

**Drug and Therapeutics Committee  
Training Course**

**Session 10:  
Standard Treatment Guidelines**

Participant's Guide

Revised Draft: May 2001

Rational Pharmaceutical Management Plus Program  
C.A. No. HRN-A-00-00-00016-00  
Center for Population, Health and Nutrition  
Strategic Objective Numbers: SSO2, SSO3, SSO4, SSO5

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## PURPOSE AND CONTENT

Experience has shown that even when drug supply is based on an approved formulary or essential drug list, ample opportunity exists for ineffective, unsafe, or wasteful prescribing. Standard treatment guidelines list the preferred drug and nondrug treatments for common health problems experienced by people in a specific health system. They represent one approach to promoting therapeutically effective and economically efficient prescribing.

When implemented effectively, a standard treatment guideline offers advantages to patients (enables more consistency, treatment efficacy), providers (gives an expert consensus, quality of care standard, basis for monitoring), supply managers (makes demand more predictable, allows prepacks), and health policymakers (provides focus for therapeutic integration of special programs, promotes efficient use of funds). But effective implementation is perhaps the greatest challenge in introducing standard treatments.

## Objectives

After completion of this session, participants will be able to—

- Understand the importance of a standard treatment guideline in promoting rational drug use
- Describe the development and implementation of a guideline in a hospital or clinic
- Develop a standard treatment guideline for a disease or medical condition

## Preparation

Read:

- Participant's Guide
- Management Sciences for Health. *Managing Drug Supply*. Second edition. West Hartford, CT: Kumarian Press. 1997: Chapter 11, "Treatment Guidelines and Formulary Manuals," pp. 138–49.



## INTRODUCTION

The Drug and Therapeutics Committee (DTC) is responsible for numerous important drug management functions. The committee is responsible for the evaluation of new drugs for the formulary, identifying and correcting drug use problems, assessing and controlling adverse drug reactions, and others. This session concentrates on an important strategy for improving drug use in the health care system—standard treatment guidelines. Guidelines are a valuable resource in the management of drug therapy because—

- Treatment of diseases may have many different approaches.
- Many practitioners will not remember the best method of treatment.
- Applying the most effective treatment benefits both the patient and the health care system.
- Formulary management will have only limited impact if drugs are used incorrectly.

The development and implementation of standard treatment guidelines is a necessary task in a health care system where there may be numerous treatments available. Physicians and nonphysician providers will use their own knowledge base, training, and preconceived ideas on the treatment rationale for each patient. Frequently, this is effective and reasonable and results in optimal care. Just as frequently, however, it may result in less than optimal care and in fact may result in dangerous medical care, resulting in poor outcomes for the patient. The use of standard treatment guidelines is a time-honored system that works well and improves patient outcomes.

## KEY DEFINITION

**Standard Treatment Guideline**—A systematically developed statement designed to assist practitioners and patients in making decisions about appropriate health care for specific clinical circumstances

## THE NEED: A SOLUTION TO THERAPEUTIC ANARCHY

Standard treatment guidelines have existed for as long as the art of healing has existed. Traditional healers developed their standard set of cures and passed them from generation to generation. In modern medicine, there is the concept that there may be more than one treatment modality available for many medical conditions. This leads to confusion and in many cases incorrect treatment. Doctors, nurses, pharmacists, community health workers, and other health care providers learn about *all* of the treatments that *could* be used, instead of focusing on the *best* treatment that *should* be used. Casual observation, as well as more systematic study of prescribing practices, frequently reveals a pattern of tremendous diversity among prescribers in the treatment of even the most common conditions. Polypharmacy is one problem; for example, there are three, four, five, six, and sometimes more drugs prescribed for acute viral

gastroenteritis, for which only oral rehydration therapy is effective in reducing morbidity and mortality. Other common problems are incorrect drug choices, overdosing, underdosing, and choice of more expensive drugs when less expensive drugs would be equally or more effective.

Standard treatment guidelines—also known as standard treatment schedules, standard treatment protocols, therapeutic guidelines, and so forth—list the preferred drug and nondrug treatments for common health problems experienced by people in a specific health system. Each drug treatment should include for each health problem the name, dosage form, strength, average dose (pediatric and adult), number of doses per day, and number of days of treatment. Other information on diagnosis and advice to the patient may also be included.

