

Rational Pharmaceutical Management Plus

Program in Armenia July 15 – August 4, 2006: Trip Report

Susanna Khachatryan
David Lee
Maria Miralles

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Rational Pharmaceutical Management Plus
Center for Pharmaceutical Management
Management Sciences for Health
4301 N. Fairfax Drive, Suite 400
Arlington, VA 22203
Phone: 703-524-6575
Fax: 703-524-7898
E-mail: rpplus@msh.org

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About RPM Plus

RPM Plus works in more than 20 developing and transitional countries to provide technical assistance to strengthen drug and health commodity management systems. The program offers technical guidance and assists in strategy development and program implementation both in improving the availability of health commodities—pharmaceuticals, vaccines, supplies, and basic medical equipment—of assured quality for maternal and child health, HIV/AIDS, infectious diseases, and family planning and in promoting the appropriate use of health commodities in the public and private sectors.

Abstract

This report documents activities that took place during the RPM Plus field visit to Armenia between July 15, 2006 and August 4, 2006.

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Key Words

Armenia, cost analysis, prescribing study, basic package of services.

Rational Pharmaceutical Management Plus Program
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Management Sciences for Health
4301 North Fairfax Drive, Suite 400
Arlington, VA 22203 USA
Telephone: 703-524-6575
Fax: 703-524-7898
E-mail: rpmpplus@msh.org
Web: www.msh/rpmpplus.org

CONTENTS

Contents	iii
Acronyms	v
Background.....	1
Purpose of Trip	1
Activities.....	3
Collaborators and Partners.....	4
Next Steps	5
Immediate Follow-up Activities	5
Recommendations.....	5
Agreement or Understandings with Counterparts.....	5
Important Upcoming Activities or Benchmarks in Program	5
Annex 1. Pending Issues for Costing Study.....	7
Annex 2. Presentation: Promoting Rational Use of Medicines In Primary Health Care	11

ACRONYMS

AUA	American University of Armenia
BBP	Basic Benefits Package
DURG PO	Drug Utilization Research Group, Public Organization
MSH	Management Sciences for Health
MOH	Ministry of Health
RPM Plus	Rational Pharmaceutical Management Plus program
PHC	Primary Health Care
PHCR	Primary Health Care Reform project
SCDMTE	Scientific Center for Drugs and Medical Technology Expertise
SHA	State Health Agency
STG	Standard Treatment Guidelines
UMCOR	United Methodist Committee of Relief
UNICEF	United Nations Children's Fund
USAID	United States Agency for International Development
WB	World Bank
WHO	World Health Organization

BACKGROUND

RPM Plus received FY05 Armenia mission funds to support technical activities in pharmaceutical management. In May 2005 a team from RPM Plus conducted a rapid assessment of the pharmaceutical system in Armenia. After discussions with the Ministry of Health (MOH) and USAID/Armenia, three streams of activities were proposed for RPM Plus support: improving prescribing practices for key PHC and Family Medicine diagnoses/treated conditions, assess the availability of essential medicines for selected standard treatment guidelines (STGs) and their costs at primary care facilities, and explore alternative supply chain strategies for the Basic Benefits Package (BBP).

The first step for these activities was to obtain baseline data of current practices and costs. To achieve these, RPM Plus has made arrangements with local institutions to support carrying out data collection activities. The evidence obtained from these studies will help to formulate the analysis of options for the MOH and partners for taking next steps to improving pharmaceutical management in support of primary health care. These options will be discussed by all stakeholders and the decision of which options to pursue will form the basis for the design of year 2 activities for RPM Plus.

Purpose of Trip

Susanna Khachatryan, David Lee and Maria Miralles visited Armenia to follow-up on data collection activities and initiate preparations for next steps, including a policy options workshop to take place in October 2006. David Lee and Maria Miralles arrived in Yerevan on July 16 and departed in July 29, and Susanna Khachatryan arrived on July 21 and departed on August 4, 2006.

ACTIVITIES

The RPM Plus team held several meetings with the research team from the Scientific Center for Drugs and Medical Technology Expertise (SCDMTE) to review data on operations costs from selected facilities in five marzes. This involved detailed discussions about the data (corrections, clarifications, etc.) to ensure that standard indicators will be correctly interpreted. This resulted in identifying several problems with data elements that required follow-up by the SCDMTE with the facilities.

