



NATIONAL OPEN UNIVERSITY OF NIGERIA

SCHOOL OF SCIENCE AND TECHNOLOGY

**COURSE CODE: CHS426**

**COURSE TITLE: Essential Drug Supply Systems**

## **COURSE GUIDE**

**COURSE CODE:** CHS 426

**COURSE TITLE:** ESSENTIAL DRUG SUPPLY SYSTEMS

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## **Introduction**

Essential Drug Supply system is a second semester course. It is a three credit course available to all students offering a Bachelor of science (B.Sc.) in Community Health. Essential drug Supply System is a special field of Pharmacy. The community health practitioner must be trained in the same way and work with the same methods as other health workers who specialize in other areas in the health care industry.

The concept of Essential drug supply system has various appendages but various meanings to people in different fields. The prime concern of Essential Drug Supply System is with the Government, Health workers and the Society at large.

It involves what roles should be played by Government in terms of policy making, how effective health workers should be in respect of drug management and most importantly how available, affordable and accessible are essential drugs to members of the community.

However, Pharmacy is a discipline which deals with the recognition, quality, purity and identification of drugs, but the Essential Drug Supply System as a whole is concerned with the concept of National drug policy and National Drug Formulary, Management of Essential drugs and supply system, Essential drug list and pharmacology of Essential in the primary health care and the concept of Drug Revolving fund. The purpose underlying the study of the Essential drug supply system is to ensure that those drugs that satisfy the health care needs of the majority of the population are available at all times in adequate amounts and in appropriate dosage forms, at a price the community can afford.

## **What you will Learn in this Course**

The Course consists of units and a course Guide. This course guide tells you briefly what the course is about, what course materials you will be using and how you can work with these materials. In addition, it advocates some general guide lines for the amount of time you are likely to spend on each unit of the course in order to complete it successfully.

It gives you guidance in respect of your Tutor Marked Assignment which will be made available in the Assignment file. There will be regular tutorial classes that are related to the course. It is advisable for you to attend these tutorial sessions.

The course will prepare you for the challenges you will meet in the field and practice of community health.

### **Course Aims**

The aim of the course is not complex. The course aims at providing you with an understanding of Essential drug supply system. It also aims to provide you with solutions to problems involving essential drug availability, management and usage, particularly at the primary health care level.

### **Course Objectives**

To achieve the aims set out, the course has a set of objectives. Each unit has specific objectives which are included at the beginning of the unit. You should read these objectives before you study the unit. You may wish to refer to them during your study to check on your progress. You should always look at the unit objectives after completion of each unit. By doing this, you would have followed the instructions in the unit.

Below are the comprehensive objectives of the course as a whole. By meeting these objectives, you should have achieved the aims of the course as a whole. In addition to the aims above, the course sets to achieve some objectives. thus, after going through course, you should be able to:

- ❖ Explain the concept of National Drug Policy and its significance
- ❖ Identify basic pharmaceutical terms and important events in the development of Essential drugs as a global concept and in Nigeria.
- ❖ Explain the concept of Management of Essential drugs and supply system
- ❖ Identify major steps involved in Essential Drug Management at all levels
- ❖ Explain the concept of Essential drug list and pharmacology of Essential drugs in primary health care.
- ❖ Identify the significance, strategies, approaches, problems, and solution in Essential drug supply system
- ❖ Explain the concept of Drug Revolving Fund
- ❖ Identify the mechanisms of drug financing, most importantly in developing countries
- ❖ Explain the principles of drug Economic strategies

### **Working through this course**

To complete this course, you are required to read each study unit, read the text book and read other materials which may be provided by the National Open University of Nigeria.

Each unit contains self assessment exercises and at certain points in the course you would be required to submit assignments for assessment purposes. At the end of the course, there is a final examination. The course should take you about a total of 17 weeks to complete. Below, you will find listed, all the components of the course, what you have to do and how you should allocate your time to each unit in order to complete the course on time and successfully.

This course entails that you spend a lot of time to read. I would advise that you avail yourself the opportunity of attending the tutorial sessions where you have the opportunity of comparing your knowledge with that of other people.

### **The Course Materials**

The main components of the course are:

1. the Course Guide
2. Study Units
3. References/Further Readings
4. Assignments
5. Presentation Schedule

### **Study Unit**

The study units in this course are as follows:

Module 1     Concept of National Drug Policy and National Drug formulary

Study Unit 1: National Drug Policy

Study Unit 2: Primary Strategies for Implementing the National Drug Policy in Nigeria.

Study Unit 3: Secondary strategies for Implementing Nigerian Drug Policy

Study Unit 4: Regulations for Prescribing and Dispensing Drugs, Pharmacovigilance, Drug Information and Financial Availability.

Study Unit 5: Drug Research and Development.

Study Unit 6: National Drug Formulary

Module 2      Management of Essential Drugs and Supply System

- Study Unit 1: Selection of Essential Drugs
- Study Unit 2: Quantification of Selected Essential Drugs
- Study Unit 3: Costing and Procurement of Selected and Quantified Essential Drugs.
- Study Unit 4: Essential Drug Ordering, Receiving, Storage, Stock control and Distribution.
- Study Unit 5: Performance Indicators for Evaluating Essential Drug Programme.

Module 3      Essential Drug List and Pharmacology of Essential Drugs in Primary Health Care

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- Study Unit 1: Essential Drug Concept
  - Study Unit 2: WHO Model list of Essential Drugs
  - Study Unit 3: Pharmacology of Essential Drugs in Primary Health Care
  - Study Unit 4: Essential Drug List for Primary Health Care in Nigeria

Module 4      Concept of Drug Revolving Fund (DRF)

- Study Unit 1: Drug Financing System
- Study Unit 2: Cost - Sharing Mechanisms
- Study Unit 3: Drug Revolving Fund, Financial System
- Study Unit 4: Drug Revolving Fund, Supply System
- Study Unit 5: DRF Drug Distribution System

The first Unit focuses on the concept of National Drug Policy and the national Drug Formulary. The second and third deals with the primary and secondary strategies for implementing the National Drug Policy in Nigeria. The fourth unit is concerned with the Regulations for prescribing and dispensing drugs, pharmacovigilance, Drug Information, finance and affordability. The fifth and sixth unit focuses on Drug research and development, and the concept of National Drug Formulary.

In model two, unit One, Two and Three deals with selection of Essential Drugs, Quantification of selected essential drugs and costing and procurement of selected drug Ordering, Receiving, Storage, Stock control and Distribution and Performance indicators for evaluating Essential drug programme.

In model three, unit one and two focuses on the concept of Essential drug and the WHO model list of Essential drugs. The third and fourth unit deals with the pharmacology of Essential drugs at the primary health care level and Essential Drug list for the primary health care system. Finally in module four, unit one and two deals with Drug Financing system and cost sharing mechanisms while unit three, four and five focuses on drug Revolving fund financial system, Drug Revolving fund supply system and finally Drug Distribution in a Drug Revolving Fund system.

Each unit consists of one or two weeks work and include an Introduction, Unit Objectives, Reading Materials, Exercises, Conclusion, Summary, Tutor Marked Assignments (TMAs), References and other Resources. The unit directs you to work on exercises related to the required reading. In general, these exercises test you on the materials you have just covered or require you to apply it in some way and thereby assist you to evaluate your progress and to reinforce your comprehension of the material. Together with TMAs, these exercises will help you in achieving the stated learning objectives of the individual units and of the course as a whole.

### **Presentation Schedule**

Your course materials have important dates for the early and timely completion and submission of your TMAs and attending tutorials. You should remember that you are required to submit all your assignments by the stipulated time and date. You should guard against falling behind in your work.

### **Assessment**

There are three aspects of the Assessment of the course. First is made up of self-assessment exercise, second consists of the tutor marked Assignment and third is the written examination / end of course examination. You are advised to do the exercises. In tackling the assignments, you are expected to apply information, knowledge and techniques you gathered during the course. The assignments must be submitted to your facilitator for formal assessment in accordance with the assignment file. The work you submit to your tutor for assessment will count for 30% of your total course work. At the end of the course, you will need to sit for a final or end of course examination of about three hour duration. The examination will count for 70% of your total course mark.



## **Tutor Marked Assignment**

The TMA is a continuous assessment component of your course. It accounts for 30% of the total score. You will be given four (4) TMAs to answer. Three of there must be answered before you are allowed to sit for the end of course examination. The TMAs would be given to you by your facilitator and returned after you have done the assignment. Assignment questions for the units in this course are contained in the assignment file. You will be able to complete assignment from the information and the material contained in your reading, references and study units. However, it is desirable in all degree level of Education to demonstrate that you have read and researched more into your references, which will give you a wider view point and may provide you with a deeper understanding of the subject.

Make sure that each assignment reaches your facilitator on or before the dead line given in the presentation schedule and assignment file. If for any reason, you cannot complete your work on time, contact your facilitator before the assignment is due to discuss the possibility of an extension. Extension will not be granted after the due date unless there are exceptional circumstances.

## **Final Examination and Grading**

The end of course examination for introduction to Essential drugs supply system will be for about 3 hours and or has a value of **70%** of the total course work. The examination will consist of questions, which will reflect the type of self testing, practice exercise and tutor marked assignment problems you have previously encountered. All areas of the course will be assessed.

Use the time between finishing the last unit and sitting for the examination to revise the whole course. You might find it useful to review your self test, TMAs and comments on them before the examination. The end of course examination covers information from all parts of the course.

### **Course Making Scheme.**

<b>Assignment</b>	<b>Marks</b>
Tutor Marked Assignment – 4	Four Tutor Marked Assignments, best three marks of the four count at 10% each 30% of the course marks
End of course Examination	70% of over all course marks
Total	100% of course materials

## **Facilitators / Tutors and Tutorials**

These are 16 hours of tutorials provided in support of this course you will be notified of the dates, times and location of these tutorials as well as the name and phone number of your facilitator, as soon as you are allocated a tutorial group. Your facilitator will Mark and comment on your assignments, keep a close watch on your progress and any difficulties you might face and provide assistance to you during the course. You are expected to mail your Tutor Marked Assignment to your facilitator before the schedule date (at least two marking days are required). They will be marked by your tutor and returned to you as soon as possible.

Do not delay to contact your facilitator by telephone or e-mail if you need assistance.

The following might be circumstances in which you would find assistance necessary, hence you would have to contact your facilitator if:

- ❖ You do not understand any part of the study or the assigned readings
- ❖ You have difficulty with the self –tests.
- ❖ You have a question or problem with an assignment or with the grading of an assignment.

You should endeavour to attend the tutorials. This is the only change to have face to face contact with your course facilitator and to ask questions which are answered instantly. You can raise any problem encountered in the course of your study.

To gain much benefit from course tutorials, prepare a question list before attending them. You will learn a lot from participating actively in discussions.

## **Summary**

Essential drugs supply system is a course that intends to provide the concept of the discipline and is concerned with all process and the entire system of Essential drug programme policy with respect to selection, Quantification, Ordering / procurement, Storage and Distribution, thus, ensuring availability, affordability and accessibility to members of the community.

Upon completing this course, you will be equipped with the basic knowledge of the concept of National drug policy, management of essential drugs, at all levels of Government, Essential drug lists and pharmacology of essential drug list and finally the Drug Financing systems and mechanisms.

In addition, you will be able to answer the following types of questions:

- ❖ What does National Drug Policy mean and its contribution to National Development.
- ❖ Of what importance is the National drug formulary to health workers
- ❖ Identify the goals of National drugs use
- ❖ Describe measures to be taken in the acceptance of Donated Drugs
- ❖ Define pharmacovigilance
- ❖ Discuss briefly the concept of drug Research and Development
- ❖ Define Essential drugs and pharmacology
- ❖ Criteria for selection of Essential drugs
- ❖ Itemize the advantages of scientific Quantification
- ❖ Discuss the Drug Storage concept
- ❖ Identify general mechanism of action of drugs.

Of course, the list of questions that you can answer is not limited to the above list. To gain the most from this course you should endeavour to apply the principles you have learnt to your understanding of the essential drugs supply system. I wish you success in the course and I hope that you will find it both interesting and useful.

## **CHS 426 MODULE 1: CONCEPT OF NATIONAL DRUG POLICY AND NATIONAL DRUG FORMULARY**

### **STUDY UNIT 1: NATIONAL DRUG POLICY**

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#### **1.0 Introduction**

Having gone through the course guide, you would have acquired a general overview of what this unit is all about, how it links to the course. This unit will assist you in acquiring the basic understanding of the goals and objectives of National Drug Policy, as well as the targets of the Nigerian Drug Policy.

Meanwhile, let us have a view of what you should learn in this unit, as indicated in the unit objectives below.

#### **2.0 Unit Objectives**

At the end of this unit, you should be able to:

- Define Drug(s) and Drug Policy
- Describe the Historical Perspective of National Drug Policy

- Mention the Goals of the National Drug Policy
- Outline the objectives of the National Drug Policy
- Mention the major targets of the Nigerian National Drug Policy.

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### **3.0 Main Content**

#### **3.1 Definition of Drug and Drug Policy**

Drug includes any substance or mixture of substances manufactured, sold or advertised for use in the diagnosis, treatment, mitigation or prevention of any disease disorder, abnormal physical state, or the symptoms there of, in man or in animals; restoring, correcting or modifying organic functions in man or in animals; disinfection, or the control of vermin, insects or pests; or contraception.

A National Drug Policy (NDP) is a guide for action and the document is generally written with goals set by the Pharmaceutical Sector. It provides a useful framework to co-ordinate activities by the various partners of the Pharmaceutical Sector. The Public Sector, NGOs, Private Sector, donors and other interested partners (WHO 1995).

#### **3.2 Historical perspective of the National Drug Policy**

In 1975, the World Health Assembly in resolution WHA28.66 requested WHO to develop means to assist Member States in formulating national drug policies. It also urged WHO to assist countries in implementing strategies, such as the selection of essential drugs and appropriate procurement of quality drugs based on health needs, and in providing education and training in various elements of pharmaceutical programmes. This resolution was followed by a series of events that marked the evolution of country drug programmes with the assistance of WHO.

The first WHO Model List of Essential Drugs was published in 1977. A year later the WHO/UNICEF Conference on Primary Health Care at Alma-Ata included access to essential drugs as one of the eight

elements of primary health care. In 1979, the WHO Action Programme on Essential Drugs was established. Another landmark in promoting strategies to improve the pharmaceutical situation in countries was the 1985 Conference of Experts on Rational Use of Drugs in Nairobi.

The following year's World Health Assembly adopted resolutions that reflected the Conference recommendations on promoting rational use of drugs. Also in 1986, a WHO Expert Committee on National Drug Policies met to develop practical guidance for Member States, published as Guidelines for developing national drug policies.

This publication has proved very useful over the years. The efforts of countries, WHO and other agencies have had a considerable impact. The number of people with access to essential drugs has grown from roughly 2,100 million in 1977 to an estimated 3,800 million in 1999. By 1999, 66 countries had formulated or updated a national drug policy within the previous 10 years, compared with 14 countries in 1989. By the end of 1999, 156 WHO Member States had a national essential drugs list; 127 of the lists had been revised within the previous five years.

Nevertheless, problems of access to quality drugs and rational use persist. Although few hard data are available, it is likely that in the poorest parts of Africa and Asia more than half the population still lacks access to essential drugs. And there are new challenges that may have an impact on access, such as the expansion of the private sector's role in pharmaceuticals, health sector reforms and the effects of globalization. The changing pattern of diseases, antimicrobial resistance and emerging new diseases are other factors. Particularly important is the current trend of governments to reduce health care spending because of inadequate resources, despite increasing health needs. After a decade, and with new problems to be addressed, there was a clear need to revise the 1988 guidelines.

The Expert Committee on National Drug Policies met in 1995 to review the current pharmaceutical situation and to start the updating process. Their deliberations resulted in a report that became the basis of the present guidelines. These updated guidelines focus on the national drug policy process, strategies and options which can be used by Member States and organizations active in the pharmaceutical sector. Each policy component is discussed, with a focus on current problems and new challenges.

### **3.3 Goals of the National Drug Policy**

The goals of the policy in any nation of the world shall be to make available at all times to the entire citizenry adequate supplies of drugs that are effective, affordable, safe and of good quality to ensure the rational use of such drugs; and to stimulate increased local production of essential drugs.

### **3.4 Common objectives of the National Drug Policy**

The objectives of the policy, found to be common in most countries of the world are to:

- ❖ Ensure efficient and effective drug management in the public and private sectors
- ❖ Ensure access to safe, effective, affordable and good quality drugs at all levels of health care on the basis of health needs.
- ❖ Promote the rational use of drugs by prescribers, dispensers and consumers;
- ❖ Increase local drug manufacture/production and promote export;
- ❖ Ensure that all drugs in the national drug distribution system are safe, efficacious, effective and of good quality.
- ❖ Strengthen administrative, legislative and regulatory controls of the importation, manufacture, procurement, storage, distribution, supply, sale and use of drugs;
- ❖ Promote research on herbal remedies and integrate those found to be safe and efficacious into the health system;
- ❖ Promote pharmaceutical research and development of raw materials for the production, compounding and formulation of pharmaceutical products, as well as operational research for the effective implementation of the National Drug Policy and;
- ❖ Enlist government commitment at all levels for the achievement of the goals and objectives of the National Drug Policy.

### **3.5 Target of the Nigerian National Drug Policy**

The maiden National Drug Policy (**NDP**) for Nigeria was adopted in **1990** against the background of inadequacies in drug availability, supply and distribution resulting from various factors such as:

- An ineffective system of drug administration and control
- Inadequate functioning of drug supply and drug control activities
- High dependence on foreign sources for finished drug products; pharmaceutical raw materials, reagents and equipment;
- Inadequate facilities for storage, transportation and distribution of drugs;
  - Poor selection and procurement practices;
- Lack of political will to provide safe, efficacious and good quality drugs to meet the health needs of Nigerians.

Moreover, the implementation of the National Drug Policy in Nigeria shall be directed towards accomplishing the following targets:

- Establishment of a National Drug Policy Monitoring and Evaluation Division in the Food and Drugs Services Department of the Federal Ministry of Health by the year **2005**;
- Total adherence to the use of the essential drugs list in the public health institutions by **2008**;
- **80%** adherence to good drug procurement practices in the public sector by **2008**;
- Availability of adequate drug storage conditions in **80%** of the public and private care health facilities by **2008**;
- Establishment of three new, fully equipped and adequately staffed laboratories in strategic locations of the country for more effective quality assurance of drugs & pharmaceutical products in Nigeria by **2006**
- Inclusion of Rational use of Drugs concept and the National Drug Policy issues in the Curricula of all health professional schools and continuing education programmes by **2006**;



- Institutionalization of functional Drugs and Therapeutics committees and drug information centres in **60%** of Secondary and Tertiary Health facilities by 2007.

#### **4.0 Conclusion**

In this unit, you have learned the definition of Drug(s), Drug Policy as well as the Historical Perspective of the National Drug Policy. You have also realized that there are stereo specific common goals and objectives pre-determined and designed by the World Health Organization as well as in collaboration with Federal Ministry of Health of Individual nations of the world.

This unit has also enumerated in detail the common objectives of a National Drug Policy, furthermore, via an Historical Perspective of the formulation and adoption of a National Drug Policy in Nigeria, the background inadequacies necessitating the various targets towards which the implementation of the National Drug Policy should be implemented.

You should at this point be able to define Drug(s) and National Drug Policy in your own words. Also, you should be able to outline/enumerate the objectives and targets of the Nigerian National Drug Policy.

#### **5.0 Summary**

This unit has focused mainly on the definition of Drug (s), Drug Policy, and the Historical perspective of National Drug Policy, Goals and objectives of a National Drug Policy and most importantly the identified targets of the Nigerian National Drug Policy. Unit two will focus on the primary and secondary strategies for implementing the National Drug Policy as regard the goals, objectives and targets discussed in this unit.

#### **6.0 Tutor Marked Assignment**

- Define Drug(s) and Drug Policy.
- State at least five objectives of a National Drug Policy.
- Enumerate five targets of the Nigerian National Drug Policy.

#### **7.0 References / Further Readings**

Agreement Establishing the Eastern Caribbean Drug Service, Published by ECDS, Castries, St. Lucia, 1990

Ministerial Committee on Drug Policy, 2007, National Drug Policy 2007 – 2010, Wellington: Ministry of Health.

Federal Ministry of Health, World Health Organisation, Department for International Development and European Union (2005): National Drug Policy (First Revision, 2005), Abuja, Nigeria  
Mechanics Policy World Health Organisation, 2009.

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## **STUDY UNIT 2: PRIMARY STRATEGIES FOR IMPLEMENTING THE NATIONAL DRUG POLICY IN NIGERIA**

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- 3.6.5 Drug and Therapeutic Committees
- 4.0 Conclusion
- 5.0 Summary
- 6.0 Tutor Marked Assignment
- 7.0 References/Further Readings

## **1.0 Introduction**

You have read through the course Guide, thus, you would have acquired an overview of what this unit is expected to cover and its relevance to the course. This unit will help you acquire basic understanding of the primary strategies designed for implementing drug policies in Nigeria; thus, you will be exposed to information involving Selection and Procurement of Drugs, Drug Revolving Fund Scheme, Pricing Policy, Drug Storage, Distribution and Rational Drug Use.

Before we do this, let us have a clear overview of what you need to learn in this unit, as shown below in the unit objectives.

## **2.0 Unit Objectives**

At the end of this unit, you should be able to:

- ❖ Describe the objectives of the drug selection processes and what steps should be taken by Federal Government in doing this.
- ❖ Mention various criteria designed to ensure successful drug procurement.
- ❖ Outline the objectives of Pricing Policy, Drug Storage, distribution and Rational drug Use as a means of implementing the National Drug Policy.

## **3.0 Main Content**

The strategies that shall be used to implement the National Drug Policy shall focus on effective drug management processes, such as

rational drug selection, proper quantification of drug needs at all levels of health care delivery and effective procurement practices etc.