Standard treatments should consider both drug and nondrug treatments. “Reassurance,” for example, might be the proper standard treatment for a child who is shorter than other children of his or her age, but who shows a normal growth curve, shows no signs of malnutrition or chronic disease, and has shorter than average parents.

Health problems, including specific diagnoses (“malaria”), symptoms (“headache”), and preventive health services (EPI immunizations, antenatal vitamin and mineral supplements), may also be included in the guidelines.

Standard treatments are currently in use in parts of the United States, Europe, Latin America, Asia, Africa, and the Western Pacific. Experience shows that even the shortest essential drug list or formulary list offers ample opportunity to misuse drugs by improper treatment of common problems. Thus, essential drug programs are finding that the development of standard treatments is necessary for therapeutically effective and economically efficient use of drugs.

Standard treatments are used at different points of the therapeutic process. They may be used to diagnose, decide on treatment and drug supply, and assist with adherence to the prescribed treatment. This will more likely lead to the desired clinical outcome.

Listed below are the primary advantages and disadvantages of developing and using standard treatment guidelines.

## **Advantages**

- For health care providers
  - Provides standardized guidance to practitioners
  - Dictates the most appropriate drugs for use
  - Produces the best quality of care since patients are receiving optimal therapy
  - Utilizes only formulary drugs or essential drugs, so the system need only provide the drugs in the guideline

- Provides invaluable assistance to all practitioners, especially those with lower skill levels, as it provides the guidelines necessary to ensure good-quality care
- Enables providers to concentrate on making the correct diagnosis because treatment options will be provided for them
- For health care officials
  - Provides a system for controlling cost by using funds more efficiently
  - Provides the most effective therapy in terms of quality
  - Provides a basis for evaluating quality of care provided by the health care professionals
  - Provides information for practitioners to give to patients concerning the institution's standards of care
  - Can be a vehicle for integrating special programs (diarrhea disease control, acute respiratory infection, tuberculosis control, malaria) at the primary health care facilities
- For supply management
  - Provides information for forecasting and ordering (drugs and quantities for common diseases will be known)
  - Provides information for purchase of prepackaged drugs
- For patients
  - Patients receive optimal drug therapy
  - Enables consistent and predictable treatment from all levels of providers and at all locations within the health care system
  - Allows for improved availability of drugs because of more consistent use and ordering
  - Enables improved outcomes because patients are receiving the best treatment regimens available
  - Lowers cost

## Disadvantages

- Inaccurate or incomplete guidelines will provide the wrong information for providers and therefore do more harm than good. Guidelines may not be based on the most reliable information.
- Updating guidelines is difficult and time-consuming and must be done on a regular schedule or they will become obsolete very quickly.
- Guidelines have been referred to as “cook book” medicine. They provide information to treat the population, but not necessarily the individual patient.
- Guidelines provide a false sense of security, i.e., many providers will limit their evaluation of a particular patient as soon as it fits into a particular standard treatment.

Disadvantages of treatment guidelines do exist, but seldom are they proven to have any serious effects on overall patient outcomes. When looking at the risk-benefit of a guideline, most authorities agree that the benefits of a guideline far outweigh any risks or disadvantages.

Standard treatment guidelines are disease-oriented while formulary manuals are very much drug-oriented documents. These two documents provide the very essence of the DTC’s efforts to provide rational drug therapy. Every effort should be expended to publish both of these manuals, have them readily available for all practitioners, and update them on a regular basis to ensure accuracy of the information provided.

## ESTABLISHING THE GUIDELINE

Establishing a standard treatment guideline is a lengthy process, one that must be done methodically and completely in order to have a product that all practitioners are willing to accept. The process can be described in five steps—

1. Establish a committee to address the development of the guidelines.

The DTC may take responsibility for this task or select individuals to form a new committee for the purpose of establishing the guidelines.

2. Develop an overall plan for guidelines.

A comprehensive plan with well-defined time frames is necessary to ensure that the product is started and finished within a reasonable period of time.

