

Ambulatory Drug Utilization Review: Opportunities for Improved Prescription Drug Use

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GOAL

To explain ambulatory prospective and retrospective drug utilization review (DUR), focusing on their potential to support improved prescription drug use.

LEARNING OBJECTIVES

The reader should gain a fuller appreciation for:

1. The extent of ambulatory medication use and the risk of inappropriate prescription drug use.
2. The development of DUR and its potential to support improved prescription drug use.
3. The terms associated with DUR.
4. Emerging Internet and wireless technology used for implementing DUR.

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Ambulatory prescription drug use and the risks associated with it are growing. Between 1983 and 1993, hospital inpatient days decreased by one-fifth and outpatient visits increased by three-quarters,¹ shifting medical care from more-to-less controlled environments for medication use. Of the more than 800 million office visits in 1998, 65% resulted in a drug being prescribed or given—75% or more for family practice and internal medicine specialties.² The risks of adverse drug events are substantial in the outpatient setting, with outpatient medication error deaths (7391 deaths in 1993) increasing faster than the number of prescriptions filled. These risks were greatest for African American males, then for white males, African American females, and white females.¹ In 1995, more than 2 million office visits were for medication-related morbidity, most commonly by women and by those aged 65 to 74 years.³

Medication errors occur for individuals when a mistake is made in prescribing, filling, and/or taking prescription drugs. Avoidable risk exposures and errors also occur at the healthcare delivery system level due to fragmented care and incomplete clinical information. Even in a hospital setting, adverse drug events are often the result of incomplete information when a prescription is being written⁴—a problem requiring an intervention at the level of the system in which medication use occurs. When ambulatory patients see multiple providers, change health plans, and have variable adherence to prescription medication regimens, exposure to the risk of adverse drug events increases substantially. A senior physician with extensive clinical and management experience recently asserted that “actual prescribing is not acceptable by any industry standard.”⁵ An observational study⁶ of medication-related emergency department visits found that 70% were preventable. The accumulated evidence on avoidable

adverse drug events has made their resolution a national priority. This article discusses a process to reduce exposure to adverse drug events: drug utilization review (DUR).

Formerly, pharmacists reviewed individual prescriptions based on their training and a patient consultation (if available), perhaps supplemented by available literature and patient prescription records. With the introduction of point-of-sale technology in the late 1980s, however, online prospective DUR (pDUR) programs grew significantly⁷ and enabled review of all prescriptions filled for a given patient within a pharmacy chain or by a third-party drug insurance program with an integrated database rather than just those filled in one pharmacy, thus making pDUR reviews more comprehensive. At the same time, retrospective DUR (rDUR) increasingly concentrated on population-level, disease-focused profiling.

... DRUG UTILIZATION REVIEW:
DEFINITION AND USE IN
ALTERNATIVE SETTINGS ...

Drug utilization review is not a new technology—it was described in 1968 by the Department of Health, Education, and Welfare Task Force on Prescription Drugs as “a dynamic process aimed first at rational prescribing and the consequent improvement of the quality of healthcare, and second at minimizing needless expenditures.”⁸ Essentially, the DUR process consists of concurrent and retrospective review of medication and other relevant data against predetermined standards (criteria) to assess drug therapy appropriateness. Criteria are “predetermined elements of drug use supported by FDA-approved labeling, compendia, and peer reviewed literature, developed by qualified health professionals, against which aspects of quality, medical necessity, cost effectiveness, and clinical outcomes of drug use may be compared.”⁹ Those managing and using DUR should determine that the criteria do in fact screen for significant problems that are preventable. With increasing computerization, algorithms might be used to automate this first screening. Recommended guidelines for selecting prospective DUR screening criteria based on administrative data (medical and pharmacy service claims) are as follows: (1) severe medical consequences (or high costs) are likely if an action is not taken; (2) evidence exists to support the connection between screening criteria violation and the outcome; and (3) the criteria are logistically

feasible and can be implemented with routinely available data.¹⁰ When exceptions to criteria are identified, the pharmacist should make an in-depth assessment, potentially including patient consultation, to understand the therapeutic context in which the medication is to be used. The interventions resulting from this review might range from a determination that no action needs to be taken to the pharmacist counseling the patient to the pharmacist alerting the physician of the need to change or not fill the prescription.