### **3.1 Selection of Drugs**

The objective of the drug selection process is to have a national list of drugs rationally closer to satisfy the health needs of the majority of the population. Such a list shall be revised regularly and shall form the basis of drug selection by primary, secondary and tertiary public health care institutions. In this regard, the Federal government shall take the following steps:

- A revised Essential Drug List shall be published by the Federal Ministry of Health and made available to health professionals in state and local governments, primary, secondary and tertiary health institutions.
- As much as possible, formulations containing more than one active ingredient shall be avoided, unless one or more of the following criteria are met:
  - Clinical condition justifies the use of more than one drug in a fixed combination.
  - Patient compliance is enhanced by the combination
- When two or more drug are therapeutically equivalent or several drugs are available for the same indication, preference shall be given to products with the
  - Most scientific research and clinical data
  - Most favourable pharmacokinetic properties
  - Best cost advantage and patient compliance
- The Essential Drug List Review Committee shall update the list every four years;
- Suggestions for amendment shall be made in writing on a prescribed form to the Federal Ministry of health, justifying each suggested amendment.

### **3.2 Procurement of Drugs**

The procurement process is a major determinant of the safety, efficacy, quality, affordability and availability of drugs on the basis of relevant information, need and available resources. To address the situation, the understated are some of the criteria required to adhere to:

- Government shall be committed to good pharmaceutical procurement practices in the public sector;
  - Procurement of drugs shall be restricted to drugs registered in Nigeria and on the Essential Drugs List;
  - Procurement in the public sector shall be by International Non-proprietary Names (**INN**) or generic names only,
  - Drugs procured at all levels shall be subjected to quality assessment before distribution to dispensing units.
- 
- In order to keep prices low and undertake adequate quality assessment, drugs, shall as much as possible, be purchased in bulk.

### **3.3 Drug Revolving Fund Scheme**

The Drug Revolving Fund scheme is a very effective strategy for ensuring uninterrupted drug supply in the health care delivery system. Experience from several health institutions in the country, however, has shown that its advantages have not been apparent due to a variety of reasons, including the following:

- ❖ Poor management
- ❖ Wrong application of the fund
- ❖ Purchasing of drugs at exorbitant prices,
- ❖ Lumping of the proceeds of the fund into a general account, and
- ❖ Non- reimbursement of the cost of drugs for exempted patients.

Consequently, the Drug Revolving Fund Scheme should be strengthened at all levels of Government through:

- Establishment of a **DRF** committee in every health Institution for an effective and transparent fund management.
- Provision of adequate capital for the procurement of required drugs;
- Maintenance of a separate account for the **DRF** scheme while ensuring strict accountability for the drugs; and

- Provision of appropriate training for the **DRF** personnel.

### **3.4 Pricing Policy**

Experience in recent years has shown that drugs have been procured at much higher prices in public health institutions than in private retail pharmacies. Even within the public sector, there are wide variations in the prices of the same drugs from one institution to another. Therefore, to ensure affordability of drugs in public health institutions, Government shall establish necessary mechanisms to guarantee that drug supply to patients shall cost less than in the private sector.

### **3.5 Drug Storage and Distribution**

The objectives of drug storage shall be to ensure stock security and the maintenance of the quality of drugs throughout their shelf life. Government shall ensure that suitably located, constructed and equipped storage facilities will be available at every level of the drug distribution system, in both public and private sectors.

The efficient and successful operation of a drug storage and distribution system requires the professional skills of pharmacists. Therefore, pharmacists shall be in charge of the drug stores operated by the Federal, State and Local Government as well as in the private sector.

In the same vein, Rational Drug Distribution Channels shall be promoted in both public and private sectors. In this regard, the following measures shall be enforced by the Federal government:

- ❖ Drug distribution, supply, sale and dispensing shall be under the control
- ❖ and supervision of pharmacists at all levels;
- ❖ Government shall ensure that drug manufacturing, wholesaling and retailing activities are registered as distinct enterprises;
- ❖ Government shall ensure that all drugs purchased or donated to governments at all levels are channeled through the central medical stores.

### **3.6 Rational Drug Use**

The requirements for rational drug use are that the right drugs shall be used for the right indications in the right dose and dosage form for the right duration. Rational drug use as an essential element of a National Drug Policy seeks to avoid the all too-frequent problems of under- and over-prescription, in appropriate prescription, and the use of new, expensive drugs when equally effective, well-tried, safe and cheaper alternatives are available.

### **3.6.1 Education and Training**

The objective is to ensure that all health personnel involved in the diagnosis, prescription and dispensing of drugs, as well as consumers receive adequate theoretical and practical training in rational drug use. It will, therefore, be necessary to take the following initiatives:

- ❖ Promote the teaching of the concepts of rational drug use in pharmacy, medical, nursing and veterinary schools;
- ❖ Teach communication skills in pharmacy, medical, nursing and veterinary schools to promote rational prescribing and dispensing; and
- ❖ Develop educational strategies and programmes directed at the public on appropriate use of drugs.

### **3.6.2 Rational Prescribing**

The objective is to ensure that drugs are prescribed rationally. Consequently,

- Up-to-date Standard Treatment guidelines and a National formulary shall be made available to all prescribers according to the level of care;
- Prescribing shall be by International Non-Proprietary Names (INN) or generic names; and
- At health care facilities, diagnostic services appropriate to the level of health provided so as to improve the accuracy of diagnosis.

### **3.6.3 Rational Dispensing**

The objective of rational dispensing shall be to ensure that patients receive adequate information on the use of dispensed drugs in order to

derive the desired benefits to them. In this regard the following shall be put in place:

- Dispensing shall only be carried out on duly licensed premises;
- The minimum information requirement on the label of a dispensed medicine shall be the following:
  - ✓ Name of patient,
  - ✓ Generic name of dispensed drug,
  - ✓ Strength of the drug,
  - ✓ Dosage Instruction in symbols or words as may be appropriate, duration of treatment, Date of Dispensing, and the Name of the Institution where the drug was dispensed.
- The patient shall be counseled on the use of dispensed drugs, in a conducive environment suitable for effective communication, and
- Dispensing shall be carried out in a suitable container that will be child proof and ensure the stability of the drug dispensed.

#### **3.6.4 Drug Information Services**

Drug Information is intended to provide unbiased, scientifically validated drug information to promote rational prescribing, dispensing and use. In this respect, therefore, the following measures shall be taken:

- The Drugs Information Unit shall be established in all public health institutions.
- The Drug Information Unit/Centre shall, at all times, be suitably equipped and provided with up to date reference materials and equipment, including computers, and internet access, to guarantee the acquisition and dissemination of current and accurate drug information.

#### **3.6.5 Drug and Therapeutic Committee**

Drugs and Therapeutics Committees are institutionalized mechanisms for promoting, implementing and monitoring the concept of



rational drug use in health care institutions. Therefore, the following measures shall be taken:

- A **DTC** shall among other duties, be responsible for the accurate selection of drugs for use in the institution, based on the national essential drug list, estimation of pharmaceutical requirements for the hospital and monitoring of the rational use of drugs in the institution.

### **3.6.6 Self – Medication**

Self-medication is especially useful in any situation where access to health care facilities is limited. It can offer the advantage of providing quick and effective relief that does not require medical attention. However, as advantageous as it could be, it also could lead to drug misuse and abuse. Hence, in order to obtain the benefits of self-medications while avoiding its risks, the following steps shall be taken:

- A list of drugs that can be sold without prescription and used for the short term relief of symptoms, without prior medical consultation and precise diagnosis, shall be drawn up and published by government.
- Information on, and the labeling and promotion of drugs, meant for self-medication, shall conform to laws and regulations set out for such categories of drugs;
- Health Education to the public on Appropriate Self-medication shall be provided through use of print and electronic media, and other communication methods.

## **4.0 Conclusion**

In this unit, you have learned the objectives and steps designed to ensure proper selection and, procurement of drugs at all levels, Drug Revolving Fund Scheme, Pricing Policy, Drug Storage and Distribution, and the concept of Rational Drug Use as primary or initial strategies for implementing the National Drug Policy in the Nigeria context.

You should by now be able to itemize all in your own words, ways through which rational drug use can be promoted as an essential element of a National Drug Policy.

## **5.0 Summary**

This unit focused on the effective drug management processes, such as Rational Drug Selection, proper quantification of drug needs at all levels of health care delivery, and effective procurement practices amidst other strategies.

Unit 3 will focus on secondary strategies for implementing the Nigerian Drug Policy.

## **6.0 Tutor Marked Assignment**

- a. State at least 5 steps the Nigerian Government should take to ensure proper selection of drugs?
- b. What do you understand by Rational Drug Use?

## **7.0 References/Further Readings**

Discussion Paper, South Pacific Pharmaceutical Project, WPR/HRH/HRH(1) 199.5 (a), WPRO, 1999

Draft Report of Experience on Bulk Purchasing of Essential Drugs, AFRO, 1999.

Federal Ministry of Health, World Health Organisation, Department for International Development and European Union (2005): National Drug Policy (First Revision, 2005), Abuja, Nigeria Mechanics Policy World Health Organisation, 2009.

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### **1.0 Introduction**

Since you have gone through the Course Guide as well as Unit **1 & 2** upon which this unit is built, you would have then acquired a general overview of what this unit is about, how it connects specifically to the course.

Moreover, this unit will help you to acquire further understanding of those strategies designed as being secondary to those previously discussed in Study Unit 2, this includes Donated Drugs, Local Drug Production, Drug Inspection, Importation and Exportation etc.

Before doing this, let us have a view of what you should learn in this unit, as indicated in the unit objectives below.

### **2.0 Unit Objectives**

At the end of this unit, you should be able to:

- Describe measures to be taken in the acceptance of Donated Drugs.
- Identify steps through which the Nation can achieve the target of greater reliance on Local Drug Protection

- Define the legal basis of the various strategies for achieving the objectives of the policy.
- Mention measures required to meet the required standards of quality, safety and efficacy of drugs via Importation and Exportation.
- Describe, Registration of Drugs, Patents, Quality Assurance in the Nigerian Context.

### **3.0 Main – content**

#### **3.1 Donated Drugs**

Experience has shown that some donated drugs have often not been relevant to the emergency situation for which they were donated or for the disease pattern, or for the level of care that was available. They may sometimes be unknown to Local Health Professionals and Patients and may not comply with locally agreed policies and standard treatment guidelines; they may even be harmful. In the light of this experience, the following measures shall be taken;

- All drugs donations for use in the country shall be processed through the Federal Ministry of Health as a clearing house to ensure compliance with the guidelines for drug donations.
- Donated drugs shall among other things be required to
  - Be registered for use, both by the drug regulatory authority of the donor country and in Nigeria
  - Have at least twelve months remaining shelf life after arrival in the Country.
- The Federal Ministry of Health shall put in place an adequate machinery for monitoring the distribution of donated drugs

#### **3.2 Local Drug Production**

The actual need for increased capacity in Local Drug Production has been well recognized. Such capacity should cover the production of raw materials and intermediate products, not just for mutilation and packaging.

In order to achieve the target of greater reliance on Local Drug Production, steps shall be taken by Government to;

- Encourage the development of a stable Economic and Political Environment.
- Intensify efforts to improve basic Infrastructure and Facilities.
- Provide an efficient regulatory Environment.
- Encourage Small Scale Industries.
- Encourage research on pharmaceutical raw materials.
- Encourage patronage of Local Drug manufacturers by Public and Private Health Care Institutions.

### **3.3 Drugs Inspection and Legislation**

Effective inspection of drug production and manufacturing facilities is critical to ensuring the quality, safety, and efficacy of drugs. It is also necessary in order to ensure storage, supply, distribution and sale of drugs etc.

Therefore, National Regulatory Authorities shall establish effective mechanisms for inspection in all drug manufacturing establishments, Public and Private Institutions, as well as; in drug sales and distribution outlets.

Legislation is the instrument by which the implementation of a drug policy is given a legal basis by statutorily defining the various strategies for achieving the objectives of the policy. It also defines the Qualification, Duties, Privileges, and Obligations of individuals, Organisations, Institutions, and other Bodies concerned with the implementation of the various strategies of the policy, and provides for sanctions in the event of violations.

However, for the implementation of Legislation, there is need to review and update the relevant laws regularly. In consultation with relevant stakeholders, in order to achieve the desired objectives some of the existing drug laws are in dire need of review and harmonization.

### **3.4 Importation and Exportation of Drugs**

A substantial proportion of drugs consumed in Nigeria are imported, while the export of drugs from the country is quite

insignificant. Ideally, there should be a balance between Importation and Exportation of Drugs. The National Drug Policy shall seek to promote self-reliance in National Drug consumption, as well as, the contribution of the Local Pharmaceutical Industry to the National Economy through Exportation.

Therefore, the following measures shall be implemented:

- ❖ Drug Imports and Exports shall be restricted to designated ports which shall be equipped with adequate storage facilities and on – the – spot facilities to ensure quality;
- ❖ Personnel of regulatory authorities shall be regularly trained to effectively carry out inspectorate activities.
- ❖ Pharmaceutical manufacturers shall be encouraged to maximize the use of their installed production capacity for export purposes.
- ❖ A strong Advocacy Machinery shall be established to promote the export of drugs manufactured in Nigeria.

### **3.5 Drug Registration, Patent and Quality Assurance.**

Drug registration is the vehicle for ensuring that Government has control over drugs that are offered for sale and use in the country. It ensures that drugs distributed in the country have been produced under good manufacturing practices and have passed the test of need, efficacy, safety and good quality. It is an Essential element in limiting the number and types of drug products brought into or manufactured in the Country. It is also the instrument by which new drugs can be added to, and old drugs found unsuitable removed from, the list of approved drugs.

In the light of this, Government shall:

- ❖ Continue to strengthen the drug registration mechanism that is presently in place within the National Agency for Food and Drug Administration and Control (NAFDAC).
- ❖ Ensure that all drugs, Traditional, Homeopathic preparations, as well as Vitamin and Mineral supplements are registered, and
- ❖ Ensure periodic and regular publication and wide dissemination of the list of registered drugs.

Patent protection has been an incentive for promoting research and development of new drugs, while patent protection is desirable. It should not constitute a hindrance to access to essential drugs by Nigerians. Government shall therefore, put in place strategies to ensure that public health, especially in securing Co-ordination between health, justice and trade ministries to ensure that public health issues are taken into consideration in Nigeria as well as in International negotiation.

The aim of Quality Assurance of a drug product is to ensure that the drug provided to the patient is safe, efficacious and of good quality. The process of quality assurance begins from the manufacturer and continues to the point of administration of the drug to the patient. Compliance with Good Manufacturing Practices (**GMP**) is always an important component of Quality Assurance.

Therefore, Government shall among other steps take appropriate action to ensure that:

- Regulatory authorities are strengthened and empowered to monitor and enforce compliance with quality assurance provisions by manufacturers of Imported and Locally produced drugs to ensure that patients and consumers receive only safe, efficacious and good quality drugs;
- Good Manufacturing Practices (**GMP**) shall continue to be monitored and enforced in all drug manufacturing outfits in the Country.
- Manufacturers will be required to package their products in appropriate containers in order to ensure the quality and stability of such products.

#### **4.0 Conclusion**

In this Unit, you have learned measures to be taken in the acceptance and monitoring of Donated Drugs, steps through which the Nation can achieve the target of greater reliance on Local Drug Production.

However, you have also realized that proper Drugs Inspection and Legislation should not be left out in the implementation of National Drug Policy. The unit also enumerated in details measures required to be taken by Government to maintain a balance between Importation and

Exportation while promoting self – reliance in material drug consumption.

You should at this point, be able to define in your own words and outline the roles of Government in the implementation of National Drug Policy via a proper control of Drug registration, Patent and Quality Assurance.

## **5.0 Summary**

The Unit focused on acceptance and monitoring of Donated Drugs, Local Drug Production, Drug Inspection and Legislation, Importation and Exportation, Registration, Patent and Quality Assurance as through which the implementation of National Drug Policy can be strategized. Unit 4 will focus on Regulations for prescribing and Dispensing of drugs, Pharmacovigilance, Drug Information Service, Promotion, Financing and Affordability.

## **6.0 Tutor Marked Assignment**

- Define the Legal basis of the various strategies for achieving the objectives of the policy?

## **7.0 References/further Readings.**

Quick, J.D. et al (Editor) Managing Drug Supply, Kumarian press, West Hartford, Connecticut, USA 1997

Draft report of Experience on bulk Purchasing of Essential Drugs AFRO, 1999.

Federal Ministry of Health, World Health Organisation, Department for International Development and European Union (2005): National Drug Policy (First Revision, 2005), Abuja, Nigeria Mechanics Policy World Health Organisation, 2009.



**UNIT 4: REGULATIONS FOR PRESCRIBING AND DISPENSING  
DRUGS, PHARMACOVIGILANCE, DRUG INFORMATION,  
FINANCIAL AND AFFORDABILITY.**

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- 1.0 Introduction
- 2.0 Unit Objectives
- 3.0 Main Content
  - 3.1 Regulations for prescribing and dispensing drugs,
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  - 3.4 Drug Financing and Affordability

- 4.0 Conclusion
- 5.0 Summary
- 6.0 Tutor Marked Assignment
- 7.0 Reference/Further reading

## **1.0 Introduction**

Since you have gone through the Course Guide, you would have acquired an overview of what this unit is about, how it links to the Course. This unit will assist you in acquiring the understanding of

## **2.0 Unit Objectives**

At the end of this unit, you should be able to:

- Describe the regulations for prescribing and dispensing Drugs
- Describe pharmacovigilance, as well as the reasons why it should be introduced and developed.
- Itemize steps to be taken and continued by government to ensure and sustain proper drug information and promotion system.
- State clearly what Government should do to realize the objectives of the National Drug Policy in respect of Drug Financing and Affordability.

## **3.0 Main Content.**

### **3.1 Regulations for Prescribing and Dispensing Drugs**

A prerequisite for effective drug control is that prescribing, dispensing and the sale of drugs be undertaken by duly authorized persons. Regulations for prescribing, dispensing and sale of drugs shall take into consideration the policy goal of rational drug use and the supply of safe and efficacious essential drugs at affordable cost. In view of the fact that drugs will be prescribed and dispensed at all levels of health care, including the most peripheral health stations manned by village health workers, regulations for prescribing and dispensing of drugs shall be sufficiently flexible to cover the activities of such health workers.

In view of the fact that research in many countries has shown that dispensing Doctors or prescribing Pharmacists use more drugs than others, it has become necessary to separate prescribing and dispensing functions, therefore, the laws and regulations regarding those who are allowed to prescribe, supply, sell and dispense drugs to the public at the different levels of the health care system shall be periodically updated, with the following minimum provisions:

### **3.1.1 Prescribing**

- ❖ In Tertiary and Secondary Institutions, only duly qualified and licensed Medical Practitioners shall have the authority to prescribe drugs. At the Primary Health Care level, Government shall designate appropriate Health Care Personnel to prescribe drugs;
- ❖ Only qualified and licensed medical practitioners shall have the authority to prescribe drugs in the Private Sector; and
- ❖ Prescriptions shall be made, using the International Non-Proprietary or Generic Names. It shall be made in a manner to ensure that proper records are kept at the records and pharmacy departments of Health Care Institutions in both Private and Public Sectors.

### **3.1.2 Dispensing**

- ❖ Only duly licensed Pharmacists shall have the authority to supply, sell and dispense drugs to the public. Such sales shall take place in premises licensed for the purpose, which shall be subject to regular inspection.

Continuing registration of a licensed premise shall depend on a satisfactory report by inspectors of the Pharmacists' Council of Nigeria (**PCN**) and the payment of prescribed fees;

- ❖ In view of the need for every Nigerian to have access to appropriate drugs, it shall be permissible for certain over-the-counter (**OTC**) drugs to be sold in patent medicine stores operated by Patent and Proprietary Medicine Vendor's Licensees (**PPMVL**), particularly in areas where there are no licensed pharmacists in practice. The premises for the sale of such drugs shall be approved and licensed and be subject to periodic inspection by pharmaceutical inspectors of the **PCN**. The list of drugs to be sold in such premises shall be those approved by government;

- ❖ In every Health Care Facility where there is a qualified and licensed medical practitioner, there shall be a qualified and licensed pharmacist to manage drugs; and
- ❖ In order to enhance total patient care, particularly as regards in-patients, government shall promote the practice of clinical pharmacy in secondary and tertiary health care institutions.

### **3.2 Pharmacovigilance**

Since no active drug is entirely free from adverse reactions, the introduction of an adverse drug reaction reporting system is an essential component of a national healthcare delivery system, government shall, therefore encourage the establishment of adequately equipped Pharmacovigilance Units Nation-wide, to collect, evaluate and disseminate relevant information on adverse drug reactions and poisoning. All drugs shall be regularly monitored with respect to their efficacy, safety, quality as well as adverse reactions to evaluate the need to exchange the conditions of their continuing registration or withdrawal from the market.

Any drug withdrawn or banned in many countries, due to unacceptable health risks, shall be automatically withdrawn from distribution in Nigeria.

### **4.0 Conclusion**

In this unit, you have learned what standards/regulations are required to ensure an effective drug control, the need to introduce and substation an adverse drug reaction reporting system (Pharmacovigilance) as an essential component of a national health care delivery system.

You should at this point be able to state clearly why the participation in the National Health Insurance scheme by individuals, organizations and communities is necessary. This participation shall however, be encouraged by Government to realize the objectives of the National Drug Policy.

### **5.0 Summary**

This unit has focused on the regulations for prescribing and dispensing drugs, the need to establish adequately equipped Pharmacovigilance units, nation-wide, to collect, evaluate and disseminate relevant information on adverse drug reaction and poisoning.

#### **6.0 Tutor Marked Assignments.**

- Using your own words define Pharmacovigilance
- Itemize what the federal Government should put in place to realize the objectives of National Drug Policy

#### **7.0 References/Further Readings**

WHO Medicine Strategy (2004 – 2007): Countries at the Cox.

Quick. J.D. et al. (Editors) Managing Drug Supply, Kumarian Press, West Hartford, Connecticut, USA 1997.

Federal Ministry of Health, World Health Organisation, Department for International Development and European Union (2005): National Drug Policy (First Revision, 2005), Abuja, Nigeria.

Mechanics Policy World Health Organisation, 2009.

## **STUDY UNIT 5: DRUG RESEARCH AND DEVELOPMENT**

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3.3	Human Resources Development
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6.0	Tutor Marked/Further Assignment
7.0	References/Further Readings.

### **1.0 Introduction**

You have gone through the course guide, you would have acquired a general overview of what this unit is about, how it links to the course. This unit will help you in acquiring the basic understanding of the

aims and objectives of Drug Research and Development, Herbal and other Traditional remedies, Human Resources Development, International Co-operation, Monitoring and Evaluation of Drug usage

Before we start doing this, let us have a clear overview of what you should learn in this unit, as stated below in the unit objectives.

