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A Concept Of Drug Utilization Evaluation In Clinical Pharmacy Practice

Gurivindapalli Sucharitha[1], Deta Velangini[1], Pagidipalli Aruna[1], Vanukuru Sai Harshini[1], Dr. Purushothama Reddy K[2], Dr. Evangelin Blessy[3], & Dr. K. Padmalatha[4]

[1]V Year Pharm.D, Department of Pharmacy Practice, Vijaya Institute of Pharmaceutical Sciences for Women, Department of Pharmacy Practice, Enikepadu, Vijayawada – 521 108, Adhara Pradesh, India.

[2]Professor and Head, Department of Pharmacy Practice, Vijaya Institute of Pharmaceutical Sciences for Women, Department of Pharmacy Practice, Enikepadu, Vijayawada – 521 108, Adhara Pradesh, India.

[3]Assistant Professor, Department of Neurology, Siddhartha Medical College (SMC), Government General Hospital, Vijayawada – 520 008, Adhara Pradesh, India.

[4]Principal, Vijaya Institute of Pharmaceutical Sciences for Women, Department of Pharmacy Practice, Enikepadu, Vijayawada – 521 108, Adhara Pradesh, India.

Abstract

In recent years studies on drug utilization (DU) have become a potential tool to be used in the evaluation of health systems. Studies on the process of DU focus on factors related to prescribing, dispensing, administering and taking of medication and its associated events. DU data is available from databases - computerized or otherwise. From these databases different types of information, qualitative or quantitative or referring to a particular population are available. Patient files and computer registries are widely used as instruments for collecting information on DU. Prospective, Concurrent or Retrospective Drug utilization evaluation (DUE) may be used depending upon the timing of data collection. Importance of DUE in Pharmacoepidemiology (PE) have been increasing due to their close association to other areas like - public health, Pharmacovigilance (Pv), Pharmacoeconomics and pharmacogenetics. This review article highlights various aspects, scope, types and future perspectives of DUE.

Keywords - Drug utilization (DU), Pharmacoepidemiology (PE), Pharmacoeconomics, Data collection, Drug utilization evaluation (DUE) cycle.

Introduction: Drug Utilization (DU) research is an essential part of Pharmacoepidemiology (PE) as it describes the extent, nature and determinants of drug exposure.[1] The World Health Organization (WHO) in 1997 defined DU as the marketing, distribution, prescription and use of drugs in a society, with special emphasis on the resulting medical, social and economic consequences.[2]

Drug use is a complex process. In any country a large number of socio-cultural factors contribute to the ways drugs are used. In India, these include national drug policy, illiteracy, poverty, use of multiple health care systems, drug advertising and promotion, sale of prescription drugs without prescription, competition in the medical and pharmaceutical market place and limited availability of independent, unbiased drug information. The complexity of drug use means that optimal benefits of drug therapy in patient care may not be achieved because of underuse, overuse or misuse of drugs. Inappropriate drug use may also lead to increased cost of medical care, antimicrobial resistance, adverse effects (AEs) and patient mortality.[3] Hence in recent years studies on DU have become a potential tool to be used in the evaluation of health systems.[4] The interest in DUE began in the early 1960s[5, 6] and its importance has increased since then because of increase in marketing of new drugs, wide variation in the pattern of drug prescribing and consumption, growing concern about delayed AEs and the increasing concern regarding the cost of drugs.[7, 8, 9, 10]

In the United States (US), DUE have been primarily developed at an institutional level or as part of local health programs.[11] In Europe, the Scandinavian countries, Scotland and Northern Ireland[12, 13, 14] pioneered the research at national and international levels. The European DUE have been predominantly quantitative, describing and comparing patterns of use of specific groups of drugs according to geographic regions and time, showing wide variations in the utilization of drugs pertaining to several pharmaceutical classes.[15]

Scope of DUE: Studies on the process of DU focus on factors related to prescribing, dispensing, administering and taking of medication and its associated events, covering the medical and non-medical determinants of DU, the effects of DU, as well as studies of how DU relates to the effects of drug use, beneficial or adverse.[11, 16, 17]

DUE is an ongoing, authorized and systematic quality improvement process, which is designed to;

