

Drug utilization research: a review

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ABSTRACT

Data from drug utilization research is an invaluable resource for all stake holders involved in drug and health policies. Drug utilization is “marketing, distribution, prescription and use of drugs in a society, with special emphasis on the resulting medical, social and economic consequences”. Research on drug utilization includes factors related to prescribing, dispensing, administering and intake of medication and its associated events. The ultimate purpose of drug utilization research is to estimate the optimal quality of drug therapy by identifying, documenting, analysing problems in drug utilization and monitoring the consequences. It encourages the prescribers to prescribe correct drug at appropriate dose and affordable price. It contributes to the knowledge of rational use of drugs in the society; whether the drug is being prescribed appropriately, whether the drug is taken in correct dosage, whether the drug is available at affordable price or misused. It provides valuable feedback about the rationality of the prescription to the doctors. It also assesses whether an intervention affects the drug use in the population by examining the outcomes of different types of intervention given to improve rationality in drug use. Drug utilization research can be qualitative or quantitative and can be done by various methods. This review highlights the understanding of various aspects, different designs and WHO guidelines for conducting drug utilization research.

Keywords: ATC classification, Aspects of drug utilization research, Drug utilization research, Defined daily dose, Drug use indicators, Drug and therapeutic committee

INTRODUCTION

Drug utilization research as defined by WHO (World Health Organization) is “marketing, distribution, prescription and use of drugs in a society, with special emphasis on the resulting medical, social and economic consequences”. Rational use of drug requires that patient receive medication appropriate to their clinical needs, in dose that meet their own individual requirements for the adequate period and the lowest cost to them and their community.¹ Poor management and irrational use of drugs leads to increased morbidity and mortality, wastage of resources, prolonged suffering, death and loss of confidence in the health care system.² There are many factors underlying irrational use of drugs. Major factors

can be patients, prescribers, workplace and supply system.^{3,4} Therefore, it is important to recognize negative consequences of inappropriate drug use to promote rational use of drug.⁵ The development of drug utilization as research area made it possible to study drug use in a scientific manner.⁶ Studies on drug utilization have become a potential tool to be used in the evaluation of healthcare system.⁷ The main objectives of drug utilization research are to identify drug use related problems and analyze their consequences. Drug utilization research encourages rational prescribing of drug, contributes to the knowledge of current use of drugs in the society and explore whether a particular intervention affects the drug use in the population by observing the drug use pattern.⁸

LITERATURE REVIEW

The principal aim of drug utilization research is to facilitate rational use of drug in population. The objectives of the drug utilization research are to ensure that the pharmaceutical therapy meets current standards of care, to promote optimal medication therapy, to prevent medication related problems, to identify specific medicine use problems that require further evaluation, to create guidelines for appropriate medicine use, to define threshold for quality of medicine use and to control pharmaceutical cost.

Aspects of drug utilization research

Review of reported studies on drug use indicates that drug utilization research can be carried out focusing on three aspects: medical aspects, social aspects and Economical aspects

Medical aspects

Medical aspects of drug utilization research focus on efficacy of drugs in preventing, relieving and curing the disease as well as short and long term adverse effects of drugs and their management.

It can be used to increase our understanding of how drugs are being used, to estimate what extent drugs are being properly used, overused or underused, to determine the pattern or profile of drug use and the extent to which alternative drugs are used to treat conditions, to compare the pattern of drug use for the treatment of a certain disease like malaria, hypertension, acute respiratory illness, acute diarrhoea in children and common infections like urinary tract infections, respiratory tract infection etc. with current recommendations or guidelines. Studies can also look at what happen to the patient after drug prescribed. This can be done by following up the patient to check if they are taking the drugs as advised, if there is improvement in the disease condition or if any adverse drug reactions developed after taking drugs.

Social aspects

Social aspects include patient attitude to drugs, drug abuse and dependence, improper use of drugs (non-compliance, use of drugs for purpose for which they were not prescribed), unavailability of important drugs to those who need them etc.