## **2.0 Unit Objectives**

At the end of this unit, you should be able to:

- ❖ Itemize in your own words the aims of Drug Research and Development
- ❖ List possible areas of research and interventions in herbal remedies
- ❖ List the actions required by Government to implement National Drug Policy via well trained and experienced professionals.
- ❖ List ways through which better co-operation between drug importing and exporting nations can be achieved.
- ❖ Understand how government can put in place, mechanisms for monitoring, measuring and evaluation of the Policy's performance and impact.

## **3.0 Main content**

### **3.1 Research and Development**

The aim of Research and Development (R&D) is to promote, encourage and support ethical, scientific and operational research in the Pharmaceutical sector and facilitate the effective implementation of the National Drug Policy to meet the health care needs of the Country. Considering the enormous cost of research and development, governments shall provide support and an enabling environment to encourage such activities, specifically as described below:

#### **3.1.1 Drug Research and Development**

This aims at developing new drugs and improving existing ones, with the ultimate goal of producing safer, more effective and better quality drugs. Drug research and development are essential components of health

research that enhance the attainment of the goals and objectives of the National Health Policy.

Drug Research and Development shall be encouraged especially in the following areas:

Local raw materials with particular emphasis on petro-chemicals as sources for new drug and excipients;

Traditional medicines for the promotion of health and the treatment of diseases, and enhancing the quality of pharmaceutical products

### **3.1.2 Operational Research**

Operational research is necessary for the successful implementation of the National Drug Policy. Its aim is to identify the best methods of selecting, procuring, distributing and using drugs rationally. Its application shall lead to practical and cost – effective measures which would inform managerial, educational and regulatory interventions to improve access to and use of drugs.

## **3.2 Herbal/Traditional Remedies**

Herbal and traditional medicines are widely used in most nations of the world and most importantly Nigeria. Most of the drugs used in modern medicine today originate from plants and there is no doubt that new drugs can still be discovered from plants including those indigenous to Nigeria. The following list, of possible areas of research and interventions, which is by no means exhaustive should be supported with the provision of grants for their attainment by government, Local and International development partners;

Rational use of herbal medicines co-ordinated promotion, support and sponsorship of research on medicinal plants; Standardisation of products to ensure efficacy compilation of a compendium of herbal medicines. Encouragement of the development of a “code of practice” by herbal medicine practitioners. Regulation and control of advertisement of traditional medicine and practices by the government.



### **3.3 Human resources Development**

Well trained and experienced professionals, managerial technical and other personnel are necessary for planning, organizing and implementing the national drug policy, government shall, therefore, take the following actions

- ❖ Expand the facilities in the Universities and award scholarships for the training of Pharmacists and other relevant professionals required for the successful implementation of the National Drug Policy,
- ❖ Ensure constant review of pharmacy, medical and veterinary surgeon curricula, to reflect the need of drug policy implementation
- ❖ Strengthen the capacity of trainers to appropriately train undergraduates and postgraduates on the relevance and challenges of the National Drug Policy and
- ❖ Develop in - service training programmes to address on - the – job requirements in the implementation of the policy.

### **3.4 International Co-operation**

Co-operation between nations, particularly between importing and exporting countries can be advantageous in combating the influx of sub-standard and counterfeit drugs into importing countries, and thereby help to reduce substantially illicit drug trafficking. Such a co-operation shall be achieved through:

- ❖ The establishment and maintenance of appropriate channels of communication between drug regulatory and law enforcement authorities
- ❖ Promoting the training of personnel and human resource development
- ❖ The use of diplomatic channels for the exchange of information on substandard and counterfeit drugs in international commerce.
- ❖ Using WHO certification scheme on the quality of pharmaceutical products moving in international commerce or any similar scheme for all drug imports and exports

### **3.5 Monitoring and Evaluation**

The success of the National Drug Policy would depend on how well its provisions are implemented. Mechanisms shall therefore, be put in place for monitoring, measuring and evaluating the policy's performance and impact, and for identifying possible problems and evolving effective strategies to address them. In this regard, Government shall ensure;

- ❖ The setting up of a National Drug Policy monitoring and evaluation unit in the Federal Ministry of Health, to measure progress in the implementation of the policy and to run a National evaluation scheme;
- ❖ Institutionalizing of drug management information systems as a basis for deriving drug management and other relevant information for taking decisions on the National drug policy;
- ❖ Close monitoring of the effects of international trade agreements on Nigerian's access to essential drugs; and
- ❖ Undertaking of a full evaluation of the National Drug Policy every three years.

### **4.0 Conclusion**

In this unit, you have actually learned the concept of Drug Research and Development, Herbal and other traditional remedies as regards their relevance and what Government should put in place to ensure a proper but successful implementation of the National Drug Policy.

You should by now be able to itemize clearly actions required of Government to strengthen the capacity of personnel necessary for planning, organizing and implementing the National Drug Policy.

You also have learned ways through which international co-operation, monitoring and evaluation, as elements of a National Drug Policy can be developed and sustained.

## **5.0 Summary**

This unit focused on the Drug Research and Development, Herbal and other traditional remedies, Human Resource Development, International Co-operation, Monitoring and Evaluation, highlighting areas through which the National Drug Policy can be better implemented. Unit 6 will focus absolutely on National Drug Formulary.

## **6.0 Tutor Marked Assignment**

- (a) List the areas through which drug research and development should be encouraged
- (b) List possible areas of research and interventions as regards Herbal/traditional remedies

## **7.0 References/Further Readings**

WHO medicine strategy (2005)

Federal Ministry of Health, World Health Organisation,  
Department for International Development and European Union  
(2005):

National Drug Policy (First Revision, 2005), Abuja, Nigeria

Medicines Policy, World Health Organisation, (2009).

## **UNIT 6: NATIONAL DRUG FORMULARY**

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3.3	Sources of National drug Formulary Information
3.4	How to use a National Drug Formulary
4.0	Conclusion
5.0	Summary
6.0	Tutor Marked Assignment
7.0	References/Further Readings

### **1.0 Introduction**

Since you have gone through the course guide, you would have acquired a general overview of what this unit is about, how it links specifically to the course. This unit will help you acquire basic understanding of what the National Drug Formulary is, its basic components and objectives.

Before we do this let us have a view of what you should learn in this unit, as indicated in the unit objectives below.

### **2.0 Unit Objectives**

At the end of this unit, you should be able to:

- Define National Drug Formulary
- List objectives of a National Drug Formulary
- Describe Construction of a National Drug Formulary
- Enumerate Sources of National Drug Formulary
- Describe how to use a National Drug Formulary

### **3.0 Main Content**

#### **3.1 Introduction**

A National Drug Formulary is an official publication, issued first by the WHO Model Formulary in 1979, now a global concept, accepted by most nations of the world, issued yearly but designed to give the composition, description, method of preparation and dosage for drugs e.g. United States Pharmacopoeia and National Formulary (USP-NF), British National Formulary and the Nigerian EMDEX.

In some countries, there are regional or provincial formularies instead of or in addition to the National Formulary. By the turn of the millennium, 156 countries had national or provincial essential medicines lists and 135 countries had national treatment guidelines and/or formulary manuals.

The United States Pharmacopoeia USP, established in 1820, contains legally recognized standards of identity, strength, quality, purity, packaging and labeling for drug substances, dosage forms and other therapeutic products, including nutritional and dietary supplements.

In the same vein, the National Formulary (NF) established in 1888 by the American Pharmaceutical Association, includes standards for excipients, botanicals and other similar products. The USP-NF monographs contains specifications (tests, procedures, and acceptance criteria) that helps ensure the strength, quality and purity of named drug substances to ensure the quality of compounded preparations. USP-NF Monographs which are recognized world wide.

##### **3.1.1 Objectives of National Drug Formulary**

To entrench rational drug use among health care practitioners at every level of health care delivery system for the ultimate goal of the patient, the following are the main objectives of a National Drug Formulary as established by the WHO model formulary.

- To present in a single, convenient and easy-to-use volume, a quick reference source of information on drug prescribing, dispensing and administration.
- To provide access to drug information for physicians, dentists, pharmacists, nurses, individuals and auxiliary health officers in tertiary, secondary and primary health care institutions.
- To promote rational drug use which flows from rational drug prescribing and embraces rational dispensing and patient use, thus completing the cycle of rational drug therapy.
- To check the rising trend of therapeutic failure, adverse drug reaction treatment complications and wastages in drug use resulting from extravagant prescribing, over prescribing, in correct prescribing, multiple prescribing and under prescribing currently the case in most hospitals and clinics.
- To provide a teaching aid for the training and supervision of all categories of health care personnel and their auxiliaries.
- To promote the use of drug product and services of genuine and registered pharmaceutical companies through constant sourcing and updating of their corporate and product information.

### **3.2 Construction of National Drug Formulary**

Using the British National Formulary (BNF) as an example. The BNF is unique in bringing together authoritative, independent guidance on best practice with clinically validated drug information, enabling health care professionals to select safe and effective medicines for individual patient. Information in the BNF has been validated against emerging evidence, best practice guidelines, and advice from a network of clinical experts.

However, hundreds of changes are made between editions and the most clinically significant changes are listed at the front of each edition. A number of committee, team and experts advisers, the main ones are hereby discussed below.

- Joint Formulary Committee: (JFC) is responsible for the content of the BNF. This includes doctors, pharmacists, they decide on matters of policy and reviews amendments to the BNF in the light of new evidence and expert advice

- Editorial teams: BNF staff editors are pharmacists with a sound understanding of how drugs are used in clinical practice. They are responsible for editing, maintaining and updating specific chapters of the BNF. They also prepare the text for publications and undertake a number of checks on the knowledge at various stages of the production.
- Experts Advisers: The BNF uses about 60 experts clinical advisers (including doctors, pharmacists, nurses and dentists), throughout the U.K to help with the production of each edition. The role of these advisers is to review existing text and to comment on the amendments drafted by the staff editors. In addition to consulting with regular advisers, the BNF calls on other clinical specialists for specific developments when particular expertise is required.

### **3.3 Sources of Information (National Drug Formulary)**

A National Drug Formulary should exploit variety of sources for its information; the main ones are shown below:

- Summaries of product characteristics
- Expert-Advisers
- Literatures from Cox medical and pharmaceutical journals
- Systematic-reviews (Cochrane library & various web-based resources)
- Consensus guidelines of expert bodies
- Reference sources e.g. the Complete Drug Reference, the Martindale
- Statutory information from Government bodies
- Pricing information from the prescription pricing division
- Comment from readers via letters, emails etc
- Comments from the industry, and virtual user groups and market research

### **3.4 How to use a National Drug Formulary**

Using EMDEX, the complete drug formulary for Nigerian's health professional based on WHO model formulary with a guide to Drug-Administration as an example. To be able to get the best from the formulary users are advised to study the following information together with the table of contents most of the drug product monographs have been reproduced from the WHO model formulary plus the introductory clinical notes containing guidance on selecting the right machine for a

range of conditions. Appendixes 1 to 5 are also reproduced directly from the WHO Model Formulary (WMF).

At the end of a drug monograph, the WHO and/or Essential Drug List of Nigeria (EDL) recommended formula is provided accordingly. This is followed by the proprietary preparations of that particular drug which are approved for use in Nigeria.

The new EMDEX now has Appendices 1 to 8 as follows:

- Appendix 1 - Interaction
- Appendix 2 - Pregnancy
- Appendix 3 - Breast Feeding
- Appendix 4 - Renal Impairment
- Appendix 5 - Hepatic Impairment
- Appendix 6 - Caution and advise to parents on the use of use of dispensed machines
- Appendix 7 - Abbreviations
- Appendix 8 - Guide to Drug Administration

#### **4.0 Conclusion**

In this unit, you have learned what a National Drug Formulary is as well as its objectives. You have also realized that it originated from the WHO becoming a global concept which rose from the model list of the WHO. You have also been exposed to the construction and sources of information of a National Dry Formulary using the British National Formulary as a model. This unit has also described the use of a Nigerian Drug formulary “EMDEX”. You should at this point be able to define a national drug formulary in your own words.

#### **5.0 Summary**

This unit has focused on the definition of the National Drug Formulary. Objectives of a National Drug Formulary, how information of the British National Formulary is being sourced amidst various ways of constructing it.

#### **6.0 Tutor Marked Assignment**



- 1a. Define the National Drug Formulary
- b. List the sources of information for National Drug Formulary

## **7.0 References / Further Readings**

A National Formulary for Canada, Department of Economics, University of Calgary, (2005) [www.wikipedia.org/wiki/National\\_Formulary](http://www.wikipedia.org/wiki/National_Formulary)

The Complete Drug Formulary for Nigeria's Professionals  
2007 Edition

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## **MODULE 2: MANAGEMENT OF ESSENTIAL DRUGS AND SUPPLY SYSTEM**

### **STUDY UNIT 1: SELECTION OF ESSENTIAL DRUGS**

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### **1.0 Introduction**

Since you have gone through the course guide, you would have acquired a general overview of what this unit is about, how it links specifically to the course. This unit will help you acquire basic understanding of what management of essential drugs is and its basic components, particularly selection of essential drugs.

Before we do this, let us have a view of what you should learn in this unit, as indicated in the unit objectives below:

### **2.0 Objectives.**

At the end of this unit, you should be able to

- ❖ Define the term management of essential drugs
- ❖ Itemize the steps in drug management
- ❖ List the criteria for selection of essential drugs

### 3.0 **Main Content**

#### 3.1 **Definition and steps in drug management**

Essential drug management is the efficient use of drugs that are safe, effective, and affordable and which satisfy the health care needs of the majority and cover prevalent diseases and conditions of the people.

It can also be defined as the process of selection, procurement, storage, distribution and use of drugs in such a manner that will avoid drug wastage.

However, in discussing the various elements of an essential drugs system, the under stated steps are of utmost importance, particularly in drug management.

- ❖ Selection of drugs that are essential
- ❖ Quantifying selected essential drugs
- ❖ Costing the selected and quantified essential drugs
- ❖ Ordering of selected drugs according to the required quantities and ordering intervals
- ❖ Receiving and storage drugs
- ❖ Distribution, which includes issuing, inventory control, prescribing, dispensing and using drugs.

#### 3.2 **Selection of Essential Drugs**

This is the first step in the development of an essential drug programme. Drug selection carries a lot of responsibility. The choice of any preparation is based on its efficacy, safety, cost, route of administration and the health needs of the society amongst others. The criteria for the selection of drugs are given below. This will also requires the right team, process, communication, following standard procedures to arrive at a manageable list and communicating the list to all concerned.

### **3.2.1 Criteria for selection of essential drugs**

At national level of the nation, the list is based on essential drugs considered to be safe, cost effective and generically named having the following criteria:

- ❖ The drug should meet the health care needs of the majority of the people
- ❖ Must be efficacious
- ❖ Should be in dosage forms, acceptable to the people and should have a reliable shelf life
- ❖ Quality certification should be readily obtainable
- ❖ They should be as far as possible, drugs that can be easily manufactured locally
- ❖ They should preferably be in their generic forms
- ❖ Single drug formulations are mostly preferable

Apart from the above, it is important to state briefly some additional criteria, particularly for selection at community or facility level or local level.

- ❖ Training experience of the personnel in charge
- ❖ Prevailing ailments
- ❖ Type of health facility
- ❖ Genetic and environmental factors
- ❖ Demographic factors with respect to that community

### **3.2.2 Selection Team and the process**

The team preferably should be multi disciplinary, involving physicians, pharmacists and community health workers depending on the staff on ground. The committee is often empowered to consult other experts and to investigate prevailing drug use and supply.

By definition, an essential drug list must address the common health problems in the community. It therefore, follows that the major health problems must be identified. Health facility and community records will be of immense use where dependable data exists. The drug use pattern and related practices are also for review using available

records, extensive consultations and survey where necessary. A drug should only be chosen using identified criteria.

### **3.2.3 Decision making on the list**

The list should not be too long otherwise the aims of the exercise would be defeated. The WHO and the National Essential drug lists are invaluable references. The agreed list may then be subdivided into categories depending on the levels of care. In primary health care system, these may include separate lists for use by village health workers in the health posts and clinics with identified categories of staff as well as the health centres.

### **3.2.4 Communication**

For the list of drugs arrived at, to be meaningfully utilized, it should be distributed to all those involved in prescribing, dispensing, training and management of drugs. This will enable them to take informed decisions in respect of the programme. At some levels, it may also be necessary to have a formulary to provide health workers with recent information on the drugs in the essential drug lists.

However, different formularies may be provided for various categories of workers reflecting the level of their training on drugs as well as their responsibilities to the patient. The formulary is without prejudice to the use of standing order but provides highlights on dosages, indications, contra-indications and cost of drugs. Due to high cost of production and the need to update regularly, it may be more feasible to use existing manuals like “MIMS” EMDEX, Medipharm” or the “National Formulary”. Notes may then be made of the drugs appropriate to any given level

## **3.3 Methods of selection of essential drugs**

A scientifically based method of approach to selection is known as systematic cost reduction using 2 basic methods”

ABC Value Analysis and VEN system

ABC Value Analysis: This is a method based on the therapeutic value and cost of the drugs. It identifies the relatively small number of items which accounts for the majority of funds spent.

The VEN system: A method of categorizing drugs according to their potential health impact. All drugs on the supply list are placed into 3 categories as follows: Vital, Essential and Non-Essential.

#### CONDITIONS REQUIRED TO USE VEN

- ❖ During temporary severe restriction of funds – purchase restricted to only vital drugs
- ❖ To set safety stocks ensuring that vitally needed drugs are never out of stock
- ❖ To establish prices in drug sales programme – change higher for popular items with small health impact to subsidize vital expensive drugs

V = Vital – Potentially life saving drugs

E = Essential – drugs against less severe but significant form of illness

N = Non-Essential – drugs used for minor self limiting illnesses with high cost for marginal therapeutic advantage.

#### **4.0 Conclusion**

In this unit you have learned what the management of essential drugs is and that in defining it, parameters such as selection, quantification cost, procurement etc make up the management of essential drugs. You have also realized that there are standardized criteria for selection of essential drugs at different levels.

You should at this point be able to define management of essential drugs in your own words. You should be able by now to describe the methods of selection of essential drug, in its entirety.

#### **5.0 Summary**

This unit has focused on the definition of the management of essential drugs, steps in drug management, selection of essential drugs as the first step and most importantly the criteria and methods of selecting essential drugs.

Unit two will build on the second step of drug-management namely Quantification of Essential Drugs.

## **6.0 Tutor Marked Assignment**

1. (a) Using your own words define management of essential drugs  
(b) Itemise the criteria for selection of drugs
2. State steps involved in drug management

## **7.0 References / Further Readings**

Susan Foster (1991). "Supply and use of Essential Drugs in Sub-Sahara Africa: Some issues and possible solutions. Soc. Sci. Med. Vol. 32, No.II, pp. 1201 – 1218

H.V. Hogaerzeil, Bimo. D. Ross – Degnan, R.O. Laing, D. Ofori – Adjei, B. Santoso, A.K. Azad Chowdhury, A.M. Dsas, K.K. Kafle, A.F.B.

Mabadeje, A.Y. Massele. (1993). "Field Tests for Rational Drug Use in Twelve Developing Countries." The Lancet. Vol 342

# **STUDY UNIT 2: QUANTIFICATION OF SELECTED ESSENTIAL DRUGS**

## **TABLE OF CONTENTS**

1.0	Introduction
2.0	Unit Objectives
3.0	Main Content
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3.2	Advantages of Scientific Quantification
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### 3.3.1 Morbidity data method

#### 3.3.1.1 Steps in Quantification using morbidity data

### 3.3.2 Consumption patterns

### 3.3.3 Epidemiology/population base

## 3.4 Steps involved in Quantification

4.0 Conclusion

5.0 Summary

6.0 Tutor Marked Assignment

7.0 References/Further Readings

## 1.0 Introductions

Since you have gone through the course guide, you would have acquired a general overview of what this unit is about, how it links specifically to the course. This unit is a continuation of the previous unit. It explains the second step in the development of an essential drug programme vis-à-vis management and supply system. It will help you to acquire basic understanding of definition and rudiments of quantification of selected essential drugs.

Before we do this, let us have a view of what you should learn in this unit, as indicated in the unit objectives below.

## 2.0 Unit Objectives

At the end of this unit, you should be able to:

- ❖ Define quantification of selected essential drugs
- ❖ List the advantages of scientific quantification
- ❖ Itemize the quantification methods
- ❖ Enumerate steps involved in quantification

## 3.0 Main Content

### 3.1 Introduction



Quantification of selected essential drugs can be defined as the process for determining the quality of drugs given for a certified health problem and is expected to prevent or cure the health problem. This ensures that adequate supplies are available to treat the case loss of patients presenting to the health facility. In general, drug quantification calls for inputs from the various departments of the facility which will be adequately co-ordinated by the pharmacist or pharmacy technician or senior health personnel as applicable.

However, after deciding on the list of drugs required, the next logical step is to work out the quantity of each item. This is usually for a period of one year. The aim of quantification is to procure the right amount of drugs the patients need in a cost effective manner. Under stocking of drugs in the health facility leads to frustration and the people will eventually abandon the health centre. The alternative is to use other outlets where they may be forced to buy branded drugs at many times cost of generic drugs. The patients are also exposed to fake drugs in some of these places.

On the other hand, over stocking will not only tie down fund, unduly, but leads to wastage arising from the expiration of drugs, increased risk of pilferage and difficulty in providing adequate storage spaces and facilities.

### **3.2 Advantages of Scientific Quantification**

Quantification of selected essential drugs can be done both scientifically or by the old but conservative means, however, the scientific method is often employed in most parts of the world today, hence the under stated advantages.

- ❖ Prevents over stocking with its associated wastage
- ❖ Prevents under stocking with its attendant frustrations
- ❖ It provides strategies for judicious use of resources especially when they are scarce as in many developing nations
- ❖ Encourages rational use of drugs as in appropriate demands and wasteful prescription practices are not provided for
- ❖ Can be used as management tool to convince and justify budget for drugs

### **3.3 Methods of Quantification**

Various methods are used in the quantification of selected essential drugs, but the most commonly used, includes the followings:

- ❖ Morbidity / Standard treatment method
- ❖ Consumption patterns
- ❖ Epidemiology / Population base
- ❖ Estimate
- ❖ Define daily dose.