3. Identify the diseases that the STG will cover.

The most common and serious diseases and medical conditions should be selected from available morbidity statistics. All of the medical departments and specialty areas should be consulted to identify important diseases to be addressed in the guideline.

4. Determine appropriate treatment options.

This is a critical step. Evidenced-based information must used to identify appropriate treatment guidelines. Experts and clinical specialists should be consulted to confirm proposed treatment options. Guidelines must be consistent with national formularies and guidelines.

STGs should as a general rule—

- Use the fewest drugs necessary to treat the medical condition
- Choose cost-effective treatment
- Use formulary drugs (from local and national formularies)
- Give first-, second-, and third-line drugs when appropriate
- Provide dose and duration, contraindications, side effects

5. Determine what information should be included in the STG.

Information provided in the STG can vary widely. The following are some suggestions for a comprehensive STG.

- Clinical condition, pathophysiology, diagnostic criteria, including laboratory tests
- Treatment objectives (e.g., elimination of plasmodium parasites from a blood smear)
- Nondrug treatment
- Drugs of choice (and alternatives) for the medical condition
- Important prescribing information—dose, duration, contraindications, side effects, warnings, drug interactions
- Referral criteria
- Patient education information

The amount of information to provide is a difficult decision. Ideally the STG manual should be concise and small enough to fit into a practitioner's pocket. Also, the final products must be comprehensive so as to describe the medical condition and its appropriate treatment.

6. Draft the STGs for comments and pilot testing.

STGs are controversial documents and may not be accepted by all practitioners in a hospital or clinic. It is important to circulate the draft document and obtain comments as to content, ease of use, presentation, and overall acceptability. This step is vital to determine future use of the guidelines and to garner buy-in from practitioners in the hospital.

7. Publish and disseminate.

After completion and approval of the final draft, the document must be published and distributed widely to the professional staff. An official launch, training of users, and monitoring/evaluation are all necessary components to the distribution of the guidelines. This important activity is described in more detail later in this session.

8. Revise and update.

Treatment recommendations change rapidly and consequently so must the standard treatment guidelines. The STGs should be updated regularly to reflect changes in accepted treatment strategies. If this is not done on a regular schedule, the STGs will quickly lose their credibility.

Treatment guidelines must have the most up-to-date and accurate information available. Any attempt at providing a guideline without this accurate information will lead to failure of the guideline. Therefore, the use of evidence-based medicine in preparing the guideline and the use of expert authors and reviewers cannot be overemphasized.

Key features of a successful guide include—

- **Simplicity**—The number of health problems is limited. For each health problem, a few key clinical diagnostic criteria are listed. Drug and dosage information is clear and concise.
- **Credibility**—The treatments are initially developed for patients by the most respected clinicians in the country using evidence-based information. Revisions based on actual experience have further added to the credibility. Input from paramedical staff has been actively sought and acknowledged.
- **Same standards for all levels**—Doctors and other health care providers use the same standard treatments. The referral criteria differ, but the first-choice treatment for a patient depends on the patient's diagnosis and condition, not on the prescriber. If a patient attends a teaching hospital or a low-level dispensary with a common condition, the treatment will be exactly the same. If the patient does not respond to treatment, he or she may be referred to a higher level to receive the second-line therapy, which would be given in hospital.

- Drug supply based on standards—The standard treatments are coordinated with the supply of drugs. If changed circumstances require a new drug for the standard treatment, then the supply system responds.
- Introduced in preservice training—Standard treatment manuals are distributed during preservice training and their use becomes habit.
- Dynamic (regular updates)—As bacterial resistance patterns change or other factors alter therapeutic preferences, the standards are revised to reflect current recommendations.
- Durable pocket manuals—The standard treatments are published as small, durable pocket manuals, which makes them convenient to carry and use.

In the interest of therapeutic and economic efficiency, standard treatments should target those conditions that have the highest morbidity and mortality rates. Note that some conditions that contribute substantially to the number of patients treated, and therefore to the total cost of drugs provided, contribute little to decreasing morbidity and mortality. Skin conditions are a common example. Such problems may nevertheless be priorities for the development of standard treatments precisely because they do absorb a large percentage of the drug budget.

