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# SYMPOSIUM ON DRUG UTILIZATION REVIEW ISSUES

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## *SUMMARY REPORT*



**OFFICE OF INSPECTOR GENERAL**  
**OFFICE OF EVALUATION AND INSPECTIONS**

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# **SYMPOSIUM ON DRUG UTILIZATION REVIEW ISSUES**

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## *SUMMARY REPORT*

**Richard P. Kusserow  
INSPECTOR GENERAL**

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## SYMPOSIUM PRESENTERS

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Harvard Medical School  
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Harvard Medical School*

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Department of Pharmacy Health Care Administration,  
University of Florida*

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Philadelphia College of Pharmacy  
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## SUMMARY REPORT

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The idea for this symposium began in mid-1989 when the Office of the Inspector General published a report on drug utilization review (DUR) and the Medicare Catastrophic Coverage Act. This report considered a number of issues:

- misedication problems among the elderly;
- the gaps in the health care system that affect misedication; and
- initiatives the Administration and the Congress could take to address some of those problems.

When the original DUR report was released, it became clear that it identified several very complex problems. This symposium represented an attempt to expand on those issues and to bring together scientists, practitioners, and policymakers to pursue these issues further.

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### ■ Prescribing For The Elderly And Nursing Home Use

Dr. Jerry Gurwitz of Harvard Medical School began the symposium with a discussion from the physicians' perspective of the unique aspects of prescribing for the elderly. He pointed out that pharmacotherapy is perhaps the single most important medical intervention in the care of the elderly, and its proper performance requires a special understanding of the changes in physiology and pharmacology that occur with aging. Cross-sectional and longitudinal studies involving community-dwelling populations indicate that increasing age is often accompanied by reductions in the physiologic reserve of many organ systems, reductions that are separate from the effects of disease. The ability of an organism to maintain homeostasis in the face of an external threat often depends upon the reserve capacity of the heart, the lungs, the kidneys, the liver, etc. These changes have important implications for the biological basis of drug effects in the elderly.

Pharmacokinetics is most simply defined as what the body does to a drug. Changes in pharmacokinetics that occur with advancing age provide an important basis for concern about adverse drug reactions (ADRs) in the old. For certain medications, drug distribution can vary importantly with advancing age. The volume of distribution is the theoretical space in a given patient that is available for a particular drug to occupy. An age-related increase in body fat at the expense of muscle can lead to a greater volume of distribution in older patients for some medications. These changes are more prominent for drugs like diazepam and flurazepam, highly-lipid soluble benzodiazepines prescribed for anxiety and insomnia.

Pharmacodynamics is the study of the sensitivity of the organism to a drug. The aging process appears to be associated with an *increase* in the sensitivity to many medications commonly prescribed to the elderly. Changes in pharmacodynamics, together with age-related changes in

pharmacokinetics, could well be expected to place the elderly patient at some increased risk for ADRs.

A few studies suggest a trend toward increasing risk of ADRs with advancing age, although this conclusion is open to question because none of the reviewed investigations controlled for potentially important covariates including clinical status, length of hospitalization, and number of medications taken concurrently. Findings do support, however, an obvious association between the number of drugs taken concurrently and the risk of ADRs. More importantly, the number of drugs that a patient is receiving is directly related to the number of coexisting diseases.

The diagnosis of drug-induced illness in elderly patients is frequently complicated by the tendency by patients, families, and even physicians to mislabel many symptoms as signs of “just growing old.” One maneuver with very useful diagnostic as well as therapeutic potential is the “therapeutic untrial” of a medication of dubious value that is currently in a patient’s regimen. Older patients are at risk of accumulating layers and layers of drug therapy as they move through time. Medications used for symptomatic relief (e.g., of insomnia) are fairly easy to “prune,” as their *careful* removal does not put the patient at significant medical risk.

More challenging is the reassessment of medications that may be vital to the patient’s regimen or may be presenting the risk of toxicity with no therapeutic benefit, such as digoxin, quinidine, thiazides, antihypertensives, and anticonvulsants. Some clinicians may argue that if patients are stable and in no overt distress, it is too risky to change their regimen by removing drugs that may not be needed. However, it is often not appreciated that any medication that has the potential for toxicity with no continuing indication can represent a “time bomb” to a patient.