The RPM Plus team also visited the Erebuni warehouse to interview the current manager. The visit allowed for a better understanding of what changes have occurred with respect to warehouse management over the past year. This is important as one of the options that may be presented to the MOH is to eliminate the current role of the warehouse in the provision of PHC medicines.

In order to follow-up on the status of data collection for the prescribing study, the RPM Plus team visited with the research team at the American University of Armenia (AUA). The consultants conducted a site visit while data collection was underway, observed how data was being entered into a database, and previewed data entered from one set of facilities.

The consultants also updated the general director of the State Health Agency (SHA) on the status of the work while learning about recent events relevant to RPM Plus work. RPM Plus requested some information from SHA including marz and the national level data that would help in understanding the representativeness of the facility level data obtained from the SCDMTE.

Similarly, RPM Plus met with the MOH Pharmacy Department to provide and update on the status of activities and request information on the types and values of medicines procured by the MOH in the past year or two.

David Lee prepared a seminar for Primary Health Care Reform project (PHCR) on a framework to improve the safe, effective and cost effective use of medicines (Annex 2), including an overview of effectiveness of interventions, including STGs. The close collaboration with PHCR will be a priority as planning begins for year 2 activities.

RPM Plus received some of the deliverables from the agreement with Drug Utilization Research Group (DURG), including price lists and a review of STGs for selected conditions.

The RPM Plus team made a presentation to public health students at the American University of Armenia on the general topic of rational pharmaceutical management for public health.

The RPM Plus debriefed the Mission on these activities and presented preliminary results of the costing study.

Following the USAID Health Advisor's suggestion, Susanna Khachatryan met with Dr. Liana Hovakimyan, UNICEF Program Assistant, to clarify issues pertaining to procurement, distribution, and use of vaccines in the country. On August 1-4, Susanna Khachatryan met with

USAID, carried out some follow-up activities with SCDMTE and AUA, and addressed a number of administrative issues (contract with an accounting firm, HR-related issues, etc).

Collaborators and Partners

SCDMTE	Drugs and Medical Technologies Agency
DURG PO	Drug Utilization Research Group, Public Organization
MOH	Ministry of Health
PHC	Primary Health Care
PHCR	Primary Health Care Reform project
SHA	State Health Agency
WB	World Bank
WHO	World Health Organization

NEXT STEPS

Immediate Follow-up Activities

RPM Plus will continue to work with the SCDMTE to finalize the data collection required to complete the cost analysis. In addition, RPM Plus will expect to receive the final deliverables from DURG.

In September, 2006, RPM Plus will conduct an additional follow-up visit specifically to work with the data being collected on prescribing by AUA. In this, the intent is to work closely with the PHCR team to ensure that the two projects share a common understanding of approaches to development and implementation of standard treatment guidelines, and training methodologies.

A list of next steps leading to the options analysis workshop has been prepared (Annex 1). RPM Plus will work closely with USAID/Armenia, SCDMTE, SHA and MOH to identify the appropriate invitees to the options workshop to be held in October. The agenda will be jointly developed with SCDMTE.

Recommendations

None.

Agreement or Understandings with Counterparts

AUA and SCDMTE will continue with data collection and data entry issues. RPM Plus will work with these to develop the corresponding analyses and to finalize workshop preparations.

Important Upcoming Activities or Benchmarks in Program

Policy Options Workshop is tentatively planned for October 2006. Participants of this workshop will include the Ministry of Health (Dr. Darbinyan, First Deputy Minister; Dr. Hakobyan, Deputy Minister; Dr. Daveyan, Pharmaceutical Management Department; Dr. Ter-Grigoryan, Director of State Health Agency), SCDMTE (Albert Sahakyan, Deputy Director/Team Leader; Lilit Ghazaryan, Deputy Director; and Vardan Grigoryan, Deputy Director), PHCR, AUA, and marz representation.