In terms of selection of health problems to be addressed, standard treatment falls into three categories—

- Individual—Standard treatments are prepared for only one problem or set of problems, such as only diarrheal disease, only ARI, or only malaria.
- Selective—Standard treatments are prepared for a small number of high-priority problems, perhaps 6 to 12, for example, a “package” of treatments for diarrheal disease, ARI, antenatal care, immunization screening, malaria, and tuberculosis.
- Comprehensive—Standard treatments are prepared for 30, 50, 100, or even more common health problems. When published, such standard treatments become more like textbooks than basic references.

The number of treatment guidelines developed should be appropriate to the specific situation. But individual treatments developed one by one may miss the opportunity to use the process to integrate several special programs. At the other extreme, comprehensive standard treatments risk overwhelming health workers with new information, thus reducing the chance that *any* of the standard treatments—even those for common, high-priority problems—will be followed. There may be a place for targeting different levels of the health system with manuals containing differing amounts of information.

Information on local disease patterns should also be considered. Seldom do primary care clinics have access to clinical laboratories. But results from surveys using available district, regional, or national laboratory facilities can be used to make scientifically based selections of preferred

drugs for certain types of diarrhea, ARI, malaria, tuberculosis, and other infectious diseases. Dynamic standard treatments are periodically updated to reflect changes in treatment patterns.

Development of standard treatments should aim at therapeutic integration through coordination with special programs such as diarrheal disease control, ARI, malaria, and so forth. Hospital or primary health care standard treatments should reinforce recommendations of special programs and, at the same time, special programs should use their experience in developing their treatment recommendations.

Individual drug selections should, of course, be based on the principles of choosing the fewest drugs necessary to effectively treat an individual condition, choosing the most cost-effective treatment, and adhering to the essential drug list (if one exists). If an essential drug list does not exist for the level of health care at which the treatments will be used, then the process of producing standard treatments should also produce an essential drug list.

Development of standard treatments must involve respected clinicians from all levels. These might include leading professors from local medical schools as well as experienced district medical officers and outstanding community health staff. Department heads of major hospitals should also be consulted and their advice obtained in preparing and authoring the document. It is also necessary to involve many staff-level physicians and pharmacists in order to obtain a broad-based participatory approach, one that will ensure buy-in later when the manual is completed.

Finally, the patient perspective must be considered. Issues of patient adherence to treatment (compliance) and prevailing patient preferences must be weighed against considerations of efficacy, safety, quality, and cost.

## IMPLEMENTING THE GUIDELINE

In terms of impact on prescribing and drug use patterns, the greatest weakness in past efforts to introduce standard treatments has probably not been in the *development* of reasonable standards, but in the *effective implementation* of the standards once they have been developed. Prescribing patterns change slowly; consequently, practitioners must be educated in the use and importance of the guidelines. Marketing of the guideline will be very important.

The following are important elements for a plan to implement standard treatments:

- Printed reference materials
- Official launch
- Initial training
- Reinforcement training
- Monitoring
- Supervision

Printed reference materials can include manuals, posters, and training materials. Depending on the number of treatments involved, printed references may be in the form of wall charts, pocket handbooks, or larger “shelf-size” reference books.

Some people feel that wall charts provide a better reminder to health workers, are more permanent, and help the patient better understand the treatment process. Others feel that a handbook is more effective, provided it fits into the pocket, is durable, and is well organized. Pocketbooks can also include information about individual drugs or other reference data. The contents of pocket manuals can be organized in summary tables, in diagnostic and treatment decision trees or flow charts, or simply in written text.

An official launch is very important. The Minister of Health, the leaders of professional bodies, and leading clinicians should present the new guidelines at a public forum. Ideally, the presentation should be covered by the press and broadcast media and attended by representatives of health worker associations.

Initial training is also important. Ideally, standard treatments should be introduced during formal preservice training for doctors and other health care providers. Use of the standard treatments and the reference manual or wall chart early in training develops good habits for later clinical practice. This implies that examinations should include questions on standard treatments.

The length of initial in-service training will depend on the number and complexity of standard treatments. Training should specifically consider prescribers’ inhibitions about using standard treatments. Some may be afraid that “looking things up in front of the patient” will detract from their credibility. Participants should therefore practice the use of reference materials in actual patient care situations or in role-plays.