Economic aspects (Pharmacoeconomics)

Pharmacoeconomics is the sciences that evaluate the costs of drug therapy. The goal of pharmacoeconomics is to select least costly and most effective drug therapy for a given disease condition.⁵

Studies on pharmacoeconomics can be classified into 4 types.⁸

- Cost minimization analysis- When two drugs are equal in terms of outcome, cost of each drug may be evaluated and compared. This method used for comparing two drugs from same therapeutic and chemical group.
- Cost-effectiveness analysis- Cost-effectiveness analysis compares therapies with similar outcome in particular therapeutic area.
- Cost is measured in a monetary unit and outcome is measured in a natural unit e.g. no. of successfully treated patients, no. of life years gained.
- Cost benefit analysis - This method involves direct calculation of the net expenditure to achieve healthy outcome.
- Cost utility analysis- This analysis is used to determine the cost of utilities such as quantity and quality. It compares two drugs which have different outcomes i.e. differences in their benefits. This type integrates both, the increase in the survival time and the changes and the quality of life, either with or without the increase in the survival time.

Levels of drug utilization research⁶

Drug utilization research can be done at various levels of health care depending on the purpose of study as shown in Table 1. Studies can be conducted at a primary health centre level by analyzing prescriptions. At tertiary care level, studies can be done to compare cost effectiveness of medicines procured by pharmacy.

Table 1: Various levels of drug utilization research.

First level	Second level
Drug	Single drug
	Group of drugs
	All the drugs
Area	Country/countries
	Region(s)
	Pharmacy/pharmacies
	Hospital ward/hospitals
Level of therapy	Prescribers
	Prescriptions
	Patient compliance/non-compliance
	Pharmacokinetics/pharmacodynamics etc.

Quantitative versus qualitative drug utilization research

Quantitative DUR

Quantitative DUR used to quantify current state and trends of drug use. It involves collection, organization and display of estimates or measurement of drug use. The information is generally used for making decisions or preparing drug budgets. Data from quantitative drug use studies are generally suggestive but not conclusive in respect to quality of drug use.

Qualitative DUR

Qualitative DUR include research on quality of health care and factors affecting the quality of health care. Qualitative DUR based on concept of “criteria”. Criteria are standards or reference (such as Standard Treatment Guideline, National Drug Formulary, and National Essential Drug List) against which quality of care to be evaluated.⁹

Study design in drug utilization research^{9,10}

Observational research methods are most commonly used design in drug utilization research. It involves observing the prescribing practices for rationality as well as observing the availability of infrastructure and other facilities required for effective provision of medicine use like availability of qualified practitioners and dispensers, availability of essential medicines, availability of NEM list and standard treatment guidelines etc.

Cross-sectional study

Involve analyzing drug use at a single point.

Pre and post study design

Where drug use is examined before and after intervention to improve prescribing pattern.

Prospective studies

It involves evaluating drug utilization while follow up of patients or health facility over a period of time.

Retrospective studies

Involves review of drug therapy after the patient has received treatment. Retrospective studies are usually record based which includes review of prescriptions, checking stock out in the pharmacy for previous year.

How to investigate drug use in health facilities: WHO guidelines¹⁰

The WHO and INRUD (International Network of Rational Use of Drug) developed indicators to be used as measure of performance in the rational use of drug in primary care. These indicators are commonly known as core drug use indicators (Table 2) list of indicators to be used to study drug utilization in health facility and the rational and formula to calculate each indicator has been mentioned in Table 3.

How to investigate drug use in community: WHO guidelines¹¹

Studies on drug use in community helps to identify the type of drug misuse such as non-compliance with health worker’s prescriptions, self-medication with prescription

drugs, misuse of antibiotics, overuse of injections, overuse of relative safe drugs, use of irrational combinations of drugs or use of needlessly expensive drugs. It helps to gain insight into various channels through which people in community obtain drugs.

