



Reading Material
on
Drug Store Management
&
Rational Drug Use
For
Medical Officers, Nurses & Pharmacists



An ISO 9001: 2008 Certified Institution

State Institute of Health & Family Welfare,
Rajasthan

December 2010



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Drug Store Management and Rational Drug Use

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Chapter 1: Introduction

Drugs & Medicines being expensive and resources limited, it becomes imperative to improve their supply, increase the use, and minimize the cost through a pharmaceutical management system to be effectively put in place. There are some 3000-4000 drugs at any point in time, registered in any country; of which almost 70% are non essential (WHO). Ideally, a National list of essential drugs should have 300-400 drugs; a district hospital needs some 150 to 200, while a health centre can manage with 40-50 drugs. Shorter the list, it is easier to manage, procure and offer to the patients within the resources available.

In the overall management of drugs, the following objectives have to be borne in mind:

- 1 All **essential drugs** needed for health care should be **available** at all the times, at all the health facilities.
- 2 Drugs so made available should be of good **quality** and should be **safe**.
- 3 Systems of procurement should be such that **quality drugs** are procured at the most **competitive prices**.

Drugs have always remained and are likely to remain the core element in preventive as well as in curative health care. Medicinal drugs inclusive of vaccines, contraceptives, nutritional supplements etc. are indispensable for the prevention, control, treatment and amelioration of a number of maladies that affect human beings. Interestingly, pharmaceuticals are the largest item of expenditure within the public health sector budgets of developing countries, ranging from 8 to 12% of recurrent health budget; therefore asking for prudence.

There are four major areas related to drug management:

- a) Rational use,
- b) Affordable price,
- c) Sustainable financing and
- d) Reliable health and supply systems.

Let us start by learning **some common terms and their definitions** used in drug management:

Medicine:

- a) An agent, such as a drug, used to treat disease or injury.
- b) Something that serves as a remedy or corrective
- c) Any drug or remedy for use in treating, preventing, or alleviating the symptoms of disease
- d) Any substance administered in the treatment of disease; a remedial agent; a remedy; physic.



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Drug:

- a) A drug is a chemical substance that affects processes of body and mind.
- b) Any chemical compound used or administered to humans and/ or animals in the process of diagnosis, treatment or prevention for relief of pain or sufferings or to control or improve a physiological process or pathological state.
- c) A substance used recreationally for its effects on Central Nervous System.

Generic drugs:

The term "generic" has several meanings as regards drugs:

1. The chemical name of a drug.
2. A term referring to the chemical makeup of a drug rather than to the advertised brand name under which the drug is sold.
3. A term referring to any drug marketed under its chemical name without advertising

The use of generic names for these purposes has many advantages, like:

1. Easy recognition of type of drugs, particularly when many selected drugs exist in that category (e.g. all Benzodiazepines have generic name ending with "zepam").
2. Drugs can be purchased from multiple suppliers giving the advantage of buying at competitive prices.
3. Product substitution is easy where bioavailability presents a problem.
4. Confusion with brand names can be avoided.

Since chemical names are usually long and complicated, the drugs are given a standard, shorter generic name. Manufacturers will usually give drugs brand names to identify that manufacturer's version of the product. An example of these three names, using a well known prescription drug is as follows:

Chemical name — 7-chloro-1, 3-dihydro-1- methyl-5-phenyl-2H-1, 4-benzodiazepin-2-one;

Generic name — diazepam

Brand name — Valium.

Since the research and development of the drug molecule has already been done, the cost of the generic drug is usually less.

All drugs considered to be generically equivalent to a brand name product must meet strict manufacturing requirements. These requirements include tests which assure that the product is bioequivalent to the brand name product.

Spurious Drugs

Spurious drugs a drug shall be deemed to be spurious, if

- a) it is imported under a name which belongs to another drug; or
- b) it is an imitation of or a substitute for, another drug or resembles another drug in a manner likely



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to deceive or bears upon it or upon its label or contains the name of another drug unless it is plainly and conspicuously marked so as to reveal its true character and its lack of identity with such other drug ; or

- c) the label or the container bears the name of an individual or company purporting to be the manufacturer of the drug, which individual or company is fictitious or does not exist; or
- d) it has been substituted wholly or in part by another drug or substance; or
- e) it purports to be the product of a manufacturer of whom it is not truly a product .

Substandard Drugs

Substandard Drugs/ medicines (also called out of specification (OOS) products) are genuine medicines produced by manufacturers authorized by the Central Drugs Standard Control Organization (CDSCO) which do not meet quality specifications set for them by national standards.

Some **important terms** used according to Drug and Cosmetic Act that one should know in relation to Drugs are-

Standards of quality means-

- a) In relation to a drug, that the drug complies with the standard set out in the Second Schedule,
- b) In relation to a cosmetic, that the cosmetic complies with such standard as may be prescribed.

Misbranded drugs - a drug shall be deemed to be misbranded-

- a) if it is so colored, coated, powdered or polished that damage is concealed or if it is made to appear of better or greater therapeutic value than it really is; or
- b) if it is not labeled in the prescribed manner; or
- c) if its label or container or anything accompanying the drug bears any statement, design or device which makes any false claim for the drug or which is false or misleading in any particular;

Adulterated drugs a drug shall be deemed to be adulterated-

- a) if it consists, in whole or in part, of any filthy, putrid or decomposed substance; or
- b) if it has been prepared, packed or stored under insanitary conditions whereby it may have been contaminated with filth or whereby it may have been rendered injurious to health; or
- c) if its container is composed in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or
- d) if it bears or contains, for purposes of coloring only, a color other than one which is prescribed; or
- e) if it contains any harmful or toxic substance which may render it injurious to health; or
- f) if any substance has been mixed therewith so as to reduce its quality or strength.



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Classes of drugs:

The two main classes of drugs are: (1) **non-prescription drugs**, and (2) **prescription drugs**.

Non-Prescription drugs are commonly called over-the-counter, or OTC drugs, and can be bought without a prescription.

Prescription drugs (or legend drugs) are drugs that require a prescription because they are considered to be potentially harmful if not used under the supervision of a licensed health care practitioner. Certain prescription drugs have additional controls placed upon them. These drugs are called controlled (or scheduled) drugs.

Drug classification according to schedules:

Controlled Drugs

A controlled (scheduled) drug is one whose use and distribution is tightly controlled because of its abuse potential or risk. The drugs with the highest abuse potential are placed in Schedule I, and those with the lowest abuse potential are in Schedule V. These schedules are commonly shown as C-I, C-II, C-III, C-IV, and C-V. Some examples of drugs in these Schedules are as follows:

Schedule I –

Drugs with a high abuse risk. These drugs have no safe, accepted medical use. Some examples are heroin, marijuana, LSD, PCP, and crack cocaine.

Schedule II –

Drugs with a high abuse risk, but also have safe and accepted medical uses. These drugs can cause severe psychological or physical dependence. It includes certain narcotic, stimulant, and depressant drugs. Some examples are morphine, cocaine, oxycodone.

Schedule III, IV, or V –

Drugs with an abuse risk less than Schedule II. These drugs also have safe and accepted medical uses. Schedule III, IV, or V drugs include those containing smaller amounts of certain narcotic and non-narcotic drugs, anti-anxiety drugs, tranquilizers, sedatives, stimulants and non-narcotic analgesics. Some examples are acetaminophen with codeine.

Other classifications:

Schedule G:

Details of drugs to be labeled with words “Caution – it is dangerous to take this preparation except under medical supervision” e.g., aminopterin, insulin, metformin, promethazine etc.

Schedule H:

Deals with drugs and medicines, which must be sold by retail only when a prescription by registered medical practitioner is produced e.g., captopril, atenolol, allopurinol, haloperidol, norfloxacin, etc.



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Schedule J:

Disease and ailment (by whatever name described), which a drug may not purport to prevent or cure e.g., appendicitis, blindness, blood poisoning, blood pressure (high or low), etc.

Schedule N:

Deals with minimum equipment of a pharmacy and gives direction regarding (a) entrance of a pharmacy; (b) premises; (c) furniture and apparatus; (d) general provisions,

Schedule P:

Defines life period of drugs (shelf life), the period up to which the drug will remain stable under the storage conditions from the date of manufacture;

Schedule W:

List of drugs that are to be marketed under generic name only.

Schedule X:

Gives name of psychotropic drugs, requiring special license for manufacture and sale e.g. alprazolam, amfepramone, barbital, benzphetamine, clobazam, clonazepam, clorazepate, etc.



Chapter 2: Laws, Regulations and Organizations

Drug Acts & Regulations: Historical Perspective

The Poisons Act and the Dangerous Drugs Act were passed in India in 1919 and 1930 respectively. Then in 1931, Indian Government appointed a Drugs Enquiry Committee under the Chairmanship Lt. Col. R. N. Chopra which was asked to make sifting enquiries into the whole matter of drug production, distribution and sale by inviting opinions and meeting concerned people. The Committee recommended the establishment of a well-equipped Central Drugs Laboratory for an efficient and speedy working of the controlling department; the permission of Central Pharmacy Council, and the Provincial Pharmacy Councils.

However, the Drugs Act was passed in 1940 partly implementing the Chopra recommendations. With the achievement of independence in 1947 the rest of the required laws were put on the Statute Book. In 1985, the Narcotic Drugs and Psychotropic Substances Act were enacted repealing the Dangerous Drugs Act 1930 and the Opium Act of 1878.

The Drugs and Cosmetics Act, 1940 (amended 2008) and The Drugs and Cosmetics Rules, 1945:

The object of the Act is to regulate the import, manufacture, distribution and sale of drugs. Under the provisions of this Act, the Central Government appoints the Drugs Technical Advisory Board to advise the Central Government and the State Governments on technical matters arising out of the administration of this Act.

The Act was amended many times in public interest, the last being in the year 2008 which focused on making the Act stricter in terms of imprisonment and penalties.

Pharmacy Act, 1948 (amended 1984)

The Act aims to regulate the profession of Pharmacy in India. Under the provisions of this act the Central Government constitutes a Central Pharmacy Council of India. The Central Council can approve qualifications granted by an outside authority for qualifying for registration under this Act.

The Drugs (Control) Act, 1950

An Act to provide for the control of the sale, supply and distribution of drugs and also provide guidelines for fixing of maximum prices and maximum quantities which may be held or sold, marking of prices and exhibiting list of prices and stocks, obligation to state price separately on composite offer, prohibition or regulation of the disposal of drugs, penalties and offences by corporations.



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The Narcotic Drugs and Psychotropic Substances Act, 1985

This is an Act to consolidate and amend the law relating to Narcotic Drugs, to make stringent provisions for the control and regulation of operations relating to Narcotic Drugs and Psychotropic Substances.

Drug Policy, 1986 (revised 1994)

The drug Policy was framed with the main objectives of ensuring abundant availability, at reasonable prices, of essential life saving and prophylactic medicines of good quality; strengthening the system of quality control over drug production and promoting the rational use of drugs in the country; creating an environment conducive to channelizing new investment into the pharmaceutical industry, to encouraging cost-effective production with economic sizes and to introducing new technologies and new drugs, and strengthening the indigenous capability for production of drugs.

Pharmaceutical Policy, 2002

The change in nomenclature from 'Drugs Policy' to 'Pharmaceutical Policy' may empower the Ministry of Chemicals and Fertilizers to bring under their domain some more activities logically placed, for the present under the Ministry of Health & Family Welfare. Policy has kept minimum number of drugs under the price control and has also abolished industrial license system.

National Drug Authority

In view of the Pharmaceutical Policy, it is envisaged that a National Drug Authority may be set up by a separate Act of Parliament to perform the following functions:

1. Develop and define basic appropriate standards relating to the manufacture, import, supply, promotion and use of drugs.
2. To approve and register pharmaceutical products for use in the country only if
 - a) it meets real medical needs,
 - b) it is therapeutically effective, and
 - c) it is acceptable and safe
3. To enforce effectively appropriate quality standards of medicines and good manufacturing practices, throughout the country, having full regard to the needs of public health and standardize dosage strengths and pack sizes of formulations with a view to check proliferation.
4. To monitor standard practices in drug promotion and use and to clearly identify those which are acceptable and prohibit those which are unethical and against the consumer interest.
5. To monitor the prescribing practices and to evaluate their appropriateness for the purpose of guiding the medical profession and for achieving the aim of rational prescribing.
6. To ensure that appropriate information about registered pharmaceuticals is made available for the guidance of consumers having regard to:



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- a) the adverse consequences of non-compliance by patients particularly in the case of antibiotics, steroids etc.,
 - b) dangers of self-medication, and
 - c) the need to involve consumers as full partners in the health care system .
7. To prepare and publish a national formulary and formularies relevant to various levels (like district hospital, community centre, primary health centre) for the guidance of consumers as well as doctors.

Drug Standard Control Organizations

Central Drug Standard Control Organization

The Central Drugs Standard Control Organization (CDSCO) is headed by the Drugs Controller General (India) (DCGI) which discharges the functions allocated to Central Government by the Drugs and Cosmetics Act. The CDSCO is attached to the office of the Director General of Health Services in the Ministry of Health and Family Welfare. The DCGI is a statutory authority under the Act and has port offices, zonal offices with drug inspectors and drug testing laboratories functioning under him.

Statutory functions of CDSCO:

- a) Laying down standards of drugs, cosmetics, diagnostics and devices.
- b) Laying down regulatory measures, amendments to Acts and Rules.
- c) To regulate market authorization of new drugs.
- d) To regulate clinical research in India.
- e) To approve licenses to manufacture certain categories of drugs as Central Licence Approving Authority i.e. for blood banks, large volume parenterals and vaccines & sera.
- f) To regulate the standards of imported drugs.
- g) Work relating to the Drugs Technical Advisory Board (DTAB) and Drugs Consultative Committee (DCC).
- h) Testing of drugs by Central Drugs Labs
- i) Publication of Indian Pharmacopoeia

Other functions:

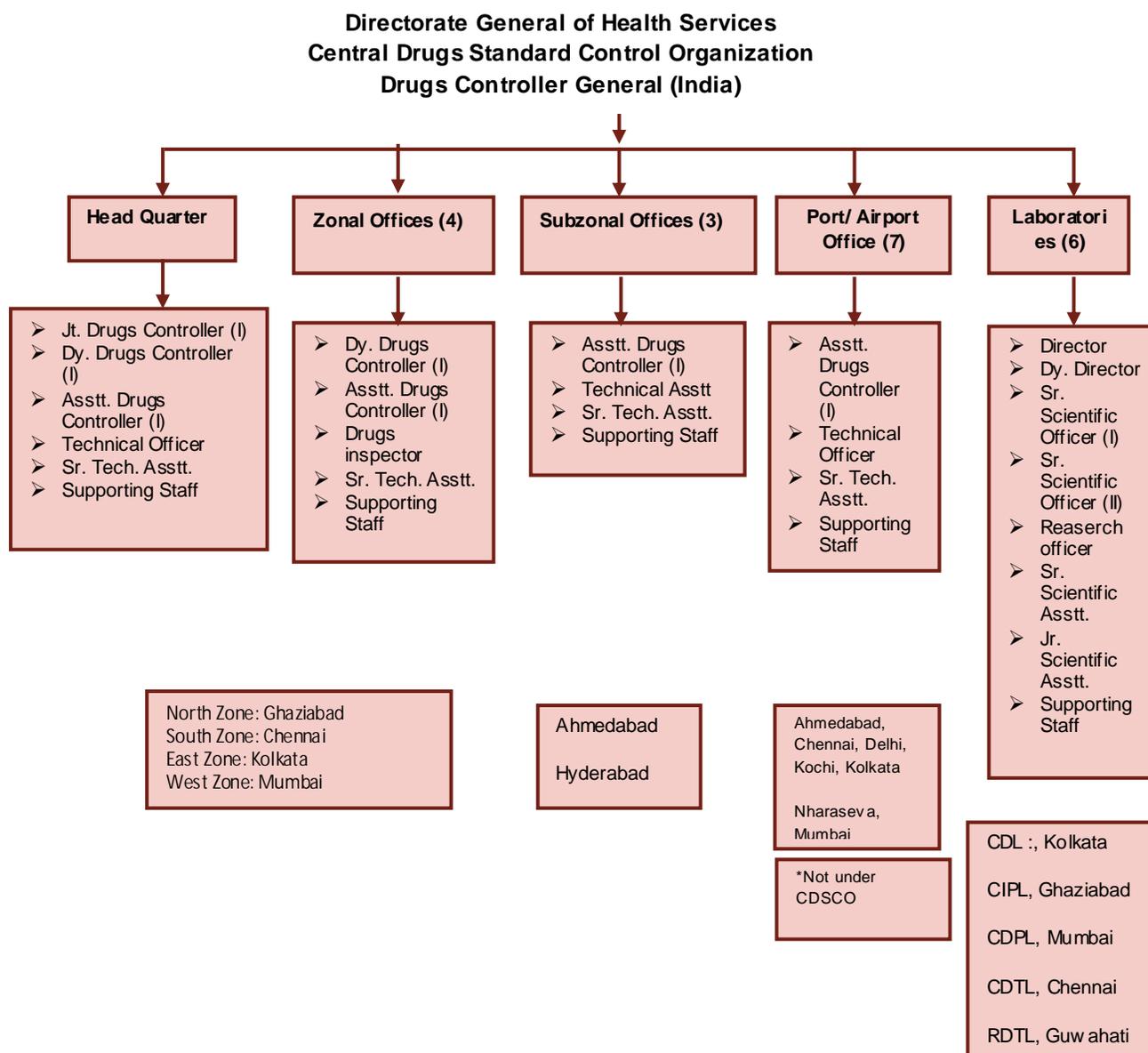
- a) Coordinating the activities of the State Drugs Control Organizations to achieve uniform administration of the Act; and policy guidance
- b) Guidance on technical matters
- c) Participation in the WHO GMP certification scheme.
- d) Monitoring adverse drug reactions (ADR).
- e) Conducting training programs for regulatory officials & Govt. Analysts



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- f) Distribution of quotas of narcotic drugs for use in medicinal formulations
- g) Screening of drug formulations available in Indian market
- h) Evaluation/Screening of applications for granting No Objection Certificates for export of unapproved/banned drugs.

CDSCO – Organogram





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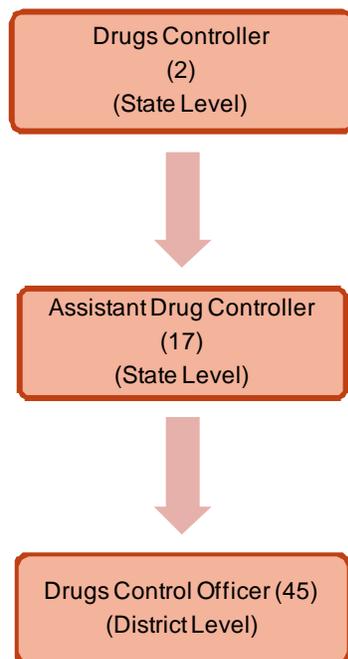
State Drugs Control Organizations:

The State Drugs Control Organization was set up in the state to implement the provisions of the Drugs and Cosmetics Act, 1940 and its subsequent amendments.

The **major functions** of the organization are:

- a) Licensing of drug manufacturing and sales establishments.
- b) Licensing of drug testing laboratories
- c) Approval of drug formulations for manufacture
- d) Monitoring of quality of Drugs & Cosmetics, manufactured by respective state units and those marketed in the state.
- e) Investigation and prosecution in respect of contravention of legal provisions
- f) Administrative actions
- g) Pre- and post- licensing inspection
- h) Recall of sub-standard drugs

State Drugs Control Organization – Organogram





Chapter 3: Rational Drug use

Medically inappropriate, ineffective and economically inefficient use of pharmaceuticals is commonly observed in health care systems at the level of decision making and delivery of services, throughout the world, especially in developing countries. The costs of such irrational drug use are enormous in terms of both scarce resources and the adverse clinical consequences of therapies that may have real risks but no objective benefits.

Obviously, this should also become the concern of all the stake holders, practitioners, pharmacists and nurses.

Defining Rational Use of Drugs

The concept of rational drug use is age old, as evident by the statement made by the Alexandrian physician Herophilus 300 B.C that is “Medicines are nothing in themselves but are the very hands of god if employed with reason & prudence.”

Rational use of drugs requires that patients receive medicines appropriate to their clinical needs, in doses that meet their own individual requirements, for an adequate period of time, and at the lowest cost to them and their community. (*WHO Conference on Rational Use of Drugs in Nairobi in 1985*).

In simplest words rational use means-

“prescribing right drug, in adequate dose for the sufficient duration & appropriate to the clinical needs of the patient at lowest cost”.

The requirements for rational use will be fulfilled if the process of prescribing is appropriately followed.

This process includes steps like-

1. Defining a patient's problems (or diagnosis);
2. Effective and safe treatments (drugs and non drugs);
3. Selecting appropriate drugs, dosage, and duration;
4. Writing a prescription;
5. Giving patients adequate information; and
6. Planning to evaluate treatment responses.

Unfortunately, in the real world, prescribing patterns do not always conform to these steps and can be classified as inappropriate, irrational or pathological prescribing.



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Common pattern of irrational prescribing

- a) The use of drugs when no drug therapy is indicated, e.g., antibiotics for viral upper respiratory infections.
- b) The use of the wrong drug for a specific condition requiring drug therapy, e.g., antibiotics in childhood diarrhea requiring ORS.
- c) The use of drugs with doubtful or unproven efficacy, e.g., the use of antimotility agents in acute diarrhea.
- d) Available, safe, and effective drugs.
- e) The use of correct drugs with incorrect administration, dosages, and duration, e.g., metronidazole vs. albendazole.
- f) Indiscriminate use of injections, e.g., in malaria treatment (for ignorance/ pressure from patients).
- g) Multiple or over-prescription (the use of a third generation antimicrobial) for treating minor ARI, anti-diarrheal for nonspecific childhood diarrhea and multivitamins and tonics for malnutrition.
- h) Under-use of effective drugs in conditions for which effective medicines exist. (hypertension, depression, and anemia during pregnancy).

Problem of Irrational Use of Drugs

Factors underlying irrational use of drugs

1. Patients
 - a) drug misinformation
 - b) misleading beliefs
 - c) patient demands/expectations
2. Prescribers
 - a) lack of education and training
 - b) inappropriate role models
 - c) lack of objective drug information
 - d) generalization of limited experience
 - e) misleading beliefs about drugs efficacy
 - f) less consultation time
 - g) poor communication between health professional and patient
 - h) profit driven attitude
3. Workplace
 - a) heavy patient load
 - b) pressure to prescribe
 - c) lack of adequate lab capacity
 - d) insufficient staffing



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4. Drug Supply System
 - a) unreliable suppliers
 - b) drug shortages
 - c) expired drugs supplied
 - d) less dispensing time
 - e) profit driven attitude
5. Drug Regulation
 - a) nonessential drugs available
 - b) informal prescribers
 - c) lack of regulation enforcement
6. Industry
 - a) lucrative promotional activities
 - b) misleading claims
 - c) lack of diagnostic facilities and uncertainty of diagnosis

Various causes that lead to the realization of irrational drug use included the increase in number of drugs available and thus complicating the choice of appropriate drug for particular indication, development of resistance to highly efficacious & life saving new antimicrobial drugs, increased cost of the treatment and extension of Consumer Protection Act in medical profession to restrict the irrational use of drugs.

Impact of Inappropriate Use of Drugs

The impact of this irrational use of drugs can be seen in many ways:

1. Reduction in the quality of drug therapy leading to increased morbidity and mortality and consequent drug resistance.
2. Waste of resources leading to reduced availability of other vital drugs and increased costs of health care.
3. Increased risk of unwanted effects such as adverse drug reactions and the emergence of drug resistance, e.g., malaria and Multiple Drug Resistant Tuberculosis.
4. Psychosocial impacts, such as when patients come to believe that there is "a pill for every ill" leading to increased drug demand.

Measures To Promote Rational Drug Use

The pre-requisites of rational drug use are: -

- a) Critical assessment & evaluation of benefits & risk of drug used.
- b) Compare the advantages, disadvantages, safety & cost of the drug with existing drug for some indication.



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Steps to improve rational drug prescribing are as follows:

- Step I:** Symptom based identification of patient need for drugs.
- Step II:** Diagnosis of the disease. Identify underlying cause & associative factors.
- Step III:** List possible intervention or treatment. Drug to be chosen, based on efficacy, convenience & safety of drugs including, drug inter-actions & high risk group of patients.
- Step IV:** Accurate & complete prescription e.g. name of drugs with dosage forms, dosage schedule & total duration of the treatment.
- Step V:** Informing patients on side effects (ADR), dosage schedule & dangers/risk of stopping the therapy suddenly.
- Step VI:** Monitor the treatment to check:
 - a) **Passive monitoring** is done by the patient himself. He should be explained him what to do if the treatment is not effective or if too many side effect occurs
 - b) **Active monitoring** is done by physician and he makes an appointment to check the response of the treatment.

Medication Error

Experts estimate medication errors are a leading cause of death and disability.

“Medication error is any preventable event that may cause or lead to inappropriate medication use or patient harm, while the medication is in the control of the health care professional, patient or consumer.”

A major medication error is one which may result in permanent harm to the patient or transfer to the ICU.

Why do medication errors happen?

Medications error may result from problems in practice, products, procedures or systems. Other factors, such as training deficiencies, undue time pressure and poor perception of risk can also contribute to medication errors.

Children are particularly vulnerable to medication errors because of their unique physiology and developmental needs. For example – Incorrect recording of patient weights leading to an incorrect medication dose and failure to note drug allergy are common causes for medication errors in the pediatric emergency department.

Characteristics of Medication Errors

An analysis of medication errors can help healthcare professionals and managers to identify error-prone medications or categories of drugs, and make improvements to prevent or reduce them.



Table 1: Types of Medication Errors

Types	Contributing Factors	Causes
Extra dose	Distractions	Performance deficit
Improper dose/quantity	Workload increase	Procedure/protocol not followed
Omission error	Inexperienced staff	Knowledge deficit
Prescribing error	Shift change	Inaccurate or lack of documentation
Unauthorized drug	Agency/temporary staff	Confusing communication
Wrong administration & technique	No 24 hour pharmacy	Inaccurate or omitted transcription
	Insufficient staffing	Computer entry
Wrong dosage form	Emergency situation	Drug distribution system
Wrong drug preparation	Cross coverage	Inadequate system safeguards
Wrong patient	Code situation	Illegible or unclear handwriting
Wrong route	Untrained staff	Lack of knowledge
Wrong time – Before or after meals viz. Rifampicin, Drugs to be diluted-potassium, alkalinizers should be diluted.	No access to patient information	Lack of knowledge
Loading of drug wrongly; Wrong speed of administration		Errors in decimal/zero Errors in units

Other reasons for medication errors

1. Dispensing errors

- a) Dropper confusion – practice of prescribing dropper full preparation of injections in advance
- b) Injectable solution color changes

2. Equipment errors

- a) Faulty monitors
- b) Faulty infusion pumps

3. History taking errors

- a) Not taking history of
 - i. allergy to drug
 - ii. concurrent illness
 - iii. previous drug dosages
 - iv. drugs already taken personal history,
- b) Telephonic consultant errors
- c) Errors in description of disease/symptoms
- d) Errors in noting down drugs



Reporting errors

There are basically four factors why medication errors are not reported: fear; disagreement on error, administrative responses to medication errors, and effort required to report Medication Administration Errors, as reporting is non-automated and voluntary process.

Reporting errors is only the first step in the process of reducing errors and continuous quality improvement. An approach that is commonly used in human factor analysis is a *critical incident analysis*. This analysis examines adverse events to understand where the system broke down, why the incident occurred, and the circumstances surrounding the incident. Analyzing critical incidents, whether or not the event actually leads to a bad outcome, provides an understanding of the conditions that produced an actual error or the risk of error as well as the contributing factors.

Feedback and dissemination of information can create an awareness of errors that occur in the system and improve system design to reduce or eliminate medication errors.

Preventing medication errors

1. It is important that five "Rights" are practiced strictly viz.,
 - a) Right Patient,
 - b) Right Drug,
 - c) Right Dose,
 - d) Right Route and
 - e) Right Time.
2. Drug should be administered after being cross-checked by another nurse.
3. In case prescription is not legible, confirm with doctor rather than guessing.
4. Read package insert before administering drug by intravenous or intramuscular route and follow the instructions on rate and speed of administration, diluents to be used.
5. Check the generic name of the drug in case of confusing brand names.
6. Be careful about look-alike and sound-alike drugs. They are one of the major sources of errors.
7. Never hesitate to report the Medication Error so that others do not make same error.



Chapter 4: Drug Store Management

The pharmaceutical management:

The pharmaceutical management has different components, like

- a) Selection of products
- b) Procurement
- c) Distribution
- d) Use

The entire drug management can be assessed based on four major indicators

1. Total expenditure on drugs and medicines (percentage of total expenditure on health)
2. Total expenditure on drugs and medicines (per capita average)
3. Government expenditure on drugs (per capita average)
4. Private expenditure on drugs (per capita average)

The operational framework depends on the regulatory framework, morbidity pattern, and system's priorities, type of services, level of health facility and availability of drugs besides the cost and management support (skilled manpower, financial resources and the information system)

Process of pharmaceutical management:

The general issues in drug management relate to overall Health care system in the state, particularly with reference to:

- a) Facilities and level of care (Primary, Secondary, Tertiary)
- b) Presence of voluntary sector-NGOs
- c) Services
- d) Manpower
- e) Priorities
- f) Resources

The basic components of Drug management:

1. Component 1
 - a) Drug policy, laws and regulations
 - b) Selection of drugs
 - c) Procurement
 - d) Storage and distribution
2. Component 2
 - a) Rational use
 - b) Availability
 - c) Access
 - d) Financing



Drug policy and regulations are the larger issues for drug regulation and are dealt separately in this module. Here we shall deal with operational areas that have a direct bearing on Drug management.

The **Drug selection process** involves:

- a) Listing of common health problems
- b) Review standard treatment options
- c) Develop National guide lines
- d) Develop list of Medicines (Essential drug list
- e) Spell out Activities in procurement
 - i. Selection
 - ii. Procurement
 - iii. Distribution
 - iv. Storage
- f) Rationalizing use

The Health sector determines the type of drugs and dosage forms that are put in use in health care facilities, depending upon available financial resources, level of health care and the morbidity profile.

