

Drug Supply Management

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Objectives

- After completion of this chapter you will be able to:
- Define what is DSM mean
- What are essential drugs(medicines),
- What is meant by Drug Formulary, Treatment Guide line and National Drug Policy and their difference.

What is Primary Health Care ?

- ***Primary Health Care*** is the first level of contact with the health system to promote health, prevent illness, care for common illnesses, and manage ongoing health problems.
- Primary health care is essential health care made accessible at a cost a country and community can afford, with methods that are practical, scientifically sound and socially acceptable.

(Reference: Alma Ata Declaration, WHO, Geneva, 1978).

Components of primary health care

- Health Education: education concerning **prevailing health problems** and the **methods of preventing and controlling them**.
- Promotion of **safe food supply and proper nutrition**
- An adequate supply of **safe water** and **basic sanitation**
- **Maternal and child health care** including family planning
- **Immunization** against major infectious diseases
- **Prevention and control** of locally endemic diseases
- Appropriate treatment of **common diseases** and **injuries**
- Provision of **essential medicines**

National Drug Policy

INTRODUCTION

- The world pharmaceuticals market has witnessed an increase in the number of pharmaceutical products circulating worldwide, leading to a **rapid growth in both medicines consumption and expenditure.**
- However WHO estimates that, as of 1997, **at least one-third** of the world's population still lacks access to EMs,
 - In poorer areas of Asia and Africa this figure may be as high **as one-half.**
- Because:
 - EMs are not available or
 - EMs too expensive, or
 - there are no adequate facilities or trained professionals to prescribe Ems.

Cont'd

- As a result,
 - millions of children and adults **die** or **suffer** needlessly, although their disease could have been prevented or treated with **cost-effective** and **inexpensive essential medicines**.
- Experience in many countries has shown that these complicated and interdependent problems can best be addressed within a common framework;
 - because piecemeal approaches can leave important problems unsolved and often fail.

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- B/C the different policy objectives are sometimes contradictory, and so are the interests of some of the stakeholders.
- ➔ WHO recommends that all countries formulate and implement a comprehensive national drug policy (NDP).
 - A policy is not static and will usually evolve over time.
 - Most countries will need to revise their policies within five years.

What is a national drug policy?

- A national drug policy (NDP) is a commitment to a goal and a guide for action.
- NDP expresses and prioritizes the medium-to long-term goals set by the government for the pharmaceutical sector, and identifies the main strategies for attaining them.
- NDP provides a framework within which the activities of the pharmaceutical sector can be coordinated.
- NDP covers both the public and the private sectors, and involves all the main actors in the pharmaceutical field.

What is a national drug policy?....

- An NDP, presented and printed as an official government statement, is important because it acts as a formal record of aspirations, aims, decisions and commitments.
- Without such a **formal policy document** there may be no general overview of what is needed;
 - Some government measures may conflict with others, because the various goals and responsibilities are not clearly defined and understood.

What is a national drug policy?....

- The policy document should be developed through **a systematic process of consultation** with all interested parties.
- In the Policy process:
 - The objectives must be defined,
 - Priorities must be set,
 - Strategies must be developed and
 - Commitment must be built.

What is a national drug policy?....

- Progress in **developing** and **implementing** national drug policies has been impressive since the concept was launched in the **mid-seventies**.

➤ By the end of 1999 over 100 countries had a national drug policy

Absence of strong drug policy, legislation, and regulations

- Leads to **failure to use** available budgets & funds efficiently and consequently shortage of essential drugs.

What is a national drug policy?....

- Does two countries have the same NDP?
- NDP of one country may be similar in many ways to NDP of other countries.
- But b/c their starting situations will vary, the policies will likely differ in what they emphasize and in how problems can best be tackled.
- A national Gov't will be the principal agency responsible for creating the overall NDP and putting it in to practice.

Main participants of NDP

- However, government is not the only actor involved in developing and implementing of NDP.
- A partnership is required with:
 - Health professionals (HPs) MDs, Pharmacists & others
 - public and private wholesalers,
 - academia's,
 - NGOs,
 - consumer groups
 - Pharmaceutical industries
 - Donors, and other interested parties

Why NDP is needed?

