Drug and Therapeutics Committee
Training Course

Trainer’s Guide
All Sessions
This document was made possible through support provided by the U.S. Agency for International Development, under the terms of cooperative agreement number HRN-A-00-00-00016-00. The opinions expressed herein are those of the author(s) and do not necessarily reflect the views of the U.S. Agency for International Development.

About RPM Plus

RPM Plus works in more than 20 developing and transitional countries to provide technical assistance to strengthen pharmaceutical 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.

Recommended Citation

This document may be reproduced if credit is given to RPM Plus and WHO. Please use the following citation.

CONTENTS

ABBREVIATIONS AND ACRONYMS ............................................................................................... vii

SESSION 1. DRUG AND THERAPEUTICS COMMITTEE—OVERVIEW ........................................ 1
Purpose and Content .................................................................................................................. 3
Organization of the Session ...................................................................................................... 7

SESSION 2. DEVELOPING AND MAINTAINING A FORMULARY ............................................. 13
Purpose and Content ................................................................................................................. 13
Organization of the Session .................................................................................................... 15
Activity 1. Adding a New Antibiotic to the Formulary .......................................................... 17
Activity 2. Analyze the Quality of a Formulary—The Case of NSAIDs .................................... 18

SESSION 3. ASSESSING MEDICINE EFFICACY ................................................................... 23
Purpose and Content ............................................................................................................... 23
Organization of the Session .................................................................................................... 25
Activity 1. Comparing Antimicrobial Medicines for Pneumonia ............................................ 27
Activity 2. Interpreting the Data: The Helsinki Heart Study .................................................. 28
Activity 3. Critically Evaluating an Article ............................................................................. 29
Activity 4. Critically Interpreting the Data: A Medicine Trial to Compare Artesunate with Mefloquine to Treat Malaria ......................................................................................... 30
Answers to Exercises .............................................................................................................. 31

SESSION 4. ASSESSING AND MANAGING MEDICINE SAFETY .......................................... 35
Purpose and Content ............................................................................................................... 35
Organization of the Session .................................................................................................... 37
Activity 1. Penicillin Anaphylaxis Reported .......................................................................... 39
Activity 2. Acute Respiratory Infection in a Two-Year-Old .................................................... 40
Activity 3. Serious ADRs with Phen-Fen Combination Medicine ........................................... 41

SESSION 5. PHARMACEUTICAL QUALITY ASSURANCE ................................................... 45
Purpose and Content ............................................................................................................... 45
Organization of the Session .................................................................................................... 47

SESSION 6. EVALUATING THE COST OF PHARMACEUTICALS ......................................... 53
Purpose and Content ............................................................................................................... 53
Organization of the Session .................................................................................................... 55
Activity 1. Cost Minimization Analysis of NSAIDs .............................................................. 57
Activity 2. Cost Effectiveness Analysis of Two Antimalarial Treatments ............................... 59

SESSION 7. IDENTIFYING PROBLEMS WITH MEDICINE USE ......................................... 65
Purpose and Content ............................................................................................................... 65
Organization of the Session .................................................................................................... 69
Part A. Identifying Problems with Medicine Use: Indicator Studies ....................................... 69
Activity 1. Calculating Prescribing Indicators from Prescriptions .......................................... 72
Activity 2. Calculating Patient Care Indicators from Observing Role-Play Consultations ....... 72
Part B. Identifying Problems with Medicine Use: Aggregate Methods ........................................ 73
Activity 3. Performing a VEN Analysis .................................................................................... 75
Activity 4. Performing an ABC Analysis ................................................................................. 76
Activity 5. Performing an ABC/VEN Analysis Using Participants’ Data ............................... 76

SESSION 8. UNDERSTANDING THE PROBLEMS ASSOCIATED WITH MEDICINE USE—QUALITATIVE METHODS ........................................................................................................ 81
Purpose and Content .................................................................................................................. 81
Organization of the Session ....................................................................................................... 83
Activity 3 (Optional). Preparing interview questions for prescribers .................................... 86
Annex 1. Sample Interview Questionnaire for Prescribers ..................................................... 88
Annex 2. Four Qualitative Methods to Understand Reasons for Medicine Use Behavior ....... 90

SESSION 9. STRATEGIES TO IMPROVE MEDICINE USE—OVERVIEW .......................................................... 93
Purpose and Content .................................................................................................................. 93
Organization of the Session ....................................................................................................... 95
Activity 1. Case Study: Generic and Brand Name Antibiotics ................................................. 97

SESSION 10. STANDARD TREATMENT GUIDELINES ........................................................................... 101
Purpose and Content .................................................................................................................. 101
Organization of the Session ....................................................................................................... 103
Activity 1. Developing a Guideline for Use during the Field Trip ............................................ 104
Annex 1. Sample Form 1 ........................................................................................................... 108
Annex 2. Sample Form 2 ........................................................................................................... 110

SESSION 11. DRUG USE EVALUATION .......................................................................................... 115
Purpose and Content .................................................................................................................. 115
Organization of the Session ....................................................................................................... 116
Activity 1. Developing Criteria and Thresholds for Conducting a DUE ................................. 118
Annex 1. Sample Form 1 for Activity 1 .................................................................................. 120
Annex 2. Sample Form 2 for Activity 1 .................................................................................. 122

SESSION 12. INFECTION CONTROL .......................................................................................... 127
Purpose and Content .................................................................................................................. 127
Organization of the Session ....................................................................................................... 129
Activity 1. Describing Infection Control Practices at Your Facilities or Institutions .......... 130
Activity 2. Developing Recommendations for Your Facilities or Institutions .................... 132
Annex 1. Internet and CD-ROM Resources: Infection Control Information, Guidelines, and Protocols .......................................................... 134

SESSION 13. ANTIMICROBIAL RESISTANCE .................................................................................. 139
Purpose and Content .................................................................................................................. 139
Organization of the Session ....................................................................................................... 142
<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>SESSION 14. GETTING STARTED</td>
<td>147</td>
</tr>
<tr>
<td>Purpose and Content</td>
<td>147</td>
</tr>
<tr>
<td>Organization of the Session</td>
<td>148</td>
</tr>
</tbody>
</table>
# ABBREVIATIONS AND ACRONYMS

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>A+L</td>
<td>artesunate plus lumefantrine</td>
</tr>
<tr>
<td>A+M</td>
<td>artesunate plus mefloquine</td>
</tr>
<tr>
<td>ACT</td>
<td>artemisinin-based combination therapy</td>
</tr>
<tr>
<td>ADR</td>
<td>adverse drug reaction</td>
</tr>
<tr>
<td>AIDS</td>
<td>acquired immunodeficiency syndrome</td>
</tr>
<tr>
<td>AMR</td>
<td>antimicrobial resistance</td>
</tr>
<tr>
<td>AOF</td>
<td>antibiotic order form</td>
</tr>
<tr>
<td>ARI</td>
<td>acute respiratory infection</td>
</tr>
<tr>
<td>AUD</td>
<td>Australia, dollars</td>
</tr>
<tr>
<td>BCG</td>
<td>bacillus Calmette-Guérin</td>
</tr>
<tr>
<td>bid</td>
<td>twice a day (<em>bis in die</em>)</td>
</tr>
<tr>
<td>BUN</td>
<td>blood urine nitrogen</td>
</tr>
<tr>
<td>CD4</td>
<td>human T helper cells expressing CD4 antigen (T helper cell)</td>
</tr>
<tr>
<td>CEA</td>
<td>cost-effectiveness analysis</td>
</tr>
<tr>
<td>CER</td>
<td>cost-effectiveness ratio</td>
</tr>
<tr>
<td>CI</td>
<td>confidence interval</td>
</tr>
<tr>
<td>CMA</td>
<td>cost-minimization analysis</td>
</tr>
<tr>
<td>COA</td>
<td>certificate of analysis</td>
</tr>
<tr>
<td>Cr</td>
<td>creatinine ratio</td>
</tr>
<tr>
<td>CUA</td>
<td>cost-utility analysis</td>
</tr>
<tr>
<td>DALY</td>
<td>disability-adjusted life year</td>
</tr>
<tr>
<td>DDD</td>
<td>defined daily dose</td>
</tr>
<tr>
<td>DOB</td>
<td>date of birth</td>
</tr>
<tr>
<td>DPT</td>
<td>diphtheria, pertussis, tetanus</td>
</tr>
<tr>
<td>DTC</td>
<td>Drug and Therapeutics Committee</td>
</tr>
<tr>
<td>DUE</td>
<td>drug use evaluation</td>
</tr>
<tr>
<td>EDP</td>
<td>essential drugs program</td>
</tr>
<tr>
<td>EML</td>
<td>essential medicines list</td>
</tr>
<tr>
<td>FGD</td>
<td>focus group discussion</td>
</tr>
<tr>
<td>g</td>
<td>gram</td>
</tr>
<tr>
<td>GMP</td>
<td>Good Manufacturing Practices</td>
</tr>
<tr>
<td>HbA1c</td>
<td>glycosylated hemoglobin</td>
</tr>
<tr>
<td>HIV</td>
<td>human immunodeficiency virus</td>
</tr>
<tr>
<td>HMO</td>
<td>health maintenance organization</td>
</tr>
<tr>
<td>IC</td>
<td>infection control</td>
</tr>
<tr>
<td>ICAT</td>
<td>Infection Control Assessment Tool</td>
</tr>
<tr>
<td>ICC</td>
<td>Infection Control Committee</td>
</tr>
<tr>
<td>ICER</td>
<td>incremental cost-effectiveness ratio</td>
</tr>
<tr>
<td>IM</td>
<td>intramuscular</td>
</tr>
<tr>
<td>INN</td>
<td>international nonproprietary name</td>
</tr>
<tr>
<td>INRUD</td>
<td>International Network for Rational Use of Drugs</td>
</tr>
<tr>
<td>IV</td>
<td>intravenous</td>
</tr>
<tr>
<td>kg</td>
<td>kilogram</td>
</tr>
</tbody>
</table>
mcg microgram
MDR-TB multidrug-resistant tuberculosis
mg milligram
MI myocardial infarction
ml milliliter
MRSA methicillin-resistant staphylococcus aureus
MSH Management Sciences for Health
n or N number
NDA national drug authority
ng nanogram
NSAID nonsteroidal anti-inflammatory drug
OM otitis media
PHC public health care
po per os (by mouth)
PTC Pharmacy and Therapeutics Committee
QA quality assurance
QI quality improvement
RCQI rapid cycle quality improvement
RCT randomized controlled trial
RPM Plus Rational Pharmaceutical Management Plus [Program]
SK streptokinase
STG standard treatment guideline
TB tuberculosis
tid three times a day (ter in die)
TOR terms of reference
tPA tissue plasminogen activator
UC usual care
UNICEF United Nations Children’s Fund
UNIPAC UNICEF Supply Division Warehouse Procurement and Assembly Center
USD U.S. dollar
VA visual aid
VEN vital, essential, nonessential
VRE vancomycin-resistant enterococcus
VRSA vancomycin-resistant Staphylococcus aureus
WHO World Health Organization
XDR-TB extensively drug-resistant tuberculosis
Session 1.
Drug and Therapeutics Committee—Overview
SESSION 1. DRUG AND THERAPEUTICS COMMITTEE—OVERVIEW

Purpose and Content

The Drug and Therapeutics Committee (DTC) is an essential component of a health care organization’s medicine selection, use, and distribution program. This committee has many different functions that will contribute to the goal of improving medicine selection and rational use of medicines. This session provides an overview of the role and functions of a DTC and describes all aspects of this important committee.

This training series is intended for practitioners who serve on a DTC. The emphasis of this session and of the entire training series is on the technical aspects of a DTC, including medicine selection for the formulary, identification of medicine use problems, and the promotion of interventions to improve medicine use. Participants are referred to the “Further Readings” section for information on the establishment and implementation of a new DTC. The World Health Organization (WHO) publication Drug and Therapeutics Committee: A Practical Guide provides step-by-step procedures for starting a new DTC.

Objectives

After attending this session, participants will be able to—

- Understand the role of the DTC
- Understand DTC structure and organization and its relationship to other hospital committees
- Understand the functions of a DTC, including advisory responsibilities, development of policies and procedures, formulary management, identification of medicine use problems, and promotion of strategies to improve medicine use and medicine safety.
- Discuss the importance of the DTC in promoting rational use of medicines, especially antimicrobial use and injections

Outline

- Key Definitions
- Introduction
- Role and Functions of the DTC
- Organization and Structure of the DTC
• Activity 1. Review of participants’ DTCs and discussion of the issues and challenges to starting and maintaining a DTC

• Summary

**Preparation and Materials**

• Read the Trainer’s Guide and the Participants’ Guide, and review the visual aids (VAs).

• Instruct participants to read the Participants’ Guide the evening before the session presentation.

• For the first session, instruct participants to bring the following to show what is available in their countries. These materials should also be given to the course facilitators who will then analyze this information for later use in the course.

  o Drug and Therapeutic Committee policies and procedures
  o Drug formularies and standard treatment guidelines
  o Hospital procurement and pharmaceutical use data (preferably electronic copies), including—

    ▪ Formulary list of all medicines
    ▪ Acquisition cost of each formulary item
    ▪ Quantity purchased in past 12 months
    ▪ Acquisition cost and quantity purchased over past 12 months for each medicine in the following categories—
      — Nonsteroidal anti-inflammatory drugs
      — Third-generation cephalosporins

**Further Readings**


**Visual Aid Listing**

1. Title slide
2. Objectives
3. Outline
4. Key Definitions (1)
5. Key Definitions (2)
6. Introduction: Why DTCs Are Important
7. 30–60% of PHC Patients Receive Antibiotics
8. 6–90% of Patients Receive Inappropriate Antibiotics in Teaching Hospitals
9. Variation in Outpatient Antibiotic Use in 26 European Countries in 2002
10. Treatment of ARI by Prescriber Type
11. Treatment of Diarrhea in Private and Public Sectors
12. Percentage Compliance with Clinical Guidelines over Time by Region
13. 5–50% of PHC Patients Receive Injections
14. Adverse Drug Reactions (ADRs)
15. Role of the DTC
16. Functions of a DTC
17. DTC Advisory Functions
18. Drug Policies and Procedures
19. Evaluating and Selecting Medicines for the Formulary
20. Identifying Medicine Use Problems (1)
21. Identifying Medicine Use Problems (2)
22. Promoting Interventions to Improve Pharmaceutical Use
23. Managing ADRs and Medication Errors
24. DTC: Structure and Organization (1)
25. DTC: Structure and Organization (2)
26. Antimicrobial Subcommittee
27. Infection Control Committee
28. Liaison between Committees
29. DTCs: Guiding Principles
30. Factors Critical to Success
31. Monitoring DTC Performance: Process Indicators
32. Monitoring DTC Performance: Impact and Outcome Indicators
33. Activity 1
34. Summary (1)
35. Summary (2)
36. Summary (3)
Organization of the Session

Total time: 2.5 hours

Session 1 introduces the whole course and the concept of DTCs. During the session, the trainer will need to learn about the participants’ DTCs to fully understand how to present this and other DTC sessions. Activity 1 is designed to obtain information about the DTCs in the participants’ home countries. This information can be used to tailor subsequent sessions to participants’ needs both in terms of content and level of detail.

Since this first session usually is taught immediately after the introduction of experts and perhaps an opening ceremony, it often gets cut short. Abridging this session is not a good idea because not only does it set the tone for the whole course, it is also an opportunity for the trainers to find out what experience participants have had with DTCs and what they expect from the course. Ideally, the session should be highly interactive; however, the degree of interaction will depend on the amount of time available.

First component: 30 minutes

VAs 1–6: Introduction

This component introduces DTCs and covers terminology and definitions. Ask the participants about their DTC experiences—what they are and what they do. Some participants do not have committees specifically called Drug and Therapeutic Committees, Pharmacy and Therapeutic Committees, or Medicines and Therapeutic Committees but do have a committee that manages the formulary or implements rational use of medicines programs. For example, in Laos and Cambodia such committees are called Technical Committees. Everyone should understand the functions of a DTC are what is important, not the title. Therefore, if their committees have different names but perform the functions of a DTC, they, in fact, have DTCs.

Second component: 15 minutes

VAs 7–14: Medicine Use Problems and the Need for a DTC

This component briefly reviews the different types and scale of medicine use problems and the consequences of inappropriate use. These slides clearly show the overuse of antimicrobials in respiratory tract infections and in the treatment of diarrhea. They also illustrate the lack of compliance with treatment guidelines in many countries. You can introduce the component by asking the participants what medicine use problems they have encountered in their own institutions.
Third component: 30 minutes
VAs 15–23: Role and Functions of a DTC

This component explains the different functions of the DTC. Each of these functions will be discussed in greater detail in separate sessions later in the course. To make the session interactive and bring out important functions of the DTC, good questions to ask include the following—

- Who selects new medicines for the formulary and how?
- What interventions have your institutions used to promote rational use of medicines?
- Do you monitor ADRs?

Highlight the point that undertaking DTC activities is often difficult and conflicts of interest may arise, particularly concerning pharmaceutical selection for the formulary. Time control is very important in this component because active participant discussion can cause you to run over time.

Fourth component: 30 minutes
VAs 24–32: Organization of a DTC

This component covers structure and organization of DTCs and issues of ethics and authority. Ask the participants, “In your health care setting, who is responsible for quality of care?”—it may be the hospital director, senior medical staff committee, or individual directors. Point out that a DTC needs authority to undertake many of its functions and that this authority must be given by the most senior body. Also emphasize that the DTC requires a strong chairperson and certain guiding principles and factors (VAs 30 and 31) for success. Point out that a DTC committee must work with other committees to undertake certain functions (e.g., with the Infection Control Committee when forming antimicrobial medicine policies).

Fifth component: 15–30 minutes
VA 33: Activity

Ask the participants to fill out the questionnaire and collect it immediately afterward. Explain that these questionnaires will be analyzed to tailor the course to the needs of the participants and also to identify problems for a problem-solving group session (session 14, “Getting Started”). If you have enough time, hold a plenary discussion. Start by asking again who has a DTC and who does not. Then ask—

- One or two people who have DTCs to state what their DTCs have achieved and what the difficulties have been.
- One or two people who do not have DTCs how formulary lists are decided and who undertakes rational medicine use programs.

The questionnaire will have sensitized participants to important DTC functions. The resulting discussion will help participants and facilitators see the differences in DTCs that currently exist in other countries.
Sixth component: 5–15 minutes
VA 34–36: Summary

Summarize the key points of the session.
Session 2.
Developing and
Maintaining a Formulary
SESSION 2. DEVELOPING AND MAINTAINING A FORMULARY

Purpose and Content

Session 2 is intended to provide information about the formulary system and how it functions within the Drug and Therapeutics Committee (DTC). There will be discussion about implementing and maintaining a formulary, a description of criteria for evaluating medicines for the formulary, and a review of pharmaceutical information resources.

As many as 50 percent of all medicines on the market today are either duplicative or questionable value, so the health care system is forced to institute its own complex screening methods to provide the most efficacious, safe, and cost-efficient medicines. The problem of an over-selection of medicines will only get worse as more medicines are produced by manufacturers and distributors in search of even greater profits.

Benefits arising from the appropriate selection of medicines are numerous and well known and include improved drug therapy, decreased adverse drug reactions (ADRs), improved efficiency in procurement and inventory management, and decreased overall health care cost.

Objectives

After attending this session, participants will be able to—

- Define the formulary system concept
- Understand basic formulary management principles
- Describe the benefits of an effective formulary system
- Identify criteria used for selection of medicines
- Describe basic pharmaceutical information resources for evaluating medicines

Outline

- Key Definitions
- Introduction
- Formulary Management Principles
- Maintaining a Formulary System
- Process for Selecting New Medicines
- Selection Criteria for New Medicines
- Nonformulary Medicines
- Restricted Pharmaceutical Use
- International Nonproprietary Pharmaceutical Names
- Information Sources for Evaluating New Medicines
- Formulary Manual
- Activity 1. Adding a New Antimicrobial to the Formulary
- Activity 2. Analyze the Quality of a Formulary—The Case of NSAIDs
- Summary
Preparation and Materials

- Read the Trainer’s Guide and the Participants’ Guide, and review the visual aids (VAs).

- Instruct participants to read the Participants’ Guide the evening before the session presentation.

- Instruct participants to bring examples of formulary lists and manuals to the session. Participants and facilitators will then be able to see what formularies are being used in different countries.

- Read the following—

Further Readings


Visual Aid Listing

1. Title slide
2. Objectives
3. Outline (1)
4. Outline (2)
5. Key Definitions
7. Benefits of an Effective Formulary System (1)
8. Benefits of an Effective Formulary System (2)
9. Benefits of an Effective Formulary System (3)
10. Benefits of an Effective Formulary System—Summary
11. Formulary Management Principles (1)
12. Formulary Management Principles (2)
13. Maintaining a Formulary
14. Steps to Add or Delete a New Medicine
15. Steps to Evaluate a Medicine
Session 2. Developing and Maintaining a Formulary

16. Criteria for Evaluating and Selecting Medicines for the Formulary (1)
17. Criteria for Evaluating and Selecting Medicines for the Formulary (2)
18. Nonformulary Medicines
19. Restricted Medicines (1)
20. Restricted Medicines (2)
21. International Nonproprietary Names
22. Information Resources
23. Primary Literature—Examples
24. Secondary Literature—Examples
25. Tertiary Sources—Examples
26. British National Formulary
27. Internet Resources—Examples
28. Formulary Manual (1)
29. Formulary Manual (2)
30. Formulary Manual (3)
31. Formulary Manual (4)
32. Formulary Manual (5)
33. Formulary Manual (6)
34. Examples of Rational Pharmaceutical Selection
35. Activity 1. Adding a New Antibiotic to the Formulary
36. Activity 2. Formulary Management of NSAIDs
37. Summary (1)
38. Summary (2)
39. Summary (3)

Organization of the Session

Total time: 3 hours

Session 2 is designed to give an overview of the whole subject of managing a formulary, particularly the practical aspects. The course contains an additional four sessions on individual aspects of evaluating medicines for the formulary—efficacy, safety, quality, and cost.