The criteria for selection of Drugs, depends on factors, like:

1. Cost and dosage form that are affordable making it cost-effective in view of the maximum use of resources
2. Availability of drugs for majority of illnesses
3. Availability of safe, efficacious and cost effective drugs
4. National Health policy (Free/ subsidized drugs)
5. National Drug policy (Pricing and production)
6. Cost recovery/ sharing

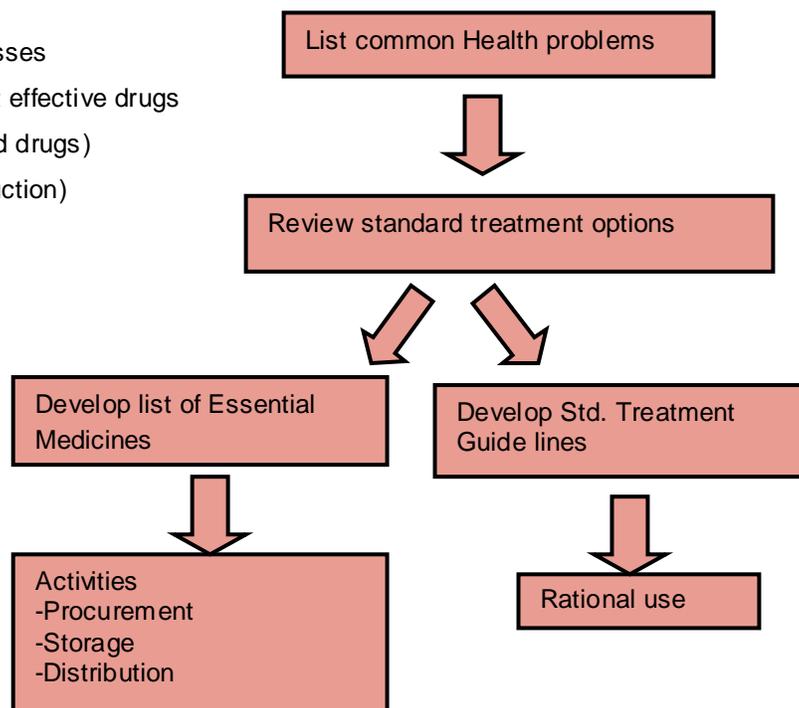


Figure 1: Drug selection cycle



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Drug Procurement:

Principles of Drug Procurement:

Good procurement is a linchpin of access to quality and appropriate medicines. The WHO, in partnership with UNICEF, United Nations Population Fund (UNFPA) and the World Bank, has drawn on a common bank of extensive experience to produce “Operational Principles for Good Pharmaceutical Procurement”, to assist all involved in procurement to obtain lower prices, better quality and more reliable delivery of essential medicines, based on four strategic objectives:

- 1 Procure the most cost-effective drugs in the right quantities.
- 2 Select reliable suppliers of high quality products.
- 3 Ensure timely delivery.
- 4 Achieve the lowest possible total cost.

The **12 guiding principles** of good Drug procurement, grouped in four categories, are outlined below:

A. Efficient and Transparent Management

1. Different procurement functions and responsibilities (selection, quantification, product specification, pre-selection of suppliers and adjudication of tenders) should be divided among different offices, committees and individuals, each with the appropriate expertise and resources for the specific function.
2. Procurement procedures should be transparent, following formal written procedures throughout the process and using explicit criteria to award contracts.
3. Procurement should be planned properly and procurement performance should be monitored regularly; monitoring should include an annual external audit.

B. Drug Selection and Quantification:

1. Public sector procurement should be limited to an essential drugs list of national/local formulary list.
2. Procurement and tender documents should list drugs by their International Nonproprietary Name (INN), or generic name.
3. Order quantities should be based on a reliable estimate of actual need.

C. Financing and Competition

1. Mechanisms should be put in place to ensure reliable financing for procurement. Good financial management procedures should be followed to maximize the use of financial resources.
2. Procurement should be effected in the largest possible quantities in order to achieve economies of scale; this applies to both centralized and decentralized systems.
3. Procurement in the public health sector should be based on competitive procurement methods, except for very small or emergency orders.
4. Members of the purchasing groups should purchase all contracted items from the supplier(s) which hold(s) the contract.



D. Suppliers Selection and Quality Assurance

1. Prospective suppliers should be pre-qualified, and selected suppliers should be monitored through a process, which considers product quality, service reliability delivery time and financial viability.
2. Procurement procedures/systems should include all assurance that the drugs purchased are of high quality, according to international standards. The “**Delhi Model**” of drug procurement has been applauded worldwide for pooled procurement resulting in enormous savings and better availability of drugs.

Procurement of Drugs:

In view of the ever developing sophistication, modernization, automation and up-gradation of manufacturing technologies competing environment, an efficient procurement system is the only way to improve access to medicines for the majority of the population within the given budgetary ceilings. Since availability of financial resources is always a constraint for developing countries, it becomes all the more important to improve efficiency in all aspects of management in the countries.

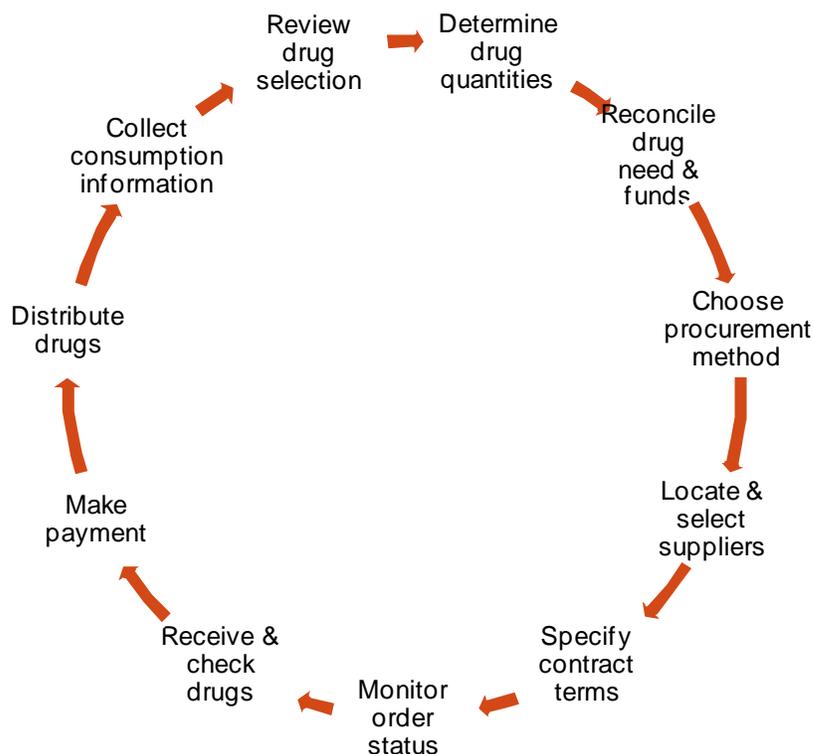


Figure 2: Drug procurement cycle



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The procurement of drugs is dictated by a number of factors:

- a. Estimating quantity of each drug required at given period
- b. Assessing cost of drug dosage from required
- c. Allocating resources to each drug dosage form depending on
 - i. Priority
 - ii. Resources

The requisition of drugs and dosage form has to come after consultation with the drug prescribers

Drug Procurement Mechanism in India: Case studies

Here we discuss the Delhi model, Drug procurement system in Tamil Nadu, Andhra Pradesh, and Orissa.

Delhi Model

The Delhi Society for Promotion of Rational Use of Drugs (DSPRUD) introduced the centralized drug procurement system with the government hospitals of Delhi in 1996 with the technical support of the WHO. The objective was to ensure availability of good quality medicines with these hospitals and to promote rational drug use.

Despite that 30-35% of the health budget of the government was spent on medicines, each hospital in Delhi used to procure the drugs independently. The system was ruined by mismanagement and corruption. Many of the drugs so procured by the hospitals were rarely needed while the required medicines were almost perennially in short supply.

The new system procures drugs centrally for half a dozen main and many smaller hospitals run by the Delhi government. Under the initiative, it was found that only a limited number of basic drugs were actually needed for treatment in almost 90% of the hospital cases. These were identified and procured centrally for supply to the hospitals.

As per WHO guidelines, the expensive combination drugs were kept out of the supply list, as a result of this, the actual cost of drugs to the hospitals was cut by as much as half, so that 75-90% of the medicines are in the affordable cost. The system has resulted in a fall in drug prices to the hospitals by 30-40%, better quality assurance and less duplication of effort.

The WHO has hence recommended extension of the Delhi Model to other states. Many states including Maharashtra, Rajasthan, Punjab, Tamil Nadu and Himachal Pradesh are now implementing the program with minor modifications. Moreover, the components of the Delhi model are being implemented in countries like Thailand, Myanmar, Vietnam, Laos and Kampuchea, as recommended by WHO. A list of 250 essential drugs was prepared for larger hospitals and a list of 100 for smaller hospitals which is revised from time to time. The hospitals in Delhi now spend over 90% of their drug purchase budget to buy these listed medicines and 10% to buy drugs outside the list. Standard Treatment Guidelines



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covering 15 diseases affecting adults and five childhood diseases have been drawn up for the benefit of doctors working in primary health centers.

The pooled procurement system uses a two-stage tender system. This ensures that only those companies that are capable of supplying products of adequate quality receive orders. The tender process is limited to companies that fulfill the technical criteria. Through a **two-envelope system** (technical bid and price bid), the drug purchase committee of the society is able to ensure that the purchases are made from companies complying with the Good Manufacturing Practices. A company which does not fulfill the technical criteria of a minimum annual turnover of Rs 12 crores and adherence to prescribed Good Manufacturing Practices (GMP), is automatically disqualified for making a price bid. The companies are required to undergo GMP inspections and random testing of products. There are instances of companies being blacklisted for want of proper compliance with GMP and poor quality of products. Doctors are asked to prescribe only products present on the procurement list, although hospitals are allowed to use up to 10% of their drug products.

State of Tamil Nadu (TN)

Tamil Nadu Medical Service Corporation (TNMSC), with the primary objective of ensuring ready availability of all essential drugs and medicines in all the Government health facilities by adopting a streamlined procedure for their procurement, storage and distribution, started functioning from January 1995.

The first step taken by TNMSC was to finalize the list of essential drugs to be procured. Keeping in view the WHO's Model List of essential drugs, the then existing list of nearly 900 drugs was pruned to a list of 240 drugs. Now, TNMSC has 271 items of drugs and medicines on its list, accounting for around 90% of the budget outlay for the purpose, leaving other drugs of small quantities to be purchased locally by the institutions from out of the remaining 10% budget. The TNMSC follows WHO's recommendation for the use of the international non-proprietary name (INN, commonly known as generics) for each drug. In order to ensure the procurement of only quality drugs at competitive prices, an open tender system is followed and purchases are made only from manufacturers (having GMP certificate and market standing for at least three years) and not through agents or distributors. A minimum turnover is also fixed in order to eliminate the very small firms since such firms may fail to keep delivery commitments. To eliminate sole dependence on one supplier, the next two lower suppliers willing to match the lowest price were also approved.

With the dual objectives of maintaining quality and preventing wastages and pilferages, all tablets and capsules are procured with only strip or blister packing, as against the earlier practice of bulk packing which required manual handling at the time of distribution. Both inner and outer packages of all items are required to bear the logo of TNMSC with a marking to show that the drugs are manufactured only for the state government supply and are "Not for Sale". On account of this, the credibility and acceptability of the



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drugs by the public also improved immensely. Samples drawn from different batches are coded and sent to private approved laboratories to ensure effective quality control.

In order to ensure a **regular supply** and for preventing stock-outs, TNMSC has established a chain of go downs to stock all items of drugs. Each district has a drug warehouse as a point of distribution for all medical institutions in the district. The suppliers are required to supply the drugs to the district warehouses, which would keep a working stock of three months requirement at any point of time. Each institution is given a passbook indicating its annual entitlement (i.e. budgetary allocation) within which it can draw drugs from the district warehouse. There is no need for an advance indent because any drug in the approved list could be obtained within the entitled financial limit.

One of the **outstanding features** of TNMSC is the **total computerization** in all aspects. Each district warehouse has a computer linked to the Head Office computer via the Internet. As the receipt and issue of drugs at all the district warehouses level is done using computers, the information on the inventory level for any drug at any warehouse at any point of time is readily available with the central computer at the Head Office, on the basis of which the stock position is effectively monitored and reorder is effected to prevent any stock out situation.

Further, on the basis of the inventory levels of all the warehouses, transfer of items from one warehouse to another are effected so as to optimize the utilization of drugs and to maintain minimum required stock levels. Other activities such as accounting, quality control, warehouse monitoring and administration are also conducted through computers for total error free strong logistic management. The solution starts from the identification of drugs to the Management Information System (MIS). Computerization of the entire operation has improved inventory management, and cost control, and enhanced availability of drugs in government health facilities.

This system of **pooled procurement** aimed at quality drugs and a transparent tender system with well-defined pre-qualification criteria has resulted not only in substantial (36%) savings on drugs, but also in a better perception in people in addition to **enhanced availability** of drugs at all facilities.

State of Andhra Pradesh (AP)

The nodal agency for purchase of drugs in AP is the Drug Procurement Wing of the Andhra Pradesh Infrastructure State Development Corporation (APISDC).

Key features of APISDC

1. A centralized pooled procurement system
2. Suppliers of repute, and following GMP
3. This two-part system of bidding and procurement (technical and financial bid)
4. Discourages quoting of unreasonably low rates in their bids to be included in the rate contract
5. A notified committee draws the selected list for procurement
6. Rate contracts are finalized on the selected list of drugs centrally by another notified committee.



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7. Indents are collected from hospitals and consolidated by the nodal agency and orders are placed before the firm to make the delivery to the medical stores in each district with following

Advantages:

1. the drugs when purchased in bulk may be bought for a lower price directly from the manufacturers,
2. transportation of these drugs is borne by the supplying firm and
3. loss/ theft during transport is the responsibility of the firm.

A pass book system has also been introduced and generally institutions draw their supply on a quarterly basis. A Primary Health Centre (PHC) can draw only 43 listed items. The superintendents of district hospitals have 10% of the allotted funds at their disposal for purchase of emergency medicines and the Superintendents of tertiary hospitals have 20% of the allotted funds at their discretion for similar purpose. Drug samples are drawn from district drug stores and sent to a recognized laboratory for testing.

This experience reflects that an autonomous organization with a supportive board can perform very well and approve the rates of procurement of drugs centrally, availing the advantage of bulk/pooled procurement, yet affect the deliveries of supplies in decentralized district drug stores, the cost of which is borne by the supplier. A single window system for all inputs, processes and outcomes can work effectively with a fairly close monitoring of flow of funds etc. The initial reluctance of the staff leading to slow improvement in financial and inventory management was overcome through a process of training and once the changes were set in motion, they proved to be very effective and finally computerization was also put into place.

State of Orissa

Orissa shifted from its earlier decentralized system of drug procurement to a more centralized, need based, procurement system with its Essential Drug List (EDL) based on the WHO model list comprising of 278 drugs in generic nomenclature.

Key features

Bidder to submit a pre-qualification stipulation in the form of two envelopes,

1. containing quality parameters and
2. containing price quotation has been envisaged.

Envelopes 'B' of only those who are technically qualified are opened. Only manufacturers having GMP certificate from the licensing authority are allowed to participate in the tender process and there is a provision for drawing samples from each batch of supply for testing.

Small Scale Industries (SSI) units are entitled to 5% price preference along with partial exemption from earnest money deposit, concession in sales tax, exemption from quality testing charges and a provision for midcourse correction of prices during the year.



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Good pharmaceutical procurement practices

- a) Procurement by generic names
- b) Procurement limited to essential drugs
- c) Procurement in bulk
- d) Procurement supplier quantification
- e) Competitive procurement
- f) Order quantities based on reliable consumption needs
- g) Reliable payment and good financial mechanism
- h) Transparency and written procedures
- i) Separation of key functions
- j) Product quality assurance
- k) Annual audit
- l) Regular reporting on procurement performance

Drug Distribution:

The primary management goal is to maintain a steady supply of drugs and supplies to facilities where they are needed while ensuring that resources are being used in the most effective way. A well-managed distribution system should:

- a) Maintain a constant supply of drugs
- b) Keep drugs in good condition
- c) Minimize drug losses due to spoilage and expiry
- d) Rationalize drug storage points
- e) Use available transport as efficiency as possible
- f) Reduce theft and fraud
- g) Provide information for forecasting drug needs

The distribution cycle begins when drugs are dispatched by the manufacturer or supplier. It ends when drug consumption information is reported back to the procurement unit.



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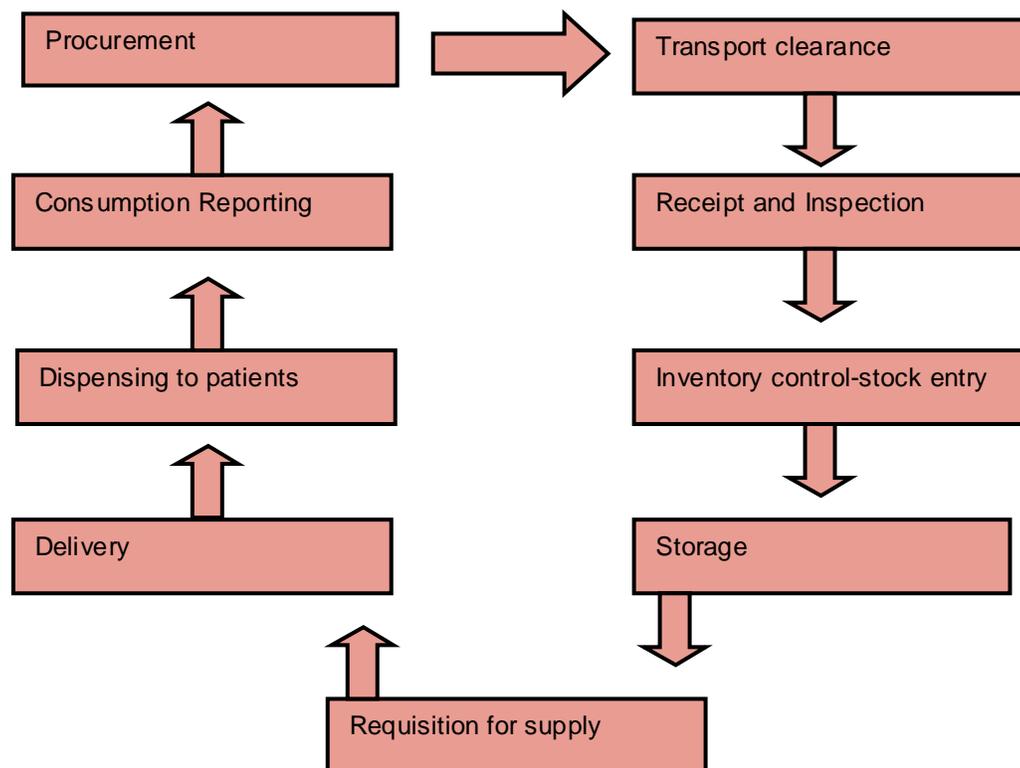


Figure 3: Drug distribution cycle

The drug supply management at a health facility has **seven components**:

- A. Preparation of drug store
- B. Supply ordering
- C. Receiving supplies
- D. Organization of drug supplies
- E. Inventory Management
- F. Record keeping

This module shall discuss each component in detail:

A. Preparation of drug store at a health facility:

The drugs and medicines including kits are expensive and sensitive to changes in temperature and need to be kept under ideal conditions to avoid deterioration.

Location: It must be accessible to all units to be served and there should be provision for vehicles bringing the supplies directly to the store.

Shading: Locate the store in an area where trees can be planted to provide shade and offset high temperatures.



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Drainage: Build the store on a raised foundation to allow rainwater to drain away from the store.

Security: There should be proper fencing or perimeter walls to improve security and control access besides double locking door of the rooms where costly medicines and supplies are kept.

Protection against fire:

1. Availability of standard fire extinguishers in every storage facility and inspecting them every 2-3 months to ensure pressures are maintained and the extinguisher is ready for use.
2. Service of fire extinguishers at least every 12 months.
3. Placing smoke detectors and checking them every 2-3 months.
4. Prohibiting smoking in the storage.
5. Conducting fire drills every 6 months.
6. Emergency exits should be clearly marked and checked regularly for accessibility and any blockage.
7. Display of fire protection signs at appropriate places.
8. Use of sand to extinguish fires where there are no fire extinguishers. Placing the sand bucket near the door.



Protection against pests:

1. Inside the storage facility:
 - a) Regular cleaning to prevent conditions that favor pests.
 - b) Do not store or leave food in the storage facility.
 - c) Keeping the interior as dry as possible.
 - d) Paint or varnish woods.
 - e) Regular inspection for evidence of pests.
2. Outside the storage facility:
 - a) Regularly inspect and clean the outside premises specially areas where garbage is stored.
 - b) Check for rodent burrows.
 - c) Using mercury vapor lighting where possible, and locate lighting away from the building to minimize the attraction of pests.



Designing a medical store

Consider the following when designing a storage facility:

Capacity/space: Storage facilities must have the capacity for both storage and handling. The required space will depend on– quantity and time of receiving supplies, space required for each item, length of stay, need of cold storage (refrigerator or freezer).



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Cold storage: In larger facilities it is more efficient to use cold rooms while in smaller ones freezers or refrigerators can be used. Ideally, larger facilities should have one room with a negative temperature for frozen products (-20°C) and another room with a positive but cold temperature (2°-8°C) for products requiring refrigeration.

Ventilation: The location and design should ensure maximum air circulation to avoid concentrations of fumes or gases. Exhaust fan should be used. Windows should be high and wide. There should be provision for proper temperature and humidity control.

Roof: Proper drainage of water should be there from both roof and floor. Roof should be extended over the windows to give extra protection from rain and direct sunlight. Double ceiling should be installed to provide insulation and ensure that supplies are kept cool.

Walls and floor: These should be permanent and smooth for easy cleaning. Walls preferably should be constructed of brick or concrete blocks. Floors should withstand the frequent movement of heavy products and equipment.

Doors: They should be wide enough to allow for the free and easy movement of supplies and strong enough to provide adequate security.

Lighting: Provision of natural light should be there while florescent or incandescent bulb lighting should be avoided as these emit ultraviolet rays and heat respectively, which have a negative effect on certain products.

Cupboards: To keep specific products free from dust or light, cupboards should be there.

Shelves: Adjustable shelves and racks should be used in line with a passageway not less than 90 cm wide. Also place the shelves 90 cm from the walls of the storeroom to ensure they are accessible from both sides. Avoid placing shelves only around the edge of the room.



B. Ordering supplies:

Ordering supplies has different steps to be followed. These are-

a. Demand planning:

There are three methods to plan or forecast the demand for drugs and medicines in any health care facility:

1. Consumption Method
2. Morbidity Method
3. Adjusted Consumption Method

1. **Consumption Method:** This method uses records of past consumption of individual drugs to project future needs. It is the most precise method for forecasting drug usage, provided the



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source data are complete, accurate and properly adjusted for stock-out periods and anticipated changes in demand and use.

It does not normally address the appropriateness of past consumption patterns, which may or may not correspond with public health priorities and needs. Thus irrational drug use may be perpetuated by total reliance on this method.

Steps of Consumption Method:

Step 1: Prepare a list of drugs to be quantified. The drug list should be prepared, sorted into the order that will best facilitate data collection and distributed to those concerned who will enter the consumption data.

Step 2: Determine the period of time to be reviewed for consumption. Data of twelve months, if available, can be reviewed. But if there are significant seasonal variations, it is best to use the same six-month period from the preceding year.

Step 3: Enter consumption data for each drug. Following should be entered for each drug on the list:

- a) Total quantity used during the review period, in basic units,
- b) Number of days in the review period that the drug was out of stock,
- c) Lead time for the last procurement (or the average from last several procurements),

$$\text{Consumption} = \text{opening stock} + \text{drugs received} - \text{closing stock}$$

It is important to use the most accurate and current records available. The consumption and lead time data can be taken from Stock records and distribution reports; invoicing from suppliers and dispensing records besides daily use records and drug registers.

Step 4: Calculate the average monthly consumption. The simple way to get monthly consumption is to divide total consumption by the number of months reviewed. If there were stock-outs during that period, the average must be adjusted to include the consumption that would have occurred if stock had been available.

In practice, relatively short stock-outs of up to one month may be ignored because they are not likely to have significant effect on estimated drug requirements. But for stock-outs more than 30 days an adjustment should be made. The formula to be used is:

$$\text{Consumption adjusted} = \text{recorded consumption} \times \frac{\text{period in calculation (in days, months)}}{\text{period in stock (in days, months)}}$$

Example:

Consider entry for ampicillin 250mg capsule. The total consumption for a six month review period was 89, 000 capsules. The drug was out of stock for 34 days in the six month period. Therefore, the average monthly consumption (C_A) adjusted for stock-outs is:

$$\text{Consumption adjusted for stock-outs} = 89,000 \times \frac{6 \text{ months}}{\text{period in stock}}$$



Consumption based forecast

Drug	Strength	BU	Pack size	Total consumption in period (BU)	Days out of stock	Adjusted average monthly consumption (BU)	Stock on hand (BU)	Stock on order (BU)	Safety stock level (BU)	Suggested quantity to order (BU)	Adjusted order quantity	Order quantity (packs)
Ampicillin	500mg	Capsule	100	59500	0	9917	32000	42000	29750	45000	50737	510
Ampicillin	250mg	Capsule	100	89000	34	18218	81000	58000	54654	79616	89766	900
Ampicillin sodium injection	500mg	Ampoule	100	3879	0	647	111	7600	1940	47	53	1
Ampicillin suspension 100mL	125mg/5ml	Bottle	1	4128	0	688	1513	3000	2064	3743	4220	4220
Antihistamine decongestant elixir	250mL	Bottle	1	853	29	169	351	929	507	747	843	843

BU – Basic unit

Step 5: Calculate the safety stock needed for each drug. Safety (buffer) stock is needed to prevent stock-outs, although high levels of safety stock increase inventory holding costs and should be avoided. The preferred method is to calculate the safety stock based on the average consumption and the expected lead time. The average monthly consumption is multiplied by the average lead time. This safety stock should avoid stock-outs assuming that the item is reordered when only the safety stock remains, the supplier delivers within the projected lead time, and consumption is no greater than average.

$$\text{Safety stock} = \text{LT} \times C_A$$

Using this formula, the safety stock for Ampicillin 250mg capsules in the examples is $18,218 \times 3 \text{ months} = 54,654$.

For vital items, it may be necessary to adjust the safety stock to cover variations in consumption or lead time. The simplest method multiplies the basic safety stock by an adjustment factor. For example, an adjustment factor of 1.5 would increase the safety stock of Ampicillin 250 mg capsules to 81,981 capsules. If this sort of adjustment is done for all items, the cost of safety stock will increase substantially; therefore, adjustments should be made only when there is true uncertainty about the lead-time or consumption.

Step 6: Calculate the quantity of each drug required in the next procurement period with the



following formula:

$$Q_O = C_A \times (LT + PP) + SS - (S_1 + S_0)$$

Q_O = Quantity to order

C_A = Monthly consumption adjusted for stock-outs

LT = Average lead time in months

PP = Procurement period in months

SS = Safety stocks

S_1 = Stock now in inventory

S_0 = Stock now on order

The calculation is done in three steps: firstly, the average consumption is multiplied by the sum of the lead time and the procurement period, yielding the total needs before considering safety stocks, stock on hand, or stock on order. Secondly, add the quantity needed for safety stock. Lastly, the quantity of stock on hand and the stock on order are added together, and then subtracted from the previous total. For our example the quantity to order is:

$$Q_O = 18218 \times (3 + 6) + 54654 - (81000 + 58000) = 79616$$

Step 7: Adjust for expected changes in consumption pattern. Using our example, if it is expected that utilization will increase by 5 % in the coming year, it would be reasonable to adjust the six month forecast by 2.5%, this would raise the expected need by 1990 capsules, bringing the total to 81606 capsules.

Some changes in consumption may be independent of trends in overall patient utilization like seasonal variations in the consumption of cough and cold remedies.

Step 8: Adjust for losses: to avoid stock-outs, it is necessary to adjust quantification estimates to allow for losses. If the supply system averaged 10% per year in losses, and this was applied to Ampicillin 250mg capsules, the allowance would add 8160 capsules to the estimate from step 7, bringing the total purchase quantity to 89766.

Step 9: Compile decentralized quantifications: In a decentralized quantification, staff at each facility or storage point enters their own consumption quantities and stock-out information, and the estimates of the individual facilities are totaled and compiled on the master quantification list.

Step 10: Estimate costs for each drug and total costs. In order to estimate procurement costs, multiply the quantities estimated for each drug by the most accurate prediction of the next purchase price. After the estimated value has been calculated for each drug, the final step in the basic quantification process is to add up the estimated procurement values for all drugs to obtain the total expected cost for the procurement.

Step 11: Compare total costs with budget and make adjustments. If the total expected procurement cost exceeds the available budget, there are really only two choices, either



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obtain more funds or reduce the number of drugs and/or the quantities ordered.

2. **Morbidity Method:** This estimates the need for specific drugs based on the expected number of attendances, the incidence of common diseases and their standard treatment patterns.

The quantification by this method assumes that prescribing is rational and standard treatment guidelines should be made available.

The basic formula used is:

Quantity of the drug specified for a standard course of treatment x Number of treatment episodes of the health problem = total quantity of a drug required for a given health problem

A treatment episode is a patient contact for which a standard course of drug treatment is required. If a standard treatment is specified for particular health problem, then a new patient contact for this problem counts as treatment episode. However, if this patient has to return for repeat contact before the problems is cured each repeat visit, where the standard treatment is again required also counts as a treatment episodes. If no new drug treatment is again required, for example because the repeat visit is for a follow-up check on the patients' progress, then it does not count as a treatment episode.

A single patient contact may give rise to more than one treatment episode, if several health problems are diagnosed and a standard course of drug treatment is required for each one.

Where a particular health problem has several different standard treatments for different age groups or severities, then the number of treatment episodes for each of these must be established separately.

It is complex and time consuming method. Data on patient attendance are often incomplete and inaccurate and it is difficult to predict what percentage of prescribers will actually follow the standard treatment regimens used for quantification. But this is the best alternative for health facilities where there are limited ranges of health problems.

3. **Adjusted Consumption Method:** The method uses data on disease incidence, drug consumption or utilization, and/or drug expenditures from a "standard" supply system and extrapolates the consumption or utilization rates to the target supply system, based on population coverage or service level to be provided. This method is best suitable when the other two methods are not feasible. This method is most likely to yield accurate projections when used to extrapolate from one set of facilities to another set that serves the same type of population in the same geographic and climatic area.



b. Reordering

Calculation of re-order is based on consumption data which is taken as average consumption over a period of time as in some months the health facility will use more as compared to others.

Reorder point: This is that level of drugs available at which a new order for supply of drugs is to be placed. In other words, at this level a purchase requisition is made out. This level is fixed somewhere between maximum and minimum levels. Order points are based on usage during time necessary to requisition order, and receive materials, plus an allowance for protection against stock out.

The order point is reached when inventory on hand and quantities due in are equal to the lead time usage quantity plus the safety stock quantity.

How to reorder: Formula

The following two formulas are used for the calculation of reorder level or point.

Ordering point or re-order level = Maximum monthly usage x Lead time

The above formula is used when usage and lead time are known with certainty; therefore, no safety stock is provided.

When safety stock is provided then the following formula will be applicable:

Ordering point or re-order level = Maximum monthly usage x Lead time + Safety stock

Buffer Stock/ Safety Stock is the minimum quantity of supplies set apart as an insurance against variation in supplies and demand. This can be calculated by multiplying the average demand for maximum delay or the probable delay.

Delivery period/Lead time

It is important to know how long it will take to receive the supplies after placing the order and this period is referred as Delivery time or Lead Time. This could be days, weeks or months depending upon:

1. Distance and road conditions
2. Availability of delivery vehicle
3. Work load at issuing store
4. Consumption rate

Time to reorder: if the balance is less than the reorder level, reordering should be done.

c. Placing an order:

Make a written request for supplies

- a) Use a requisition or order form to make a written request to get medicines and other supplies. Example of Requisition and Issue Voucher or Requisition for Pharmaceutical Supplies are given the annexure.
- b) Order information should be completed accurately.
- c) Use generic name of the medicines.