- A national drug policy is needed for many reasons.
 1. To present a **formal record**
 2. To define the national **goals and objectives** for the pharmaceutical sector, and set priorities
 3. To create a **forum for national discussions** on these issues

Why NDP is needed?

4. It provides a framework to coordinate activities of

- Pharmaceutical sector participants
- Public and the private sectors
- Non-governmental organizations
- Donors, and other interested parties

General Objectives of NDP

- The general objectives of a national drug policy are to ensure:
 1. **Access:** to make essential drugs available and affordable to those who need them.
 2. **Quality:** to ensure the safety, efficacy and quality of all medicines provided to the public.
 3. **Rational use:** to improve prescribing and dispensing of practices and to promote ethical practices among HPs and the correct use of drugs by HWs and consumers.

Specific objectives of NDP

- 1. Determine the types of drugs to be used in the health services on the basis of the country's health problems and capability.**
- 2. Provide essential drugs in line with the responsibilities of the government for public health care.**

Specific objectives of NDP

3. Facilitate the gradual integration of traditional drugs with modern medicine by giving due attention to traditional practices and identifying the beneficial and harmful aspects through investigation and research.
4. Offer incentives to public and private industries involved in the production of raw and packing materials directly related to the manufacture of drugs.

Specific objectives of NDP

5. Give special incentives to manufacturers who manufacture essential drugs and market them in their generic names.
6. Create favorable conditions to encourage private investors to participate in the manufacture, import and distribution of drugs.

Specific objectives of NDP

- 7. Establish an effective system of drug administration and control at all levels, especially by developing the capacity to ensure drug safety, efficacy and quality.**
- 8. Make the necessary efforts to establish rational use of drugs among the health professionals and the public at large.**

Specific objectives of NDP

9. Devise a program for the training of professionals able to contribute to solving the health problems of the country as required and create conditions for the application and development of their skills.
10. Conduct a coordinated research on modern and traditional drugs attuned to the country's problems and capacity and strive for the application of their results.

Specific objectives of NDP

11. Create favorable conditions for the transfer and further development of appropriate technology and modern know-how that could assist in meeting the drug needs of the country.
12. To develop a domestic drug manufacturing capacity and create favorable conditions for the export of local products.

Specific objectives of NDP

13. Make the necessary efforts to deter the illegal manufacturing, distribution and consumption of narcotics and psychotropic drugs.
14. Strengthen National and International relations to help develop and expand the pharmaceutical sector and give due attention to the implementation of international obligations.

Specific objectives of NDP

15.To meet the country's demand for essential drugs and to systematize its supply, distribution and use.

16.To create conducive situations to make the prices of drugs compatible with the people's purchasing power

Specific objectives of NDP

17.To *expand the training of manpower* and drug research and development.

18.To *devise ways and means* for the utilization of traditional drugs in the regular health services after ensuring their safety and efficacy.

Components of NDP

1.Choice of essential drugs(selection of drugs):

Principles of EDs selection

Selection process (market approval and national morbidity)

Selection criteria(safety, efficacy, quality and cost effectiveness)

Use of EDL

Traditional and herbal medicines

- A national drug advisory committee composed of highly skilled professionals in medicine & pharmacy is organized.

Components of NDP

2. Drug supply

Local production

Supply system strategies and alternatives, including mix of public and private sectors

Procurement mechanisms

Inventory control, including prevention of theft and waste

Distribution and storage

Disposal of unwanted or expired drugs

Components of NDP

- Government shall **establish an enterprise** which is independent of producers and suppliers to procure and distribute drugs at national & regional levels (PFSA).
- Government shall **give incentives** to private importers and distributors of essential drugs at reasonable prices.
- Foreign procurement shall be carried in such away that it does not weaken local drug manufacturing.

Components of NDP

3. Stock management & distribution

- Issue specification for the establishment of storage facilities and pertinent to the climatic conditions of the locality.
- Give priority & efficient transport for the movement of drugs from ports and distribution points
- Every distribution net work shall be subject to strict drug inventory control and supervision

Components of NDP

- Distribution of drugs shall be carried out in accordance to a standard list of drugs appropriate for the level of the health institution and retail enterprise.
- Public health institutions and pharmacies within them shall be given priority by the government owned drug distribution system.