Other prescribers may not appreciate how the treatments were prepared and at first may not trust the treatments. Most importantly, if the standard treatments differ substantially from current practice (for example, fewer injections or fewer antibiotics than currently prescribed), these differences should be identified and discussed. Participants should be strongly encouraged to accept the standard treatments, perhaps even by signing a written agreement.

Especially for health care providers already in practice, reinforcement training during the first 6 to 12 months after the initial training can play an important role in reemphasizing the importance of following standard treatments and can allow an opportunity for the DTC to respond to questions that have arisen from attempts to apply the treatments.

Finally, the monitoring system and supervisory efforts should focus on the priority health problems and standard treatments for these problems. Routine reports that focus on high-priority problems such as diarrheal disease and ARI can also include information on treatment of these problems and, of great importance, on adequacy of supply of the few drugs needed for these conditions. The use of drug use evaluations can be helpful in monitoring and ensuring compliance with standard treatment guidelines.

## ACTIVITY

### Activity 1. Preparation of a Standard Treatment Guideline

Your DTC has information from indicator studies and ABC analysis that shows that use of certain antituberculosis drugs is increasing dramatically. The incidence of multidrug-resistant tuberculosis is also increasing in the hospital, but remains at relatively low levels. There are also indications (including many anecdotal reports) that tuberculosis drugs are being prescribed incorrectly, indiscriminately, and without appropriate follow-up. An ABC analysis showed that the antituberculosis drug pyrazinamide accounts for 65 percent of the budget for drugs in this category.

The DTC intends to address this problem with several different strategies, including educational programs for medical providers, the institution of a drug use evaluation program for tuberculosis drugs, and revision of the standard treatment guidelines.

Participants should meet in their usual groups and collaborate on the development of a standard treatment guideline for the treatment of tuberculosis. Keep the guideline brief, but address all of the important aspects of care that are necessary to guide the appropriate treatment and improve patient outcomes with this disease. Keep the standard treatment guideline relevant to your home country.

## SUMMARY

Standard treatment guidelines are one of the most important concepts in providing rational drug use. These guidelines have been shown to provide valuable guidance to practitioners at all levels, especially those with minimal training.

Guidelines need to be prepared with the ultimate goal of providing a protocol for the health care system to follow that will produce improved patient care and outcomes.

Standard treatment guidelines will improve outcomes for patients by—

- Providing standardized guidance to practitioners
- Listing the most appropriate drugs for use
- Producing the best quality of care because patients are receiving optimal therapy
- Utilizing only formulary drugs or essential drugs so the system need only provide the drugs in the guideline
- Providing invaluable assistance to all practitioners, especially those with lower skill levels, as it provides the guidelines necessary to ensure good quality care

- Enabling providers to concentrate on making the correct diagnosis because treatment options will be provided for them

Annex 1 lists publications that are relevant to the development of standard treatment guidelines.

## ANNEX 1. PUBLICATIONS RELEVANT TO DEVELOPMENT OF STANDARD TREATMENTS

The following publications are just some examples of standard treatment guidelines developed by countries and health care organizations. More recent editions may be available.

### AUSTRALIA

*Antibiotic Guidelines*, 9th Edition, 1997

*Psychotropic Drug Guidelines*, 2nd Edition, 1993

*Analgesic Guidelines*, 3rd Edition, 1997

*Gastrointestinal Drug Guidelines*, 1st Edition, 1994

*Neurology Guidelines*, 1st Edition, 1997

*Cardiovascular Drug Guidelines*, 1st Edition, 1996

*Endocrinology Guidelines*, 1st Edition, 1997



Available from:

Victorian Medical Postgraduate Foundation Inc.