First component: 30 minutes
VAs 1–10: Introduction

The first component introduces the subject of formulary management—what a formulary is and its benefits—and covers terminology and definitions. The component can be introduced by asking the question, “What is a formulary?” Mention the World Health Organization (WHO) definition of essential medicine (which is quoted in the Participant’s Guide), and point out that WHO maintains a model essential medicines list (EML) for just the same purpose and is operating on just the same principles as would a DTC in a district hospital.
Second component: 45 minutes  
VAs 11–21: Formulary Management and Maintenance Principles

The second component covers management of a formulary, adding and deleting medicines, and dealing with the use of nonformulary medicine and restricted medicines. You can begin the session by asking participants, “How are medicines added and deleted from the formulary list in your own institutions?” Point out (a) that not only is having a formulary list important but also prescribers must comply with it and (b) that for effective compliance, transparency and consistency in decision making are essential when adding and deleting medicines. Explain that if a formal, written process is not used, then the medicines suggested by those who shout loudest (e.g., the chiefs) will be the ones chosen, irrespective of the evidence. Furthermore, the process and the criteria should be agreed upon in advance with the chiefs, so that they cannot argue if their own suggestions for new medicines are rejected on the basis of rules to which they have previously agreed.

Third component: 15 minutes  
VAs 22–27: Information Sources

You can introduce the third component by asking what sources of information participants use to evaluate medicines for addition to the formulary in their home institutions. Explain the importance of using evidence-based pharmaceutical selections to reap the benefits of a formulary system, and describe where to find this evidence. Information sources can then be briefly summarized here. Be prepared for discussion on terminologies, for example, the phrases evidence-based medicine, evidence-based formulary, and selecting medicines based on evidence.

New and expanded Internet sources of pharmaceutical information are becoming available every year. Many quality pharmaceutical information sites are available, and a few are listed in the text and on the slides for this session. Certainly many more are available, and a discussion of these sites would add to this session. Convey to the participants that there are also many Internet sites information that is less than evidence-based, so one must be very careful about what information is being accessed and used in formulary management activities.

Fourth component: 15 minutes  
VAs 28–33: Formulary Manual

The fourth component explains what a formulary manual is and the type of information it contains. Point out that for these manuals to be useful and used, (a) the senior physicians and end-users must be involved in their development, and (b) the manuals must be in a handy format, easy to read, regularly updated, and evidenced-based. Be clear about the difference between a formulary list and a formulary manual.
Activity 1. Adding a New Antibiotic to the Formulary

In this example, tell the participants that their DTC is considering a new antibiotic for the formulary. This antibiotic, which we’ll call cepafime, is very similar to a formulary product, cefotaxime, a third-generation cephalosporin. It would be used in the emergency room as a single dose for treating febrile children with the diagnosis of acute respiratory infection (ARI) or otitis media (OM). This medicine is an injectable with a high cost of 2.50 U.S. dollars (USD) per dose. Although it is expensive, cepafime is required (according to the requesting physician) because of a high incidence of antimicrobial resistance (AMR) in the hospital to commonly used medicines. The physician also states that use of the medicine will decrease overall cost because hospitalizations of these sick children will be decreased with appropriate use. Mid-level providers who staff the emergency room at night would be the primary prescribers of this medicine. This medicine is heavily promoted by a pharmaceutical manufacturer for treating many different pediatric infections. Other medicines for these problems that are available on the formulary include amoxicillin, co-trimoxazole, and cefalexin. Typically the DTC has provided very little evaluation of a new medicine because a physician’s recommendation was enough for approval by the committee.

The participants should work on the activity as a group at their tables (ideally five or six persons per group) for 30 minutes. At the end of this time, one group can be chosen randomly to answer one of the questions and then the other groups can be asked to comment. Such discussion may take an additional 30 minutes. If time allows, groups may like to use a flipchart or overhead projector.

The following discussion questions have many possible answers (a few proposed answers are provided in italics)—

- What criteria are necessary to evaluate this medicine for addition to the formulary?
  - Efficacy
  - Safety
  - Quality
  - Cost
    - Also mention disease patterns of the health care region, well-known medicines, and availability of health system personnel and financial resources

- Using the criteria discussed in this session, what major concerns do you have before adding this medicine to the formulary?
Is it efficacious? What is comparative efficacy? What is the evidence for this efficacy? What is the evidence that it will decrease hospitalizations? Should the medicine be used by mid-level providers?

What is the extent of AMR in the hospital and how would this medicine affect the problem? Where is the proof that resistance is established?

What is the state of the budget at the hospital? Can the system actually afford such an expensive medicine when effective alternatives are available?

What drug information resources would be used to analyze this medicine for the DTC? Which source would be the most useful?

Cochrane and a review of clinical trials may be the best source of information of unbiased information.

Secondary sources including drug bulletins may be useful.

Activity 2. Analyze the Quality of a Formulary—The Case of NSAIDs

Below is a list of nonsteroidal anti-inflammatory drugs (NSAIDS) from the formulary of a large private hospital in East Africa. Ask the participants to use the principles of formulary management learned in this session to answer the following questions about this category of medicines (possible answers are in italics below the list)—

- Do you think the listed medicines appear logical and well chosen?
- How many chemical entities are available on the formulary?
- How many NSAID medicines are necessary for a formulary?
- What medicines would you recommend be added or deleted?
- What is the best method to list medicines in a formulary? Is this list easy to read and understand?
### Table 1. NSAID List from a Large Private Hospital

<table>
<thead>
<tr>
<th>No.</th>
<th>NSAID</th>
<th>Quantity Sold (over 6 months)</th>
<th>Unit Cost (USD)</th>
<th>Total Cost (USD) (6 months)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>LYSINE ACETYLSALICYLIC ACID 500 mg</td>
<td>2,026</td>
<td>0.357</td>
<td>723.54</td>
</tr>
<tr>
<td>2</td>
<td>ASPEGIC (lysine acetylsalicylic acid) 1,000 sachet ADULT (1)</td>
<td>27</td>
<td>0.264</td>
<td>7.14</td>
</tr>
<tr>
<td>3</td>
<td>ASPEGIC 250 mg sachet INFANT (lysine acetylsalicylic acid)</td>
<td>40</td>
<td>0.126</td>
<td>5.05</td>
</tr>
<tr>
<td>4</td>
<td>ASPEGIC sachets (lysine acetylsalicylic acid) 100 mg</td>
<td>51</td>
<td>0.109</td>
<td>5.56</td>
</tr>
<tr>
<td>5</td>
<td>ASPIRIN tablets 500 mg</td>
<td>237</td>
<td>0.004</td>
<td>0.90</td>
</tr>
<tr>
<td>6</td>
<td>ASPIRIN tablets 100 mg (1)</td>
<td>1,877</td>
<td>0.002</td>
<td>2.84</td>
</tr>
<tr>
<td>7</td>
<td>ASPIRIN tablets 300 mg (1)</td>
<td>1,190</td>
<td>0.002</td>
<td>2.44</td>
</tr>
<tr>
<td>8</td>
<td>ASPIRIN tablets 80 mg</td>
<td>3,145</td>
<td>0.002</td>
<td>4.86</td>
</tr>
<tr>
<td>9</td>
<td>DICLOFENAC 100 mg SR</td>
<td>8,475</td>
<td>0.016</td>
<td>135.88</td>
</tr>
<tr>
<td>10</td>
<td>DICLOFENAC ampoule ADCO 75 mg/3 ml (1)</td>
<td>7,797</td>
<td>0.061</td>
<td>477.61</td>
</tr>
<tr>
<td>11</td>
<td>DICLOFENAC gel</td>
<td>188</td>
<td>0.380</td>
<td>71.46</td>
</tr>
<tr>
<td>12</td>
<td>DICLOFENAC ointment 30 g</td>
<td>5</td>
<td>0.364</td>
<td>1.82</td>
</tr>
<tr>
<td>13</td>
<td>DICLOFENAC suppositories 100 mg</td>
<td>22,186</td>
<td>0.077</td>
<td>1,707.56</td>
</tr>
<tr>
<td>14</td>
<td>DICLOFENAC tablet 50 mg</td>
<td>23,835</td>
<td>0.006</td>
<td>133.71</td>
</tr>
<tr>
<td>15</td>
<td>IBUPROFEN syrup 100 mg/5 ml (60 ml)</td>
<td>3,080</td>
<td>0.498</td>
<td>1,533.65</td>
</tr>
<tr>
<td>16</td>
<td>IBUPROFEN tablet 200 mg (1)</td>
<td>85,197</td>
<td>0.004</td>
<td>320.16</td>
</tr>
<tr>
<td>18</td>
<td>INDOMED capsules 25 mg (1)</td>
<td>4,199</td>
<td>0.003</td>
<td>11.45</td>
</tr>
<tr>
<td>20</td>
<td>KETOPROFEN 150 mg (1)</td>
<td>128</td>
<td>0.427</td>
<td>54.69</td>
</tr>
<tr>
<td>21</td>
<td>MEFENAMIC ACID 500 mg</td>
<td>2,328</td>
<td>0.198</td>
<td>460.84</td>
</tr>
<tr>
<td>22</td>
<td>MEFENAMIC capsules 250 mg</td>
<td>37</td>
<td>0.044</td>
<td>1.61</td>
</tr>
<tr>
<td>23</td>
<td>NAPROXEN tablets 250 mg</td>
<td>252</td>
<td>0.340</td>
<td>85.63</td>
</tr>
<tr>
<td>24</td>
<td>NIFLUGEL POMMADE (niflumic acid)</td>
<td>634</td>
<td>3.091</td>
<td>1,959.73</td>
</tr>
<tr>
<td>25</td>
<td>NIFLURIL (niflumic acid) capsules 250 mg (1)</td>
<td>1,537</td>
<td>0.119</td>
<td>182.52</td>
</tr>
<tr>
<td>26</td>
<td>NIFLURIL cream topical (niflumic acid)</td>
<td>649</td>
<td>2.186</td>
<td>1,419.02</td>
</tr>
<tr>
<td>27</td>
<td>NIFLURIL suppositories 700 mg (ADULT) (niflumic acid)</td>
<td>1,319</td>
<td>0.305</td>
<td>402.08</td>
</tr>
<tr>
<td>28</td>
<td>NIFLURIL suppositories (INFANT) (niflumic acid) 400 mg</td>
<td>314</td>
<td>0.258</td>
<td>81.13</td>
</tr>
<tr>
<td>29</td>
<td>NIMESULIDE tablets 100 mg</td>
<td>22,260</td>
<td>0.038</td>
<td>848.67</td>
</tr>
<tr>
<td>30</td>
<td>PIROXICAM 20 mg</td>
<td>643</td>
<td>0.021</td>
<td>13.37</td>
</tr>
</tbody>
</table>

This list of NSAIDs was taken from a formulary in an East African country. The formulary has a large number of duplications and includes some medicines that have limited efficacy and safety. Participants should be able to review and eliminate many of the duplications. Some medicines that could be deleted include the following—

- Aspegic
- Mefenamic acid
- Niflural
- Nimesulide
The point here is that there are too many NSAIDs with similar efficacy and safety, and many could be deleted resulting in substantial cost savings and good formulary management.

**Sixth component: 15 minutes**

*VA 37–39: Summary*

Summarize the key points of the session.
Drug and Therapeutics Committee
Training Course

Session 3.
Assessing Medicine Efficacy
SESSION 3. ASSESSING MEDICINE EFFICACY

Purpose and Content

Session 3 is designed to provide participants with a basic guide on how to determine medicine efficacy, primarily through review of the pharmaceutical literature with an emphasis on evaluating randomized controlled trials (RCTs), systematic reviews, and meta-analyses. Systematic and thorough evaluations of the pharmaceutical literature will provide the Drug and Therapeutics Committee (DTC) with the unbiased information necessary to select appropriate medicines for the formulary.

In most countries, evaluating the pharmaceutical literature is commonly done by physicians and pharmacists. Unfortunately, this review is often done incorrectly. With the tools presented in this session and practice at home, participants will be better equipped to evaluate the literature systematically and scientifically.

Objectives

After attending this session, participants will be able to—

• Understand the importance of determining efficacy and evaluating the clinical literature
• Discuss the major types of medicine study design
• Describe the key components of a journal article
• Understand how to evaluate and interpret results of a randomized controlled trial
• Discuss the use of systematic reviews and meta-analyses in evaluating medicines

Outline

• Introduction
• Assessing medicine studies in the clinical literature
• Systematic review and meta-analysis
• Activities
• Summary

Further Readings


**Preparation and Materials**

- Read the Trainer’s Guide and the Participants’ Guide, and review the visual aids (VAs).
- Prepare for the activity of critically reading an article by—
  - Thoroughly reading all the articles and critiques of the articles (that you have obtained locally)
  - Deciding whether you want to cover one, two, or three articles
- Instruct participants to read—
  - Participants’ Guide the evening before the session presentation
  - The article(s) assigned to them
- Distribute the chosen article(s) to each participant at least one day in advance. If you are using more than one article, instruct the participants that they need only prepare to critique one article in depth but they will want to read the other article(s) so they will understand the plenary discussion during which one group will present a critique on one article. Make sure that you instruct all the members of each table group to read the same article in depth because they will be working in groups the next day.
- Ensure that you have at least two calculators per table (of five to eight people).

**Visual Aid Listing**

1. Title slide
2. Introductory graphic
3. Objectives
4. Outline
5. Introduction
6. Getting Started Evaluating an Article: Formulating the Question
7. Evidence: What Kind and How to Find It
8. Example from PubMed
9. Assessing the Quality of the Evidence: What Makes a Good Clinical Trial?
Organization of the Session

Total time: 4–6 hours

Reading clinical literature critically to evaluate medicine efficacy is difficult and requires time, skill, and experience. Session 3 is designed to introduce the participants to the skills needed, and difficulties encountered, in evaluating the literature to determine medicine efficacy and effectiveness. The session is long and difficult, and it will require a minimum of four hours to
complete if the participants are given an article to read critically and in detail at least one day in advance of the session. If they need time during the session to read the article, add an extra hour at least (preferably two hours) to the session if you plan to use the activity on reading and criticizing an article. Run this session from first thing in the morning, reaching the end of the group discussion by lunch time. Group presentations critiquing the articles with plenary discussion can be run after lunch.

How the activity is carried out will depend on the English language skills of the participants. A group of fluent English speakers of sufficient educational level (i.e., a degree in medicine or pharmacy) will be able to read more articles in greater depth. For such a group, you may choose to give three different articles to everyone to read but with instructions that each group need only prepare one of the articles (assigned by the facilitator) for presentation in the plenary discussion the next day. For groups with language difficulties or with participants of a lower educational level, distribute only one article in advance, and limit the plenary discussion to only the major points of this one article.

**First Component: 15 minutes**

**VAs 1–5: Introduction**

Explain that this session will be only an introduction to the topic of evaluating medicine efficacy, a difficult task requiring sophisticated skills. Ask if anyone has experience of evaluating the clinical literature for medicine efficacy.

**Second Component: 60 minutes**

**VAs 6–26: Evaluating an Article and Methodology Used in Medicine Studies**

The second component, which covers basic methodological issues, can be technical and heavy going. To keep the participants’ interest and to ensure that they understand, ask questions from time to time such as—

- What kind of evidence should we obtain?
- What do we want to know from a medicine trial?
- What kinds of study design are there?
- How do we select patients for a medicine trial?
- What is an adequate sample of patients?
- What are outcome variables? Give some examples.
- What is confounding?
- What is a control group?
- Why do we need randomization?

Bring out in the discussion how important answering the research question is for methodology. A good understanding now of the basic methodological components of a study will enable the participants to better understand the later discussion about the various methodological problems frequently encountered in the literature.
Third Component: 30 minutes

VAs 27–32: Understanding the Numbers (Interpreting the Data)

The third component covers the common measures for assessing medicine efficacy. Refer to the Participants’ Guide, and demonstrate the calculations on an overhead projector or blackboard.

Fourth Component: 15 minutes

VAs 33–37: Systematic Reviews and Meta-analysis

Stress the importance of systematic reviews and the advantages to DTC members in using them.

Fifth Component: 20 minutes

VAs 38–43: Common Problems with Clinical Studies and Systematic Reviews

The fifth component is best started by asking the participants to brainstorm common problems with clinical studies, and then use the VAs to summarize the main problems. Try to avoid simply reading the slides to the participants. You need not cover every point because all the points are in the Participants’ Guide. Point out that a reader needs to study an article carefully before accepting what is said in the article’s conclusions.

Sixth Component: 120 minutes

VA 44: Activities

Activity 1. Comparing Antimicrobial Medicines for Pneumonia (15 minutes)

This activity is optional depending on the skill levels of the participants. Higher level participants will find this much too easy. Responses to look for in the discussion are in italics below the questions.

For activity 1, assume that your DTC is considering the formulary addition of a new antimicrobial medicine to treat lower respiratory tract infections in children. The medicine study abstract you have just read concludes that this medicine’s efficacy is equal to a combination of antibiotics in treating pneumonia in hospitalized children. This study looked at 35 children in the treatment group and 43 in the control group. The setting was a large university hospital. This study was an open-label study, and children receiving a new antimicrobial were compared with other children in the hospital who were receiving different antibiotic combination regimens to treat pneumonia. Patients were chosen to receive this antibiotic by the physician depending on the severity of the pneumonia. The medicine requested for the formulary was typically given to children with less severe pneumonia (based on the judgment of the physician), and the combination medicine therapy was reserved for children who appeared to be sicker and at higher risk. Results showed that the study medicine was equally effective as a combination of antibiotics and was less costly. No difference in the incidence of adverse drug reactions (ADRs) was found. The manufacturer of the medicine sponsored the study.
You are especially interested in such a medicine since it is less costly and the study shows that it is effective. Safety information is limited at the early stages of its marketing.

- How would you describe the study design? Is it valid?

*Non-random, non-blinded, biased, comparative medicine trial. Not valid*

- What are the controls in the study?

*The study lacks proper control because the children treated with the new medicine had milder pneumonia than the so-called control group of those treated with the old regime of two medicines.*

- How are the patients randomized?

*They are not randomized. The individual physicians decided which regime to prescribe based on the severity of pneumonia.*

- What kinds of bias can be introduced into this study?

*Selection bias—Only the milder cases were given the new medicine; the more severe cases received the old regime of two medicines.*

*Measurement bias—All patients and physicians knew which regime had been prescribed so the judgment of prescribers concerning outcome and occurrence of ADRs could have been influenced by their opinions about the two medicine regimes. More hard evidence of outcome and safety is needed.*

*Confounding bias—The two groups being compared were different in terms of severity of pneumonia as well as being exposed to different medicine regimes, both of which (severity and medicine regime) are related to the outcome (recovery from pneumonia).*

- Are the results of this study usable in your country?

*No.*

**Activity 2. Interpreting the Data: The Helsinki Heart Study (15 minutes)**

This activity should always be done to ensure that all participants understand how to calculate measures of efficacy.

- *Subjects:* 4,081 asymptomatic men aged 40–55 with dyslipidemia (total cholesterol minus high-density lipoprotein > 5.2 mmole/liter)
• Treatment: gemfibrozil 600 milligram (mg) twice daily (2,051 men) or matched placebo (2,030 men) in a five-year randomized double-blind study

• Results: number of events (fatal, nonfatal myocardial infarction, or cardiac death)
  Gemfibrozil—56 events
  Placebo—84 events

Please calculate the following—

Event rate for placebo = 84 ÷ 2,030 = 4.13%

Event rate for gemfibrozil = 56 ÷ 2,051 = 2.73%

Relative risk reduction = 1- (2.73 ÷ 4.13) = 34%
—large reduction in risk of myocardial infarction, cardiac death

Absolute risk reduction = 4.13 – 2.73 = 1.4%
—small number of people benefit from the reduced risk

Number needed to treat for 5 years to prevent 1 event = 1 ÷ 1.41 = 71
—need to treat 71 patients to see the beneficial effect in one patient

Activity 3. Critically Evaluating an Article
(45 minutes)

This activity should be used if time permits.

There are three articles for review and discussion by the participants (which you already have). You can use any or all of them in this activity. You may want to use all three articles for higher level participants and just one article for lower level participants. If using more than one article, have at least two groups review the same article so that adequate discussion can result from the presentations.

Assuming that all have read their assigned articles the night before, the groups should spend 60 minutes discussing and preparing a presentation of a critique of their assigned articles. The next 30 minutes is spent on five-minute presentations by three groups you pick at random. Each presentation should be on a different article if all three articles are used. After each presentation, the group that also reviewed the article should be invited to report on which points they agree and disagree and then the floor should be opened to general questions and discussion. The groups should be briefed in how to give their presentations, including the following points—

• A succinct summary of what the study is about
• The strong points
• The weak points
• Whether the conclusions of the study are justified
Activity 4. Critically Interpreting the Data: A Medicine Trial to Compare Artesunate with Mefloquine to Treat Malaria
(45 minutes)

This activity can be done in addition if time allows and the skill levels of the participants are sufficient. The answers are in italics in the two grids. (Source: Looareesuwan S, Viravaian C, Vanijanont S et al. 1992. Randomised Trial of Artesunate and Mefloquine Alone and in Sequence for Acute Uncomplicated Falciparum Malaria. *Lancet* 339:821–24.)
Answers to Exercises

Dosage Regimen and Baseline Characteristics in Trials

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Looareesuwan et al. (1992)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Artesunate N=42</td>
</tr>
<tr>
<td>Dosage regimen</td>
<td>100 mg then 50 mg q 12 h for 5 days (total 600 mg)</td>
</tr>
<tr>
<td>Proportion male [n (%)]</td>
<td>38 (90.5%)</td>
</tr>
<tr>
<td>Age [mean (standard deviation)]</td>
<td>27 (9.2)</td>
</tr>
<tr>
<td>Parasite count [mean(range)]</td>
<td>14,195 (172, 180, 950)</td>
</tr>
</tbody>
</table>

Efficacy Results from Looareesuwan et al. (1992)

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Artesunate N=42</th>
<th>Mefloquine N=43</th>
<th>Difference in Means (95% confidence interval [CI])</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fever clearance time [mean (standard deviation)]</td>
<td>35.1 (23.4)</td>
<td>69.7 (37.5)</td>
<td>−34.6 (−48.1, −21.1)</td>
</tr>
<tr>
<td>Parasite clearance time [mean (standard deviation)]</td>
<td>35.9 (10.1)</td>
<td>63.5 (25.5)</td>
<td>−27.6 (−36.0, −19.2)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Artesunate N=42</th>
<th>Mefloquine N=43</th>
<th>Relative risk (95% CI)</th>
<th>Risk difference (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients cured at 28 days [n (%)]</td>
<td>35</td>
<td>30</td>
<td>1.19 (0.94, 1.56)</td>
<td>−13.6% (−4.7, 31.3)</td>
</tr>
<tr>
<td>Patients completing 28 days follow-up [n (%)]</td>
<td>40</td>
<td>37</td>
<td>1.11 (0.96, 1.32)</td>
<td>9.2% (−3.9, 23.4)</td>
</tr>
</tbody>
</table>

Seventh Component: 15 minutes
VA 45: Summary

Summarize the key points of the session and allow time for questions.
Drug and Therapeutics Committee
Training Course

Session 4.
Assessing and
Managing Medicine
Safety
SESSION 4. ASSESSING AND MANAGING MEDICINE SAFETY

Purpose and Content

Session 4 provides participants with basic information about assessing and managing medicine safety issues.