Components of NDP

4. Legislative and regulatory framework

- Laws and regulations shall be instituted and enforced governing the supply, stock management, distribution, use and disposal of narcotic and psychotropic drugs.
- Qualified inspectors shall be assigned to enforce laws and regulations issued to implement the policy

Components of NDP

- Registration, classification and licensing of professionals in the sector shall be carried out by the appropriate body
- Any pharmaceutical org. can only be established under license from the policy enforcing body.

Components of NDP

- Pharmacovigilance

An appropriate system shall be devised for the collection of new information about the harmful and beneficial effects of drugs from health professionals compiled and analyzed, the findings shall be publicized at national and international level.

- Infrastructure for good governance in medicine

Components of NDP

5. Manpower Training and utilization

- Formal pharmaceutical trainings shall be based on the requirements and health needs of the country.
- Strategies shall be devised to upgrade professionals who are in service including other HRs
- Professionals in the sector shall receive on the job training and continuing education.
- Conducive situations shall be created so as to engage trained manpower in the best possible service of the public.
- Various incentives and conducive career structures for professionals shall be instituted

Components of NDP

6. Drug information and promotion

- The content and distribution of drug information to health professionals and the public shall be subject to monitoring & control.
- Current and accurate information and reference materials on drugs shall be produced and distributed to practitioners in the field.
- Drug promotion shall be carried out by trained professionals who have appropriate registration.

Components of NDP

7. Rational use of drugs

Multidisciplinary national body to coordinate drug use policies

STGs as the basis to select essential drugs and training HPs.

Independent drug information

Rational drug use training for HPs

Education about rational use of drugs for drug consumers

Components of NDP

8. Traditional drugs

- Attention shall be given to strengthening the sector through research and development.
 - Research priorities shall be given to those traditional drugs which are in **wide use**.
- Create favorable conditions for the application of traditional drugs ascertained to be safe & effective for treatment.

Components of NDP

9. Research and development

- Favorable conditions shall be created for the introduction of appropriate technology and know how to vitalized the drug sector.
- Appropriate means shall be instituted to strengthen the drug sector through research and development.
- Research and development activities shall be conducted at manufacturing plants, compounding laboratories, training & research institutions etc.

Components of NDP

10. National, regional and International relations.

- National, and international relations shall be established with the aim of strengthening and expanding the sector
- Attention shall be given to the implementation of conventions on narcotics, psychotropic drugs, radioactive pharmaceutical & poisons

Components of NDP

1 1. Affordability

- Taxes or tariffs on EDs
- Distribution margins and pricing
 - The government shall make all efforts to make sure that the public gets drugs at reasonable price.

1 2. Policy enforcement

- Relevant laws, regulations, and rules shall be instituted to enforce the policy.

Components of NDP

13. Monitoring and evaluation

Responsibilities and commitments

Baseline survey of the country

Indicators for monitoring

Periodic monitoring

Independent external evaluation every 2-3 yrs.

Essential Drugs

- Essential drugs are those that satisfy the needs of the majority of the population and should be available in the appropriate dosage forms and strength at all times (WHO).
- The choice depends on many factors such as:
 - pattern of prevalent disease
 - treatment facilities
 - training experience of available personnel
 - safety, efficacy & quality
 - financial resources
 - genetic, demographic and environmental factors

Essential Drugs...

- They are intended to be available **at all times, in adequate amount**, appropriate dosage forms & strength **with assured quality**.
- Principle of essential medicine
 - The *vast majority of health problems* for most members of the population can *be treated with a small, carefully selected* number of drugs.

Essential Drugs...

- Continuous availability of essential drugs and their rational use
 - Increase the credibility of the health service by community
 - Increase utilization of health service and community involvement in their own health affairs

Essential Drugs...

