

심포지움 I

미국에서의 DUR제도와
약물경제학

서동철

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Drug Utilization Review: Pharmacoeconomics Perspective

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Drug utilization review (DUR) has been defined as ‘an authorized, structured, ongoing program that evaluates, analyzes, and interprets drug usage against predetermined standards and undertakes actions to elicit improvements and measure the results’ (Omnibus Budget Reconstruction Act of 1990). The purpose of DUR is to improve quality of patient care and drug use and to assist in containing health care and drug costs.

DUR can be conducted either retrospectively or prospectively. In retrospective DUR, prescribing practices are reviewed after a drug has already been dispensed and attempts are made to detect inappropriate patterns in prescribing, dispensing, or administering drugs. In prospective DUR, the appropriateness and correctness of drug therapy is examined before the medication is dispensed, and is commonly performed by pharmacists and pharmacy benefits managers.

DUR has become of increasing importance in the recent years. One reason for this includes the rapid growth of drug expenditures, which has been influenced by the introduction of more expensive drug products and an increased utilization of drugs. Other reasons include an increased misuse and abuse of drugs, a lack of communication amongst healthcare providers, a growth of third party prescription drug benefit programs, and legislative mandates.

Legislative mandates in the early 1990s brought about some changes for DUR in the U.S. due to the passing of the Omnibus Budget Reconstruction Act of 1990 (OBRA '90). This act required that in order for payment to be made for covered outpatient drugs, the pharmaceutical manufactures had to enter into a rebate agreement with the Medicaid programs. Importantly, it also required states to establish DUR programs for their Medicaid programs to assure that prescription medications are appropriate, are medically necessary, and are not likely to result in adverse events. States were required to develop both retrospective and prospective DUR programs, and were required to establish state DUR boards. OBRA '90 also mandated that pharmacist must offer to counsel all patients covered by Medicaid. The Health Care Financing Administration (HCFA; now Center for Medicaid and Medicare Management) was

assigned to demonstrating the efficiency and effectiveness of DUR. This was accomplished through several demonstration projects that examined online, prospective DUR, reimbursing pharmacists for cognitive services, and face-to-face DUR interventions vs. mailed communications.

Over the years, traditional DUR has been reforming into a more cost-effective DUR. Traditionally, DUR focused on cost savings and clinical outcomes and now focuses on economic, clinical and humanistic outcomes. It has also moved from solely using retrospective DUR to using online-prospective and retrospective DUR. Reducing drug utilization and costs has been replaced by attempting to reduce overall medical costs while maintaining quality of care. Instead of trying to correct prescribing by reviewing drug use and dispensing patterns, DUR now focuses on developing treatment guidelines that consider the impact drug therapy choices on overall treatment costs. Also, sanctions and reprimands are being replaced by education and redirection.

Pharmacoeconomics is often referred to in many ways, including cost effectiveness or cost benefit, health economics, outcomes research or economic evaluation of medicine and drug therapy. In general, pharmacoeconomics identifies, measures, and compares the costs and consequences in the areas of clinical, humanistic and economic outcomes.

True pharmacoeconomic studies measure and compare both the costs and the outcomes of a program, yet few studies have examined the direct effects of DUR on patient outcomes. It is therefore important to use pharmacoeconomics as a tool to evaluate DUR programs so that in addition to cost savings produced by a program, the outcomes and efficiency of DUR interventions can be compared. Comparisons between the methods used in the DUR interventions can also be made. DUR can also be specifically used as a tool for pharmacoeconomic evaluation. For example, a DUR program can be used to obtain the costs and effects of drugs, which in turn can be used to make pharmacoeconomic comparisons, to compare the prevalence of illness between two areas for use in cost of illness analyses, to monitor irrational prescribing and reveal whether resources are being wasted on inappropriate therapies, and used to determine the incidence of adverse drug events and their associated cost of treatment.

Clinical outcomes can include the incidence of drug-related adverse medical events, the appropriateness of drug regimens, or compliance with therapy. Humanistic outcomes deal with patient quality of life and patient satisfaction with health care services. Economic outcomes relate to medical care utilization and treatment and drug costs. Several types of costs must be considered when performing analyses, which consist of direct medical costs, direct non-medical

costs, indirect costs, and intangible costs. These costs and other data may be obtained from data sources such as administrative data, medical records, and patient-derived data.

Pharmacoeconomic analyses include cost-effectiveness analysis, cost-utility analysis, cost-benefit analysis, and cost-minimization analysis. Cost-effectiveness analyses measure the costs and effects of drug therapies in their physical or natural units and can compare drugs or treatments with same outcome units (i.e., life years saved, mmHg). Cost-utility analyses evaluate drug therapies or other treatments in terms of their costs and estimated utility (usually in terms of quality adjusted life years or QALYs) and thus integrate multiple outcomes into a single utility value by patient's preferences. Cost-benefit analyses measure both the costs and benefits of drug therapies in terms of monetary units, so a comparison can be made between widely different drugs/treatments with different outcomes. Cost-minimization analyses are performed to choose the least costly alternative by evaluating the costs of drug therapies in which the outcomes have been demonstrated to be clinically identical or assumed to be equivalent.

Once drug therapy has been assessed through DUR and changes need to be made to prescribing, dispensing, or administration, several feedback mechanisms are available to disseminate the information. One method is through the use education interventions targeted at patients or prescribers. Printed education materials can be mailed to prescribers, distributed as printed copies of protocols and guidelines, or used as self-education materials. Group education can also be used, provided as rounds, conferences, lectures, seminar or tutorials. Reminders at time of prescribing are another means of improving drug therapy, such as computerized reminders based on prescribing standards. Face-to-face education has been suggested to be the most effective approach to changing prescribing behaviors. Sanctions which referral persons to regulatory agencies for prosecution for fraud and abuse can also be used.