Table 2: Types of indicators.

Type of indicator	Name of indicators
Prescribing indicators	Average number of drugs per encounter.
	Percentage of drugs prescribed by their generic names.
	Percentage of encounters with an antibiotic prescribed.
	Percentage of encounters with an injection prescribed.
Patient care indicators	Percentage of drugs prescribed from essential drug list of formulary
	Average consultation time
	Average dispensing time
	Percentage of drugs actually dispensed
	Percentage of drugs adequately labeled
Health facility indicators	Patient knowledge of correct dosages.
	Availability of key essential drugs.
	Availability of copy of essential drug list or formulary

People may be in habit of obtaining their drugs from other drug distribution channels than health centers that are distributing essential drugs. Such people receive drug related information which may or may not be appropriate. Community health workers are trained to distribute drugs in primary health centers.

It is important to study the appropriateness of drug distribution by community health workers: How adequate is the supply of drug? What is the coverage of community health workers? How rational are their prescriptions practices? To what extent people rely on community health workers for their drug needs? It helps to gain knowledge about people’s ideas of drug safety and their self-medication practices. List of indicators to be used to study drug utilization in community has been mentioned in Table 4.

Stepwise approach to drug utilization research¹²

The following flow chart outlines the basic steps to conduct a drug utilization research (Figure 1).

Define study objectives

Most important step in drug use study is to specify the objectives of study. Study design, sample size required, and data collection depends upon objectives of study. Studies are more useful when designed to meet specific objectives.

Table 3: Purpose and formula to calculate each indicator.

Indicator	Purpose	Calculation
Prescribing indicators		
Average number of drugs per encounter.	To measure the degree of polypharmacy	Average: Total number of different drug products prescribed ----- Total number of encounters surveyed.
Percentage of drugs prescribed by generic names	To measure the tendency to prescribe by the generic names	Percentage: Number of drugs prescribed by generic names ----- $\times 100$ Total number of drugs prescribed
Percentage of encounters with an antibiotic/injection prescribed	To measure the overall level of use of two important but commonly overused and costly forms (antibiotic and injection) of the drug therapy.	Percentage: Number of encounters during which an antibiotic or an injection are prescribed ----- $\times 100$ Total number of encounters surveyed.
Percentage of drugs prescribed from essential drug list or formulary	To measure the degree to which practices confirms to a national drug policy as indicated by prescribing drugs from EML or formulary.	Percentage: Number of products prescribed which are listed on the essential drugs list or local formulary ----- $\times 100$ Total number of products prescribed, multiplied.
Patient care indicators		
Average consultation time	To measure the time that medical personnel spend with patient in the process of consultation and prescribing	Average: Total time for series of consultation ----- Number of consultations.
Average dispensing time	To measure the average time that personnel dispensing drugs spend with patient.	Average: Total time for dispensing drugs to a series of patients ----- Total number of encounters.
Percentage of drugs actually dispensed	To measure the degree to which health facilities are able to provide the drugs which are prescribed.	Percentage: Number of drugs dispensed ----- $\times 100$ Total number of drugs prescribed
Percentage of drugs adequately labeled.	To measure the degree to which dispenser's record essential information on the dug package they dispense.	Percentage: Number of drug packages containing at least patient name, drug name and when the drug should be taken ----- $\times 100$ Total number of drug packages dispensed
Patient knowledge of correct dosage	To measure the effectiveness of the information given to patient on the dosage schedule of the drugs they received	Percentage: Number of patients who can adequately report the dosage schedule for all drugs ----- $\times 100$ Total number of patients interviewed
Facility indicators		
Availability of copy of essential drug list or formulary	To indicate the extent to which copies of the EML or formulary are available at health facility.	Yes/No
Availability of key drugs	To measure the availability of key drugs at health facility	Percentage: Number of specified products actually in stock ----- $\times 100$ total number of drugs on the checklist

Table 4: Indicators to be used to investigate drug use in the community.