Objectives

After attending this session, participants will be able to—

• Describe the significance of adverse drug reactions (ADRs)
• Describe the significance of medication and prescribing errors
• Understand the principles of medicine safety evaluation
• Understand the evaluation of spontaneous case reports of ADRs and medication and prescribing errors
• Understand the process of monitoring, evaluating, and preventing ADRs and adverse drug events.

Outline

• Key Definitions
• Introduction
• ADRs—Pre- and Postmarketing Surveillance
• Causality
• Implications for the Drug and Therapeutics Committee (DTC)
• Adverse Drug Events and Medication Errors
• Activities
• Summary

Preparation and Materials

• Read the Trainer’s Guide and Participant’s Guide, and review the visual aids (VAs).
• Instruct participants to read the Participant’s Guide the evening before the session presentation.

Further Reading


**Visual Aid Listing**

1. Title slide
2. Objectives
3. Outline
4. Key Definitions (1)
5. Key Definitions (2)
6. Key Definitions (3)
7. Introduction
8. Adverse Drug Reactions (1)
9. Adverse Drug Reactions (2)
10. Determining Medicine Safety
11. Postmarketing Surveillance of ADRs: Spontaneous Reporting of ADRs
12. Postmarketing Surveillance of ADRs: Postmarketing Clinical Studies
13. Postmarketing Surveillance of ADRs: Other Methods
14. Action for Newly Discovered ADRs
15. Determining Causality of an ADR
16. Classifying Causality of an ADR
17. Classifying Causality of an ADR: Naranjo Algorithm
18. Implications for the DTC: Surveillance of ADRs
19. Potential Role of the DTC in ADR Reporting
20. Managing ADRs: Step 1. Evaluate the nature of the event.
21. Managing ADRs: Step 2. Establish the cause.
23. Prevention of ADRs
24. DTC’s Role in Preventing ADRs
25. Adverse Drug Events (1)
26. Adverse Drug Events (2)
27. Causes of Adverse Drug Events
28. Cost of Adverse Drug Events
29. Medication Errors (1)
Organization of the Session

Total time: 3 hours

Session 4 is intended to provide the participants with basic information about assessing and managing medicine safety issues.

First Component: 15 minutes
VAs 1–9: Definitions and Introduction

Introduce the session by asking participants what their specific concerns are about medicine safety. What are the main concerns concerning safety of medicines? How common are ADRs? What are the consequences of ADRs: morbidity, mortality, costs, hospitalization? Next, summarize the definitions on the VAs. Please remember that the literature has many definitions for these terms. The ones listed here are consistent with World Health Organization (WHO) definitions.

Second Component: 15 minutes
VAs 10–14: Premarketing Clinical Studies and Postmarketing Surveillance

This section is designed to give the participants an appreciation of the activities and efforts that go into proving safety and the limitations of these efforts. Explain that medicines do not have sufficient evaluation in premarketing studies, so DTCs must have a system of postmarketing surveillance to determine true safety. Ask the participants how they handle ADR reporting in their countries. Point out that spontaneous reporting is the most common form of reporting and the most effective at identifying new ADRs. Despite this, many health professionals do not bother to report, so the spontaneous reporting often results in the false identification of new ADRs.
**Third Component: 30 minutes**  
*VAs 15–24: Managing and Preventing ADRs*

This component is designed to give the participants practical knowledge of how to manage and prevent ADRs. Brainstorm with the participants about how they handle an ADR that is reported in their home institutions. After a short discussion, summarize the main steps on how to manage ADRs. Ask the participants what the DTC can do to prevent and reduce the rate of ADRs.

When explaining the Naranjo algorithm, explain that this chart (which is old) is one of many that may help in determining causality. Stress that it does *not* replace clinical judgment.

After a short discussion, summarize the main points on prevention from VAs 20 and 21. Point out that closer monitoring is needed of high-risk patients (e.g., pregnant or breast-feeding patients, children, the elderly, or those with liver or renal impairment) and of patients taking high-risk drugs (e.g., digoxin, warfarin, antineoplastics, aminoglycosides).

**Fourth component: 30 minutes**  
*VAs 25–37: Adverse Drug Events and Medication Errors*

Define clearly how adverse drug events differ from ADRs. Participants may be confused, so do not proceed until this distinction is clear to all. Adverse drug events involve a medicine, but no causal relationship between the event and the medicine is evident. Therefore, the reaction could be related to medication errors, genetic factors, environment, other diseases, diet, or some other cause.

Use the VAs on studies from the United States to clarify the different types of adverse drug events, their frequency, and cost. Approach the section on medication errors by brainstorming with participants, first—on the different types of error; second—on their causes; and third—on how to prevent them. After brainstorming each aspect of medication errors, use the VAs to summarize the main points. Point out that a surveillance system for medication errors is needed just as it is for ADRs. All errors should be compiled and reported in a non-confrontational way without mentioning the names of the responsible persons. This approach is necessary to gain the cooperation and trust of the staff who would not otherwise report. Stress that without any reports, the DTC cannot improve the situation.

**Fifth component: 60–90 minutes**  
*VA 38: Activities*

The participants should work on the three activities as a group at their tables (ideally five or six persons per group) for 30–45 minutes. At the end of the group work, one group can be randomly chosen to present the answers for activity 1, another group for activity 2, and a third group for activity 3. After each presentation, allow time for discussion, and ensure that the correct answers are finally revealed. (Possible answers are in italics following each discussion question below.) Discussion may take an additional 30–45 minutes (10–15 minutes per activity). If time allows, groups may like to use a flipchart or overhead projector.
Activity 1. Penicillin Anaphylaxis Reported

A DTC in Panama serves 11 clinics and a hospital. Recently, a different brand of procaine penicillin had been purchased and distributed. Shortly after introduction of the new penicillin product, one clinic reported to the DTC that they had experienced an unusually high number of adverse events associated with intramuscular penicillin injections within a short period. The nursing staff became alarmed, refused to use the product that had been distributed, and asked the clinic director to replace the suspect product with an equivalent product from another supplier. They described the adverse event as an adult patient suddenly (within seconds of the injection) experiencing feelings of doom, anxiety, and faintness, which necessitated lying down. Patients were reported to be pale but with normal or slightly high blood pressure. The nurses immediately gave the patients diphenhydramine IV or IM for a suspected anaphylactic reaction to penicillin. Patients would recover 10 to 15 minutes later and would leave the clinic without further assistance. Following this intervention, the DTC again measured recorded event rates and found that the ADR rate had decreased and was similar in all clinics.

- How would you analyze this situation? What investigations would you carry out?

  - The DTC should evaluate the situation carefully, including a detailed description of the reaction, methods of injection, sources of the medicine, and location of the clinics where the reaction occurred.
  - The DTC needs to determine causality, that is, the strength of association, consistency of reaction, temporality of the reaction, dose-response, and confounding factor. Determining causality would also involve reviewing the literature to determine what medicine the reaction might be attributed to (i.e., penicillin or procaine). The Naranjo algorithm can be used to help guide in investigating the reaction.

You might explain to the participants that the DTC in Panama investigated the ADR outbreak and resolved the issue as follows—

1. Upon reviewing the standard medicine information literature, the clinical syndrome was found to be consistent with Hoigné’s syndrome or pseudo-allergy to penicillin, caused by the procaine component of accidental intravascular (rather than intramuscular) injection of penicillin. Diphenhydramine was thought to be inappropriate treatment of this reaction.

2. Using the number of penicillin-related ADR events recorded in clinic injection rooms and the number of procaine penicillin doses used, DTC staff calculated an event rate for each facility for a fixed-time period. This analysis revealed that the rate of related adverse events in two clinics was double the rate found in the other clinics and that those two clinics also had a relatively high work load.

3. DTC staff visited the two clinics with the higher event rates, interviewed the nursing staff, and observed injection practice. They observed that the nursing
assistants were using less water to reconstitute the injections. The DTC concluded that accidental intravascular injection of more concentrated procaine penicillin was accounting for the ADRs.

4. DTC staff discussed the findings and conclusions of the investigation with the corresponding nursing staff, which reviewed how to prepare and give penicillin injections and agreed to continue using the product. DTC staff also discouraged the use of diphenhydramine for treatment of this clinical syndrome, because it was not an allergic reaction.

- What would you recommend to management regarding the procurement of an alternative or equivalent product?

*Continue same procurement. There is no evidence that quality of the product is in question.*

- What would you communicate to the nursing staff and physicians?

*Educate in proper administration and dosing. Educate concerning generic equivalents. Continue ADR reporting. This particular report was instrumental in identifying the actual cause of the reaction and preventing the unnecessary labeling of the patients as having allergic reactions to penicillin.*

**Activity 2. Acute Respiratory Infection in a Two-Year-Old**

A two-year-old patient and mother present at the clinic on May 19, 1999. The child has a 48-hour history of fever, irritability, cough, and altered consciousness. Questioning of the mother reveals the following—

- 5/14/99—child was administered DPT and oral polio vaccine
- 5/15/99—child was seen with mild upper respiratory tract infection symptoms and treated with amoxicillin and cough syrup
- 5/17/99—child experienced the onset of fever, irritability, altered consciousness
- 5/18/99—child had been seen at the health center and diagnosed with acute respiratory infection and treated with co-trimoxazole and paracetamol

Consider the following—

- What is the possibility of the patient having an ADR in addition to the acute respiratory infection?

*This picture is confusing. This patient may have an acute respiratory infection, a central nervous system infection, an ADR to one of the medicines, or a combination of these*
events. (Pertussis vaccine that is a component of DPT vaccine in particular may cause these symptoms and may be delayed for up to seven days.)

- If you think it is an ADR, which medicine or medicines might be responsible? How did you arrive at this conclusion?
  - It could be one of several medicines, but this a classic example of a pertussis reaction. It is a delayed reaction (3 days), but this happens with pertussis.
  - The DTC needs to determine causality (strength of association, consistency of reaction, temporality to the medicine, dose-response, and confounding factors). In this case, the correlation with pertussis vaccine is high. Confounding factors include acute respiratory infection and other medicines.
  - Many participants in past courses thought that the reaction could have been due to anticholinergic reaction to a possible antihistamine in the cough syrup. Good insight.

- What kind of action by the DTC is warranted in this case?
  - Review the literature concerning the ADR and the medicines in question.
  - Educate the medical staff about ADRs concerning pertussis.
  - Collect and monitor reports of pertussis ADR (and other medicines).

**Activity 3. Serious ADRs with Phen-Fen Combination Medicine**

The combination medicine phenteramine and fenfluramine (commonly called phen-fen) was a popular diet medicine throughout Europe and North America. Like all anti-obesity medicines, this combination leads to tolerance after several months of use, and weight gain invariably occurs when the medicine is discontinued. Short-term effectiveness was dramatic, however, with countless success stories and many patients demanding prescriptions. Safety of this combination was confirmed through the usual premarketing clinical trials. Because phen-fen was another weight control product, testing and evaluation were extensive, and the approval process was not fast-tracked. Soon after the marketing of the medicine, spontaneous reports began to appear describing serious cardiovascular problems including valvular heart disease and pulmonary hypertension—including among younger women. Spontaneous reports continued until it became obvious that the combination was highly suspect for causing the adverse effect.

- What are some other possible causes for the cardiac conditions listed in the activity?
  - This activity is definitely American, but provides an excellent example of a serious ADR that can be detected via spontaneous reports.
  - These cardiovascular disorders are extremely rare in women this age as are other cardiovascular disorders at this age.
• The association with this particular combination medicine is significant because no other reasons for the outcome could be found.

What would have prevented this serious side effect from being detected in premarketing trials?

Small number of patients in clinical trials

Why would spontaneous reports be so effective in detecting this ADR after phen-fen’s distribution to the general market?

Spontaneous reports will be observed over a larger number of patients and will eventually indicate that a medicine may have an ADR associated with it. The large number of women using phen-fen made spontaneous reports an ideal method to detect a serious reaction like this.

Without spontaneous reports it would have been difficult to determine that phen-fen was the causative agent in these cardiovascular problems.

Sixth component: 5-10 minutes

VAs 39–40: Summary

Summarize the key points of the session. Emphasize the practical things DTCs can do to prevent ADRs, adverse drug events, and medication errors.
Session 5. Pharmaceutical Quality Assurance
SESSION 5. PHARMACEUTICAL QUALITY ASSURANCE

Purpose and Content

The Drug and Therapeutics Committee (DTC) is the cornerstone of a health care organization’s medicine use and distribution program. This committee has many different functions that will contribute significantly to the goal of improving medicine selection and rational use of medicines. Session 5 provides an overview of medicine quality and the responsibilities of the DTC for assuring that high-quality products are obtained for the formulary.

Objectives

After attending this session, participants will be able to—

• Define medicine quality
• Understand how medicine quality is assessed
• Understand how medicine quality is ensured
• Describe the role of the DTC in pharmaceutical quality assurance

Outline

• Key Definitions
• Introduction
• Determinants of Medicine Quality
• How is Quality Assessed?
• How is Quality Assured?
• Important Pharmaceutical Quality Issues for the DTC
• Implications for the DTC

Preparation and Materials

Read the Trainer’s Guide and the Participants’ Guide and review the visual aids (VAs).

Further Readings


**Visual Aid Listing**

1. Title slide
2. Acknowledgment
3. Objectives
4. Outline
5. Key Definitions (1)
6. Key Definitions (2)
7. Introduction: Goals of Medicine Quality Assurance Programs
8. Characteristics of a Comprehensive QA Program (1)
9. Characteristics of a Comprehensive QA Program (2)
10. Impacts of Low-Quality of Medicines
11. Determinants of Medicine Quality
12. Potential Bioavailability Problems
13. Standard Method for Bioavailability Studies
14. Rifampicin 450 mg Capsules: > 100% Variation among Brand Names
15. Captopril 25 mg: Variation among Brand Names
16. Nifedipine 20 mg: Generic vs. Brand Name
17. Slow-Release Diclofenac Tablet
18. Medicines with a Stability Problem
19. How is Quality Assessed?
20. How is Medicine Quality Assured? (1)
21. How is Medicine Quality Assured? (2)
22. How is Medicine Quality Assured? (3)
23. How is Medicine Quality Assured? (4)
24. Who Ensures Medicine Quality?
25. Implications of Pharmaceutical QA for the DTC
26. Activity
27. Summary (1)
28. Summary (2)
29. Summary (3)
Organization of the Session

Total time: 3 hours

Session 5 is intended to provide the participants with basic information about assessing and managing pharmaceutical quality issues. Many participants may feel that quality assurance (QA) is not their problem and that other departments are responsible for this area. The message of session 5 is that QA is the responsibility of everyone: DTC, providers, pharmacists, procurement officials, and patients. You will need to convince the participants early in the session that a DTC should be concerned with quality issues so that the participants will be able to make the most of the session activity using presentations from their own home situations.

You will need a substantial working knowledge of pharmaceutical QA, procurement, storage, and distribution practices to facilitate this session.

First component: 10 minutes
VAs 1–6: Introduction

Introduce the session by asking participants what their specific concerns are about medicine quality. What types of problem occur and why in their home countries? Afterward carefully go through the definitions.

Second component: 20 minutes
VAs 7–11: Medicine Quality Assurance Programs

Point out the two main goals of a comprehensive QA program—

- **Obtaining** quality products that are safe and effective through structured selection and procurement methods
- **Maintaining** quality products through the appropriate storage, distribution, monitoring, and prescribing methods

Discuss the important components of a comprehensive QA program. It is unlikely that many of the physicians (and also some of the pharmacists) would be this involved in QA or realize that they should be. Ask the participants to describe the various problems that can occur with poor quality medicines and all the various consequences. The subsequent discussion should lead to more interest by the participants in obtaining better QA programs.

Discuss the determinants of medicine quality, and use pharmacopoeia standards as examples

Third component: 30 minutes
VAs 12–18: Problems of Bioavailability and Stability

Define *bioavailability* before starting the discussion: bioavailability refers to the speed and completeness with which an administered medicine enters the blood stream.
Explain that bioavailability must be consistent to provide a predictable therapeutic result. Medicine bioavailability differences exist between manufacturers of the same product. Therefore, careful evaluation of generic medicines may be necessary before purchase and use.

Obtain participant feedback concerning this well-known problem. Encourage discussion within the groups so that all can learn from others concerning this important and controversial issue.

**Caution:** Obtaining bioavailability information is difficult, and it is frequently inaccurate or difficult to interpret.

Acknowledge that the slides were provided by Suryawati and Santoso of Indonesia.

Define *stability:* The activity of the medicine is ensured for the period of time stated on the product label, that is, until the expiration date. Explain that stability is a particular problem in hot and humid climates.

*Fourth component: 30 minutes*

**VAs 19–25: Assuring Medicine Quality**

Ask how many participants actually do laboratory testing at their facilities. How much does it cost? Discuss the need for obtaining bioavailability data and the difficulty in obtaining this important information.

Ask how many participants actually do structured procurement with prequalified suppliers. This particular aspect of procurement will reduce the number of low-quality products by screening out suppliers with a poor history of service and quality.

Reinforce to all the participants the need to be involved at all levels of the health care system to ensure that quality medicines are made available.

*Fifth component: 60 minutes*

**VA 26: Activity**

The rationale for this activity is for the participants to identify the scope and extent of individual participant and DTC responsibilities for pharmaceutical QA. This activity will give participants the opportunity to discuss their medicine quality programs and concerns and to provide input for solutions of other participants’ problems.

Participants should list the specific QA concerns in their programs in hospitals and primary care clinics. List them under the following headings—

- Obtaining quality products (source issues): problems with the quality of medicines being supplied by commercial sources, government production, or donors
- Maintaining quality products (supply system issues): problems with quality assurance at the central warehouse, in transit, at local facilities, and the like
- Examples of poor quality: anecdotes illustrating poor quality that do not clearly fit under the above headings

As a part of this exercise, ask the participants to answer the following questions concerning their QA programs—

1. Are you satisfied with the quality of medicines you receive?
2. Is quality maintained throughout your distribution network?
3. Are there complaints of poor quality by patients or health workers?
4. Is there a formal mechanism for reporting and investigating product quality complaints?
5. What role do you see for the DTC in improving and maintaining quality in your health care system?
6. Does anyone have a particular quality assurance issue with which he or she needs help?

**Sixth component: 10 minutes**

*VAs 27–29: Summary*

Summarize the key points of the session. Remind everyone that—

- Poor medicine quality produces poor patient outcomes, increases cost, erodes credibility for the entire health system, and decreases confidence in health care staff and patients

- Medicine quality is the responsibility of everyone and the DTC is in a position to supervise overall pharmaceutical quality assurance
Drug and Therapeutics Committee
Training Course

Session 6.
Evaluating the Cost of Pharmaceuticals
SESSION 6. EVALUATING THE COST OF PHARMACEUTICALS

Purpose and Content

Session 6 is designed to provide participants with basic information about analyzing the cost of pharmaceuticals and, to a limited extent, pharmacoeconomic principles. Participants will learn the value of a basic cost analysis and its importance to the DTC in evaluating and selecting medicines for the formulary.

Objectives

After attending this session, participants will be able to—

• Define and understand the different types of cost analysis methods relevant to choosing medicines for the formulary
• Understand how to read and assess journal articles concerning an economic study
• Apply session materials to conduct a basic cost analysis for a medicine being requested for the formulary

Outline

• Introduction
• Definitions
• Cost-Evaluation Methods
  o Cost-Minimization Analysis (CMA)
  o Cost-Effectiveness Analysis (CEA)
• Evaluating Pharmacoeconomic Studies
• Activities
• Summary

Preparation and Materials

• Read Trainer’s Guide and Participants’ Guide, and review visual aids (VAs).
• Instruct participants to read the Participants’ Guide the evening before the session presentation.
• Do all the calculations yourself before teaching the session.
• Ensure that there are at least two calculators per table (of five to eight people).
Further Readings


Visual Aid Listing

1. Title slide
2. Introduction
3. Objectives
4. Outline
5. Key Definitions (1)
6. Key Definitions (2)
7. Direct Costs of a Medicine
8. Indirect Costs of a Medicine
9. Cost-Minimization Analysis
11. Cost-Minimization Analysis: Example 1
12. Cost-Minimization Analysis: Example 2
13. Cost-Effectiveness Analysis (CEA)
14. CEA: Steps
15. Incremental Cost Effectiveness Ratio
16. Example of CEA: Medicine Costs
17. Example of CEA: Benefits
18. Example of CES: Incremental Cost-Effectiveness
19. CEA of Two Thrombolytics in MI in Australia (1)
20. CEA of Two Thrombolytics in MI in Australia (2)
21. CEA of Two Thrombolytics in MI in Australia (3)
22. CEA of Two Thrombolytics in MI in Australia (4)
23. CEA of Two Thrombolytics in MI in Australia (5)
24. CEA of Two Thrombolytics in MI in Australia (6)
25. Other Controversial Cost Analyses
26. Sensitivity Testing
27. Discounting
28. Evaluating Pharmacoeconomic Studies (1)
29. Evaluating Pharmacoeconomic Studies (2)
30. Evaluating Pharmacoeconomic Studies (3)
31. Activities
32. Summary
Organization of the Session

Total time: 3 hours

The Drug and Therapeutics Committee (DTC) is responsible for careful evaluation of new medicines before they are added to the formulary. As discussed in previous sessions, this evaluation must involve efficacy, safety, quality, and cost. Session 6 provides information on how to evaluate the cost of a medicine, not only its procurement cost, but also the cost impact on the entire health care system including the patient. The discussion is important so that the overall evaluation of a medicine is complete and the DTC knows all of the cost implications when considering the addition of a new medicine. Economic evaluation techniques are used not only for medicines, but also for health care services such as disease management programs.