The available evidence suggests some useful questions which physicians should use far more often concerning drugs prescribed for an older patient:

- Can I avoid using a drug here?
- Could *stopping* a medication help with the patient’s symptoms?
- Is this the lowest feasible dose?
- Does this drug have any particular side effects that are more likely to occur in an elderly patient?

Symposium participants agreed that it takes precise attention to the individual characteristics of a patient in deciding on appropriate drug use. It is difficult to establish simple age-based rules or algorithms that will be useful in all cases. The types of guidelines identified by Dr. Gurwitz, however, can be of great value. The regulatory or policy implications are that there must be a cooperative effort among those who are involved in science, regulation, and policy

formulation in the creation of such guidelines. Determining appropriate drug use also requires that particular attention be given to patient and family satisfaction with the medication as well as its clinical effectiveness.

There are few firm, fast rules in geriatric pharmacology, but following the very simple principle which says, “start low — go slow” may be the best rule a physician can use in prescribing medications for older patients — and even that is not a very rigorous principle.

There is interest at the regulatory level in learning more about the effects of drugs on the elderly. Specifically, the National Institute on Aging and the FDA have expressed the concern that so few data are available on drug testing in elderly populations.

With increased consumer involvement in our society and our ability to communicate much more thoroughly, there is an important opportunity to see to it that users of medications are playing as active a role as possible in interacting with health care professionals. For example, there is at least one drug company that has started to produce well designed, easy to read, large print statements of potential drug reactions, and they are providing them with prescriptions. That is technically called for in FDA regulations, that a user has a right to ask for information about adverse drug reactions, but, in fact, it is not actively provided in most instances. Likewise, the American Association of Retired Persons (AARP) maintains an active program of geriatrically-oriented patient education leaflets for members who use their pharmacy service. Increased interaction between the users of medications and professionals involved in the prescribing and dispensing of drugs can make up for some of this deficit in compliance.

While the FDA approves a drug for one indication, physicians are then free to use it for other indications. The FDA does not approve it for one age group and then prohibit or prevent a physician from using a drug tested in one age group on an age group which has not been tested. The solution will go wanting until the responsibility is placed on all parts of the drug development, approval, and use process. Efficacy and toxicity in the elderly are often determined primarily by whether clinicians and patients are using drugs intelligently.

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### ■ Medication Prescribing And Utilization In The Nursing Home: Literature Review

The nursing home setting is an area of particular concern for drug utilization review in the elderly. A number of studies have suggested approaches designed to reduce inappropriate prescribing and drug utilization in this environment. Therefore, a review of this literature was prepared for this symposium by Jerry Avorn, M.D., Jerry Gurwitz, M.D., and Stephen B. Soumerai, Sc.D., of Harvard Medical School. In contrast to the wide range of approaches which have been evaluated and implemented in the hospital setting, interventions in the nursing home have centered around consultant pharmacist activities. Although these activities are now Federally mandated in all nursing homes, their review found that much of the evaluation of such programs has been methodologically inadequate, and there is little evidence from adequately controlled studies to document their impact or cost-effectiveness. No data

exist on the quality of implementation of such consultant pharmacist programs on a large scale, to address the important question of whether nominal “paper compliance” producing a minimum number of written recommendations per month is more common than actual impact on quality of care. By contrast, face-to-face educational interventions directed at physicians have been shown to be effective in improving prescribing for several medications.

Polypharmacy is the rule rather than the exception in the nursing home. A 1976 study by the Office of Long Term Care based on a sample of 3,458 nursing home patients reported an average 6.1 drugs per patient, with some patients receiving over 20 different medications. There is compelling evidence to suggest that medications are frequently used inappropriately in many nursing homes. A 1980 study by Ray *et al.* reported that as nursing home practice size increased, doctors were found to prescribe more antipsychotic medication per patient. Antibiotics are another class of medication whose utilization in the long-term care setting has been evaluated. A possible consequence of the excessive use of antibiotics is the development of increasingly virulent bacterial strains, forcing reliance on potentially more toxic and expensive antibiotic regimens. Additionally, the underuse of potentially beneficial medications represents another kind of problem in nursing home drug use.