Indicator	Purpose	Calculation
Percentage of illness episodes treated on health worker's prescription / in self-medication	To measure the extent to which people consult a health worker and extent to which they practice self-medication	$\frac{\text{Total no. of illness episodes in which a health worker was consulted}}{\text{Total no. of illness episodes reported during 2 weeks of survey}} \times 100$
		$\frac{\text{Total no. of illness episodes in which a drug was used without consulting a health worker}}{\text{Total no. of illness episodes reported during 2 weeks of survey}} \times 100$
Percentage of treatment obtaining from the health center/pharmacy	To measure the extent to which people obtain their treatment from the health center or pharmacy.	$\frac{\text{No. of treatment obtained from pharmacy}}{\text{Total no. of treatment reported in 2 weeks of survey}} \times 100$
		$\frac{\text{No. of treatment obtained from the health center}}{\text{Total no. of treatment reported in 2 weeks of survey}} \times 100$
Percentage of children under-five treated with ORT/ anti-diarrheal products.	To measure the appropriateness of self-medication in an important health condition where clear standards of pharmaceutical treatment exists. (e.g. always use ORS or home fluids and never use anti-diarrhoea drugs.	$\frac{\text{No. of respondents mentioning ORS or home fluids.}}{\text{Total no. of respondents interviewed}} \times 100$
		$\frac{\text{No. of respondents mentioning anti-diarrhoea products}}{\text{Total no. of respondents interviewed}} \times 100$

Drug use studies should focus on the most important medicines, those with the highest potential problems such as high-volume medicine use, medicines with low therapeutic index, medicines with high incidence of ADR, expensive medicines, antimicrobial medicines, injections, medicines undergoing evaluation of addition to the formulary, medicines used for off-label indications or medicines used for high-risk patients

Recruit and train data collector

Data collection can be tedious work and requires dedication and attention. Data collector should be familiar with pharmaceuticals terms to record information in a standard way. Data collectors may include persons with clinical experience such as physicians, nurses, pharmacists and paramedical staff. Training should be provided to data collectors before visiting health facilities.

Data collection

It is important to limit data collection to only the most important and relevant aspects of drug use. The appropriateness of data collection form can be tested by performing a pilot study on a small number of patients.

Data can be collected prospectively or retrospectively based on design of study.

Evaluate result

Data should be summarized into major categories of results and checked where exactly the data shows deviations from the guidelines and usage criteria that are previously identified. Then the reason for this deviation should be evaluated.

Provide feedback of result

Success of any drug utilization research depends on feedback of the result to prescribers, other hospital staff and to administrative heads.

Develop and implement interventions

Intervention to improve drug use can be educational or operational. Educational intervention consists of educational meetings, workshops, circulating of protocols, letters to individual physicians etc. Operational intervention includes changes in formulary, changing of STGs, relocating staffs, prescribing restrictions etc.

Re-evaluating to determine the impact of intervention

Drug use and prescribing pattern need to be monitored to determine the success of intervention. Re-evaluation should be done 3-12months after the introduction of intervention.