However, in this context, emphasis will be placed on the first three methods

#### **3.3.1 Morbidity / Standard treatment method**

This is based on adequate statistics on health services utilization. The major focus here is the number of people treated for various diseases over a given period of time in the facility. The quantity of drugs to treat an illness must be known either from standing orders or worked out.

Since there are many dosage forms, the age groups of those attending the facility must, as a routine, be recorded so that those receiving syrups can be separated from those treated with tablets. The use of morbidity data for quantification of drugs is a costly and painstaking exercise based on accurate and complete data which are often not easy to come by. Where morbidity data had been collated over time, they may be used directly. Otherwise, one may have to extract the required information from the patient's records.

##### **3.3.1.1 Steps in Quantification using morbidity data**

The under stated steps are often used in morbidity data method

- ❖ Collect information on number of treatment episodes requiring drugs
- ❖ Identify major health problems seen in the facility
- ❖ Get standard treatment schedule for each drug formulation
- ❖ Calculate the quantity of drug formulation required for each disease using the formula below

$$\begin{array}{lcl} \text{Quantity of drug required} & \text{No of treatment} & \text{Amount of drug} \\ \text{For each condition} & = & \text{treatment episode of} \quad \text{X per episode} \\ & & \text{Of the same condition} \end{array}$$

- ❖ Adjust quantity above upward to allow for damages, loss etc.
- ❖ Where a drug is used for more than one condition, repeat steps 1 – 5 for each condition and then add up for the total quantity of drugs required by the clinic / facility.

### **3.3.2 Consumption Method**

This approach depends on the information on the quantity of drugs previously used over time in determining future needs. Since wastage is inevitable, corrections are made for it and periods when some drugs are out of stock

Consumption method does not require much data as in morbidity data use. All the data needed are in the pharmacy unit. It is, therefore, faster, easier and has been found useful where special drugs are required in hospitals. It, however, suffers from some serious deficiencies like;

- ❖ Wastage due to expiration of drugs, pilferage, breakages are assumed to have been consumed
- ❖ Encourages irrational drug prescription and use as the focus is the quantity of drugs consumed and not how it was arrived at
- ❖ Does not provide for programme expansion either through planned activities or disease out breaks

### **3.3.3 Epidemiology/Population base Method**

A survey of the disease pattern and care seeking behavior in the area may be conducted. From the result, the quantity of drugs required to treat each condition for a certain period may be extrapolated.

## **3.4 Steps involved in Quantification**

For a meaningful and more reliable quantification, a combination of morbidity and consumption pattern methods are recommended as both are based on data concerning the actual or projected use of health

services. The importance of complete, accurate and fully understandable record keeping can not be under rated. The above assertions leads to the need to enumerate as stated below the various steps involved in the quantification of selected essential drugs.

- ❖ Data collection
- ❖ Data harmonization
- ❖ Identification of health problems
- ❖ Identify common diseases and develop standard treatment schedules
- ❖ Actual quantification exercise resulting in actual quantity needed for a period of time, dosage forms and packs

#### **4.0 Conclusion**

In this unit, you have learned what drug quantification is as well as the advantages of a scientific quantification of selected essential drugs. You have also realized that there are many methods of quantifying drugs. You should at this point be able to enumerate in your own words the various steps involved in the quantification of selected essential drugs.

#### **5.0 Summary**

This unit focused mainly on the definition of quantification, advantages of scientific quantification, methods of quantification and various steps involved in the quantification exercise.

Unit 3 will build on these and focus on the procurement of selected and quantified essential drugs.

#### **6.0 Tutor Marked Assignment**

1. (a) Using your words, define quantification of drugs.  
(b) List methods of quantification of drugs.
2. Enumerate steps involved in quantification of drugs.

#### **7.0 References / Further Readings**

Lucy Gilson and Stephen Russell (1994) “Canfees Recover

Cost “ Health Action, Issue No 9. AHRTAG London  
WHO (1992) “The Use of Essential drugs. Technical Report  
Series 825. WHO Geneva

### **STUDY UNIT 3: COSTING AND PROCUREMENT OF SELECTED AND QUANTIFIED ESSENTIAL DRUGS**

#### **TABLE OF CONTENT**

1.0	Introduction
2.0	Unit Objective
3.0	Main Content
3.1	Introduction
3.2	Components of procurement
3.3	Steps in procurement
3.4	Sources/suppliers of essential drugs
3.5	Purchasing methods of essential drugs
3.6	Drug donations
4.0	Conclusion
5.0	Summary
6.0	Tutor Marked Assignment
7.0	References/Further Readings

#### **1.0 Introduction**

Since you have gone through the course guide, you would have acquired a general overview of what this unit is about, how it links specifically to the course. This unit will help you acquire basic understanding of costing and procurement of selected quantified essential drugs.

Before we do this, let us have a view of what you should learn in this unit, as indicated in the unit objectives below;

## **2.0 Unit Objectives**

At the end of this unit, you should be able to:

- ❖ Define procurement of selected and quantified essential drugs
- ❖ Itemize various sources /suppliers of essential drugs
- ❖ Enumerate the purchasing methods of essential drugs
- ❖ Describe drug donations
- ❖ List the components and steps in procurement

## **3.0 Main Content**

### **3.1 Introduction**

Costing of selected and quantified essential drugs can always be deduced by using either of the previously stated strategies

#### **The ABC Analysis and VEN system**

The ABC value analysis: Is based on therapeutic value and cost of drugs:

- |   |   |                                       |
|---|---|---------------------------------------|
| A | = | Drugs accounting for high % of cost   |
| B | = | Drugs accounting for medium % of cost |
| C | = | Drugs accounting for low % of cost    |

Thus, if you select a lot of “A” drugs, your drug budget will not be efficiently utilized. Go for “C” drugs especially if they are effective.

The VEN system: Categorises drug according to their potential health impart

V= Vital, life saving in PHC, 5% of population, proven efficacy

E= Essential, treat significant problems, 1 – 5% of population, proven efficacy

N= Non-Essential, marginal therapeutic advantage, self limiting conditions + or – proven efficacy

Choose more of V and less of N

Total cost = Unit cost X (Dosage form, Quantity)

Procurement is the actual process of acquiring needed drugs and medical supplies after due processes of selection, quantification, and costing of drugs. It is a critical stage in the essential drug system. The efforts and gains made in earlier stages of drug management can easily be wiped off, if drugs are sourced from questionable suppliers with the attendant risk of fake and substandard and products.

Effective procurement strategies, therefore, aims at obtaining high quality drugs at the lowest possible cost and delivered timely. Conserved funds may then be ploughed back to drug purchase. The uses of staff reasonably knowledgeable in the areas of pharmaceutical, medical managerial as well as marketing and political interplay in the drug trade are vital. Funding and logistics back up should be adequate as well.

### **3.2 Components of Procurement of Essential drugs**

Having defined procurement of drugs, the following are the components of the procurement of a properly selected, and quantified essential drugs.

- ❖ Training of personnel
- ❖ Well designed procurement
- ❖ Functional information system
- ❖ Suitable organizational structure
- ❖ Adequate funds, facilities and equipments.

### **3.3 Steps in Procurement of Essential drugs**

Procurement of essential drugs previously selected and quantified can be put in place by following the understated steps;

- ❖ Determining how often to order drugs
- ❖ Listing the drugs needed
- ❖ Completing the requisition forms

- ❖ Calculating the cost of drugs ordered
- ❖ Forwarding money for drugs ordered together with requisition materials.

### **3.4 Sources/Suppliers of Essential drugs**

Suppliers of medicines and medical supplies must be reputable. There are many options available. The items may be purchased from private or even international suppliers on agreed terms. On the basis of how the drugs are sourced, suppliers may be grouped into three;

#### **PRIMARY SUPPLIERS**

These are the manufacturers themselves. The drugs manufactured may either be procured by special request or part of their usual output. Irrespective of the supplier, it is important for the essential drugs programme to know the drug manufacturers since they play a major role in determining drug quality. No amount of proper storage and careful handling will turn around an unwholesome product.

#### **SECONDARY SUPPLIERS**

These are groups that procure directly from the manufacturers and supply to others. They may be local wholesale distributors or international supply group like UNIPAC/UNICEF

#### **TERTIARY SUPPLIERS**

These are procurement agents commissioned by essential drugs programmes to procure drugs and medical supplies on their behalf. The tertiary suppliers may buy from secondary sources to meet their commitment to their clients.

### **3.5 Purchasing methods of essential drugs**

As important as the purchasing exercise is, there are various methods as analysed below;



## OPEN—TENDERS

Invitation for bids is given the widest publicity using, in most cases, the print and electronic media. Competition among prospective suppliers is, therefore, intense resulting in low prices as the suppliers try to outdo one another. The volume of work in open tendering is much as each submission has to be documented and analysed. Large number of staff is, therefore, necessary to cope with the exercise. This is not a fast method of purchasing drugs and for the efforts to be rewarding, large quantity of drugs or supplies must be involved.

## CLOSED—TENDERS

Participation in closed tenders is restricted to those who satisfy certain predetermined criteria. Such includes registration with the purchasers, history of satisfactory performance and the availability of the suppliers at short notice.

Administrative processing is less than in open tendering. It is, therefore, faster though the price may not be as favourable.

## NEGOTIATED PROCUREMENT

Rather than invite bids, the buyer approaches few potential suppliers and negotiates favourable prices and conditions with them. This method is suitable for bulk purchase of single sourced drugs or / supplies.

## DIRECT PURCHASE

This is more or less cash and carry. The buyer goes to the supplier and purchases the required items at the seller's quoted price. This method is quickest but costly. It is, therefore, suitable for emergency situations only as a stop – gap.

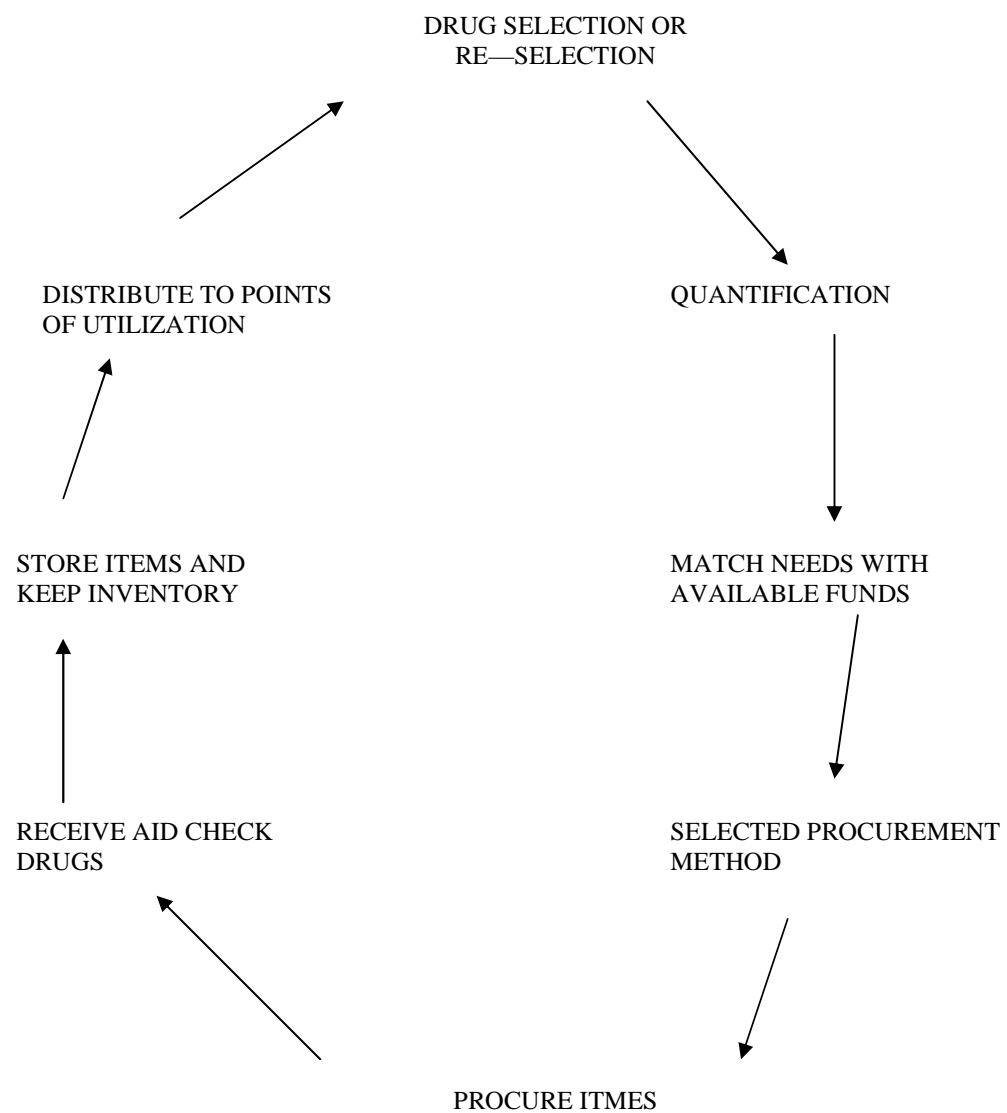


Figure 3.1: Relationship between key elements of the essential drug system

### **3.6 Donations**

Donations have come to represent one way of showing concern by those who are better placed for the less fortunate ones. This assistance could be a response to some form of disaster or part of bilateral aid. The humanitarian relief may be within a given country or across international boundaries.

Drugs are specialized items and experiences from various parts of the globe have shown that drug donation may fail to achieve the desired goal. Often, new problems are created for the recipient (especially international) for example; drugs that have no relevance to disease conditions in the recipient countries and, therefore, not in the essential drugs list are sent, expired or expiring items may also be included, sometimes, donated drugs may be of too small quantities to be useful and the instructions may be written in French which may not be understandable in the recipient countries.

Disposing of expired and unusable drugs is time – conscious, costly and often poses environmental hazards as was the case in Kosovo in 1999.

In addition, the useless drugs cost money to clear through customs and to transport. To eliminate these donation related problems, the WHO, in collaboration with UNICEF, UNHCR, the international committee of the Red Cross, the international federation of Red cross and Red Crescent Societies, OXFAM, Medicines Sans Frontières and the Churches Action for health of the World Council of Churches, developed guidelines on drugs donation in 1996.

This was revised in 1999 with more organizations participating. The guidelines are based on four principles:

- ❖ Maximum benefit to the recipient
- ❖ Respect for the values, wishes and authority of the recipient
- ❖ Eliminating double standards in quality
- ❖ Promotion of effective communication between the donor and the recipients.

The highlights of the guidelines are as follows:

- ❖ All donations of medicines should be based on need and be relevant to the disease pattern in the recipient country. Drugs should not be sent without prior consent of the recipients
- ❖ All donated drugs should be approved for use in the recipient country and should be on the National or WHO essential drug list
- ❖ The presentation, strength and formulation of donated medicines should be similar to those usually used in the receiving country.
- ❖ All donated drugs should be obtained from reliable sources and comply with quality standards in both the donor and recipient countries
- ❖ Professional samples and drugs returned to pharmacies by patients should not be donated
- ❖ On arrival in the recipient country, there should be at least one year before the expiry date of the drugs. Unless, adequate arrangements have been made to use them up before expiring
- ❖ Labeling should be in the language understood in the recipient country and should include the generic names batch number, dosage form etc.
- ❖ Bulk packs of donated drugs are preferable
- ❖ Recipients should be notified of all donations being considered
- ❖ The cost of transportation, handling at the ports, including storage, should be paid by the donor except otherwise.

#### **4.0 Conclusion**

In this unit, you have learned what costing and procurement of selected and quantified essential drugs is about as well as the steps, components, sources/suppliers of essential drugs. You have also realized that there are many methods of purchasing drugs.

You should by this point be able to in your own words define procurements of drugs. Also, you should by now be able to highlight the guidelines of donations.

#### **5.0 Summary**

This unit has focused on the definition of costing, procurement, various sources/suppliers of selected and quantified essential drugs. It also focused on the concept of drug donations. Unit four will build on content of this unit and focus on drug receiving, storage and stock control.

#### **6.0 Tutor Marked Assignment**

1. (a) Define procurement  
(b) List the major steps in procurement
2. Enumerate the components of procurement

#### **7.0 References / Further Readings**

Lucy Gilson and Stephen Russel (1994).” Canfess Recover Costs”  
Health Action, Issue No.9. AHRTAG London.  
WHO / UNHCR / UNICEF / ICRC / IFRC and RCS / Medicines San  
Frontiers/ WCC and OXFAM (1996). Guidelines for Drug Donations.  
WHO Document No. WHO/DAP/96.2.

### **STUDY UNIT 4: ESSENTIAL DRUG ORDERING, RECEIVING, STORAGE, STOCK CONTROL AND DISTRIBUTION**

#### **TABLE OF CONTENTS**

1.0	Introduction
2.0	Unit Objective
3.0	Main Content

3.1 Ordering and Receiving of Essential Drugs

3.2 Drug Storage

3.2.1 Temperature and Sunlight

3.2.2 Humidity

3.2.3 Burglar Proofing and Pests

3.3 Stock Control (Essential drugs)

3.3.1 Stock cards and stock control books

3.3.2 Stock Taking

3.4 Distribution of Drugs

4.0 Conclusion

5.0 Summary

6.0 Tutor Marked Assignment

7.0 References/Further Readings

## **1.0 Introduction**

Since you have gone through the course guide, you would have acquired a general overview of what this unit is about, how it links specifically to the course. This unit will help you acquire basic understanding of how to receive, store, control stock and distribute selected, quantified and procured essential drugs

Before we do this, let us have a view of what you should learn in this unit, as indicated in the unit objectives below

## **2.0 Unit Objectives**

At the end of this unit, you should be able to:

- ❖ Describe how to order drugs
- ❖ Discuss drug storage concept
- ❖ List steps towards effective stock control
- ❖ Describe distribution of essential drugs

- ❖ Identify factors affecting quality of drugs in storage

### **3.0 Main Content**

#### **3.1 Ordering and Receiving of Essential Drugs**

Having procured essential drugs previously selected and properly quantified, an important step which sometimes forms part of the procurement exercise is put in place to ensure a balanced procurement.

However, stated below, are highlights of the steps in effective ordering of drugs:

- ❖ Determine ordering interval; set by policy, using experience or according to buffer stock
- ❖ Select and quantify as previously discussed
- ❖ Cost and compute total cost of order
- ❖ Forward payment with requisition
- ❖ Make adequate provision for a long supply time, i.e. the interval between the order and the supply of the ordered drugs.

Drug storage is often preceded by the art of receiving drugs previously ordered for or procured. Stated below are the basic steps involved:

- ❖ Data collection for estimating drug requirement
- ❖ Check the quantity of supply
- ❖ Sign a receipt voucher
- ❖ Complete a ledger for each drug
- ❖ Put drugs away as appropriate

#### **3.2 Storage of Essential drugs**

Storage can be defined as the housing of the drugs in a safe place to safeguard the quality and potency of the drug pending dispensing or distribution to users.

Drugs are highly priced perishable items that need to be handled with care. Some are more stable than others and information on storage is often provided by manufacturers. Drug storage aims at ensuring that the

quality and potency of the preparations are maintained for as long as is practicable. Adequate storage also shields the drugs from theft.

Housing, conditions, space and ventilation must be favourable. When drugs deteriorate, there may be change in colour, consistency and odour. Often times, there may be no physical change except that the expiry date has passed. Some of the factors that affect the quality of drugs in storage are as follows:

### **3.2.1 Temperature and Sunlight**

Excessive heat as often experienced in the tropics destroys drugs. Stores should be well ventilated. Where electricity is available, air conditioners have proven very useful, especially in the afternoon. On the other hand, some preparations e.g. vaccines must be stored under low temperatures for them to remain potent.

The ultra violet rays in sunlight cause drugs to go bad. Some are more sensitive to light and may require special packaging. Medicines must be stored away from direct sunlight. The use of screens is recommended

### **3.2.2 Humidity**

Under humid conditions, drugs may absorb moisture and deteriorate fast. All leaks in the roof should, therefore, be repaired promptly. Doors and windows should also be appropriately secured to keep away the elements like wind, rain, dust etc. The floor must also be of good material and generally drugs should not be stored on the floor. Good ventilation is also one of the requirements of a good store.

### **3.2.3 Burglar, Proofing and Pests.**

It is assumed that this will make it difficult for thieves to break in. Pilfering of drugs is often an in house problem as health workers pinch items for “family use”. This could be considerable as more persons are involved or the officers become more daring.



Insects and rodents especially may attack primarily the packaging. In the process, the drugs are exposed to contamination or other adverse conditions. This underlines the need to keep the store neat and tidy.

From the above, it may be concluded that losses may be incurred in the store from poor storage, expiration and theft. Drugs are best stored on shelves, in cupboards and refrigerators as appropriate

When drugs are stored, it is more convenient to arrange them in an orderly manner. One method is to arrange drugs by classification according to their pharmacological actions. e.g. all *analgesics* are put together and *antibiotics* similarly grouped.

Another approach is to arrange the drugs according to their preparation (types) as follows: *Tablets and Capsules, Liquids, Injections, Topical preparations*.

In each group (eg. Tablet, capsules), the items are arranged in *alphabetical* order using their generic names. Irrespective of what method is used, the shelves must be appropriately labeled.

### **3.3 Stock Control of drugs**

Good inventory of drugs is necessary to avoid embarrassing the drug supply system. Stock control ensures that essential drugs are available, prevents overstocking and makes early detection of missing drugs possible. It also provides data that may be used in estimating drugs for re-ordering.

#### **3.3.1 Stock Cards and Stock Control book**

Each stock and form of any drug is expected to be assigned a card called stock or bin card. It is on this card that vital information is entered as soon as there is any transaction or development in respect of the preparation. This includes the quantity of drugs received or issued, stock balanced, date and signature of the person making the entry. The card may be kept close to the medicines on the shelf or together in a secured place with good filing system

Besides this, the stock control book is also called the ledger. At regular intervals, e.g. every month, the information on the stock cards is

transferred into the ledger. The information in the ledger is organized to show the quantity of each preparation used since last entry and the quantity to order if necessary.