The general lack of organized medical staff in nursing homes further impairs the ability to institute educational programs or to enforce standards of drug usage in this setting. Since approximately 50 percent of all medication orders for nursing home patients are written by the physician with directions for PRN (take as needed) administration, the nursing staff, by default, take responsibility for a substantial proportion of prescribing decisions. In addition, the bulk of direct care for nursing home patients is provided by nurses’ aides, who often have little experience or formal training, and who experience high turnover rates. The expectations and demands of patients and their families must also be considered. The pressures exerted by patients and family members both for and against the prescribing of many medications can be enormous. In addition, a factor of particular importance is the frequent inadequacy of staff, making it more likely that “chemical restraints” will be applied rather than interpersonal, non-pharmacologic solutions.

### ***Approaches to Improving Drug Prescribing and Utilization in the Nursing Home***

#### **Controlled Trials**

Studies employing these research designs provide the opportunity to control for non-program influences in the evaluation of a particular nursing home intervention. The comparability of the control impacts on the ability to generalize from the results of such studies.

#### **Time-Series Studies**

The essence of the time-series design is a frequently repeated periodic measurement in a group or individual, with introduction of an intervention into this time series of measurements.



## **One-Group Pre-test/Post-test Design**

Conclusions based on the results of such studies are open to question due to the lack of a control group, the limited number of observations, and the associated difficulties in controlling for confounding factors extraneous to the intervention being studied.

While drugs are often indispensable in the medical care of elderly nursing home patients, the inappropriate use in this setting is of great concern. Medications can become a substitute for careful diagnostic maneuvers and/or effective non-pharmacologic therapies, increasing the risk of serious adverse drug reactions in this already vulnerable population. In an era of cost containment and rising drug costs, the overuse of medications can also divert resources from more important purposes.

## **Findings**

Although it is generally accepted that well-designed clinical trials of pharmacologic interventions should serve as the basis for rational medication prescribing, health care delivery interventions are rarely subjected to the same quality of evaluation. Of the many research designs employed in the review literature, only one utilized an adequate control group. Further, the intervention being tested should be implemented in such a way that the influence of extraneous factors on measured outcomes of interest is minimized. Finally, the “active ingredient” of the intervention must clearly be defined. For example, the term “drug utilization review” can mean different things, from a simple review of the physician order book to make certain that regulatory policies are being enforced, to scheduled face-to-face interactions with medical and nursing staff employing sophisticated educational protocols.

Several other methodological issues were identified in the literature review conducted by Dr. Avorn and colleagues. They are summarized below. Factors driving prescribing in the nursing home are more complex than either the acute care hospital or outpatient settings, where physicians are the predominant decisionmakers. These differences must be taken into account in all regulatory or educational efforts. In measuring outcomes, if reported changes in medication “orders” include PRN medications, which many patients never use, any conclusions about the impact on actual drug utilization must be questioned. Reductions in PRN medications are often reported to comprise a large proportion of the favorable effect of intervention. However, many PRN orders are never administered. Programs to improve drug utilization and prescribing in the nursing home must also be evaluated in economic terms, ideally comprising a comparative analysis of at least two alternative programs in terms of both their costs and consequences. The economic implications of an improvement in drug therapy which reduces patients’ utilization of more expensive resources (e.g., acute hospitals) must also be considered.

Unfortunately, very few published studies have attempted to address the issue of clinical outcomes resulting from changes in drug utilization in nursing home patients. Assessment of clinical outcomes is essential for the complete evaluation of any program designed to improve medication prescribing and drug utilization. Examples of important clinical outcomes might

include: (1) changes in the incidence of adverse drug effects (overall or specific reactions) following implementation of a drug utilization review program; (2) changes in the cognitive, behavioral, and functional status of nursing home patients associated with a program to improve prescribing of psychoactive medications; and (3) changes in the incidence of falls following a program designed to limit the occurrence of hypotensive episodes associated with antihypertensive medications.

### ***Implications for Future Research and Policy***

- (1) Little evidence currently exists with which to evaluate the effectiveness of the current nationally mandated program of DUR by consultant pharmacists.
- (2) Face-to-face educational interventions directed at physicians and focusing on principles of geriatric pharmacology have been shown to be effective in improving prescribing to nursing home patients of selected medications.
- (3) The prominent role played by the nurses and aides in the utilization of many other medications in this setting suggests that educational interventions must involve nursing staff.
- (4) Any study designed to evaluate the true impact of intervention on drug utilization must provide data concerning doses of medication administered to patients rather than merely “ordered.”
- (5) Greater attention must be paid to the actual clinical and economic outcomes of any such interventions.