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- d) Keep a record of the order.
- e) Make and keep a copy of the requisition or order form, or record the name of item, its strength and form, and unit size. Write down the code number if the number is available in a medical supplier's catalogue or list and the amount requested. Sign the form.
- f) Send or deliver your requisition or order form to your suppliers
- g) Write down the date your order was sent to your suppliers.

C. Receiving supplies

When you receive health commodities-

- 1. Ensure there is sufficient storage space.
- 2. Prepare and clean the areas used for receiving and storing the products.
- 3. Inspect packages for damaged or expired products

If	Then
Supplies are damaged or expired	<ul style="list-style-type: none"> 1. Separate the damaged or expired stock from the usable stock. 2. If damage or expiry is discovered while the delivery truck is still at your site, refuse to accept the products and note the problem(s) on the delivery note. 3. If damage or expiry is discovered after the delivery truck has departed, follow your facility's procedures for handling damaged or expired stock.
Supplies are not damaged or expired	<ul style="list-style-type: none"> 1. Count the number of units for each product received and compares to issue voucher. 2. Record the date and quantity received on stock card and bin card (if applicable). 3. Ensure the expiry date is visibly marked on every package or unit. 4. Arrange products in the storage area to facilitate the first-to-expire, first-out (FEFO) procedure. (See section on stock rotation.)

Identification of poor quality and damaged supplies:

- 1. Packaging, look for
 - a) Broken or ripped packaging (vials, bottles, boxes, etc.)
- 2. Labels, Look for
 - a) Missing, incomplete or unreadable labels
- 3. If liquids, look for
 - a) Discoloration
 - b) Cloudiness
 - c) Sediment
 - d) Broken seal on bottle
 - e) Cracks in ampoule, bottle or vial
 - f) Dampness or moisture in packaging



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- g) Torn or ripped packaging
- 4. If Latex products are there, look for
 - a) Dryness
 - b) Brittleness
 - c) Cracks
- 5. If Lubricated latex products, look for
 - a) Sticky packaging
 - b) Discolored product or lubricant
 - c) Stained packaging
 - d) Leakage of the lubricant (moist or damp packaging)
- 6. If foil packs, look for
 - a) Perforations in the packaging
- 7. If Chemical reagents, look for
 - a) Discoloration
- 8. If tablets (pills), look for
 - a) Discoloration
 - b) Crumbled pills
 - c) Missing pills
 - d) Stickiness (especially coated tablets)
 - e) Unusual smell
- 9. If capsules, look for
 - a) Discoloration
 - b) Stickiness
 - c) Crushed capsules
- 10. If Injectables, look for
 - a) Liquid not returning to suspension after shaking
- 11. If sterile products (including intrauterine devices), look for
 - a) Torn or ripped packaging
 - b) Missing ports
 - c) Broken or bent parts
 - d) Moisture inside the packaging
 - e) Stained packaging
- 12. If tubes, look for
 - a) Stickiness
 - b) Leaking contents
 - c) Perforations

D. Organizing Drug supplies:

The basic concept in supply organization is that we should be able to locate the supply in the store easily which means supplies are shelved in a predetermined manner. The principle for organizing supplies of drugs and medicines are:

- a) Drugs to be stored in original containers
- b) Similar drugs (Oral/injectable, internal/external use) to be kept





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on same shelf

- c) Supplies to be arranged in alphabetical order/groups
- d) Items with short shelf life to be kept in front
- e) Ensure expiry dates are visible clearly
- f) Shelf storing principle to be followed-
 - i. Top Shelves: dry medicines
 - ii. Middle shelves: liquid/injectables/ointments
 - iii. Bottom shelves: surgical items, laboratory supplies, condoms
- g) Within each drug group, arrange supplies in a alphabetical orders
- h) Store items in groups (easy to count)
- i) Store medicines and supplies with expiry dates by labeling “first expiry first out”
- j) Clear all expired/damaged supplies
- k) Identify overstocked items

While storing the supplies, ensure

- a) Supplies are kept at least 10 cms above the floor.
- b) Supplies are kept at least 30 cms away from wall.
- c) Supplies are kept at a height not more than 2.5 mts.
- d) Manufacturer’s directions are followed.
- e) Liquids are placed on the lower shelves.
- f) Appropriate temperature is to be maintained.
- g) High value products are kept at security zones.
- h) Expiry date is visible from front



It is essential to follow the product manufacturer’s storage instructions to the extent possible. If this is not possible, the product must be kept in the most suitable conditions available and used as quickly as possible. The product manufacture should be consulted before violating recommended storage conditions to determine how long the product will remain safe and effective under the actual storage conditions.

If no specific storage instructions are given, “normal storage conditions” apply. Normal storage conditions for drugs have been defined as “storage in dry, well ventilated premises at temperatures of +15°C to 25°C, or depending upon climatic conditions, up to +30°C. Each storage zone should have at least one thermometer, and temperatures should be recorded daily at the hottest time of day.

Orderly arrangement of essential medicines

Medical stores must have a system for classifying or organizing medicines, and must ensure that all employees know the system being used.



Some common systems for arranging medicines include-

- a) **Alphabetical order by generic name:** When using this system, the labeling must be changed when the Essential Medicines List is revised or updated.
- b) **Therapeutic or pharmacologic category:** Most useful in small storerooms or dispensaries where the storekeeper is very knowledgeable about pharmacology.
- c) **Dosage form:** Medicines come in different forms, such as tablets, syrups, injectables, and external use products such as ointments and creams. In this system, medicines are categorized according to their dosage form. Within the area for each form, a fixed, fluid, or semi-fluid system is used to store items. Any of the other methods of categorizing can be used to organize the items more precisely.
- d) **System level:** Items for different levels of the health care system are kept together. This works well in stores at a higher level when storage of kits is required.
- e) **Frequency of use:** Frequently used products that move quickly or often through the store should be placed in the front of the room or closest to the staging area. This system should be used in combination with another system.
- f) **Random bin:** Identifies a specific storage space or cell with a code that corresponds to its aisle, shelf, and position on the shelf. This system requires computer automation.
- g) **Commodity coding:** Each item has its own article and location code. This system has the greatest flexibility, but it is also the most abstract. Stores staff do not need any technical knowledge of the products to manage this system because the codes contain the information needed for storing products properly, such as temperature requirements, level of security, and flammability. This system works well in computerized inventory control systems.
- h) **Separate storage** of items of resale potential (high value items, narcotics, psychotropic drugs) and flammable liquids (acetone, alcohol, anesthetic ether and store in security zones.
- i) **Stock rotation**
 - a. Follow **First to Expire First to be Out** (FEFO) procedure.
 - b. Place products that will expire first in front.
- j) Write expiry date on product card.
- k) For items which do not have an expiry date, the principal to be followed is FIFO-First in First Out.
- l) Put newly received items at the back of existing stock
- m) Always remove expired and poor quality stock from the store
- n) Identify overstocked items and items that are not in use and distribute them to other facilities
- o) Keep a record of all items removed so that balances can be tallied later.



Cold storage of Drugs & Vaccines

Indian Pharmacopoeia describes conditions for storage of some official substances which are likely to deteriorate, if not stored properly. It is important to follow the manufacturer's recommended storage conditions for all products. The terms used under definite meaning of the pharmacopoeia are:

1. **Store frozen:** Some products, such as certain vaccines, need to be transported within a cold chain and stored at -20°C . Frozen storage is normally for longer-term storage at higher-level facilities.
2. **Do not freeze or do not store over 8°C :** To be kept in refrigerator (from $+2^{\circ}\text{C}$ to $+8^{\circ}\text{C}$ but not in the freezer chamber).
3. **Keep Cold:** Storage at any temperature NOT exceeding 8°C and usually between 2°C and 8°C but must not be frozen. These are usually kept in the first and second part of the refrigerator (never the freezer). This temperature is appropriate for storing vaccines for a short period of time. A refrigerator is a cold place in which the temperature is maintained thermostatically between 2°C and 8°C .
4. **Keep Cool:** Store at 8° - 25°C . An article for storage in a cool place is directed, may, alternatively, be stored in a refrigerator (at temperature between 2°C and 8°C), unless otherwise specified in the individual monograph. Store at room temperature or do not store over 30°C : store at 15°C - 30°C .
5. **Storage at ambient temperature:** Store at the surrounding temperature. This term is not widely used due to significant variation in ambient temperatures. It means "room temperature" or normal storage conditions, which means storage in a dry, clean, well-ventilated area at room temperatures 15° to 25°C or up to 30°C , depending on climatic conditions.
6. **Protect from moisture:** To be stored in normal humidity at room temperature (Relative Humidity less than 60%).
7. **Protect from light:** To be stored in a light-resistant cupboard/drawer; to be provided by the manufacturer in a light-resistant container.

The potency of vaccines, sera, test kits, and many other items depends on cold storage. Vaccine, in particular, must be kept at precisely controlled temperatures from the point of manufacture to the point of administration. Also daily temperature record should be maintained properly.

Storage of vaccines:

All vaccines and diluents must be stored in the refrigerator for short term between 2°C and 8°C in a pharmacy that issues to the end-user or clinics. For long terms storage -20°C is preferred only for BCG, OPV and measles/MMR. Do not freeze other vaccines. Domestic refrigerator, ice lined refrigerator are used for short term storage and deep freezer for long term storage.

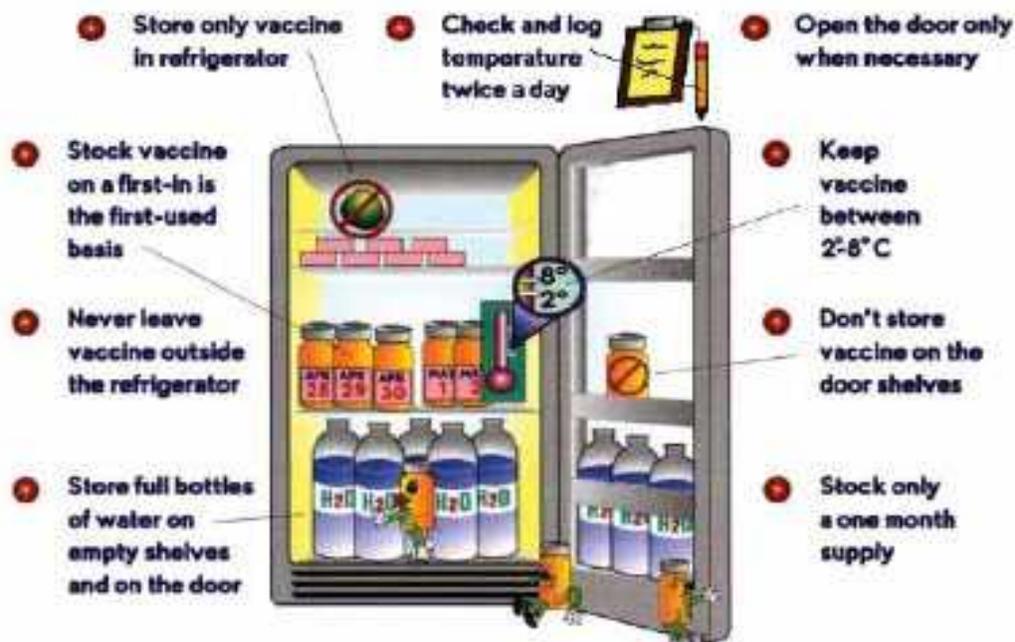


Figure 4: Storage of vaccines in refrigerator

Table 2: Potency & temperature for storage vaccines.

Vaccine	Temperature	Potency maintained	Remarks
Oral Polio (OPV)	-20°C	1 year	Avoid repeated thawing
	4°C to 8°C	3 months	Keep on ice while using
Bacillus Calmette Guerine (BCG)	4°C to 8°C	1 years	Reconstituted vaccine, if not used within four hours must be discarded
Diphtheria Pertussis Tetanus (DPT)	4°C to 8°C	2 years	Must not be frozen
Diphtheria, Tetanus (DT)	4°C to 8°C	2 years	Must not be frozen
Measles	0°C to 2°C	2 years	Should be used immediately after reconstitution
Typhoid (TAB)	4°C to 8°C	8 months	Must not be frozen
Tetanus toxoid (TT)	4°C to 8°C	8 months	Must not be frozen. Unused portion must be discarded
Hepatitis B	4°C to 8°C	4 years	Must not be frozen



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National and regional vaccine stores should be equipped with standby generators; ideally, district vaccine stores should have them as well. Having backups ensures that vaccines and other products are protected in the event of a power failure.

Checklist for drug warehouse management

1. Daily/Weekly

- a. Monitor storage conditions
- b. Clean receiving, storage, packing, and dispensing areas
- c. Sweep or scrub floors
- d. Remove garbage
- e. Clean bins, shelves, and cupboards, if needed.
- f. Ensure that passages are clean.
- g. Ensure adequate ventilation and cooling
- h. Ensure that products are protected from direct sunlight.
- i. Monitor store security and safety.
- j. Check the store roof for leaks, especially during rains.
- k. Monitor product quality (visually inspect commodities and check expiration dates)
- l. Ensure that products are stacked correctly.
- m. Update stock records
- n. Conduct physical inventory and update stock keeping records
- o. Monitor stock levels, stock quantities, and safety stocks.
- p. Submit emergency order (as needed, using local guidelines)
- q. Update bin cards
- r. Separate expired stocks and move to secure area



2. Monthly

- a. Conduct physical inventory or cycle count, and update stock keeping records
- b. Check for signs of rodents, insect or roof leaks.
- c. Inspect the storage structure for damage, including the walls, floors, roof, windows, and doors.

3. Every 3 months (quarterly)

- a. Conduct physical inventory or cycle count, and update stock keeping records
- b. Use established procedures to dispose of expired or damaged products.
- c. Visually inspect fire extinguishers to ensure that pressures are maintained and extinguishers are ready for use.

4. Every 6 months

- a. Conduct fire drills and review fire safety procedures



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5. Every 12 months
 - a. Service fire extinguishers and smoke detectors
 - b. Conduct complete physical inventory and update stock keeping records.
 - c. Reassess maximum/minimum stock levels, and adjust if needed.

E. Inventory Management

Inventory Management Inventory Management is the scientific process by which an organization is supplied with the goods and services which needs to achieve its objectives at optimum cost.

Inventory control can be viewed as the attainment of a cost balance between shortage and excess of stock. It is one of the modern management techniques of operations research. Without proper control over the inventory, serious problems can precipitate, related to manufacturing, marketing, revenue generation and customer satisfaction. Likewise, availability of life saving drugs and other hospital supplies can be crucial to good hospital care and patient satisfaction. Hence, it helps in attaining goal of a good hospital supply system to ensure adequate stock of required items for uninterrupted supply of all essential items.

Aims and Objectives

Inventory control deals with physical control of inventories. It is the process of deciding as to when, what and how much of each item is to be kept in stock, minimizing the ineffective stock and optimizing the various causes associated with the inventories.

Objectives:

1. Utilize the available resources most efficiently and effectively.
2. Maintain availabilities of materials whenever and wherever required in optimal quantity
3. Minimize the in-effective stock
4. Optimize the various cost associated with the inventories.

Scope of Inventory Control

An efficient inventory control system can:

1. Reduce costs
2. Improve service delivery
3. Increase return on investment
4. Improve liquidity
5. Improve service conditions
6. Increase efficiency of man and machine
7. And hence improve patients satisfaction



Inventory Control Methods

1. **Purchase cost** – It is the actual cost of materials. It is an apparent type of cost which is easily understood. The effort should be to reduce this as much as possible by following the simple techniques like bulk buying, under generic names and at negotiated rates.
2. **Carrying cost** – This is hidden cost and not amenable to easy calculations. It includes the cost incurred on storage space, capital borrowing, additional manpower, obsolescence, deterioration and pilferage.
3. **Ordering cost** – It is the cost of placing an order like the cost involved in stationery, postage, telephone, fax, manpower etc.
4. **Shortage cost** – It deals with the cost of not having a particular material. The direct cost is the higher price we pay for procuring a substitute from an alternate source.

Techniques of inventory control

The types of Inventory control analysis, which are carried out for classifying materials so that materials and processes can be treated differently, are mentioned here as follows:

1. **A-B-C Analysis**

A-B-C analysis is a basic analytical management tool. It is also known as “Always Better Control.” It is based on value of consumption of item per year.

A – (Highest annual usage) around 10 – 20% of the drugs would cost for 70 - 80 % of the resources.

B - (Moderate annual usage) 10 - 20 % of the drugs generally consume 15 - 20% of the resources.

C – (Low annual usage) remaining 60 - 80% of drugs would consume just about 5 - 10% of the resources.

Steps to perform ABC Analysis

1. List all items purchased or consumed and enter the unit cost.
2. Enter consumption quantities (over a defined period of time e.g. one year).
3. Calculate the value of consumption.
4. Calculate the percentage of total value represented by each item.
5. Rearrange the list, rank items in descending order by value starting at the top with higher value.
6. Calculate the cumulative percentage of the total for each item beginning with the first item at the top; add the percentage to that of the item below it in the list.
7. Choose cut-off points or boundaries for A, B, and C drugs



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Table 3: Steps to Perform ABC Analysis

ABC Analysis of the Expenditure for Drugs 2009-10

	Cost/Unit			% of total value	
Name of Item	In Rs.	Qty.	Cost (Rs.)		Cumu %
Tab. Carbamazepie (CR) – 200mg	1.19	1600000	1904000	26.11	26.11
Tab. Sodium Valpoate (SR) 500mg	3.48	300000	1044000	14.32	40.43
Tab. Sodium Valpoate (SR) 200mg	1.39	700000	973000	13.34	53.78
Tab. Lithiu Carbonat – 300mg	0.84	900000	756000	10.37	64.15
Tab. Trihexyphenydil – 2mg	0.18	2000000	360000	4.94	69.08
Tab. Buprenorphin- 0.2mg	2.04	170000	346800	4.76	73.84
Tab. Risperidone – 2mg	0.78	300000	234000	3.21	77.05
Cap. Fluoxetine – 20mg	0.23	1000000	230000	3.15	80.2
Tab. Chlorpromazine – 100mg	0.36	500000	180000	2.47	82.67
Inj. Haloperidol (LA)	93.26	1800	167868	2.3	84.98
Tab. Triguoperazine- 5mg	0.19	700000	133000	1.82	86.8
Tab. Imipramine 25mg	0.26	500000	130000	1.78	88.58
Inj. Fluphenazine – 5mg	10.4	11000	114400	1.57	90.15
Tab. Haloperidol – 5 mg	0.119	800000	95200	1.31	91.46
Tab. Phenytoin Sodium – 100mg	0.14	600000	84000	1.15	92.61

Table 4: Applications of A-B-C analysis

	A Items High consumption value	B Items Moderate value	C Items Low consumption value
1.	Very strict control	Moderate control	Loose control
2.	No safety stocks (or very low)	Low safety stocks	High safety stocks
3.	Frequent ordering or weekly deliveries	Once in 3 months	Bulk ordering once in 6 months
4.	Weekly control statements	Monthly control reports	Quarterly control reports
5.	Maximum follow up and expediting	Periodic follow up	Follow up and expediting in exceptional cases
6.	Rigorous value analysis	Moderate value analysis	Minimum value analysis
7.	As many sources as possible for each item	Two or more reliable sources	Two reliable sources for each item
8.	Accurate forecasts in materials planning	Estimates based on past data on present plans	Rough estimates for planning
9.	Minimization of wastes, obsolete and surplus (review every 15 days)	Quarterly control over surplus and obsolete items	Annual review over surplus and obsolete materials
10.	Individual postings	Small group postings	Group postings
11.	Central purchasing and storing	Combination purchasing	Decentralized purchasing
12.	Maximum efforts to reduce lead time	Moderate	Minimum clerical efforts
13.	Must be handled by senior officers	Can be handled by middle management	Can be fully delegated



2. V-E-D Analysis:

V-E-D Analysis is based on critical values and shortage costs of the items based on their critically, the items could be classified into three categories: Vital, Essential and Desirable.

- a. Vital Items: There are several vital items in the inventory of a hospital which could make the difference between life and death. There can be serious functional dislocation of patient care when such items are not available even for short period adversely affecting the image of the hospital. Such items should always be stocked in sufficient quantity to ensure their constant availability. This group of items should be controlled by top management.
- b. Essential Items: The shortage of such items can be tolerated for a short period. If these items are not available for a few days or a week, functioning of the hospital can be adversely affected. These items should preferably be controlled by top/middle level management.
- c. Desirable Items: The shortage of these items will not adversely affect the patient care or hospital functioning even if the shortage is prolonged items like Vitamins. Desirable items should be controlled by middle/ lower level management.

Table 5. Sample Guidelines for VED categories

Characteristics of Drug or Target Condition	Vital	Essential	Desirable
Occurrence of Target Conditions			
Persons Affected (% of Population)	Over 5%	1-5%	Less than 1%
Persons Treated (No. per day at Average Health Centre)	Over 5%	1-5%	Less than 1
Severity of Target Condition			
Life-threatening	Yes	Occasionally	Rarely
Disabling	Yes	Occasionally	Rarely
Therapeutic Effect of Drug			
Prevents Serious Disease	Yes	No	No
Cures Serious Disease	Yes	Yes	No
Treats Minor, Self-limited Symptoms and conditions	No	Possibly	No
Has Proven Efficacy	Always	Usually	May or may not
Has Unproven Efficacy	Never	Rarely	May or may not

Steps to perform VED Analysis

1. Classify all drugs on the list as V, E, and D.
2. Analyze D items, where possible, reduce quantities to be purchased or eliminate purchases entirely.
3. Identify and limit therapeutic duplication.
4. Reconsider proposed purchased quantities.
5. Find additional funds if needed.



Application of VED Analysis

1. VED classification should be done at regular basis as list is updated regularly and public health priorities also change.
2. Drugs ordering and stock monitoring should be directed at vital and essential drugs.
3. Safety stock should be higher for vital and essential drugs.
4. Enough quantities of vital and essential drugs should be bought first.
5. Procuring and storing of VED drugs ensures all time availability of very essential drugs in health facilities.

Once VED analysis is done, a comparison should be made between the ABC and VED analyses in order to identify whether there is relatively high expenditure on low priority drugs. In particular, effort should be made to delete “D” drug that are in the high cost/high consumption category of the ABC analysis.

3. FSN Analysis:

Classification of materials based on movement i.e. Fast Moving Slow Moving and Non Moving. Sometimes also called as FNS (Fast Moving, Normal Moving and slow moving).

By doing FSN analysis materials can be classified based on their movement from inventory for a specified period. Items are classified based on consumption and average stay in the inventory. Higher the stay of item in the inventory, the slower would be the movement of the material.

F - Fast Moving

S - Slow Moving

N - Non moving

Sometimes the terms FNS is also being used, where

F – Fast Moving

N – Normal Moving

S – Slow Moving

Following steps in doing the FSN analysis

1. Calculation of average stay and the consumption rate of the material in warehouse
2. FSN Classification of materials based on average stay in the inventory
3. FSN classification of the material based on consumption rate

Finally classifying based on above FSN analysis.

Process

Let's take 10 materials for analysis. Following is the analysis of SKU01. Period of analysis is 15 days
Calculation of consumption rate and average stay of the material in the inventory



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Opening Balance: 50

Date	Received Quantity	Returned quantity	Adjustment quantity	Issued quantity	Closing balance	Invoice holding days
1.1.09	10	0	0	0	60	60
1.1.09	15	7	0	15	67	127
1.1.09	0	0	0	0	67	194
1.1.09	0	0	0	0	67	261
1.1.09	0	0	5(+)	0	72	333
1.1.09	20	0	0	0	92	425
1.1.09	0	0	0	12	80	505
1.1.09	0	4	0	0	84	589
1.1.09	0	0	0	0	84	673
1.1.09	10	0	0	7	87	760
1.1.09	0	0	0	0	87	847
1.1.09	0	0	0	12	75	922
1.1.09	0	0	0	0	75	997
1.1.09	10	0	3(-)	0	82	1079
1.1.09	0	0	0	0	82	1161
Total	65	11	2(+)	46	-	-

Average stay of the material = Cumulative No of Inventory Holding Days/(Total quantity received + Opening Balance) =1161/115 =**10.09 Days**

Consumption Rate = Total Issue Qty/Total Period Duration =46/15 =**3.06 Nos./Day**

Now list down the materials with average stay and consumption rate

Item Code	Average stay	Consumption
1	10.09	3.06
2	7.5	5.2
3	8.23	4.71
4	4.2	2
5	6	5.1
6	12	5.76
7	8	3.98
8	9.11	4.48
9	11.2	5.23
10	7.21	4

Now Carry out the FSN analysis on the basis of Average Stay only as below in MS Excel as below by sorting down in descending order of Average stay. Every company has its policy for defining FSN. Here FSN has been taken as F--10%, S-20%, and N -70%

Item Code	Average stay	Cumulative average stay	% average stay	FSN classification
6	12	12	14.36	N
9	11.2	23.2	22.77	N
1	10.09	33.29	39.85	N
8	9.11	42.4	50.75	N



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3	8.23	50.63	60.61	N
2	7.5	66.13	79.16	S
10	7.21	73.34	87.79	S
5	6	79.34	94.97	F
4	4.2	83.54	100	F

Now carry out the FSN classification only on the basis of consumption rate similarly as above

item code	consumption rate	Cum. consumption rate	% consumption rate	FSN classification
6	5.76	5.76	13.24	F
9	5.23	10.99	25.25	F
2	5.2	16.19	37.2	F
5	5.1	21.29	48.92	F
3	4.71	26	59.74	F
8	4.48	30.48	70	F
10	4	34.48	79.23	S
7	3.98	38.48	88.37	S
1	3.06	41.52	95.4	N
4	2	43.52	100	N

Now carry out final classification by combining both as under

FSN (Consumption rate)	FSN (Average stay)	Final FSN classification
F	F	F
F	S	F
F	N	S
S	F	S
S	S	S
S	N	N
N	F	S
N	S	N
N	N	N

Accounting

Stock verification and physical verification is necessary from time to time. There are two methods of undertaking this:

- Annual stock taking method: Physical verification of all the items in all the departments is done once in a year at a simultaneous time. This has to be completed in minimum time as normal work has to be suspended.
- Perpetual inventory method: Verification is carried out by two persons unconnected with the store. This is done almost on a daily basis so that few items are checked every day to ensure that all the store items are checked at least 2-3 times in a year. Any discrepancy between the ledger stocks and actual stocks is immediately investigated.

Accounting of stores is another important aspect of store manager's duties. Many kinds of ledgers for entry of receipts, issue, balances, and their values are maintained. Bin cards as per material code



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numbers are maintained, so that they are readily accessible and brought up-to-date. Flags of different color codes can be mounted on the cards to indicate the stock position to facilitate prompt reordering. Computerization has revolutionized the inventory control methods. It also reduces the paper work. Good software programs are available at affordable prices.

F. Keeping record of drugs and supplies:

Besides, selection, procurement and storage, it is important to keep a record of drugs and supplies that are kept in stock. The basic questions that one should ask are

- a) What items are available
- b) How much is available of each item
- c) How much is used on a regular basis
- d) When and how much of an item should be reordered.

Keeping record helps in ensuring smooth flow of stocks and taking a decision for reordering the supplies.

The minimal information that should be collected on stock records includes-

- a) Product name /description
- b) Stock on hand
- c) Receipts
- d) Issues
- e) Breakage/losses
- f) Closing balance
- g) Transaction references i.e issue voucher numbers/name of supplier.

Stock record should also have additional information such as-

- a) Special storage conditions (e.g. temperature)
- b) Unit prices.
- c) Lot number.
- d) Item code.
- e) Expiry dates.

For an effective drug management /logistics information system it is imperative to have 3 different types of records, like

- a) Stock keeping records
- b) Transaction records
- c) Consumption records

Apart from this certain calculated data items are also to be included in stock records these are

- a) Consumption data (Average monthly consumption)
- b) Lead time for ordering
- c) Maximum and minimum stock levels



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- d) Emergency order point

There are various options for keeping drug and supply records.

- a) Stock card
- b) Bin card
- c) Requisition/issues vouchers
- d) Receiving forms
- e) Deliveries/issue vouchers
- f) Expired stocks disposal forms
- g) List of approved medicines and prices.

Stock Card:

There should be a stock card for each item, to be kept with the item on shelf so that movement of item can be tracked by recording when and how the item is used.

The top of the stock card has the following information

1. Item, name of product including its form and strength.
2. Code number to identify the item.
3. Unit and size of container and the amount contained in.
4. Price and per unit cost.
5. Recorder level (Numbers of units needed in the stock, below which order to be placed).

There are many forms/ strengths in which drugs/ medicines are available, understanding of which is essential for proper stock keeping. These are:

- a) Forms: Tablet/liquid/ointment/injectables.
- b) Strengths: 250 mg/500mg and ilk.
- c) Unit sizes: Pack of 50, 100, 500, or more.

For example:

A store may have-

- a) Tab. Amoxicillin(Dispersible kid tablet)
- b) Cap. Amoxicillin 250 mg
- c) Cap. Amoxicillin 500 mg these may be in loose packing of 500 or 1000 capsules per bottle, or
- d) Amoxicillin dry syrup

For all these different forms and strengths of the same drug-Amoxicillin, it is expected to keep a separate Stock card.



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The columns on a stock card are-

Item: Cap Amoxicillin-250		Unit and Size: Bottle , 1000 capsules			Price:		Code no.: Amoxy cap Reorder level:1000	
Date	Received from	Quantity received	Issued to	Quantity issued	Balance in stock	Remarks	Signature	
					5 X 1000	Carried forward		
8.1.09	CMHO	2 X 1000			7 X 1000			
15.1.09			PHC dispensary	1 x 1000	6 x 1000			
25.1.09			RCH Camp	5 x 1000	1 x 1000	Re-order for supply		

In the “Remarks” column record, the balance brought forward, requisition no. and expiry date of items received apart from reasons for removing expired stock, poor quality or overstocked items.

To keep an accurate stock of drugs and medicines, you are expected to do-

1. Record **date** of receipt
2. Record **from where** drugs are received
3. Record **quantity** received in units
4. Add the **quantity received** to the **previous balance**
5. Keep an accurate **running tally of no. of units** in the “ balance in stock” column
6. **Physically Count** the stock at regular intervals
7. **Investigate**, if physical count and balance do not match-excess or shortage
 - a. Entry of movement not recorded
 - b. Fix up responsibility
 - i. Who was on duty
 - ii. Who had the access to keys
8. See if **stock card is missing**
 - a. Make a new stock card
 - b. Enter in remarks column-“Replacement card” made

Bin Card: It is a record of movement of materials against each kind of stock in respect of daily transaction, which is attached to each bin. It shows daily receipts, issues, balance quantity on hand, maximum and minimum and reorder levels.



Chapter 5: Handling of Drugs

The goals of medical stores management are to protect stored items from loss, damage, theft, of wastage and to manage the reliable movement of supplies from source to user in the least expensive way. Effective use of information is the key to achieving these goals.

Handling of Narcotics/ Schedule Drugs

There are specific procedures in place for the procurement, reception, storage, dispensing, and administration of controlled substances. Special ordering forms should be used.