### **3.3.2 Stock Taking**

Each month, the information on the bin card is matched with what is actually on ground. The following are noted:

- ❖ Quantity of the preparations on the shelves, in case of discrepancies are detected, the quantity in the bin card is adjusted to reflect the actual balance. Investigation then follows while the ledger is also updated
- ❖ The expiry dates of the drugs. Items that will expire or were manufactured first are put in front of the shelf to be used first, in line with FIFO principle. FEFO means First in, First out.
- ❖ The condition of the containers to see if the seals or any part of the container has been broken or tampered with.

### **3.4 Distribution of Essential Drugs**

This step consists mainly of issuing, inventory control, prescribing and dispensing and rational drug use.

Distribution is often defined as a process which requires the receipt of drugs from the supplier and its movement in a safe, secure and expeditious manner to the health facility for proper storage at which point the drugs will be dispensed to the consumers.

Issuing of drugs entails a number of processes including file request from the requesting unit, justify/reduce quantities requested, if applicable, collect money for order, then issue the drugs.

Control of inventory also involves:

- ❖ Balancing the ledger (Old balance + New issue = New Balance)
- ❖ Ensuring that the receiving unit signs the receipt vouchers as well as other necessary papers

Rational prescribing is based on accurate diagnosis, avoidance of poly pharmacy, use of standard treatment protocols such as the standing orders.

In the same vein, dispensing provides patients with clear and accurate instruction on use of dispensed drugs, it also includes the following:

- ❖ Pre – packaging
- ❖ Standardized treatment
- ❖ Correct dose, reduces error
- ❖ Instructions printed on envelope (labeling)
- ❖ Faster to use during clinic day
- ❖ Tedious to pack after clinic

Finally, rational drug use is equally an important component of drug distribution. Drugs have their own norms, and deviation from their prescribed use could spell disaster. Misuse of drugs occurs; it is described as irrational use. Apart from being a health hazard, irrational drug use leads to wastage of scarce resources

However, to prevent irrational use, continuing education for health workers at all levels of the essential drug system is vital. People should not be assigned responsibilities for which they have not been trained. For example, all those who prescribe drugs must be reminded to always consider the following while prescribing:

- ❖ Is the medicine essential?
- ❖ Is it safe?
- ❖ Is it easy to administer and comply with?
- ❖ Is it of good value?

## **4.0 Conclusion**

In this unit, you have learned what receiving, storage, stock control and distribution of essential drugs is all about. You have also realized that good storage facilities/conditions plays important roles in the maintenance of the quality and potency of drugs. You should at this point be able to define distribution of drugs in your own words. also, you should by now be able to describe rational drugs use.

## **5.0 Summary**

This unit has focused on the concept of ordering; receiving of essential drugs as well as effective storage, stock control and distribution of carefully, selected quantified, ordered and received essential drugs.

## **6.0 Tutor Marked Assignment**

1. (a) List steps in effective ordering
- (b) Enumerate steps involved in drug storage

## **7.0 References / Further Readings**

WHO/UNICEF/Government of Mali (1999). "Report on the Review of the implementation of the Bamako initiative in Africa  
WHO (1992). "The use of Essential drugs. Technical Report series 825, WHO Geneva.

# **STUDY UNIT 5: PERFORMANCE INDICATORS FOR EVALUATING ESSENTIAL DRUGS PROGRAMME.**

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1.0	Introduction
2.0	Unit Objective
3.0	Main Content
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3.2	Evaluation at (State Level) Central Medical stores
3.2.1	Procurement
3.2.2	Wharf clearance
3.2.3	Inventory control and storage
3.3	Evaluation at (Local Government Level) LG medical stores
3.3.1	Requisitioning and purchasing

	3.3.2 Inventory (Stock) control and storage
3.4	Evaluation at State, General and Specialist Hospitals
	3.4.1 Inventory (Stock) control and storage
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3.5	Evaluation at Health Centres and Health Posts.
4.0	Conclusion
5.0	Summary
6.0	Tutor Marked Assignment
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## **1.0 Introduction**

Since you have gone through the course guide, you would have acquired a general overview of what this unit is about, how it links specifically to the course. This unit will help you acquire basic understanding of the performance indicators for evaluating the essential drug programme at all levels of health care delivery system.

Before we do this, let us have a view of what you should learn in this unit as shown in the unit objective below.

## **2.0 Unit Objectives**

At the end of this unit, you should be able to:

- ❖ Define evaluation and performance indicator
- ❖ Enumerate the indicators for evaluating the efficiency of the various components of the programme at all levels of care.

## **3.0 Main Content**

### **3.1 Introduction**

It is necessary to evaluate the essential drug programme in order to determine its efficiency and how it has met other objectives it sets out to

achieve. Indicators therefore should be developed to help in this process of evaluation.

However, evaluation can be defined as a process of assessing the performance and success/achievements of a set objective

Also, performance indicators as an instrument or means of measuring the effectiveness of the supply and Drug Revolving Fund system of the programme.

### **3.2 Evaluation at State Level (Central Medical stores)**

The success or achievement of the essential drug programme at the state central medical stores can be effectively monitored, measured and evaluated through a number of ways as treated below

#### **3.2.1 Procurement of Essential Drugs**

This involves the evaluation of the percentage of drugs from different sources of supply (Procured or received) on individual or country basis e.g. Nigeria, Britain, Germany, Asia e.t.c.

Also, the value of total purchase and types of procurement made by value must be evaluated on a yearly basis. The various types of procurement by value include the following:

- ❖ Percentage from open and restricted tender
- ❖ Percentage from Negotiated and direct purchase
- ❖ Percentage from Government production and Donor agencies
- ❖ Percentage of complete supplier defaults on confirmed orders
- ❖ Percentage of orders obtained within the lead time period
- ❖ Average value of all lead times exceeding the expected value in months
- ❖ Value of drugs rejected or discarded because of low quality
- ❖ Cost of placing and order ie. Percentage of individual orders plus cost of placing orders.

### **3.2.2 Wharf Clearance**

The reference and evaluation procedure in this respect will always involve the understated.

- ❖ Total value consignments cleared per year
- ❖ Total value of all consignments cleared for the year
- ❖ Demurrage charges
- ❖ Value of damaged or lost consignment (total value and value as a percentage of all drugs received)
- ❖ Value of insurance claims received on this consignment
- ❖ (total value and value of percentage of damage or lost consignment)

### **3.2.3 Inventory control and storage**

Equally important to evaluate are the storage facilities methods of drug storage and how the inventory (stock) is being controlled at the central medical store, the steps involved in each case are as stated below:

#### **INVENTORY CONTROL**

- ❖ Value of average inventory (stock) at hand
- ❖ Value of average monthly and annual consumption
- ❖ Average inventory on hand as months of consumption
- ❖ Number of stock – out situation (in weeks)
- ❖ Average inventory on hand as percentage of annual issues.

#### **STORAGE**

- ❖ Value of drugs lost due to poor handling and poor storage conditions. (total value, value as percentage of annual issues)
- ❖ Value of drugs pilfered or declared unaccountable (total value, value as percentage of annual issues, value as percentage or average inventory).

### **3.3 Evaluation at Local Government Level (LG Medical Store)**

At the local government level, there are central medical stores housing the establishment of the components of the essential drug programme file every other level of government, hence the need for appropriate evaluation at this level.

### **3.3.1 Requisitioning and purchasing**

- ❖ Total value of requisition on drugs per year (received from central medical store)
- ❖ Percentage of individual order placed for drugs from the central medical stores (frequency)
- ❖ Cost of placing orders (stationery, telephone – calls, staff – wages, overtimes – payments etc)
- ❖ Approximate cost of placing the order.

### **3.3.2 Inventory (stock) control and storage**

The evaluation will include the following:

- ❖ Value of average stock at hand
- ❖ Value of average monthly consumption
- ❖ Average stock at hand as months of consumption
- ❖ Number of stock out (out – of – stock)
- ❖ Length of complete stock – out in weeks
- ❖ Number of emergency deliveries as percent of all delivered
- ❖ Value of expired drugs as percentage of monthly or annual issues
- ❖ Value of drugs lost due to poor handling and poor storage conditions. (total value, value as percentage of annual issues, value as percentage of average inventory)

## **3.4 Evaluation at State General and Specialist Hospitals**

The evaluation of the programme, in order to determine its efficiency and the level of achievement at this level of care is also important and it follows as stated below

### **3.4.1 Inventory (Stock) control and storage**

- ❖ Value of average inventory at hand
- ❖ Value of average on hand as month of consumption



- ❖ Number and length of complete stock out in weeks
- ❖ Number of emergency deliveries as percentage of all deliveries
- ❖ Value of expired drugs as percentage of monthly or annual issues
- ❖ Value of drugs lost to poor storage conditions (total value, value as percentage of annual issues, value as percentage of average inventory)

### **3.4.2 Issuing and dispensing of Drugs**

Like every other levels this will also includes the following:

- ❖ Value of drugs issued out to out patient departments
- ❖ Value of drugs issued out to health centres. Health post etc.
- ❖ Total value of issues
- ❖ Out patient's index i.e. value of drugs issued out to all out patient's department (OPD) and number of out patients treated.
- ❖ In – patient index i.e. value of drugs issued to all in – patients and number of in – patients treated.

### **3.4 Evaluation at Primary Health Centres and Health Posts**

At the primary health care, there are primary health centres and Health posts, which must not be left out in the evaluation of essential drug programmes, as they are they are the sources of health care delivery closest to the grass-root.

The inventory (stock) control will always include the determination of the value of average inventory at hand, value of average monthly consumption and finally average inventory (stock) at hand as months consumption.

However, dispensing activities at this level also needs to be evaluated, particularly as it involves the value of drugs dispensed/ monthly/year and most importantly patient index i.e., value of drugs issued and number of patients treated.

## **4.0**

### **Conclusion**

In this unit you have learned what performance indicators for evaluating essential drug programmes is and that in evaluating essential

drug programmes, it involves all levels of health care delivery. You have also realized that important areas of evaluation will also include procurement, inventory control, storage, requisition and dispensing of drugs

You should at this point be able to define evaluation and performance indicators in your own words

## **5.0 Summary**

This unit has focused on the definition of evaluation and performance indicators and must importantly the parameters of evaluation at different health care level including the state central medical stores, general and specialist hospitals, local government central medical stores and health centres / health post.

## **6.0 Tutor Marked Assignment**

1. (a) Define performance indicators and evaluation
- (b) Enumerate the types of procurement by value that should be evaluated annually in a state central medical store.

## **7.0 References / Further Readings**

WHO (1992). "The use of Essential drugs. Technical Report series 825, WHO Geneva.

## **MODULE 3: ESSENTIAL DRUG LIST AND PHARMACOLOGY OF ESSENTIAL DRUGS IN PRIMARY HEALTH CARE.**

### **STUDY UNIT 1: ESSENTIAL DRUG CONCEPT**

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- 3.0 Main Content
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  - 3.2 Historical perspective of the Essential drugs concept
  - 3.3 The Need for an Essential drug policy
  - 3.4 Objectives of Essential drug policy
  - 3.5 Selection of Essential drug list
    - 3.5.1 Criteria for selection of Essential drug list
- 4.0 Conclusion
- 5.0 Summary
- 6.0 Tutor Marked Assignment
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#### **1.0 Introduction**

Since you have gone through the course guide, you would have acquired a general overview of what this unit is all about, how it links specifically to the course. This unit will help you acquire basic understanding of the definition of essential drugs, and essential drug list, Historical perspective, theory and practice of essential drug programme.

Before we do this, let us have an overview of what you should learn in this unit, as indicated in the unit objectives below.

## **2.0 Unit Objective**

At the end of this unit, you should be able to:

- Define the terms, essential drug (s) and essential drug lists
- Describe the historical perspective of essential drug policy
- Itemize the selection criteria for the essential drug lists.
- List the objectives of essential drug policy

## **3.0 Main Content**

### **3.1 Definition of Essential drugs and Essential drug list**

Essential drugs, as defined by the World Health Organization are “those drugs that satisfy the health care needs of the majority of the population, they should therefore be available at all times in adequate amounts and in appropriate dosage forms, at a price the community can afford.”

However, the original 1977 WHO definition of “essential medicines” was that they were of utmost importance, basic, indispensable, and necessary for the healthcare needs of the population. The concept was mentioned in one of the ten points of the 1978 Alma Ata Declaration on primary health care.

The difficulty of putting this into practice is reflected in the rather longer and more categorical 2002 definition. “Essential medicines are those that satisfy the priority health care needs of the population. They are selected with due regard to public health relevance, evidence on efficacy and safety, and comparative cost effectiveness. Essential medicines are intended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality and adequate information, and at a price the individual and the community can afford. The implementation of the concept of essential drugs is intended to be flexible and adaptable to many different situations; exactly which medicines are regarded as essential remains a national responsibility.

Besides, the Essential drug list is thus defined as the List of those drugs that satisfy the health care needs of the majority of the population.

The WHO model list of Essential drugs has been updated every two years since 1977. The current version, the 16<sup>th</sup>, was published in 2009. There is also a “WHO” model list of Essential medicines for children”, whose 2<sup>nd</sup> edition was also published in 2009.

### **3.2 Historical Perspective of Essential drug List**

In the year 1897, aspirin was introduced as the first synthetic pharmaceutical, in the 100 years since, the world has seen the introduction of the first modern antibiotic (1941), the first commercially formulated anti malarial (1943), and the first antitubercular (1944). The 1950s saw the first clinical use of oral contraceptives, of drugs for diabetes and mental illness. The development of drugs for other infectious diseases, for cardiovascular diseases and for a wide range of other conditions quickly followed. In 1975, the twenty eight World Health Assembly requested the Director General to assist member states by “advising on the selection and procurement, at reasonable cost, of essential drugs of established quality corresponding to their national health needs”

The first WHO model list of essential drugs was prepared by a WHO Expert committee in 1977. in 1978, the thirty first world health Assembly requested the Director General interalia, “to continue to identify the drugs and vaccines which, in the light of scientific knowledge, are indispensable for primary health care and control of diseases prevalent in the population, and to update periodically this aspect of the report of the WHO Expert Committee on the selection of “Essential drugs” and “to cooperate with member states in formulating drug policies and management programmes that are relevant to health needs of populations and are aimed at ensuring access of the whole population to essential drug at a cost the country can afford.

When WHO published the first model list of Essential drugs in 1977, it identified 208 individual medicines which together could provide safe, effective treatment for the majority of communicable and non communicable diseases.

The model list is a guide for the development of national and institutional essential drug lists. It was not designed as a global standard. However, for the past 30 years, the model list has led to a global

acceptance of the concept of essential medicines / drugs as a powerful means to promote health equity. By the end of 2003, 156 member states had official essential medicines lists, of which 99 has been updated in the previous 5 years. Most countries have national lists and some have provincial or state lists as well. National lists of essential medicines usually relate closely to national guidelines for clinical health care practice which are used for the training and supervision of health workers.

### **3.3 The Need for an Essential drug Policy**

Drugs occupy a unique position in health care. They can cure diseases, relieve symptoms and alleviate suffering. The psychological satisfaction produced by drugs creates a favourable environment on which the preventive and educational elements of healthcare can be built with consequent further improvement in health. Therefore, there is need for a programme that will ensure the availability of these drugs and their rational use. Essential drug list is needed for the following reasons:

- To give priority to drugs with therapeutic efficacy, with the aim of satisfying the health need of the population
- To improve the availability of the most needed drugs in the country's health care delivery system.

### **3.4 Objectives of the Essential drug Policy**

According to the WHO Technical committee on Essential drug programme, National drug formulary, the understated should be the objectives of the Essential drug policy in any nation of the world;

- To continuously ensure that drugs that are needed to the entire population are available
- To reduce the cost of drugs by purchasing drugs with generic names instead of brand names
- To impart management skills to health workers
- To prevent production, distribution and use of fake and sub-standard drugs at all levels
- To encourage the use of only safe and effective drugs at all levels.

### **3.5 Selection of Essential drugs**

Essential medicines are selected with due regard to disease prevalence, evidence on efficacy and safety, and comparative cost effectiveness. Cost effectiveness is the subject of fierce debate between producers (pharmaceutical companies) and purchasers of drugs (national health services).

The number of drugs has nearly doubled, from 186 in 1977 to 320 in 2002. The range has increased substantially over the years and now includes antimigraine drugs, antidotes and antineoplastic drugs.

The essential drugs are one of the most cost effective elements in modern healthcare and their potential health impact is remarkable.

#### **3.5.1 Criteria for the Selection of Essential Drug List**

- The choice of essential medicines depends on several factors, including the disease burden, sound and adequate data on the efficacy, safety and comparative cost effectiveness of available treatments. Stability in various conditions, the need for special diagnostic or treatment facilities and pharmacokinetic properties are also considered if appropriate.

When adequate scientific evidence is not available on current treatment of a priority disease, the expert committee may either defer the issue until more evidence becomes available, or choose to make recommendations based on expert opinion and experience

- Most essential drugs should be formulated as single compounds. Fixed – ratio combination products are selected only when the combination has a proven advantage in therapeutic effect, safety or compliance over single compounds administered separately. Examples of combination drugs that have met these criteria includes new formulations for tuberculosis and malaria.
- In adapting the WHO model list to national needs, countries often consider factors such as local demography and pattern of diseases; treatment facilities; training and experience of the available

personnel; local availability of individual pharmaceutical products; financial resources; and environmental factors.

#### **4.0 Conclusion**

In this unit, you have learned what Essential drug (s) and Essential drugs list are, you have also learned the Historical perspectives of the concept, Essential drugs. You have also realized that there are defined criteria for selection of drugs into the essential drug list.

You should by now be able to define Essential drug, and Essential drug list in your own words. Also, you should be able to itemize the objectives of the Essential drug list.

#### **5.0 Summary**

The unit has focused on the definition of Essential drug (s) and the Essential drug list, the Historical perspective, objectives and the vital criteria for selection of Essential drugs. Unit two will build on these and focus mainly on the WHO model list of Essential drugs.

#### **6.0 Tutor Marked Assignments**

1. Define the following
  - (a) Essential drugs(s)?
  - (b) Essential drug list?

#### **7.0 References / Further Readings**

WHO / Health topics / Essential Medicines. [www.who.int/topic/Essential](http://www.who.int/topic/Essential)

Model list of Essential Medicines, 16<sup>th</sup> Edition (2009). Medicines World Health Organization

Litvak, J.L. et al (1989). Setting the price of essential drugs: Necessity and affordability. Lancet. Vol. 334. pp376 - 379

**WHO (1992).**The Use of Essential Drugs. Technical report **Series 825.** WHO Geneva



## **STUDY UNIT 2: WHO MODEL LIST OF ESSENTIAL DRUGS**

### **TABLE OF CONTENTS**

- 1.0 Introduction
- 2.0 Objectives
- 3.0 Main Content

- 3.1 Introduction
- 3.2 Targets of the model Essential drug list
- 3.3 Use of the WHO model list of Essential drugs
- 3.4 Perceived problems with the WHO model list
- 3.5 Outcome of the Revised Procedures
- 3.6 Steps to get a New drug on the WHO model list of Essential drug
  - 3.6.1 Steps in Review of Applications to the model list
  - 3.6.2 Role of treatment cost and Global cost Effectiveness Analysis
  - 3.6.3 Presentation of Recommendations, Report
    - 3.6.3.1 Presentation of Recommendations
    - 3.6.3.2 Report, Web-site, translations.
- 4.0 Conclusion
- 5.0 Summary
- 6.0 Tutor Marked Assignment
- 7.0 Reference / Further Readings

## **1.0 Introduction**

Since you have gone through the course guide, you would have acquired a general overview of what this unit is about, how it links specifically to the course. This unit will help you acquire basic understanding of targets and use of the WHO model lists of Essential drugs, perceived problems of revised procedure and various steps to get a New drug on the WHO model list of Essential drug list.

Before we do this, let us have a view of what you should learn in this unit, as indicated in the unit objectives below.

## **2.0 Objectives**

At the end of this unit, you should be able to:

- Itemize the targets of the WHO model essential drug list
- List the use of the WHO model list of Essential drugs
- Enumerate the perceived problems with the WHO model list
- Mention the outcome of the Revised procedure

- State the steps involved in getting a New drug on the WHO model list of essential drugs.

### **3.0 Main Content**

#### **3.1 Introduction (WHO Model List of Essential Drugs)**

The first model of the list was published in 1977 with  $\sim$  200 active substances, and was revised every two years by WHO expert committee. The 16<sup>th</sup> list was published and approved by the WHO Expert committee in the year 2009. The first list was a major break through in the history of medicine, pharmacy and public health, and medicines sans frontiers (2000).

The implementation of the concept of essential drugs is intended to be flexible and adaptable to many different situations; exactly which medicines are regarded as essential remains a national responsibility. Over 156 countries has National Essential drug list, 113 within 2 years, 314 within 5 years.

#### **3.2 Targets of the Model Essential Drug List**

The essential drug are selected with due regard to disease prevalence on efficacy and safety, and comparative cost effectiveness which are intended to be available within the context of functioning health systems at all times, in adequate amounts, in the appropriate dosage forms, with assured quality, and at a price the individual and the community can afford. It is expected that clinical guidelines and a list of essential drugs should lead to better prevention and care.