New methods for improving drug prescribing and utilization must be developed and tested. For example, computer-assisted feedback of therapeutic decisions has been shown to be effective in improving care in the ambulatory setting; the technology is readily available to incorporate such a strategy into the nursing home setting. However, widespread implementation of any new intervention must be preceded by careful evaluation according to rigorous standards of health services research, particularly in this vulnerable population.

Following presentation of the literature review, symposium participants addressed strategies that should be employed in both institutional and ambulatory settings to improve the accuracy of drug use in elderly patients. It was agreed that the doctor, pharmacist, nurse, family member, and patient must be involved in the following processes:

- Taking a very careful medication history — to get a feeling for what is going on in the complex patients, including use of over the counter (OTC) drugs. (In the nursing home this is somewhat more practical because OTC drugs are dispensed by the same people who dispense the prescription meds. That is not the case in outpatient care.)

- “Brown Bag” reviews — “brown bag” has become a metaphor which came from having patients put all their medications in a brown bag to bring to the caregiver, who would go over them and throw away drugs that were outdated, abused, or not used intelligently. This process should be ongoing in the nursing home, and is critical to what ought to happen in drug regimen review in long-term care.
- Cautious withdrawal of all drugs with dubious indication: This advice sometimes causes controversy among physicians who may feel, “I’ve got a patient who has been on quinidine for the last 20 years. Either I don’t remember why I put her on it, or the doctor who put her on it has been dead for 15 years, but I’m reluctant to take her off and have an arrhythmia occur.” However, Dr. Avorn argued that a cautious withdrawal is probably safer than having patients take potentially dangerous drugs if no one can figure out why they need them.

In a program supported by the Hartford Foundation, Dr. Avorn and colleagues developed an educational intervention to reduce overuse of psychoactive drugs in the nursing home setting. It consisted of four in-service training sessions for nurses; four in-service sessions for aides; and three one-on-one visits with prescribing physicians in their offices by a pharmacist/educator. Preliminary indications are that such an intervention can be effective in reducing excessive use of sedative drugs in the nursing home.

Staffing is one of the major problems confronted in operating an educational intervention program. What is needed is a nucleus that has the clinical expertise to define the areas that will be the subject of the educational intervention, and knows enough about the use of computers and evaluation techniques to identify the providers to be educated, as well as to evaluate the effects of the program. The work done by such a skilled and highly motivated group must then be translated into the everyday world of actual health care delivery systems.

Staffing within the nursing home is of critical importance. Unless more money is put into improving staffing, problems will be encountered in changing the prescribing of psychoactive drugs. It is not necessarily an issue of the size of the staff, but rather the atmosphere in the facility.

The consultant pharmacist is not fully utilized for retrospective drug utilization review by long-term care (nursing home) facilities. Many consultant pharmacists find themselves charged with the responsibility of preparing a nursing home for a Medicaid inspection, but not truly interacting with patients or with other professionals regarding patient-specific matters. There is no standard of practice for the consultant pharmacist; professional training is lacking in geriatric pharmacology; very little is taught in American schools of pharmacy or medicine about geriatrics; and systematic instruction in the proper use of drugs is not getting proper attention.

It is possible the private sector will get involved in drug utilization review before the Federal Government enters it on a large scale. The concern for DUR in the private sector is coming from several sources: employers who pay for drug benefits, insurance companies, and HMOs.

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### ■ Preventing Drug-Related Morbidity

The symposium next turned to a discussion by C. Douglas Hepler, Ph.D., of the University of Florida regarding the role of the pharmacist in preventing drug-related morbidity (DRM). Dr. Hepler called attention to one estimate (Southwick) that places the cost of drug-related illness in the U.S. at around seven billion dollars annually. By contrast, “therapeutic failure” is an intermediate medical care outcome in which drug therapy does not secure the necessary result in an acceptable time period. It can result in therapeutic substitution or the addition of new therapy; the progress of disease; and the prolongation of symptoms and disability. Drug therapy can cause the appearance of new symptoms such as adverse drug reactions and side effects, drug toxicity, or drug interactions with food or other drugs.

Drug-related morbidity may be caused by a number of factors: inappropriate prescribing, inappropriate delivery, inappropriate patient behavior, or inappropriate monitoring of drug therapy. Unresolved drug-related problems may lead to drug-related morbidity, which, if unresolved, may lead in turn to drug-related mortality.

A drug-related problem is a circumstance of drug treatment that actually or potentially interferes with the patient’s experiencing an optimum outcome of medical care. Strand *et al.* (1989) have identified eight categories of drug-related problems.