- Rational drug use (RDU) and/or prescribing patterns
- Provide feedback of results to clinicians
- Develop criteria and standards which describe optimal drug use
- Promote appropriate drug use through education and other interventions.[3] They observe the patterns of drug use with current recommendations or guidelines for the treatment of a certain disease.
- They provide feedback of DU data to prescribers.
- They relate the number of cases of AEs to the number of patients exposed. If it is possible to detect that the reaction is more common in a certain age group, in certain conditions or at a special dose level, then information on proper use of drug can be improved such as indications, contraindications, appropriate dose etc. so that withdrawal of drug may be avoided.[1]
- They evaluate drug use at a population level, according to age, gender, social class etc.,[1, 5, 4]
- They include concept of appropriateness[11, 12, 18, 19] that must be assessed relative to the indication for the treatment, concomitant diseases (that might contraindicate or interfere with chosen drug therapy) and the

use of other drugs (interactions). Thus, they document the extent of inappropriate prescribing of drugs and also the associated adverse, clinical, ecological and economic consequences.[11, 12, 18, 20, 21]

Thus, DUE plays a key role in helping the healthcare system to understand, interpret and improve the prescribing, administration and use of medications.[3] The principal aim of DUE is to facilitate RDU, which implies the prescription of a well-documented drug in an optimal dose on the right indication, with correct information and at an affordable price. It also provides insight into the efficacy of drug use i.e., whether a certain drug therapy provides value for money. DUE can thus help to set priorities for the rational allocation of health care budgets.[1]

Types of drug use information: Different types of drug use information are required depending on the problems being evaluated. These include information about the overall drug use or use of drug groups, individual generic compounds or specific products. Often information about the condition being treated, about the patient and about the prescriber is also required. In addition, data on drug costs are required to ensure that drugs are used efficiently and economically.[1] DUE are also often drug focused, where the use of a single drug or class of drugs is examined. Less commonly DUE are indication focused, where the use of a drug for a specific condition is examined.[3]

The types of drug use information are described below;[1]

Drug based information - information about trends in total drug use, aggregation of drug use at various levels, information on indication, doses and dosage regimens.

Problem based information - information about how a particular problem (Eg; hypertension (HTN), gastric ulcer, depression) is managed.

Patient information - Demographic information about the patient is useful. Age distribution of patients, co-morbidities of patient group to determine drug of choice and AEs, quantitative information such as knowledge, beliefs and perceptions among patients and their attitudes to drugs are useful in designing consumer information/education programs.

Prescriber information - The prescriber is very important in determining drug use. Differences in drug prescribing often lack rational explanations and so analyzing the factors that determine prescribing behaviour is very important to understand how and why drugs are prescribed.

Pharmacoeconomics - DUE also include evaluation of the economic impact of clinical care and medical technology. It includes study of how pharmacotherapeutic methods influence resource utilization in health.

Types of drug use studies - DUE are either Qualitative or Quantitative.[3]

Qualitative DUE - are multidisciplinary operations which collect, organize, analyze and report information on actual drug use. They usually examine use of specific drugs or specific conditions. Qualitative DUE include the concept of criteria. Criteria are predetermined elements against which aspect of the quality, medical necessity and appropriateness of medical care may be compared. Drug use criteria may be based upon indications for use, dose, dosing frequency and duration of therapy. Qualitative studies assess the appropriateness of DU and generally link prescribing data to reasons (indications) for prescribing. Such studies are referred to as Drug utilization review (DUR) or DUE. The process is a “therapeutic audit” based on defined criteria and has the purpose of improving the quality of therapeutic care.[1]

Quantitative DUE - involve the collection, organization and display of estimates or measurements of drug use. This information is generally used for making purchase decisions or preparing drug budgets. But data from quantitative DUE are generally considered suggestive, not conclusive with respect to quality of drug use.

It is possible to combine both quantitative and qualitative DUE, which will yield information about pattern and amount of drug use as well as quality of drug use.