- However, the health service of our country is severely affected by
 - **Shortage of basic and life saving essential drugs and medical supplies**
 - **Majority of the population have no access even to those most essential drugs.**

Essential drug List

- An essential drug list names the medicines considered optimal treatment choices to satisfy the HC needs of a given population.
- It is used for one HF(e.g a hospital) or group of HFs to indicate which medicines should be procured and prescribed.
- The list can be considered supply lists, the range of drugs for the d/t levels of care, dosage forms & sometimes pack size and other specifications.
- National List of Essential drugs usually limited to the public sector.
- But it does not mean that no other medicines are available in the country(private sector).

Essential drug List...

Medicines on the world market



Medicines registered in the country



National list of essential medicines



Essential drugs in Referral Hospital



Essential drugs in Zonal hospital



Essential drugs in PHCU

Indicates Content of (EDL) decreasing down

Essential drug list...

Formulary manual: contains summary drug information.

- Commonly includes generic name, Indications, dosage schedules, CI, SEs and other important information given for patients
- **Formulary system:** for developing & updating of the EDL
- **Standard Treatment Guide line(STGs):** the information is d/se centered and focused on d/se
- Information on drugs is limited only to dosage, strength and duration of treatment.

Objective of EDL

The main objectives of Essential Drugs List are:

- ❖ To make essential drugs **available** and **accessible** to the **majority** of the population;
- ❖ To **promote** their **rational** use.

Implications of EDL

- EDL is meant to guide the selection, procurement, production, distribution and storage of medicines.
- it can improve availability and promote rational use of medicines.

Implications of EDL...

- The essential drugs concept is *central to a national drug policy*
 - B/C it **promotes equity** and **helps to set priorities** for the health care system
- Give better quality of care and better value for money
 - B/c they leads to a *better supply of drugs, to more rational prescribing* and *to lower costs.*

Implications of EDL...

- More price competition and economics of scale due to
 - the procurement of fewer items in larger quantities
- Quality assurance, procurement, storage, distribution and dispensing are all easier with a reduced number of drugs
- Training of health workers and drug information in general can be more focused
 - More recognition of drug interactions and adverse reactions with fewer drugs

Overview of The national drug policy process

- A national drug policy involves a complex process of policy development, implementation and monitoring.
 - 1st. Formulation of the national drug policy
 - 2nd. Implementing strategies and activities by the various parties aimed at achieving policy objectives
 - 3rd. Monitoring and evaluation the effect of these activities and adjust the policy if necessary

Involving all parties

- There should be consultation, dialogue and negotiations with all interested groups and stakeholders throughout the policy process (and not only in the development phase)
- These include
 - Other ministries (higher education, trade, industry)
 - Physicians, pharmacists and nurses
 - Local and international pharmaceutical industries, drug sellers
 - Academia, NGOs, professional associations and consumer groups

Political dynamics

- Formulating and implementing a national drug policy are highly political processes
- B/c such a policy usually seeks to achieve
 - Equity of access to basic health care
 - Primarily by making the pharmaceutical sector
 - More efficient
 - Cost-effective and
 - Responsive to health needs

Formulating a national drug policy

Steps in formulating a national drug policy

Step 1: Organize the policy process

- MOH- take the lead role in formulating a national drug policy
- 1st step is to decide how to organize the development process
 - Identify the structure of the policy
 - Identify major objectives and
 - Identify its priority components
- Identify all the interested parties that need to be involved,
- Identify the necessary resources, and how these can be obtained

Formulating a national drug policy...

Step 2: Identify the main problems

- In order to set realistic objectives
 - Thorough analysis and understanding of the main problems in the pharmaceutical sector are needed
- Select experts from d/t disciplines
 - Examine the situation systematically
 - Identify the main problems
 - Make recommendations about
 - What needs to be done
 - What can be done, and
 - Identify possible approaches

Formulating a national drug policy...

Step 3: Make a detailed situation analysis

- A more detailed situation analysis of the pharmaceutical sector and its components may be needed
 - Further analyze the source of the problems
 - Identify potential solutions
 - Choose the most appropriate strategies
 - Set priorities and
 - Serve as a baseline for future systems of monitoring and evaluation

Formulating a national drug policy...