1. The patient has a medical problem that requires drug therapy (a drug indication) but no drug has been prescribed for that indication.
2. A drug indication exists but the wrong regimen has been ordered.
3. A medical problem is being treated with too little of the correct drug (subtherapeutic dose).
4. A medical problem exists as the result of a patient’s not receiving the drug, e.g., for pharmaceutical, psychological, sociological, or economic reasons.
5. The patient has a medical problem that is being treated with too much of the correct drug (toxicity).
6. The patient has a medical problem that is the result of an adverse drug reaction or side effect.
7. The patient has a medical problem that is the result of a drug-drug, drug-food, drug-laboratory interaction.

8. The patient is taking a drug for no medically valid indication.

In order to prevent drug-related morbidity, the problem must be recognizable, the morbidity must be foreseeable, and the cause(s) must be controllable. Deciding what is preventable (recognizable, foreseeable, controllable) requires a standard of care. However, there is no consensus standard of care for drug therapy. In addition, there is no consensus standard for the drug use process. It is unsafe to assume that physicians, pharmacists, and nurses somehow will detect, prevent, and resolve drug-related problems. Monitoring is an especially weak point in drug use, particularly in ambulatory care.

Various studies indicate the prevalence of DRM. However, there are significant methodological problems with many of the DRM studies. They don't define the concept of preventability. To further understand preventable DRM requires: a standard of care for the drug use process; epidemiological data regarding preventable DRM (applied standard of care); and consensus on interpretation of the epidemiological data.

The pharmacist can play a much larger role in preventing, detecting, and resolving drug-related problems. Pharmacists are suited by education, availability (Manasse, 1988), and location in the drug use process. Some pharmacists have already begun new functions related to preventing DRM, under the names of "clinical pharmacy" or "therapeutic monitoring." Others call these functions "Prospective Drug Use Review." The purpose of pharmaceutical care is to achieve definite outcomes that improve a patient's quality of life by means of detecting, preventing, and resolving drug-related problems. Pharmaceutical care should be integrated with the other elements of health care, but the pharmacist accepts direct responsibility for the quality of that care.

The literature shows that some drug-related morbidity can be prevented, and that pharmacists can contribute significantly to achieving that goal. This will require significant changes in the philosophy and organization of the practices of many pharmacists. The pharmacist must recognize new purpose and responsibility; acquire additional competence; obtain resources and develop relationships; and find rewards in the new practice.

The Food and Drug Administration assessment of the impact of adverse drug reactions is that there are 27,000 to 28,000 reported adverse reactions annually, with hospitalization or death resulting from 19 percent of the cases. However, these figures may be quite below what is actually occurring. Although good data on costs are lacking, it is possible that the figure could reach four billion dollars in terms of bearing the load for the treatment of the consequences of drug-related disease. There is no systematic reporting for treatment failure, and that could mean that the four billion dollar figure is not really indicative of the problem, which could be much larger than anticipated.

At present, pharmacists remain outside the medical "information loop." They need to learn how to tie information about drug use and the drug user together and relearn the idea of focusing on individual patients. Pharmacists should be held accountable for what they do and evaluated for their ability to prevent drug-related morbidity. The profession might look to the

Federal Government and agencies such as HCFA for standards of practice or training. Dr. Hepler stated that the mission of HCFA, however, is financing, and only very recently has it become involved in quality care issues. It is possible that the "Effectiveness Initiative," developed by the Department of Health and Human Services to focus on outcomes in quality care, could be an indication of greater awareness at the Federal level.

The responsibility for training, retraining, or resocializing pharmacists might fall to the employer in the case of the thousands of pharmacists who work for chain stores. But unless the employer is given some incentive or penalty for training or not training, cooperation will be minimal. One way the Government can help is by setting up demonstration projects. An advantage of demonstration projects is the fact that the effect on economic and clinical outcomes can be evaluated.

It might be advantageous to link the dispensing fee to counseling, especially at a time such as now when robots and computers are handling much of what was once the job of the pharmacist. A possible model might be that a dispensing fee is not paid when the function is turned over to a computer or machine, but when the pharmacist takes time to counsel the patient, whether the prescription is filled or not, a dispensing fee might be appropriate. No matter what is done or how it is done, the pharmacist must have individual accountability in the drug utilization review process, and the performance of individual pharmacists should be tracked.

