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
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

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Developed in Collaboration with the
World Health Organization
Geneva, Switzerland
ABBREVIATIONS AND ACRONYMS

g     gram
IV    intravenous
STG   standard treatment guideline
VA    visual aid
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**

2nd ed. West Hartford, CT: Kumarian Press. (Chapter 11, “Treatment Guidelines and Formulary
Manuals”)

**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)
18. Establishing the Guideline (7)
19. Implementing the Guideline
20. Activities
21. Summary (1)
22. Summary (2)

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.

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
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:

<table>
<thead>
<tr>
<th>Eligible for standard prophylaxis*</th>
<th>Yes ___</th>
<th>No ___</th>
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<tbody>
<tr>
<td>Received standard prophylaxis*</td>
<td>Yes ___</td>
<td>No ___</td>
</tr>
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</table>

*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>
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</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:

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

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

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

1. ______________________________________________________________________

2. ______________________________________________________________________

3. ______________________________________________________________________

4. ______________________________________________________________________

5. ______________________________________________________________________