Sources of DU data: DU data are available from databases - computerized or otherwise. From these databases different types of information, qualitative or quantitative or referring to a particular population are available. Data may be diagnosis linked or non-diagnosis linked. Diagnosis linked data gives information about drug consumption for a particular condition and outcome while non-diagnosis linked data gives information only about drug consumption in a population.[15]

Some databases generate information about patterns of DUE and adverse drug reactions (ADRs). Databases may also provide data in the form of drug sales, drug movement at various levels of the drug distribution chain, pharmaceutical and medical billing data or samples of prescription.[1] Such data are helpful in measuring the economic impact of drug use but does not provide information on the amount of drug exposure in the population.[15]

Data or information about sales are available through pharmacy records.[14, 22, 23] They provide detailed information on the drugs but data on consumer is very limited. Also, the data lacks information on morbidity.[22] Data from general practitioners records of prescriptions can be more informative about the indications for drugs prescribed, diagnosis and other health related data, but these data are not always consistently completed.[24]

Data on DU may also be obtained directly from the population through Health Surveys at National level or smaller surveys such as surveys conducted in specific settings such as among university students,[25] female population[26] or elderly outpatients.[27] Such studies provide information on drug use from consumer themselves[28] and are a source of data on many other health related issues.[24]

Data obtained from medical practices and health facilities are used to measure specific aspects of health provision and drug use. Such data may be used to generate indicators that provide information on prescribing habits and aspects of patient care. These indicators may be used to determine where drug use problem exists, provide a mechanism for monitoring and supervision and motivate health care providers to follow established health care standards.[1]

Prescription and dispensing data are useful for determining some of the quality indicators of drug use recommended by WHO. These include;[1]

- Average number of drugs per prescription (encounter)
- Percentage of drugs prescribed by generic name
- Percentage of encounters with an antibiotic prescribed
- Percentage of encounters with an injection prescribed
- Percentage of drugs prescribed from essential drug list or formulary
- Average drug cost per encounter

Instruments for data collection on DU: Patient files and computer registries are widely used as instruments for collecting information on DU. Home inventories where an interviewer visits the home of the patients and list all drugs in the medicine cabinet, this is considered by some as the best method of obtaining accurate and complete drug use data.[29, 30, 31] Questionnaires however are one of the easiest tools for data collection on DU and are the most widely used in population surveys.[13] Self-reported data obtained through questionnaires is also used as a source of dug exposure information.[32] However, data collected by self-reports is subject to recall inaccuracy.[30, 33, 34, 35] Despite being accurate, carefully constructed questionnaire can be subject to recall bias due to its characteristics and noncompliance can influence the reliability.[30, 32, 33, 35]

Establishment of a DUE program: The DUE program is a continuous process occurring/repeating cyclically and will be more valuable if the cycle is completed rather than different steps being performed in isolation. The DUE cycle includes the following major activities or phases;[3]

- Planning
- Data collection
- Evaluation
- Feedback of results
- Interventions
- Re-evaluation
- Feedback of results

Steps involved in conducting drug use study:[3]

Step 1 Identify drugs or therapeutic areas of practice for inclusion in the program: All drugs used in a hospital cannot be evaluated. Hence the DU evaluation committee should identify drugs whose evaluation and improvement in use will result in greatest clinical impact. Generally, drugs with a high volume of use, high cost or high frequency of adverse drug events are subject to DU studies.

Common targets for DU studies include –

- commonly prescribed drugs Eg; Antibiotics, Proton pump inhibitors (PPIs)
- drugs associated with potentially significant drug interactions Eg; Warfarin, Theophylline, Phenytoin • expensive drugs Eg; LMWH, Cephalosporins
- new drugs
- drugs with a narrow therapeutic index Eg; Digoxin, Theophyllin
- drugs causing serious adverse reactions Eg; aminoglycoside antibiotics, NSAIDs etc.,
- drugs used in high-risk patients Eg; elderly, pediatric patients
- drugs used in the management of common conditions Eg; RTI or UTI

Step 2 Design of study: Various research methods are used in DU studies. Observational research methods are more commonly used.

Cross-sectional studies, where drug use is examined at a single point in time are useful. Also, the pre and post design where drug use is examined before and after interventions to improve prescribing is another commonly used observational method.

Prospective, Concurrent or Retrospective DU studies may also be used depending upon the timing of data collection.

Prospective DU studies involve evaluating a patient's planned drug therapy before a medication is administered.

Concurrent DU studies are performed during the course of treatment and involve the ongoing monitoring of drug therapy. It involves consideration of laboratory test results and other monitoring data when appropriate.