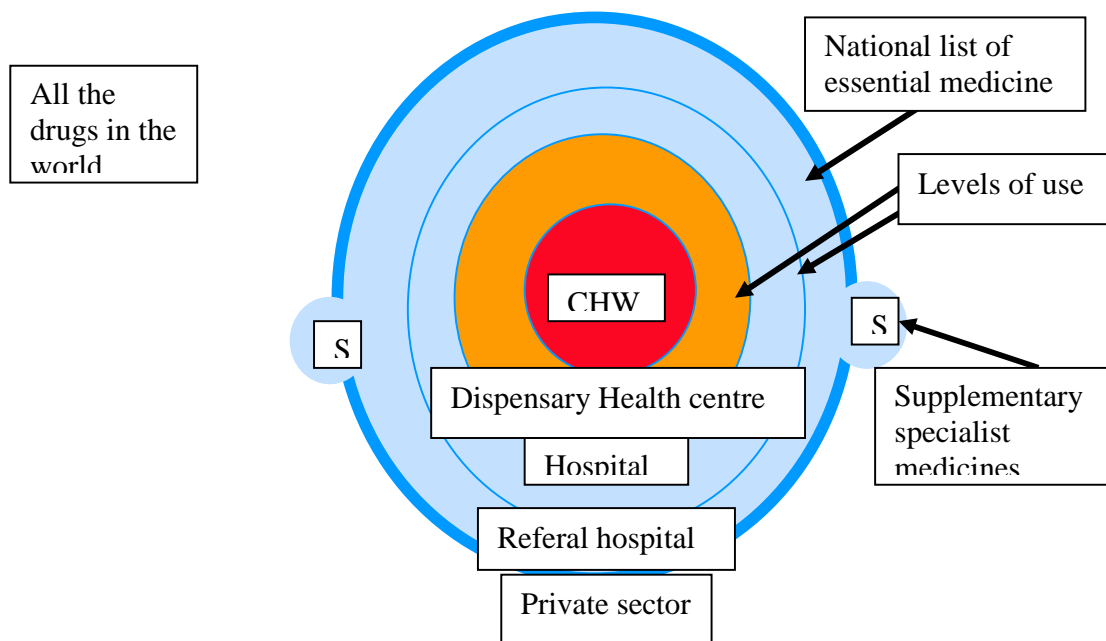


Figure 2.1: Essential Medicine Target: Department of Essential Drugs and Medicine Policy

### 3.3 Uses of the WHO Model list of Essential Drugs

- 186 countries have a national list of essential drugs, of which 81% have been updated in the last 5 years
- Major international agencies (UNICEF, UNHCR, IDA) base their catalogue on the WHO model list
- Subsets: UN list of recommended essential drugs for the emergency relief (85 drugs): inter agency New Emergency Kit (55 drugs for 10,000 Consultations).
- Normative tools: WHO Model Formulary. International pharmacopoeia. Basic Quality Tests and development of Reference standards follow the WHO model list

### 3.4 Perceived Problems with the WHO model list prior to 2002 Revision of Procedure

- Range of diseases covered by the model list is not clear
- Discrepancies between model list and treatment guidelines
- Selection is more consensus – based than evidence – based
- Use of data on cost effectiveness unclear
- Reasons for selection in sufficiently recorded
- Drugs included without pharmacopoeal standard or supplier

- Official report comes out too late, and in English only.

### **3.5 Outcome of the Revised Procedures**

The WHO model list of Essential Drugs is a model process, model product and public health tool

- The independent membership of the committee, careful consideration of conflict of interest.
- Transparent process, standard application, review
- Link to evidence based treatment recommendations, in accordance with WHO Recommended Process for developing clinical practice Guidelines.
- Systematic review of comparative efficacy, safety and cost effectiveness, and review of public health relevance
- Rapid dissemination, electronic access
- Regular review

### **3.6 Steps to get a New Drug on the WHO Model List of Essential Drugs**

- Identification of public – health need for a drug
- Development of the Drug: phase I – II - III trials
- Regulatory approval in a number of countries
- More experience under different field circumstances: post-marketing surveillance
- Price indication for public sector use
- Review by WHO disease programme: define comparative effectiveness and safety in real life situations
- Submission to WHO committee on Essential Drugs

#### **3.6.1 Steps in Review of Applications to the Model List**

- Summary of application posted on WHO medicines web-site
- Specialist assessment of comparative efficacy, safety and cost effectiveness
- Review of assessments by Expert committee member (“Presenter”); formulation of draft recommendation
- Review of draft recommendation by relevant Expert advisory panel members: and posted on WHO medicines web-site

- Review by presenter; prepares final draft recommendation
- Discussion of draft recommendation and proposed text for WHO model Formulary by the Expert committee

### **3.6.2 Role of Treatment Cost and Global Cost effectiveness Analysis**

- High cost alone should not exclude an essential drug
- Cost effectiveness (C/E) comparisons will be made among alternative drugs within the same therapeutic group
- Price information from existing UN sources will be used
- Sample indicators will be used: cost per unit, cost per treatment / month, cost per cure, cost per case prevented
- Emphasis on usual outcome measures, and use of existing and published comparative cost effectiveness analysis
- Now C/E calculations will be transparent and can be adapted.

### **3.6.3 Presentation of Recommendations, Report**

#### **3.6.3.1 Presentation of Recommendations**

- Summary of reasons for each recommendation
- Reference to underlying evidence and systematic reviews
- Reference to existing clinical guidelines
- Inclusion in WHO Essential medicines Library

#### **3.6.3.2 Report, Web-site, Translation:**

- Report of the meeting published on WHO medicines web-site
- Report issued in WHO Technical Report series
- List and recommendations translated into other languages.

## **4.0 Conclusion**

In this unit, you have learned that the concept of essential drugs is a global concept, you have also realized that the WHO clinical guidelines are the foundation for the model list of essential drugs; the model list remains a strong public health tool

The unit has also shown that the WHO Essential drug library is a valuable information base for all member states international organizations, drugs and therapeutic committees and health insurance organizations.

## **5.0 Summary**

This unit has focused on the Targets of the essential drug list, perceived problems outcome of the revised procedures, and presentation of the Recommendations of the WHO model list of essential drugs. Unit 3 will build on this and focus mainly on essential drug list for primary health care system in Nigeria.

## **6.0 Tutor Marked Assignments**

- (a) Itemize the targets of the WHO Model Essential drug list
- (b) List the outcome of the Revised Procedure drugs

## **7.0 References / Further Reading**

WHO Model list of Essential Medicines (2007).  
[www.who.int/medicines/publications/08\\_English](http://www.who.int/medicines/publications/08_English)

Model list of Essential Medicines, 16<sup>th</sup> Edition (2009). Medicines World Health Organization

**WHO (1992).**The Use of Essential Drugs. Technical report  
**Series 825.** WHO Geneva

Soucat. A., et al (1997).Affordability, cost effectiveness and Efficiency of primary health care: the Barmako Initiative Experience in Benin and Guinea. Int. Journal of Health Planning and Management. Vol.12. supp.I. pp 81-108

## **STUDY UNIT 3: PHARMACOLOGY OF ESSENTIAL DRUGS IN PRIMARY HEALTH CARE**

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  - 3.2 Sources of Drugs
  - 3.3 Routes of Drug- administration
    - 3.3.1 Enteral Route
    - 3.3.2 Parenteral Route
  - 3.4 Drugs at site of Administration
  - 3.5 Drug Distribution
  - 3.6 General mechanism of action of Drugs
- 4.0 Conclusion



- 5.0 Summary
- 6.0 Tutor Marked Assignment
- 7.0 Reference / Further Readings

## 1.0 Introduction

Since you have gone through the course guide, you would have acquired a general overview of what this unit is about, how it links specifically to the course. This unit will help you acquire basic understanding of the primary health care level.

Before we do this, let us have a view of what you should learn in this unit, as indicated in the unit objectives below.

## 2.0 Objectives

At the end of this unit, you should be able to:

- Define drug (s) and Pharmacology
- Classify essential drugs at PHC level
- Enumerate sources of drugs
- List factors that could affect absorption and drug metabolism
- Explain general mechanism of action of drugs
- Enumerate factors affecting drug stability and spoilage

## 3.0 Main Content

### 3.1 Definitions

The subject of pharmacology was known as material medica until 1890 when the current term began to come into use. Pharmacology is defined as the study of drugs and their actions the sub-sciences of pharmacology and their specific fields of study are as follows:

**Pharmacology:** The recognition, quality, purity and identification of drugs.

**Pharmacy:** The preparation, stability, preservation and storage of pharmaceutical preparations.

**Posology:** Dosage or amount of drugs to be administered.

**Pharmacodynamics:** The response of living tissue to chemical stimulation in the absence of disease. This almost exclusively deals with research and development.

**Pharmacotherapeutics:** The action of drugs on living tissues in the presence of disease; treatment of the sick

**Toxicology:** The study of toxic or poisonous effects of substances.

### 3.2 Sources of Drugs

Medications are commonly called therapeutic or pharmaceutical drugs, or just “drugs”. These are many sources of drugs and many resources are readily available to help identify, dispense and administer medications completely, safely and in accordance with the law, whenever health care professionals.

There are several sources from which medication are derived, but drugs are derived from the following four main sources:

- ❖ **Plant sources:** Obtained from plants or products, seeds, stem, roots, leaves, resin and other parts yield these drugs. Examples include digitalis and opium
- ❖ **Animal sources:** Glandular products from animals are used, such as insulin and thyroid
- ❖ **Mineral sources:** Some drugs are prepared from minerals. E.g. potassium, chloride and lithium carbonate (An Anti-psychotic)
- ❖ **Synthetic sources:** Laboratories duplicate natural processes. Frequently, this can eliminate side effects and increase the potency of the drug. Examples include the Barbiturates, sulfonamides and Aspirin

### 3.3 Routes of Drug Administration

Drugs are administered through appropriate routes so that they can get to their sites of action still effective and of the right concentration. The route of administration is determined primarily by the properties of the drug (e.g. water or liquid solubility, ionization, etc.), and by the therapeutic objectives (for example, the desirability of a rapid onset of

action or the need for long-term administration or restriction to a local site).

There are 2 major routes of drug administration, namely the Enteral and Parenteral.

### **3.3.1 Enteral Routes**

This can be divided into oral, sublingual and the Rectal Routes. *Oral:* Giving a drug by mouth is the most common and preferred route where possible. Taking drugs by mouth is advised for all those who can eat or swallow. Oral preparation especially tablets are cheaper and safer to handle. This route is also the most variable and involves the most complicated pathway to the tissues.

However, some drugs must be given through other routes when:

- They cannot be absorbed in the gastrointestinal tract, some are destroyed as they are exposed to various secretions in the digestive system
- The patient is unconscious and, therefore, not in a position to swallow. This is also true for those in shock.

*Sub-Lingual:* This involves placement under the tongue, it allows a drug to diffuse into the capillary network and, therefore, to enter the systemic circulation directly. The main advantage of this route is that the drug bypasses the intestine and liver and thus avoids first pass metabolism.

*Rectal:* Fifty percent of the drainage of rectal region bypasses the portal circulation; thus, the biotransformation of drugs by the liver is minimized. The route is also useful, if the drug induces vomiting when given orally or if the patient is vomiting.

### **3.3.2 Parenteral Routes**

These routes are used for drugs that are poorly absorbed from the GI tract, and for agents, such as insulin, that are unstable in the GI tract. It is also useful for the treatment of unconscious patients and when rapid onset of action is required.

The three major parenteral routes are intravenous, intramuscular and subcutaneous. Each route has its own merits and demerits.

- *Intravenous Route (I.V)*

In this route, drugs are directly injected to the circulatory system through the vein, it is the most common parenteral route. For drugs that are not absorbed orally, there is often two choice control over the circulating levels of the drug.

- *Intra Muscular Route (I.M)*

This as drug ad ministration through the muscle, drug administered through this route can be acquired solutions or specialized depot preparations. e.g. polyethylene glycol. Absorption of drugs in aqueous solution is fast, where as that depot preparations is slow.

- *Subcutaneous Route (S.C)*

In this type of route, drug substances are directly injected to subcutaneous layer of the skin (under the skin). Like that of I.M route, requires absorption and is slower than the I.V routes. Subcutaneous injection minimizes the risk associated with I.V injections.

### 3.3.3 Other Routes of Drug Administration

There are other useful routes of drug administration which does not fall under categories above this includes

- *Inhalation:* The drugs in form of vapours are inhaled. They are expected to dissolve in blood vessels of the lungs. This route provides a rapid delivery of drug across the large surface area of the mucons membrane of the Respiratory tract and that can be dispersed in an aerosol.
- *Intranasal:* This route allows drugs to be administered directly into nasal surface in form of spray for a local / system effect. E.g. the abused drug cocaine is often taken by suiffing.

- *Intrathecal/Intraventricular*: It is sometimes necessary to introduce drugs directly into the cerebrospinal fluid. E.g. Amphotericin B used in the treatment of meningitis.
- *Topical Route*: Topical application is used when a local effect of the drug is desired. E.g. clotrimazole is applied as a cream directly to the skin in the treatment of skin disease.
- *Transdermal Route*: This route of administration achieves systemic effects of application of drugs to the skin. Usually via a transdermal patch. This route is not often used.

### **3.4 Drugs at the site of Administration**

The aim of drug therapy is to prevent, cure, or control various diseases states. To achieve this goal, adequate drug doses must be delivered to the target tissues so that the therapeutic yet non-toxic levels are obtained. The clinician must recognize that the speed of drug action, the intensity of the drug's effect and the duration of drug action are controlled by four fundamental pathways of drug movement and modification in the body.

First, drug Absorption from the site of administration (input) permits entry of the therapeutic agent (either directly or indirectly) into the plasma. Second, the drug may then reversibly leave the blood stream and distribute into interstitial and intra cellular fluids (Distribution). Third, the drug may be metabolized by the liver, kidney, or other tissues. Finally, the drug and its metabolites are eliminated from the body (out put) in urine, bile or faeces.

#### **3.4.2 Drug Distribution**

Drug distribution is the process by which a reversible leaves the blood stream and enters the interstitium (extracellular fluid) and / or the cells of the tissues. The delivery of a drug from the plasma to the interstitium primarily depends on blood flow, capillary permeability, the degree of binding of the drug to plasma and tissue proteins, and the relative hydrophobicity of the drug.

#### **3.4.3 Drug Metabolism**

Drugs are most often eliminated by biotransformation and /or excretion into the urine or bile. The liver is the major site for drug metabolism, but specific drugs may undergo biotransformation in other tissues. (Note: some agents are initially administered as inactive compounds. (pro-drugs and must be metabolized to their active forms)

### **3.4.4 Drug Elimination**

Removal of a drug from the body may occur via a number of routes, the most important being through the kidney into the urine. Other routes include the bile, intestine, lung, or milk in nursing mothers. A patient in renal failure may undergo extracorporeal dialysis, which will remove small molecules, such as drugs.

### **3.5 General Mechanism of Action of Drugs**

Certain drugs acts on the site pain or infection while some send impulses to the brain and the brain responds accordingly either to reduce pain or depress certain organs or elevate as the case may be

Also, at receptor site, drugs act in a lock and key mechanisms forming by-products which are mostly desirable but sometimes undesirable giving rise to side effects e.g.

- Neutralization: Antacids like magnesium trisilicate acts by neutralizing excess acids in the G.I.T.
- Binding Action e.g. Activated charcoal binds to poison and this is then vomited out from the patient
- Inhibition; some drugs e.g. Atropine act by inhibiting certain body systems or mechanisms
- Anti-infective agents: some drugs act against infective agents in the body of the host; there are two kinds of this drugs.

## **4.0 Conclusion**

In this unit, you have learned what, drug, pharmacology is and it's classification. You have also been exposed to the route of drug administration as well as the activities of drugs at site of administration.

You should at this point be able to define in your own words, drugs, pharmacokinetic and pharmacodynamics. Also, you should be able by now to describe the general mechanism of action of drugs

## **5.0 Summary**

This unit has focused on the definition of pharmacology-pharmacokinetics and pharmacodynamics. The sources of drugs, and most importantly drug effects at site of administration.

## **6.0 Tutor Marked Assignment**

- (a) Define Drug and Pharmacology
- (b) List Effects of drugs at site of Administration

## **7.0 References / Further Readings**

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## **STUDY UNIT 4: ESSENTIAL DRUG LIST FOR PRIMARY HEALTH CARE SYSTEM**

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### **1.0 Introduction**

Since you have gone through the course guide, you would have acquired a general overview of what this unit is about, how it links specifically to the course. This unit will help you acquire basic understanding of what primary health care is and its basic components, as well as essential drug list in the Nigeria primary health care system.



Before we do this, let us have a view of what you should learn in this unit, as indicated in the unit objectives below:

## **2.0 Objectives**

At the end of this unit, you should be able to:

- Describe the historical background of essential drug list in the Nigerian primary health care system
- List special problems of drug supply in Nigeria
- Itemize the advantages of essential drug list in primary health care
- Mention the hints on rational use of essential drugs
- Understand the difference between Primary Health Care list of drugs for Health Centres and Village Dispensaries

## **3.0 Main Content**

### **3.1 Definition of Primary Health Care**

Primary health care, often abbreviated as PHC, is “essential health care based on practical, scientifically sound and socially acceptable methods and technology made universally accessible to individuals and families in the community through their full participation and at a cost that the community and the country can afford to maintain at every stage of their development in the spirit of self-determination (Alma Ata international conference definition)

However, it was a new approach to health care that came into existence following this international conference in Alma Ata in 1978 organized by the World Health Organization (WHO) and the UNICEF. Primary health care was accepted by the member countries of WHO as the key to achieving the goal of Health for all.

Selective primary health care is a form of primary health care in which diseases are more specifically targeted in developing countries to initiate the process of primary health care. In developing primary health care can be a very useful tool in helping to alleviate some of the more pressing issues.

#### **3.1.1 Components of Primary Health Care**

- Universal coverage by ensuring sufficient supply of medicines and services, removing financial barriers to access and ensuring social health protection
- People centre care by transforming traditional health care delivery models (Specialist, procedure or Hospital based) into people-centred primary care networks
- Inclusive leadership by shifting from convectional “command – and – Control” approaches, increasing participation of all stakeholders and moving from supply – led to demand – led policies and programmes
- Health in all policies by ensuring that all relevant sectors (e.g. labour, environment, education) factor health into their agendas.

### **3.2 Historical background of Essential drug list in Nigeria**

The essential drugs programme of the Federal republic of Nigeria came on stream in 1988 and received legal backing when in 1989 Decree 43 was promulgated. That same year the first revision was published. The second revision soon followed in 1991 the third in 1996 and the forth in 2003;

The programme and its legal instrument came under severe criticism by the Drug Manufacturing / Distribution concerns as well as several health practitioners for obvious reasons as the impression was created that whatever drug was not included in the list could neither be imported nor used legally. The amendment to this decree that appeared in 1992, limiting the provision of the earlier decree to the public sector only, had the salutary effect of removing the pressure on the programme as well as those who implemented it.

This National Drug Formulary and Essential Drug List Review Committee has been working constantly taking care of current concerns in the management of HIV/AIDs, Tuberculosis, Integrated management of childhood illnesses (IMCI) and malaria. Newly internationally accepted names of some drugs, formulations and dosage forms have been adopted.

### **3.3 Special Problems of Drug Supply System in Nigeria**

Prior to the consideration of essential drug programme as part of the National drug policy, the drug supply system in the nation were faced with a No. of problems, believed to have been partly addressed today by the essential drugs programme, this includes;

- Poor funding of health care services
- Inadequate baseline data to enable suitable proportioning of the little fund available
- Misplaced health care priorities
- Inadequate and inappropriate communication system
- Poor instruction by prescribers and Dispensers to patients
- Self-medication without prior instruction from health worker
- Genetic variations in drug response

### **3.4 Advantages of Essential Drugs Programme**

The usually expected advantages of an Essential drugs programme includes;

- Limiting the number of drugs deployed in the health care system
- Creating opportunity for the provision of concise, accurate and comprehensive information in the form of a National Drug Formulary on all the drugs in the essential drug list
- Improving the knowledge of prescribers regarding the pharmacological properties of the prescribed drugs thus improving the quality of drug
- Improving drug utilization by the various sectors of the health care system through better monitoring
- Sound policy, legislation and essential drugs programmes that includes education of health professionals and patients in rational use of drugs are measures that should ensure better health care in all countries.

### **3.5 Classification of Essential drug list for Primary Health Care**

Essential Drugs used in primary Health Care Level is basically classified according to the fact that health facilities and village dispensaries, traditional birth attendants, all other health workers, fall under the primary health care delivery system hence; levels A and B below

### 3.5.1 The Primary Health Care List for Health Centres. (Level A)

ANAESTHETICS, LOCAL:	- Lidocaine, topical, injection	
ANALGESICS	- Acetylsalicylic acid, tablet.	
	NOT FOR CHILDREN	
	- Paracetamol, tablet, syrup	
ANTI-ALLERGICS	- Epinephrine (adrenaline), Injection	
	- Chlorpheniramine maleate,	tablet,
	Syrup	
	- Promethazine, tablet, syrup	
ANTIDOTES	- Atropine, injection	
	- Charcoal, (activated) powder	
ANTICONVULSANTS	- Diazepam, injection	
	- Paraldehyde, injection	
	- Phenobarbital, tablet	
ANTI-INFECTIVE DRUGS		
(a) Amoebicide	- Metronidazole, tablet	
(b) Anthelmintics	- Mebendazole, tablet	
	- Praziquantel, tablet	
	- Pyrante, tablet, syrup	
(c) Antifilarial drug	- Diethylcarbamazine, tablet	
(d) Antimalarias	- Chloroquine, tablet, syrup, Injection	
	- Pyrimethamine, tablet	
	- Pyrimethamine plus Sulfadoxine, tablet, syrup	
	- Quinine, tablet, injection	
(e) Antibacterial drugs	- Amoxicillin	
	- Benzathine penicillin, injection	
	- Benzylpenicillin, injection	
	- Co-trimoxazole, tablet, syrup	
	- Chloramphenicol, injection (use under supervision)	
	- Erythromycin, tablet	
	- Gentamicin, injection	
	- Nalidixic acid, tablet	

	<ul style="list-style-type: none"> <li>- Phenoxymethylpenicillin, Tablet</li> <li>- Procaine Benzylpenicillin, Injection</li> <li>- Streptomycin, injection</li> <li>- Tetracycline, capsule</li> </ul>
(f) Antileprosy and Anti tuberculosis drugs	<p>NOTE FOR CHILDREN AND PREGNANT Women</p> <ul style="list-style-type: none"> <li>- Clofazimine, capsule</li> <li>- Dapsone, tablet</li> <li>- Rifampicin, capsule or tablet</li> <li>- Thiacetazone + isoniazid, Tablet</li> <li>- Pyrazinamide, tablet</li> </ul>
DRUGS AFFECTING THE BLOOD	<ul style="list-style-type: none"> <li>- Ferrous salts, tablet, mixture</li> <li>- Folic acid, tablet</li> </ul>
DERMATOLOGICAL DRUGS	<ul style="list-style-type: none"> <li>- Benzoic acid + salicylic acid, (Whitfield's), ointment</li> <li>- Benzyl peroxide, cream or gel</li> <li>- Calamine, lotion</li> </ul>
EAR, NOSE AND THROAT DRUGS	<ul style="list-style-type: none"> <li>- Chloramphenicol, ear drops</li> </ul>
GASTRO-INTESTINAL DRUGS	<ul style="list-style-type: none"> <li>- Betamethasone plus lidocaine, Ointment, cream, suppository</li> <li>- Hyoscine N-butyl Bromide, Tablet</li> <li>- Magnesium trisilicate Compound, tablet, mixture</li> <li>- Oral Rehydration Salts</li> </ul>
OPHTHALMOLOGICAL DRUGS	<ul style="list-style-type: none"> <li>- Chloramphenicol, eye drops</li> <li>- Ointment</li> <li>- Chlorotetracycline eye Ointment</li> </ul>
OXYTOCIC	<ul style="list-style-type: none"> <li>- Ergometrine, tablet, injection</li> </ul>
PSYCHOTHERAPEUTIC DRUG	<ul style="list-style-type: none"> <li>- Chlorpromazine, injection</li> </ul>
RESPIRATORY SYSTEM DRUG	<ul style="list-style-type: none"> <li>- Beclomethasone, inhaler</li> <li>- Salbutamol, tablet, inhaler</li> </ul>
VITAMINS AND MINERALS	<ul style="list-style-type: none"> <li>- Ascorbic acid, (Vitamin C), Tablet</li> </ul>

- Calcium salts, tablet
- Calcium gluconate, injection
- Folic acid, tablet
- Vitamin A, capsule
- Water for injection, injection

### **3.5.2 List for Village Dispensaries (Health Workers) (Level B)**

Acetylsalicylic acid (Aspirin)	- Tablet, NOT FOR CHILDREN
Paracetamol	- Tablet, syrup
Chloroquine	- Tablet, syrup
Pyrantel	- Tablet, syrup
Ferrous Salts	- Tablet
Folic acid	- Tablet
Sulfadimidine	- Tablet
Condoms	- Barrier method
Calamine lotion	- Lotion
Benzyl benzoate	- Emulsion
Methyl salicylate	- Ointment
Salicylic acid + Benzoic acid (Whitfield's)	- Ointment
Chlorhexidine	- Solution
Iodine	- Tincture
Methylated spirit	- Solution
Absorbent gauze	- Dressing
Cotton wool/crepe bandages	- Dressing
Zinc oxide plaster	- Dressing
Clinical thermometer	
Surgical blades	
Plastic aprons	

### **3.6 Hints on Rational Use of Essential Drugs**

- Essential drugs are those drugs that cure or prevent the most common health problems of the majority of Nigerians
- Many drugs on a prescription do not necessarily mean treatment

- Always get examined by a trained medical personnel before you buy drugs, make sure you follow the recommendation given by the medical personnel.
- Make sure you really understand how you are supposed to take the drugs, it is always your right to ask
- Even if you start feeling better, take all the treatment
- Keep your drugs in safe cupboard away from children
- Remember that drugs are only one of the ways to cure, balance diet, rest and exercise are equally important
- Essential drugs programme provides safe, reliable, effective and affordable drugs
- A little payment for your drugs today ensures your getting another supply tomorrow

#### **4.0 Conclusion**

In this unit, you have learned what primary health care is and in defining PHC mention should be made of its four main components. You have also realized that the PHC have very valuable advantages. You have also seen the classification of the essential drug list for primary health care into level A&B.

