conducted to determine why a medicine use problems occurs
- Discuss and agree with stakeholders and senior prescribers a plan of action which may include—
 - Targeted intervention based on the detailed findings and involving the senior prescribers



Implementing the DTC

Implement and Evaluate the Agreed-upon Intervention

- Type of intervention(s) will depend on the type of medicine use problem and the underlying reasons for it that have been identified
 - Treatment guidelines, EML, educational strategies, regulatory interventions
- Implement and evaluate interventions with the full cooperation and involvement of stakeholders and senior prescribers.
- If possible, measure the cost of the intervention and any savings in terms of less drug used or different medicines used



Implementing the DTC

Present the Results of Your Interventions to Senior Prescribers

- Present the results of your findings to senior management and prescribers
- If they have been properly involved they will already know some of the results
- Emphasize during the presentation
 - Benefits in terms of better health care and reduced costs
 - Need for time and resources to achieve an improved result
 - Need for a sustainable mechanism to conduct such work
- Plan the start of a DTC or revision
 - If you have followed the previous steps administration and senior staff, whom you have kept fully informed, should support you



Implementing the DTC – Factors Critical to Success

- Establish clear goals and purpose
- Obtain wide representation on the committee—prescribers, nurses, pharmacists, and administration; obtain motivated, respected, and dynamic chairperson
- Permit no relation between committee and pharmaceutical manufacturers or suppliers
- Communicate all DTC information, policies, procedures, recommendations, and actions to staff
- Obtain official status from the administration (local hospital director and regional health bureaus) with strong management support
- Develop medical and pharmacy departments and local professional schools support
- Ensure contextual incentives



Summary

- DTC are critical to managing and improving the ways medicines are used at the health system, health facilities, prescribers and end-users.
- Benefits are numerous including
 - Ensures use of effective, safe, high quality, cost-effective medicines for the hospital (uses medicines from the approved national EML)
 - Monitoring and identification of medicine use problems
 - Management and containment of antimicrobial resistance
 - Management of adverse medicine events
 - Management of pharmaceutical expenditures



Summary (2)

Getting a DTC started or making it more functional will require a strategy based on—

- Local conditions
- Local data
- Starting small and then scaling up
- Choosing a problem that can easily be addressed
- Transparent decision making
- Political and administrative support