First Component: 15 minutes  
VAs 1–6: Introduction

Start the session by asking the participants how much it costs to treat someone for a disease such as pneumonia or hypertension. Elicit from them answers that illustrate that treatment involves many more expenses than just the price of the medicine. Then carefully go over the outline of the session and the definitions. Mention that medicine cost analyses are becoming increasingly important because medicine costs consume an increasing proportion of health care costs—maybe up to half.

Second Component: 30 minutes  
VAs 7–12: Cost of Using a Medicine and Cost-Minimization Analysis

Review the costs of using a medicine on VAs 7 and 8. These slides are important because they give details of the true cost of using a medicine over and above the acquisition cost. Explain the method of CMA (VAs 9 and 10), and mention that it is the method of cost evaluation used most often by pharmacy departments. Emphasize that cost minimization can only be used to compare two products that have been shown to be equivalent in dose and therapeutic effect. Therefore, this method is most useful for comparing generic and therapeutic equivalents or “me too” medicines. CMA cannot be used when there is not a reliable equivalence between the products being compared. Work through the examples (VAs 11 and 12) with the participants, getting them to follow the calculations step by step. The cost of salary for pharmacy and nursing will be controversial. Explain that this cost is necessary only when these costs have a significant impact on the cost of the medicine. If there is no difference between the two medicines, it is not necessary to actually calculate these costs.

Third Component: 30 minutes  
VAs 13–24: Cost-Effectiveness Analysis

Explain that cost-effectiveness introduces medicine effectiveness into the analysis. Effectiveness is measured in terms of intermediate clinical outcomes (e.g., blood pressure, blood sugar, asthma attacks) or long-term clinical outcomes (e.g., years of life saved). This form of analysis can be used to compare medicines that are not equivalent in terms of dose or therapeutic effect, but that
are used to treat the same clinical condition. Such analyses are difficult for a DTC to do, but it is important to understand the principles to be able to judge pharmacoeconomic studies when assessing new medicines for the formulary. Work through the example with the participants getting them to follow the calculation step by step. Explain that the example from Australia was an actual analysis done at the national level.

Fourth Component: 15 minutes
VAs 25–27: Other Cost Analyses, Sensitivity Analysis, and Discounting

Briefly explain other cost analyses and how controversial they are. Ask the participants to list some of the assumptions people make in cost analyses and what they think of the accuracy of these assumptions. Ask how they might deal with such assumptions. Then explain how to vary these assumptions in a sensitivity analysis to see if the cost analyses change. Briefly mention that only national health economists, not DTCs, use discounting, but that it will be encountered in the literature.

Discounting is used in cost evaluations to establish present value of a future benefit. This method is necessary to take into account the effects of inflation and aging (life span). Actual benefits of a medicine today or this year will not have the same value 5 to 10 years from now. Discounting is an important concept to give validity to the pharmacoeconomic calculations that have benefits ranging over prolonged periods of time.

Fifth Component: 15 minutes
VAs 28–30: Pharmacoeconomic Studies

Ask the participants what sort of problems they might expect to encounter in pharmacoeconomic articles. Then briefly summarize the information in the VAs.

• Discuss how the literature will provide valuable cost information from pharmacoeconomic studies.

• Discuss the shortcomings of this type of literature, such as influences of pharmaceutical companies, methodological shortcomings of the study, and occasionally incorrect conclusions.

• Discuss briefly those areas that are involved in a more comprehensive evaluation (if time permits and interest is great). This information is not on the VAs, but is included in the Participants’ Guide.

Briefly present and discuss the checklist in the Participants’ Guide. There are no VAs for the checklist, but it is important to let the participants know about it and that they need to review carefully. This checklist will be of value when reviewing pharmacoeconomic literature.
Activity 1. Cost Minimization Analysis of NSAIDs

Your hospital outpatient department sees a large volume of patients with back pain, minor trauma, and arthralgias. A medicine use indicator study in this department indicated that a high percentage—25 percent—of patients receive injections. An in-depth review showed that diclofenac injection is extensively used for all type of pain syndromes. Typically, patients are given diclofenac 75 mg intramuscular (IM) followed by diclofenac 50 mg three times a day for one week.

Review of the literature on use of this injection shows that it is no more effective than oral non-steroidal anti-inflammatory drugs (NSAIDs) and has significant adverse drug reactions (ADRs) including pain on injection and occasional neuropathies. Your DTC asks that a cost minimization study be done to evaluate the four NSAIDs that are available in the outpatient department.

For activity 1, perform a cost analysis (cost-minimization) of these medicines based on the usual treatment regimen of seven days. Acquisition costs of these products are listed in table 1. (Table 2 provides solutions in italics.)

<table>
<thead>
<tr>
<th>Medicine</th>
<th>Dose</th>
<th>Cost per Dose (USD)</th>
<th>Cost per Day (USD)</th>
<th>Cost for 7 Days (USD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ibuprofen</td>
<td>400 mg tid</td>
<td>0.0077</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Naproxen</td>
<td>500 mg bid</td>
<td>0.0216</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diclofenac</td>
<td>50 mg tid</td>
<td>0.0057</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diclofenac injection</td>
<td>75 mg IM × 1 dose only</td>
<td>0.07</td>
<td></td>
<td></td>
</tr>
<tr>
<td>+ Diclofenac 50 mg tid</td>
<td></td>
<td></td>
<td>0.0057</td>
<td></td>
</tr>
</tbody>
</table>

Note: Other costs associated with giving NSAIDS include—

- Syringe/needle: 0.90 U.S. dollars
- Nursing cost to administer one dose: USD 1.00

1. What is the least costly treatment regimen according to your analysis?

   Answer: Diclofenac (see table 2)
Table 2. Acquisition Costs (with Solutions)

<table>
<thead>
<tr>
<th>Medicine</th>
<th>Dose</th>
<th>Cost per Dose (USD)</th>
<th>Cost per Day (USD)</th>
<th>Cost for 7 Days (USD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ibuprofen</td>
<td>400 mg tid</td>
<td>0.0077</td>
<td>0.0231</td>
<td>0.16</td>
</tr>
<tr>
<td>Naproxen</td>
<td>500 mg bid</td>
<td>0.0216</td>
<td>0.0432</td>
<td>0.30</td>
</tr>
<tr>
<td>Diclofenac</td>
<td>50 mg tid</td>
<td>0.0057</td>
<td>0.0171</td>
<td>0.12</td>
</tr>
<tr>
<td>Diclofenac injection</td>
<td>75 mg IM × 1 dose only</td>
<td>0.07</td>
<td>1.97</td>
<td></td>
</tr>
<tr>
<td>+ Diclofenac</td>
<td>50 mg tid</td>
<td>0.0057</td>
<td></td>
<td>0.12</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Total diclofenac tablets and injection</td>
<td>2.09</td>
</tr>
</tbody>
</table>

2. What is the cost savings for 1,000 patients treated with diclofenac as compared to regimen of diclofenac injection + diclofenac tablets?

   *Answer: USD 2,090 vs. USD 120 for a cost savings of USD 1,970*

3. Perform a sensitivity analysis on your analysis by changing the cost of syringe/needle to USD1.50.

   Total cost for diclofenac injections = USD 2,570
   Total cost of diclofenac tablets = USD 120
   Total cost = USD 2,690 for the injection + tablets

4. What would your DTC recommend concerning the NSAIDs in this health facility?

   *Discontinue the use of the injection or limit its use to a well-defined population.*

   • There is little evidence of improved efficacy compared to oral NSAIDs.
   • ADRs are well documented for this injection, including pain on administration and neuropathies (sciatic nerve injury).
   • Cost is significantly higher than oral preparations.
   • Increased nursing time is needed to administer the injection.
Activity 2. Cost Effectiveness Analysis of Two Antimalarial Treatments

Your DTC is considering adding an artemisinin combination therapy for the treatment of uncomplicated malaria. You have two choices to consider: artesunate plus lumefantrine (A+L) or artesunate plus mefloquine (A+M).

The effectiveness of both medicines has been summarized in a systematic review—

- **A+L, 6 doses:** number of patients with parasitemia at 28 days was 11 of 289 (4 percent)
- **A+M, 3 days:** number of patients with parasitemia at 28 days was 0 of 100 (0 percent)

The dose of A+L in adults is six doses of four tablets (20 mg + 120 mg). The dose of A+M in adults is four tablet of artesunate daily for three days (200 mg per day), and 500 mg of mefloquine on day 2 and 250 mg on day 3 (for a 50 kg adult).

The cost of one pack of 24 A+L tablets is USD 5.00. The cost of A+M (two separate packets) is USD 1.54 for 12 artesunate 50 mg tablets and USD 4.57 for six mefloquine 250 mg tablets.

1. Evaluate the cost-effectiveness of A+M compared to A+L.

   The calculation is as follows:

   **Medicine costs**
   
   - **Cost for A+L at USD 5 per pack of 24 tablets per patient**
   - **Cost for A+L for 100 patients = USD 5 × 100 = USD 500**
   
   - **Cost for A+M at USD 1.54 per pack A + USD 4.57 per pack of M = USD 6.11/patient**
   - **Cost for A+M for 100 patients = 6.11 × 100 = USD 611**

   **Benefits**
   
   - **Treatment failure defined as parasitemia at 28 days**
   - **A+L: Failure rate 4 percent, so cure rate = 100 – 4 = 96 percent**
   - **A+M: Failure rate 0 percent, so cure rate = 100 – 0 = 100 percent**

   Incremental cost-effectiveness ratio (ICER) = (611 – 500) ÷ (100 – 96) = 27.75
   That is, USD 27.75 extra per patient cured treating with A+M as compared to A+L

2. Carry out a simple sensitivity analysis, by reducing the effectiveness of A+M to 5 percent lower than that of A+L. What other important criteria should be considered when adding a such a medicine to the formulary?

   The calculation is as follows:

   **Sensitivity analysis where benefits changed to the following cure rates**
   
   - **A+L: Failure rate 4 percent as before, so cure rate remains 96 percent.**
A+M: Failure rate changed to 5 percent less than A+L, so cure rate = 96 – 5 = 91%

ICER = (611 – 500) ÷ (91 – 96) = USD –22.2
That is, USD 27.75 less per patient cured treating with A+M as compared to A+L.

A+M is more expensive, and on these data, more effective, but this analysis does not include ADRs or ease of dosing. As the sensitivity analysis shows, the results are sensitive to the estimate of effectiveness difference. As soon as both products are equivalently effective, A+L is more cost-effective—as shown by the negative result for the ICER on sensitivity analysis, since in this scenario it is both cheaper and more effective. If you were not sure about the difference in treatments, then you would go with the cheaper product.

3. Which of these two medications is the preferable product for the formulary?

If effectiveness is most important, then paying an extra USD 27 per additional patient cured might be value for money. But if your hospital treats a lot of patients, then the total cost of buying enough treatment may be an important factor in your decision and the cheaper less effective treatment might be an alternative.

The answers are provided in table 3.

Table 3. Cost Effectiveness Analysis for Activity 2

<table>
<thead>
<tr>
<th>Medicine Costs</th>
<th>Per Patient</th>
<th>For 100 Patients</th>
<th>Sensitivity Analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>A+L</td>
<td>USD 5.00</td>
<td>USD 500</td>
<td>—</td>
</tr>
<tr>
<td>A+M</td>
<td>USD 6.11</td>
<td>USD 611</td>
<td>—</td>
</tr>
<tr>
<td>Benefits (cures)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>A+L</td>
<td>—</td>
<td>96%</td>
<td>96%</td>
</tr>
<tr>
<td>A+M</td>
<td>—</td>
<td>100%</td>
<td>91%</td>
</tr>
<tr>
<td>ICER: A+M compared to A+L:</td>
<td></td>
<td>USD 27.75/extra</td>
<td>USD –22.20/extra</td>
</tr>
<tr>
<td>First analysis:</td>
<td>(611 – 500) ÷ (100 – 96) = 27.75</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sensitivity analysis:</td>
<td>(611 – 500) ÷ (91 – 96) = –22.2</td>
<td>Patient cured</td>
<td>Patient cured</td>
</tr>
</tbody>
</table>
Seventh Component: 15 minutes
VAs 32: Summary

Summarize the key points of the session. Emphasize that cost minimization analysis is the most common type of analysis done by DTCs and can be used only to compare therapeutically equivalent medicines.
Drug and Therapeutics Committee
Training Course

Session 7.
Identifying Problems with Medicine Use
SESSION 7. IDENTIFYING PROBLEMS WITH MEDICINE USE

Purpose and Content

The purpose of session 7 is to introduce participants to methods for identifying medicine use problems in hospitals and primary care clinics. Many medicine use problems may be difficult to detect on a day-to-day basis unless they are obvious. The use of the methodologies in this session will enable Drug and Therapeutics Committee (DTC) members to evaluate the pharmaceutical distribution system more closely and discover those medicine use problems that may have a significant impact on patient care.

Objectives

After attending this session, participants will be able to—

• Describe how indicators can be used to identify medicine use problems

• Perform a prescribing indicator study on a sample of prescriptions and explain how it can be used to identify medicine use problems

• Discuss the use of aggregate data including defined daily dose (DDD) to analyze the consumption of medicines

• Perform an ABC analysis and explain how it can be used to identify medicine use problems, reduce costs, and improve efficiency in the pharmaceutical supply system

• Discuss how VEN system for setting priorities will assist the DTC in medicine selection, purchasing, and inventory management

Outline (Parts 1 and 2)

• Introduction

• World Health Organization (WHO)/International Network for Rational Use of Drugs (INRUD) Indicators for Hospitals and Primary Health Care Clinics

• Aggregate Data
  o DDD
  o VEN Analysis
  o ABC Analysis

• Activity

• Summary
**Preparation and Materials**

- Read the Trainer’s Manual and the Participants’ Guide, and review the visual aids (VAs).

- Instruct participants to read the Participants’ Guide the evening before the session presentation.

- Ensure that each table (of five to eight people) has at least two calculators.

- Each group should fill in the prescribing indicator form on page 68 of the WHO manual *How to Investigate Drug Use in Health Facilities*, which should be attached as a worksheet 1 in the Participants’ Guide. (See activity 1.)

- For part A on indicator studies, arrange for the local hosts to provide old prescriptions or log books for each table to use to calculate the WHO/INRUD medicine use indicators. Each table should have at least 100 prescriptions and take a random sample of 30 to calculate the indicators. The indicators suggested for calculation are—
  - Average number of medicines per patient encounter
  - Percentage of prescriptions containing one or more antibiotics
  - Percentage of prescriptions containing one or more injections
  - Percentage of medicines prescribed by generic name

- For part B on aggregate methods, do all the calculations for the ABC analysis yourself before leading the session (using an Excel® spreadsheet if possible), so you can easily explain the answers and difficulties of calculation in the session.

**Further Readings**


Session 7. Identifying Problems with Medicine Use


Visual Aid Listing

Part A. Identifying Problems with Medicine Use: Indicator Studies

1. Title slide
2. Objectives
3. Outline—Part A
4. Introduction
5. Methods to Investigate Medicine Use
6. Indicators for Health Care Facilities (1)
7. Indicators for Health Care Facilities (2)
8. Indicators for Health Care Facilities (3)
9. WHO Indicators for PHC
10. Prescribing Indicators—PHC
11. Prescription 1
12. Prescription 2
13. Prescription 3
14. Prescription 4
15. Prescription 5
16. Prescription 6
17. Patient Care Indicators—PHC
18. Health Facility Indicators—PHC
19. Complementary Indicators—PHC
20. Performing an Indicator Study (1)
21. Performing an Indicator Study (2)
22. Results of Indicator Studies
23. Graphs of Indicator Data (1)
24. Graphs of Indicator Data (2)
25. Hospital Antimicrobial Indicators (1)
26. Hospital Antimicrobial Indicators (2)
27. Hospital Antimicrobial Indicators (3)
28. Hospital Antimicrobial Indicators (4)
29. Hospital Indicators Developed and Used in Australia and Zimbabwe
30. Activities 1 and 2
31. Summary

Part B. Identifying Problems with Medicine Use: Aggregate Methods

1. Title slide
2. Objectives
3. Outline—Part B
4. Methods to Investigate Medicine Use
5. Aggregate Data (1)
6. Aggregate Data (2)
7. Defined Daily Dose (1)
8. Defined Daily Dose (2)
9. Defined Daily Dose Example 1: Captopril Use
11. VEN Analysis
12. Conducting a VEN Analysis
13. VEN Applications for DTC
14. VEN Analysis, Activity, and Discussion
15. ABC Analysis
16. ABC Analysis: A, B, and C Medicines (1)
17. ABC Analysis: A, B, and C Medicines (2)
18. Applications of ABC Analysis for a DTC
19. Steps in Performing ABC Analysis
20. ABC Step 1. List items and unit costs.
21. ABC Steps 2 and 3. Calculate consumption quantities and values—sort list by descending values.
22. ABC Step 4. Calculate the percentage of total value represented by each item.
23. ABC Step 5. Rank items in descending order.
24. ABC Step 6. Calculate the cumulative percentage of total value for each item.
25. ABC Step 7. Choose cut-off points for ABC analysis chart.
26. Activities 3, 4, and 5
27. Summary
Organization of the Session

Total time: 7½–8 hours

Session 7 is divided into two half-day sessions of at least three and half to four hours each. The first part of the session covers indicator studies and the second part, aggregate methods. The session overall is long and aims to give the participants practical experience in identifying medicine use problems. In part A (indicator studies), the participants will calculate the indicators from real prescriptions and role-play. In part B (aggregate methods), the participants will undertake VEN and ABC analyses from a list of medicines provided.

Part A. Identifying Problems with Medicine Use: Indicator Studies

Total time for part A: 4 hours
First Component: 15 minutes
VAs 1–8: Introduction

Start part A by asking the participants how they might investigate medicine use to identify problems. This discussion will help you know the level of experience within the group and to adjust the session accordingly. Then briefly introduce the topic by explaining the different methods to investigate medicine use. Point out that some methods collect medicine use data at the individual patient level and some methods collect at an aggregate level from routine data. Explain how a DTC would use indicator and aggregate methods to identify a problem area. Point out, however, that the DTC would need to undertake more in-depth investigation to define the nature of the problem and understand the underlying reasons for it—and that these topics will be covered in two sessions later in the course. Then introduce the concept of indicators (VAs 7–8).

Second Component: 60 minutes
VAs 9–19: WHO/INRUD Indicators for Hospitals and Primary Health Care Clinics

When explaining the indicators, refer to the definitions developed by INRUD and WHO and used in the WHO manual How to Investigate Drug Use in Health Facilities. Explain that these indicators have been extensively field tested and found to be valid and reliable in primary health care (PHC) settings. They are not suitable for specialist clinics such as infectious disease clinics (where everyone might correctly receive antibiotics) or hypertension clinics (where no one should receive antibiotics unless there is a concurrent bacterial infection).

Ask questions and quote examples and controversies.

Problems of defining prescribing indicators include the following—

- For average numbers of medicines, ask how many medicines are in co-trimoxazole. Mention other examples of fixed-dose combinations such as amoxicillin + clavulanic acid, rifampicin + isoniazid, sulfadoxine-pyrimethamine (Fansidar®).
- For injections, comment, “If it hurts, it’s an injection.”
• For antibiotics, ask whether metronidazole is an antibiotic. Explain that in many PHC situations, metronidazole is used as an antiprotozoal and, therefore, is not defined as an antibiotic but that where it is being used as an antibacterial, a DTC may want to classify it as an antibiotic.

• For generics, ask whether aspirin (acetylsalicylic acid) is a generic or brand name. Discuss the case of paracetamol (Panadol).

• For the essential medicines list (EML) or formulary, discuss the need to define in advance what would be an acceptable list.

For VAs 11–16, ask the participants the following questions, and anticipate the following answers—

• VA 11—Q: How many medicines are on this prescription?
  A: Three—the two chloroquine formulations are counted as one medicine.

• VA 12—Q: What do you think of this prescription?
  A: Unclear handwriting—explain how one might deal with this.

• VA 13—Q: Does this prescription list an antibiotic?
  A: No, normally metronidazole is not classified as an antibiotic.

• VA 14—Q: What does this prescription say?
  A: The last line is an instruction to pulverize tablets and mix into different packages.

• VA 15—Q: How many medicines are on this prescription? How many generics?
  A: Three medicines—Septrin is only one medicine. One generic—Septrin and Panadol are not generics.

• VA 16—Q: How many generics are on this prescription?
  A: Handwriting unclear but probably one generic—codeine

Problems of defining patient care and facility indicators include the following—

• For the patient care indicators, point out that consulting time may be affected by interruptions. How might an investigator measure consulting time if several patients are in the consulting room at the same time?

• For dispensing time, suggest the WHO/INRUD indicator may not be the most useful indicator. A more careful indicator might be dispensing communication time, which is the time the patient is actually communicating with the dispenser after the prescribed medicines have been collected.

• For facility indicators, point out that the DTC must make a decision in advance about which EML or formulary would be acceptable.
Session 7. Identifying Problems with Medicine Use

- For patient knowledge on medicine dosing, ask if anyone has any experience with this topic and, if so, what difficulties he or she has experienced. Draw some particular answers out of the participants. For example, patients must be interviewed with the medicines and prescription or label in hand because otherwise the investigator cannot judge whether the patient’s knowledge is correct. Point out that in many situations, the patient may have neither a prescription nor adequate label on the medicines.

- For labeling issues, ask what an adequate label is. An adequate label must contain the patient name, generic medicine name, medicine strength, and how to take the medicine.

Third Component: 15 minutes
VAs 20–24: Performing an Indicator Study

Brainstorm with the participants the steps involved in carrying out an indicator study. Then review the steps using VAs 20–22. Point out how a graphic presentation of the findings can identify facilities where medicine use is significantly better or worse (VAs 23–24). Refer to chapter 4, pages 32–38 in the WHO manual How to Investigate Drug Use in Health Facilities for the steps needed to undertake an indicator study.