You should at this point be able to itemize in your own words, hints on rational use of essential drugs. Also, you should be able to by now classify essential drug (s) into either levels A or B

#### **5.0 Summary**

This unit focused on the definition of primary health care and it's main components. Advantages of essential drug list for primary health care were clearly itemized, as well as the hints for rational use of essential drugs at the primary health care levels.

#### **6.0 Tutor Marked Assignment**

- (a) Itemize the advantages of essential drug programme
- (b) Define primary health care

#### **7.0 References / Further Readings**

Susan Foster (1991) "Supply and Use of Essential Drugs in Sub-Saharan Africa: some issues and possible solutions" "Soc. Sci. Med. Vol.32, No.11, pp 1201-1218

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#### **MODULE 4: CONCEPT OF DRUG REVOLVING FUND (DRF)**

##### **UNIT 1: Drug Financing System**

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## **1.0 Introduction**

You have gone through the course guide; you would have acquired a general overview of what this unit is all about, how it links to the course. The unit is designed to help you acquire the necessary understanding of mechanisms of Drug financing as well as the classified methods. In this unit, you will also be exposed to the Drug financing systems in most developing countries of the world.

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Before we do this, let us have an overview of what you will learn in this unit, as indicated in the unit objectives.

## **2.0 Unit Objectives**

At the end of this unit, you should be able to:

- ❖ Describe drug financing in your own words.
- ❖ Discuss the mechanisms of drug financing.
- ❖ Classify the mechanisms of drug financing.
- ❖ Describe drug financing in developing countries.

### 3.0

## **Main Content**

### **3.1 Introduction**

Drugs are essential for preventive and curative health services. Significant demand, limited funds and high prices contributes to frequent shortages of drugs in many public health programmes. One method for financing drugs and other pharmaceutical supplies has been the establishment of Revolving Drug Funds (DRFs ) in which, after an initial capital investment, drug supplies are replenished with the monies collected from the sales of the drugs. However, a clear opposite of this is the partial of full free health care services where drugs supplies are continuously replenished without financial revolution or benefits.

### **3.2 Mechanisms of Drug financing**

Financing of pharmaceuticals in most nations of the world is a crucial issue for several reasons. First, because drugs are designed and produced to save lives and improve health, it is important that drug financing ensures access to essential drugs for all segments of the population. Second, drugs are costly. For most health ministries at all levels of Government, drugs represent the largest expenditure after staff salaries.

In some countries, up to 80% of household's health – related spending is on drugs. In developing countries, drugs commonly represent from 25 to 50% of total public and private health expenditures (Quick, et al 1997). Third inadequate funding for drugs means that expenditures for staff salaries and other care costs may be used inefficiently or simply wasted. Fourth, the availability and effectiveness of drugs are key factors in generating and maintaining public interest and participation in health related activities.

Possible drug financing options include public financing; user charges; Private or Co-operative not-for-profit; donors and international loans. Nevertheless, it is the responsibility of Government to ensure that drug-financing mechanisms are managed in such a way as to achieve universal access to essential drugs. Those various methods of drug financing can be classified into two main categories: Free of Charge (Free Health Services) and cost sharing mechanisms.

### **3.2.1 Free of Charge Mechanisms**

The distribution of drugs free of charge is the only possible solution when the population to be served has no financial resources; examples are persons who are displaced, in refugee camps and poor rural areas. This can be done as stated below in the next annexure.

#### **3.2.1.1 Public Financing through General Revenues.**

Government in virtually every country in the world plays a role in financing health services and pharmaceuticals. This role reflects in part the recognition by society that health is a fundamental right to which all sections of the population should have access. It also reflects the realisation that the private sector does not necessarily achieve equity nor sustains the precept of solidarity.

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Though some public financing for health and essential drugs are necessary, the level of financing varies dramatically among countries. Public financing of free drugs may be through national or local Government general revenues, taxes, loans and donation.

#### **3.2.1.2 NGOs, Donors and Others:**

The percentage of aid, which contributes to health expenditure, varies considerably from country to country. In sub-Saharan Africa, the average

contribution of aid is nearly 30% whereas in Asia (excluding China and India) it is 11% and in Latin America it is under 8% (Vekasquez, et al 1998).

In pharmaceuticals, donors may support the establishment of drug supply systems and drug donations. The latter is frequently related to emergency relief or initial seeding of revolving drug funds. The external financing must not be allowed to substitute for the effort of the countries to develop sustainable financing mechanisms.

However, other mechanisms of drug financing such as employer provided health care, which can be furnished either directly, through contracts with private providers or through insurance and reimbursement. This can also contribute to the overall health provision in a country.

### **3.2.2 Cost – Sharing Mechanisms**

Drugs and other pharmaceuticals are essential for preventive and therapeutic health care and offer simple, cost effective solution to many health problems, provided, they are available, affordable and properly used. In addition to their direct health impact, the effectiveness of drugs against health professionals that they need to promote long term health improvements through environmental and nutritional changes. The importance and popularity of drugs has led many

governments in developing countries to espouse policy of free drugs.

However, because of the poor economic situation, the high international debt and the fall in the world prices of their commodities, most developing nations are unable to continue with free provision of free health services and drugs at the point of delivery. The introduction of cost sharing through user fees has been proposed as one of the strategies to lighten the physical burden of most governments, preserve the sustainability of the drug distribution system as well as to improve the efficiency of the over all public health sectors (Griffin, 1995).

### **3.3 Drug Financing in Developing countries**

The financing crisis facing the developing countries is constraining growth and forcing Governments both to rethink and to refocus their domestic programmes. This retrenchment has not only included the public sector but has hit the Government health care investments particularly hard. The health sector is frequently a source of high Government expenditure, one that contributes little to short-term economic performance or foreign exchange earnings. This, combined with high annual recurrent costs of health care services, has made the sector an easy target for hard pressed ministries of finance.

The revenues available for social expenditure in general, and health care in particular, are also constrained by the need to provide for other functions of Government (including in some cases relatively large military expenditure) and by the need in many developing countries to undertake measures of economic stabilization and structural adjustment (Cichon & Gillion 1993). Budget cuts often lead to a disproportionate reduction in non-staff inputs, leaving medical professional without sufficient drugs and equipment.

The provision of access to affordable and acceptable quality drugs is probably the most crucial element in implementing primary Health Care (PHC). As a result many developing countries have made it principle to provide drugs free of charge based on social ideals, have no intention to collect costs and have often defrayed the expenses by drawing money out of the national treasury. Unfortunately, few countries have the resources to fully implement such a policy. Significant demand, limited funds and high drug prices contribute to frequent shortages. Thus, the cost of drugs becomes a scarcity of drugs and disillusionment. Health professionals were dispirited by trying to provide services without the resource they have been trained to use and the people were frustrated by receiving so much less than they were promised.

This situation has to some extent, been deflected towards the small, rapidly growing, but expensive private sector of health care, with a result shift of quantified personnel towards the private sector and the service of wealthier clients who can pay.

In developing countries, pharmaceuticals generally account for a more significant share of overall health expenditures than in developed countries (for which this share is about 15%). In several African countries, it is believed to exceed 50%. In developing countries, 50 – 90% of the overall pharmaceuticals expenditures are privately financed, which is considerably higher than in developed countries (median is 34%) (Velasquez et al 1998)

### **3.3.1 Principles of Drugs Economic Strategy:**

The main principles behind the economic strategy for drugs recommended by the world Health Organisation (WHO) are:

- ❖ The objective of various drug financing systems must be to improve and facilitate the access of the whole population to essential drugs;
- ❖ The responsibility and will of the state to participate in paying the national drug bill are fundamental;

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- ❖ The money saved by the selection of drugs to circulate in the country and their rational use must be one of the main sources of additional income for the purchase of drugs;
- ❖ The allocation of an adequate percentage of the state budget to health, and consequently to drugs, must be a priority; for many countries this will require an increase in public spending for health.

## **4.0 Conclusion**

In this unit, you have learned the introductory aspect of the concept of Drug revolving fund (DRF), mechanisms of drug financing, classifications of the mechanisms, including free of charge and cost-sharing mechanisms. You have also learned Drug financing in Developing nations of the world. Thus you should by now be able to itemize the

recommendations on the main principles behind the economic strategies for drug by the World Health Organization (WHO).

## **5.0 Summary**

This unit focused on the introduction to the concept of drug revolving fund via the various mechanisms of drug financing, highlighting the situation of drug financing in developing countries while itemizing the recommendations of the World Health Organisation. Unit 2 will focus mainly on the cost – sharing Mechanisms.

## **6.0 Tutor Marked Assignment**

- a) Itemize the recommendations of the WHO on the main principle behind the economic strategies for drugs by the WHO
- b) Simply classify drug financing system.

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## **7.0 References/Further Reading**

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## **STUDY UNIT 2: COST - SHARING MECHANISMS**

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<b>1.0</b>	<b>Introduction</b>

You have gone through the course guide; you would have acquired a general overview of what this unit is about, how it links to the course. The unit is designed to help you acquire the necessary understanding of the



concept of cost – sharing mechanisms, its objectives and direct sales via the Drug Revolving scheme.

In this unit, you will also be exposed to payment of flat charges and pre-payment principles and most importantly roles of community in cost-sharing.

Before we do this, let us have an overview of what you will learn in this unit, as indicated in the unit objectives.

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## **2.0 Unit Objectives**

At the end of this unit, you should be able to:

- Define cost sharing mechanisms
- Itemize the objectives of cost sharing mechanism
- Differentiate between Direct sales through DRF payment of flat rates charges and pre – payment.
- Describe the roles of communities in cost sharing mechanism/DRF.

## **3.0 Main Content**

Cost – sharing is the drug financing programme that is sustainable with contribution from both public sector as well as community (through user fees). Facing shortage of drug supplies for PHC in many developing countries, it was recommended by the World Bank in 1987 (Griffin 1995) that some mechanisms of user charges should be implemented in the community and the money recovered should be used for the replenishment of drug supplies in that community.

To be successful, user fee mechanisms must generally be accompanied by perceived quality improvements in services. The World Bank suggests that the improvement in the quality of services would compensate the negative impact of prices. This implies that improved supply mechanisms for

drugs are both prerequisites and outputs of successful programmes. The properly designed cost recovery programmes can encourage higher demand for modern health care and as a result, higher level of utilization (Hotchkiss 1998).

Community cost sharing mechanism can be based on direct sales of drugs through the Revolving Drug Fund, payment of a flat rate charge, payment for services via insurance and other various income generating activities.

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### **3.1 Objectives of Cost – Sharing Mechanisms**

- ❖ Promote efficiency: user charges can move the patients from the big hospitals to the lower level of health facilities, through different drug prices at different levels of health care;
- ❖ Foster equity: by charging people who are able to pay, more money will be made available for the poor through effective exemption systems;
- ❖ Promote decentralization and sustainability: cost sharing provides ways and means for decentralization of health policy to community level;
- ❖ Foster private sector to be more competitive in providing drugs and service
- ❖ Promote consumer satisfaction: the ultimate result of cost sharing should be increased consumer satisfaction following the availability of drugs
- ❖ Generate revenues: this can be a means to generate more revenues for facilities to buy new drugs;
- ❖ Reduction of unnecessary utilization: user charges for publicly provided health services and drugs can lead to more efficiency than the health services and drugs provided free of charge.

A key issue for government officials responsible for health care financing policy in developing countries is that of how to implement cost recovery plans without adversely affecting health outcomes through decreased health care utilization. Whether individuals benefit from cost

recovery plans depends on the quality of services that are delivered, the out – of – pocket price that is charged, and how individuals respond to that quality and price. In addition, the long – term financial viability of Government investments in health care services depends on the ability to finance future improvements in quality by increasing revenues through higher user fees.

### **3.2 Direct Sales through Drug Revolving Fund**

Payment for drugs has been seen as one component of the strategy of cost sharing, but has also been seen that when this is implemented most patients, especially the poor, are unable to afford drugs at market costs. One way, proposed to help this group of patients is through the introduction of a Drug Revolving Fund (DRF) in which after an initial capital investment, drug supplies are replenished using money collected from the sales of drugs.

The World Bank (1994) defines the term Drug Revolving Fund as community financing for the availability of essential drugs at full cost prices. DRFs, which are one type of drug sales programme or cost recovery schemes, attempt to mobilize financial resources based on a domestic willingness of people to pay for health services. DRFs are attractive, because they are theoretically self-financing after a one-time capital investment by the community, the Government, outside donors or loans. The one-time initial investment could be either in medicines or in cash. In the latter case, cash is spent to purchase medicines for initial drug stock. In purchasing medicines, medicines should be chosen from among essential drugs, meaning medicines of high necessity from a medical perspective, and medicines, which can be purchased at low cost because the patent on them has expired. DRF seeks to recover drug costs in part (long-term subsidies required), in full or with marginal profit on the cost of drugs, that allows the target group to buy the drugs and allows more drugs to be bought by the fund. The supply of drugs can be continued indefinitely without further Government budget allocations as long as revenues from sales (or in some cases local health budgets) are sufficient and funneled back in purchasing new drugs.

The expected effects of the DRF are: residents would have better access to medicines, the DRF could serve as a channel to stabilize the drug supply at health facilities; improve the utilization rates of health facilities and make retail prices, prescription activities and the direction to use medicines appropriate in places where there are many private pharmacies.

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Drug Revolving Funds draw attention among health sector financing in developing countries as leading methods of community financing. They offer an appealing and potentially successful means of supplying drugs for many parts of the third world. The concept seems quite simple, but in practice, these funds have proven to be substantially more complicated to plan and implement than systems which simply have given drugs away.

### **3.3 Payment of Flat rate charges**

A flat rate charge covers both health care and drugs. The amount may vary according to the level of service (dispensary, health centre or hospital) or the condition treated (such as malaria or childbirth). The example of this type of cost sharing is the Bamako Initiative (BI). This was announced at a meeting of African ministers of health in 1987 in Bamako, the capital of Mali, as a response to the severe problems in financing health services in sub-Saharan Africa. The goal of the BI is the universal accessibility to PHC. BI advocated PHC as well as maternal and child health care financed through community financing. Drugs are sold at prices that cover their cost and make surplus to cover recurrent cost. Based on this proposal, UNICEF backed many experimental RDFs in the region by giving seeding stock. In Benin and Guinea the BI programmes have demonstrated their ability to raise preventive and curative coverage with key PHC intervention while keeping the cost of the health system low (Soucat, et al 1997).

### **3.4 Pre – payment**

Pre – payment (health insurance) separates in time the act of payment from the act of consumption, so people who are well and not patients (Jerome 1998) pay for those drugs. The fundamental concept behind health insurance is the sharing of the risk and burden of paying for illness among a group of people or society. There are different insurance

approaches, which can involve both public and private sectors such as social health insurance, community prepaid schemes and private health insurance.

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**3.5 The Role of the Community in Cost – Sharing.** addition, it is sometimes argued that community financing is a form of community

Community financing is put forward primarily as a method of providing additional resources to the health sectors. In participation, this ensures that communities are not just passive recipients of services. The scope of community financing to generate additional resources for the health sector depends on the potential to find a combination of prices (user charge or premier) and quality improvement which proves both affordable for the population, capable of attracting its willingness to pay and capable of sustaining activities given a realistic assessment of Government or donor support.

#### **4.0 Conclusion**

In this unit, you have learned the Definition of cost sharing mechanism/DRF, the main objective of cost sharing mechanisms/ DRF, principles of flat rate charges, pre-payment

You have also learned how direct sales are made via the drug revolving fund and I believe you should be able, by now, to describe in your own words the role of communities in the Drug Revolving Fund system.

#### **5.0 Summary**

This unit focused on the cost sharing mechanisms/DRF and its objectives, while discussing the roles of communities in the running of Drug Revolving fund amidst other relevant principles. Unit 3 will focus on the Drug Revolving Fund financial system.

#### **6.0 Tutor Marked Assignment**

- a) Discuss roles of communities in DRF
- b) Itemize objectives of cost sharing mechanism.

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## **STUDY UNIT 3: DRUG REVOLVING FUND FINANCIAL SYSTEM**

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3.5.2	Capitalization cost
3.6	DRF Threatening factors.
4.0	Conclusion
5.0	Summary
6.0	Tutor Marked Assignment
7.0	References / Further Readings

### **1.0 Introduction**

You have gone through the course guide, you would have acquired a general overview of what this unit is about, how it links to the course. This unit will help you acquire the necessary understanding of the financial system of the Drug Revolving Fund, the financial responsibilities of a DRF manager, financial statement and records, DRF Bank accounts and Cash Collection. However, in this unit, you will also learn common factors threatening the Drug Revolving Fund system.

Before we do this, let us have an overview of what you will learn in this unit, as indicated in the unit objectives.

## **2.0 Objectives**

At the end of this unit, you should be able to:

- ❖ Itemize the financial responsibilities of a DRF Manager
- ❖ Differentiate between DRF financial statement and Records
- ❖ Outline the DRF principles on Bank account and Cash Collections
- ❖ State clearly the DRF Threatening factors

## **3.0 Main Content**

### **3.1 Financial Responsibility of a DRF Manager**

A DRF manager is often appointed at all level of Government as the accounting officer for the Drug Revolving Fund. His responsibilities as accounting officer includes his responsibility and regularity of the public finances for which he is answerable and for the keeping of proper records required for financial order. This is in addition to paying and collecting debts and ensuring the financial health of the DRF.

### **3.2 Financial Statement**

According to the financial order given at the onset of the implementation of the DRF, statements of accounts for each year must be prepared. The accounts are prepared on an accruals basis and must give a true and fair view of the DRF's state of affairs at the year – end.

In preparing the accounts, the DRF is required to:

- Observe the accounts order direction issued by the Federal Ministry of Finance, including the relevant account and disclosure requirements and apply suitable accounting policies on a consistent basis;

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- ❖ Make judgments and estimate on a reasonable basis;
- ❖ Prepare financial statements every month



### **3.3 Financial Records**

The DRF financial records at all levels should include:

- ❖ Sales quantities and revenues by drug and type of health facilities (health centres, hospitals and warehouse).

This information is used to assess the impact of the drug pricing policies and to more accurately predict future drug requirements; regular trial balances and income statements provide periodic status reports on drug stocks and the financial reserve. Such reports are vital to assure that the revenues are achieving or at least approaching cost recovery objectives that cash flow is sufficient to procure new stock and the stock is sufficient to fill expected demand.

### **3.4 DRF Bank Account and Cash Collection**

The law of the treasury requires that revenues earned by any arm of the Government must be remitted to the purse of the account, the DRF has its own separate accounts at all levels, and thus its revenues are entirely excluded from the finance ministry budgetary information.

Besides, the DRF Cash Collection of drug sales at health facilities is based on the answering the quest supervision team must match with the drugs that had been sold during the week. Any deficit should be paid by the ion of how much money should have been, and how much money actually was collected. A high collection rate depends on a sound drug management system.

At the onset of DRF, for the first time, an inventory system on a monthly basis to reconcile the cash collection with the solid drug. However, this approach failed to prevent the deficit in cash collected against sold drugs. The cash collected by the

responsible pharmacist within one week. The cash collection system in addition to accountability measures, regular supervision and vigorous use of disciplinary and legal measures results in a high efficiency of cash collection and the entire elimination of a deficit.

### **3.5 Drug Revolving Expenses**

Expenses incurable in the implementation of a DRF expensed can basically be classified into two viz:

#### **3.5.1 Operating Expenses:**

Keeping the operating expenses of the system to a minimum has been the key prerequisite to the implementation of the DRF where fees should be affordable for the patient. The operating cost can be divided between fixed and variable costs.