ANNEX 1. PENDING ISSUES FOR COSTING STUDY

Issue	What	Lead	Target date/ Completed?
Correct value of acquisitions so that the proportions from various sources add up to 100% (tease out donations from MOH sources, and facilities purchases from SHA reimbursement values)	Need to find out from facilities	SCDMTE	
Add the value of SHA reimbursement for PHC facilities for purchases of medicines from wholesalers to the value of SHA reimbursement for purchases from retailers, in order to reflect the overall value of SHA reimbursement	Need to follow up with the SHA	SCDMTE	
What is the value of drugs distributed by Erebuni? Is this also included in the “other costs” category of inventory holding costs?	Confirm with Erebuni	SCDMTE	
What types of medicines (names, dosage forms, and quantities) are purchased through Central Procurement?	List from last few MOH procurements	SCDMTE	
<p>What is the impact of VAT laws on options for cost control.</p> <ul style="list-style-type: none"> • Reference based pricing? 	Description of how VAT is applied, and any history or previous discussions on this issue in relation to public health goods.	SCDMTE	
Has the volume and value of donations to PHC declined (in absolute terms)?	Data from UMCOR, MOH, other?	RPM Plus	
What is the total number and distribution of pharmacies in the country? Per capita?	List of registered pharmacies in Armenia (by location if possible)	RPM Plus	
Demographic and epidemiologic data	List from MOH Statistics Department	RPM Plus	

Issue	What	Lead	Target date/ Completed?
Data on value of SHA budgets/expenditures for all PHC services, drugs and other relevant categories, for all marzes for 2005 and expected for 2006	Data from SHA	RPM Plus	
Clarify what was included in the “other costs” and remove the data, which were added to this category due to a specifics of local accounting (that were not otherwise supposed to be included, e.g., a value of distributed/disbursed medicines, salaries of other personnel etc).	Data from PHC facilities	SCDMTE	
Draft report on findings and preliminary conclusions	Draft and translation	RPM Plus/SCDMTE	
Revisions		RPM Plus/SCDMTE	End of September
<p>Plan for options analysis discussion</p> <p>1. Create working group</p> <p>MOH (Deputy Minister Tatul Hakobian, Pharmaceutical Management Department, Primary Health Care Program/ Department of Organization of Medical Services of the MOH), Marz representation, RPM Plus, SCDMTE, AUA, SHA</p> <p>2. Decide on program/schedule</p> <p>3. Identify/reserve venue (logistics)</p> <p>4. Hold meeting</p>	<p>Present and confirm validity of study findings and proposed models</p> <p>Agree on participants and format for larger stakeholder meeting</p>	RPM Plus/SCDMTE	Early October
Revisions and share final draft with Working Group members		RPM Plus/SCDMTE	End of October
Organize larger stakeholder meeting	Present final study findings and proposed	RPM Plus/SCDMTE	November

Issue	What	Lead	Target date/ Completed?
<p>Working group members, MOF, pharmacy and retail association, wholesalers association, NIH, medical school, marz level representatives, PHCR, WB, WHO, USAID, patient/consumer group, humanitarian assistance agencies, Union of exporters/importers of medicines</p>	<p>models</p> <p>Give opportunity to stakeholders an opportunity to express opinions</p> <p>Achieve consensus on next steps</p>		
<p>Revise/update conclusions from findings and recommendations based on feedback from workshop</p>		<p>RPM Plus/SCDMTE</p>	

ANNEX 2. PRESENTATION: PROMOTING RATIONAL USE OF MEDICINES IN PRIMARY HEALTH CARE

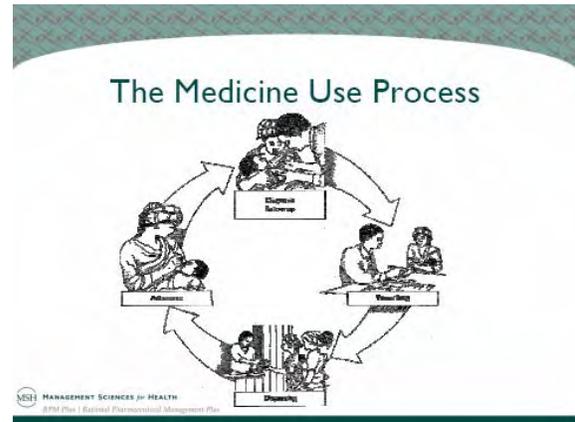
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Promoting Rational Use of Medicines in Primary Health Care
Dr. David Lee