Retrospective DU studies involve review of drug therapy after the patient has completed a course of therapy. The patients medication sheet, daily progress notes, nursing observations, pathology/biochemistry results and therapeutic monitoring results are screened to determine whether drug therapy met predetermined criteria. The main advantage of this method is that prescribers and others are unaware of data collection and results may therefore be less biased. Another advantage is ease of data collection, as records are assessed at the data collectors convenience. A disadvantage is that some information may be unclear or missing and that reviewed patients do not gain immediate benefit, as interventions are delayed until the intervention phase.

Step 3 Define criteria and standards: After DUS target has been selected, it is important to conduct a comprehensive literature review. The steps involved in literature reviews are;

- ♣ Perform an exhaustive literature search for the chosen area, using more than one search mechanism.
- ♣ Assemble full copies (not just the abstracts) of all the relevant original research papers.
- ♣ Critically evaluate the study directly relevant to the chosen drug or therapeutic area.
- ♣ Briefly summarize the literature review, identify the 'key' papers in the chosen area and the drug criteria that can be derived from the evidence-based literature.

Criteria are those predetermined statements describing optimal drug use, against which the quality of actual drug use is compared. **Standards** are professionally developed expressions of the range of acceptable variation from a criterion. Standards should be based on published literature and should describe exceptions when deviation from criteria is acceptable. Criteria should be scientifically based and be supported by clinical or research literature. They must be valid, unambiguous, realistic, easily measured and outcome oriented.

Step 4 Design the data collection form: Just as it is impossible to monitor and evaluate all drugs in a hospital, it is also impossible to address all aspects of use for each individual drug. It is important to limit data collection to only the most important and relevant aspects of drug use and to factors which may influence these.

Some aspects of drug use commonly surveyed during DU studies are;

- ❖ Patient demographics
- ❖ Prescriber details
- ❖ Disease severity
- ❖ Co-morbidities
- ❖ Indication/Contraindications for drug use
- ❖ Side/adverse effects
- ❖ Dosing information

- Drug or drug class duplication
- Preparations and administration
- Drug-drug and drug-food interactions
- Monitoring of drug therapy
- Patient education/instructions
- Cost of therapy.

To ensure the data reflects the endpoints to be evaluated and are consistent, careful attention must be given to the design of data collection form. The data collection form should have a user-friendly format to encourage completion by data collectors. The appropriateness of the collection form can easily be tested by performing a pilot audit on a small number of patients similar to a sample of patients who will be studied in the DU study.

Step 5 Data collection: Physician, pharmacists and nurses make ideal data collectors. Timing of the data collection should be during a period, which is likely to be representative of usual pattern of drug use.

Step 6 Evaluate results: Data evaluation is most critical step in a DUE. Data should be summarized into the major categories of results and checked where exactly the data shows deviation from the guidelines and usage criteria that are previously identified. Then the reasons for this deviation should be evaluated. If there is a true reason for deviation, it may be necessary to redefine the criteria. The reasons may not be evident from the DUE data and may require further investigations, surveys or interviews. Reasons for deviation may include;

a. drug being used for new indication

b. outdated procedures

c. inadequate resources

d. gaps in knowledge or misinformation/misunderstanding

Step 7 Provide feedback of results: Success of any DU study depends on feedback of the results to prescribers, other hospital staff involved in the study and to administrative heads. It is important to prepare a scientific interpretation of the results rather than a value judgment. The results can also be circulated to hospital staff via newsletters, DUE meetings or the hospital's academic meetings.

Step 8 Develop and implement interventions: If a drug use problem is identified the next step is to consider how the problem can be addressed. Interventions to improve drug use can be educational or operational. Educational interventions consist of educational meetings, circulation of protocols, academic detailing, feedback of results, letters to individual physicians, newsletters. Operational interventions include the development/modifications of drug order forms, manual or computerized reminders, prescribing restrictions, formulary additions/deletions, automatic stop orders or reallocations of staff. Some interventions may be both educational and operational in nature, such as improving the availability of information and resources to support clinical decision-making. Interventions should be chosen based on their likely success, ease of application, cost, resources required and sustainability. Interventions which are found to be effective in improving drug use include academic detailing, routine reminders, prescribing restrictions, structured prescription forms/treatment charts and interactive educational meetings.