Therapeutics Committee

“Chelsea House” 3rd Floor

55 Flemington Road

North Melbourne, VIC 3051

Australia

[[www.csu.edu.au/faculty/health/conference/vmpf.htm](http://www.csu.edu.au/faculty/health/conference/vmpf.htm)]

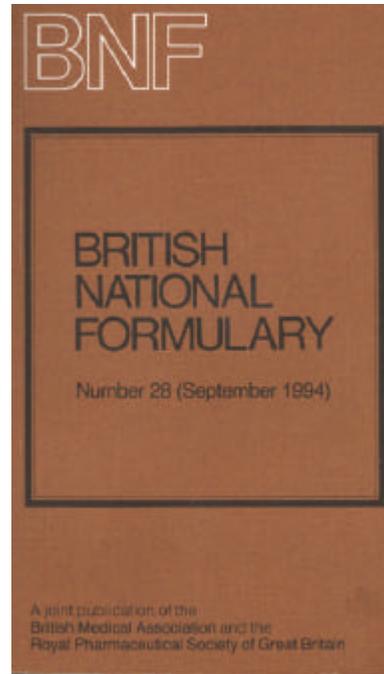
E-mail address: [vmpf@vicnet.net.au](mailto:vmpf@vicnet.net.au)

Past editions of these guidelines may be available for the cost of postage.

## BRITAIN

### *British National Formulary*

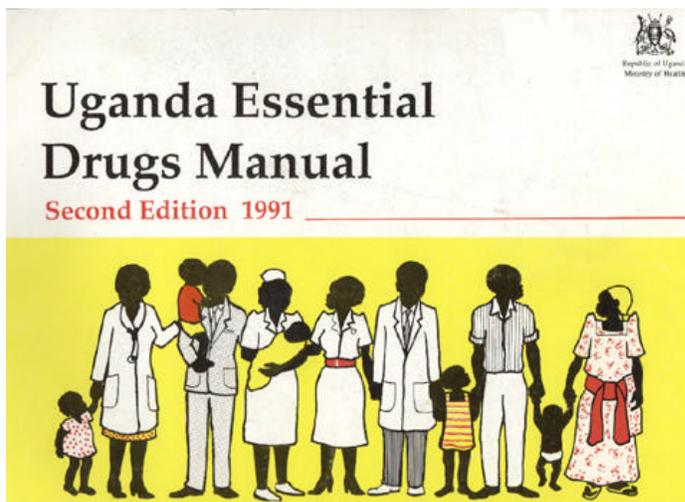
Available from:  
British Medical Association/Royal Pharmaceutical  
Society of Great Britain  
Tavistock Square  
London WC1H 9JP  
England



## KENYA

*Clinical Guidelines for the Diagnosis and Treatment of Common Hospital Conditions in Kenya*, November 1994

Available from:  
Ministry of Health  
Nairobi, Kenya



## UGANDA

*Uganda Essential Drugs Manual*,  
1997

Available from:  
Ministry of Health  
Uganda Essential Drugs  
Management Programme  
Central Medical Stores  
PO Box 16  
Entebbe, Uganda

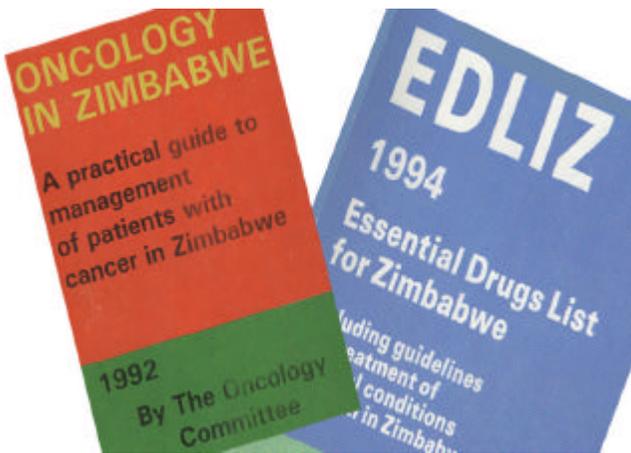
## ZIMBABWE

*EDLIZ (Essential Drugs List for Zimbabwe), 1994*

A series of 15 modules on clinical and management topics is also available

Available from:

Zimbabwe Essential Drugs Action Programme  
Ministry of Health  
Box 8168  
Causeway, Harare  
Zimbabwe