PHCR Project
Yerevan, Armenia
July 27, 2006

USAID FROM THE AMERICAN PEOPLE

Slide 1



Slide 4

Objectives

- Describe a framework for promoting the rational use of medicines
- Discuss some methods for identifying problems in the use of medicines
- Elaborate on the methods to identify the most important factors affecting use of medicines
- Identify effective evidence-based strategies to promote rational use of medicines:
 - ~ Behavior change strategies
 - ~ Combination approaches – education and management
 - ~ The need for a collaborative process between prescriber, dispenser and patient

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Slide 2

Contributors to Inappropriate Medicine Use

- Health system
- Prescriber
- Dispenser
- Patient and community

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Slide 5

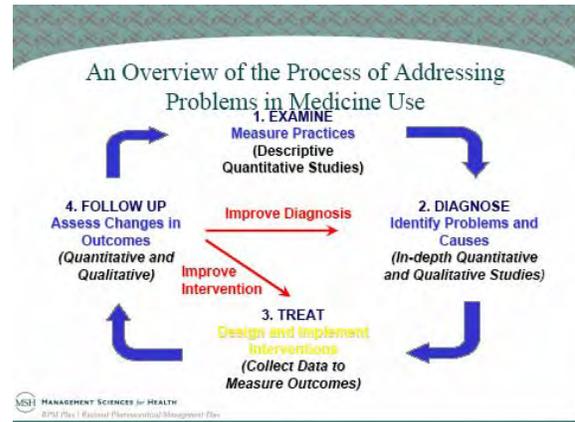
What Is Rational Use of Medicines?

The rational use of drugs requires that patients receive medicines 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 the community.

World Health Organization, 1988

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Slide 3



Slide 6

Identifying Problems with Medicine Use

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% Transactions with Inappropriately Recommended Antibiotics

Country	% Transactions
Brazil	60
Cambodia	75
El Salvador	40
Ghana	25
India	40
Tanzania	20

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Slide 10

Percentage of Medicines Prescribed from Essential Medicines List, by Sector

Country	Public	NGO/Mission	Private
Cambodia	97%	82%	65%
India (R)	70%	69%	63%
El Salvador	93%	72%	70%
Brazil (MG)	66%	62%	49%

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Source: MSH SEAM Studies, 2001

Slide 8

% Patients Receiving Some Counseling on Use

Country	Taking drug	Precautions	Fever Care
Brazil	40	10	15
Cambodia	95	40	70
El Salvador	80	15	15
Ghana	15	20	15
India	60	10	10
Tanzania	85	10	25

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Source: MSH SEAM Country Assessments, 2001

Slide 11

Adherence to STGs for Pneumonia in 16 Hospitals of Peru, 2002

Hospital	Adherence (%)
Piura	80
Vilca	80
Oronimay	80
Jaya	90
Jaya	90
El Carmen	85
DAC Huancayo	75
Pichinaki	85
SM Parango	100
Sullip	75
Sullip	75
La Merced	85
Tarma	85
Pachacambay	85
Huanuco	85
Tegre Mera	85
La Unión	100
Tobos	85

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Source: RPPI Plus Assessment in Three Regions of Peru, 2002

Slide 9

Framework for Intervention Design and Testing

FORMATIVE STUDIES

1. Define drug use problems
 - Prescribing
 - Dispensing
 - Patient use
2. Identify motivating factors/ underlying causes
 - Information
 - Economic
 - Social, cultural
 - Drug supply

INTERVENTION STUDIES

3. List possible approaches
 - Educational
 - Managerial
 - Regulatory
4. Choose approach to test
 - Cultural acceptance
 - Chance of success
 - Potential impact
 - Feasibility