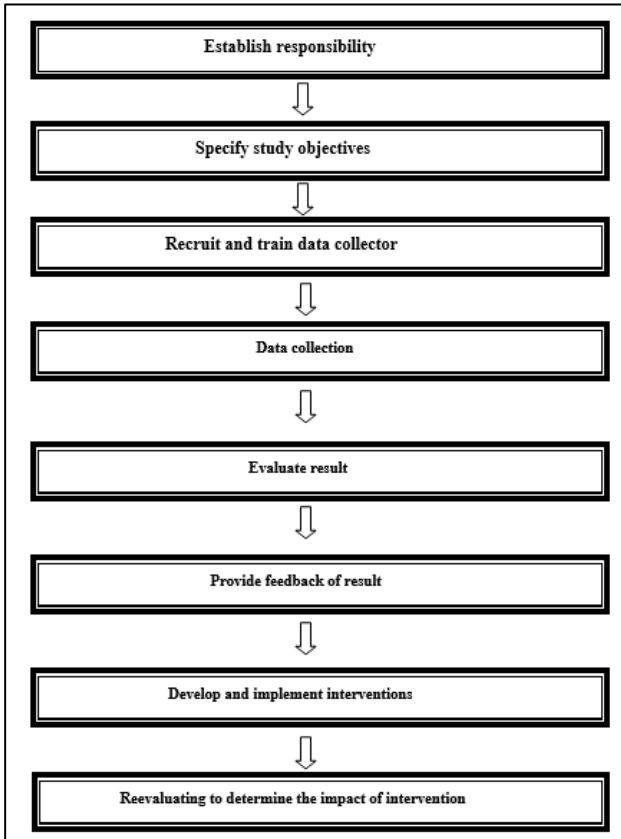


Figure 1: Stepwise approach to drug utilization research.

Anatomical Therapeutic Chemical (ATC) classification system^{8,13}

Table 5: Indicates 14 main subgroup of level 1.

Level 1	System on which drug acts
A	Alimentary and metabolism
B	Blood
C	Cardiovascular system
D	Dermatological
G	Gastrointestinal system
H	Hormonal preparation
J	Anti-infective
L	Antineoplastic and immunomodulators
M	Musculo-skeleton system
N	Nervous system
P	Antiparasitic
R	Respiratory system
S	Sensory organs
V	Various

ATC classification system is an international classification system of drugs that is commonly followed worldwide as tool for performing comparative drug utilization studies. ATC classification system can be used to compare the drug consumption both nationally and internationally.

In this system, the active substances are classified in a hierarchy with five different levels as shown in Table 5.

- Level 1: It indicates anatomical main group. It consists of 14 main subgroups.
- Level 2: Therapeutic subgroup
- Level 3: Pharmacological subgroup
- Level 4: Chemical subgroups
- Level 5: Chemical substances

Table 6: Indicates ATC code of metformin.

Code	Different ATC levels
A	Alimentary tract and metabolism
A10	Drugs used in diabetes
A10B	Blood glucose lowering drugs
A10BA	Biguanides
A10BA02	Metformin

For example; ATC code of metformin is A10BA02, which has been explained in Table 6.

There are certain general principles while using ATC classification system for assigning ATC code for drug:

Only one ATC code should be given for each route of administration. A substance can be given more than one ATC code if it is available in two or more strength or route of administration with clearly different therapeutic uses. For example, finasteride tablets are available in two different strengths which are used in two different indications. Low strength tablet of finasteride is used to treat male pattern baldness whereas a high strength finasteride tablet is used to treat benign prostate hypertrophy. Both low strength and high strength tablets have been given different ATC code i.e. D11AX for low strength tablet and G04C for high strength tablets.

Defined daily dose concept^{8,13}

“Defined daily dose is the assumed average maintenance dose per day for a drug used for its main indication in adult”. DDD provides a rough estimate of the proportion of patients within a community that would receive a drug.

The WHO has given following general principles of defined daily dose

DDD will be assigned only for drug that already have an ATC code. One DDD will be given per route of administration with an ATC code. DDD will be assigned for a substance after a product is approved and marketed in at least one country. DDD are not established for topical

products, sera, vaccines, antineoplastic agents, allergen extracts, general and local anesthetics and contrast media.

DDD for plan product

Plan products contain one single active ingredient. The average adult dose for the main indication will be assigned as DDD. The maintenance dose (long term therapeutic dose) is usually preferred as DDD. DDD will be same for various dosage forms of the same drug.

For combination products

Treatment with a combination product A containing two active ingredients i.e. 20mg of substance X and 15 mg of substance Y than DDD for a combination product will be 1 UD i.e. 1 tablet of product A.