Administrative incentives, electricity and communications are usually relatively fixed. Transportation, demurrage, insurance, bank charges and supplies will vary depending on the volume of drugs being handled

#### **3.5.2 Capitalization Costs:**

Other than the capital fund for initially stocking the system (Working capital), capitalization or development costs (indicated under other expensed in profit – loss Account) include the costs of designing and planning the system, construction, renovation of office and warehouse space, purchase of vehicles, equipment and the support of other health facilities.

### **3.6 Drug Revolving Fund Threatening Factors**

Revolving drugs funds have been established in Peru, Guatemala, India, Bolivia, Haiti, Senegal, Niger, Nigeria,

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Afghanistan, Mali, Indonesia, Thailand and else where. The establishment and / or maintenance of many of these programmes has been fraught with difficulties (Peter et al 1986).

However, the following factors too often make DRF to generate sufficient revenue to replenish their stocks and in effect, soon cease to revolve. These factors are:

- ❖ Business Orientation: many factors contribute to the failure of RDFs, one of the most important appears to be a resistance to thinking of the fund in business terms and, in particular, a lack of careful economic and financial analysis in planning the fund.
- ❖ Community Non – compliance: Community participation in the RDF is essential. For example, the Gosses, Senegal revolving fund for a vaccination programme failed to revolve when villagers prove unwilling to pay for the entire series of vaccinations and the revenues were insufficient to replenish health workers supplies (Peter et al 1986)
- ❖ Under – estimation of the Capitalisation Cost: the cost of the supply system should be planned for and the operating cost should be closely monitored;
- ❖ Unanticipated losses of the Drugs: the losses of drugs and cash through theft or deterioration or unauthorized exemption commonly lead to RDFs failure;
- ❖ High Operating Costs: may cause fund depletion. To keep the operating costs under control RDF uses a monthly profit – loss account which allows immediate intervention decision when necessary;
- ❖ Prices set too low for intended level of cost recovery: the pricing system is important exercise on the RDF , and the prices are updated regularly to cope with the local currency devaluation;
- ❖ Delay in collection of subsidies and other payment from Government Agencies: the policy of the RDFs is cash for drugs.
  - The drugs in the RDF are sold on a prescription basis in all RDF health facilities.

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## 4.0

### Conclusion

In this unit, you have learned the financial system of the Drug revolving Fund. You have been exposed to be standard financial responsibilities of a DRF manager, DRF Financial statement and Records, you have also learned DRF Bank Accounts and Cash Collections, DRF

Expenses, its classification and in the same vein, those factors militating against the success of Drug Revolving Fund.

## **5.0 Summary**

This unit focused on the financial system of DRF amidst other relevant topics including financial statements and records of DRF, DRF expensed and some of the factors threatening a successful implementation of the scheme, particularly in African Nations. Unit 4 will focus on the DRF Drug Supply System

## **6.0 Tutor Marked Assignment**

- a) Classify the DRF Expenses
- b) Itemize the DRF threatening factors.

## **7.0 References / Further Reading**

Barnett,A., et al (1980). The economic of pharmaceutical policy in Ghana. *International Journal of Health Science*. Vol. 10, pp 479-4999.

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**STUDY UNIT 4: DRUG REVOLVING FUND, DRUG SUPPLY SYSTEM**

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## 1.0 Introduction

You have read through the course guide, thus, you would have acquired an overview of what this unit is about, its relevance to the course. This unit will help you acquire the understanding of the Drug supply system under a Drug Revolving Fund Scheme, hence you will be exposed to the

selection and designs of DRF Drug list, procurement and finally the DRF Drug pricing policies.

Before doing this, let us have a clear overview of what you need to learn in this unit, as shown below in the unit objectives.

## **2.0 Unit Objectives**

At the end of this unit, you should be able to:

- ❖ State how to select and design the DRF Drug list
- ❖ Describe the procurement procedures of the DRF Drugs
- ❖ State clearly in your own words the DRF Drug Pricing Policy
- ❖ Itemize the components of the DRF Drug Pricing policy.

## **3.0 Main Content**

### **3.1 Introduction**

The economic objective of a drug supply system is to ensure supply of safe, effective, good quality drugs at the least possible cost to the people who need them. This means that criteria of cost – effectiveness must be combined with criteria of quality (Dumoulin, et al 1998). The pharmaceutical supply system is the most straight forward. It runs from the manufacturer to the patient and passes through the stages of: procurement, Distribution, Delivery and uses of Drugs. In addition to the above stages, the following functions are usually involved: Selection, Quantification and Quality Control. Information required in drug supply:

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- ❖ Supply information: This is information about the availability of drugs, usefulness and efficacy of drugs and suppliers' prices and condition of payment;

- ❖ Demand information: This includes information regarding drugs requested by prescribers and patients, quantities required for procurement, distribution and prescription and quality of drugs;
- ❖ Information on the relationship between supply and demand: Information about the actual consumption in volume and value, shortage and current prices.

RDF survival depends on a regular supply of low – cost, high quality drugs to the health facilities. If procurement and distribution are not reliable, the RDF will quickly stop functioning.

To determine the initial capital investment required to meet these criteria, it is useful to think of the RDF drug supply system as a “pipeline” (Peter et al 1986). To assure a continuous supply of drugs at health facilities, the pipeline must be filled; once filled, consumption must be matched by purchases at the central level.

## **3.2 Selection and Designs of DRF Drug List**

### **3.2.1 Selection**

Because of using a fixed drug fund (One time capital investment) and because it is not a profit – making project, the drug list is a fundamental exercise to the RDF. It is often necessary for RDF to procure and distribute only those drugs that are most needed, efficient and cheap. The selection of drugs on the RDF list focuses on these high priority drugs. From RDF economic perspective, it is good to keep the number of drug to be procured, distributed and used as small as possible as this reduces certain cost, increases the access and facilitate rational use of drugs.

Advantages of having short RDF drug list:

- ❖ The effect on the procurement costs: When fewer different drugs are selected, larger quantities of each drug can be purchased. This larger quantity will reduce the cost;



- ❖ The effect on the cost of stock – keeping: A small number of drugs eases stock management because there is less movement in and out and fewer registers and document to be kept;
- ❖ The effect on the accessibility to essential drugs: Selection of fewer essential drugs increase the access to the most essential drugs by increasing the purchased quantities of each item;
- ❖ The effect on quantification: Quantification of the limited number of drugs is easier and more accurate;

### **3.2.2 Design of RDF Drug List**

The RDF drug list design committee recognizes that the starting point for an essential drugs policy is the careful selection and quantification of drug needs according to the health needs of the population to be served. The committee of the RDF list involves balancing consideration of cost with those of efficacy, safety, ease of administration, and other local considerations. As a result, supply of high – cost, low volume drugs with limited health impact is left to the private sector, since such drugs can tie up working capital and result in losses due to expiry.

### **3.3 Procurement.**

The objective of the procurement is to acquire the drugs that are strictly necessary at the least possible cost. This cost comprises the price of purchase from the supplier in addition to many other costs that are sometimes difficult to quantify. These costs such as, transaction cost, delivery costs, cost of packaging, bank charges, custom duties, port and clearance charges, costs of insurance and freight and quality testing cost. An effective procurement process

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ensures the availability of the right drugs in the right quantities, at reasonable prices, and at recognized standards of quality (Quick, et al 1997).

#### **3.3.1 Need Assessments**

The required qualities of drugs may be calculated by the basis of the past consumption or morbidity data (actual need). Although morbidity data

is available at Ministry of Health, DRF uses the past consumption method for drug quantification. This is because the method based on past consumption is simple and most reliable because of a stable prescribing practice. Drug supplies are generally available and it takes account of the uneven demands made on the health services and of actual prescribing practices.

### **3.3.2 DRF Drug Sources**

The main sources of DRF drugs are a not – for profit organization such as UNICEF, Missionpharma, IDA, ECHO and Amstelfarma. These are European brokers of generic drugs, which do have the specialized skills required and which use international competitive bidding. They are reasonable sources for smaller amounts of essential generic drugs.

The preference of the procurement from non – profitable sources has been emphasized by:

- Very low prices are usually offered by non – profitable suppliers compared to local manufacturers. For example, the 1998 – drug order shows that only three items could be bought locally;  
Wide range of items which are not available to the local manufacturers
- Drugs, Pharmaceuticals and equipment offered by non – profitable suppliers are of proven quality.

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- Wide range of items which are not available to the local manufacturers
- Drugs, Pharmaceuticals and equipment offered by non – profitable suppliers are of proven quality.

However, their main drawbacks are:

- They require payment in foreign exchange either upon delivery, or in some cases, upon placement of the order- the ability of the RDF

- to effect payment immediately is rewarded by excellent contract terms and payment offered by two suppliers;
- Complexity of the procedures and lengthy of procurement period especially with UNICEF;
  - Ongoing quality assurance and quality procedures

### **3.3.3 DRF Procurement Strategy**

The procurement exercise remains one of the most concentrated activities on the RDF because out of stock of high priority drugs may result in costly local purchases from private suppliers and RDFs without a reliable source of low cost drugs have quickly ceased to revolve.

Using an independent procurement system, the RDF purchase drugs and other pharmaceutical supply for use in the MoH health facilities are much more quickly than through the usual Government channels. Careful monitoring and management ensure that out of stock does not occur.

DRF drug purchases are made according to the financial procedures defined by the DRF management committee. There are three strategies of DRF procurement: Direct Purchase, Negotiated Purchase mainly with local manufacturers and the main strategy is the procurement through closed (Restricted) tender to a selected number of suppliers. The list of accepted suppliers is restricted to those known for their good reputation and it is subject to revision.

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The advantages of selection of a limited number of suppliers are: its flexibility, speed and low transaction cost. Its disadvantage is that the supplier can abuse the buyers.

### **3.3.4 DRF Drug Pricing Policy**

#### **3.3.4.1 DRF Drug Pricing Objective**

Unlike a commercial pharmaceutical distributor who must recover all of his expenses plus some profit, a publicly sponsored Revolving Drug Funds objective is not to maximize profits but to maximize service delivery at a certain basic quality level. Thus, the drug price adopted on the DRF is to

ensure provision of affordable drugs, in comparison to the alternative sources i.e. private pharmacies.

#### **3.3.4.2 DRF Pricing Strategy**

The DRF pricing system can be designed with the objective of recovering the cost by using any of the following strategies;

- ❖ The first strategy: all costs, including payment of the capital investment, are relatively uncommon for DRFs. The DRF are usually not required to repay the initial capital investment;
- ❖ The second strategy: the selling price is taken to be equivalent to the actual cost of the drug purchase (direct cost) plus the operating costs, (Peter, et al 1986);

\* The third strategy: selling prices are not exactly equal to the cost; there are three possible ways of establishing the selling prices as follows:

#### **3.3.4.3 DRF Pricing Procedures**

The DRF of Ministry of Health is not a cost recovery project by definition, but a revolving drug fund.

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This difference is important to bear in mind. It is also not a profit making (commercial) institution. Thus, each review takes into account all of the cost categories associated with maintaining the DRF: drug costs, operating costs and capitalization

#### **3.3.4.4 RDF Pricing Procedures**

The RDF of Ministry of Health is not a cost recovery project by definition, but a revolving drug fund. This difference is important to bear in mind. It is also not a profit making (commercial) institution. Thus, each review takes into account all of the cost categories associated with maintaining the RDF: drug costs, operating costs and capitalization costs. Political, Social, Health care and patient preference issues are also

considered in the price setting process. Before setting a new price, the RDF makes a Find out on their drug charges. However, the result of the survey is interpreted in the light of differences in income level and perceived value of services.

In general, there are different types of fees which can be charged, (each with different impacts on consumption pattern, ease of collection and accounting, and the balancing of drug costs and revenues). These fee types are:

- ❖ Course of therapy: fixed fee for an episode of illness associated with standard treatment;
- ❖ Prescription: standard fee per prescription;
- ❖ Item fee: standard fee per drug;
- ❖ Multi – level item fee: different standards of fee for different drug levels;
- ❖ Variable item fee: fee differs with drug depending on type or cost

#### **3.3.4.4. Selling of DRF Drugs**

##### **3.3.4.4.1 DRF Health Facilities**

\ The DRF Drugs are sold to patients at MoH health facilities as a part of a health care transaction. This tight link to health care providers allows harmonization of drug prescription ensuring that drugs form an integral part of patient care.

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##### **3.3.4.4.2 Dispensing procedure**

Drug in DRF s are dispensed only on prescription issued by authorized medical staff and solely against cash payment. In general, the prescription should fulfill the following criteria to be dispensed at pharmacy.

- ❖ It should be a or DRF Health Insurance prescription

- (prescription from outside are not allowed);
- ❖ It should contain all the basic information on the patient such as Name, Sex, Residence etc;
- ❖ It should be stamped from the statistic office (To ensure that patient was registered);
- ❖ It should be attached with the consultation ticket (health centres only). This is not applied to Health Insurance patients and those who are exempted by the medical director.

#### **4.0 Conclusion**

In this unit, you have learned the selection and Designs of a DRF drug list, sources and procurement procedures of a DRF Drugs, as regards to Need assessment, sources, procurement strategies.

You should by now, be able to itemize the components of the DRF drug pricing policy.

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#### **Summary**

This unit focused on the Drug supply systems of the DRF, you have been specifically exposed to the entire concept of the Drug supply system of the Drug Revolving fund, the pros and cons, and tips for a successful take off and sustainability towards a successful drug distribution and thus affordability and accessibility. Unit 5 will then focus on the DRF drug distribution system.

#### **5.0 Tutor Marked Assignment**

- a) Itemize the DRF drug sources
- b) Enumerate the advantages of having a short DRF drug list

## **6.0 References / Further Readings.**

Murakami,H.(1998). Management of Revolving Drug Fund: Comparative case studies in Lao People's Democratic Republic. *Technology and Development*. No.11, pp49-58.

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## **STUDY UNIT 5: DRF DRUG DISTRIBUTION SYSTEM**

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## **1.0 Introduction**

Since you have gone through the course guide, you would have acquired a general overview of what this unit is about, how it links specifically to the course. This unit will help you acquire basic understanding of what the DRF Drug Distribution system is and its basic components.

Before we do this, let us have a view of what you should learn in this unit, as indicated in the unit objectives below:

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## **2.0 Objectives**

At the end of this unit, you should be able to:

- Itemize the objective of DRF distribution system
- Describe in your own words DRF Drug Storage Management
- Differentiate between DRF Drug measures, stock turnover And Quality assurance
- Describe drug delivery in a DRF system
- State how to manage DRF drugs at Health facilities.

## **3.0 Main contents**

### **3.1 Introduction**



The objective of distribution is to enable patients who need drugs to have access to them. This includes geographical, physical and economic access (Dumoulin et al 1998).

- **Geographical access:** Refers to the distance patients must travel to the nearest pharmacy. All RDF health facilities are within the walking distance (Awadalkarim et al 1996). However, the geographical access must balance the extra cost of pharmacies serving small populations against the cost to those populations traveling to more distant pharmacies.
- **Physical access:** physical access refers to the availability of the stocks of drugs normally present in a pharmacy. The RDF manages to make essential drugs (98%) available at all its health facilities (Fundafunda, 1998). In many developing countries, depletion of drug stock threatens the utilization of health services.
- **Economic access:** The price of drug to patients depends on the cost of the drugs to the procurement system, the cost of

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distribution and the system of financing consumption. Although the RDF selling price is 50 to 60% less expensive than private pharmacies (Fundafunda 1998), the accessibility to patients is 92% (Asadalkarim, et al 1996).

### **3.2 Drug Storage Management**

Drugs are fragile chemical substances and as such need special care and handling. They must be protected from excessive heat and moisture, from infestation by insects and other pests. The RDF stores were well constructed and designed to meet the WHO specifications for good drug storage.

The drug stock is the responsibility of a well trained pharmacist. Other staff includes an assistant pharmacist, three store keepers, one cash collector, two computer operators, receptionist, 16 workers (mainly for delivery), 4 drivers and 4 watch men, in addition to a police night service.

The drugs are stored in a well organized manner that enables ease inspection, recognition and retrieval of stock, and also allows free movement of drugs in and out of the store. A First – in First – out (FiFo) rule of dispatch system is applied (Awadalkarim et al 1996). Drugs with an earlier date of expiration are cleared first.

Stock management is done with combination of manual (stock record cards) and a computer programme. This provides a continuous record of each supply item in the stock and emphasizes the importance of maintaining adequate levels of the products.

Stock shortages: these occur because of inadequacies in the supply system, lack of foreign currency may limit a drug purchase, and pharmacies may receive shipment without regard to levels

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of stock or consumption and in some cases the selling price may be too low to permit the stock to be replenished.

Drugs are wasted during storage and distribution in 3 main ways.

1. They deteriorate due to poor storage condition (excessive heat, moisture, light, etc.)
2. They expire due to poor needs or estimation of needs or poor stock control and management;
3. They disappear either through pilferage by employers, theft by outsiders who break in, or are lost during distribution to the health facilities.

### 3.3 DRF Measures

- ❖ Stock shortages: To avoid stock shortages, has DRF a safety stock i.e. two month stock. However, major supply shortages are overcome by ordering small quantities from sources

- ❖ **Drugs wastage:** To ensure good storage conditions all warehouses have been refurbished, well ventilated and secured against fire and theft and three cold rooms have been installed. Drug expiration has never been experienced during the course of the last 5 years, because of the development of efficient needs of assessment and computer systems based on the past consumption data. The drugs disappearances through pilferage or theft have never occurred at the warehouse level due to selection of competent staff, good management, security measures and monthly stock taking.

### **3.4 Stock Turnover and Quality Assurance**

Is the number of times that stock is required and released in the course of a year. DRF stock turnover during 1999 for the DRF, which has limited funds, the more rapid the turnover,

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the less cash will be needed. Smaller stocks also require less storage space and are easy to manage (less expiration and losses). However, rapid stock turnover may increase total transaction cost, quality control cost and stock shortages.

The quality of the products released to the public remains of the utmost importance to MoH. The DRF drugs are authorized for use through the same procedures. The quality assurance includes the use of the WHO certification scheme (e.g. GMP, free sale certificate, batch certificate etc). Upon receipt drugs undergo a further quality control test (in the National Quality Control and Drug Research Laboratories) before release to the public.

### **3.5 Drug Delivery System**

Generally speaking, there are three types of delivery route: Circuit delivery (One vehicle supplies several consignees), linear delivery (one vehicle supplies only one consignee) and star delivery (parcels are dispatched to various consignees by hired carriers).

Delivery volumes for the DRF are determined strictly by order, which the HF pharmacist or assistant pharmacist must give to the supervision team leader during the last week of every month. The stock book is the backbone of the delivery process. The procedure avoids mistakes resulting

from transcription and arbitrary changes and guarantees sufficient lead time for delivery. It supports the DRF policy of consistently responding to demand.

To ensure even distribution to all health facilities and to avoid missed opportunities, quota delivered to the health facilities sometimes adjusted according to stock quantities available.

The advantages of monthly delivery method also include:

1. Revision of drug orders at the DRF Head Office is made by a qualified pharmacist
2. Scheduled delivery to the health facility enforces routine supply and contributes to confidence in the entire DRF system
3. Stocks can be replenished before they are exhausted
4. Smaller amounts of stock and fund are required
5. A more even spread of the workload over the time
6. Supplies are replenished at schedule intervals, saving administrative costs and transport time
7. Few losses, because stock is delivered directly to the health facility.

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Limitations of monthly delivery methods are:

1. The responsible person must monitor its stock consumption
2. Stock to be delivered must be ordered
3. Deliveries of smaller quantities mean higher distribution cost

## **Managing Drugs at Health Facilities**

### **Stock Control at Health Facilities**

Stock verification, at every location where supplies are stocked is planned to:

- ❖ Provide an additional form of evaluation that may reveal defects in the storing system
- ❖ Maintain sufficient stock to last between deliveries
- ❖ Maintain stock at the lowest possible cost

Benefits of a successful stock control system at the health facilities:

Maintaining a sufficient stock of items at health facilities has many benefits: patients receive drugs promptly, and “stock-out” are prevented even when deliveries are delayed. Patients have confidence in the health facility and seek help when they are ill.

Above all, an effective stock control system keeps track of and ensures accountability for supplies.

### **Stock inventory at health facilities**

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Drugs are highly portable, easily concealed in clothing, and they have a high market value. The incentive to steal is great, and where there are no counter balancing securing measures or penalties from infractions, it is not surprising that very high percentages of drug stocks are pilfered. Rigorous rules on management and accountability are the main remedy to ensure sustainability. This type of alertness minimizes diversion of stocks and fraud of funds.

#### **Advantages of Stock Inventory**

- ❖ Enforces procedures and regulations designed to prevent loss and waste
- ❖ Ensures that security measures and records of received stock and dispensing of drugs are adequate
- ❖ Controls cash collection by reconciliation of drugs sold and cash collected
- ❖ Identifies and removes surplus, expired and obsolete stock
- ❖ Stock taking at health facilities level has tightened loopholes suspected of creating loss through leakage.

The consequences of implementing the new inventory system and employment policy have not only been an improvement in the area of the performance, but also on the reduction of level of stock losses.

## **4.0 Conclusion**

In this unit, you have learned what the drug distribution system in a DRF scheme is and that in discussing the distribution system, parameters such as

Drug storage management, Drug measures, Drug delivery system and management of drugs at health facility level make up the Drug Revolving fund distribution system.

You have also realized that the Drug delivery system under the DRF scheme can be classified into three; hence you should be able at this point state in your own words the advantages as well as limitations of a monthly delivery method

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Also, you should be able by now describe clearly how DRF drugs can be better managed at the health facilities level.

## **5.0 Summary**

This unit has focused on drug storage management, delivery routes, stock turnover and quality assurance. It was clearly shown to you that managing drugs (DRF) at health facility level will involve a clear understanding of how to control stock as well as prepare on a regular basis stock inventory.

## **6.0 Tutor Marked Assignment**

1. (a) Itemize the advantages and limitations of monthly drug delivery method
- (b) List the advantages of stock inventory

## **7.0 References / Further Readings**

Peter,N., et al.(1986).Revolving Drug Funds: Conducting Business in the Public Sector.*Soc.Sci.Med.* Vol.22,No.3,pp335-343

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