Step 9 Reevaluate to determine if drug use has improved: Drug use and prescribing patterns need to be monitored to determine the success of interventions. Typically, the reevaluation is done 3 – 12 months after the introduction of the intervention and should involve collecting the same data as in original DU evaluation.

Step 10 Reassess and revise the DUE program: Lessons learnt from the first DUE study should be used to improve the quality, efficacy and effectiveness of future DUE studies.

Step 11 Feedback results Circulate the results of DUE to clinicians and other involved hospital staff to obtain their opinions about the success of the interventions, and how these can be improved.

Future Perspectives

The study of drug utilization in an evolving field. The use of large computerized databases that allow linkage of drug utilization data to diagnosis, subject to some inherent limitations, is contributing to expand this area of study. Importance of drug utilization studies in pharmacoepidemiology has been increasing due to their close association to other areas like- public health, pharmacovigilance, pharmacoeconomics and pharmacogenetics.

References:

1. Sjoqvist F, Birkett D, Drug Utilization, In: Bramley DW editor, Introduction to Drug Utilization Research, (WHO booklet) New York: WHO office of publications; 2003; 76 - 84.

2. WHO Expert Committee, The Selection of Essential Drugs, Technical Report Series no. 615, Geneva: World Health Organization, 1977.

3. Einarson T, Pharmcoepidemiology, In: Parthasarathi G, Hansen KN, Nahata MC, editors, A Text book of Clinical Pharmacy Practice essential concepts and skills, 1st edition, Hyderabad: Universities Press (India) Limited, 2008; 405 - 23.

4. Laporte JR, Porta M, Capella D, Drug utilization studies: A tool for determining the effectiveness of drug use, British Journal of Clinical Pharmacy, 1983; 16: 301 - 04.

5. Andersen M, Is it possible to measure prescribing quality using only prescription data? Basic Clinical Pharmacology and Toxicology, 2006; 98: 314 - 19.

6. Wettermark B, Hammar N, Michael FC, Leimanis A, Otterblad OP, Bergman U, *et al.,* The new Swedish Prescribed Drug Register opportunities for Pharmacoepidemiological research and experience from the first six months, Pharmacoepidemiology and Drug Safety, 2007; 16: 726 - 35.

7. Moore TJ, Cohen MR, Furberg CD, Serious adverse drug events reported to the Food and Drug Administration, 1998 – 2005, Arch Internal Medicine, 2007; 167: 1752 - 59.

8. Baum C, Kennedy DL, Forbes MB, Jones JK, Drug use and expenditures in 1982, JAMA 1985; 253: 382 - 86.

9. Cars O, Molstad S, Melander A, Variation in antibiotic use in the European Union, Lancet 2001; 357: 1851 - 53.

10. Rosholm JU, Gram LF, Isacsson G, Hallas J, Bergman U, Changes in the pattern of antidepressant use upon the introduction of the new antidepressants: a prescription database study, European Journal of Clinical Pharmacology, 1997; 52: 205 - 09.

11. Strom BL, Pharmacoepidemiology, 4th edition, Chichester, England: John Wiley & Sons, Ltd 2005.

12. Scheckler WE, Bennett JV, Antibiotic usage in seven community hospitals, JAMA 1970; 213: 264 - 67.

13. Bergman U, Elmes P, Halse M, Halvorsen T, Hood H, Lunde PK, *et al.,* The measurement of drug consumption - Drugs for diabetes in Northern Ireland, Norway and Sweden, European Journal of Clinical Pharmacology, 1975; 8: 83 - 89.

14. Boethius G, Wiman F. Recording of drug prescriptions in the country of Sweden, Methodological aspects, European Journal of Clinical Pharmacology, 1977; 12: 31 - 35.

15. Bergman U, Andersen M, Vaccheri A, Bjerrum L, Wettermark B, Montanaro N, Deviations from evidence-based prescribing of nonsteroidal anti-inflammatory drugs in three European regions, European Journal of Clinical Pharmacology, 2000; 56: 269 - 72.

16. Lunde PK, Baksaas I, Epidemiology of drug utilization - basic concepts and methodology, Acta Med Scand Supply, 1988; 721: 7 - 11.