Drug utilization review programs, under differing names depending on the environment, monitor drug therapy for hospital inpatients (drug use evaluation), nursing homes (drug regimen review), and other residential facilities. Ambulatory pDUR and rDUR programs have been mandated since 1993 for state Medicaid programs as a result of the Omnibus Budget Reconciliation Act of 1990,¹¹ although HMOs are exempt. Private third-party insurance programs, pharmacy benefit managers, and other managed care organizations perform DUR—although their primary focus and performance metrics vary from clinical issues¹² to medication costs and benefit contract adherence.¹³

... PROSPECTIVE DRUG
UTILIZATION REVIEW ...

Prospective DUR involves reviewing each prescription for an individual outpatient before it is dispensed to identify problems such as drug-drug interactions, therapeutic duplication, or other potential adverse drug events. The effectiveness of DUR is fundamentally determined by the criteria used to judge actual drug use as much as the technology used to implement it. Valid criteria will correctly identify those who do from those who do not have a potentially significant medication problem.

Prospective DUR screens prescriptions against predetermined criteria for drug-related problems at the time the medication is dispensed¹⁴; typically this occurs during the claims adjudication process. Because Medicaid programs and managed care organizations frequently contract with vendors for DUR services, the quality of criteria is determined by the vendor, but it should be the responsibility of those who use these criteria to evaluate them carefully. These criteria are the foundation for effective DUR,¹⁵ but there is no benchmark for assessing the accuracy, completeness, or timeliness of the criteria developed and used by vendors. Much work remains to be done

to establish a scientific basis for appropriate therapy to support DUR. Currently, the Agency for Healthcare Research and Quality is funding 7 Centers for Education and Research on Therapeutics to develop unbiased and authoritative information for selected therapeutic problems relating to prescription drug use: (1) Duke University Clinical Research Institute—cardiovascular conditions; (2) University of North Carolina—rational therapeutics in pediatrics; (3) Vanderbilt—arthritis in Medicaid managed care; (4) Georgetown University Medical Center—drug interactions; (5) University of Pennsylvania—antimicrobial resistance and drug utilization research; (6) University of Alabama—rheumatoid arthritis and musculoskeletal disorders; and (7) Harvard Pilgrim Health Center—using large databases to examine medication use in managed care organizations.¹⁶

After the prescription is sent electronically to the claims processor for adjudication and DUR screening, alert messages identify potential drug-related problems for the pharmacist. Examples of alert messages include drug-drug interactions, incorrect dose or duration of therapy, drug-disease contraindications, therapeutic duplication, early refill, and drug-allergy interactions. Pharmacists must then judge whether to act on the alert(s) and attempt to modify the patient's drug regimen(s) by talking with the patient's physician(s), the patient, or both. Pharmacists can intentionally override the alerts if they believe that the messages do not apply.

Discrepancies in the drug-drug interactions listed in leading information sources used to develop criteria¹⁷ and variations in the criteria adopted by different Medicaid programs for the same problem (eg, digoxin-quinidine drug-drug interactions)¹⁸ question the adequacy of the evidence on which criteria are based. Recent research suggests that many pDUR alerts are overridden by pharmacists because they are already aware of the issue for which they received the alert or they see the issue as clinically insignificant.¹⁹ In addition, legal liability concerns may motivate DUR vendors to code their software to generate alerts when there is even a remote possibility for an interaction, potentially overwhelming the pharmacist with trivial or inapplicable alerts.

Prospective DUR cost savings reported by vendors and/or states lack independent verification¹¹ and might be overstated.²⁰ For example, a denied prescription counted as a cost saving would overstate the potential savings if the denied prescription led to an increase in other healthcare costs or was subsequently filled. Soumerai and Lipton¹⁴ explained that

denying early refills routinely is potentially dangerous because the physician might have increased the patient's dose, or the patient might only have access to transportation to a pharmacy at restricted times. Prescribing a "therapeutic" or "preferred" alternative drug is another way in which denied prescriptions can result in increased costs, eg, if there are costly adverse effects associated with the new medication or if the discounts ultimately applicable to the replaced drug make it less costly. Anecdotes from some program administrators express concern that success as measured in cost savings attributed to DUR might result in future budget reductions.

