Drug and Therapeutics Committee Training Course

Session 2.
Developing and Maintaining a Formulary

Trainer’s Guide
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<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADR</td>
<td>adverse drug reaction</td>
</tr>
<tr>
<td>AMR</td>
<td>antimicrobial resistance</td>
</tr>
<tr>
<td>ARI</td>
<td>acute respiratory infection</td>
</tr>
<tr>
<td>DTC</td>
<td>Drug and Therapeutics Committee</td>
</tr>
<tr>
<td>EML</td>
<td>essential medicines list</td>
</tr>
<tr>
<td>INN</td>
<td>international nonproprietary name</td>
</tr>
<tr>
<td>NSAID</td>
<td>nonsteroidal anti-inflammatory drug</td>
</tr>
<tr>
<td>OM</td>
<td>otitis media</td>
</tr>
<tr>
<td>TB</td>
<td>tuberculosis</td>
</tr>
<tr>
<td>USD</td>
<td>U.S. dollar</td>
</tr>
<tr>
<td>VA</td>
<td>visual aid</td>
</tr>
<tr>
<td>WHO</td>
<td>World Health Organization</td>
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</table>
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
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 cefapime, 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, cefapime 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>17</td>
<td>INDOMED capsules 25 mg (1)</td>
<td>4,199</td>
<td>0.003</td>
<td>11.45</td>
</tr>
<tr>
<td>18</td>
<td>KETOPROFEN 150 mg (1)</td>
<td>128</td>
<td>0.427</td>
<td>54.69</td>
</tr>
<tr>
<td>19</td>
<td>MEFENAMIC ACID 500 mg</td>
<td>2,328</td>
<td>0.198</td>
<td>460.84</td>
</tr>
<tr>
<td>20</td>
<td>MEFENAMIC capsules 250 mg</td>
<td>37</td>
<td>0.044</td>
<td>1.61</td>
</tr>
<tr>
<td>21</td>
<td>NAPROXEN tablets 250 mg</td>
<td>252</td>
<td>0.340</td>
<td>85.63</td>
</tr>
<tr>
<td>22</td>
<td>NAPROXENE 50 mg</td>
<td>634</td>
<td>3.091</td>
<td>1,959.73</td>
</tr>
<tr>
<td>23</td>
<td>NAPROXENE capsules 250 mg</td>
<td>1,537</td>
<td>0.119</td>
<td>182.52</td>
</tr>
<tr>
<td>24</td>
<td>NAPROXENE cream topical (niflumic acid)</td>
<td>649</td>
<td>2.186</td>
<td>1,419.02</td>
</tr>
<tr>
<td>25</td>
<td>NAPROXENE suppositories 700 mg (ADULT) (niflumic acid)</td>
<td>1,319</td>
<td>0.305</td>
<td>402.08</td>
</tr>
<tr>
<td>26</td>
<td>NAPROXENE suppositories (INFANT) (niflumic acid) 400 mg</td>
<td>314</td>
<td>0.258</td>
<td>81.13</td>
</tr>
<tr>
<td>27</td>
<td>NAPROXENE suppositories (INFANT) (niflumic acid) 200 mg</td>
<td>22,260</td>
<td>0.038</td>
<td>848.67</td>
</tr>
<tr>
<td>28</td>
<td>NAPROXENE suppositories (INFANT) (niflumic acid) 100 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.