Secure Storage

Narcotics and other controlled substances should be kept in a secure room or in a safe. The keys to the secure store should be kept in a safe.

Guidelines for Controlled Drug (CD) Procedures in General Practice:

The guideline provides safeguards and procedures that must be adhered to ensure the environment is suitable for storing, handing and administering Controlled Drugs by meeting the required standards recommended by the Drugs & Cosmetics Act. (1945).

Healthcare practitioners must assess their individual competence in all aspects of Controlled Drug procedures ensuring appropriate continuing professional development to achieve or maintain that competence.

Procedure for safe handling of Controlled Drugs (CD)

1. On any CD entry, 2 staff members sign the CD Register, one of which would be a witness.
2. Within the bound book (CD Register) a separate page is used for each dosage form and strength of each drug. This allows keeping a running stock level for each item which can identify any discrepancies
3. Any CD that the Doctor uses outside the General Practice premises, must be transferred from a locked cupboard in the practice to a locked receptacle/bag (a locked car does not constitute as a "locked receptacle"). Once used, the practitioner should return the tablet card/vial bottle used to the Practice premises and sign it into the register with a witness, before discarding it, as soon as possible.
4. Where appropriate, patients should be encouraged to return all drugs for disposal to their local pharmacy.



The Controlled Drugs Register:

If controlled Drugs are kept on the premises, a register must be kept for each premise (not simply the main register).

A record of all controlled Drugs used outside the Practice premises must be entered into the Register, alongside the patient's details (as per normal procedure for such drugs used on practice premises).

The Register should:

1. Be a bound register (not loose-leaf version)
2. Be written in indelible ink
3. Be in chronological order.
4. Have separate sections for each class of drugs.
5. Show the class of drug at the head of each page.
6. Be made on the day of transaction or on the following day.
7. Have no cancellations or obliterations or alterations (corrections must be made in indelible ink in the margin or as a footnote and must be signed and dated).
8. Be kept on the premises to which the register relates and be available for inspection at any time.
9. Be kept safe for 2 years from the date of the last entry.

Drugs Received:

The entries must

1. Show the date received
2. Show the name and address of the person or pharmacy from whom they are received.
3. Show the amount received; show the form and strength in which supplied.

Drugs supplied/administered:

The entries must

1. Show the date on which the supply was made
2. Give the name of the person for whom it was prescribed.
3. Give the name of the practitioner who prescribed the item.
4. Record the amount supplied
5. Show the form and strength in which supplied
6. Two members of staff to sign the register, one of which would be a witness.



Stock Check

Stock levels should be checked once a week (as a minimum) to ensure no CD's are missing and to check expiry dates of all drugs. During this check, two members of practice staff should compare the actual stock with the register within the practice premises.

Regulations also cover security measures to prevent users unlawfully obtaining supplies of drugs and syringes/needles, prescription pads and headed notepaper from surgeries.

Practice staff should be aware of security:

1. Do not leave blank prescription pads 'lying around'; especially in the reception area.
2. Make sure that blank pads are not left unattended on a doctor's desk.
3. Blank prescriptions must never be signed.
4. Prescription pads should be locked away at night, in case of unlawful entry.
5. Doctor's should not use prescription pads as 'spare note pads' in pockets.

Prescribing requirements for controlled drugs

1. Show the doctor's full name (and Registration no.) address and phone no.
2. Hand written in indelible ink - by the Doctor and signed and dated (not computer generated) and clearly stating: the patient's full name, address and, if appropriate, D.O.B, if another family member shares the same name; the name and form of the drug; the strength of a preparation (where appropriate); the dose to be taken; the total quantity to be supplied in words and figures.

Prescriptions for controlled drugs are valid for **14 days only**. It is not permitted to prescribe controlled drugs by the 'repeat' method, as used in non-prescriptions.

Destruction of Controlled Drugs

1. Drugs returned by patients/patient's representatives

- a. Patients should be advised to return all unused controlled drugs for disposal to their local community pharmacist.
- b. Patients should be advised of the caution that they need to take in storing them in their own home. They should also be advised to return any unused stock from their home as soon as possible.
- c. If patients return controlled drugs to the health facility these drugs must not be re-issued. In this event these returned drugs must have the following recorded in the CD-register:
 - i. Date of Return.
 - ii. Each item returned including drug name, form, strength and quantity.
 - iii. The name of the patient they were prescribed to.



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- iv. The signatures of the accepting member of staff and the patient or patient's representative (not staff).
- v. At the earliest possible time, a practice member of staff should return the unused or out of date controlled drugs to the local pharmacy.
- vi. The return of out of date drugs should be documented in the Controlled Drugs register.

2. Procedure for a broken vial

If a vial of Controlled Drug is accidentally broken, it should be entered into the register as with the procedure for giving the drug. "Broken vial" should be entered on the appropriate page, and the entry should be signed by the practitioner who broke the vial and another staff member.

Both staff must then proceed to discard the broken vial into a sharps container.



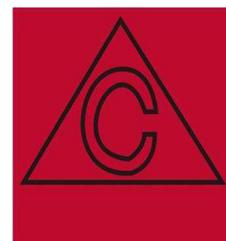
3. Procedure for a missing or unaccounted controlled drug

- a. All practice staff should be made aware that drug is missing
- b. The time and date of the discovery of the missing drug should be entered into the Register on the appropriate page.
- c. The nursing staff should do a spot check count of **all controlled drug stock**
- d. All staff should be notified that there is controlled drug stock missing or unaccounted for.
- e. The Controlled Drug procedure should be reminded to all staff
- f. The staff should be on high alert and increase their stock count procedure to daily (from weekly) to ensure that controlled drugs are not unaccounted for or missing on a regular basis.

Handling of Hazardous Drugs

In terms of occupational exposure, a hazardous drug is defined as an agent that present a danger to healthcare personnel due to its inherent toxicity. These drugs are identified based on one or more of the four following characteristics:

- a. They are carcinogenic (as reported by the International agency for Research on Cancer)
- b. They are genotoxic
- c. They are teratogenic
- d. There is evidence of toxicity at low doses in animal models or treated patients.



Hazardous drug include antineoplastic and cytotoxic agents, immune-suppressants, and antiviral medications. A list of hazardous drugs that special handling should be posted in every facility that provides drug preparation and administration services.



Sources of Hazardous Drug Exposure

Leaks, spills and the creation of aerosols of liquid drugs can occur during dose preparation. The process of priming IV tubing may lead to inadvertent environmental contamination if the priming process is not performed appropriately. In addition, during drug administration, tubing and injection port connections that are not properly secured may lead to leakage of the prepared agent.

Inappropriate disposal of hazardous drugs, either from the clean-up of spills or leaks, or from waste created during drug preparation and administration, can also lead to environmental contamination.

Impact of Hazardous Drug Exposure

Patients undergoing treatment with cytotoxic or hazardous drugs suffer a wide variety of side effects due to the drugs nonselective mechanisms of action. These side effects include diarrhea, nausea, vomiting, hair loss and irritation of the skin and mucous membranes. In addition, secondary tumors have occurred in cancer patients treated with certain antineoplastic agents. The long-term impact of low –level exposure to these antineoplastic agents, however, is unknown. Some epidemiological studies suggest that spontaneous abortions and fetal malformations suffered by nurses who worked in environment in which hazardous drugs were prepared and administered may be related to occupational exposure to these agents.

Suggested Safe Handling Methods

In general, there are three critical elements involved in the safe handling of hazardous drugs. They are personnel, equipment, and strict adherence to policies and procedures.

- 1. Personnel:** Only authorized and adequately trained personnel should receive, prepare, transport, or administer hazardous drugs. A clearly defined orientation and training program should be completed by every employee who may come into contact with a hazardous drug container. Personnel must be made aware of the unique nature of these agents and the potential risks associated with exposure to them. All employees must be educated regarding the appropriate steps to take in the event of accidental exposure to a hazardous drug. Employees who are pregnant or breast-feeding should be reassigned to areas where contact with these drugs will be avoided.
- 2. Equipment:** Class II vertical flow biohazard cabinets, or biological safety cabinets (BSC), are currently recommended for preparing hazardous drugs.

In addition to the use of BSCs, protective apparel and other supplies designed to minimize the risk of exposure to hazardous drugs must be utilized appropriately. All workers involved in the handling of hazardous drugs should wear powder-free, disposable gloves with reasonable thickness, good fit, and adequate tactile sensation. Some published guidelines recommend double-gloving.



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A low-permeability, lint-free disposable protective gown with a closed front, long sleeves, and tight-fitting elastic or knit cuffs should be worn at all times when preparing hazardous drugs. This garment should not be worn out of the immediate drug preparation or administration area.

Proper techniques and supplies designed to aid in the safe preparation of hazardous drugs must be utilized at all times. Syringes and IV administration sets with Luer-Lock type fittings should be used to prepare and administer hazardous drugs to reduce the potential for accidental leaks or separation of the fittings. The development of positive pressure in drug vials and syringes must be avoided to reduce the possibility of drug aerosols being introduced into the workspace.

- 3. Policies and Procedures:** Specific policies and clearly defined procedures are critical in guiding personnel to appropriately handle hazardous drugs. Every employee who comes into contact with hazardous drugs or their containers must be educated regarding departmental policies and procedures, and be routinely evaluated for compliance with these important safety practices.

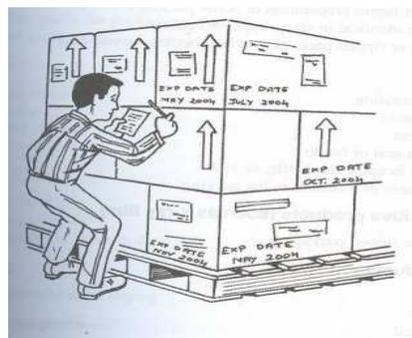
Handling of Expiry Drugs:

Drug store facilities require a sound waste drug handling system to minimize damage to health and the environment caused by their wasted drugs. Waste drug handling system is fruitful to understand different practices and disposal methods.



A comprehensive minimal program includes the following practices:

- 1. A written wasted drugs management plan.** The plan describes all the practices for handling, storing, treating, and disposing of hazardous and non-hazardous waste, as well as types of worker training required. Usually drawn up after doing a comprehensive assessment of waste handling at the facility.
- 2. Clearly assigned staff responsibilities.** Make responsibilities clear so that workers feel accountable for how well tasks are completed and so that no step in the process is overlooked.
- 3. Written internal rules for generation, handling, storage, treatment, and disposal.** Formalize desired practices, as written rules may be better maintained.
- 4. Staff trained in safe handling, storage, treatment, and disposal.** Training is necessary to ensure that staff are aware of all hazards they might meet and that they are practicing good hygiene, safe sharps handling, proper use of protective clothing, proper packaging and labeling of waste, and safe storage of waste





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5. **Protective clothing available.** Workers need specific types of clothing, such as surgical masks and gloves, aprons, and boots, to protect themselves when moving and treating various types of collected infectious wasted drugs.
6. **Good hygiene practices.** Many infectious agents must enter the mouth or be swallowed to cause disease. Even if protective clothing is worn, some organisms will get on workers' hands and faces. Thus, workers need to wash their hands and faces regularly with soap and warm water. They get sick more often when they do not observe good hygiene practices.
7. **Vaccinated workers.** Workers should be vaccinated against potentially deadly viral hepatitis B and tetanus infections.
8. **Temporary storage containers in designated locations.** Hazardous healthcare wastes should be stored only for short periods—less than 24 hrs in the warm season in warm climates Also, they should be put in a labeled, covered container in a fixed location—for example, a specific corner of the room.
9. **Minimization, reuse, and recycling procedures.** The less waste generated, the less there is to manage. Unnecessary disposal of valuable chemicals and pharmaceuticals can be avoided through good inventory practices: for example, by using the oldest batch first by never opening a new container before the last one is finished; by preventing products from being thrown out during routine cleaning; and by checking on delivery to make sure materials are not about to expire.
10. **A waste segregation system.** Segregating (sorting and separating) wasted drugs both reduces the volume of waste and enables different kinds of materials to be handled appropriately
11. **Treatment methods for hazardous and highly hazardous waste.** Treatment options available to drug store facilities for hazardous Identifying and training responsible staff are a first step in the effective management of wasted drugs.

Disposal – Steps and Methods

A series of **steps** need to be taken when disposing of unwanted pharmaceuticals:

1. Decision

The hospital, district or regional pharmacist or organizations with pharmaceutical programs decide when action needs to be initiated, because of an accumulation of unwanted pharmaceuticals which are unfit for human consumption and for veterinary treatment.

2. Approval

Approval and sanctioning of disposal of pharmaceuticals must be sought from the appropriate authority. This authority will differ from country to country and may be the department responsible for pharmaceutical management within the ministry of health, the drug regulatory authority, or the regional or local health authority (pharmaceutical officer).



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3. Planning

Planning, in terms of funding, necessary expertise, human resources, professional time, space, equipment, material and available disposal options will be required. This is essential before practical steps can be taken to start disposal.

4. Forming work teams

Work should be conducted by teams consisting of supervising pharmacists and general medical workers, who are preferably pharmaceutical technicians or experienced pharmaceutical warehouse personnel. The size of each team, and the ratio of experts to workers, will be determined by the volume and composition of the stockpiles, and working conditions at the sites.

5. Health and safety of work teams

All workers should wear appropriate protective equipment including overalls and boots at all times, and gloves, masks and caps when appropriate. Masks should be worn when tablets or capsules are being crushed as part of the disposal technique and when there is a risk of powders being liberated. Particular care is required when handling anti-neoplastics.



6. Sorting

The objective of sorting is to separate the pharmaceuticals into separate categories for which different disposal methods are required. The separation should be made into those that can be safely used and returned to the pharmaceutical supply system and those that require disposal by different methods. For example, controlled drugs (e.g. narcotics), anti-neoplastic drugs and antibiotics all require special methods of disposal. Substantial investment in human resources may be required for identifying and separating pharmaceuticals.

7. Disposal

Disposal options vary considerably between situations, and the ideal solution may not be feasible. The aim of these guidelines is to propose the simplest, safest and most practical alternatives.

8. Security

Controlled substances (e.g. narcotics and psychotropics) require tight security and control. In some countries, scavenging of material from landfills is a frequent problem, and, disposed drugs may be recovered and sold by the scavengers. Measures are therefore necessary to prevent diversion during sorting, and pilfering of drugs from landfills. Immobilization is the best method of preventing pilfering from a store or landfill. If, as a last resort, pharmaceuticals must be discarded direct to a landfill then they must be covered immediately with a large quantity of municipal wastes.



Disposal Methods

1. Burial Pits:

The bottom of the pit should be 1.5 m above the groundwater level, 3-5 m deep, and lined with a substance of low permeability, such as clay. Surround the opening with a mound to keep run-off water from entering the hole, and build a fence around the area. Periodically, cover waste layers with 10-15 cm of soil.

2. Encapsulation:

Cement-lined pits or high-density plastic containers or drums are filled to 75% capacity with health care waste. The container is then filled with plastic foam, sand, cement, or clay to immobilize the waste. The encapsulated waste is then disposed of in a landfill or left in place if the container is constructed in the ground.

3. Incineration:

Medium- and high-temperature incineration devices require a capital investment and an operations and maintenance budget. They operate on fuel, wood, or other combustible material and produce solid ashes and gases. Pollutants are emitted to varying degrees. The ash is toxic and must be buried in a protected pit. Combustible waste is reduced to incombustible waste with a decreased volume.

The high temperatures kill microorganisms:

Medium-temperature incinerators, commonly a double-chamber design or pyrolytic incinerator, operate at a medium-temperature combustion process (800°-1,000°C).

High-temperature incinerators, recommended by WHO, treat health care waste at a temperature >1,000°C. When operated by staff trained in correct use and maintenance, incineration in a device like this one-

- a) completely destroys needles and syringes
- b) kills microorganisms
- c) reduces the volume of waste
- d) generates less air pollution than low-temperature burning.

4. Low-Temperature Burning:

Burning devices not exceeding 400°C include single-chamber brick hearths, drum burners, and burning pits. They burn incompletely and do not fully destroy waste. They may not kill microorganisms. Given these shortcomings, low-temperature burning should be used only as a short-term solution.



5. Burn and Bury:

Pit burning is a low-cost but relatively ineffective means of waste disposal. A fence should surround the pit to prevent children, animals, and others from waste. The pit location should avoid walking paths (high-traffic areas). The fire, usually started with a petroleum-based fuel and allowed to burn, should be



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supervised by designated staff and located down-wind of the facility and residential areas. The low-temperature fire emits pollutants, and the ash and remaining material should be covered with 10-15 cm of dirt.

6. Other Methods:

In addition to the common methods, other methods are used in some settings, including needle removal/needle destruction, melting syringes, steam sterilization (autoclaving and hydroclaving), and microwaving (with shredding).

Table 6: Disposal methods for various categories of pharmaceuticals

Category	Disposal Methods	Comments
Solids Semi-solids Powders	Landfill Waste encapsulation Waste inertization Medium and high temperature incineration (cement kiln incinerator)	No more than 1% of the daily municipal waste should be disposed of daily in an untreated form (non-immobilized) to a landfill.
Liquids	Sewer High temperature incineration (cement kiln incinerator)	Antineoplastics not to sewer.
Ampoules	Crush ampoules and flush diluted fluid to sewer	Antineoplastics not to sewer.
Anti-infective drugs	Waste encapsulation Waste inertization Medium and high temperature incineration (cement kiln incinerator)	Liquid antibiotics may be diluted with water, left to stand for several weeks and discharged to a sewer.
Antineoplastics	Return to donor or manufacturer Waste encapsulation Waste inertization Medium and high temperature incineration (cement kiln incinerator) (chemical decomposition)	Not to landfill unless encapsulated. Not to sewer. No medium temperature incineration.
Controlled drugs	Waste encapsulation Waste inertization Medium and high temperature incineration (cement kiln incinerator)	Not to landfill unless encapsulated
Aerosol canisters	Landfill Waste encapsulation	Not to be burnt: may explode.
Disinfectants	Use To sewer or fast-flowing watercourse: small quantities of diluted disinfectants (max. 50 liters per day under supervision)	No undiluted disinfectants to sewers or water courses. Maximum 50 liters per day diluted to sewer or fast-flowing watercourse. No disinfectants at all to slow moving or stagnant watercourses.
PVC plastic, glass	Landfill	Not for burning in open containers
Paper, cardboard	Recycle, burn, landfill	

Source: WHO. 1999. *Guidelines for Safe Disposal of Unwanted Pharmaceuticals In and After Emergencies*. Geneva: World Health Organization.



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Consequences of Improper Disposal or Non-Disposal

Improper disposal may be hazardous and carry a public health risk.

The main health risks are:

- a. Contamination of drinking water.
- b. Reduced bacterial density in sewerage with non-biodegradable antibiotics, antineoplastics and disinfectants.
- c. Air pollution - release of toxic pollutants into the air during burning.
- d. Possibility of recycling of expired drugs, particularly when packing is intact.

Special handling of Flammables and Corrosives

Flammables:

Common flammables: acetone, anesthetic ether, alcohols (before dilution), and kerosene.

Handling process:

- a. Separate location (not less than 20 m away from the other buildings).
- b. Do not store large quantities.
- c. Keep firefighting equipment ready.
- d. Keep locked in steel cabinet in a well-ventilated area, away from open flames and electrical appliances with international hazard symbol displayed.
- e. Store flammables in their original container.
- f. Storage temperature to be maintained in view of flash point of each flammable.
 - i. Acetone and anesthetic ether have a flash point of -18°C .
 - ii. Undiluted alcohols have a flash point of 18° to 23°C .
 - iii. The flash point for kerosene is 23° to 61°C .

Corrosives

Common corrosives: trichloroacetic acid, glacial acetic acid, concentrated ammonia solutions, silver nitrate, sodium nitrate, and sodium hydroxide pellets.

Handling process:

- a. Store separate from flammables
- b. Store in separate steel cabinet to prevent leakage.
- c. Use appropriate industrial-type protective gloves and eyeglasses when handling these items.



Chapter 6: Drug Quality Assurance

Quality assurance (QA) is a wide-ranging concept covering all matters that individually or collectively influence the quality of a product. It is the totality of the arrangements made with the object of ensuring that pharmaceutical products are of the quality required for their intended use.

Components of QA in medicine:

1. Procurement in conformance to chemical nature and source of active ingredient of raw material.
2. Transport and storage conditions
3. Manufacturing cost
4. Standard Operating Procedures (SOP) and Good Manufacturing Practices (GMP)
5. Compliance with drug management cycle (Selection, Procurement, Distribution, Rational Use)

Various factors contributing to the decline in quality of drugs:

1. Lack of enforcement of existing laws.
2. Weak penal action.
3. High remunerative trade.
4. Ability of improved printing technology that helps counterfeiting.
5. Lack of control by exporting/ importing countries.
6. Too many wholesale and retail outlets.
7. Widespread corruption and conflicting of interests.
8. Lethargic regulatory authorities.
9. Undervaluation of human life.
10. Storage and climatic conditions damage drugs (instability).
11. Raw materials for drugs are of poor quality or counterfeited.
12. Manufacturers do not respect minimum acceptable pharmaceutical requirements. (An extreme case is when the drug does not correspond to the drug mentioned on the label, or when the drug does not contain an active ingredient).
13. The marketing of fake, counterfeit drugs by taking advantage of the original drug's reputation.
14. Drugs are expired.
15. Substandard quality
 - a. Broken Tablets
 - b. Torn packaging
 - c. Placebo packing
 - d. Fake drugs
 - i. Capsules filled with substances such as lactose
 - ii. Directly compressed starches in the form of tablets packed in company branded packaging strips.



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- iii. Expired drugs packaged in attractive containers.
- iv. Injection vials and ampoules filled with original drug look alike aqueous and oily liquids.
- v. Liquids orals such as syrups without containing any medicament.

Consequences of using poor quality drugs

1. Treatment failure,
2. Adverse reactions,
3. Drug resistance,
4. Increased morbidity and mortality.

The Government of India has, therefore, decided to set up an Expert Committee which will look into all these issues with the following Terms of Reference.

1. The setting up of a National Drug Authority.
2. Strengthen the drug regulatory infrastructure in Centre and States.
3. Evaluate the extent of the problem of spurious and sub-standard drugs and recommend measures required to deal with this problem effectively.
4. Recommend changes required in the Drugs and Cosmetics Act, 1940 as well as in judicial procedure related to offences committed under this Act.
5. Recommend steps to be taken by the Pharmaceutical Industry and Pharmacy Association to tackle the problem of spurious drugs.
6. Consider and advise on any other issue incidental to the above.
7. Devise road maps for implementation of all recommended measures.

Steps Necessary for Counterfeiting:

1. Strengthen their drug regulatory authorities and their powers to enforce drug laws and regulations.
2. Re-work the existing law and ensure that the offence is no longer considered a minor offence
3. Suspending or cancelling the licenses of chemist shops selling spurious drugs.

Various agencies, anti-counterfeiting organizations, pharmaceutical companies and security providers are already taking initiatives to solve this problem. The Global Forum provides the first opportunity for those involved in the fight - from government departments and NGOs, public health and regulatory bodies and law enforcer to pharma manufacturers, distributors and authentic suppliers - to collaborate and implement effective solution on both cooperative and international basis.



Chapter 7: Drug Use in Special Situations

The drug prescription requires an adequate assessment of the patient, proper administration of the drug, monitoring and evaluation of its effects and instructions to the patient and/or his or her family in all matters pertaining to the use of drugs. As new drugs and formulations are constantly entering in the clinical practice, unbiased appropriate information is one of the major needs for doctors, pharmacists and nurses.

Response to a particular drug depends on age, sex, race, demographic and genetic distribution and special populations, such as elderly, pregnancy, lactation, children & neonates, psychiatric and physically disabled patients also need extra efforts to achieve successful therapy.

Here we would deal in some physiological states where prescription needs a little more attention.

Elderly

On account of their physiological state, changing with chronological age the elderly population often receives multiple drugs for their multiple diseases; increasing the risk of drug interactions as well as adverse reactions, and may affect compliance; therefore requires caution in prescribing.



The factors that lead to be considered are:

Form of Medicine

Week elderly patients may have difficulty in swallowing tablets; if left in the mouth, ulceration may develop. They should always be encouraged to take their tablets or capsules with enough fluid, and whilst in an upright position to avoid the possibility of esophageal ulceration. It may be helpful to discuss with the patient the possibility of taking the drug as a liquid if available.

Careful diagnosis and prescription

In the very old, manifestations of normal ageing may be mistaken for disease and lead to inappropriate drug use. In addition, age –related muscle weakness and difficulty in maintaining balance should not be confused with neurological disease. Disorders such as light headedness not associated with postural or postprandial hypotension are unlikely to be helped by drugs.

Tendency for self medication

Just as in a younger patient self medication with over the counter products or with drugs prescribed for a previous illness (or even for another person) may be an added complication. Discussion with the patient and relatives may be needed to establish exactly what is being taken.

Sensitivity

The ageing nervous system shows increased susceptibility to many commonly used drugs, such as opioid analgesic, benzodiazepines, antipsychotics, and antiparkinsonian, all of which must be used with



caution. Similarly, other organs may also be more susceptible to the effects of drugs such as antihypertensives and pain killers (NSAIDs).

Pharmacokinetics in relation to organ functions

The most important effect of age is reduction in renal clearance. Many aged patients thus excrete drugs slowly, and are highly susceptible to nephrotoxic drugs. Acute illness may lead to rapid reduction in renal clearance, especially if accompanied by dehydration. Hence, a patient stabilized on a drug with a narrow margin between the therapeutic and the toxic dose (e.g. digoxin) may rapidly develop adverse effects in the aftermath of a myocardial infarction or a respiratory tract infection. The metabolism of some drugs may be reduced in the elderly.

Table 5: Physiological Functions in the Elderly

Age(years)	Kidneys Functions	Cardiac Functions	Maximal Breathing
45-50	100%	80%	85%
60	80%	60%	60%
80	70%	40%	40%

Adverse reactions

Adverse reaction often present in the elderly in a vague and non specific fashion. Confusion is often the presenting symptoms (caused by almost any of the commonly used drugs). Other common manifestations are constipation (with antimuscarinics and many tranquilizers) and postural hypotension and falls (with diuretics and many psychotropics).

Use of Hypnotics

Many hypnotics with long half lives have serious hangover effects of drowsiness, unsteady gait (manner of walking and running), and even slurred speech and confusion. Short courses of hypnotics are occasionally useful for helping a patient through an acute illness or some other crisis but every effort must be made to avoid dependence. Benzodiazepines impair balance, which many result in falls especially when they get up at night. Ask to the patient to sit at the corner of a bed for a while and then get up.

Diuretics

Diuretics are over prescribed in old age and should not be used on a long term basis to treat simple gravitational oedema which will usually respond to increased movement, raising the legs, and support stockings. A few days of diuretic treatment may speed the clearing of the oedema but it should rarely need continued drug therapy.

NSAIDs

Bleeding associated with aspirin and other NSAIDs is more common in the elderly who are more likely to have a fatal or serious outcome. NSAIDs are also a special hazard in patients with cardiac disease or renal impairment which may again place older patients at particular risk.



Other Drugs

Others drugs which commonly cause adverse reactions are antiparkinsonian drugs, antihypertensive, psychotropics and digoxin. The usual maintenance dose of digoxin in very old patients is 125 micrograms daily (62.5 micrograms in those with renal disease): lower doses are often inadequate but toxicity is common in those given 250 micrograms daily.

Drug induced blood disorders are much more common in the elderly. Therefore drugs with a tendency to cause bone marrow depression (e.g. co-trimoxazole, mianserin) should be avoided unless there is no acceptable alternative.

General guidelines for prescription in elderly

1. First always question whether a drug is indicated at all.
2. Write full instructions on every prescription (including repeat prescriptions) so that containers can be properly labeled with full directions. Avoid imprecision's 'as directed'. Child resistant containers may be unsuitable. A family member may also be kept instructed.
3. Instruction to patient what to do when drugs run out, and also how to dispose off any that are no longer necessary. Try to give matching quantities.

If these guidelines are followed most elderly people will cope adequately with their own medicines, if not then it is essential to enroll the help of a third party, usually a relative or a friend.

Children

Children, and particularly neonates, differ from adults in their response to drugs. Special care is needed in the neonatal period (first 30 days of life) and doses should always be calculated with care. At this age, the risk of toxicity is increased by inefficient renal filtration, relative enzyme deficiencies, differing target organ sensitivity, and inadequate detoxifying systems causing delayed excretion. Whenever possible, painful intramuscular injections should be **avoided** in children.



Adverse Drugs Reactions

The reporting of all suspected adverse drug reactions in children is strongly encouraged. The identification and reporting of adverse reactions to drugs in children is particularly important because:

1. The action of the drug and its pharmacokinetics in children (especially in the very young) may be different from that in adults.
2. Drugs are not extensively tested in children before marketing.
3. Many drugs are not specifically licensed for use in children and are used 'off-label' e.g. use of fluoroquinolones in children.
4. Suitable formulations may not be available to allow precise dosing in children.



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5. The nature and course of illnesses and adverse drug reactions may differ between adults and children.
6. State the strengths of capsules or tablets.
7. Prefer sugar free medicines for long term treatment.
8. Use oral syringe of the quantity to be administered is less than 5 ml.
9. Do not add medicines to infant feed (possibility of drug interaction).
10. Keep medicines out of reach of children.

Dosage in Children

Dosages are generally based on body –weight (in kilograms) or the following age ranges:

1. First month (neonate)
2. Up to 1 year (infant)
3. 1-5 years
4. 6-12 years

Unless the age is specified, the term 'child' includes persons aged 12 years and younger.

Dosage Calculation

Children's doses may be calculated from adult dose by using age, bodyweight, or body- surface area, or by a combination of these factors. The most reliable methods are those based on body- surface area.

- **Body-weight** may be used to calculate doses expressed in mg/kg. Young children may require a higher dose per kilogram than adults because of their higher metabolic rates. Other problems need to be considered. For example, calculation by body weight in the obese child may result in much higher dose being administered than necessary; in such cases, dose should be calculated from an ideal weight related to height and age.
- **Body-surface area (BSA)** estimates are more accurate for calculation of pediatric doses than body weight since many physiological phenomena correlate better to body–surface area. The average body surface area of a 70- kilogram human is about 1.8 m². Thus, to calculate the dose for a child the following formula may be used:

Approximate dose for patient = surface area of patient (m²)/1.8 = adult dose

Dose Frequency

Antibacterial are generally given at regular intervals throughout the day. Some flexibility should be allowed in children to avoid waking them during night. For example, the night-time dose may be given at the parent's bed –time.

Where new or potentially toxic drugs are used, the manufactures recommended dose should be carefully followed.



Pregnancy

During pregnancy the mother and the fetus form a non –separable functional unit. Maternal well- being is an absolute prerequisite for the optimal functioning and development of both parts of this unit. Consequently, it is important to treat the mother whenever needed while protecting the unborn to the greatest possible extent.

Drugs can have harmful effects on the fetus at any time during pregnancy. It is important to remember this when prescribing for a woman of childbearing age. However, irrational fear of using drugs during pregnancy can also result in harm. This includes untreated illness, impaired maternal compliance, sub-optimal treatment and treatment failures.