FOLLOW UP

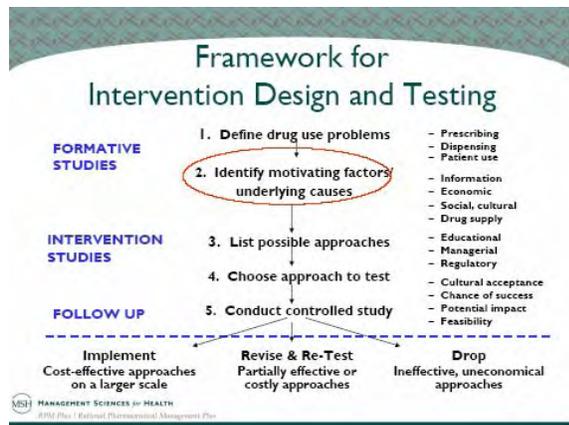
5. Conduct controlled study

Outcomes:

- Implement Cost-effective approaches on a larger scale
- Revise & Re-Test Partially effective or costly approaches
- Drop Ineffective, uneconomical approaches

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Slide 12



Slide 13

- ## Some Qualitative Methods
- Four qualitative study methods:
 - ~ Focus group discussions
 - ~ In-depth interviews
 - ~ Structured observations
 - ~ Questionnaires
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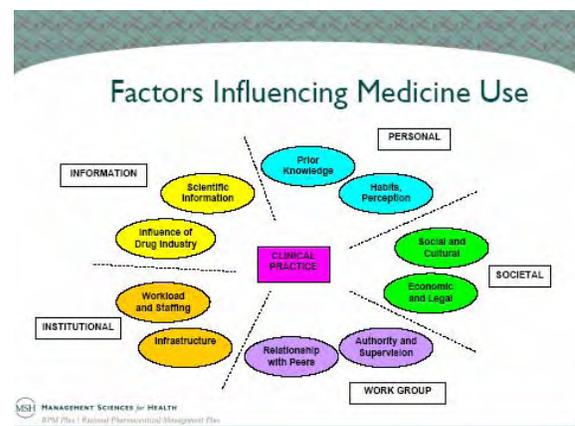
Slide 16

Learning about Factors Underlying Drug Use

Use qualitative methods to identify motivations and incentives of prescribers, dispensers, sellers, and patients

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Slide 14



Slide 17

- ## Applying Qualitative Methods
- Complement results of a quantitative study
 - Explore a topic about which little is known
 - Provide background data prior to deciding on an intervention, the intended audience and the content of the messages
 - Provide information for tailoring training materials for a planned educational intervention and for developing managerial and regulatory interventions.
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- ## Patient Factors Associated with Non-adherence
- Related to the patient
 - Related to the treatment regimen
 - Related to doctor-patient relationship
 - Related to system of medical care
- Source: Cheever, L. W. Adherence to HIV Therapy. 2001. In A Guide to the Clinical Care of Women with HIV, edited by J. Anderson. Washington, DC: US Department of Health and Human Services.
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Slide 18

Patient Factors Strongly Associated with Non-adherence

- Depression
- Alcohol/substance abuse
- Self-efficacy (belief in one's ability to take medication as instructed)
- Belief that medication can fit into their daily life
- Understanding relationship between viral resistance and adherence
- Previous adherence

Source: Cheever, L. W., and A. W. Wu. 1999. Medication Adherence Among HIV-Infected Patients: Understanding the Complex Behavior of Patients Taking This Complex Therapy. *Current Infectious Disease Reports* 1(4):40-47.

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Slide 19

Strategies to Improve Drug Use

USE OF MEDICINES

- Educational**
 - to persuade
 - formal and informal
 - reliance on materials
- Managerial**
 - to guide
 - target providers, systems
 - improved drug/lab supply
- Economic**
 - to induce
 - provider: budgets, incentives
 - patient: shared costs
- Regulatory**
 - to restrict
 - barriers to market entry
 - enforcement

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Slide 22

Framework for Intervention Design and Testing

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INTERVENTION STUDIES

3. List possible approaches
 - Educational
 - Managerial
 - Regulatory
4. Choose approach to test
 - Cultural acceptance
 - Chance of success
 - Potential impact
 - Feasibility

FOLLOW UP

5. Conduct controlled study

Implement Cost-effective approaches on a larger scale | **Revise & Re-Test** Partially effective or costly approaches | Drop Ineffective, uneconomical approaches