As per WHO Defined Daily Dose can be calculated as following:

DDD for out-patients expressed as DDDs/1000 inhabitants/day and can be calculated as following:

$$\frac{\text{(Utilization in DDDs)}}{\text{(Number of inhabitants)} \times \text{(Number of days in the period of data collection)}} \times 1000$$

Where utilization in DDD can be calculated as:

$$\text{(Number of package used)} \times \text{(Number of DDD in a package)}$$

DDD for inpatients expressed as DDD/100 bed days and can be calculated as following:

$$\frac{\text{(Utilization in DDDs)}}{\text{(Number of occupied bed days)}} \times 100$$

Drug utilization research in India

Irrational use of medicines is a major problem worldwide.¹⁴ Data of drug utilization studies conducted in India shows irrational use of medicines. Studies conducted in psychiatric OPD of various tertiary care teaching hospitals to assess the prescribing pattern of anti-psychotic drugs reported poly pharmacy was common.¹⁵⁻¹⁷ A prospective prescription monitoring study was carried out to investigate drug use pattern of anti-asthmatic drugs in Gujarat.¹⁸ Another similar study was conducted in three famous hospitals of Shamli.¹⁹ Similar study conducted in various hospitals of Gorakhpur.²⁰ All these studies reported that prescribing pattern of anti-asthmatic drugs was not according to standard treatment guidelines. Studies conducted in India in speciality clinics of psychiatry, orthopaedics, ENT, have found poly pharmacy of anti-epileptic drugs, anti-psychotic drugs and NSAIDs in addition to irrational use of medicines. One study

conducted to evaluate prescribing pattern in six speciality departments (surgery, orthopaedics, ENT, ophthalmology, medicine and pediatrics).²¹ Another study conducted to analyse usage of antibiotics in outpatient facilities in 24 districts of west Bengal.²² Both these studies reported that use of antibiotics was inappropriate and lack of adherence to standard treatment guidelines. Inappropriate or over prescribing is major driving force for the emergence of antibiotic resistance also. A report from WHO documented high rate of antibiotic resistance across a range of bacteria that cause common infections. Resistance to antibiotics is worldwide challenge to public health and directly related to the antibiotic use in community. Quality of antibiotic prescribing in developing countries is not satisfactory. There is considerable overuse of common antibiotics across countries particularly in primary health canters which lead to increase in resistance rate, morbidity, mortality and cost.^{23,24}

DISCUSSION

Appropriate use of medicines plays a central role in achieving standard healthcare services. A large number of drug utilization studies have been conducted across the country. With few exceptions, studies show irrational use of medicines and suggest rational use of medicines at all levels of healthcare delivery system. The factors related to medicines misuse or overuse can be based on the various parties involved in the distribution of medicines like health care providers, pharmacists and patients. Primary causes of medicine misuse are poor script regulations, non-qualified practitioner, unregulated dispensing of medicines, non-availability of health care services especially in rural area and weak drug policies. Drug utilization research plays a key role in helping the health-care providers to understand, interpret and improve the prescribing, administration and use of medications. It involves a comprehensive review of a patient's medication and health history before, during, and after dispensing in order to attempt to achieve appropriate therapeutic decision-making and positive patient outcomes. It can increase our understanding on how drugs are used.

Researcher can estimate to what extent drugs are properly used, misused or overused. Drug use research information also allows prescribers to compare their approach to treating certain diseases with their peers. The benchmarking generated by these comparisons is useful in stimulating prescribers to change their prescribing habits in an effort to improve care. Qualitative drug utilization research can be done to analyze quality of use of medicines which involve determining the pattern or profile of drug use, comparing the pattern of drug use for the treatment of certain disease with current treatment guidelines whereas quantitative drug utilization research can be done to find extent of health facilities are available like availability of essential medicines, availability of standard treatment guidelines. Drug utilization research can be done on different levels based on objectives of study.

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