Prospective DUR program limitations include (1) insufficient flexibility in vendor-supplied software, resulting in an excessive number of alerts to pharmacies^{7,14,21}; (2) the ability of pharmacists and/or technicians to override potentially important DUR messages²¹; and (3) programs being focused on denying early refills (potential overutilization) rather than on improving patient adherence, late refills, or people who discontinue taking a long-term medication.¹⁴

Managed care organizations must carefully negotiate with the vendors that provide pDUR services to be certain that (1) criteria are validated and the pharmacy alerts are clinically significant; (2) pharmacy alerts cannot be overridden without the pharmacist's input²¹ (overriding messages before they can be seen by the pharmacist defeats the purpose of the program); and (3) pDUR addresses underutilization of pharmaceuticals, such as late refills or discontinued medications for chronic conditions, as well as overutilization.

Prospective DUR might be moving from the pharmacy to the physician. Electronic prescribing and use of the Internet for medication management is growing. The main advantages of electronic prescribing include (1) decision support for drug prescribing choice(s); (2) DUR screening (offering the possibility of moving pDUR back to the prescriber); (3) consolidated medical information—including diagnostic, ancillary, and pharmacy information; and (4) coordination and communication among different providers.²² Combined with an electronic patient record, electronic prescribing could substantially reduce many of the situations that currently lead to medication-related illnesses. Concerns regarding the ability of providers to maintain patient confidentiality and secure communications have been barriers to integrated electronic medical transmissions, although the primary barriers have not been technology. This goal has been elusive, but

advances in personal digital assistants make handheld digital communications logistically feasible, affordable, and inevitable. Laptop computers could have supported electronic prescribing, but handheld personal digital assistants more closely conform to a prescriber's clinical practice. There are many competing products, including Allscripts™, ePhysician™, ePocrates™, and iScribe™. Allscripts™ uses a handheld device that is closer to a subnotebook for "point-of-care medication management" to select a patient, a diagnosis from a list of the most common codes used by the physician, and the medication from a menu with formulary information; the medication can then be transmitted to the pharmacy.²³ iScribe™ supports both Palm™ or Windows® CE devices,²⁴ whereas ePhysician™ uses a Palm® OS platform²⁵ and ePocrates™ uses the Palm Computing® platform. The growing acceptance of personal digital assistants is reflected by ePocrates™ recently exceeding 130,000 users.²⁷ In recognition of the potential for electronic prescribing to reduce errors, a malpractice premium reduction was offered by one insurer to physicians who adopt electronic prescribing for a year.²⁸ Handheld technology and medical practice integration develop quickly so that any list of specific technical attributes is likely to be outdated by publication; readers are encouraged to explore Web sites for those companies mentioned and for competing products to compare features for themselves.

... RETROSPECTIVE DRUG
UTILIZATION REVIEW ...

Both rDUR and pDUR try to improve the appropriateness of prescribing, but their focus differs. Prospective DUR concentrates on individual patients, whereas rDUR focuses at the population level. Retrospective DUR uses practice pattern analysis to identify the use of high-cost drugs, to compare particular classes of drug use by different facilities or providers, or to monitor adherence to pharmacotherapy recommendations from practice guidelines for the treatment of particular diseases. Medical practice profiling has been described for a range of services^{29,30} as a technique to improve quality and reduce costs concurrently³¹ and as a method for explicit assessment(s) of quality of care.³² There are, however, some concerns. Individual physician "report cards" have been reported to be unreliable in detecting differences in diabetes care accurately, partially because of the small number of cases for

individual physicians. This may reward physicians who select patients based on their potential contribution to the practice profile rather than accepting all, even difficult-to-treat and noncompliant patients.³³ Little, however, has been reported on computer-based DUR—specifically, comparison of individual drug use patterns with peer groups. A recent article by MacKinnon and Lipowski³⁴ provides background and insight into the strengths and weaknesses of provider profiling as perceived by stakeholders. The drug measures developed by the National Committee for Quality Assurance for HEDIS 2000® move toward selected, health plan-level drug and disease profiles for ambulatory patients,³⁵ whereas advanced quality indicators of medication use have been developed by the Center for Health Systems Research and Analysis³⁶ for nursing home use.