Such approaches may impose risk to maternal well- being, and may also affect the unborn child. It is important to know the 'background risk' in the context of the prevalence of drug-induced adverse pregnancy outcomes. Major congenital malformations occur in 2-4% of all live births. Up to 15% of all diagnosed pregnancies will result in fetal loss. The cause of these adverse pregnancy outcomes is understood in only a minority of the incidents.

During the first trimester, drugs may produce congenital malformations (spermatogenesis), and the greater risk is from third to the eleventh week of pregnancy. During the second and third trimester drugs may affect the growth and functional development of the fetus or have toxic effects on fetal tissues. Drugs given shortly before term or during labour may have adverse effects on labour or on the neonate after delivery. Few drugs have been shown conclusively to be teratogenic in man but no drug is safe beyond all doubt in early pregnancy. Screening procedures are available where there is a known risk of certain defects.

If possible counseling of women before a planned pregnancy should be carried out including discussion of risk associated with specific therapeutic agents, traditional medicines, and abuse of substances such as smoking and alcohol. Folic acid supplements should be given during pregnancy planning because per conceptual use of folic acid reduces neural tube defects.

Drugs should be used in pregnancy only if the expected benefits to the mother are thought to be greater than the risk to the fetus. All drugs should be avoided if possible during the first trimester. Drugs which have been used extensively in pregnancy and appear to be usually safe should be prescribed in preference to new or untried drugs and the smallest effective dose should be used. Well known single component drugs should usually be preferred to multi-component drugs.

Breastfeeding (Lactation)

Administration of some drugs (for example, ergotamine) to nursing mother may harm the infant, whereas administration of others (for example, digoxin) has little effect. Some drugs inhibit lactation (for example, estrogens).



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Toxicity to the infant can occur if the drug enters the milk in pharmacologically significant quantities. The concentration in milk of some drugs (for example, iodides) may exceed in the maternal plasma so that therapeutic doses in the mother may cause toxicity to the infant. Some drugs inhibit the infant's sucking reflex (for example, Phenobarbital). Drug in breast milk may, at least theoretically, cause hypersensitivity in the infant even when the concentration is too low for a pharmacological effect.

For many drugs insufficient evidence is available to provide guidance and it is advisable to administer only drugs essential to a mother during breastfeeding. Because of the inadequacy of information on drugs in breast milk the above stated Appendix should be used only as a guide; absence from the table does not imply safety. It is WHO (World Health Organization) policy to encourage breastfeeding whenever possible, particularly in situations where there is no safe alternative.

Psychiatric Patients

This class of patients is required to be treated with specific care and more so sympathetically. Quite often they are unable to follow the instructions fully and sometimes on account of negative mental orientation may deliberately avoid compliance to therapy. Therefore, it is always important to show empathy with such patients, provide assurance of support and care and keep their moral boosted up with constant motivation. As treatment is usually longer, it is important to infuse the feeling in their minds that regular compliance to the medications will help them to return to the normal life.



Administration of medicines at appropriate time, dosage, and duration must be ensured by the carrying nursing staff for indoor patients and relatives/ attendants of psychiatric patients being treated at home. Medicines shall always be kept away from the patients in order to prevent over-indulgence, misuse or abuse of medicines. Repeats shall always be allowed only in consultation with a treating doctor.

Physically Challenged

This class of patients includes blind, deaf and dumb, in addition, to handicapped patients. These patients deserve a sympathetic behavior from the caring nursing staff or their kith and kins attending the patients. Depending upon the disability, the patients are to be dealt in the specific manner. While blind patients may be administered medicines by a nurse or an attendant, deaf and dumb patients can be instructed with appropriate verbal and body language for proper use of medicines. Physically handicapped patients may be provided medicines in such a way, so as to cause least physical stress while seeking and taking medicines.





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Patient Counseling:

The health worker should be able to give the patient additional information to re-enforce the right instructions. This should be in a language that is familiar to the patient. The information in the form of verbal instructions should including the following:

- a) How often to take the drug,
- b) When to take the drug (e.g. before or after the meals),
- c) How long the treatment is to last (e.g. why the entire course of an antibiotic treatment must be taken),
- d) How to take the drug (e.g. with water, chewing or swallowing),
- e) How to store the drug (e.g. avoid heat, light and dampness),
- f) Not to share drugs with other persons. (Keep drugs out of the reach of children.)



General drug and patient information to be provided when counseling patients includes the following:

- 1. Make sure the doctor(s) know about every drug the patient is taking, including prescription and non-prescription drugs, herbal products and any dietary supplements, including vitamins and minerals;
- 2. Only take medication that has been specifically prescribed.
- 3. Concurrent use of alcohol with medicine should be avoided.
- 4. Consuming excessive quantities of chocolate and beverages containing caffeine (coffee, tea, colas) should be avoided; and
- 5. If the patient has any questions or concerns about the medicine or believe that an adverse drug reaction or drug interaction is there, the pharmacist or physician should be consulted immediately.

Chapter 8: Antimicrobials – Use and Resistance

As all infections are potential threats to life, antibiotics are life-saving instruments, comparable to mechanical ventilation, dialysis and other advanced life-support devices. They are largely responsible for improved quality of life and increased life expectancy.

Irresponsible and erratic use of these life-saving instruments has resulted in the development of drug resistance in many organisms and deaths due to hospital-acquired infections are on the rise.

Organisms have become resistant to the antimicrobials due to use, overuse and misuse by health professionals, quacks, and by patients themselves. Pharmacists, nurse, chemists do not educate patients on proper use of antimicrobials as they too have no knowledge about it.



Why antimicrobials are over-prescribed?

1. Inability to make a fairly accurate clinical diagnosis.
2. Inability to convince the patient about the nature and simplicity of the illness and about the non-requirement of antibacterials.
3. Misconception to give "something powerful" for every patient so as to achieve "dramatic" results (Shot Gun therapy).
4. Fear of law-suits for 'negligence' ('act of omission') and hence 'defensive' practice may also be another reason.
5. Fear that if they do not prescribe, their 'next door' colleague may prescribe these 'powerful' drugs and get all the credit for 'curing' the patient.
6. Patient may pressurize under half-knowledge to prescribe for antibacterials so as to get better at the earliest.
7. Selling pressures from pharma houses.

The three most common situations for antibiotic abuse

It has been observed that the three commonest reasons for prescribing antibacterials are fever, sore throat and diarrhoea. In all these three situations, antibiotics are most often prescribed unnecessarily. Viruses being more abundant, these diseases are also most often due to the viral infections and antibacterials have no role to play in their management. Use of antibacterials, in non-bacterial illness result only in the destruction of susceptible bacteria and selective proliferation of resistant bacteria; thus aiding to the propagation of bacterial drug resistance.

Since the organisms are not killed by antimicrobial, it results into

- a) therapeutic failure, as patient's disease is not cured;



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- b) one may have to use latest and expensive antimicrobials increasing the cost of treatment;
- c) patient may only get adverse drug reactions and no therapeutic response; and
- d) quality of life is worsened due to therapeutic failure.

Rational Use of Antibiotics

Antibiotics are the most important weapons in our hands. Each one of them has been invented after spending considerable amount of time, energy and money. Therefore, we cannot afford to lose them. We must exercise considerable restraint in prescribing antibacterials and restrict the use of antibacterials to only certain definite indications.

Indications for antibacterial therapy:

1. **Definitive therapy:** Attempts should be made to confirm the bacterial infection by means of staining of secretions/fluids/exudates, culture and sensitivity, serological tests and other tests. Based on the reports, a **narrow spectrum, least toxic, easy-to-administer and cheap drug** should be prescribed.
2. **Empirical therapy:** Empirical antibacterial therapy should be restricted to critical cases, when time is inadequate for identification and isolation of the bacteria and reasonably strong doubt of bacterial infection exists: septicemic shock/ sepsis syndrome, immunocompromised patients with severe systemic infection, hectic temperature, neutrophilic leukocytosis, raised ESR etc. In such situations, drugs that cover the most probable infective agent/s should be used.
3. **Prophylactic therapy:** Antimicrobial prophylaxis is administered to *susceptible patients* to prevent *specific infections* that can cause *definite* detrimental effect. These include antitubercular prophylaxis, anti rheumatic prophylaxis, anti endocarditis prophylaxis and prophylactic use of antimicrobials in invasive medical procedures etc. In all these situations, only narrow spectrum and specific drugs are used. It should be remembered that there is NO single prophylaxis to 'prevent all' possible bacterial infections.

Which antibacterial?

There are more than 100 antibacterials available today, and each one has its own spectrum of activity, adverse effect profile and cost. The doctor should consider many factors before prescribing an antibacterial agent so as to make the treatment most effective with least adverse effects and cost.

The following factors should be considered while prescribing an antibacterial agent:

1. Site of infection
2. Type of infection
3. Severity of infection
4. Isolate and its sensitivity



5. Source of infection
6. Host factors
7. Drug related factors

1. **Site of infection:**

As a *Rule Of The Thumb*, it can be remembered that the infections above the diaphragm are caused by Cocci and Gram positive organisms and infections below the diaphragm are caused by Bacilli and Gram negative organisms, although there are exceptions.

2. **Type of infection:**

Infections can be localized or extensive; mild or severe; superficial or deep seated; acute, sub acute or chronic and extracellular or intracellular. For extensive, severe, deep seated, chronic and intracellular infections, higher and more frequent dose, longer duration of therapy, combinations, lipophilic drugs may have to be used.

3. **Severity of infections:**

Bacteremia / pyemia / sepsis syndrome / septic shock; abscesses in lung/ brain/ liver/ pelvis/ intra-abdominal; meningitis/ endocarditis/ pneumonias/ pyelonephritis/ puerperal sepsis; severe soft tissue infections / gangrene and hospital acquired infections can be life threatening and rapidly fatal. In such situations the drug absorption, distribution and excretion could be altered due to tissue hypoxia, changes in hemodynamics, renal and hepatic perfusion, GI absorption etc. The drug dynamics can also be altered due to acidosis, altered permeability, presence of hydrolysing enzymes at the site of infection etc. Also in such situations, possibility of infection with multiple organisms and of drug resistance makes the choice difficult. In all such situations therefore, attempts should be made to identify and isolate the infecting organism from the site as well as blood by staining (of infected specimen and buffy coat smear) and culture (of infected specimen and two specimens of blood). In treating the severe infections, drugs should be administered by only intravenous route to ensure adequate blood levels. Only bactericidal drugs should be used to ensure faster clearance of the infection. If the site of infection is known, narrow spectrum drugs should be used. If the site is unknown, attempt should be made to cover all possible organisms, including drug resistant *Staphylococcus*, *Pseudomonas* and anaerobes. A combination of penicillins/3rd generation cephalosporins, aminoglycosides and metronidazole may be used. The dose should be higher and more frequent. Whenever possible, a switch to oral therapy should be made.

4. **Isolate and sensitivity:**

Ideal management of any significant bacterial infection requires culture and sensitivity study of the specimen. If the situation permits, antibacterials can be started only after the sensitivity report is available. Narrow spectrum, least toxic, easy to administer and cheapest of the effective drugs



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should be chosen. If the patient is responding to the drug that has already been started, it should not be changed even if the in vitro report suggests otherwise.

5. **Source of infection:**

Community acquired infections are less likely to be resistant whereas hospital acquired infections are likely to be resistant and more difficult to treat (e.g. *Pseudomonas*, MRSA etc.).

6. **Host factors:**

Age of the patient, immune status, pregnancy and lactation, associated conditions like renal failure, hepatic failure, epilepsy etc. should be considered in choosing the antibacterial agent.

7. **Drug factors :**

- a) **Hypersensitivity:** If the patient has prior history of hypersensitivity the concerned antibacterial agent should be avoided. It is therefore important to elicit this history in all patients.
- b) **Adverse reactions:** Certain adverse reactions warrant discontinuation of therapy and the doctor should adequately educate the patients on these adverse effects.
- c) **Interactions:** Interactions with food and other concomitant drugs should be considered before instituting antibacterial therapy so as to maximize efficacy and minimize toxicity.
- d) **Cost:** The cost of therapy should be considered in choosing the antibacterial agent and in a developing country like India with limited spending on healthcare, this does assume significance. It should always be remembered that just because a particular drug is expensive, it need not be superior than the cheaper ones. For example, cheaper drugs like doxycycline or co-trimoxazole would be as effective as the costlier clarithromycin or cephalosporins in the management of LRTI.

Methods of administration of antimicrobials

Route of administration: The route of administration depends on the site, type and severity of the infection and the availability of a suitable drug.

- a) **Oral route** is the most preferred, easy and cheap, but it may not be reliable in all circumstances, particularly in patients with severe infections, non-compliant patients, in the presence of vomiting etc.
- b) **Intramuscular route** should be generally restricted for the administration of procaine and benzathine penicillin and single shot of ceftriaxone; the absorption is not very reliable and it is painful and disliked by the patients.
- c) **Intravenous route** is the best for the management of severe and deep-seated infections since it ensures adequate serum drug





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levels. Procaine penicillin and benzathine penicillin should never be given I.V. However, some drugs are not available for parenteral use (e.g. most macrolides, sulfa, tetracyclines).

- d) **Topical:** Antibacterials are also used topically, but drugs used for systemic administration should not be used in skin ointments.

Dosage: Dose depends on the age of the patient, weight of the patient, associated conditions like pregnancy, renal and hepatic failure and site, type and severity of infection. Generally the dose should be higher in cases of severe, deep-seated infections and in pregnancy and lower in cases of renal failure. While unnecessary overdosage only adds to the cost and adverse effects, there should not be any compromise on adequate dose.

Frequency of administration: The drug should be administered 4-5 times the plasma half-life to maintain adequate therapeutic concentrations in the serum throughout the day. Frequency can be increased in cases of severe, deep seated and sequestered infections and reduced in cases of renal and hepatic failure.

Duration: Duration of therapy depends on the site, type and severity of infection. (e.g. Tonsillitis-10 days; bronchitis-5-7 days; UTI-single shot to 21 days; lung abscess-2-8 weeks; tuberculosis-6-24 months etc.).

Combinations: Judicious and intelligent combination of different antibiotics can be very useful in treating certain difficult infections and in preventing or overpowering resistance. On the other hand irrational and unnecessary combinations can add to the cost and adverse effects and help in the development of drug resistance.

Antibacterial combinations can be useful in the following situations:

1. **To sharpen the effect:** Synergistic combination of two static drugs - e.g. Combination of Trimethoprim and Sulfamethoxazole - Co-Trimoxazole
2. **Treatment of infections with multiple organisms:** Mixed infections in lung abscess, peritonitis, soiled wounds etc., naturally require multiple antibiotics for complete clearance of the infection - Penicillins (for gram positive and certain anaerobes) + Aminoglycosides (for gram negative); metronidazole for bacteroides etc.
3. **To prevent resistance:** Use of combinations is a well known method of preventing drug resistance. The classic example is the antitubercular therapy.
4. **To overcome resistance:** Combination of specific drugs can be useful in overcoming the resistant infections. Examples include Penicillins + β lactamase inhibitors/ β lactamase resistant penicillins for *S. aureus*; Penicillins/cephalosporins + aminoglycosides for *Pseudomonas* etc.

Resistance to Antimicrobial Agents

Resistance to antimicrobial agents is one of the greatest problems faced by the medical community. These powerful weapons, developed by spending millions and years of dedicated research, have been



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rendered less effective or totally ineffective only because of our own negligence and complacency. This is indeed frustrating.

Factors contributing to antimicrobial resistance:

- a) Used by too many people to treat the wrong kind of infection,
- b) in the wrong dosage and ,
- c) For the wrong period of time in both industrialized and developing countries.
- d) Poverty, overcrowding, have all contributed in spreading the resistant bacterial infection.
- e) Size of the high immune-compromised population,
- f) The increased frequency of invasive medical interventions and
- g) Prolonged survival of patients with chronic debilitating disease.

Resistance to antimicrobial agents can be due to various mechanisms:

- a) Inability of the drug to reach the organisms
- b) Inactivation of the drug
- c) Alteration in the target
- d) Mutation In Organisms Passed Onto The Next Generations.
- e) Horizontal transfer from a donor cell by transformation, transduction or conjugation.

Resistance to antimicrobials can be contained by promoting rational use of antimicrobials i.e. patients receive antimicrobials appropriate to their clinical needs, in doses that meet their own requirement for an adequate period of time at a lowest cost to them and the community. Resistance can also be contained by:

- a) Isolating patients infected with resistant microorganisms.
- b) Hand hygiene and personal protective devices.
- c) Proper biomedical waste management.
- d) Constituting Infection Control Committee.
- e) Issuing guidelines for use of antimicrobials (Antibiotic Policy).
- f) Antimicrobial use surveillance.

Control of use of antimicrobial agents: The following methods can be used to control the use of antimicrobial agents in hospitals: Education programs like staff conferences, lectures and audiovisual programs; availability of clinical pharmacist consultants; control of contact between pharmaceutical representatives and staff physicians and of various sponsorships from companies; restriction of hospital formulary to minimum number of agents needed for most effective therapy; availability of diagnostic microbiology laboratory sensitivity tests and appropriate selection of sensitivity tests for organism and site; automatic stop orders for specific high-cost agents and written justification for high-cost agents etc.



Chapter 9: Adverse Drug Reactions

Some common terms:

- a. **Unexpected Adverse Reaction:** An adverse reaction, the nature or severity of which is not consistent with domestic labeling or market authorization, or expected from characteristics of the drug.
- b. **Serious Adverse Event or Reaction:** A serious adverse event or reaction is any untoward medical occurrence that at any dose:
 - i. results in death
 - ii. requires inpatient hospitalization or prolongation of existing hospitalization
 - iii. results in persistent or significant disability/incapacity
 - iv. is life-threatening

Note: To avoid any confusion or misunderstanding of the difference between the terms 'serious' and 'severe', the following note of clarification is provided:

The term 'severe' is not synonymous with serious. 'Severe' is used to describe the intensity (severity) of a specific event (as in mild, moderate or severe); the event itself, however, may be of relatively minor medical significance (such as severe headache).

Seriousness (not severity) which is based on patient/event outcome or action criteria serves as guide for defining regulatory reporting obligations.

- c. **Side Effect:** Any unintended effect of a pharmaceutical product occurring at doses normally used in man which is related to the pharmacological properties of the drug.
- d. **Adverse Event / Adverse Experience:** Any untoward medical occurrence that may present during treatment with a pharmaceutical product at the same time does not necessarily have a causal relationship with this treatment.
- e. **Signal:** Reported information on a possible causal relationship between an adverse event and a drug, the relationship being unknown or incompletely documented previously. Usually more than a single report is required to generate a signal, depending upon the seriousness of the event and the quality of the information.

National Pharmacovigilance Program (NPP): The nation-wide Program, sponsored and coordinated by the country's central drug regulatory agency – Central Drugs Standard Control Organization (CDSCO) – to establish and manage a data base of Adverse Drug Reactions (ADR) for making informed regulatory decisions regarding marketing authorization of drugs in India for ensuring safety of drugs.

Peripheral Pharmacovigilance Centers (PPC): Primary pharmacovigilance centers. Relatively smaller medical institutions including individual medical practitioners' clinics, private hospitals, nursing homes,



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pharmacies etc. First contact ADR data collection unit at a health care facility. They would be identified and coordinated by RPCs / ZPCs in consultation with CDSCO.

Regional Pharmacovigilance Centers (RPC): Secondary pharmacovigilance centers. Relatively larger healthcare facilities attached with medical colleges. They would act as second level centers in the administrative structure of the NPPI. They will function as first contact ADE data collection units also. They would be identified and coordinated by ZPCs in consultation with the CDSCO.

Zonal Pharmacovigilance Centre (ZPCs): Tertiary pharmacovigilance centers. Large healthcare facilities attached with medical colleges in metro cities identified by the CDSCO for the purpose. They would act as third level centers in the administrative structure of the NPPI. They will function as First contact ADE data collection units also.

Coordinator: Designated in-charge of a particular participating Pharmaco-vigilance centre

Investigator: A healthcare professional involved in investigation of drug related adverse events.

Notifier: Any person who suspects to have experienced / observed an ADE and informs any participating Pharmacovigilance centre about it.

Reporter: A healthcare professional reporting ADR on the ADR form.

Monitoring: The process of overseeing drug related adverse events at the Pharmaco-vigilance centre participating in the Pharmaco-vigilance Program.

Reporting: The process of providing ADR information by filling in the ADR form appropriately and forwarding the same to the appropriate level.

Notification: Process of informing by a notifier to any participating pharmacovigilance centre about the occurrence of a suspected ADR. The process may involve informing over telephone, in person, email, fax or any other means of communication-verbal or written. All notifiers must give their contact details. Appropriate and adequate measures must be taken to keep track of the notifier. Any follow up action will be initiated on a notification only after the due verification of the notifier. If the notifier cannot be traced back, it will be recorded on the notification slip before closing the case.

Notification slip: A pre-designed structured form made available by the NPPI for written communication of a suspected ADR by the notifier duly signed by him/her wherever feasible.

ADR Form: It's the pre-designed structured form issued by NPPI to record ADR.

Archiving: This is to be done at the Regional / Zonal Centers for a period of 5 years

Audit: A systematic and independent examination (conducted by personnel, independent of the centre) of center's activities and documents to determine whether center's activities were conducted and the data were recorded, analyzed and accurately reported according to the protocol



Adverse Drug Reactions

All medicines are capable of producing adverse effects along with desired therapeutic response. Adverse effects may either develop promptly or after prolonged medication use or even after stoppage of medicines. An incidence of 10-20% adverse drug reactions has been documented in different settings

Adverse drug reactions (ADR) are defined as "an appreciably harmful or unpleasant reaction, resulting from an intervention related to the use of a medicinal product, which predicts hazard from future administration and warrants prevention or specific treatment, or alteration of the dosage regimen, or withdrawal of the product."



FDA Definition - Any adverse event associated with the use of drugs in humans whether or not considered drug related including the following:

- a. an adverse event occurring in the course of the use of drug in professional practice
- b. an adverse event from drug overdose whether accidental or intentional
- c. an adverse event occurring from drug abuse
- d. an adverse event from drug withdrawal
- e. any significant failure of expected pharmacological action

WHO Technical Report (1972): "A response to a drug which is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function."

In simpler words, an ADR is an expression that describes harm associated with the use of given medications at a normal dose. The study of ADRs is the concern of the field known as pharmacovigilance.

ADR- Types and Severity

Types

1. **Type A (Augmented) Reaction:** are those related to the exaggerated pharmacological effects of the drugs and tend to be fairly common (usually more than 1 in 100), dosage related (more frequent and more severe at higher dosage) and may often avoided by using dosages that are appropriate for the individual patients e.g., hypoglycemia with insulin, constipation with morphine. Type A reactions are usually reproducible and can be studied experimentally.
2. **Type B (Bizarre) Reactions:** are those that are unexpected and unpredictable and often related to patient factors like genetic predisposition, allergy etc. they occur in a minority of the patients (say less than 1 per 100), are often serious, may show little or no relationship with dosage and may be difficult to detect. Those reactions are often suspected with their relationship to time and a low background frequency.



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3. **Type C (Chronic) Reactions:** which are due to long term use of a drug, e.g., tardive dyskinesia with neuroleptics, analgesic nephropathy etc.
4. **Type D (Delayed) Reactions:** e.g., teratogenesis, carcinogenesis like clear cell carcinoma of the female reproductive tract in matured women whose mothers have received diethylstilbestrol during pregnancy.
5. **Type E (End of use) Reactions:** which occur when the discontinuation of the drug is too abrupt, especially after long term therapy with the drug e.g., adrenocortical insufficiency due to sudden withdrawal of corticosteroids, rebound hypertension after sudden withdrawal of Clonidine.

Severity of ADRs:

ADRs are divided into three categories viz., (a) Mild, (b) Moderate, and (c) Severe.

Mild ADRs: The ADR is considered to be mild when it does not need any treatment. It does not cause any intolerable discomfort to the patient and sometimes tolerance develops to such reaction viz., drowsiness with antihistamine, patient will gradually develop tolerance to the sedative action of antihistamine.

Moderate ADRs: ADR is considered to be moderate, when there is a need to change the medicine or even the development of ADR needs treatment and may prolong the stay of patient in the hospital.

Severe ADRs: They are potentially life threatening ADRs and need hospitalization or may cause permanent damage to some organ(s).

An adverse reaction may be tolerated to obtain a necessary therapeutic effect, or it may be hazardous and unacceptable and require discontinuation of the drugs. Some adverse reactions subside with continuous use viz., drowsiness caused by paroxetine and orthostatic hypotension caused by prazosin usually subside after some days as the patients develops tolerance to these effects. However, many adverse reactions are dosage related and disappear only if the dose is reduced.

An adverse event can be classified as:

1. **Highly Probable:** The event follows a reasonable temporal sequence from administration of the drug and is confirmed by positive de-challenge and positive re-challenge.
2. **Probable:** The event follows a reasonable temporal sequence from administration of the drug; is confirmed by de-challenge and is not reasonably explained by the known characterization of patient's clinical state.
3. **Possible:** The event follows a reasonable temporal sequence from administration of the drug and follows a known response pattern to the suspected drug but could have been produced by the patient's clinical state or other modes of therapy administered to the patient.



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4. **Remote:** Any event that does not meet the above criteria especially if the event has no temporal association with use of the drug. Ideally an adverse reaction of a drug should have a profile consisting of the following elements:

- a) Manifestation
- b) Severity and seriousness
- c) Mechanism of action
- d) Frequency of occurrence
- e) Casualty
- f) Predisposing factors
- g) Therapy if any
- h) Reversibility or sequelae

Table 7: Examples of adverse effects associated with specific medications

Condition	Substance
Abortion, miscarriage or uterine hemorrhage	Misoprostol (Cytotec), a labor-inducing drug (this is a case where the adverse effect has been used legally and illegally for performing abortions)
Addiction	Many sedatives and analgesics such as diazepam, morphine, etc.
Birth defects	Thalidomide and Accutane
Bleeding of the intestine	Aspirin therapy
Cardiovascular disease	COX-2 inhibitors (i.e. Vioxx)
Deafness and kidney failure	Gentamicin (an antibiotic)
Death, following sedation	Propofol (Diprivan)
Stroke or heart attack	Sildenafil (Viagra) when used with nitroglycerine

Drugs frequently causing Allergic Reactions

- Penicillin
- Cephalosporin
- Sulphonamide
- Tetracycline
- Quinolones (Ciprofloxacin)
- Anti-tubercular drugs
- Local anesthetics
- Salicylates
- ACE inhibitors
- Carbamazepine

Most drugs produce several effects, but usually only one effect—the therapeutic effect—is wanted for the treatment of a disorder. The other effects may be regarded as unwanted, whether they are intrinsically harmful or not. For example, certain antihistamines cause drowsiness as well as control the symptoms of allergies. When an over-the-counter sleep aid containing an antihistamine is taken, drowsiness is considered a therapeutic effect. But when an antihistamine is taken to control allergy symptoms during the daytime, drowsiness is considered an annoying, unwanted effect.



Monitoring of Adverse Drug Reaction:

The discovery of the adverse drug reaction (ADR) profile of a new drug prior to marketing lies entirely within the sphere of the pharmaceutical company and therefore, they have the responsibility for providing adequate information on a new drug. After a drug is marketed, the responsibility for extending the knowledge of the adverse reactions of a new drug spreads to all the prescribers of that drug, as well as to specific organizations set up for that purpose.

There are several algorithms for establishing casual relationship between drug administration and an event. All these include the following criteria:

- a) A temporal relationship between the suspected drug and the adverse event.
- b) Improvement after removal of the drug.
- c) Recurrence of the adverse event when administration of the drug is resumed, i.e., positive re-challenge
- d) The lack of confounding effect i.e., the event is unlikely to be due to concomitant disease.

How to recognize ADRs:

The following step-wise approach helps in assessing possible drug related ADRs:

- a) Ensure that the medicine ordered is the medicine received and actually taken by the patient at the dose advised;
- b) Verify that the onset of suspected ADR was after the drug was taken, not before and discuss carefully the observations made by the patient;
- c) Determine the time interval between the beginning of drug treatment and the onset of event;
- d) Evaluate the suspected ADR after discontinuing the drugs or reducing the dose and monitor the patient's status. If appropriate, restart the drug treatment and monitor recurrence of any adverse events.
- e) Analyze the alternative causes (other than the drug) that could on their own have caused the reaction;
- f) Use relevant up-to-date literature and personal experience as a health professional on drugs and their ADRs and verify if there are previous conclusive reports on this reaction;
- g) Report any suspected ADR to the person nominated for ADR reporting in the hospital or directly to the National ADR centre

How to deal with ADR:

To deal with ADR correctly, one needs to be alert to even minor changes in patient's clinical status. Such minor changes may be an early warning to future reactions. Each of patient's complaints should be considered objectively. ADR can be reduced in several ways: reducing the dose after consulting the prescriber or rescheduling of the same dose can help viz. antihistamines produce sedation.



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It is important to tell the patient what ADR to expect, so that he/she does not get worried or even stop taking drug on his/her own.

Recognizing drug allergies or serious idiosyncratic reactions can sometimes be life saving. Asking the patient about drug history and any reaction occurred with any drug in the past would help. If a severe reaction is suspected it is best to withhold the drug unless checked with the prescriber. Elderly and children are more prone to ADRs to certain drugs. It is important that they are observed more closely especially children who are unable to report ADRs on their own. In case of children, mothers should be educated to observe and report any unwanted sign or symptoms in their children.

Signs and symptoms of anaphylaxis:

- a) Constriction of the airways, including wheezing and a swollen tongue or throat, that results in difficulty in breathing.
- b) Shock associated with a severe decrease in blood pressure
- c) Weak and rapid pulse
- d) Dizziness or fainting
- e) Hives and itching
- f) Pale skin



Adrenaline is the only life saving drug in the treatment of anaphylaxis. Other useful drugs are antihistamines and corticosteroids.

Prevention of ADRs

It is estimated that 35% ADRs can be prevented; in case some of these measures are taken:

- a) Always elicit history of allergy to drugs as well as allergic diseases. It has been observed that patients who suffer from allergic diseases are prone to develop ADR.
- b) Avoid inappropriate use of drugs.
- c) Use appropriate dose, route, frequency based on patient's need.
- d) Adopt correct drug administration technique viz., NSAID to be taken after meals.

If drug is given for a long duration, laboratory test should be carried out to monitor the effect of drug on blood, liver and kidneys etc.

Pharmacovigilance

Pharmacovigilance is defined as the detection, assessment and prevention of adverse drug reactions in humans. It is the process of:

- a) Monitoring medicines as used in everyday practice to identify previously unrecognized adverse effects or changes in the patterns of their adverse effects
- b) Assessing the risks and benefits of medicines in order to determine what action, if any, is necessary to improve their safe use



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- c) Providing information to users to optimize safe and effective use of medicines
- d) Monitoring the impact of any action taken

India has more than half a million qualified Doctors and 15,000 hospitals having bed strength of 6,24,000. It is the fourth largest producer of pharmaceuticals in the world. It is emerging as an important Clinical trial hub in the world.