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### ■ Intervention Opportunities In Community Pharmacy Practice

The perspective of the community pharmacist was analyzed by Calvin Knowlton, president of Amherst Pharmacy, Lumberton, New Jersey. He argued that pharmacists in community pharmacy practice, whether independent or chain settings, are slowly shifting their focus from the drug product to the patient. Although community pharmacists have always been available to respond to patient inquiries, until now their priority has been directed to the drug product.

It has not been an easy task for community practitioners to adopt a more proactive patient-attention style, noted Mr. Knowlton. The change in priority has been an evolving process, not an event. The newer pharmacists seem to be nudging the profession to re-orient its mission. Amidst the constraints of the commercial backdrop of the majority of community pharmacies and the highly technical nature of pharmacy education, the pharmacy graduates of the past decade are intent on moving the profession in a more humanistic direction. While prescription or non-prescription drug *products* are still the mainstay and preeminent domain of the practice, the *patient-centered* approach apparently is more satisfying to contemporary community pharmacy practitioners. Patients taking multiple drugs from one or more physicians need someone to monitor and intervene to reduce the chance for drug-drug interactions and/or drug-disease state incompatibilities. Community pharmacists (if not constrained by "management") are increasingly welcoming the opportunity to fulfill the role of outpatient *drug therapy monitors*.

Approximately 170,000 pharmacists are currently practicing in traditional settings. These settings include: 50,000 chain pharmacists; 75,000 independent pharmacists; and 45,000 hospital pharmacists. The community pharmacists (chain and independent) practice in approximately 50,000 pharmacies and fill over 1.6 billion outpatient prescriptions annually. A varying number of these prescriptions are filled by mail-order pharmacies (estimated to be about 2 percent).

Activities performed by community pharmacists have changed to reflect more patient-oriented approaches. These include hypertension monitoring and screening, patient education regarding self-care testing equipment (such as glucose monitoring machines), and providing patient information or literature. Although community pharmacists assert that drug distribution requires over 50 percent of their time, some have stated that drug information and patient care activities encompass 25 percent of their time. Sixteen to 18 percent of community pharmacists' time is devoted to management and/or business tasks. Many community pharmacists practice a form of "hospital pharmacy" within the community setting by serving as the pharmacy provider and/or consultant to nearby nursing home facilities.

Perhaps the most important outcome of the evolving drug-to-patient paradigm shift of focus will be to encourage community pharmacists to use judgmental intervention on behalf of (or, in conjunction with) patients. This opportunity exists both before and after filling a prescription. Yet, this judgmental intervention is constrained by the lack of formal authority to alter the prescription.

Prior to filling a prescription, community pharmacists have an opportunity to bring the patient into the decisionmaking process regarding certain aspects of the drug therapy. As the health care infrastructure continues to move in the direction of patient autonomy via the process of informed consent (and away from the paternalistic model in which "the health care provider knows all and will decide for me"), pharmacists could enable patients to select from a limited menu of prescription drug therapy options. These include the use of generic substitution; pharmaceutical alternatives (e.g., use of inexpensive short-acting vs. costly long-acting drugs); therapeutic interchange (i.e., when the pharmacist contacts the physician and, on behalf of the patient, requests a change in the prescription drug); the provision of smaller starter doses; or the use of protocols, in which (for managed care settings) a pharmacist provides input regarding cost-comparison data for treatment of a particular disease. Step-care protocol developed with active physician input is an alternative, creative, prospective DUR method which considers both quality of drug care and economy of drug care.

Community pharmacists are able to help patients with prescription drug education (but formal, pedagogical, prescription drug education is also needed, starting in the elementary schools). Nuances are plentiful and important but not always obvious; but prescription drugs can now be demystified, standardized, and understandable. Some policy options embodying these concepts are:

- require current Pharmacy and Therapeutics Committees in each nursing home to perform DUR (both prospective and retrospective);

- require all pharmacies serving Medicaid patients (as a condition of participation) to perform prospective patient profile reviews;
- require all pharmacies serving Medicaid patients to counsel patients on each new prescription;
- policymakers and organizational decisionmakers ought to consider restoring the elasticity of the prescription drug market demand by retiring the fixed-dollar prescription deductible; and
- the Government should establish criteria to seek rebates directly from drug manufacturers based upon drug utilization for Medicaid patients.