Retrospective DUR spans data from multiple prescribers and pharmacies for individual patients; it may involve linking drug claims data with other databases to access additional information, such as patient diagnosis, to define patterns of treatment for a given condition or use of a drug product across populations of patients. Although each individual prescription might have been acceptable, the pattern that emerges over time might be suboptimal. Practice pattern analysis and subsequent actions offer DUR's greatest potential for a durable change in prescribing behavior. Panels composed of physicians and pharmacists review the profiles using implicit judgment based on predetermined drug utilization criteria to determine whether an action is necessary.³⁷ Actions typically begin with an educational intervention conducted with physicians and/or pharmacists on evidence-based standards for the medications under review (also known as academic or counter detailing). Retrospective DUR interventions usually focus on 1 therapeutic area (eg, antibiotic use and otitis media). Although pattern analysis might generate a profile for a reason that is subsequently rejected, another issue for the same patient might be identified in the course of the review and lead to an intervention. This process makes it difficult to quantify the effectiveness of an rDUR program because the focus may shift on any given review from a product to a patient to a provider.

Retrospective DUR interventions are generally conducted by mail and occasionally by telephone or in person.²⁰ At first only academic detailing interventions were considered effective for changing physician prescribing patterns and reducing patient care costs. In a study by Avorn and Soumerai,³⁸ one-

to-one physician visits by clinical pharmacists reduced the costs and amount of 4 targeted drugs prescribed compared with physicians who received only printed material. In a review of DUR by Soumerai and Lipton, the authors cite the lack of evidence of efficacy for computer-based DUR and note that cost-effectiveness claims were based on poorly controlled, unpublished, or biased studies.^{14,15} Results of more recent studies,³⁹⁻⁴⁴ however, also indicate that mailed rDUR interventions can be effective in changing physician prescribing behavior and in reducing patient healthcare costs. Sleath et al⁴¹ found that state Medicaid rDUR programs were performing the following types of DUR activities: (1) 88.0% of the programs sent letters about individual patients with drug therapy problems to physicians; (2) 78.5% sent letters about individual patients with drug therapy problems to pharmacists; and (3) 54.8% profiled physicians with prescribing problems. These actions may be made redundant with more effective pDUR. Following the rDUR pattern identification process, 4 main actions were taken by these programs: (1) 11.9% conducted face-to-face interventions with physicians; (2) 16.7% conducted telephone interventions with physicians or pharmacists; (3) 7.1% wrote journal or newsletter articles; and (4) 4.8% gave continuing education programs or presentations at hospitals and other institutions.²¹

Retrospective DUR program limitations include (1) the temptation to focus primarily on the drug product and insufficiently on the use of related health services such as hospitals or emergency departments; (2) some vendors being unable to create physician-level profiles and not meeting the needs of the organizations with whom they have contracted¹⁴; and (3) the reliance on information that was written in the medical chart or electronic patient record—patients may have adverse drug reactions or contraindications to medications that were not recorded and, therefore, those evaluating the medical chart cannot make an accurate assessment. Retrospective DUR complements pDUR. A pattern of drug-drug interaction(s) detected under rDUR can be used to refine pDUR program activities. The ability to identify patterns might be hampered by the low interrater reliability between the healthcare providers who review the profiles.^{37,45} Disease management programs address these shortcomings, although they currently suffer from a lack of standardization among those who offer products under this label. Typically, disease management programs are understood to include (1)

identification of a population of people with the same disorder; (2) a multidisciplinary approach; (3) use of evidence-based guidelines; (4) outcomes measurement; and (5) reporting detailed information to clinicians (and aggregated information to others).⁴⁶

Three main opportunities exist to improve the DUR process. First, managed care organizations could negotiate contracts with DUR vendors to ensure provision of (1) evidence that the criteria their vendors use are validated and based on drug compendia and the peer-reviewed literature; and (2) vendors to perform physician profiling that provides information in sufficient detail to be useful for management and for educational interventions.²¹ Second, the physicians and pharmacists who review the profiles generated by the criteria algorithms should be well trained so that their actions reflect adequate intercoder reliability.³⁷ Actions that would make pattern analysis more effective are (1) defining a standard set of objective criteria as a basis for DUR decisions; (2) intensively training reviewers about the specific content of the objective criteria and the process by which reviews should be conducted; and (3) incorporating an assessment of rater reliability as part of the DUR program's quality assurance activities.³⁷ Third, algorithms of best practices could be shared among managed care organizations to lead to overall improvement. As a starting point, numerous retrospective interventions have been published in the literature and can be a source of ideas for interventions.^{40-42,47} There is little evidence currently in the peer-reviewed literature as to whether these programs are cost effective.²⁰ A recent study¹² using online DUR to improve geriatric pharmacotherapy suggests a positive impact but also illustrates the challenges in performing research in this area, notably, weakness in a control group, baseline, and possible selection bias.⁴⁸ Evaluation of several state pDUR programs mandated under the Omnibus Budget Reconciliation Act of 1990 did not provide evidence of effectiveness; consequently, there was no cost-effectiveness calculation. For a limited number of interventions, the same study supported rDUR impacts on prescription drug use.⁴⁹ Consequently, DUR program directors might benefit from specific training to measure the cost savings or cost effectiveness of their programs, perhaps using the guide for year-end final reports to the Health Care Financing Administration required for Medicaid DUR program directors.⁴⁷