Need for Pharmacovigilance:

- a) Regulatory agencies are increasingly proactive in seeking out potential safety issues with marketed drugs - you must be ready to respond quickly
- b) Political and social pressures have increased along with faster communication channels
- c) Litigation due to the lack of pharmacovigilance can be devastating for all concerned
- d) Failure to practice pharmacovigilance can lead to the suspension or withdrawal of license
- e) Need for a vibrant pharmacovigilance system to protect the population from the potential harm due to introduction of many new drugs.
- f) Rising costs of patient care
- g) Increasing awareness of patients towards the untoward effects of drugs
- h) Rise in the frequency of cases of litigation against doctors and hospitals

Central Drugs Standard Control Organization (CDSCO) has initiated a well structured and highly participative National Pharmacovigilance Program. It is largely based on the recommendations made in the WHO document titled "Safety Monitoring of Medicinal Products – Guidelines for Setting up and Running a Pharmacovigilance Centre".

The National Pharmacovigilance Program will be overseen by the National Pharmacovigilance Advisory Committee (NPAC) based at the CDSCO, New Delhi.

CDSCO is coordinating this country-wide Program. The Drug Controller General of India will function as the member secretary of the Committee. NPAC has been given the sole responsibility of putting in place machinery for monitoring of the pharmacovigilance Program throughout the country. It has established 2 zonal centers, 5 regional centers and 28 peripheral centers for monitoring Adverse Drug Reaction (ADR) in India. Two zonal centers, the South-West zonal centre (located at the Department of Clinical Pharmacology, Seth G S Medical College and KEM Hospital, Mumbai) and the North-East zonal centre (located at the Department of Pharmacology, AIIMS, New Delhi), will collate information from all over the country and send it to the Committee as well as to the Uppsala Monitoring centre in Sweden. Three regional centers will report to the Mumbai centre, and two to the New Delhi one. Each regional centre, in turn, will have several peripheral centers reporting to it. Presently, there are 24 peripheral centers.



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Objectives:

Short-term objectives: To foster a culture of notification

Medium-term objectives: To engage several healthcare professionals and NGOs in the drug monitoring and information dissemination processes.

Long-term objective: To achieve such operational efficiencies that would make Indian National Pharmacovigilance Program a benchmark for global drug monitoring endeavors.

The specific aims of the Pharmacovigilance Program are to:

- a) contribute to the regulatory assessment of benefit, harm, effectiveness and risk of medicines, encouraging their safe, rational and more effective(including cost effective) use
- b) improve patient care and safety in relation to use of medicines and all medical and paramedical interventions
- c) improve public health and safety in relation to use of medicines
- d) promote understanding, education and clinical training in pharmacovigilance and its effective communication to the public

Since there are considerable social and economic consequences of adverse drug reactions and the positive benefit/cost ratio of implementing appropriate risk management – there is a need to engage health-care professionals and the public at large, in a well structured Program to build synergies for monitoring adverse drug reactions. The purpose of the Program is to collate data, analyze it and use the inferences to recommend informed regulatory interventions, besides communicating risks to healthcare professionals and the public.

Before a product is marketed, experience of its safety and efficacy is limited to its use in clinical trials, which are not reflective of practice conditions as they are limited by the patient numbers and duration of trial as well as by the highly controlled conditions in which clinical trials are conducted. The conditions under which patients are studied during the pre-marketing phase do not necessarily reflect the way the medicine will be used in the hospital or in general practice once it is marketed. Information about rare but serious adverse drug reactions, chronic toxicity, use in special groups (e.g. pregnant women, children, elderly) and drug interactions are often incomplete or not available. Certain adverse drug reactions may not be detected until a very large number of people have received the medicine. Pharmacovigilance is therefore one of the important post-marketing tools in ensuring the safety of pharmaceutical and related health products.

Reporting ADR

The National Pharmacovigilance Centre is based at CDSCO and it:

1. Monitors the adverse drug reactions of medicines in order to identify previously unexpected adverse drug reactions or indicate that certain reactions occur more commonly than previously believed. This will include the collation, review and evaluation of all spontaneous ADR reports



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received by the unit on a nation-wide basis. This information will then be keyed into the ADR database for use in aggregate analysis. These reports shall also be submitted to the WHO International Drug Monitoring Program for international collaboration on drug safety.

2. Review Periodic Safety Update Reports (PSURs) submitted by pharmaceutical companies. Pharmaceutical companies are required to submit the PSURs of all new chemical drugs. PSURs shall be expected to be submitted every 6 months for the first 2 years of marketing in India, and annually for the subsequent 2 years.
3. Maintain contacts with international regulatory bodies working in pharmacovigilance and exchange information on drug safety.
4. Assess the regulatory information relating to safety in order to determine what action, if necessary, needs to be taken to improve safe use. Based on the available data, the Advisory Committee shall make recommendations on product label amendments, product withdrawals and suspension.
5. Provide information to end-users through adverse drug reaction news, bulletins, drug alerts and seminars.

The main sources of ADR data are:

1. Spontaneous reporting by doctors, pharmacists nurses etc. in form of case reports or case series
2. ADR monitoring schemes in hospitals
3. Animal experiments
4. Clinical trials (all phases including post-marketing surveillance)
5. Vital statistics (mortality, morbidity registers, birth registers for congenital defects)
6. Special studies: case control studies; cohort studies
7. Record linkage – computerized registers of exposure, diagnoses, patient information and outcome

Computerization of ADR data and the availability of on-line data bases allow easy retrieval of information.

The administrators intending to invest in such a package should carefully consider factors such as:

- a) The requirements and the applications of the system
- b) The degree of user friendliness
- c) The robustness of the package
- d) Its cost
- e) Performance on existing hardware

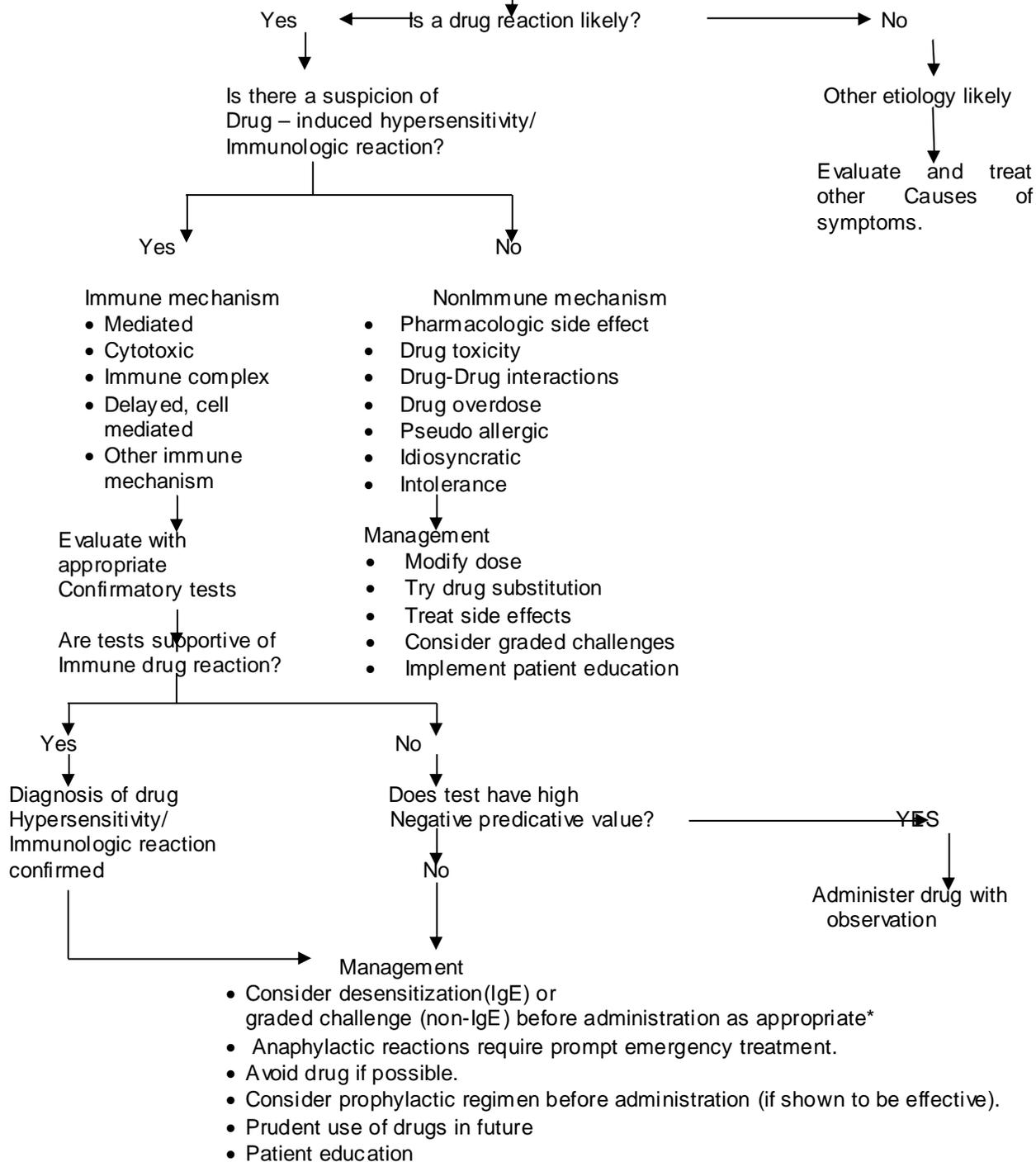
Detection and recording of ADRs is of vital importance and this should be followed by reporting. It is the responsibility of all health professionals (doctors, pharmacists, nurses) to report these reactions. Their dissemination may help in preventing ADR in some other patient(s).



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Evaluation and Management of Drug Reactions

Medical history: symptoms, detailed
Medication list, temporal sequence
Physical examination
Clinical laboratory data





Drug Interaction

A drug interaction occurs when one drug is given with or shortly after another drug alters the effect of one drug or both drugs. It is estimated that a hospitalized patient receives an average of 5-10 drugs. When several drugs are given together, interactions may occur.

Drug-drug interactions can be defined as the “modulation of the pharmacologic activity of one drug (i.e., the object drug) by the prior or concomitant administration of another drug (i.e., the precipitant drug). In these reactions, the pharmacologic properties of the object drug and/or the precipitant drug can be either severely enhanced or diminished”.

The interaction can be potentiated, or synergistic, when the combined effect of the two drugs is greater than the total effects of the drugs used separately.

The interaction can be expressed as antagonized when the resulting effect is less than the combined effects of the two drugs when used separately or when the effect partially or completely nullifies the effect(s) of each drug.

In some instances, predictable drug-drug interactions in patients are beneficial, and clinicians allow them to occur because they result in lower doses of the drug(s) being administered while still achieving therapeutic serum drug levels. For example, administering penicillins (renally excreted) with the drug probenecid significantly elevates serum levels of penicillin and prolongs its half-life. However, beneficial effects are very few, most are harmful. These can be in terms of lack of efficacy or toxicity. Whenever the levels of drugs in the body are increased due to interactions, toxicity of that drug is enhanced. If levels are decreased viz., due to enhanced metabolism of the drug it may result into lack of response.

Not only do drug interactions present a danger to the patient, but they can also greatly increase healthcare costs. Patients on a combination of drugs require hospitalization or more laboratory tests to monitor resolution of these interactions.

Mechanism of Drug Interaction

The causes and significance of drug interactions are multifaceted and include drug dose; serum drug level; route of administration; drug metabolism; duration of therapy; and patient factors, such as age, gender, weight, genetic predisposition, and other factors. All interactions are not clinically important, as slight change in drug concentration in the body may not produce significant alternation in drug response.

- a) **Pharmacodynamic Drug Interactions:** Interactions generally take place between drugs acting on same type of receptors or physiological system viz., the effect of anti-histaminic like chlorpheniramine on CNS is increased by alcohol as both cause CNS depression. Such interactions are predictable and it is important to observe them when such drugs are administered together.
- b) **Pharmacokinetic Drug Interactions:** Pharmacokinetic means absorption, distribution metabolism and excretion of drugs.



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- i. Absorption: Most drugs in tablet, liquid or capsule form are absorbed from small intestines. Once absorbed, they circulate in blood stream and available for action. The quantity of drug available is known as bioavailability. Drugs, food and drinks can alter the absorption of drugs. This is one important site of drug interaction.
- ii. Distribution: The drug moves from blood stream into various fluids and tissues or drug may get bound to plasma proteins. One drug may displace another drug from these sites.
- iii. Metabolism: Most drugs are metabolized in the liver. The liver has many enzymes that metabolize the drugs and these enzymes can be induced or inhibited by drugs thus causing increase or decrease in metabolism of other drugs.
- iv. Excretion: Drugs are excreted primarily by kidneys. One drug may decrease or increase the excretion of drugs.

Thus, due to drug interaction at any of the above site the concentration of one drug in the body may either decrease or increase; if it is decreased, there is a lack of therapeutic response and if it is increased there may be toxicity.

Examples of some common drug interactions inside the body

Isoniazid (INH)

- a) Antacids and laxatives reduce INH absorption from GIT, therefore INH should be administered an hour before these drugs are given.
- b) INH inhibits excretion of diazepam. Patient monitoring is important as diazepam response may be enhanced.
- c) Use of alcohol may enhance liver toxicity of INH, Paracetamol.

Rifampin

It may increase metabolism of anticonvulsants, theophylline, verapamil due to enzyme induction in the liver responsible for their metabolism resulting into reduced action of these drugs.

Ampicillin

Ampicillin when taken with food, its absorption decreases. Therefore, it should be taken empty stomach.

Ampicillin and Amoxicillin

These medicines when taken with allopurinol, chances for skin rashes are increased.

Cephalosporines

All cephalosporines when given with aminoglycosides (gentamicin, amikacin) increase renal toxicity. Close patient monitoring for renal toxicity is very important. It is recommended that renal function tests should be done frequently.



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Glipizide; glimepride

Corticosteroid decreases their hypoglycemic response. Beta blockers mask the symptoms of hypoglycemia. Patient monitoring is very important for any hypoglycemic response.

Furosemide

It is a diuretic and interacts with many drugs. When given with NSAID, furosemide's clinical response is decreased. Concomitant administration of furosemide and lithium results into lithium toxicity. When furosemide is given with gentamicin ototoxicity is potentiated.

Iron supplements

Iron when taken with calcium or milk products chelates, therefore, not absorbed into the body.

Iron supplements taken with antibiotics can reduce or stop the ability of the antibiotics to fight infection (Iron and the antibiotic bind together in the stomach, instead of being absorbed into the bloodstream).

Drug Interactions outside the Body

Patients in intensive care units (ICU) often receive numerous medications by the parenteral route. Frequently two or more drugs are delivered simultaneously through the same line and the risk of physicochemical incompatibilities is thus important. Physical or visual incompatibilities present in the form of precipitation, effervescence, color change, and related visual changes. Interactions can occur during formulation and mixing of drugs and some examples are shown as below:

- a) Thiopentone and suxamethonium react chemically, therefore, should not be withdrawn in the same syringe.
- b) Ketamine is incompatible with barbiturate & diazepam, therefore, should not be withdrawn in the same syringe.
- c) Protamine zinc insulin should not be combined with soluble insulin, if combined a precipitate will be formed.
- d) Phenytoin precipitates in dextrose solutions e.g. D5W.
- e) Valproate infusion should NOT be given with saline.
- f) Amphotericin precipitates in saline and fat emulsion.
- g) Gentamicin is physically/chemically incompatible with most beta-lactams, resulting in loss of antibiotic effect.
- h) Absorption of tuberculin PPD to glass and plastic surfaces.

Food Drug Interactions

Generally, administering oral medication along with food or at a mealtime is a convenient manner of drug dosing. However, drug interactions can occur that modify the activity of the drug (decrease or increase



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drug effects) or impair the nutritional benefit of certain food. The most commonly observed type of drug-food interaction affects drug absorption.

Food can decrease a drug's rate of absorption and/or decrease the extent of absorption of numerous drugs. Examples of drugs whose absorption is decreased when taken with food include penicillin, tetracycline, erythromycin, levodopa, phenytoin, and digoxin. Drugs whose absorption increases when taken with food include spironolactone, griseofulvin, and itraconazole.

Table 8: Effects of Food on Drugs

Drugs	Effect(s) of Food*
Acetaminophen, aspirin, digoxin	Decreased/delayed drug absorption
ACE inhibitors (captopril and moexipril)	Significant decrease in serum drug levels
Fluoroquinolones (ciprofloxacin, levofloxacin, ofloxacin, trovafloxacin), Tetracycline	Avoid taking with antacids (esp. magnesium and aluminum types) and iron products; significantly decreased drug absorption
Didanosine or ddl	Food in general and acidic foods juices significantly decrease drug absorption
Saquinavir, griseofulvin, itraconazole, lovastatin, spironolactone	Food, especially high-fat meals, improves drug absorption; take with food, or within two hours of a meal
Famotidine	Decreased/delayed drug absorption
Ketoconazole	Acidic foods/juices and sodas (e.g., cola) significantly increase drug absorption
Iron, levodopa, penicillins (most), tetracycline, erythromycin	High-carbohydrate meals decrease drug absorption
<i>*when the increased or decreased absorption effects of food are undesirable, take drug on an empty stomach, either one hour before or two hours after meals.</i>	

Drug Disease Interactions

Certain drugs have the capability to exacerbate acute and/or chronic disorders. Beta-adrenergic blocking agents can precipitate and exacerbate diseases such as asthma, chronic obstructive pulmonary disease and peripheral vascular disease. These drugs can also blunt the typical signs and symptoms of a hypoglycemic reaction in diabetic patients and alter insulin utilization in the body.

The magnitude of the drug interactions problem increases significantly in certain patient populations and as the number of medications taken each day increases. Drug interactions that may be of minor clinical significance in patients with less severe forms of a disease can cause significant exacerbation of the clinical condition in patients with more severe forms of the disease; patient populations of high risk include the elderly, critical care patients, and patients undergoing complicated surgical procedures.



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Conditions that Place Patients at High Risk for Drug Interactions

- **High risk associated with the severity of disease state being treated**
 - Asthma
 - Cardiac arrhythmia
 - Critical care/intensive care patients
 - Diabetes
 - Epilepsy
 - Hepatic disease
 - Hypothyroid
 - Aplastic anemia
- **High risk associated with drug interaction potential of related therapy**
 - Autoimmune disorders
 - Cardiovascular disease
 - Gastrointestinal disease
 - Infection
 - Psychiatric disorders
 - Respiratory disorders
 - Seizure disorders

Recall of Drugs

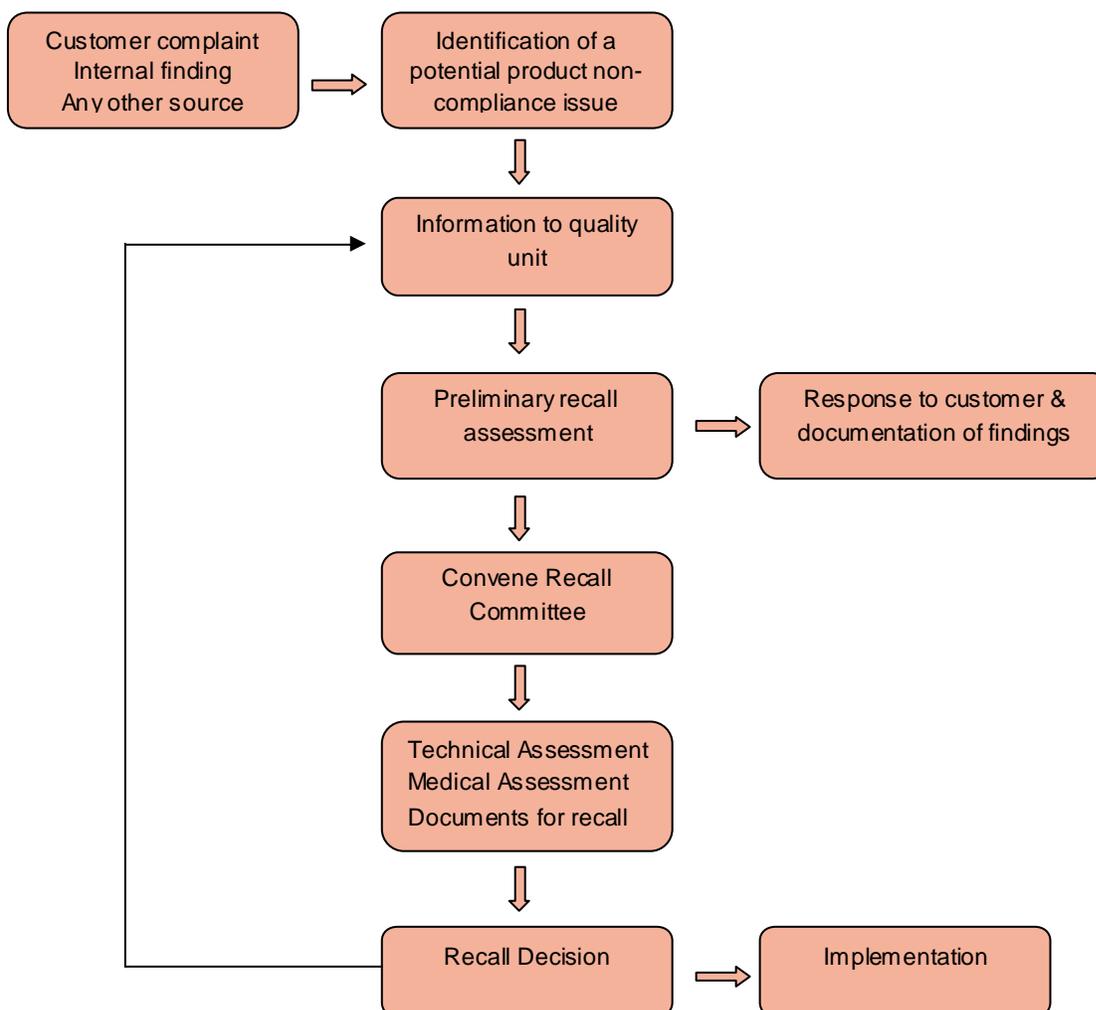
Products on the market that are suspected or known to be seriously defective and/or pose a potential risk to patient health must be recalled. This must be done promptly, comprehensively and in accordance with governmental health agency regulations and requirements governing distributed products. This applies to all products manufactured and distributed from a site, including physician samples and products used for market studies and clinical trials.

It is vital that all hospitals respond effectively and promptly to any recall advice. In order to streamline responding to recalls, hospitals should:

- a) Establish internal procedures and appoint a coordinator responsible for coordinating prompt removal of goods which are the subject of recall from all locations in the hospital and community area and for keeping staff informed of recalls and problem alerts.
- b) Goods that have been transferred to another hospital in the area must also not be overlooked.
- c) All hospital staff must be alert to the possibility of defects in the goods they handle and must report any anomaly which may indicate a deficiency in the quality, safety or efficacy of the goods to the appointed hospital coordinator.
- d) Any suspected or known problems or defects with drugs should be reported promptly by the coordinator since these may indicate a fault in a manufacturer's processes or be symptomatic of a general problem which requires correction and/or recall. Such problems could include incorrect or illegible product labeling, discoloration, cloudiness, foreign tablets or capsules in a pack, faulty devices, etc.



Figure 5: Decision on recall



The implementation includes:

1. Initiation of the recall, which may be voluntary, requested or mandatory (by Central Purchase Authority, Drugs Regulating Authority or manufacturer).
2. Reviewing of information and assessing the health hazard presented by the recalled product.
3. Notification and public warning through press releases ensuring that the public is warned about products that are hazardous to health.
4. Monitoring and auditing the recall to ensure that the recall action has been effective.
5. Termination of a recall.
6. Appropriate regulatory action or other measures when the firm fails to recall product or when a recall action fails.



Chapter 10: Drug Management Information System

The concept of Information System is an artificial system, which consists of people, hardware, software and data resources whose aim is timely, correct collection, processing, storage, transmission and provision of information to achieve the activities of the organization management, regulation and control. Management information system can be used in a variety of pharmaceutical operation that use past data to predict the future, assess the overall situation from the pharmaceutical support decisions and the use of information to control the functioning and help achieve planned objectives.

Steps in Designing or Revising a DMIS

1. Identify users
2. No. of drugs maintained at formulary
3. Identify information needs
4. Review the existing information system
5. Match the existing information system with needs
6. Draft record-keeping and reporting procedures to fill the gaps
7. Develop procedures for users to analyze data and present findings
8. Field test new forms and records
9. Make modifications according to the field test results
10. Prepare a detailed instruction manual
11. Develop feedback procedures
12. Train users in data collection, reporting procedures and use of information
13. Train users in basic computer skills, if necessary
14. Monitor the system
15. Adapt the records, report forms, software, etc. as information needs evolve.

Key Issues in Designing a DMIS

1. Be selective in choosing indicators
2. Aim for representativeness, not comprehensiveness
3. Use appropriate data collection methods
4. Integrate data collection systems
5. Develop practical analysis methods
6. Computerize at appropriate levels
7. Ensure effective communication



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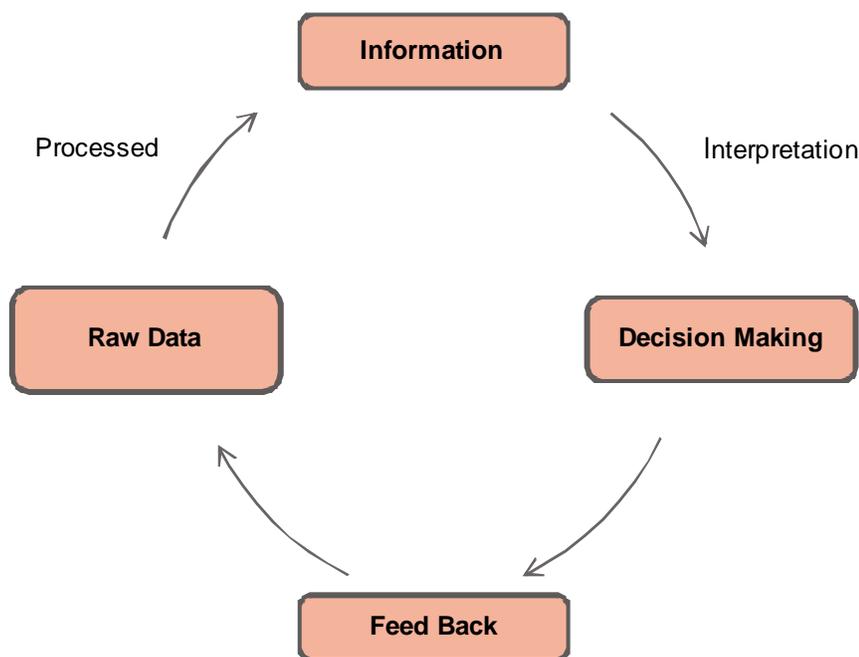


Figure 6: Steps in transforming data into action

Role of Computers in Drug Store Management:

Computers can be used in all aspects of the drug management cycle, from selection to use. They are capable of manipulating text and numbers and practicing newsletters, forms, reports, tables, graphs and charts. Using communication devices, users can exchange or share this information with other computers at the same site via local area network (LAN) or with computers anywhere in the world.



When used effectively, computer systems save money promote efficiency, and improve the quality of services. However, poorly conceived or implemented computer systems waste money, decrease efficiency, and distract attention from other management improvements.

Computer technology change very quickly, with machines continually becoming faster, more capable, and less expensive. The benefits of computer in managing drugs depend on the choice of tools, the commitment to using the tools and the ability to overcome the hurdles involved in incorporating computers into the organization. There is no standard formula for successful computerization in drug management, but rather a mix of elements: the right mix can yield great benefits.



Benefits and Limitation of Computerization

Benefits:

1. Simplify and speed up complex tasks
2. Increase accuracy by checking spelling, calculations, and data integrity
3. Update and access information quickly
4. Automate repetitive tasks
5. Provide management information for decision making.
6. Allow organizations to expand the volume and scope of operations.
7. Streamline administrative processes.
8. Generate timely reports without repeated efforts in compiling data.

However, computers still have **limitation**. They cannot assume responsibilities, make decision, define problems, set objectives, improve the basic data available, or make a person more organized. They cannot fulfill needs if appropriate hardware and software are not chosen, and they are not a one-time expense: funds are required for upgrades, training and support over time for both hardware and software.

Conditions supporting computerization include

1. Efficient existing manual procedures;
2. Other department that have computerized successfully;
3. Staff capable of, and interested in, operating computers;
4. A reliable power supply;
5. Adequate funds to support maintenance, training and equipment upgrades

Conditions impeding computerization include:

1. Hardware or software not suited to the task
2. Not enough trained operators
3. Lack of a maintenance plan
4. Lack of reliable power (voltage surges ruin computers and databases)
5. Inadequate supply of diskettes, paper or print ribbons;
6. Unsuitable physical environment (exposure to dust, heat or magnets, which can damage hardware and software.

Key Steps in Computerization Process

1. Identify the tasks or the system to be computerized with a detailed analysis of needs versus current systems.
2. Survey the environment and consider integrating with other system to the extent feasible. (What software and hardware are being used by other departments? Is there an institutional computer policy? What equipment is already available?)



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3. Evaluate the staff situation (actual versus needed).
4. Select software before hardware.
5. Identify whether the software needed is available in the local-language and to which original version it is equivalent (non-English- Language versions are sometimes not as current as English Versions).
6. Ensure the availability of supplies and maintenance.
7. Select the hardware and software suppliers that provide the most support.
8. Plan progressive implementation (one step at a time) and involve current and future users in the design and implementation process.

Checklist for selecting or creating procurement and Inventory management software

General features of Procurement and Inventory Software

- a) Restricts user access to a particular module with password protection
- b) Allows multiple users
- c) Uses various pricing options
- d) Automates backup routines
- e) Checks data integrity (for example, it is impossible to enter a letter or other character if a number is expected, and vice versa)
- f) Links with a full accounting package
- g) Exports data such as to a spreadsheet for specific analysis.

Specific Features of Procurement Software

- a) Manages simultaneous tenders
- b) Generates all tender documents
- c) Manages bids and purchase orders in multiple currencies
- d) Compares bids using a common unit regardless of pack size variation.
- e) Generates contracts and purchases orders for suppliers.
- f) Monitors supplier performance (lead time; Contract price versus invoiced price)
- g) Generates receiving reports
- h) Updates inventory databases

Specific Features of Inventory Software

- a) Tracks monthly consumption
- b) Keeps track of stock out periods
- c) Calculates average monthly consumption, taking into consideration past consumption and stock out periods
- d) Calculates minimum and maximum stock levels
- e) Calculates optimum reorder level, taking into consideration minimum stock, actual stock balance, lead time, procurement and for casting periods and outstanding orders, as well as use –defined maximum and minimum stock levels
- f) Monitors expiry dates by lot
- g) Generates lists by location
- h) Manages distribution according to expiry date and/ or location



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- i) Monitors clients consumption and budget
- j) Allows multiple purchase and selling prices, as well as the possibility to enter discounts, surcharges and taxes.
- k) Generates audit report
- l) Generates ABC analysis report

Building a Drug Master file in a database

Drug Master File

Common to nearly all forms of database management is a master file, which includes features for drug management such as drug name, strength, dosage form and therapeutic category. For procurement and inventory control systems, the drug master file usually has supplementary information on cost and pack size. The full description of a product can be split into database field to sort and classify the data.

