Session 11.
Drug Use Evaluation

Trainer’s Guide
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Developed in Collaboration with the
World Health Organization
Geneva, Switzerland
<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>bid</td>
<td>bis in die (twice a day)</td>
</tr>
<tr>
<td>BUN</td>
<td>blood urine nitrogen</td>
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<tr>
<td>Cr</td>
<td>creatinine ratio</td>
</tr>
<tr>
<td>DUE</td>
<td>drug use evaluation</td>
</tr>
<tr>
<td>IV</td>
<td>intravenous</td>
</tr>
<tr>
<td>mg</td>
<td>milligram</td>
</tr>
<tr>
<td>po</td>
<td>per os (by mouth)</td>
</tr>
<tr>
<td>VA</td>
<td>visual aid</td>
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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>
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Assessment of renal function during treatment

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

Week 2 serum creatinine/BUN _____/_____  not done ___
Session 11. Drug Use Evaluation

Classification of ciprofloxacin use

Indication appropriate* (proven or suspected serious infection caused by aerobic gram-negative bacilli) ___
Indication inappropriate** (community-acquired pneumonia, meningitis, streptococcal 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 ______