17. Costa J, Rosa MM, Ferreira JJ, Sampaio C, Vaz Carneiro A, Cardiac effects of acute poisoning with tricyclic antidepressants: systematic review of the literature, Part I. Rev Port Cardiology, 2001; 20: 671 - 78.

18. Naqvi SH, Dunkle LM, Timmerman KJ, Reichley RM, Stanley DL, O'Connor D, Antibiotic usage in a Pediatric medical center, JAMA 1979; 242: 1981 - 84.

19. Shapiro M, Townsend TR, Rosner B, Kass EH, Use of antimicrobial drugs in general hospitals, Analysis of patterns of use, Journal of Infectious Disease, 1979; 139: 698 - 706.

20. Castle M, Wilfert CM, Cate TR, Osterhout S, Antibiotic use at Duke University Medical Center, JAMA 1977; 237: 2819 - 22.

21. Townsend TR, Shapiro M, Rosner B, Kass EH, Use of antimicrobial drugs in general hospitals: IV. Infants and children, Pediatrics, 1979; 64: 573 - 78.

22. Hartz I, Sakshaug S, Furu K, Engeland A, Eggen A, Njolstad I, *et al.,* Aspects of statin prescribing in Norwegian countries with high, average and low statin consumption – an individual-level prescription database study, BMC Clinical Pharmacology, 2007; 7: 14.

23. Duarte RF, Cabrita J, Using a pharmaco-epidemiological approach to estimate diabetes type - II prevalence in Portugal, Pharmacoepidemiology and Drug Safety, 2006; 15: 269 - 74.

24. Neutel CI, Walop W, Comparing two different approaches to measuring drug use within the same survey, Chronic Dis Can 2000; 21: 150 - 56.

25. Cabrita J, Ferreira H, Iglesias P, Baptista T, Rocha E, Lopes da Silva A, *et al.,* Patterns and determinants of psychoactive drug use in Lisbon University students-a population-based study, Pharm World Science, 2004; 26: 79 - 82.

26. Rocha O, Lunet N, Costa L, Barros H, Osteoporosis treatment in Portugal: trends and geographical variation, Acta Med Port 2006; 19: 373 - 80.

27. de Oliveira MS, Soares MA, Foppe van Mil JW, Cabrita J, Inappropriate drug use by Portuguese elderly outpatients-effect of the Beers criteria update, Pharm World Science, 2006; 28: 296 - 301.

28. Marques VP, Dias CM, Hypnotic consumption in the Portuguese population: data from the National Health Survey 1998 – 1999, Pharmacoepidemiology and Drug Safety, 2006; 15: 63 - 69.

29. Psaty BM, Lee M, Savage PJ, Rutan GH, German PS, Lyles M, Assessing the use of medications in the elderly: methods and initial experience in the Cardiovascular Health Study, The Cardiovascular Health Study Collaborative Research Group, Journal of Clinical Epidemiology, 1992; 45: 683 - 92.

30. Johnson RE, Vollmer WM, Comparing sources of drug data about the elderly, Journal of American Geriatric Society, 1991; 39: 1079 - 84.

31. Lau HS, de Boer A, Beuning KS, Porsius A, Validation of pharmacy records in drug exposure assessment, Journal of Clinical Epidemiology, 1997; 50: 619 - 25.

32. Klungel OH, de Boer A, Paes AH, Herings RM, Seidell JC, Bakker A, Influence of question structure on the recall of self-reported drug use, Journal of Clinical Epidemiology, 2000; 53: 273 - 77.

33. Van den Brandt PA, Petri H, Dorant E, Goldbohm RA, Van de Crommert S, Comparison of questionnaire information and pharmacy data on drug use, Pharm Weekbl Science, 1991; 13: 91 - 96.

34. West SL, Savitz DA, Koch G, Strom BL, Guess HA, Hartzema A, Recall accuracy for prescription medications: self-report compared with database information, American Journal Epidemiology, 1995; 142: 1103 - 12.

35. Goodman MT, Nomura AM, Wilkens LR, Kolonel LN, Agreement between interview information and physician records on history of menopausal estrogen use, American Journal Epidemiology, 1990; 131: 815 - 25.