Table 9: Example of information commonly contained in a basic drug master

Description	Example	Explanation
Product Code	AMP250C	Each entry in the drug data file must have a unique code. (See text for discussion coding options)
Generic name	Ampicillin	The official international nonproprietary name (INN) is generally preferred. The list of Essential Drugs, which is regularly updated, uses the INN
Strength	250mg	The International System of Units (SI), with related SI abbreviations, should be used, "Strength" can be split into " strength number" (250 for example) and " strength unit" (such as mg). but this often creates unnecessary confusion and coding difficulties.
Routine of administration	PO	Standard abbreviations should be used. For example, PO = per os (oral), IV = intravenous, TOP = topical
Dosage form	CAP	Standard abbreviations should be used. For example, CAP= capsule, TAB= tablet
Issue Unit	CAP	The smallest unit by which a drug can be conveniently distributed (see text for further explanation) The usual total daily therapeutic dosage for an adult.
Defined daily dosage (DOD)	4	In computer system, this is best defined in terms of issue unit per DDD
DDD unit	G	The unit in which the DDD is measured.
National essential drugs list (EDL)/formulary status	Y	Is the drug listed in the national EDL or formulary? Y= Yes N=no
Level of care	A	National EDL may categorize drugs according to level care. For example, A= all levels, B= all levels except dispensary and so forth.



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ABC classification	A	Classification of a drug as A,B, or C according to the volume consumed and unit cost (see chapter 7 for discussion of ABC analysis)
VEN Classification	V	Classification of a drug as V,E, or N, according to its therapeutic value as vital, essential, or nonessential.

Drug Master File code

A computer program must be able to identify each drug product quickly and without confusion. Once a coding system has been chosen, it must be without ambiguity, or duplication will occur. There are many options for coding systems. The simplest system is the “dummy” code, which has no intrinsic meaning- for example, 12345 is assigned to the first item entered in the list, 12346 for the second, and so on. With this system, the only question is how many digits are needed; the key point is that the code should be unique. In most systems a five-digit code is sufficient for many years. If there are a large number of different items, a six-digit code might be prudent. A more complex option is an “information bearing” code, in which each digit has significance – for example Ampicillin 500 mg capsules might be coded as AMP500C.

Successful Computerization

1. Assess what software is needed before choosing hardware
2. Ensure software and hardware compatibility
3. Secure local support for hardware and software
4. Have well-functioning manual system
5. Provide adequate staff training and involve staff in computerization process
6. Computerize in phase, allowing sufficient time for each step
7. Establish and enforce strict procedures for data and equipment protection, using backups, virus checkers, restricted access, surge suppressors and so on.
8. Set aside adequate funds in each years' budget for hardware and software maintenance, supplies and staff training
9. Plan and budget for timely hardware and software upgrade.



Chapter 11: Waste Management and Infection Control

Biomedical Waste Management

With the advancement of medical science most of the hospitals/nursing homes are now equipped with latest instruments for diagnosis and treatment of various diseases. One of the most important aspects associated with hospitals is the safe management of the wastes; generated from these establishments, which contains human anatomical wastes blood, body fluid, disposable syringe, used bandages, surgical gloves, blood bags intravenous tubes etc.

Biomedical waste (BMW) is the waste generated during the diagnosis, treatment or immunization of human beings or animals, or in research activities pertaining to these, or in the production or testing of biological.

The Bio-medical waste generated from various sources has become a problem and much attention is being given worldwide to find out solution of this problem. Bio-medical wastes, if not handled in a proper way, is a potent source of diseases, like AIDS, Tuberculosis, Hepatitis and other bacterial diseases causing serious threats to human health.

Health Care Waste Management: A process to help ensure proper hospital hygiene and safety of health care workers and communities.

Need for Health Care waste Management

- a. Proper health care waste management helps in controlling nosocomial infections.
- b. It aids in reducing community exposure to transmission from disposed medical items.
- c. It cuts the cycle of infection.
- d. It helps in dealing with health care worker safety issues easily and cost effectively.
- e. It prevents illegal repacking and resale of contaminated medical items especially needles.
- f. It avoids negative long term health effects.

Waste Management Approach

- | R₃ | D₃ |
|--|---|
| <ul style="list-style-type: none">• Reduce• Reuse• Recycle | <ul style="list-style-type: none">• Disinfect• Distort• Dispose |

Health care Waste Management Plan

1. **Minimization of Generation** of waste.
2. **Waste Segregation** at the point of generation.



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3. **Collection** in non-chlorinated plastic collection bags. Daily waste collection and transportation to designated storage site / deep burial pits. Bags removed after 2/3 rd filled with bio medical waste.
4. **Transportation:** Designated routes and time of transfer of wastes to avoid the passage of waste through crowded and patient care areas. Use of wheeled containers, trolleys/carts.
5. **Storage:** A storage location for hospital waste collection.
6. **End Treatment and Disposal:** CTFs responsible for waste collection and transportation from the hospitals site, followed by treatment, destruction and final disposal.
7. **Burial Pits / Storage:** in absence of CTF, infectious waste along with the anatomical waste and other hazardous waste disposed off into deep burial pits.



Bio-medical Waste (Management & Handling) Rule 1998 which was later amended in 2003:

With a view to control the indiscriminate disposal of hospital waste/ biomedical waste, the Ministry of Environment & Forests, Govt. of India notified the Bio-medical Waste (Management and Handling) Rules, 1998. These have been amended from time to time, the last in the year 2003.

These rules apply to hospitals, nursing homes, veterinary hospitals, animal houses, pathological laboratories and blood banks.

It contains **13 Rules** which are related to

- a) Duty of occupier
- b) Segregation, packaging, transportation, storage of waste
- c) Treatment and disposal of waste
- d) Prescribed authority and authorization



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- e) Advisory committee
- f) Annual report and maintenance of records
- g) Accident reporting
- h) Appeal

It has **6 Schedules** related to

- a) Categories of bio-medical waste
- b) Colour coding and type of container for disposal of bio-medical wastes
- c) Label for bio-medical waste containers/bags
- d) Label for transport of bio-medical waste containers/bags
- e) Standards for treatment and disposal of bio-medical wastes
- f) Schedule for waste treatment facilities like incinerator/ autoclave/ microwave system



The **3 Forms**

- **Form I - Application For Authorization**
 - By waste generator and operator of CTF to prescribed authority along with prescribed fee
- **Form II – Annual Report**
 - By Waste generator/operator to prescribed authority
 - Include information about the categories and quantities of bio-medical wastes handled during preceding year.
- **Form III - Accident Reporting**
 - By authorized person of facility where accident occurred to prescribed authority

Main Features:

1. Pollution Control Boards: permitting and enforcing Biomedical Waste Rules.
2. Rules apply to all who generate, collect, receive, store, transport, treat, dispose, or handle BMWs in any form.
3. Each operator handling BMWs and providing services to 1,000 or more patients per month required to obtain a permit from the prescribed authority.
4. Duty of the occupier of a health care facility to ensure that BMWs are handled without any adverse effect to human health and the environment, and according to the prescribed treatment and disposal requirements in the Biomedical Waste Rules.
5. Each occupier (operator) required to maintain records on the generation, collection, reception, storage, transportation, treatment, and disposal of BMWs. All records subject to inspection and verification by the prescribed authority at any time.
6. Reporting of accident related to the management of BMWs.



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7. Submission of annual report to the prescribed authority about categories and amounts of wastes generated and treated, and modes of treatment.
8. Local public entities required providing common disposal/incineration sites, and occupiers (operators) of such sites required to comply with Biomedical Waste Rules.
9. BMWs to be segregated into labeled bags/containers.
10. Transportation in authorized vehicles.
11. No untreated waste to be stored more than 48 hours, unless special permission is obtained.
12. Technology and discharge standards for incineration, autoclaving, microwaving, liquid waste discharges, and deep burial prescribed in the Biomedical Waste Rules.

Waste in colored bags/bins

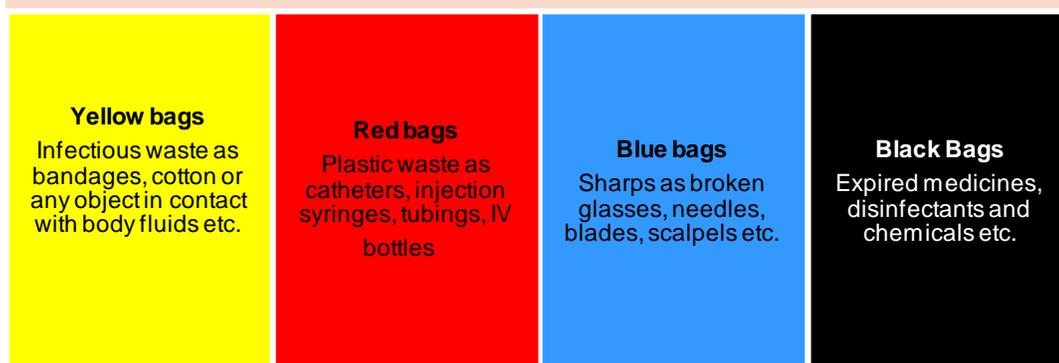


Table 10: Category of biomedical waste, color coding and their treatment and disposal

Waste category	Type of waste	Color	Treatment & disposal
1	Human anatomical waste	Yellow	Incineration/ deep burial
3	Microbiology & biotechnology waste	Yellow	Local autoclaving/ microwaving/ incineration
4	Waste sharps	Blue	Disinfection
5	Discarded medicines & cytotoxic drugs	Yellow	Incineration & destruction and disposal in secured landfills
6	Solid waste (items contaminated with body fluids)	Red	Incineration & autoclaving/ microwaving
7	Solid waste (disposable items other than sharps)	Red	Disinfection by chemical treatment/ autoclaving/ microwaving/ mutilation/ shredding
8	Liquid waste		Disinfection by chemical treatment & discharge into drains
9	Incineration ash	Black	Disposal in municipal landfill
10	Chemicals (disinfectants)	Black	Chemical treatments & discharge into drains/ landfills



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Glossary of Clinical Terms

Alcohol-based hand rinse: a waterless antiseptic designed for application to the hands to reduce the number of viable micro-organisms. In Canada, such preparations usually contain 70 percent ethyl alcohol.

Antiseptic: a substance that destroys or stops the growth of micro-organisms on living tissue (e.g., skin).

Blood-borne pathogens (BBPs): viruses found in blood which produce infection, such as hepatitis B virus (HBV), hepatitis C virus (HCV) or human immunodeficiency virus (HIV).

Carrier: an individual who is found to be colonized (culture-positive) for a particular organism, at one or more body sites, but has no signs or symptoms of infection.

Disinfectant: a chemical agent with a drug identification number (DIN) used on inanimate objects (non-living) to kill micro-organisms.

Disinfection: a process that destroys or kills some, but not all, disease-producing micro-organisms on an object or surface.

Exposed: a circumstance where contact with an infected person or item, in a manner that may allow the transfer of micro-organisms, either directly or indirectly to another person.

Germicide: an agent that destroys microorganisms, especially pathogenic organisms. A product with the suffix "cide" indicates that it is an agent that destroys the microorganism identified by the prefix (e.g., virucide, fungicide, and bactericide). Germicides may be used to inactivate micro-organisms in or on living tissue (antiseptic) or on environmental surfaces (disinfectants).

Hand hygiene: a general term that applies to hand washing, antiseptic hand wash, antiseptic hand rub (i.e., alcohol-based hand rinse) or surgical hand antisepsis.

Isolation: the physical separation of infected individuals from uninfected individuals for the period of communicability of a particular disease.

Micro-organism: microscopic organisms such as bacteria, virus or fungus, commonly known as germs that can cause infections in humans.

Mucous membrane: thin sheets of tissue that line various openings of the body such as the mouth, nose, eyes or genitals.

Nosocomial infection: infection acquired in a health care setting.

Personal protective equipment (PPE): specialized clothing or equipment worn by an employee for protection against an infectious hazard (e.g., gloves, masks, protective eyewear, gowns). General work clothes (e.g., uniforms, pants, shirts or blouses) are not intended to function as protection against a hazard and are not considered personal protective equipment.

Precautions: interventions implemented to reduce the risk of transmitting micro-organisms from patient to patient, patient to health care worker, and health care worker to patient (precautions can include gloves, masks, eye protection, gowns and client accommodations).



Infection Control

Infection is the invasion by and multiplication of pathogenic microorganisms in a bodily part or tissue, which may produce subsequent tissue injury and progress to overt disease through a variety of cellular or toxic mechanisms.

Infection control demands a basic understanding of the epidemiology of diseases caused by commonly encountered micro-organisms, of the risk factors that increase patients' susceptibility to infection by these micro-organisms, and the practices, procedures and treatments that promote infections.

Every health care worker plays a vital part in helping to minimize the risk of cross infection – for example, by making certain that hands are properly washed, the clinical environment is as clean as possible, ensuring knowledge and skills are continually updated and by educating patients and visitors.

Standard precautions underpin routine safe practice, protecting both staff and patients from infection. By applying standard precautions at all times and to all patients, best practice becomes second nature and the risks of infection are minimized. They include:

1. Achieving optimum hand hygiene
2. Using personal protective equipment
3. Safe handling and disposal of sharps
4. Safe handling and disposal of clinical waste
5. Managing blood and bodily fluids
6. Decontaminating equipments
7. Achieving and maintaining a clean clinical environment
8. Appropriate use of indwelling devices
9. Managing accidents
10. Good communication – with other health care workers, patients and visitors
11. Training/education

1. Hand hygiene

Hand hygiene is widely acknowledged to be the single most important activity for reducing the spread of disease, yet evidence suggests that many health care professionals do not decontaminate their hands as often as they need to or use the correct technique which means that areas of the hands can be missed.



Figure 7: Areas missed during hand washing



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Six steps of proper hand washing

1. Rubbing palm to palm
2. Rubbing the back of both hands
3. Rubbing palm to palm interlacing the fingers
4. Rubbing the back of fingers by interlocking the hands
5. Rubbing the thumbs
6. Rubbing palms with fingers



Figure 8: Hand washing steps

Hands should be decontaminated before direct contact with patients and after any activity or contact that contaminates the hands, including following the removal of gloves. Hands that are visibly dirty or potentially grossly contaminated must be washed with soap and water and dried thoroughly. Hand preparation increases the effectiveness of decontamination. One should:

- a. Keep nails short, clean and polish free
- b. Avoid wearing wrist watches and jewellery, especially rings with ridges or stones
- c. Artificial nails must not be worn
- d. Any cuts and abrasions should be covered with a waterproof dressing.

Hand drying

Improper drying can re-contaminate hands that have been washed. Wet surfaces transfer organisms more effectively than dry ones and inadequately dried hands are prone to skin damage. Disposable paper hand towels of good quality or hand dryers should be used to ensure hands are dried thoroughly.

2. Using personal protective equipment-

Personal protective equipment (PPE) is used to protect both self and patient from the risks of cross-infection. It may also be required for contact with hazardous chemicals and some pharmaceuticals. PPE includes items like gloves, aprons, masks, goggles or visors. In certain situations such as operation theatre, it may also include hats and footwear.



a. Disposable gloves-

Gloves should be worn whenever there might be contact with blood and body fluids, mucous membranes or non intact skin. **They are not a substitute for hand washing.** They should be put on immediately before the task to be performed, then removed and discarded as soon as the procedure is completed. Hands must always be washed following their removal.



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Nitrile or latex gloves should be worn when handling blood, blood-stained fluids, cytotoxic drugs or other high risk substances.

Polythene gloves are not suitable for use when dealing with blood and/or blood and body fluids, i.e., in a clinical setting. Neoprene and nitrile gloves are good alternatives for those who are sensitive to natural rubber latex.

b. Disposable plastics aprons-

These should be worn whenever there is a risk of contaminating clothing with blood and body fluids and when a patient has a known infection, for example, direct patient care, bed making or when decontaminating equipments. These should be discarded as soon as the intended task is completed and then hands should be washed. They must be stored safely so that they don't accumulate dust which can act as a reservoir for infection. Impervious gowns should be used when there is a risk of extensive contamination of blood or body fluids.

c. Masks, visors and eye protection-

These should be worn when a procedure is likely to cause blood and body fluids or substances to splash into the eyes, face or mouth. Masks may also be necessary if infection is spread by an airborne route – for example, multi drug resistant tuberculosis or severe acute respiratory syndrome (SARS). One should ensure that this equipment fits correctly, is handled as little as possible and changed between patients or operations. Masks should be discarded immediately after use.

3. Safe handling and disposal of sharps-

Sharps include needles, scalpels, stitch cutters, glass ampoules and any sharp instrument. The main hazards of a sharps injury are hepatitis B, hepatitis C and HIV.

To reduce the risk of injury and exposure to blood borne viruses it is essential to follow safe working procedures. All health care workers should get targeted education and awareness training. Some procedures have a higher than average risk of causing injury. These include intra-vascular cannulation, venepuncture and injection. Devices involved in these high-risk procedures are:

- a) IV cannulae
- b) Winged steel – butterfly – needles
- c) Needles and syringes
- d) Phlebotomy needles

One should ensure that:

- a) Sharps are not passed directly from hand to hand
- b) Handling is kept to a minimum
- c) Needles are not broken or bent before use or disposal
- d) Syringes or needles are not dismantled by hand and are disposed off as a single unit.





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- e) Needles are never re-sheathed
- f) Staff takes personal responsibility for any sharps they use and dispose them off in a designated container at the point of use. The container should conform to standard.
- g) Sharps containers are not filled by more than two thirds
- h) Sharps trays with integral sharps bins are in use
- i) Sharps are disposed off at the point of use
- j) Sharps boxes are signed on assembly and disposal
- k) Sharps are stored safely away from the public and out of reach of children
- l) Staff is aware of inoculation injury policy.

4. Safe handling and disposal of chemical waste-

The workplace should have a written policy on waste disposal, which provides guidance on all aspects, including special waste, like pharmaceuticals and cytotoxic waste and segregation of waste. This should include color coding of bags used for waste.

5. Managing blood and bodily fluids spillages-

These should be dealt with quickly, following workplace's written policy for dealing with spillages. The policy should include details of the chemicals staff should use to ensure that any spillage is disinfected properly, taking into account the surface where the incident happened.



Collecting, handling and labeling specimens

A written policy should be in place for the collection and transportation of laboratory specimens.

One should:

- a) Be trained to handle specimens safely
- b) Collect samples (wearing protective clothing) in an appropriate sterile and properly sealed container
- c) Complete form using patient labels (where available) and check that all relevant information is included
- d) Take care not to contaminate the outside of the container and the request forms
- e) Ensure that specimens are transported safely.
- f) Make sure specimens are sent to the laboratory as soon as possible.
- g) Under no circumstances should specimens be left on window sills or placed in staff pockets.
- h) Once results are available check and enter into the patient's records. Any results outside normal limits should be highlighted to the patient's clinician. Act on any infection control issues immediately.



6. Decontaminating equipment-

Decontamination is the combination of processes – cleaning, disinfection and sterilization – used to ensure a re-usable medical device is safe for further use.

All Health care staff must be aware of the implications of safe decontamination and their responsibilities to their patients, themselves and their colleagues.

Table 8: Decontamination according to associated risks

	Equipment description	Level of cleaning needed	Examples
High risk	Equipment that: - enters a sterile body cavity - penetrates the skin - touches a break in the skin or mucous membranes.	Equipments must be cleaned and sterilized – fully decontaminated – after each patient use. It should be left in a sterile state for subsequent use.	Examples include surgical instruments.
Medium risk	Equipment that touches intact skin or mucous membranes.	Equipments does not need to be sterile at the point of use but must be cleaned and sterilized (decontaminated) between each patient.	Examples include a bedpan.
Low risk	Equipment that does not touch broken skin or mucous membranes, or is not in contact with patients.	Equipments must be cleaned and/or disinfected after use.	Examples include an ophthalmoscope receiver; a bedframe

Single use equipment (where the item can only be used once) should not be reprocessed or re-used.

Devices designated for single patient use (where the item cannot be repeatedly used for the same patient) are clearly marked by a symbol. Such devices include nebulizers, disposable pulse oximeter probes and certain specified intermittent catheters.



Figure 8: Symbol for single use equipment

Preparing Bleach solutions at Facility:

Bleach solution must be prepared daily as they lose their strength after 24 hours. If anytime the odor of chlorine is not present the solution should be discarded.

Strong Bleach Solution: 1:10 - Prepared by adding one part of bleach to ten parts of water.

Used to clean and disinfect:

- heavily contaminated areas or very high-risk body fluid exposure.
- all blood spills or blood contaminated items.
- gross contamination with body fluids, such as large amounts of vomit or feces.

Bleach Solution: 1:100 - Prepared by adding 100ml bleach to 10 liters of water.

Used to disinfect:

- gloved hands



- b) bare hands and skin
- c) floors
- d) clothing
- e) equipment
- f) bedding

Steps in decontamination

1. **Cleaning**

This uses water and detergent (enzymatic cleaner) to remove visible contamination but does not necessarily destroy micro-organisms, although it should reduce their numbers. Effective cleaning is an essential prerequisite to both disinfection and sterilization. Manual cleaning should be performed with extreme care.

2. **Disinfection**

This uses chemical agents or heat to reduce the number of viable organisms. It may not necessarily inactivate all viruses and bacterial spores. Where equipment will tolerate sterilization, disinfection should not be used as a substitute. If an ultra sonic cleaner is used the machine should be drained, cleaned, dried, covered and left dry until required for further use.

3. **Chemical disinfectants**

These are classified generically and their bio-cidal capabilities vary. Efficacy depends on choosing and using the disinfectant correctly. Chemical disinfection is not as effective as heat disinfection.

4. **Sterilization**

This ensures that an object is free from viable microorganisms, including bacterial spores. Both acute and primary care facilities should actively work towards achieving central sterilizing of reusable equipments, using local Sterile Services Department (SSD) where available.

Where SSD are not possible, alternatives are:

- a) Using pre-sterilize, single-use, disposable items. The advantages include convenience and suitability for use in areas where decontamination could be hard to achieve.
- b) A bench top vacuum steam sterilizer. These must be installed, validated and maintained.
- c) All steam sterilizers are subject to the Pressure Systems Safety Regulations 2000 and must be examined annually by a competent person.

Table 11: Steam sterilization times and temperatures

Sterilizing Temperature (min-max)	Approximate pressure	Minimum hold time
134-137°C	2.25 bar	3 minutes
126-129°C	1.5 bar	10 minutes
121-124°C	1.15 bar	15 minutes



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7. Maintaining a clean clinical environment

Cleaning removes contaminants, including dust and soil, large number of micro-organisms and the organic matter that may shield them, for example, faeces, blood and other bodily fluids.

Additionally, cleaning equipment such as vacuums, floor scrubbing machines and polishers should be cleaned and properly maintained. Information on recommended methods of cleaning and disinfection should be available for staff.

8. Appropriate use of indwelling devices

80 percent of urinary infections can be traced back to indwelling urinary catheters. Use of correct technique when using indwelling devices should be ensured to reduce the risk of these acquired infections.

Similarly, over 60% of blood infections are introduced by insertion of intravenous feeding lines, catheters or similar devices which promote entry of micro-organisms into the deeper tissues or the bloodstream.

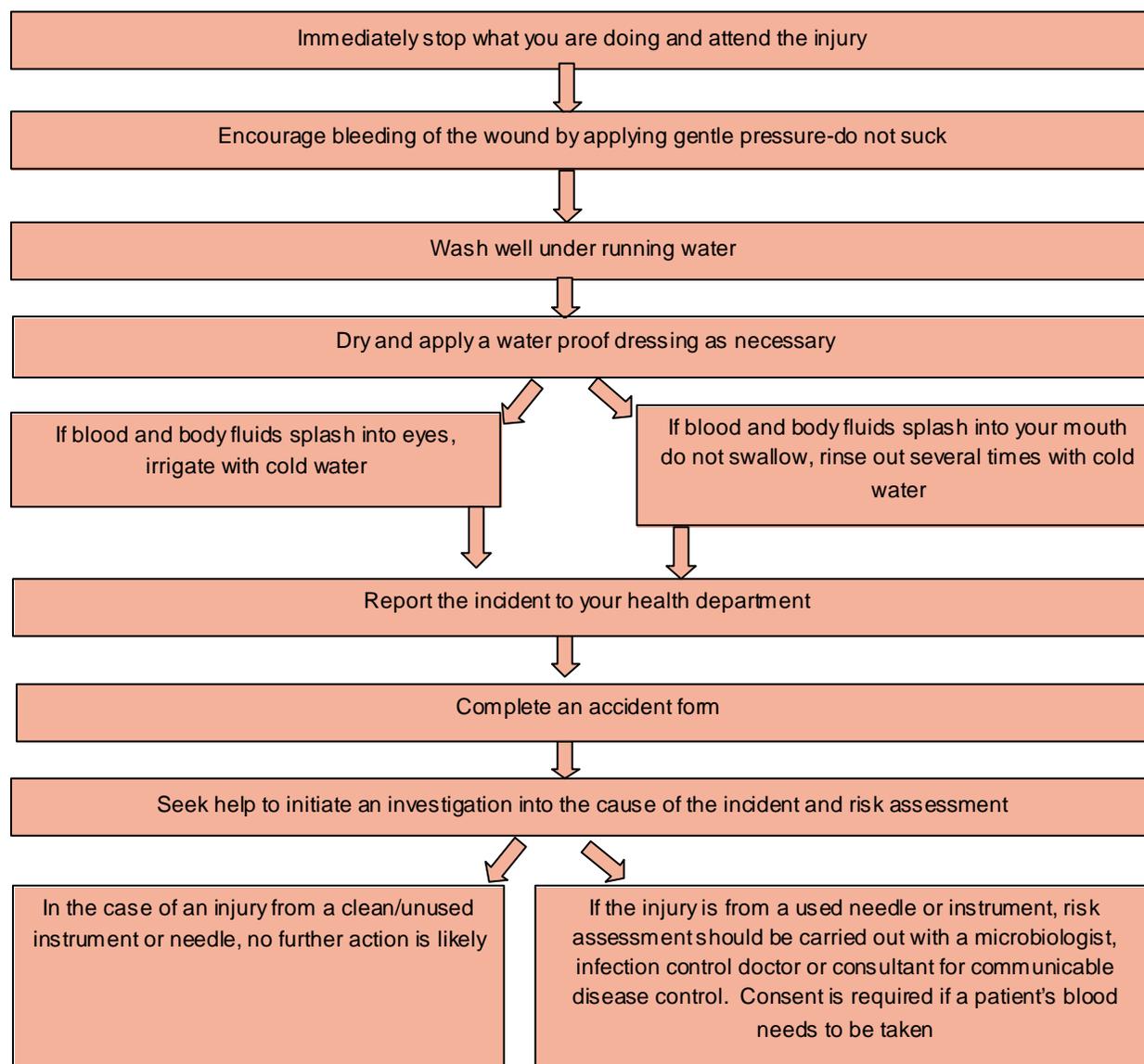
9. Managing accidental exposure to blood-borne virus

Accidental exposure to blood and body fluids can occur by:

- a) Percutaneous injury – for example, from needles, instruments, bone fragments or significant bites that break the skin
- b) Exposure of broken skin – for example, abrasions, cuts or eczema
- c) Exposure of mucous membranes, including the eyes and the mouth



Figure 9: Actions to be taken immediately following accidental exposure to bodily fluids including blood





10. Good communication

Ignorance about the risks of infection and the precautions to prevent transmission leads to anxiety about Hospital acquired infections including MRSA. Service providers can do a great deal to allay fears by communicating effectively, without breaking confidentiality. For example, nurses should:

- a) Provide information leaflets for patients, visitors and staff.
- b) Provide notices which describe the precautions needed.
- c) Talk to patients about how they can help themselves.
- d) Include support staff in team meetings during outbreaks.
- e) Tell the patient how their care might be affected by a hospital acquired infections and how long precautions will be needed.
- f) Ensure that other staff understands the actions.
- g) They need to take – for example, if the community nurse needs to continue care at home.
- h) Inform general practitioners on discharge or transfer if their patient has acquired a hospital infection.

An effective infection control audit Program can encourage change in infection control practice in the hospital. The aim of audit is to improve the delivery of care to patients as well as promote multidisciplinary working in teams. It simply involves taking note of what nurses do, learning from it and changing practices if necessary. Clinically-based audits ensure that the infection control nurse can examine practices where care is actually being delivered. A standardized infection control audit tool could be used by all care providers.

The hospital staff should be educated in the basic principles of infection control in order to be able to apply them to various hospital policies and procedures.

11. Training

All health care professionals who have a clinical responsibility for patients must include infection prevention and control as part of their every day practice. They should receive mandatory infection control training as part of their induction and on an ongoing annual basis.

Training should include:

- a) Practical hand washing sessions/use of alcohol hand sanitizer
- b) Aseptic technique
- c) The importance of environmental/equipment cleaning and whose responsibility
- d) Who to go to for advice/more information
- e) Trust infection and prevention policies
- f) What you can do to help yourself, your colleagues and your patients (uniform, hair, general hygiene).



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Chapter 12: Rajasthan Medicare Relief Societies (RMRS)

Evolution

In order to make public health care services sustainable, ensure stable financing mechanism, enhance financial protection and social safety nets, achieve more resource allocation and government spending on cost effective health interventions and improve institutional capacity and capability in budgeting, pricing, financial planning and management, various options such as pay clinics and auto finance schemes were explored since the 1980s.

In view of the increasing health care cost on account of technological advancements, inflation, expansion of services, autonomy to institutions and payment capacity of people; a health care financing mechanism was developed by Rajasthan and was baptized as Rajasthan Medicare Relief Society.

Started in 1995-96, at SMS hospital, Jaipur; the success of RMRS led to its replication in other medical colleges, district hospital and sub-divisional hospitals, Community Health Centres (CHC) and Primary Health Care Centres (PHCs).

Basic Features

- a) NGO-Registered society-Autonomy
- b) Self-sustainable
- c) Reducing cost of care –No middle man
- d) Instrument for cost recovery (user fee)
- e) Cross subsidy to marginalized
- f) Promote PPP for capital intensive facilities in Health care
- g) Reformatory step
- h) Registered under section 20 of Rajasthan societies Act
- i) Equipments transferred to RMRS
- j) Jan sahbhagita (50:50)
- k) User fee introduced
- l) Reimbursement rules amended

Present status:

53 Hospitals, 376 CHCs and 1504 PHCs.



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Operational Mechanism:

Bye laws:

1. Name of society:

The name of the society would be Rajasthan Medicare Relief Society.

2. Registered office and work space:

The registered name of the society office would include the name of the hospital and the office will be situated in the hospital premises.

3. Objectives of the society:

- a) Providing high quality services on nominal prices
- b) To provide drugs & medicines on reasonable prices.
- c) To run drug store for providing good quality of IV fluid, medicines and surgical items.
- d) To provide free treatment to BPL patients, widows, senior citizen, orphans, disabled and other free categories said by Government.
- e) To provide general services for the patients and their attendants like trolley, security, ren basera, telephone booth, toilets, cafeteria, cottage wars etc.
- f) Obtaining funds, instruments and buildings from the donors, finance organizations and other resources to fulfill the above objectives.

4. Membership: Eligibility to become a member of society are

- a) Resident of the district
- b) Adult
- c) Mentally and financially stable
- d) Has interest in the objectives of the society

5. Suspension of membership:

- a) On death of the member
- b) On resigning from the membership
- c) Having interest against the objectives of the society

6. Formation of committee:

Committee would include three officials and at least five members.