When discussing training of field workers refer to table 5, page 35 in How to Investigate Drug Use in Health Facilities, which describes how the enumerators can be trained. Stress how important it is to conduct field practice to gain shared experience in conducting such surveys. Briefly discuss the scope and sampling issues for a survey, and refer to pages 25–31 of How to Investigate Drug Use in Health Facilities. Point out that the type of survey will depend on who will use the information and the purpose of the survey. For sampling, characterize the most common situation in which 20 facilities are surveyed with 30 prescriptions or observations, which gives results with confidence intervals of ±7.5 percent for the entire sample. For an individual facility with 100 prescriptions or observations, the confidence interval would be ±10.0 percent.

Fourth Component: 15 minutes
VAs 25–29: Hospital Indicators

VA 25 shows a variety of indicators that have been used in different countries. VAs 26–28 show indicators of antimicrobial usage developed by Management Sciences for Health (MSH). These latter indicators are relatively new. Since they have not been extensively field-tested their reliability and validity is less certain than for the PHC indicators. An example of hospital related indicators developed in Zimbabwe and Australia are also included.

Fifth Component: 120 minutes
VA 30: Activities
Activity 1. Calculating Prescribing Indicators from Prescriptions  
(60 minutes)

Each group should be given at least 100 (preferably more) prescriptions and asked to randomly select 30 and calculate the following—

- Average number of medicines per encounter
- Percentage of medicines prescribed by generic name
- Percentage of encounters with an antibiotic prescribed
- Percentage of encounters with an injection prescribed
- Percentage of medicines prescribed which are from the EML or formulary list

Each group should fill in the prescribing indicator form on page 68 of the WHO manual How to Investigate Drug Use in Health Facilities, which should be attached as a worksheet 1 in the Participants’ Guide. Ask the participants how they will select 30 prescriptions randomly from the 100 and suggest several methods, some of which may require numbering prescriptions. Suitable methods include random selection of prescription numbers from a “hat” or random selection of a number between 1 and 10 and then selecting every third prescription (if there is a total of 100 prescriptions) starting from that number.

During the group work, check that all groups have correctly calculated the indicators. Numerator and denominator mistakes are frequent. For example, participants often calculate the percentage of medicines that are antibiotics instead of the percentage of patients who are receiving one or more antibiotics. For the latter, the numerator is the number of patients receiving one or more antibiotics (irrespective of whether two or more antibiotics were prescribed for each patient), and the denominator is the number of patients (not medicines)—that is, 30 patients in this exercise. For the percentage of medicines prescribed by generic name, the numerator is the number of medicines prescribed by generic name, and the denominator is the total number of medicines prescribed (for all 30 patients).

Each group should present its results at the end and explain how the members selected 30 prescriptions. Facilitate a short discussion about the reasons for similarities or differences in the results between groups. Indicator results may be similar or different depending on whether the facility types, prescriber types, seasons, or other parameters are similar. Indicator results may be slightly different even from the same prescriptions in the same facility because of differences in how prescriptions were selected—hence the need for random samples of sufficient size.

Activity 2. Calculating Patient Care Indicators from Observing Role-Play Consultations  
(60 minutes)

Develop a role-play in which a facilitator acts as a physician and the participants are the patients. During this role–play, several medical consultations are enacted, the consultation times are recorded, and the average consultation time is calculated. As the lead facilitator of the session, you should not take the role of physician because your job is to observe the role-play and time
the consultations just as the observing participants should do. At the end of the role-play, ask each observing participant what the average consultation time was and record it on a flipchart. Within a short time, it should become clear that the average consultation time varies greatly with different observers. This fact can then be used to discuss the importance of (a) field testing (i.e., how one would measure an indicator), (b) training observers, and (c) the various problems that can be encountered.

If time allows, another role-play for other indicators can be enacted. A role-play for dispensing time can be arranged in a similar manner to that for consultation time, but role-plays for the other indicators (e.g., patient knowledge) are more difficult and require more time (see activity 1 in session 8 on understanding medicine use problems).

**Sixth Component: 15 minutes**

**VA 31: Summary**

Performing an indicator study is useful method to—

- Identify medicine use problems at the patient level
- Monitor medicine use by prescribers
- Evaluate the impact of interventions

Emphasize (a) the importance of defining each indicator, (b) the importance of field testing the measurement of each indicator, and (c) the steps of conducting an indicator study.

**Part B. Identifying Problems with Medicine Use: Aggregate Methods**

**Total time for part B: 3½–4 hours**

**First Component: 10 minutes**

**VAs 1–6: Introduction**

Start part b by reviewing VAs 2–3 and explaining that in part A, the participants have received training on indicator studies, and that part B will be devoted to other ways of investigating medicine use. Then ask the participants what is meant by the term *aggregate data*, and brainstorm with them about what different sources of aggregate data exist. Explain that aggregate data methods use routine data sources and are often much quicker and easier to use than looking at individual patient records or prescriptions to identify problem areas in medicine use.

**Second Component: 20 minutes**

**VAs 7–10: Defined Daily Dose (DDD)**

DDDs are often confusing for participants. Therefore, explain carefully that the DDD is the assumed average daily maintenance dose for the medicine’s main indication as decided by the WHO Collaborating Center for Drug Statistics Methodology in Oslo, Norway (http://www.whocc.nmd.no); it is not the actual prescribed dose for any particular patient. The DDD provides a unit of measurement that is independent of price and formulation and, thus, can
be used to assess trends in consumption of medicines and to perform comparisons between countries, population groups, and health care systems. Without DDDs, countries would report medicine consumption in different units, such as milligrams, gram tons, kilograms, DDD, dollars, and so forth. Carefully explain each step of the calculations in VAs 8–9 and in box 1 to the class.

**Box 1. Example of a Calculation Using DDD**

<table>
<thead>
<tr>
<th>District hospital and clinics use 22.5 million tablets yearly of captopril 25 mg and 3.0 million tablets yearly of captopril 50 mg. This medicine usage is for a population of 2.7 million people.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calculating the consumption of captopril utilizing DDD methodology would be as follows—</td>
</tr>
<tr>
<td>Quantity of medicine used in 1 year multiplied by the strength of the product</td>
</tr>
<tr>
<td>(22.5 million × 25 mg) + (3.0 million × 50 mg) = 7.125 million mg (total quantity consumed)</td>
</tr>
<tr>
<td>Divide total quantity consumed by the assigned DDD for that medicine (for captopril = 50 mg)</td>
</tr>
<tr>
<td>7.125 million mg / 50 mg = 14.25 million DDD</td>
</tr>
<tr>
<td>Divide total quantity by 2.7 million and multiply by 1,000 (this is the population denominator for this method) to obtain the DDD / 1,000 inhabitants / year (divide by 365 to obtain DDD/1,000 inhabitants/day)</td>
</tr>
<tr>
<td>DDD / 1,000 inhabitants / year = 5,278</td>
</tr>
<tr>
<td>DDD / 1,000 inhabitants / day = 14.46</td>
</tr>
<tr>
<td>This calculated dose could then be used to compare consumption of this medicine to other hospitals, regions, or countries. The DDD can also be used to compare consumption in the same region over extended periods of time.</td>
</tr>
</tbody>
</table>

**Third Component: 20 minutes**

**VAs 11–14: VEN Analysis**

After explaining the VAs, discuss the following points briefly—

- Assignment to the “nonessential” category does not mean that a medicine is no longer on the system’s formulary or EML; it means only that it may be considered a lower priority than other medicines on the list.
- Some people find three categories difficult and prefer to use only two categories (e.g., vital and nonessential or essential and nonessential). This preference does not matter as long as the categories used are relevant and allow for clear prioritization among medicines.
- VEN classification should be done on a regular basis, for example, as the formulary or EML is updated or as public health priorities change.
- Monitoring of pharmaceutical orders should be more frequent and safety stocks should be higher for vital and essential medicines.
Slide 13 presents a short list of medicines for a primary health care facility. Ask the participants how they would classify some of the medicines listed. This brief discussion and interaction will help the participants perform a VEN analysis later in a session activity.

**Fourth component: 20 minutes**

*VAs 15–25: ABC Analysis*

After explaining the principles of ABC analysis and its uses, go through the steps of calculation in the example shown in VAs 19–24. ABC analysis will be completely new to doctors and any other participants who are not pharmacists, so clear presentation at this stage will help the practical activity that follows. Discuss how ABC analysis should be done regularly and that the use of the medicines consuming most of the budget should be regularly assessed in-depth.

**Fifth Component: 120 minutes**

*VAs 26: Activities*

**Activity 3. Performing a VEN Analysis**

*(30–40 minutes)*

The participants at each table should work as a group, representing a medicine selection committee. They should perform a VEN analysis on the medicines listed in worksheet 2 on performing an ABC analysis. At the end, all groups should list, in a plenary session, the categories into which they have placed each medicine—V, E, or N.

As the groups present, type the category assigned each medicine into a spreadsheet projected on an LCD projector. Alternatively, write on a transparency for an overhead projector or on a flipchart. Table 1 provides an abbreviated example of how your spreadsheet might look. A short discussion can then follow on why different groups have assigned the same medicine to different categories.

**Table 1. Sample Display of Participants’ Work by Group**

<table>
<thead>
<tr>
<th>Medicine Name</th>
<th>Group 1</th>
<th>Group 2</th>
<th>Group 3</th>
<th>Group 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Procaine penicillin</td>
<td>V</td>
<td>E</td>
<td>V</td>
<td>V</td>
</tr>
<tr>
<td>Paracetamol</td>
<td>E</td>
<td>E</td>
<td>E</td>
<td>N</td>
</tr>
<tr>
<td>Multivitamin</td>
<td>N</td>
<td>E</td>
<td>N</td>
<td>N</td>
</tr>
<tr>
<td>Normal saline</td>
<td>V</td>
<td>V</td>
<td>V</td>
<td>V</td>
</tr>
</tbody>
</table>

If time allows, ask the participants at the beginning of the group work to consider the following scenario; presentations from each group can be heard at the end.
Your hospital has received the new budget for the next annual procurement. It is $250,000—$46,046 less than what was used in the previous procurement presented in the ABC analysis on the worksheet. Having completed the VEN analysis—

- Which medicines would you assign a lower priority to for next year’s procurement?
- Would you reconsider any quantities? Why?
- Select a group representative to present your conclusions to the larger group.

If this activity is included, then the groups would present their answers to the class after they have listed the categories they have assigned to each medicine.

**Activity 4. Performing an ABC Analysis**  
(90 minutes)

The participants at each table should work as a group, representing a medicine selection committee. They should perform an ABC analysis using worksheets 2 and 3 on performing an ABC analysis.

They should answer the following questions—

- How many “A” items are there? “B” items? “C” items?
- What percentage of all items do “A” items represent? “B” items? “C” items?
- What is the value of consumption for each category?
- What percentage of the total consumption is represented by each category?
- What particular product(s) may need to be reviewed more closely by the DTC because of their consumption levels?

Use the set of Excel spreadsheets with the answers to explain the correct calculations and answers (annex 1).

Other issues for discussion include the following—

- Why are there so many disinfectants (20 percent of total)? Are they all essential?
- Why are there so many antibiotics?
- Why is dipyrone used, especially at this health care level?
- What should the DTC do concerning these problems?

**Activity 5. Performing an ABC/VEN Analysis Using Participants’ Data**

If time permits, use data that you have brought from your hospital, perform an ABC analysis and VEN analysis on all medicines that are available. Utilize computers available at the course or if your medicine list is short, manually perform the analysis.
Prepare a brief report on your analysis including the following—

- Number of medicines
- Top 10 medicines by value
- Number of medicines in “A” category
- List of all “V” medicine
- Recommendations concerning the formulary from this ABC/VEN analysis

**Sixth Component: 15 minutes**

**VAs 27: Summary**

Summarize key points. Emphasize that VEN and ABC analyses together can identify nonessential medicines that are consuming large parts of the budget. The use of these medicines should be further investigated in-depth.
Annex 1. ABC Analysis Answers—Results of Calculations and Ranking

<table>
<thead>
<tr>
<th>Product Description</th>
<th>Basic Unit</th>
<th>Unit Tender Price (USD)</th>
<th>Total Units</th>
<th>Value (USD)</th>
<th>Percentage of Total Value</th>
<th>Rank by Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ampicillin 125 mg/5 ml powder for suspension, 100 ml</td>
<td>Bottle</td>
<td>$0.5119</td>
<td>43,970.00</td>
<td>22,508.74</td>
<td>7.60</td>
<td>4</td>
</tr>
<tr>
<td>Benzoin, compound tincture</td>
<td>Milliliter</td>
<td>$0.0067</td>
<td>532,000.00</td>
<td>3,581.98</td>
<td>0.12</td>
<td>19</td>
</tr>
<tr>
<td>Benzylpenicillin 1 MU injection</td>
<td>Ampoule</td>
<td>$0.5276</td>
<td>144,000.00</td>
<td>75,971.19</td>
<td>25.66</td>
<td>1</td>
</tr>
<tr>
<td>Calcium gluconate 600 mg tablet</td>
<td>Tablet</td>
<td>$0.0032</td>
<td>995,000.00</td>
<td>3,171.46</td>
<td>1.07</td>
<td>22</td>
</tr>
<tr>
<td>Chlorhexidine 5% solution</td>
<td>Milliliter</td>
<td>$0.0073</td>
<td>2,504,000.00</td>
<td>18,347.98</td>
<td>0.62</td>
<td>5</td>
</tr>
<tr>
<td>Chlorhexidine/cetrimide 1.5% + 15% solution</td>
<td>Milliliter</td>
<td>$0.0064</td>
<td>1,552,000.00</td>
<td>9,964.24</td>
<td>3.37</td>
<td>6</td>
</tr>
<tr>
<td>Chloroquine 50 mg base/ml syrup</td>
<td>Milliliter</td>
<td>$0.0014</td>
<td>5,610,000.00</td>
<td>7,682.00</td>
<td>2.59</td>
<td>10</td>
</tr>
<tr>
<td>Chloroxylenol 5% solution</td>
<td>Milliliter</td>
<td>$0.0034</td>
<td>10,728,000.00</td>
<td>35,994.11</td>
<td>12.16</td>
<td>2</td>
</tr>
<tr>
<td>Chlorphenamine maleate 4 mg tablets</td>
<td>Tablet</td>
<td>$0.0009</td>
<td>555,000.00</td>
<td>498.33</td>
<td>0.17</td>
<td>29</td>
</tr>
<tr>
<td>Codeine phosphate 15 mg/5ml linctus</td>
<td>Milliliter</td>
<td>$0.0052</td>
<td>490,000.00</td>
<td>2,529.86</td>
<td>0.85</td>
<td>23</td>
</tr>
<tr>
<td>Co-trimoxazole 400 mg/80 mg tablets</td>
<td>Tablet</td>
<td>$0.0098</td>
<td>860,000.00</td>
<td>8,455.34</td>
<td>2.86</td>
<td>8</td>
</tr>
<tr>
<td>Dipyrone 500 mg/ml injection, 5 ml</td>
<td>Ampoule</td>
<td>$0.0898</td>
<td>65,000.00</td>
<td>5,836.29</td>
<td>1.97</td>
<td>14</td>
</tr>
<tr>
<td>Erythromycin 250 mg tablets</td>
<td>Tablet</td>
<td>$0.0350</td>
<td>262,000.00</td>
<td>9,175.24</td>
<td>3.10</td>
<td>7</td>
</tr>
<tr>
<td>Ferrous salts, equivalent to 60 mg iron tablets</td>
<td>Tablet</td>
<td>$0.0007</td>
<td>3,280,000.00</td>
<td>2,208.44</td>
<td>0.75</td>
<td>24</td>
</tr>
<tr>
<td>Fortified procaine penicillin 4 MU injection</td>
<td>Vial</td>
<td>$0.3026</td>
<td>100,000.00</td>
<td>30,259.14</td>
<td>10.22</td>
<td>3</td>
</tr>
<tr>
<td>Gentamicin sulfate 80 mg injection, 2 ml</td>
<td>Ampoule</td>
<td>$0.0628</td>
<td>130,800.00</td>
<td>8,209.19</td>
<td>2.77</td>
<td>9</td>
</tr>
<tr>
<td>Hydrogen peroxide 6% solution</td>
<td>Milliliter</td>
<td>$0.0016</td>
<td>632,000.00</td>
<td>1,005.64</td>
<td>0.34</td>
<td>25</td>
</tr>
<tr>
<td>Hyoscine N-butylbromide 10 g tablets</td>
<td>Tablet</td>
<td>$0.0174</td>
<td>380,000.00</td>
<td>6,597.83</td>
<td>2.23</td>
<td>12</td>
</tr>
<tr>
<td>Metronidazole 200 mg tablets</td>
<td>Tablet</td>
<td>$0.0052</td>
<td>1,080,000.00</td>
<td>5,575.78</td>
<td>1.88</td>
<td>15</td>
</tr>
<tr>
<td>Metronidazole 200 mg/5 ml suspension</td>
<td>Milliliter</td>
<td>$0.0055</td>
<td>900,000.00</td>
<td>4,985.00</td>
<td>1.68</td>
<td>17</td>
</tr>
<tr>
<td>Multivitamin tablets/capsules</td>
<td>Tablet</td>
<td>$0.0022</td>
<td>3,395,000.00</td>
<td>7,621.62</td>
<td>2.57</td>
<td>11</td>
</tr>
<tr>
<td>Nitrofurantoin 100 mg tablets</td>
<td>Tablet</td>
<td>$0.0055</td>
<td>860,000.00</td>
<td>4,710.53</td>
<td>1.59</td>
<td>18</td>
</tr>
<tr>
<td>Oxytocin 10 IU injection, 1 ml</td>
<td>Ampoule</td>
<td>$0.2468</td>
<td>14,500.00</td>
<td>3,578.06</td>
<td>1.21</td>
<td>20</td>
</tr>
<tr>
<td>Pheno-barbital 60 mg tablets</td>
<td>Tablet</td>
<td>$0.0047</td>
<td>135,000.00</td>
<td>636.40</td>
<td>0.21</td>
<td>27</td>
</tr>
<tr>
<td>Piroxicam 20 mg capsules</td>
<td>Capsule</td>
<td>$0.0099</td>
<td>97,000.00</td>
<td>958.27</td>
<td>0.32</td>
<td>26</td>
</tr>
<tr>
<td>Prednisolone 8 mg tablets</td>
<td>Tablet</td>
<td>$0.0079</td>
<td>65,000.00</td>
<td>510.64</td>
<td>0.17</td>
<td>28</td>
</tr>
<tr>
<td>Propranolol 40 mg tablets</td>
<td>Tablet</td>
<td>$0.0067</td>
<td>33,000.00</td>
<td>222.19</td>
<td>0.08</td>
<td>30</td>
</tr>
<tr>
<td>Pseudoephedrine 60 mg/triprolidine 2.5 mg tablets</td>
<td>Tablet</td>
<td>$0.0536</td>
<td>100,000.00</td>
<td>5,359.61</td>
<td>1.81</td>
<td>16</td>
</tr>
<tr>
<td>Vitamin B complex tablets</td>
<td>Tablet</td>
<td>$0.0025</td>
<td>1,440,000.00</td>
<td>3,555.48</td>
<td>1.20</td>
<td>21</td>
</tr>
<tr>
<td>Water for injection 10 ml</td>
<td>Ampoule</td>
<td>$0.0287</td>
<td>220,500.00</td>
<td>6,335.52</td>
<td>2.14</td>
<td>13</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
<td></td>
<td></td>
<td>296,046.08</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*USD = U.S. dollars
Session 8. Understanding the Problems Associated with Medicine Use—Qualitative Methods
SESSION 8. UNDERSTANDING THE PROBLEMS ASSOCIATED WITH MEDICINE USE—QUALITATIVE METHODS

Purpose and Content

Session 8 is intended to provide information on how members of the Drug and Therapeutics Committee (DTC) can investigate the underlying reasons for medicine use problems in their health systems. The discussion covers four qualitative methods used to understand and document how factors such as knowledge, economic incentives, or attitudes and beliefs affect medicine use.

Reviewing the consequences of inappropriate medicine use emphasizes the need to investigate the reasons for health provider-patient behavior. The following examples illustrate how varied inappropriate medicine use can be—

- Prescribing too many medicines for a patient
- Prescribing the incorrect dose or wrong medicine
- Use of antibiotics for patients with viral infections
- Overuse of narcotics for patients with minor pain
- Prescribing medicines when none is needed

Once a medicine use problem has been identified, the DTC must develop a plan, including interventions, to resolve or improve the specific problem. Before planning an intervention, however, DTC members should first understand the reasons for the behavior behind the problem. The DTC can use the methods discussed in this session to identify the causes underlying the problem behavior and then recommend the most appropriate interventions.

Objectives

After attending this session, participants will be able to—

- Identify four qualitative methods to investigate medicine use and prescribing behavior
- Understand the use of the qualitative methods to identify why documented medicine use problems occur
- Design a simple qualitative instrument to investigate medicine use

Outline

- Introduction
- Key Definitions
- Applying Qualitative Methods to Medicine Use Studies
- Description of Qualitative Methods
  - Focus Group Discussions
In-depth Interviews
Structured Observations
Questionnaires

Activities
Summary

Preparation and Materials

Read the Trainer’s Guide and the Participants’ Guide, and review the visual aids (VAs)

Instruct participants to read the Participants’ Guide the evening before the session presentation

Further Readings


Visual Aid Listing

1. Title slide
2. Objectives
3. Outline
4. Introduction (1)
5. Introduction (2)
6. Applying Qualitative Methods (1)
7. Applying Qualitative Methods (2)
8. Some Factors Influencing Medicine Use
9. Focus Group Discussions (1)
10. Focus Group Discussions (2)
11. Focus Group Discussions (3)
12. In-depth Interview (1)
13. In-depth Interview (2)
14. Structured Observation (1)
15. Structured Observation (2)
16. Structured Observation (3)
17. Structured Questionnaire (1)
18. Structured Questionnaire (2)
19. Structured Questionnaire (3)
Organization of the Session

Total time: 4 hours

Session 8 is designed to give the participants an overview of qualitative investigation and what is involved. It cannot give them the skills of a social scientist, but it can give them an appreciation of the skills needed (many participants might be unaware of all that is involved). The practical activities, in particular, are designed to give them sufficient skills for measuring the indicators of patient care such as observing the consultation to learn how long the consultation time was, or interviewing exiting patients to find out if they know their dosing schedules.

First Component: 10 minutes
VAs 1–8: Introduction

Introduce the session by reviewing the need for investigating the causes of irrational medicine use. Without knowing the causes of certain behaviors, one cannot design interventions to change them. VAs 6–7 give some examples of how qualitative investigation has been used to explain the reasons for medicine use problems that have been identified in quantitative studies. Brainstorm with the participants the different reasons for irrational use and then summarize them using VA8.