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Slide 20

Educational strategies

- **Training for prescribers**
 - Changes in pre-service training
 - In-service training seminars
 - Face-to-face persuasive outreach
 - Clinical supervision or consultation
- **Printed materials**
 - Clinical literature and newsletters
 - Formularies or therapeutics manuals
- **Media-based approaches**
 - Posters
 - Audio tapes, plays, radio, television

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Selecting an intervention strategy

- Synthesize data to choose targets
 - ~ Key behaviors to change
 - ~ Target group
- List possible interventions
- Consider available resources
- Assess technical, economic and political feasibility
- Consider likely outcomes and sustainability
- Potential funding support

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Managerial Methods for Structuring and Guiding Decisions

- **Changes in selection, procurement, distribution**
 - ~ Essential drugs lists
 - ~ Morbidity-based quantification
- **Changes aimed at prescribers**
 - ~ Utilization review and feedback
 - ~ Diagnostic and treatment guidelines
 - ~ Structured drug order forms
 - ~ Peer group monitoring

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Managerial methods for structuring and guiding decisions (2)

- Changes aimed at dispensers
 - Allowing generic substitution
 - Improved labeling
 - Course of therapy packaging

- Changes in economic incentives
 - Patient cost-sharing
 - Revolving drug funds
 - Cost controls

Slide 25

What interventions have proven effective?

- PHC level:
 - Focused, problem-oriented, repeated training
 - Supervision or self-monitoring with simple indicators
 - Peer group oriented guideline development

- Recently new evidence for:
 - Private sector, adults and long-term treatment
 - Few interventions documented at hospital level
 - Effect of economic and drug sector policy changes

Slide 28

Regulatory strategies to restrict decisions

- Market controls
- Limiting drug registration
- Banning previously registered drugs
- Rx-only to OTC
- Controlling drug advertising
- Prescribing and dispensing controls
 - Restricting specific drugs to higher levels of care
 - Generic prescribing or generic substitution
 - Limits on number or quantity of drugs per patient

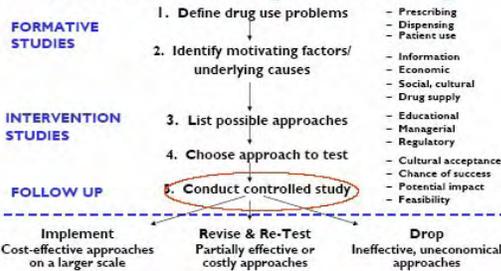
Slide 26

Interventions consistently effective

- Educational outreach visits
- Reminders
- Multifaceted interventions
- Interactive educational meetings
- Provider or facility-level restrictions
- Required consultations
- Structured prescription forms

Slide 29

Framework for Intervention Design and Testing



Slide 27

Interventions with variable or little effect:

- | | |
|--|---|
| <p>Variable Effectiveness</p> <ul style="list-style-type: none"> • Audit and feedback • Use of opinion leaders • Local consensus processes • Patient-mediated interventions | <p>Little or No Effect</p> <ul style="list-style-type: none"> • Dissemination of educational materials • Didactic educational meetings |
|--|---|

Slide 30

Recommendations

- Multifaceted interventions
- Involve multidisciplinary team
- Address several audiences
- Educational interventions take time but have a “dose response” that is, effect increases with reinforcement
- Interactive, problem-based training is useful
- Some policy interventions are successful when there is capacity for enforcement and industry has been involved

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Slide 31

Key Points to Consider

- **Intervention orientation:**
 - ~ There is no gold standard intervention
- **Interdisciplinary approach:**
 - ~ Requires an understanding of the specific problem behavior in order to identify a design or adapt a strategy that addresses the determinants of the problem behavior
- **Evidence-based recommendation:**
 - ~ Following interventions, effects should be measured to determine if changes are in the desired direction so that adjustments may be made

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Slide 32

New research agenda from ICIUM 2004

- Assess effect of financial incentives in public and private practices
- Need to demonstrate effects of DTC activities
- Need to assess impact of STGs
- Necessary to assess impact of reimbursement policies in Rational Use
- Effect of decentralization and other HSR strategies on quality care and rational use needed
- Important to measure effect of FDCs on adherence

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Slide 33