DUR can have a significant impact on managing drug costs and improving patient outcomes. This can be achieved by improving adherence to formularies, promoting appropriate prescribing to avoid duplicate prescriptions, and reducing the cost of treating adverse reactions due to drug-drug interactions and medication errors. Overall, DUR can have a major impact by establishing common standards of practice to influence physician prescribing behaviors, managing drug use patterns, developing policies for drug use and administration, and adverse drug reaction monitoring. In addition, DUR can assist in developing cost-effective intervention and education programs for physicians, patients and pharmacists.

The following example projects demonstrate importance of economic aspect of DUR. According to OBRA '90, most states reported cost savings from Medicaid DUR programs. Online prospective DUR savings have been found to range from \$500,000 in West Virginia to \$22 million in New York. Also, retrospective DUR savings ranged from \$16,000 in New Hampshire to \$3 million in Massachusetts. For programs that examined both the costs and savings of the DUR program, cost to benefit ratios for retrospective DUR ranged from 1:1.7 to 1:2.

For a demonstration project, an analysis was performed in the state of Washington to test effects of paying pharmacists for providing and documenting cognitive services. Pharmacists were paid \$4-\$6 per service for providing cognitive services and \$40 per month for documenting problems, interventions, and results of services. This study resulted in an increased number of documented pharmacist cognitive services, but no significant reductions in the frequency of drug problems or in drug utilization or expenditures. A demonstration project of online DUR in Iowa examined drug-related problems including: drug-drug interactions, therapeutic duplications, high daily doses, and early refills for 8 classes of drugs (ACE inhibitors, calcium channel blockers, cardiac glycosides, benzodiazepines, antidepressants, antipsychotics H2 receptor antagonists, and NSAIDs). The analysis showed that no significant reduction in drug utilization or expenditures were found from this program

A pharmacy benefit manager conducted a retrospective DUR study to evaluate the impact of an asthma intervention on treatment cost, utilization and trends of medication use from a third party prospective. The intervention program targeted the following: (a) patients who over-utilized quick-relief medications without using adequate long-term controller medications; and (b) patients who appeared noncompliant with their long-term controller medications with or without the use of 'quick-relief' medications. Case managers reviewed patients' asthma medication utilization and if either of the preceding problems were identified, asthma interventions were initiated for patients and their physicians in order to ensure that patients receive appropriate asthma treatment. An asthma-management fact sheet was developed and sent along with the patients' profiles, intervention letters, and response forms to the physicians of all the identified patients. In addition to the drug utilization review, sequential educational materials were mailed every 3 months to the study patients for the duration of the study intervention (i.e., 1 year). The total asthma treatment cost decreased from \$499 to \$415 per patient. Targeted asthma intervention resulted in decreased average cost per patient associated with hospitalization (13%) emergency room (29%), physician visit costs (36%), and asthma medication (18%).

Another DUR study was conducted to determine the impact of an intervention targeted at improving the use of lipid-lowering therapy in patients with CAD in the hospital setting. Cardiac case managers prompted physicians to order lipid profiles for patients with CAD who were not on lipid-lowering therapy on admission, and to order lipid-lowering therapy for patients with LDL \geq 130 mg/dL during hospitalization. Patients were identified by admission diagnosis of coronary artery disease (for PTCA, CABG, or MI). The percentage of patients with CAD not on lipid-lowering therapy on admission who had fractionated lipid profile performed during hospitalization increased from 27% pre-intervention to 89% during the intervention period. The percentage of patients with an LDL \geq 130 mg/dL for whom lipid-lowering therapy was initiated during hospitalization increased from 17% before the intervention to 82% during intervention.

In the future, DUR will become an even more important component of disease management. Traditional DUR is progressively moving towards disease management DUR programs, and therefore these programs need to consider health outcomes and pharmaco-economic findings. DUR will also continue to be an important tool in the development of cost-effective treatment guidelines. Cost-effectiveness modeling will also be used more often to predict probability of success of a DUR intervention before the intervention is implemented and cost-benefit analyses will also be completed more frequently to compare the net benefit between alternative strategies. Also in the near future, electronic prescribing will aid in the implementation of DUR programs and allow for easier data collection.

In order for the successful completion of cost-effective DUR, several conditions must be met. Healthcare providers must be educated in the areas of pharmaco-economics and medical decision-making. Also, there must be an enhancement of communications to help facilitate the collaboration between physicians, patients, and pharmacists, which allow physicians and pharmacists to focus on patient care and education. Furthermore, both rapid feedback and comprehensive information are required to maintain successfulness and accuracy of a cost-effective DUR program.

The pharmacist must continue to play a vital role in the completion of DUR by reviewing patient drug profiles, assessing information received from patients and physicians, and monitoring drug response and reactions. Pharmacists also should be intimately involved in the development of drug treatment guidelines. Education of patients and other healthcare professionals is another role pharmacists. Evaluating patient outcomes can also be completed by pharmacists, which should include both clinical and humanistic outcomes.

In summary, DUR is a powerful tool for planning and monitoring the evolution of the patterns of drug use and costs. However, proper pharmaco-economic analyses are required to

comprehensively examine the economic impact of DUR programs. Pharmacists need to actively participate in DUR through increased communication and collaboration with physicians to help contain treatment costs and ensure patients are achieving optimal outcomes.