Before proceeding to the next section, ask who has experience with the various qualitative methods. Knowing this will help you adapt the level of detail needed in the rest of the presentation before the activities.

For each component on the different methods, discuss the content of the VAs even though it is not specifically mentioned in the section on the components (below).

Second Component: 15 minutes
VAs 9–11: Focus Group Discussions

Ask any participants who have conducted focus group discussions (FGDs) to share with the class what they did and what the difficulties were. Explain that FGDs can elicit a range of ideas, but that they cannot be used for providing quantitative data. Emphasize the need for a skilled moderator who can involve all participants but can keep the discussion focused.

Third Component: 15 minutes
VAs 12–13: In-depth Interviews

Ask any participants who have conducted in-depth interviews to share with the class what they did and what the difficulties were. Explain that this method allows the investigator to explore a subject in detail and learn relevant, subtle detail that may not previously have been expected.
Once again a skilled interviewer—one who understands the medicine use problem and the questions that need to be answered—must be used. An unskilled interviewer will not gather any unexpected information.

**Fourth Component: 15 minutes**  
**VAs 14–16: Structured Observations**

Ask any participants who have conducted structured observations to share with the class what they did and what the difficulties were. Explain that this method allows the investigator to observe actual behavior as opposed to stated behavior, which is often different. Discuss the “Hawthorne” effect, in which people change their behaviors when they are observed, and how this effect can be minimized through silent, nonthreatening observation in a quiet corner.

**Fifth Component: 15 minutes**  
**VAs 17–19: Questionnaires**

Ask any participants who have used structured questionnaires to share with the class what they did and what the difficulties were. Explain that this method allows the quantification of ideas and motives but that great skill is needed to design questionnaires that are clear and easily understood. Unclear questionnaires often result in biased or incorrect information being collected.

**Sixth Component: 160 minutes**  
**VAs 20–21: Activities**

These activities require a facilitator experienced in qualitative methods. The activities are as described in the review of the Participants’ Guide in this document.

**Activity 1. Deciding what questions to ask when using qualitative methods to determine the reasons for excessive antibiotic use in your hospital (60 minutes)**

*Instructions to the participants for activity 1*

The first step to developing qualitative instruments is to decide what questions you need to ask of which people to determine why a particular medicine use problem is occurring. For this activity, assume your hospital has very high antibiotic use level, and you want to investigate this through—

- Exiting patient interviews
- Observation of the consultation
- In-depth interviews with the prescriber

Using these three methods, discuss in your groups what questions you need to answer to determine the motivations underlying the problem of high antibiotic use. You may use indirect
questions and observation as well as direct questions depending on the type of instrument. After discussing in your group, you will be asked to present your findings.

*Notes for the facilitator for activity 1*

Explain that the participants at each table represent a DTC of a hospital where antibiotic consumption is high. When explaining the activity, emphasize that the different methods will examine the behavior of different target groups (patients, prescribers, patient-prescriber interaction) and that they may use indirect questions and observation as well as direct questions depending on the type of instrument. Remind them that all questions should be designed to answer the basic question of why antibiotic use is high. After discussing in the group, use a plenary session to brainstorm the questions that could be answered.

During the plenary session, constantly ask the participants whether the questions they want to ask are really going to tell them something about the reasons for excessive antibiotic use. It is useful to write on a flipchart the questions suggested for each method. If this activity is done well, it greatly helps the participants with activity 2, since they will be slightly more familiar with what questions and observations are useful and which are not.

Allow 30 minutes for group work and 30 minutes plenary discussion.

**Activity 2. Designing a qualitative instrument to investigate why antibiotic use is so high in a district hospital**  
(100 minutes)

*Instructions to the participants for activity 2*

For this activity, assume that not only is antibiotic consumption in your hospital high, but also according to a recent prescription audit, it is often inappropriate. Each group will develop one qualitative instrument to investigate the reasons underlying this antibiotic overuse. These instruments include—

- In-depth interview with prescribers
- Structured interviews with exiting patients
- Structured observation of the consultation

Each group will prepare a role-play based on the instrument. During preparation, each group will construct their instrument on two transparent sheets for the overhead projector using capital letters of sufficient size to be seen from the farthest point of the classroom. During the role play, one group member will show the transparencies of the instrument on the overhead projector and another group member will play the role of investigator (i.e., interviewer or observer). The other roles will be played by participants selected randomly from other groups by the facilitator. The transparencies will allow other members of the class to judge your instrument more effectively.
During each role-play, everyone will need to determine the following—

- Was the instrument clear and useful?
- Did the instrument detect an underlying motive for the excessive antibiotic use?

Notes for the facilitator for activity 2

During the group work, set up an area, with chairs and microphones, to conduct the role-plays so all participants may clearly see and hear what is going on and at the same see the instrument on the overhead projector. Usually, time allows for only three role-plays, one for each method. Therefore, randomly select one group to perform the role-play and show its instrument. After the role-play, another group that prepared the same instrument may be asked to comment. For each role-play, ask for volunteers to play the non-investigator roles, and allow someone from the group that prepared the instrument to play the investigator role (i.e., interviewer, observer).

During the role play, note whether the instrument was clear and useful and whether it detected any underlying motive. After getting comments from the participants, summarize what was learned about the behavior, if anything. At the end of all three role plays, ask the groups what they learned about the reasons for high levels of antibiotic use in the hospital. Triangulation of the findings from the different methods should be discussed and overall conclusions drawn.

Allow 60 minutes to prepare the instrument, 5 minutes per role-play, and 5 minutes for discussion of each role play (i.e., 30 minutes total for three role-plays), and 10 minutes to discuss the overall findings and triangulation of the results.

Activity 3 (Optional). Preparing interview questions for prescribers (Optional and if time allows—approximately 30 minutes required)

Instructions to the participants for optional activity 3

Develop a questionnaire to evaluate the use of antibiotics in a health care facility. In developing the questionnaire, participants should consider the following sample elements of study design because they may impact the appropriateness of the questions and how respondents comprehend the meaning of the questions.

- Prescriber target groups—one group or several groups, such as physicians, nurses, or others
- Health facilities—all hospitals, specialty hospitals, outpatient departments, primary health care clinics, others
- Geographic location of facilities
- General education and training levels of prescriber target groups
• Age groups of children

• All antibiotics prescribed for the specific health problems in children

*Notes for the facilitator for optional activity 3*

Instruct the participants to word the actual interview questions to ensure that data will be collected on *which* antibiotics the prescriber normally orders for the specified health problems by age group studied and also *why* the prescriber orders the antibiotics he or she does (e.g., standard or approved treatment, no time to review modern practices in the literature, or laboratory tests such as antibiotic sensitivity not available). See a sample interview questionnaire in annex 1. One group will be selected to interview another group using its prepared questionnaire. This role-play exercise will be useful to determine the kinds of information and problems that actually arise out of a questionnaire and interview.

*Seventh Component: 10 minutes*

*VA 22: Summary*

Summarize the key points. See annex 2 for additional summary items.
Annex 1. Sample Interview Questionnaire for Prescribers

1. Introduction of interviewer

2. Purpose of interview

I know that treatment of children in our health facilities often involves prescription of antibiotics. The Drug and Therapeutics Committee is interested in knowing more about the types of antibiotics prescribed and your views about antibiotic use.

3. Respondent’s background

What is your position in this clinic?
Your educational background?
Other training?
What is your age?

4. Clinical experience

On an average day, how many children do you treat?
What are the most prevalent health problems of children you treat in this clinic?

5. For each type of infection you encounter in children, please explain how you treat them.

Medicines prescribed
Instructions to mother
Care in clinic
Care at home
Other

6. When treating a child at the clinic, what factors determine whether you give an antibiotic?

Your personal experience
Your knowledge of peer practices
Mothers’ expectations
Knowledge of standard treatment guidelines for the health facility
Use of an essential medicines list or formulary
Results of laboratory tests

7. Where do you get medicine information to make the decision to prescribe medicines?

None available in clinic
Professional journals
Clinic treatment guidelines
Professional training in school
Continuing education classes (What is the frequency of these classes?)
8. Closing remarks

I appreciate your time and willingness to respond to the questions. Do you have anything you would like to add to what we discussed? Are there related topics that were not covered and for which you would like to provide some information?

Thank you
Annex 2. Four Qualitative Methods to Understand Reasons for Medicine Use Behavior

<table>
<thead>
<tr>
<th>Method</th>
<th>Characteristics</th>
</tr>
</thead>
</table>
| Focus group discussion| • Less than a two-hour discussion  
                          • Moderator leads discussion  
                          • Respondents have similar characteristics such as age, gender, social status  
                          • Discussion topics are predefined  
                          • Informal, relaxed ambience  
                          • Reveals beliefs, opinions, and motives |
| In-depth interviews   | • One-on-one extended interview  
                          • Questions are predetermined and open-ended  
                          • Often covers up to 30 topics  
                          • Reveals beliefs, attitudes, and knowledge |
| Structured observation| • Data collection instrument is structured  
                          • Observers are trained to blend into their surroundings  
                          • Observers are trained to record what they actually see  
                          • Useful for recording provider-patient interactions  
                          • Assesses actual behavior |
| Questionnaires        | • Questions are standardized with a fixed set of responses or options  
                          • Respondents are selected to represent the larger population  
                          • Useful for a large sample of respondents  
                          • Measures the frequency of attitudes, beliefs, and knowledge |
Session 9.
Strategies to Improve Medicine Use—Overview
SESSION 9. STRATEGIES TO IMPROVE MEDICINE USE—OVERVIEW

Purpose and Content

Session 9 is designed to provide information on how members of the Drug and Therapeutics Committee (DTC) can apply interventions to resolve medicine use problems. Considered to be one of the most important functions of a DTC, implementing appropriate strategies to improve medicine use will affect improved health outcomes and decrease cost.

Strategies that will be discussed include the following educational, managerial, and regulatory methods—

- In-service education programs
- Pharmaceutical bulletins and newsletters
- Formulary manual
- Face-to-face communication
- Standard treatment guidelines (STGs)
- Audit and feedback (drug use evaluations [DUEs])
- Clinical pharmacy programs
- Formulary management, including medicine selection
- Medicine restrictions and control
- Medicine registration and professional licensing

Session 9 comprises an overview of this subject; a more detailed breakdown of STGs and DUEs is provided in later sessions.

Objectives

After attending this session, participants will be able to—

- Identify effective strategies to improve medicine use based on an understanding of the factors underlying medicine use problems
- Choose an appropriate strategy for improving medicine use based on an identified problem
- Understand the importance of educational, managerial, and regulatory interventions in promoting rational use of medicines

Outline

- Key Definitions
- Introduction
- Methods to Improve Medicine Use
  - Educational
Managerial
  Regulatory

- Activity 1
- Summary

**Preparation and Materials**

- Read the Trainer’s Guide and the Participants’ Guide, and review visual aids (VAs).
- Instruct participants to read the Participants’ Guide the evening before the session presentation.

**Visual Aid Listing**

1. Title slide
2. Objectives
3. Outline
4. Key Definitions
5. Introduction
6. Consequences of Irrational Use of Medicines (1)
7. Consequences of Irrational Use of Medicines (2)
8. Changing a Medicine Use Problem
9. Strategies to Improve Medicine Use
10. Educational Methods: To Persuade and Inform
11. Printed Educational Materials (1)
12. Printed Educational Materials (2)
13. Printed Educational Materials (3)
14. Face-to-Face Educational Methods (1)
15. Face-to-Face Educational Methods (2)
16. Face-to-Face Educational Methods (3)
17. Face-to-Face Educational Methods (4)
18. Effects of Opinion Leader
19. Face-to-Face Educational Methods (5)
20. Impact of Patient-Provider Discussion Groups
21. Sites for Face-to-Face Education
22. Strategies to Improve Medicine Use
23. Managerial Methods: To Structure and Guide Decisions
24. Standard Treatment Guidelines
25. Randomized Controlled Trial in Uganda
26. Audit and Feedback
27. Clinical Pharmacy Programs
28. Pharmaceutical Restrictions and Control
29. Controlling Pharmaceutical Promotion
30. Avoiding Perverse Economic Incentives
31. Improving Prescribing by Changing Financial Incentives from User Fees
32. Polypharmacy and Antibiotic Use
33. Injection and Vitamin or Tonic Use
Session 9. Strategies to Improve Medicine Use—Overview

34. Treatment Cost and Compliance with STGs
35. Strategies to Improve Medicine Use
36. Regulatory Methods: To Restrict or Limit Decisions
37. Choosing an Intervention (1)
38. Choosing an Intervention (2)
39. Combined Intervention Strategy
40. Impact of Training on Use of Diarrhea Treatment Algorithm in Three Mexican Settings
41. Review of 30 Studies in Developing Countries
42. Activity 1. Case Study: Generic and Brand Name Antibiotics
43. Summary (1)
44. Summary (2)

Organization of the Session

Total time: 3 hours

Session 9 is designed to give the participants an overview of the different strategies that can be used to promote rational use of medicines. The session should be participatory, drawing on the experiences of participants in their home countries. Emphasize that effective interventions can be chosen only if the factors underlying irrational use of medicines are known and addressed by the intervention.

First Component: 15 minutes
VAs 1–9: Introduction

Introduce the session by briefly explaining the objectives and outline of the session and reviewing with the participants the consequences of irrational use of medicines. Then ask the participants what the first two steps are to promote more rational use of medicines. Draw out of them that the first step is to measure medicine use and the second step is to investigate the factors underlying medicine use problems. Then summarize the process of changing a medicine use problem (VA 8). Following this, explain the types of strategies to improve medicine use (VA 9).

Second Component: 30 minutes
VAs 10–21: Educational Methods

Explain that educational interventions aim to inform or persuade people. Ask the participants what kinds of educational strategies they have used in their home countries. Ask what form of in-service training takes place. Then review the various kinds of educational strategies summarized in the VAs. Discuss the advantages and disadvantages of printed materials versus face-to-face education. Explain the various examples of different educational interventions.

Third Component: 30 minutes
VAs 22–34: Managerial and Economic Methods

Explain that managerial interventions aim to structure or guide decisions. Ask the participants
what kinds of managerial strategies they have used in their home countries. Then review the various kinds of managerial strategies summarized in the VAs paying special attention to the following points—

- Guidelines with training and supervision can have a considerable impact, but guidelines alone have little impact (VA 25). Do not spend much time on advantages and disadvantages of STGs because they will be covered in session 10.

- Some participants may not be familiar with certain terminology, which should be explained (e.g., structured order forms and automatic stop orders).

- When discussing generic substitution under clinical pharmacy programs, emphasize the importance of getting prior agreement from the clinicians and explain how getting this agreement will depend on ensuring the quality of the generic medicines.

- No prescriber is exempt from the influence of pharmaceutical promotions. The DTC might deal with pharmaceutical promotion by holding meetings between prescribers and medical representatives where a balanced discussion can be encouraged. This approach would be dependent on receiving advanced notice of which medicine will be discussed so that the pharmacist (or other medical staff member) can investigate that particular medicine in the independent literature before the meeting.

- Many participants will be unfamiliar with economic incentives and disincentives, so VA 30 on avoiding perverse financial incentives will need careful explanation. The example in VAs 31–34 will also need to be carefully explained, in particular, the difference between flat and item fees. With the flat fee, patients paid the same amount for however many medicines they were prescribed in whatever quantity—so why have fewer medicines for the same price as for more medicines? (Flat fees are a positive incentive for polypharmacy, i.e., negative incentive for rational use of medicines.) With the item fee, patients paid a fixed fee for each medicine (covering a full course)—the more medicines you have, the more you pay. (Item fees are a positive incentive for not taking medicines unnecessarily.)

**Fourth Component: 30 minutes**

**VAs 35–41: Regulatory Methods and Combined Intervention Strategies**

Explain that regulatory interventions aim to restrict or limit decisions. Then brainstorm with the participants about what kinds of regulatory strategies are used in their countries. Summarize the regulatory strategies that DTCs can follow (VA 35–36).
When discussing how to choose interventions, emphasize that a package of interventions is better than a single intervention alone (VAs 37–38). When explaining the example of a combined intervention strategy in Mexico (VAs 39–40), bring out the points that the intervention was—

- Very effective but localized when conducted by the highly trained physician researchers
- Less effective (but still effective) and much more widespread when conducted by the less trained “health coordinators”

In describing the review of intervention studies (VA 41), bring up the point that printed materials alone are not effective and that face-to-face educational interventions have variable results. Interventions involving group process, supervision and audit, essential medicine programs and supply, and economic strategies have a moderate to sizable impact.

**Fifth Component: 60 minutes**  
**VA 42: Activity**

The participants should work in table groups. Allow 25 minutes for discussion in groups and then 20 minutes for discussion in plenary. For the plenary discussion, invite one table at random to answer each question (i.e., three different groups will each present answers to one of the questions). Possible answers are provided in italics below the questions in the activity. Once a group has presented an answer allow a few questions from other groups.

**Activity 1. Case Study: Generic and Brand Name Antibiotics**

For this activity, assume that your DTC has noticed an increased use of certain brand name antibiotics for treating adult infections in the outpatient clinic. Less expensive generic products have recently been out of stock, but are now available. Health care providers are reluctant to use the generic products because of a lack of confidence in their quality.

The STGs available for these infections are not specific and therefore allow for a wide selection of different antibiotics. The costs of the brand name medicines are approximately 50 percent higher than similar generic medicines available on the formulary. Most physicians and pharmacists agree that the brand name products seem to work better and that patients are less likely to return to the clinic for follow-up visits.

The hospital has significant budget problems and the administration is looking for ways to decrease cost without compromising quality. The administration has also had many patient complaints about poor-quality medicines, especially generic products.

- What are the major pharmaceutical management issues in this case presentation?
  - Use of brand name medicines
  - STG not well developed and not followed
• Perception that certain medicines work better than others, even though no evidence supports this perception; individual opinions used in making decisions

• Education levels of health care staff

• Clearly define the beliefs and motivations of the prescribers that may contribute to the observed behavior.

• Belief that brand name medicines have better quality

• Financial interests for some prescribers to use certain medicines

• Once the problem has been defined, what kinds of strategies or interventions would you use to improve pharmaceutical therapy in this hospital and lower medicine cost?

• Define the quality of medicines both generic and brand name products (i.e., retrieve evidence to show that the bioavailability of the products is equivalent).

• Use generic medicines of high quality if possible to reduce health care cost.

• Introduce generic substitution provided the DTC is sure of the quality of the generic medicines and gets prior agreement from the clinicians

• Purchase medicines from pre-qualified and reputable suppliers

• Educate physicians and pharmacists about generic medicine issues

• Educate patients

• Revise STGs

Sixth Component: 15 minutes
VA 43–44: Summary

Summarize the key points. Restate how interventions may be educational, managerial, or regulatory, and how combinations of interventions that address the factors underlying irrational use are most likely to be effective.
Session 10.
Standard Treatment Guidelines

Note: This session is based on the World Health Organization and the International Network for Rational Use of Drugs. *Promoting Rational Drug Use—Standard Treatments* (PowerPoint and Study Guides).
http://mednet3.who.int/prduc/rducd/TOC.htm
SESSION 10. STANDARD TREATMENT GUIDELINES

Purpose and Content

Experience has shown that even when pharmaceutical supply is based on an approved formulary or essential medicines list, ample opportunity exists for ineffective, unsafe, or wasteful prescribing. Standard treatment guidelines (STGs) list the preferred pharmaceutical and nonpharmaceutical treatments for common health problems experienced by people in a specific health system. As such, they represent one approach to promoting therapeutic effective and economically efficient prescribing.

When implemented effectively, an STG offers advantages to patients (e.g., it provides more consistency and treatment efficacy), providers (e.g., it gives an expert consensus, quality of care standard, and basis for monitoring), supply managers (e.g., it makes demand more predictable and allows for prepackaging), and health policy makers (e.g., it provides focus for therapeutic integration of special programs and promotes efficient use of funds). Effective implementation, however, is perhaps the greatest challenge in introducing STGs.

Objectives

After attending this session, participants will be able to—

- Understand the importance of an STG in promoting rational use of medicines
- Describe the implementation of a guideline in a hospital or clinic
- Develop an STG for a disease or medical condition

Outline

- Key Definition
- Introduction
- Advantages of STGs
- Disadvantages of STGs
- Establishing and Implementing a Guideline
- Activities
- Summary

Preparation and Materials

- Read the Trainer’s Guide and Participants’ Guide, and review the visual aids (VAs).
- Instruct participants to read the Participants’ Guide the evening before the session presentation.
• Ask your hosts and participants to bring to the class STGs from their own countries and institutions. During the session, display these STGs on a table for all participants to look at.

• Read relevant reference materials concerning the prophylaxis for cesarean section or the treatment of childhood pneumonia if you intend to do activity 1. (If at all possible, do activity 1—particularly if a field visit to a local hospital is included in the course.) Usually, time allows for making only one guideline during the session, and cesarean section prophylaxis is preferred because it is easier to find sufficient cases during the field visits to local hospitals.

• If possible, distribute relevant reference materials (e.g., most recent Cochrane Library systematic review, locally available articles, and treatment guidelines) to the participants at least one day in advance so they have a chance to read the evidence concerning cesarean prophylaxis.

• Provide an overhead projector, transparencies, and nonpermanent marker pens for group presentations of their guidelines.

• Study the forms from previous courses used to measure STG compliance because these will give an idea of what information must be included in such forms and what to extract from the participants during activity 1. (A selection of previous forms to measure STG compliance is attached to this Trainer’s Guide as annexes 1 and 2).

Further Reading


Visual Aid Listing

1. Title slide
2. Objectives
3. Outline
4. Key Definition
5. Introduction
6. Advantages for Health Care Providers (1)
7. Advantages for Health Care Providers (2)
8. Advantages for Health Care Officials
10. Advantages for Patients
11. Disadvantages
12. Establishing the Guideline (1)
13. Establishing the Guideline (2)
14. Establishing the Guideline (3)
15. Establishing the Guideline (4)
16. Establishing the Guideline (5)
17. Establishing the Guideline (6)
Organization of the Session

Total time: 3–4 hours

The intention of session 10 is to introduce participants to STGs and to move their understanding of these manuals from the *product* to the *process*. The key learning objective of this session is to persuade participants of the importance of the process in producing these STGs. Too often when STGs are produced, they are not used because the end users either were not involved or do not respect or accept the process that was used to produce the materials. A key activity in this session is to make a guideline for later use in the field trip to a local hospital. If time allows, the fictitious Pagalia case study should also be done because it allows discussion of the development process in broader context. Allow enough time for adequate discussion for at least the first activity and, if possible, the second one also. Therefore, the presentation should not take longer than one hour. The trainer should be experienced in facilitating plenary discussion and in critical appraisal of the literature and interpretation of evidence to complete successfully the first activity.