Step 4: Set goals and objectives for a national drug policy

- Goals and priority objectives identified after the problem is defined
- The selection of appropriate strategy is more complex
 - A workshop involving a small number of key policy-makers may be helpful
- Outlined main objectives and strategies be discussed with all interested parties

Formulating a national drug policy...

Step 5: Draft the text of the policy

- A draft text of the national drug policy be prepared
- Set out the general & specific objectives , followed in each case by the strategy to be adopted
- In most countries this is used to ensure that essential drugs are accessible to the entire population
- Drafting of the policy can be done by a small group of experts who have been involved in the earlier stages of the process

Formulating a national drug policy...

Step 6: Circulate and revise the draft policy

- The draft document should be widely circulated for comments (with in and outside the org.)
- The draft document should be revised in the light of the comments received, and finalized

Formulating a national drug policy...

Step 7: Secure formal endorsement of the policy

- The parliament endorse the proposed document

Step 8: Launch the national drug policy

- Extent of the policy's *success* depends on
 - The level of understanding of different sectors of society, and
 - Their support for its objectives
- Information should be disseminated through a variety of channels to reach different target groups

Implementing a national drug policy

- Every drug policy needs an overall implementation plan or “master plan”
- Each component of the policy needs a detailed strategy and specific action plans

Priorities for implementation

- Severity of the problems
- Available resources

Implementing a national drug policy...

Implementation (master) plan

- Covers 3–5-year period
- This implementation plan spells out for each component of the policy
 - What needs to be done
 - Who is responsible
 - Estimates the budget requirement and
 - Proposes a rough time frame
 - Set a priority activities (insufficient resources)

Implementing a national drug policy...

Master plan ...

- Facilitates monitoring and follow-up
- Communicated to all parties involved
- Broken down into annual work plans with various agencies involved in the implementation

Work plan

- Should outline the approaches and activities for each component, specifying in detail
 - Who is responsible
 - Listing the major tasks
 - Describing the target output,
 - The detailed time frame and the exact budget

Financial resources

- Match the strategies and action plans with available financial resources
- Allocations from government funds and revenue from drug registrations and fees are the usual funding sources
- Contributions from international and local donors are also possible sources
- However, there should be no conflict of interest in accepting donor contributions
 - E.g. NGOs might be interested in funding activities that are of low priority in the national drug policy

Monitoring and evaluation

- **Monitoring**
 - A form of continuous review which gives a picture of the implementation of planned activities
 - Indicates whether targets are being met
 - Carried out using a combination of various methods
 - E.g. Supervisory visits

Monitoring and evaluation...

Evaluation

- Way of analyzing progress towards meeting agreed objectives and goals
- Done in three phases
- *Start of a program*- used to provide a clear needs assessment
- *A mid-term evaluation*- provide valuable information about whether the program is working, and if not, why not.
- *Final evaluation* - allows a complete review of program achievements from which lessons can be drawn for the future

Indicators for monitoring national drug policies

- Standardized indicators determine whether adequate progress is being achieved or not
- Indicators can be selected and used
 - To measure changes
 - Make comparisons and
 - Assess whether the targets are being met
- Indicators should be
 - Clear
 - Useful
 - Measurable
 - Reliable and valid

Indicators ...

- Currently there are four categories of drug policy indicators:
 - Background information
 - Structural indicators
 - Process indicators and
 - Outcome indicators.
- Core indicators cover the following aspects
 - A. Access to essential drugs, and other indicators on drug financing schemes, and public supply management;**
 - Provide information on access to essential drugs

Indicators for monitoring...

B. Functions and efficiency

- Drug regulatory authority
- Quality control laboratory and
- Drug handling to maintain good quality
 - Provide information about drug quality

C. Drug prescribing and dispensing,

- use of the list of essential drugs and clinical guidelines
 - Provide information about drug use patterns

Who can use the results?

- Policy-makers
- Implementers and
- Managers can get a clear picture of the problems in the country so that they can reassess their strategies and priorities.
- Results can be used as a guide
 - To set priorities and
 - To strengthening those strategies that can have the best impact

Periodic evaluations of the national drug policy

- The national drug policy should be periodically evaluated
 - E.g. Every four years

***THANK
YOU!!***