... CONCLUSIONS ...

An aging population, a growing number of marketed pharmaceuticals, an increase in the overall number of prescription drug users, and patients who see multiple providers and who may regularly switch health plans combine to increase the risk of medication-related illness. There is no one solution to prevent all medication-related illness, but DUR, coupled with new handheld technologies; integrated clinical information; and current, evidence-based rules for pharmacotherapy screening, might reduce the occurrence of those that are preventable. Drug utilization review is a work in progress, with the automated components still requiring professional judgments to apply the general rules to the individual patient being treated. One possible consequence might be better pharmacotherapy and improved medication adherence, which might increase the drug line-item expense for the organization. The challenge to managed care and to other healthcare delivery systems is to move beyond management of individual categories of resources and costs, such as pharmacy, hospital, or physician costs, to assessing the global impacts of appropriate prescription drug use. Although the DUR process and its likely positive impacts have face validity, the challenge to convincingly demonstrate changes in costs and outcomes resulting from DUR interventions is substantial and, as yet, largely remains to be done.

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Instructions

After reading the article "Ambulatory Drug Utilization Review: Opportunities for Improved Prescription Drug Use," select the best answer to each of the following questions. In order to receive 1 CME credit, at least 7 of the 10 answers must be correct. Estimated time for this activity is 1 hour. CME credits are distributed on a yearly basis.

1. Because of improvements in information technology, deaths from medication errors decreased from 1983 to 1993.

- a) true
- b) false

2. The risk of death from an outpatient medication error during 1983 to 1993 was greatest for:

- a) African American females
- b) white females
- c) African American males
- d) white males

3. Most medication errors resulting in visits to the emergency department are unavoidable?

- a) true
- b) false

4. Prospective drug utilization review (DUR) can be used only in combination with the paper medical chart?

- a) true
- b) false

5. Guidelines for implementing the clinical rules for selecting prospective DUR screening criteria based only on administrative data (medical and pharmacy service claims) do not include which of the following:

- a) severe medical consequences are likely if an action is not taken
- b) high costs are likely if an action is not taken
- c) there is evidence linking the screening criteria violation and the outcome
- d) the criteria link laboratory results to enhance active monitoring

6. The main advantages of electronic prescribing do not include which of the following:

- a) offers decision support for drug prescribing choice(s)
- b) ability to perform DUR screening
- c) provides consolidated medical information
- d) maintains confidentiality of patient data by restricting providers to their own information

CME TEST FORM

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4. a b
5. a b c d
6. a b c d
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Were any portions of this program unsatisfactory or inappropriate?

yes no

If so, which?

Do you find the information presented in these articles to be fair, objective, and balanced?

yes no

Is there subject matter you would like included in the future?

yes no

Comments:

In your opinion, were the authors biased in their discussion of any commercial product or service?

yes no

Comments:

Program Title

Physician Name

Address

City, State, ZIP

Specialty

7. Unlike prospective DUR, it is easier to quantify the effectiveness of a retrospective DUR program because the focus of a given review may be limited to a product, a patient, or a provider.

- a) true
- b) false

8. There are benchmarks to measure and compare the effectiveness of the criteria used in prospective DUR programs.

- a) true
- b) false

9. Vendors being unable to create individual physician profiles is principally a limitation of:

- a) prospective DUR
- b) medical service claims billing systems
- c) retrospective DUR
- d) inconsistent physician identifiers

10. Sleath et al²¹ found that 1 in 10 Medicaid programs were doing face-to-face educational interventions with physicians in an attempt to improve prescribing.

- a) true
- b) false