First Component: 15 minutes
VAs 1–11: Introduction

Start the session by explaining the objectives and outline of the session. Then ask some participants to describe their experiences with STGs. Ask the participants why we need STGs and what their advantages and disadvantages are. The advantages and disadvantages of the STGs may then briefly be summarized.

Second Component: 40 minutes
VAs 12–19: Establishing and Implementing the Guideline

Ask whether any of the participants have had experience developing STGs. If so, invite two or three people to describe what they did. Explain the steps needed to establish STGs using the VAs. Emphasize the point that STGs are often not used because of inadequate development and implementation processes. If possible, refer back to the participants’ own experiences (discussed earlier in the session) to draw out the importance of process during development and implementation.
Third Component: 2–3 hours
VA 20: Activities

Activity 1. Developing a Guideline for Use during the Field Trip
(2 hours)

This activity is designed to give participants hands-on experience in (a) developing a guideline in a participatory way using evidence and (b) developing a tool to measure compliance with their own guideline.

Group work to develop a guideline (30 minutes)—The participants should work in table groups to develop a guideline for either prophylaxis of uncomplicated cesarean section or treatment of childhood pneumonia. (Cesarean section is recommended because the guideline is likely to be less complicated to develop and it will normally be easier to find cases during the field visit to hospitals.) Each group should prepare a short presentation on a transparency to show the class on the overhead projector.

Presentation of the group work to the class (20 minutes)—At the end of the group work, choose two or three groups randomly to present their guideline to the class (allowing each group no more than five minutes). Then ask the other groups to comment (allowing no more than two or three minutes per group). Draw out of the subsequent discussion points of agreement and disagreement among the groups, and record these points on a flipchart. (A member of the class or another assistant facilitator might be asked to do the recording.)

Plenary discussion to reach a class consensus on the guideline (20 minutes)—Facilitate a plenary discussion to reach a class consensus on the points of difference between the groups, referring to the relevant articles. If the participants have already read the articles, reaching consensus will be much easier.

Designing a form to measure STG compliance in plenary (50 minutes)—This section needs two facilitators, one to facilitate the discussion and the other to type into the computer the questions to be asked as participants suggest them. The computer output should be immediately available for all the class to see through an LCD projector. In this way, a form to measure STG compliance may be designed in class. The facilitators should already be familiar with what type of information must be included in such a form from having studied annexes 1 and 2 (previous forms used). At the beginning of this activity, explain that the class is now going to design a form to measure compliance with their STG, and that they will use this form during the field trip.

Following the class, the form must be finalized by the facilitators and photocopies made, 15 copies per group, for use by the groups during the field trip. Examples of collection forms are provided in annexes 1 and 2.
(1 hour)

From the World Health Organization and the International Network for Rational Use of Drugs’
Promoting Rational Drug Use)

Designing and implementing STGs that truly improve prescribing practices is challenging. The
task requires not only an understanding of the issues involved in each step of the process, but
also sufficient commitment, cooperation, financial resources, and effort. This case study is
intended to stimulate thinking and discussion about some of the critical issues in the effective
introduction of STGs in a health care system.

Allow 30 minutes for group work and 30 minutes to discuss the questions, which may be
presented by the groups. Choose one group randomly to answer one question. Instruct the
participants as follows (possible answers are in italics below):

Read the case study in the Participants’ Guide and be prepared to discuss the following questions
in your groups.

- How were the Pagalia STGs developed and implemented?

  These STGs were developed in a nonparticipatory way. They are not user-friendly and
  were developed by people who had no training in STG development. The STGs were—

  - Developed by four doctors from preventive health services, one person from the
    Ministry of Health, three people from faculty of medicine, and one outside
    member

  - Written for 100 conditions developed with lots of reference material included

  - Put into a manual that is not quite pocket-sized, but has the Ministry of Health
    logo

  - Distributed but not incorporated into curricula of medical schools and other
    health institutions

- How have the treatments affected prescribing thus far?

  STGs have not affected prescribing so far. Two surveys done show—

  - Underuse of recommended antibiotics and overuse of non-recommended ones

  - Over-prescribing for common gastroenteritis where only oral rehydration salts
    are recommended

  - Overuse of antibiotics for influenza and acute upper respiratory tract infections

  - More use of vitamins than oral rehydration salts
Use of tetracycline in children younger than five years

Lack of availability of some of the recommended medicines

Should a second edition of the STGs be prepared at this time? Is it the best use of time and money?

A second edition should be developed only if a new process, which is more participatory, is undertaken.

What should be done? What should be proposed to Mr. Domingo at the next meeting?

Develop a second edition using a more participatory method with an official launch and accompanied by training that will accomplish the following—

- Ask end-users why they don’t use the first edition of the STGs and address these reasons in the development process for a second edition
- Involve more end-users (people who will use the guideline) in the development process
- Use evidence in developing the guidelines.
- Concentrate on fewer diseases
- Include only the most essential information and not large amounts of reference material, which end-users may find difficult to read.
- Present the material in a simple, clear format in a pocket-sized manual
- Officially launch the second edition from the Ministry of Health
- Promote and advertise the guidelines widely and frequently
- Get agreement for inclusion of the STGs in the curricula of medical schools, other health training institutions, and in-service medical education

What other pharmaceutical management problems exist in this case study and how would you deal with them?

Lack of availability of recommended medicines

- Negotiate with the relevant department for the supply of recommended medicines and discontinue the purchase and stock of others

STGs not included in curricula of training institutions for health staff
o Negotiate with the Ministry of Education for inclusion of the STGs in the curricula of medical schools and other training institutions.

Fourth Component: 5 minutes
VAs 21–22: Summary

Summarize the key points of the session.
Annex 1. Sample Form 1

Cesarean Section Prophylaxis: Patient Record Review  
(form for review of record for individual cases)

September 7, 2004

Drug and Therapeutics Committee–Training of Trainers Course, Kampala, Uganda

Hospital designation (abbreviation) ______________

Patient designation (case number for survey) _______

Date of admission ________

Date and time of cesarean section ____________          Time of cord clamping ________

Elective ____       Non-elective _____

Allergy to beta-lactam antibiotics                 Yes ___     No ___        Not recorded ___

Antibiotic treatment during 1 week before cesarean section      Yes ___    No ___

Fever (T>38.5) before cesarean section        Yes ___     No ___

Obstetrician (initials) ______

Antibiotic prophylaxis for cesarean section:

Antibiotic #1  Date and time of first dose ______________     last dose ____________
Drug, dose, interval, and route _________________________________

Antibiotic #2  Date and time of first dose ______________     last dose ____________
Drug, dose, interval, and route _________________________________

Antibiotic #3 Date and time of first dose ______________     last dose ____________
Drug, dose, interval, and route _________________________________
Classification:

Eligible for standard prophylaxis*  Yes ___  No ___
Received standard prophylaxis*  Yes ___  No ___

*Eligibility for standard prophylaxis = no allergy to beta-lactam antibiotics, no antibiotic treatment during previous week, and no fever (amnionitis). Standard prophylaxis regimen = single dose of ampicillin 1 gram (g) intravenous (IV) or cefazolin 1 g IV given within 2 hours before incision or immediately after cord clamping.

Characteristics of non-standard antibiotic prophylaxis regimen (record this if the patient was eligible for standard prophylaxis but did not receive it):

Antibiotic(s) started more than 2 hours before incision:  Yes ___  No ___
Antibiotic(s) started more than 5 minutes after cord clamping:  Yes ___  No ___
More than one dose of prophylactic antibiotic(s) given:  Yes ___  No ___
Antibiotic other than cefazolin or ampicillin given to patient who is not allergic to beta-lactam antibiotics:  Yes ___  No ___
Ampicillin or cefazolin given in dose other than 1 g:  Yes ___  No ___
Annex 2. Sample Form 2

Summary Data for Cesarean Section Prophylaxis
(based on the records of 15 cases reviewed during the field visit)

September 7, 2004

Drug and Therapeutics Committee–Training of Trainers Course, Kampala, Uganda

Hospital designation (abbreviation) _______

Number of patient records evaluated _____

Number of patients eligible for standard prophylaxis (no allergy to beta-lactam antibiotics, no antibiotic treatment during the previous week, and no amnionitis) _____

Number of patients who received standard prophylaxis _____

Non-standard regimens administered to patients eligible for standard prophylaxis:

<table>
<thead>
<tr>
<th>No. of Patients</th>
<th>Antibiotic Regimen</th>
<th>Days of Administration</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Deviations from standard prophylaxis (enter number of patients):

Initial dose >2 hrs before incision _____ Initial dose >5 min after cord clamping _____

>1 antibiotic dose given _____ Antibiotic other than ampicillin or cefazolin given _____

Ampicillin or cefazolin dose other than 1 g given _____

Number of physicians ordering non-standard prophylaxis _____
Summarize cesarean section prophylaxis at the hospital, in terms of number of antibiotics, antibiotic spectrum, time of onset of prophylaxis, and duration of prophylaxis:

[Blank lines]

Characterize the magnitude of the problem of inappropriate cesarean section prophylaxis:

[Blank lines]

What might be the consequences to individual cesarean section patients and to the hospital?

[Blank lines]

List steps that the DTC can take to improve cesarean section prophylaxis:

1. ________________________________________________________________

2. ________________________________________________________________

3. ________________________________________________________________

4. ________________________________________________________________

5. ________________________________________________________________
Drug and Therapeutics Committee
Training Course

Session 11.
Drug Use Evaluation
SESSION 11. DRUG USE EVALUATION

Purpose and Content

Session 11 provides information on the concept of drug use evaluation (DUE), a quality assurance method that is used worldwide, especially in North America and Europe, and that has been shown to be effective in identifying medicine use problems and as a method to improve medicine use. A broad-based, ongoing, and systematic DUE program is invaluable in improving outcomes for patients in hospitals and clinics.

Objectives

After attending this session, participants will be able to—

- Understand the concept of DUE
- Understand the process for implementing and performing a DUE
- Discuss the use of a DUE for improving pharmaceutical therapy
- Prepare criteria and thresholds for a DUE

Outline

- Introduction
- Definitions
- The Need for DUE
- Stepwise Approach to Performing a DUE
- When DUEs Go Wrong
- Activity 1
- Summary
- Annexes 1 and 2

Preparation and Materials

- Read the Trainer’s Guide and the Participants’ Guide, and review the visual aids (VAs).

- Instruct participants to read the Participants’ Guide the evening before the session presentation.

- Read relevant reference materials concerning the medicine chosen for the DUE in activity 1. If at all possible, do activity 1—particularly if a field visit to a local hospital is included in the course. Developing criteria and thresholds is possible for only one medicine during the session. Likely medicines suggested from previous courses include ciprofloxacin, gentamicin, third-generation cephalosporins, and cesarean section antimicrobial prophylaxis.

- If possible, distribute relevant reference materials on the selected medicine to the participants at least one day in advance so that they have a chance to read about the medicine. (These
reference materials can be obtained locally and could include relevant sections from the British National Formulary, the World Health Organization model formulary, local national formularies.)

- Gather equipment and materials, including an overhead projector, transparencies, and nonpermanent marker pens for group presentations of their guidelines.

- Study the forms from previous courses used to undertake a DUE because they will give you an idea of what information must be included in such forms and what to extract from the participants during activity 1. (See annex 1 and 2.)

**Visual Aid Listing**

1. Title Slide  
2. Objectives  
3. Outline  
4. Key Definition: Drug Use Evaluation  
5. Introduction  
6. Indicators Suggesting Need for DUE  
7. The Need for DUE: Examples  
8. The Need for DUE in Malaysia  
9. The Need for DUE in India  
10. Objectives of a DUE  
11. Stepwise Approach to DUE  
12. Step 1. Establish Responsibility  
13. Step 2. Develop the Scope of Activities  
14. Step 3. Establish Criteria  
16. Ciprofloxacin DUE Criteria and Thresholds (1)  
17. Ciprofloxacin DUE Criteria and Thresholds (2)  
18. Step 5. Collect Data and Organize Results  
19. Step 6. Analyze Data  
20. Step 7. Develop Recommendations and a Plan of Action  
21. Step 8. Conduct DUE Follow-Up  
22. When DUEs Go Wrong  
23. Activity 1  
24. Summary (1)  
25. Summary (2)

**Organization of the Session**

*Total time: 4 hours*

The goal of session 11 is to introduce participants to DUE and give them the skills to conduct a DUE. The key activity in this session is to make criteria and thresholds to conduct a DUE during
the field trip to the local hospital. Since the activity is long, the presentation should not take more than 1 hour.

To teach this session and successfully complete activity 1, the trainer should be experienced in facilitating a plenary discussion, conducting a critical appraisal of the literature, and interpreting evidence.

First Component: 15 minutes
VAs 1–9: Introduction and Definitions

Introduce the session by briefly reviewing the objectives and session outline. DUE will be new to many participants, so explain it clearly and slowly. Note that DUE is the same as drug use review or medication use review. You may ask some participants to share their experiences of DUE and why they chose the medicine upon which they conducted a DUE. After this discussion, review the indicators and examples suggesting the need for a DUE.

Second Component: 30 minutes
VAs 10–22: Objectives and Steps of a DUE

Because many participants are unfamiliar with DUE, the objectives and each step must be explained clearly. Make sure that all the participants understand what criteria and thresholds are, if necessary by giving examples.

One way of explaining criteria and thresholds is to pose the following questions—

- What is the correct dose of co-trimoxazole for an adult, nonpregnant woman with an uncomplicated urinary tract infection? (An answer of, say, 960 milligram (mg) twice daily would be the criteria for the daily dose.)

- Would you be happy if 70 percent of patients were given the correct dose? If not, what percentage would you be happy with? (An answer of, say, 90 percent of patients would be the threshold below which one would feel the need to do something to correct the problem.)

Emphasize the importance of deciding criteria and thresholds and the process for collecting the data with the clinicians whose prescribing will be assessed. If the clinicians are not involved, they will not accept the findings.

End this section by asking the participants what can go wrong in a DUE and then summarize the major problems (VA 21).

Third Component: 2 hours
VA 23: Activity 1
Activity 1. Developing Criteria and Thresholds for Conducting a DUE

Activity 1 is designed to give participants hands-on experience of (a) developing DUE criteria and thresholds in a participatory way using evidence and (b) developing a tool to measure compliance with their own DUE criteria. (See annex 1 and 2 for examples of DUE data collection forms.)

Group work to develop a criteria and thresholds—30 minutes

The participants should work in table groups to develop DUE criteria and thresholds for a medicine chosen in advance by the facilitator. If possible, choose an antibiotic because finding cases on antibiotics should normally be easy during the field visit to hospitals. Each group should prepare a short presentation on a transparency to show the class on the overhead projector.

Presentation of the group work to the class—30 minutes

At the end of the group work, choose two or three groups randomly to present their criteria to the class. Each group should not take more than five minutes to present. Then ask the other groups to comment, allowing no more than two to three minutes per group. From the ensuing discussion, draw out points on which the groups agree and disagree, and record these points on a flipchart. Alternatively, ask a member of the class or another assistant facilitator to summarize on a flipchart the points of agreement and disagreement.

Plenary discussion to reach a class consensus on the criteria—30 minutes

Facilitate a plenary discussion to reach a class consensus on the points of difference between the groups, referring to the relevant literature as you direct the discussion. If the participants have already read the literature provided, reaching consensus will be much easier.

Designing a form to measure compliance with criteria in plenary—30 minutes

This section requires two facilitators: one to facilitate the discussion and the other to type into the computer the questions to be asked as participants suggest them. The computer output should be immediately available for the class to see on an LCD projector. In this way, a form to measure compliance with the criteria may be designed in class. The facilitators should already be familiar with what type of information must be included in such a form from having studied the forms previously used (annexes 1 and 2). At the beginning of this activity, the facilitator should explain that the class is now going to design a form to measure compliance with their criteria and that they will use this form during the field trip. Explain that compliance with their thresholds will be ascertained in group work after the field trip through analysis of the forms recorded for each case receiving the antibiotic.

Following the class, the form must be finalized by the facilitators and 15 photocopies made for each group to use during the field trip.
Fourth Component: 15 minutes
VAs 24–25: Summary

Summarize the key points, emphasizing the importance of involving the prescribers in the process.
Annex 1. Sample Form 1 for Activity 1

Ciprofloxacin Due: Individual Patient Record Review

September 7, 2004

Drug and Therapeutics Committee–Training of Trainers Course, Kampala, Uganda

Hospital designation (abbreviation) _____

Patient designation (case number for survey) _______ Age ____ Gender _____

Department ______________

Days of ciprofloxacin treatment _____ Ciprofloxacin dose and route _______________

Other antibiotics given concurrently with ciprofloxacin ___________________________

Infection for which ciprofloxacin was given (infection diagnosed to be present by treating doctors)

Hospital acquired pneumonia ____ Community-acquired pneumonia ____

Intra-abdominal infection ____ Surgical site infection ____ Sepsis ____

Meningitis ____ Skin/soft tissue infection ____ Dysentery/severe diarrhea ____

Enteric fever ____ Other (specify) ________________________________

Indeterminate (inadequate information in patient record) ____

Results of cultures taken during four days prior to the start of ciprofloxacin therapy

<table>
<thead>
<tr>
<th>Specimen site or type</th>
<th>Pathogen(s)</th>
<th>Susceptibility to ciprofloxacin (Y/N)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Assessment of renal function during treatment

Week 1 serum creatinine/blood urea nitrogen (BUN) _____/_____ not done ___

Week 2 serum creatinine/BUN _____/_____ not done ___
Classification of ciprofloxacin use

Indication appropriate* (proven or suspected serious infection caused by aerobic gram-negative bacilli) ___
Indication inappropriate** (community-acquired pneumonia, meningitis, streptoccal infection, or Staphylococcus aureus infection) ____
Indication indeterminate ___

Dose appropriate (500–750 mg per os [po—by mouth] bis in die [bid—twice daily] or 400 mg intravenous (IV) bid for normal or minimally impaired renal function, or dose 500–750 mg po or 400 mg IV per 24 hours for moderate or severe renal impairment [creatinine ratio > 2–3 or BUN > 40–50]) _______
Dose inappropriate _____
Dose indeterminate (no laboratory test performed to assess renal function) ____

Duration appropriate (1–2 weeks for infection other than prostatitis, osteomyelitis, or endocarditis) ___
Duration inappropriate (>2 weeks except prostatitis, osteomyelitis, or endocarditis) ___
Duration indeterminate ___

Regimen appropriate (in the case of mixed infections, additional antibiotic added to cover anaerobes and gram-positive cocci; no 3rd generation cephalosporin or aminoglycoside antibiotic given concomitantly) ___
Spectrum inappropriate ___
Spectrum indeterminate ___

* Appropriate indications
Clinical diagnosis: hospital acquired pneumonia, urinary tract infection, enteric fever, dysentery

Clinical diagnosis, if ciprofloxacin is given in combination with another antibiotic, such as clindamycin, metronidazole, or ampicillin-sulbactam: sepsis, surgical site infection, intra-abdominal infection, skin/soft tissue infection

Microbiological diagnosis: positive culture for aerobic gram-negative bacillus from likely site of infection

** Inappropriate indications
Clinical diagnosis: community acquired pneumonia, meningitis, sinusitis

Microbiological diagnosis: streptococcal or staphylococcal infection
Annex 2. Sample Form 2 for Activity 1

Hospital Summary Data for Ciprofloxacin Due

September 7, 2004

Drug and Therapeutics Committee–Training of Trainers Course, Kampala, Uganda

Hospital designation (abbreviation) ______   Number of patient records reviewed ______

Patient characteristics

Mean age ____    Age range _______    No. (%) male ____    No. (%) female____
No. (%) on specified department: Medicine ________             Surgery _________
Ob-Gyn __________     Other (specify) _________________________________

Ciprofloxacin treatment

Mean days of treatment _____        No. patients treated <1 week ____
No. patients treated 1–2 weeks _____     No. patients treated >2 weeks _____
No. of patients receiving concomitant antibiotics ______
No. patients receiving concomitant gentamicin or third generation cephalosporin ______

Indication for ciprofloxacin (enter number of patients with each diagnosis)

Hospital acquired pneumonia ____   Community acquired pneumonia ______
Intra-abdominal infection ____   Surgical wound infection ____   Sepsis ______
Meningitis ____   Skin/soft tissue infection ____   Dysentery/severe diarrhea ___
Enteric fever ______   Other (specify) _________________________________

Culture results during four days prior to the start of ciprofloxacin
No. patients from whom at least 1 specimen obtained _____

No. patients from whom at least 1 specimen grew aerobic gram-negative bacilli _____

No. of patients from whom at least specimen grew aerobic gram negative bacilli susceptible to ciprofloxacin _____

Assessment of renal function during treatment

No. (%) in whom Cr or BUN measured

  week 1 ______(%)
  week 2 ______ ( %)

Classification of appropriateness of treatment

No. (%) in whom indication for ciprofloxacin appropriate ______
inappropriate ______  indeterminate ______

No (%) in whom ciprofloxacin dose inappropriate ______
inappropriate ______  indeterminate ______

Number (%) in whom ciprofloxacin duration appropriate ______
inappropriate ______  indeterminate ______

Number in whom antibiotic treatment regimen appropriate ______
inappropriate ______  indeterminate ______
Drug and Therapeutics Committee
Training Course

Session 12.
Infection Control
SESSION 12. INFECTION CONTROL

Purpose and Content

Session 12 introduces basic infection control (IC) practices for members of Drug and Therapeutics Committees (DTCs). An IC program, working in conjunction with an active DTC, is an essential tool in hospitals for preventing and controlling nosocomial infections and the morbidity, mortality, and cost associated with them.

As with many of the sessions in this DTC training course, participants are encouraged to review the articles in the “Further Readings” section for more information. Session 12 is brief, providing basic information primarily for DTC members, and cannot provide all the information and skills necessary for implementing a comprehensive IC program.