7. Rights & responsibilities of committee

- a) To prepare the annual budget
- b) To secure the assets of society
- c) To appoint the employees and decide their perks and terms of reference
- d) To decide the expenditure on different services like AMC & CMC
- e) Other interests of society

8. Meetings of committee :

- a) Meeting is called in every two months
- b) Member will be informed at least 7 days prior to the meeting date
- c) If the quorum is incomplete the meeting can be cancelled.



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9. Rights & responsibilities of committee's officers:

a) Chairman

- i. To chair the society
- ii. Decisive vote if the consensus is not there
- iii. To call the meetings
- iv. To represent the society
- v. Signing authority on the documents of the society

b) Deputy Chairman:

- i. To work according the rights given by the society.
- ii. To work as chairman in his absence

c) Member Secretary

- i. To organize meetings
- ii. To make minutes of meetings and keep records
- iii. To control on income and expenditure
- iv. To control on the contractual staff and their salary, and honorarium.
- v. To represent the society and sign the legal documents.
- vi. Letter correspondence
- vii. To control the services running under society like drug store etc.

10. Society's treasury

- a) Donations
- b) User charges
- c) Charity funds
- d) Financial aid
- e) Fund from state
- f) Income from Medicare drug store, Canteen, Cycle stand, cottage wards etc.

Income from the above sources will be secured in any nationalized bank.

Apart from the member secretary the bank transactions are possible by the joint signatures of Chairman, and designated member.

11. Special rights related to treasury;

The member secretary can pass a consolidated amount to work in the favor of society.

12. Society Audit

An Annual audit of all the income & expenses is done by a Chartered Accountant designated by the society.

13. Changes in constitution of the society

With two-third majority the amendments may be done but these should be in accordance with the RSR Act (1958).



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14. Dissolution of society

If dissolution becomes necessary, all the assets of the society would be handed over to state government.

15. Regulation of Rajasthan Society Registration Act 1958

User Fee

RMRS introduced User Fee keeping in view that there are large number of people who use the services while the resources are limited.

Charging User Fee is rational because-

1. People misuse services just because they are free,
2. Revenue generated can improve quality,
3. Marginal sections can be better served,
4. System can be made self sustainable to a larger extent,
5. Payment increases the sense of ownership and participation.

The user charges are determined by the cost of care; cross subsidy costs and replacement cost including inflation and rupee devaluation.

1. The charges for services and investigations are decided by a committee chaired by Member Secretary and specialist of respective specialty and accountant will be member of this committee.
2. The proposal of the user fee will be produced in the meeting of governing body to pass.
3. The charges will be decided by considering the market rates, maintenance cost and AMC and CMC.
4. The amendments in the above charges can be made as per the requirements.

Financial Norms:

1. Being an autonomous organization, the financial norms of state government are not applied to RMRS. These norms are formulated by the society itself.
2. RMRS supplements the untied fund given by state government for the various purposes in favor of patients by different sources of earnings.

• Income sources:

- a) Registration fees from OPD & IPD patients
- b) Visitor's Pass fee
- c) User charges for different general and specific diagnostic investigations.



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- d) Various services like surgical operations, ICU, different therapy and charges on various special services.
- e) Rent for cottage wards/special wards/ren basera, guest house
- f) Tender money by cycle stand STD booth and Canteen etc.
- g) Interest on different savings.
- h) Income from auction of different
- i) Income by condemns items.
- j) Training fees by different nursing colleges for their students.
- k) Local income sources establish by the society.

• **Utilization of Income:**

Society can use its income to strengthen the services to patient. Society is entitled to spend total income which includes untied fund as shown in table:

1	Medicines and Investigation charges for BPL patients	25 %
2	Other free category patients	5 %
3	Senior Citizens	20 %
4	Hospital maintenance , cleanliness and other services	20%
5	Investigation materials, chemicals, X-Ray, CT Scan, Sonography film , & AMC for equipments	25%
6	Free transportation services for Emergency and patients suffering by life threatening diseases.	5 %

• **Statement of expenditure:**

The Statement of income and expenditure should be prepared every month and in every six months the head-wise budget statement should be produced in the Meeting of Society.

• **Annual Budget:**

The calculation of income and expenditure of coming financial year and amended calculations in form of annual budget of current financial year should be passed by the committee of society in month of February every year.

• **Entitlement for procurement:**

Health facility	Entitlement
District level and more than 100 bedded hospitals	Rs. 30,000
30 to 100 bedded hospital	Rs. 10,000
PHC	Rs. 5,000
For treatment and transportation in special situations of Law & Order disruption	Rs. 10,000

Only the signature of member secretary will be required for issuing of the cheques of up to above said amounts.



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- **Society's Treasury**

The total capital of society will be deposited in nationalized banks and the conduction of the account will be done jointly by Chairman and member Secretary.

- a) The cheque amounting more than rupees one lakh will be signed jointly by the Chairman & Member Secretary only.
- b) The payment up to one lakh rupees will be released by the sign of Member Secretary and Accountant.
- c) Seed money granted by state government and NRHM will be converted into aid.
- d) Capital under society is tax free.
- e) The patients under free category except BPL will be provided free services only on the recommendations of two members of the governing body.
- f) The governing body will ensure to utilize the capital in the interest of hospital and patients and the fund sanctioned for one year will be utilized the same year.

- **Emergency Expenses by Member Secretary**

The Member Secretary is entitled to spend thirty thousand rupees at a time on routine work as maintenance of equipments and item of daily needs. But this expenditure must not go beyond 30% in a year.

- **Free Services**

Following categories of patients are entitled to utilize free services:

- a) BPL Card Holders
- b) Freedom Fighters,
- c) Orphans,
- d) Prisoners,
- e) Accident Cases
- f) Senior Citizens,
- g) Widows.

Life Line Fluid Drug Store:

Started in 1996, the objective of Life Line Fluid Drug Store (LLFS) is to provide good standard medicine and surgical items to patients at the lowest possible rate compared to market prices, but with a marginal profit for the private contractor who would run the pharmacy store. The authority controlling LLFS is the Rajasthan Medicare Relief Society (RMRS).

Features:

1. Quality drugs purchasing
2. Directly from manufacturer/ distributor
3. Competitive pricing



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4. Liquidity based payment to suppliers
5. Marginal profit to cover operational cost
6. Drugs identified through a committee of doctors at hospital

Advantage:

1. Revenue generation
2. Financial Autonomy
3. Improved efficiency in the system

Challenges:

1. Management skills: Continuous enhancement of the management capabilities of hospital administrators, systems and procedures of procurement, maintenance of equipment and hospital buildings as well as contracting and outsourcing is necessary for smooth functioning of RMRS.
2. Maintenance: A lack of clear policy regarding with whom rests the decision-making authority for repair and maintenance. A study found 53% societies report difficulty in repairing and maintaining equipment.
3. User charges: Procedures for exemption of user charges to vulnerable groups are usually informal and discretionary. Increase in proportion of patients visiting the health facility will make it difficult for RMRS to spend money on upgrading services.
4. Utilization of RMRS funds: Hospital managers fail to spend the generated revenue efficiently, as most of spending is on equipment in absence of trained personnel to operate the machines.
5. Subsidy: The government subsidies to hospitals have not declined because of the transfer of matching grants to participating hospitals. So, it has not relieved the state's burden.
6. Monitoring: Regular systemic monitoring of the RMRS has to be undertaken at all levels.



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RMRS at different level of health facilities

Category	Classification of health facility	Chairperson	Dy. Chairperson	Member Secretary	Members
A	District Hospitals at District HQ	District Collector	Joint Director (Zone)	PMO	Public representatives/ MLA/ CMHO/ Senior Specialist/ Health Manager
B	Satellite Hospitals and District Hospitals (other than above)	Joint Director (Zone)	CMHO	PMO	BCMO/ MLA/ Senior Specialist/ Public representatives
C	Sub-division Hospitals & CHCs	CMHO	BCMO	MO I/C, CHC	MLA/ Reputed citizens/ Social workers/ Donors/ Junior Specialist
D	PHCs	BCMO	MO I/C, CHC	MO I/C, PHC	Reputed citizens/ Social workers/ Donors



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Chapter 13: Roles and Responsibilities of Pharmacists

Pharmacists are often the first point-of-contact for patients with health inquiries. This means that pharmacists have large roles in the assessing medication management in patients, and in referring patients to physicians.

These roles may include, but are not limited to:



- a) Prepare list of need based medicines.
- b) Proper drug quantification to maintain continuous supply of drugs and medical items.
- c) Proper arrangement and storage of drugs to maintain the potency and quality of drugs.
- d) Drug dispensing and distribution.
- e) Keeping accurate inventory record to provide stock movement information for forecasting the needs.
- f) Separate inventory record for controlled substances.
- g) Develop monthly consumption record.
- h) Preparation of indenting and with higher canter for procurement of drugs as and when required and placing of orders timely.
- i) Cleanliness and sanitation of hospital pharmacy.
- j) Management of hospital pharmacy infrastructure.
- k) Display of available medicines and prices outside the pharmacy.
- l) Computerized Drug management information system.
- m) Assessment of patients with undiagnosed or diagnosed conditions and for decisions about the clinical medication management required.
- n) Reviewing medication regimens
- o) General health monitoring
- p) Providing general and specific education to patients about disease states, medications and route of administration & side effects.
- q) Provision of non-prescription medicines
- r) Counseling and advice on optimal use of medicines and referral to health professionals if necessary
- s) Advice and treatment of common ailments
- t) Limited prescribing of medications only in collaboration with other health care professionals



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Chapter 14: Roles and Responsibilities of Nursing Staff

Nursing service provides safe, efficient, and therapeutically effective nursing care through the planning of the care of each inpatient and the effective implementation of nursing care plans by understanding and performing duties as allocated.



Essential Duties and Responsibilities of nursing staff

- a) Supervise the nursing assistants and follow up performance of tasks of all staff working within the health facilities.
- b) Assist the medical coordinator in setting up and running the maternal and child health routine activities.
- c) Regularly update medical coordinator and program manager on drugs/medical supplies and ensure that medical orders are timely done.
- d) Monitor drug and medical supply stocks through monthly consumption and inventories, noting drugs and material expiring dates and submit the same to medical coordinator in time.
- e) In collaboration with the medical coordinator arrange for regular training and clinic staff meeting as required.
- f) Supervise the running of the pharmacy and ensure rational use of drugs as per the guidelines laid down by the medical coordinator and program manager.
- g) Organize the work shift schedule for staff working in both the inpatient and outpatient facilities.
- h) Ensure proper follow up of patients within public health facility and that the clinics are clean, orderly and equipment and supplies are moved and stored as per the laid guidelines.
- i) Perform outreach activities as may be required.
- j) Ensure that service statistics and all the required reports are properly collected from each department and submitted timely to the immediate supervisor.
- k) Participate in emergency preparedness, rapid assessments and eventual emergency responses in collaboration with the entire team.
- l) To coordinate the nursing care plan for each patient with medical plan of care.

Guidance for Registered Nurses, Midwives and Health Visitors

A Registered Nurse or Midwife is accountable for all actions and omissions. In administering medication, including overseeing self-administration, they must exercise their professional judgment and apply knowledge and skill in the given situation.



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- a) One must be aware of the inter-relationship with the multidisciplinary team in the administration of medicines, for example in theatres. Even where there is joint or team involvement, one remains accountable for their actions and omissions.
- b) One should follow clear procedures to ensure the right patient receives the right drug, in the right dose, by the right route, at the right time.
- c) One must know the therapeutic use of the medicine to be administered including normal dosage, side effects, precautions and contra-indications.
- d) One must check that the prescription is clearly written and unambiguous and based wherever possible on the patient's informed consent. If there is any uncertainty about the prescription, one must check with the prescriber or another authorized prescriber and clarify the prescription before administering the medication.
- e) One must be certain of the identity of the patient to whom the medicine is to be administered.
- f) One must check the expiry date of the medicine to be administered.
- g) One must check the patient is not allergic to the medicine before administering it.
- h) Where complex calculations are required to ensure the correct volume or quantity of medication is administered, second practitioner must be asked to calculate separately to avoid error.
- i) Blood transfusions and intravenous medications shall be administered by trained nurses for this purpose.
- j) An emergency drug card or kit shall be available, maintained, and used in accordance with emergency pharmaceutical services.
- k) One must **not** prepare substances for injection in advance of their immediate use or administer medication drawn into a syringe or container by another practitioner not in one's presence.

Drug administration

- a) Each dose of drug shall be recorded in the medical record of the patient and properly signed after the drugs have been administered.
- b) Any medication error or apparent drug reaction shall be reported immediately to the practitioner who ordered the drug and recorded.
- c) Notification of all drug sensitivities, including any apparent adverse reaction and medication errors shall be recorded and sent to the physician.
- d) One must not take any part in the prescribing, collection or administration of cytotoxic agents unless have received appropriate training. This must be recorded in accordance with Govt. policy.



Annexure: A: Exercises

Exercise 1: Stock card

Paracetamol Tablet 500MG

DATE 2003		IN	OUT	STOCK
1 Jan	OPENING STOCK			10,000
20 Jan	To hospital pharmacy		10,000	0
1 Feb	From central store	30,000		30,000
25 Feb	To hospital pharmacy		10,000	20,000
20 Apr	-do-		10,000	10,000
1 Jun	-do-	1500	10,000	0
31 Jul	From central store	50,000		50,000
1 Aug	To hospital pharmacy		10,000	40,000
7 Sep	-do-		10,000	30,000
20 Oct	-do-		10,000	20,000
10 Dec	-do-		10,000	10,000
31 Dec	Closing stock			10,000

1. What is the recorded consumption for the year?
2. Has the drug been out of stock?
3. If so, how long were the stock-out periods?
4. Which stock-outs require adjustments to be made?
5. What is the effective period during which the drug has been in stock?
6. What is the consumption adjusted for stock-outs?

Exercise 2: Stock card

Chlorpheniramine 4 MG

DATE 2003		IN	OUT	STOCK
1 Jan	OPENING STOCK			2,000
15 Jan	To hospital pharmacy		1,000	1,000
15 Feb	To hospital pharmacy		1,000	0
1 Mar	From central store	5,000		5,000
10 Mar	To hospital pharmacy		1,000	4,000
7 Apr	To hospital pharmacy		2,000	2,000
10 Jun	To hospital pharmacy		1,000	1,000
7 Jul	To hospital pharmacy		1,000	0
10 Oct	From central store	5,000		5,000
11 Oct	To hospital pharmacy		2,000	3,000
30 Nov	-do-		1,000	2,000
15 Dec	-do-		1,000	1,000
31 Dec	Closing stock			1,000

1. What is the recorded consumption for the year?
2. Has the drug been out of stock?



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3. If so, how long were the stock-out periods?
4. Which stock-outs require adjustments to be made?
5. What is the effective period during which the drug has been in stock?
6. What is the consumption adjusted for stock-outs?

Exercise 3: How to do ABC Analysis.

Step 1-4, List all items, and enter unit cost, consumption quantities and total value.

Column number	1	2	3	4	5	6
			Multiply col 1 and 2	Divide Value/ Col 3		
	Cost/ unit	Qty.	Value (Rs.)	% of total value	Rank by Value	Cumulative %
Inj Cefotaxime	65	45,3000	2944500			
Anti rabies vaccine	100	12060	1206000			
Inj Ceftriaxone	62	23400	1450800			
Sterilium hand scrub	70	12600	882000			
Cap Amoxycillin 500 mg	4.5	54890	247005			
Cap Amoxycillin 250 mg	1.78	60890	108384.2			
Nimesulide drops	10.5	9876	103698			
Betadine Ointment	5.32	10210	54317.2			
Ciprofloxacin eye drops	4.78	11,200	53536			
Vitamin B complex	0.5	86540	43270			
Tab Co-trimoxazole	1.05	40780	42819			
Inj Benzyl penicillin	4.78	6790	32456.2			
Tab Albendazole	0.45	36780	16551			
Tab Cetirizine 10 mg	0.35	45700	15995			
Tab Chloroquin 150 mg base	0.14	56070	7849.8			
Tab Paracetamol 500 mg	0.2	14580	2916			
Tab Salbutamol 4 mg	0.12	15690	1882.8			
Tab Amlodepin 5 mg	0.15	5060	759			
			Total Value			

Total Value = _____

Add up all values in column 3



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Step 5. Calculate the percentage of the total represented by each item.

	Cost/ unit	Qty.	Value (Rs.)	% of total value	Rank by Value	Cumulative %
Inj Cefotaxime	65	45,3000	2944500	40.81		
Anti rabies vaccine	100	12060	1206000	16.11		
Inj Ceftriaxone	62	23400	1450800	20.11		
Sterilium hand scrub	70	12600	882000	12.22		
Cap Amoxicillin 500 mg	4.5	54890	247005	3.42		
Cap Amoxicillin 250 mg	1.78	60890	108384.2	1.50		
Nimesulide drops	10.5	9876	103698	1.44		
Betadine Ointment	5.32	10210	54317.2	0.75		
Ciprofloxacin eye drops	4.78	11,200	53536	0.74		
Vitamin B complex	0.5	86540	43270	0.60		
Tab Co-trimoxazole	1.05	40780	42819	0.59		
Inj Benzyl penicillin	4.78	6790	32456.2	0.45		
Tab Albendazole	0.45	36780	16551	0.23		
Tab Cetirizine 10 mg	0.35	45700	15995	0.22		
Tab Chloroquin 150 mg base	0.14	56070	7849.8	0.11		
Tab Paracetamol 500 mg	0.2	14580	2916	0.04		
Tab Salbutamol 4 mg	0.12	15690	1882.8	0.03		
Tab Amlodepin 5 mg	0.15	5060	759	0.01		
			7214739.2	100.00		

Step 6. Rearrange and rank the items in descending order

	Cost/ unit	Qty.	Value (Rs.)	% of total value	Rank by Value	Cumulative %
Inj Cefotaxime	65	45,3000	2944500	40.81	1	
Anti rabies vaccine	100	12060	1206000	16.11	2	
Inj Ceftriaxone	62	23400	1450800	20.11	3	
Sterilium hand scrub	70	12600	882000	12.22	4	
Cap Amoxicillin 500 mg	4.5	54890	247005	3.42	5	
Cap Amoxicillin 250 mg	1.78	60890	108384.2	1.50	6	
Nimesulide drops	10.5	9876	103698	1.44	7	
Betadine Ointment	5.32	10210	54317.2	0.75	8	
Ciprofloxacin eye drops	4.78	11,200	53536	0.74	9	
Vitamin B complex	0.5	86540	43270	0.60	10	
Tab Co-trimoxazole	1.05	40780	42819	0.59	11	
Inj Benzyl penicillin	4.78	6790	32456.2	0.45	12	
Tab Albendazole	0.45	36780	16551	0.23	13	
Tab Cetirizine 10 mg	0.35	45700	15995	0.22	14	
Tab Chloroquin 150 mg base	0.14	56070	7849.8	0.11	15	
Tab Paracetamol 500 mg	0.2	14580	2916	0.04	16	
Tab Salbutamol 4 mg	0.12	15690	1882.8	0.03	17	
Tab Amlodepin 5 mg	0.15	5060	759	0.01	18	
			7214739.2	100.00		



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Step 7. Calculate the cumulative percentage

	Cost/ unit	Qty.	Value (Rs.)	% of total value	Rank by Value	Cumulative %
Inj Cefotaxime	65	45,3000	2944500	40.81	1	40.81
Anti rabies vaccine	100	12060	1206000	16.11	2	57.53
Inj Ceftriaxone	62	23400	1450800	20.11	3	77.64
Sterilium hand scrub	70	12600	882000	12.22	4	89.86
Cap Amoxicillin 500 mg	4.5	54890	247005	3.42	5	89.86
Cap Amoxicillin 250 mg	1.78	60890	108384.2	1.50	6	93.29
Nimesulide drops	10.5	9876	103698	1.44	7	94.79
Betadine Ointment	5.32	10210	54317.2	0.75	8	96.23
Ciprofloxacin eye drops	4.78	11,200	53536	0.74	9	96.98
Vitamin B complex	0.5	86540	43270	0.60	10	97.72
Tab Co-trimoxazole	1.05	40780	42819	0.59	11	98.32
Inj Benzyl penicillin	4.78	6790	32456.2	0.45	12	98.91
Tab Albendazole	0.45	36780	16551	0.23	13	99.36
Tab Cetirizine 10 mg	0.35	45700	15995	0.22	14	99.56
Tab Chloroquin 150 mg base	0.14	56070	7849.8	0.11	15	99.81
Tab Paracetamol 500 mg	0.2	14580	2916	0.04	16	99.81
Tab Salbutamol 4 mg	0.12	15690	1882.8	0.03	17	99.96
Tab Amlodepin 5 mg	0.15	5060	759	0.01	18	99.99
			7214739.2	100.00		100.00

Step 8. Choose cut-offs for the boundaries of A,B,C and do VEN classification

	Cost/ unit	Qty.	Value (Rs.)	% of total value	Rank by Value	Cumulative %	VEN Class
Inj Cefotaxime	65	45,3000	2944500	40.81	1	40.81	
Anti rabies vaccine	100	12060	1206000	16.11	2	57.53	
Inj Ceftriaxone	62	23400	1450800	20.11	3	77.64	
Sterilium hand scrub	70	12600	882000	12.22	4	89.86	
Cap Amoxicillin 500 mg	4.5	54890	247005	3.42	5	89.86	
Cap Amoxicillin 250 mg	1.78	60890	108384.2	1.50	6	93.29	
Nimesulide drops	10.5	9876	103698	1.44	7	94.79	
Betadine Ointment	5.32	10210	54317.2	0.75	8	96.23	
Ciprofloxacin eye drops	4.78	11,200	53536	0.74	9	96.98	
Vitamin B complex	0.5	86540	43270	0.60	10	97.72	
Tab Co-trimoxazole	1.05	40780	42819	0.59	11	98.32	
Inj Benzyl penicillin	4.78	6790	32456.2	0.45	12	98.91	
Tab Albendazole	0.45	36780	16551	0.23	13	99.36	
Tab Cetirizine 10 mg	0.35	45700	15995	0.22	14	99.56	
Tab Chloroquin 150 mg base	0.14	56070	7849.8	0.11	15	99.81	
Tab Paracetamol 500 mg	0.2	14580	2916	0.04	16	99.81	
Tab Salbutamol 4 mg	0.12	15690	1882.8	0.03	17	99.96	
Tab Amlodepin 5 mg	0.15	5060	759	0.01	18	99.99	
			7214739.2	100.00		100.00	



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Exercise 4: Comparing Total Costs with VEN Priorities and the Available Limited Budget

	Cost/ unit	Qty.	Value (Rs.)	% of total value	Rank by Value	Cumulative %	VEN Class	Adjusted Qty.	Adjusted values
Inj Cefotaxime	65	45,3000	2944500	40.81	1	40.81			
Anti rabies vaccine	100	12060	1206000	16.11	2	57.53			
Inj Ceftriaxone	62	23400	1450800	20.11	3	77.64			
Sterilium hand scrub	70	12600	882000	12.22	4	89.86			
Cap Amoxicillin 500 mg	4.5	54890	247005	3.42	5	89.86			
Cap Amoxicillin 250 mg	1.78	60890	108384.2	1.50	6	93.29			
Nimesulide drops	10.5	9876	103698	1.44	7	94.79			
Betadine Ointment	5.32	10210	54317.2	0.75	8	96.23			
Ciprofloxacin eye drops	4.78	11,200	53536	0.74	9	96.98			
Vitamin B complex	0.5	86540	43270	0.60	10	97.72			
Tab Co- trimoxazole	1.05	40780	42819	0.59	11	98.32			
Inj Benzyl penicillin	4.78	6790	32456.2	0.45	12	98.91			
Tab Albendazole	0.45	36780	16551	0.23	13	99.36			
Tab Cetirizine 10 mg	0.35	45700	15995	0.22	14	99.56			
Tab Chloroquin 150 mg base	0.14	56070	7849.8	0.11	15	99.81			
Tab Paracetamol 500 mg	0.2	14580	2916	0.04	16	99.81			
Tab Salbutamol 4 mg	0.12	15690	1882.8	0.03	17	99.96			
Tab Amlodepin 5 mg	0.15	5060	759	0.01	18	99.99			
			7214739.2	100.00		100.00			



Annexure: B: Samples

Medication Error Reporting Form

Patient Identifier

Name: Sex (M/F): Age:

Floor: Bed No:

Diagnosis:

Describe the error (what went wrong, how it happened, name & details the drug involved, if any):

Type of Medication error: (Please tick the correct observation)

- a) Prescription error ()
- b) Indent error ()
- c) Dispensing error ()
- d) Administration error ()
- e) Allergy information missing ()
- f) Improper storage ()
- g) Misinterpretation of verbal order ()

Action taken on identification of the error:

Outcome

1. An error occurred that may have the capacity to cause error.
2. An error occurred but the error did not reach the patient.
3. An error occurred that reached the patient but did not cause any harm.
4. An error occurred that reached the patient but required monitoring.
5. An error occurred that contributed to temporary harm to the patient/hospital admission/prolonged hospital stay.

Recommendation for error prevention:

Signature of reporting person:

Date:



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ADR Reporting Form

Patient Details

Patient's initials _____ Sex: _____ (M/F)

Weight (if known, in kgs.) _____

Age (at time of reaction) _____ identification

(Hospital Ref) _____

Floor No. _____ Bed No. _____

Suspected Drug(s)

(Give generic/brand name of drug)

Batch No. (if known) Route, Dosage, Date & Time

Prescribed for

Started

Stopped

Concomitant medication administered:

- | | |
|----------|----------|
| 1. _____ | 4. _____ |
| 2. _____ | 5. _____ |
| 3. _____ | 6. _____ |

Treatment given for ADR

- Did reaction disappear after stopping the suspected drug? Yes/No
- Did you restart the suspected drug? Yes/No
- Did reaction appear after starting the suspected drug? Yes/No

Suspected Reaction(s)

Outcome: Recovered, Recovering, Continuing

Date reaction (s) started _____ Date reaction (s) stopped _____

Do you consider the reaction to be serious? Yes/No

Please ensure the report card is completely filled

Signature of the reporting person:

Date:



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STOCK RECORD CARD

Generic Name : Chloroquine
Code No. : 8022

Strength: 300mg
Unit of issue: tab

Dosage Form: tab
Unit Price: Rs. 0.3400

Date	From Whom Rec./Issue/	Qty.	Qty. Issued	Balance 100,000	Remarks Exp.	Signature
1.3.98	Inventory				9/2000	
2.3.98	PCH I		5000	95000		
7.4.98	PCH I		10000	79000		
20.4.98	PCH III		5000	74000		
2.5.98	RCH	50,000	121000			
7.5.98	PCH II		1000	120000		
8.7.98	HOSP		10000	100000 5/2001	Exp.	
15.7.98	PCH I		5000	95000		
3.8.98	PCH I		1000	92000		
30.9.98	PCH I		7000	80000		
5.10.98	PCH III		2000	78000		
1.11.98	HOSP		5000	70000		
7.12.98	PCH I		3000	67000		
1.1.99	PCH I		5000	60000		
13.1.99	PCH III		6000	54000		

Fiscal year	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct.	Nov	Dec	Jan	Usage	Exp
Fy. 97/98	5000	15000	1000	0	15000	1000	7000	2000	5000	3000	11000		
Drug Consumption													

Pharmacy



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Bin/Stock Card

Description: Paracetamol tab 500 mg
Stock No. : 02

Unit of issue: 1000 tabs

Date 1998	Document/ Number	Received from/Issued to	Units received	Units issued	Balance	Initials
Apr 5	Balance Brought Forward				1665	PF
Apr 5	N 98534	PHC 42		10	1655	RS
Apr 6	N 98543	HOSP 6		200	1445	RS
May 6	N 98546	PHC 55		16	1429	BJ
May 6	N 98561	PHC 53		10	1419	PF
May 7	N 98573	PHC 66		5	1232	RS
May 7	N 98575	PHC 62		5	1227	RS
June 7	N 98574	PHC 68		5	1212	RS
June 8	N 98166	NOV APHARM	10000		11202	BJ
June 8	N 98605	HOSP 9		200	11002	BJ
July 8	N 98604	HOSP 8		200	10802	BJ
July 8	N 98609	PHC 71		10	10729	RS
Aug 8	N 98613	PHC 78		12	10770	RS

Receiving Report

Supplier: Apotex Inc.
Po No. DMS 116/04
Port of entry: Raipur
Date received at port of entry: 05/12/04
Number of shipping cartons/containers: 3

Invoice No. : 686033
Carrier: Fast Forwardes
Date Cleared: 05/17/98

Certified that from external inspections, all containers appear to be suitable and without damage except as follows:

Clearing Officer

Date:

Certified that all item on the invoice and the purchase order (specified above) were received and after inspection, released for removal to shelving except as follows (or as marked on the invoice).

Receiving clerk

Date:

Chief storekeeper

Date:



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Requisition/Issue Voucher

Requisition No.: _____

Health Facility: _____

Authorised by: _____

Date: _____

Supply period _____ to _____

Status of requisition

Regular

Interim

Emergency

Item No.	Stock No.	Description	Unit of Issue	Stock on Hand	Quantity Issued	Amount (Rs)	Notes
	1	2	3	4	5	6	7
1	02-0500	Aspirin tab 300mg	100T	12	18	165.60	
2	02-2200	Chloroquine tab 150mg	100T	3	5	61.00	
18	02-4600	Paracetamol tabs 500mg	1000T	6	8	209.60	
19	02-4800	Phenoxymethyl tab 250mg	1000T	3	4	81.40	Short
20	02-4850	Piperazine tabs 500mg	1000T	1	1	11.20	

Hour and date requisition received

Hour and date shipment received

Clearances:

In-charge of medical stores

Driver or custodian accepts
shipment

Recipient, acknowledgment
of receipt of shipment



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Delivery Voucher

Deliver to: _____
Requisition No.: _____
No. : _____

Issue voucher

Received from Central Medical Stores _____ sealed cartons and _____ containers described below:

for delivery to the above- named requisitioner/facility

Stores issuing officer

Driver/custodian of shipment

Date and time

Received by requisitioner from the above-named custodian of shipment, the containers and/or items stated above in good order, except as follows:

Receiving officer of requisitioning facility

Date and time

IF ANY DISCREPANCY IS RECORDED BY THE RECEIVING OFFICER, THIS DELIVERY VOUCHER IS TO BE INITIALED BY THE CUSTODIAN OF THE SHIPMENT AS WELL.

Register of Requisitions

(Stores Issues Ledger)

Stores No.	Date	Requisition No.	Issue Voucher No.	Values of Issues (Rs.)				Certified
				Drugs	Med/surg	Others	Total	
01	Mar 5	98-3-2R	PHC 42 98534	2412.60	836.50	-	3249.10	Ramnarayan
02	Mar 5	98-3-2R	PHC 44 98541	2933.50	1078.50		4012.00	Ramnarayan
03	Mar 5	98-3-4R	HOSP6 98543-45	28364.20	6517.60	937.50	35819.30	Ramnarayan
023	Mar 8	98-3-4R	PHC75 98611	3545.30	948.60	---	4493.90	Madhav
024	Mar 8	98-3-4R	PHC78 98613	2266.40	592.30	---	2858.70	Madhav
025	Mar 8	98-3-4R	PHC72 98614	2947.70	876.10	---	3823.80	Madhav