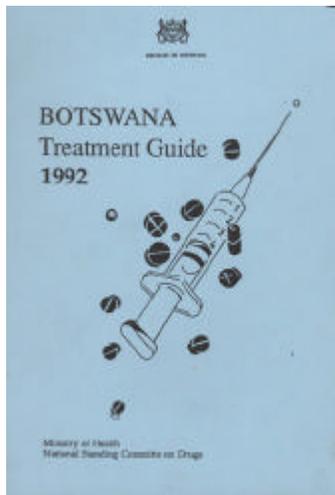


## BOTSWANA

*Botswana Treatment Guide, 1992*

Available from:

National Standing Committee on Drugs  
Ministry of Health  
Gaborone, Botswana





## MALAWI

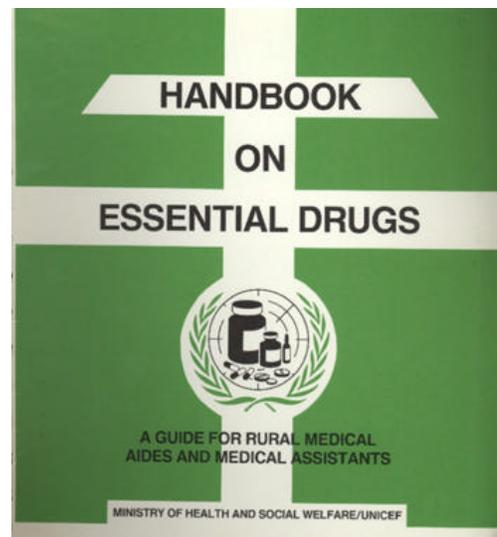
*Standard Treatment Guidelines*  
(available in both pocket and desktop  
versions), 1993  
*The Malawi Prescriber's Companion*,  
1993

Available from:  
Malawi Essential Drugs Programme  
PO Box 30390  
Lilongwe 3, Malawi

## TANZANIA

*Standard Treatment Guidelines and The  
National Essential Drug List for Tanzania*, 1991

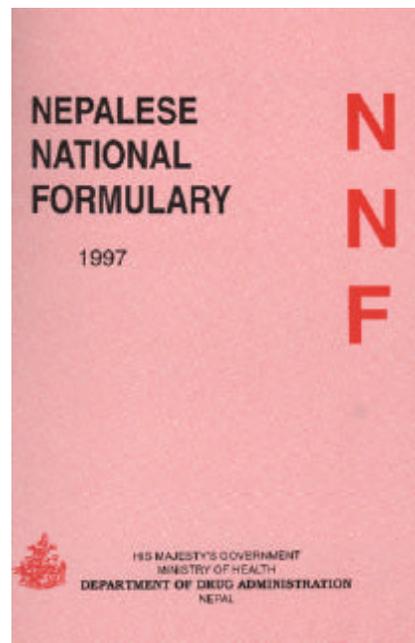
Available from:  
Ministry of Health  
Dar es Salaam  
United Republic of Tanzania

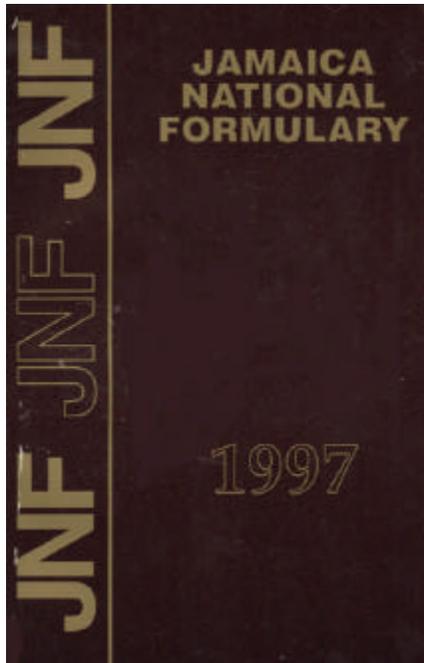


## NEPAL

*Nepalese National Formulary*, 1997

Available from:  
Department of Drug Administration  
Bijulbazar, Naya Baneshwor  
Katmandu Nepal  
Fax: (977-1) 244927  
E-mail: [dda@npl.healthnet.org](mailto:dda@npl.healthnet.org)





## JAMAICA

*Jamaica National Formulary, 1997*

Available from:  
Pharmaceutical Services Division  
Ministry of Health  
Kingston 5, Jamaica