Objectives

After attending this session, participants will be able to—

• Understand basic infection control concepts

• Understand the causes of nosocomial infections

• Understand the components of an infection control program

• Understand how the Infection Control Committee (ICC) and DTC can decrease the incidence of nosocomial infections and antimicrobial resistance (AMR)

Outline

• Key Definitions
• Activity 1
• Introduction
• Epidemiology of Nosocomial Infections
• Control and Prevention of Nosocomial Infections
• Core Strategies for Reducing the Risk of Nosocomial Infections
• Implications for the DTC
• Activity 2
• Summary

Preparation and Materials

• Read the Trainer’s Guide and the Participants’ Guide, and review visual aids (VA).

• Instruct participants to read the Participants’ Guide the evening before the session presentation.
Further Readings


Websites for infection control information, guidelines, training materials, and articles are available from the U.S. Centers for Disease Control and Prevention, the World Health Organization, EngenderHealth, and American International Health Alliance (see annex 1 for website addresses).

Visual Aid Listing

1. Title slide
2. Objectives
3. Outline
4. Key Definitions (1)
5. Key Definitions (2)
6. Activity 1
7. Introduction—Why Infection Control? (1)
8. Introduction—Why Infection Control? (2)
9. Introduction —Development of AMR
10. Epidemiology of Nosocomial Infections (1)
11. Epidemiology of Nosocomial Infections (2)
12. Epidemiology of Nosocomial Infections (3)
13. Root Causes of Nosocomial Infections (1)
Session 12. Infection Control

14. Root Causes of Nosocomial Infections (2)
15. Infection Control Committee (1)
16. Infection Control Committee (2)
17. Infection Control Committee (3)
18. Core Strategies to Reduce Nosocomial Infections—Hand Hygiene
19. Effect of Antiseptics on Colony Counts after Hand Scrub
20. Isolation and Standard Precautions
21. Ensuring a Clean Environment
22. Cleaning, Disinfection, and Sterilization of Instruments and Supplies
23. Sterile Invasive Procedures and Intravenous Medications
24. Respiratory Therapy
25. Surgery and Surgical Site Care
26. Employee Health and Training Program
27. Food and Water Precautions
28. Antimicrobial Use and Monitoring (DTC and IC Collaboration)
29. Case Study—Cesarean Section
30. Inappropriate Timing of Antibiotic Prophylaxis for Cesarean Section
31. Effect of Appropriate Perioperative Antibiotic Prophylaxis on Surgical Site Infections after Cesarean Section
32. Infection Control Priority Matrix
33. Implications for the DTC
34. Infection Control Resources
35. Infection Control Assessment Tool
36. Activity 2
37. Summary (1)
38. Summary (2)

Organization of the Session

Total time: 2–3 hours

Session 12 introduces basic IC practices for members of DTCs. The length of the session depends on whether the activities are completed; allow three hours if both activities are used. This session is not meant to provide in-depth information and is not intended in any way to imply that the DTC should also be an IC committee. DTC members should be aware of IC practices and work closely with an established IC committee to implement the appropriate activities in infection control that will lead to lower nosocomial infections and containing AMR.

First Component: 5 minutes
VAs 1–5: Introduction

Briefly discuss the objectives of the session, the outline, and the key definitions.
Second Component: 45 minutes
VA 6: Activity 1

Activity 1. Describing Infection Control Practices at Your Facilities or Institutions

This activity is intended to get an overview of what kinds of IC programs exist at each participant’s health care facility. Ask the participants to describe their hospital IC program or current practices at a hospital or clinic (or at the ministry level). Include the following—

- Committee membership
- Available policies and procedures
- Surveillance of nosocomial infections
- Hand hygiene and use of gloves
- Isolation and universal precautions
- Cleaning strategies (housekeeping), including waste disposal
- Cleaning, disinfection, and sterilization of instruments and supplies
- Intravenous (IV) catheter and IV fluids and medication
- Urinary catheters and urine drainage systems
- Mechanical ventilation and respiratory equipment
- Surgical site care
- Food and water monitoring
- Training
- Employee health and immunization for staff
- Antimicrobial use monitoring

As a part of this exercise, have the participants answer the following questions concerning their IC practices—

- Are you satisfied with the infection control procedures and activities?
- Is infection control maintained throughout your health care system?
- Are there complaints of inadequate infection control and resultant nosocomial infections?
- Is there a formal mechanism for reporting and investigating nosocomial infections?
- Are outbreaks of infectious diseases in the hospital a common problem? What is the usual source of the outbreak?
- Is the DTC involved in any infection control activities? Please describe these activities.

Ask the participants to discuss each individual IC program in their groups, to select one, and to be prepared to present a summary of the program.
Session 12. Infection Control

Third Component: 30 minutes
VA 7–17: Nosocomial Infections and Infection Control Committees

Describe the most likely sites for nosocomial infections, and mention the importance of methicillin-resistant Staphylococcus aureus (MRSA) and the spread of blood-borne pathogens such as hepatitis B and C and HIV/AIDS. Ask the participants about their experience with ICCs in their countries, and then review the structure and functions of an ICC.

Ask participants about specific nosocomial infections that affect their institutions. Ask about surveillance and possibilities of implementing new programs to improve the situation in their hospital.

Fourth Component: 30 minutes
VA 18–33: Strategies to Reduce Nosocomial Infections

Brainstorm with the participants to cite different strategies for reducing nosocomial infections. Then review all the strategies using the VAs. Emphasize the importance of all hospitals having an IC program and the role of the DTC in supporting an ICC or instituting IC activities in the absence of such a committee. The specific strategies discussed can improve infection control, but what is really needed is a comprehensive program based in an IC program that is supported by the DTC. Some members of the DTC may also be members of the IC committee.

The case study on VAs 27–30 is important to discuss in some detail. This case study is illustrative of the acute need to have better prophylaxis for cesarean section prophylaxis and will lead into the field study that will also have cesarean section prophylaxis review.

This important case study is a classic example of inappropriate antimicrobial use in surgical prophylaxis. This kind of antimicrobial use leads to increased infections, antimicrobial resistance, higher health care costs, and increased adverse drug reactions.

Slide 28 of the case study is a comparison of two hospitals and their antimicrobial prophylaxis—

- Hospital A uses a prophylaxis for too many patients because it should be used only for high-risk procedures. Only 32 percent received the medicine on time, adding to the inappropriate use in this case.
- Hospital B uses prophylaxis appropriately (i.e., administered to the high-risk population) and gives the medicine at the appropriate time in 70 percent of cases—still too low for administering a single dose. This 70 percent represents an improvement over hospital A, but is still unacceptable because many failures will result from the poor timing of the doses.

In slide 29, squares represent the surgical procedure, and circles represent antimicrobial prophylaxis administration. Diamonds represent post-operative infections. As the antimicrobial administration is given closer to the surgical procedure, there is a corresponding decrease in the incidence of post-operative infections.
Slide 30 describes the IC activities undertaken to improve cesarean section outcomes. The appropriate use of antimicrobials tops the list because it is within a hospital personnel capacity to improve practices in a short period of time.

Appropriate use of antimicrobials is an important issue for the DTC and the ICC. The committees must work together to achieve rational use.

VA 31 summarizes the implications for the DTC concerning infection control activities. Give sufficient time to this slide so that all participants have a good understanding of these concepts as they apply directly to DTCs.

**Fifth Component: 15 minutes**

*VA 34–35 Infection Control Resources*

Discuss the availability of infection control resources online. (See the resources list in annex 1.)

Discuss the utility of using the new Infection Control Assessment Tool (ICAT) and quality improvement program developed by the Rational Pharmaceutical Management (RPM) Plus Program of Management Sciences for Health (MSH). The ICAT and quality improvement (QI) program provides a standardized approach by combining an infection control self-assessment tool (ICAT) and rapid cycle quality improvement (RCQI) (or rapid team problem solving) methods to improve hospital infection control practices. RCQI is a quality improvement approach in which a multidisciplinary team collaborates on improving an identified situation. The team identifies and prioritizes areas that need improvement, agrees on specific goals for improvement, and uses QI (or problem solving) tools to analyze available data about existing systems. The team then develops, tests, and implements a series of focused and affordable changes that can be implemented locally in the system to improve the situation and achieve the agreed-upon goals. The strength of RCQI is in synergizing team ideas in learning about systems and developing appropriate solutions to improve them. The methodology has been applied in various health care settings around the world.

For more information, contact MSH’s RPM Plus/SPS programs in Arlington, Virginia (e-mail: rpmplus@msh.org; website: www.msh.org/rpmplus).

**Sixth Component: 45 minutes**

*VA 36: Activity 2*

**Activity 2. Developing Recommendations for Your Facilities or Institutions**

Tell the participants to review this session and make recommendations for their hospitals for starting an ICC, improving the current committee, or making an infection control subcommittee of the DTC. Consider these questions—

- What would be the benefits to your hospital if an effective infection control program is started?
• How can your DTC contribute to improving infection control practice within your health care facility?

In your groups, discuss recommendations for each individual IC program, select one, and be prepared to present a summary of recommendations for the program.

The facilitator should select 2–3 groups to make presentations. Allow 30 minutes for group work and a maximum of 5 minutes per group presentation.

**Seventh Component: 10 minutes**

**VAs 37–38: Summary**

Summarize the key points. Discuss information sources available online including training programs, policies and procedures, and assessment tools.
Annex 1. Internet and CD-ROM Resources: Infection Control Information, Guidelines, and Protocols

RPM Plus/MSH


U.S. Centers for Disease Control and Prevention (CDC) Documents and Guidelines

Centers for Disease Control infection control index:
http://www.cdc.gov/ncidod/dhqp/a_z.html

Hand hygiene:
http://www.cdc.gov/handhygiene/

Guidelines for preventing the spread of TB in hospitals:
http://www.cdc.gov/epo/mmwr/preview/mmwrhtml/00035909.htm

Guidelines for surgical site infections:
http://www.cdc.gov/ncidod/dhqp/gl_surgicalsites.html

Improving compliance with hand hygiene:
http://www.cdc.gov/ncidod/eid/vol7no2/pittet.htm

Infection control guidelines for hospital personnel:
http://www.cdc.gov/ncidod/dhqp/gl_hcpersonnel.html

Intravenous catheters:
http://www.cdc.gov/ncidod/dhqp/gl_intravascular.html

Isolation procedures:
http://www.cdc.gov/ncidod/dhqp/gl_isolation.html

Prevention of needle stick infections:
http://www.cdc.gov/niosh/docs/2000-135
“Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HBV, HCV, and HIV and Recommendations for Postexposure Prophylaxis”:
http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5011a1.htm

Urinary catheters:
http://www.cdc.gov/ncidod/dhqdp/gl_catheter_assoc.html

Utilizing surveillance data:
http://www.cdc.gov/ncidod/eid/vol7no2/gaynes.htm

**Alliance for Patient Safety (World Health Organization)**
(Hand Hygiene and Safe Surgery)

http://who.int/patientsafety
http://who.int/patientsafety/challenge/en

**American International Health Alliance Website**

Website and training manuals:
www.aiha.com

**EngenderHealth Website**

Online infection control training program:
http://www.engenderhealth.org/IP/index.html
Drug and Therapeutics Committee
Training Course

Session 13.
The Role of the DTC in Containing Antimicrobial Resistance
SESSION 13. ANTIMICROBIAL RESISTANCE

Purpose and Content

Session 13 is designed to provide information about the Antimicrobial Subcommittee and how it functions within the Drug and Therapeutics Committee (DTC). The session begins with description of global problem of antimicrobial resistance (AMR) with country level examples. A discussion about implementing and maintaining an Antimicrobial Subcommittee and multifaceted strategies to contain AMR follows.

Objectives

After attending this session, participants will be able to—

- Understand the global situation of antimicrobial resistance
- Describe the role of the DTC in containing AMR
- Discuss multifaceted strategies to contain AMR

Outline

- Introduction and Background
- Global Situation and Impact of AMR
- Causes of AMR
- Role of DTC in Containing AMR
- Activity
- Summary

Preparation and Materials

- Read the Trainer’s Guide, Participants’ Guide, and review the visual aids (VAs).

- Instruct participants to read the Participants’ Guide the evening before the session presentation.

- Ask participants to critically think about any examples about their experiences about problems in antimicrobial use and related interventions. Having participants come prepared with such examples will greatly benefit the group’s understanding of the role of an Antimicrobial Subcommittee.

Further Readings


Visual Aid Listing

40. Title slide
41. The Threat of AMR
42. Objectives
43. Outline
44. Introduction
45. Global Situation of AMR (1)
46. Global Situation of AMR (2)
47. Global Situation of AMR (3)
48. Global Situation of AMR (4): Running out of Options—Example of *N. Gonorrhea*
49. AMR in Hospitals
50. Nosocomial Infections and AMR
51. Impact of AMR
52. Impact of AMR: Example of Multidrug Resistant TB
53. Impact of AMR: Example of XDR-TB
54. Impact of AMR: Cost Implications of Nosocomial MRSA
55. Impact of AMR: Cost Implications of Changing to an ACT Regimen for Malaria Treatment
56. Causes of AMR (1)
57. Causes of AMR (2)
58. Inappropriate Use Is a Major Contributor to AMR
59. Reasons for Irrational Prescribing
60. Global Strategies to Address AMR
61. Key Approaches to Contain AMR
62. DTC is a key body in the hospital setting
63. DTCs Can Help Preserve Effectiveness of Existing Antimicrobials by— (1)
64. DTCs Can Help Preserve Effectiveness of Existing Antimicrobials by— (2)
65. Antimicrobial Policies: Classification
66. Monitoring Antimicrobial Sensitivity Patterns (Surveillance)
67. DTC Can Create an Antimicrobial Subcommittee to Help
68. Establishment of an AMR Subcommittee within DTC: Experience from Kenya 2006
69. AMR Subcommittee Functionality: Experience from Kenya (1)
70. AMR Subcommittee Functionality: Experience from Kenya (2)
71. Success of Antibiotic Order Form: Example from Thailand (1)
72. Success of Antibiotic Order Form: Example from Thailand (2)
73. Example of Policy for Switching from IV to Oral Antibiotics: U.K. Experience (1)
74. U.K. Experience (2)
75. U.K. Experience (3)
76. DTC Can Collaborate with Other Units to Create Synergy in Action
77. Activity
78. Summary (1)
79. Summary (2)
80. Summary (3)
81. Summary (4)
Organization of the Session

Total time: 2.5 hours

Session 13 is designed to provide an overview of practical strategies of containing the threat of AMR through various methods. Relate the contents of this session to session 9, “Strategies to Improve Medicine Use—Overview.” The session should be participatory, drawing on the experiences of participants in their home countries or respective health facilities.

First Component: 5 minutes
VAs 1–5: Introduction

Introduce the session by briefly explaining the objectives and outline of the session and reviewing with the participants the consequences of AMR.

Second Component: 30 minutes
VAs 6–16: Global Situation of AMR and Impact

Discuss the commonly known global situation of AMR with respect to various infectious diseases such as malaria, tuberculosis (TB), dysentery, and pneumonia. Information on the global situation of AMR illustrates that it has no geographic boundaries and is a common problem everywhere. Inform the participants as well that developing new antimicrobials is limited and that existing therapies cease to be effective in many cases. Ask participants about their challenges of uncertain diagnoses, and solicit their observations of irrational antimicrobial use. Transition to the hospital scenario where AMR is a major problem, and link the information to the purpose of this session.

The impact of AMR on the health care system is enormous. Explain thoroughly the issues around increased morbidity and mortality. The increased cost of treatment as a result of AMR is problematic. The cost of MDR-TB is increasing and many reports show that it is up 300 times the cost of standard treatment. Switching to artemisinin-based combination therapy (ACT) therapy for malaria is increasing the cost of treatment significantly in countries where chloroquine resistance is found.

Third Component: 15 minutes
VAs 17–20: Causes of AMR

Use this set of slides as a guide to engage in active discussion with participants. Ask the participants to provide examples with some of the information from the slides. Obtain a few examples of problems that are known to contribute to the cause of AMR. Subsequently, use these participant examples as potential activities at the end of the session.
Fourth Component: 30 minutes
Vas 21–27: Key Approaches to Contain AMR and the Role of DTC

Information in these slides forms the core of this session. Discuss this information in depth, and be sure that participants understand the importance of each activity that a DTC can do to address AMR.

Fifth Component: 15 minutes
VAs 28–37: Examples of DTC Activities to Contain AMR

The Kenya example describes the process of establishing a DTC along with initial activities. (Mention that this example was provided by a former DTC participant who implemented lessons learned from this session in her hospital.) The Thailand example specifically provides evidence of the benefits of the antibiotic order form and associated costs savings. The United Kingdom (U.K.) example illustrates the reduction of lengthy intravenous (IV) antimicrobial use and the development of a policy to switch to oral antimicrobials. Emphasize that the success of the Antimicrobial Subcommittee depends on effective relationships with prescribers and various hospital departments.

Sixth Component: 40–60 minutes
VAs 38: Activity

Allow 20 minutes for group discussion and 20 minutes for plenary discussion. If you have time, you could allow 30 minutes for each part instead of 20 minutes and this would result in better discussion.

Ask each group to identify known problems of antibiotic use in its hospital. If some of the problems already have been mentioned during the session, assign one problem (i.e., case study) to each group.

Ask the participants to develop practical strategies to solve the problem in the context of a DTC or Antimicrobial Subcommittee.

- What strategy will you use to solve the antibiotic use problem? How will you utilize the DTC (if it exists) to lead or support the process?
- How will you monitor your strategy?
- What may be the potential barriers in implementing your strategy?

Seventh Component: 5 minutes
VAs 39–42: Summary

Certainly, antimicrobial medicines have greatly contributed to the decline in morbidity and mortality due to infectious diseases over the past half-century. This achievement is being undermined, however, by the rapidly growing problem of AMR. The World Health Organization
has identified the DTC has an important intervention mechanism to manage and contain AMR in hospitals.

A DTC can do much to contain AMR, such as setting up programs and interventions to identify antimicrobial use problems and implementing specific interventions to improve the prescribing, use, and management of antimicrobials.

Stress the main strategies to contain AMR highlighted above. Point out that all the strategies actually consist of developing guidelines and protocols concerning how antimicrobial medicines should be used and taking measures to ensure that everyone complies with these guidelines. Critical to the success is that monitoring and surveillance of use and resistance are undertaken and that all stakeholders be involved in the development and implementation of interventions.
Drug and Therapeutics Committee
Training Course

Session 14.
Getting Started
SESSION 14. GETTING STARTED

Purpose and Content

Session 14 will provide information on the practical methods of getting a Drug and Therapeutics Committee (DTC) started from the beginning or improving a DTC that has only limited activity. Practical applications are discussed, and problems with starting or maintaining a DTC are covered in detail. Solutions to participants’ issues with starting and maintaining a DTC are developed in small groups as well as in a plenary session.

Objectives

After attending this session, participants will be able to—

- Understand the basics of starting a DTC where none exists
- Understand how to improve the functioning of an existing DTC
- Identify and solve management and medicine use problems in establishing and maintaining a DTC

Preparation and Materials

- Read the Trainer’s Guide and the Participants’ Guide, and review the visual aids (VAs).

- Analyze the questionnaires filled out by the participants during the activity in session 1, “Drug and Therapeutics Committee—Overview.” Identify five or six problems (including medicine use problems, management issues, challenges, or barriers) concerning the implementation of a DTC or effective functioning of a DTC. Try to choose different types of specific problems from different countries, but ensure that at least one group tackles the problem of having no DTC and another group the problem of having a nonfunctional DTC. Identifying problems and assigning one per group requires knowledge of which participants are sitting at which table and what their countries are as well as their specific DTC problems. After identifying and assigning problems to groups, prepare either a PowerPoint® slide or a transparency for the overhead projector or write on a flipchart the problem that each group must tackle. This VA can be used when explaining the session to participants.

Visual Aid Listing

1. Title slide
2. Objectives
3. Addressing the Problem
4. Step 1. Do the Groundwork
5. Step 2. Gain a Friend in Authority
6. Step 3. Meet Relevant Stakeholders
7. Step 4. Measure Your Medicine Use Problem
8. Step 5. Present Your Findings, and Plan the Next Steps with Your Stakeholders
9. Step 6. Undertake a Detailed Medicine Use investigation
10. Step 7. Present Your Detailed Findings to Stakeholders and Plan an Intervention
11. Step 8. Implement and Evaluate the Agreed-upon Intervention
12. Step 9. Present the Results of Your Interventions to Senior Prescribers
14. Revitalizing Nonfunctioning DTCs
15. Activity
16. Summary

Organization of the Session

Total time: 3 hours

First Component: 30 minutes
VA 1–14: Getting Started

The slides show a methodology for starting and maintaining an effective DTC. Although there is no universal formula for starting a DTC, the steps described in the VAs can work to implement a functional DTC in most settings. A key issue here is identifying a specific medicine use problem, studying it carefully, and resolving it. From this successful approach to a medicine use problem, a DTC can develop credibility and a successful beginning.

Participants should be encouraged to participate in this discussion because many will have been faced with challenges of getting a DTC started and may have solved some of the problems that are commonly encountered.

Second Component: 10 minutes
VA 15: Introducing the Activity

Explain that the activity is designed to address the participants’ own practical problems with starting and maintaining a DTC. These problems may be related to management or clinical issues. Explain that the participants’ survey forms (questionnaires) from the activity in session 1 have been analyzed, and one problem per group has been identified and assigned. Instruct each group to develop a plan of action to solve the identified problem and present the problem and their proposed solution to the class. Emphasize that the solutions must be practical and feasible.
**Third Component: 60 minutes**  
**Group Work for the Activity**

Instruct each group to work on the assigned problem and prepare a presentation to include—

- A succinct description of the problem and the reasons underlying the problem
- A practical plan of action to solve the problem.

**Fourth Component: 75 minutes**  
**Presentation in Plenary for the Activity**

Ask each group to present its problem and solution in not more than five minutes. Each presentation should be followed by a five- to ten-minute discussion in plenary. Facilitate the discussion, allowing questions from the participants and asking whether the group’s solution is practical. Sum up the discussion at the end saying that usually something can be done to solve any problem.

**Fifth Component: 5 minutes**  
**VA 16**

Summarize the main points of the session and the lessons learned from the activity.