The profession of pharmacy is poised to contribute to enhance the quality and efficiency of medication usage in the country. Community pharmacists, particularly, ought to be encouraged to apply their cognitive resources to improve the drug distribution function which they have responsibly discharged. While pressures from within the profession nudge practitioners to adopt a stronger patient-centered standard, external mandates from the public sector decisionmakers would be a favorable catalyst for change.

In the discussion following the presentation of Mr. Knowlton's paper, symposium participants indicated that until the 1950's, pharmacists were compounding and recommending drugs for patients but with the passage of the Durham-Humphrey legislation in 1952, pharmacists were constrained from prescribing or getting involved with treatment decisions regarding the drug products on their shelf. That constraint now has put them in a situation in the community pharmacy of possible terminal displacement as they find themselves just "counting, pouring, licking, and sticking."

An interim step occurred in the early 70's when capitation money came from the Government into the colleges of pharmacy. There was money and no shortage of students. Money was supplied to local hospitals and pharmacy staff people and faculty people were placed in local hospitals as teachers, in part giving birth to the idea of hospital clinical pharmacy. During that time a new degree was created for those people entering pharmacy. Also, as a result of Medicare, the consultant pharmacist's role evolved in the nursing home setting. Through all of this, however, there has not been any focus on community pharmacy. More and more pharmacists are going to work for chains — however, chain pharmacies fill less than 40 percent of the prescriptions that are filled in this country. Most prescriptions are still filled in independent pharmacies.

Statistics also show that 70 percent of practicing pharmacists are happy with their jobs, although happiness is not the most important indicator of their performance. There should be more focus on the question "Are pharmacists satisfied with providing suboptimal service when they know they are capable of doing much more?" There are some internal mandates for change in pharmacies. A recent conference on "Pharmacy in the Twenty-first Century"



identified three key areas of need: the pharmacy in the community has to demonstrate its value; higher expectations are needed in the practice of pharmacy; and there should be standards of care of pharmacy practice. In addition to these needs, nursing homes should be urged to gear up their therapeutics committees and include mandatory prospective and retrospective drug utilization review on their agenda with pharmacist input on those committees.

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### ■ Computerized Databases For Educational Drug Utilization Review

In the final presentation, Wayne A. Ray, Ph.D., of Vanderbilt University, discussed the use of computerized databases for educational drug utilization review. Educational drug utilization review, which works by educating prescribers and other caregivers, can be an important component of the drug utilization review program. The advantages of this method are that it is minimally intrusive upon the physician-patient relationship; it improves the physician's knowledge base and may thus have benefits that accrue to persons other than those in the target population or receiving the target drug; and it has good provider acceptance. Much of the research in the field of educational drug utilization review has employed computerized databases. Computerized medical care databases frequently originate from systems for providing medical care to a defined population in which providers are reimbursed by a single third party. For administrative reasons, these systems often maintain files that identify the persons belonging to the system and contain brief summaries of the medical care the members receive. These files include the enrollment file, the pharmacy file, the provider file, and several other files.

**Enrollment file.** The enrollment file enumerates persons who are members of the defined population.

**Pharmacy file.** The most crucial file for the purposes of drug utilization review is the pharmacy file. This file includes records of prescriptions filled at the pharmacy in outpatient practice.

**Provider file.** The provider file enumerates the physicians who provide care for the members of the defined population.

The first step in drug utilization review is specification of the therapeutic area of interest. This requires selection of the drug or group of drugs for which prescribing is to be improved. The next step in a program of educational drug utilization review is the identification of those physicians or other caregivers who are to receive the educational program. To be cost effective, drug utilization review should focus on those providers who frequently use the target drugs. Given the provider group to receive the educational program, the next step is the intervention, or presentation of the educational materials to the providers. The only method that has been proven to be effective is a personal visit. Evaluation is an essential component of educational drug utilization review. It is needed to assess the efficacy of the educational

program and to define subgroups of nonrespondent providers for whom different methods may be required.

The detailed information on the use of prescription medications in a defined population is the primary strength of computerized databases for educational drug utilization review. This permits one to identify high volume prescribers of target drugs, who can then be selected to receive the educational intervention. The availability of this database then permits rapid and economical evaluation of intervention efficacy.

The key limitation of computerized databases is the lack of clinical detail that would permit more precise definition of substandard prescribing. For example, some diuretics may induce hypokalemia. With appropriate monitoring of serum potassium, this adverse effect can be prevented by provision of supplemental potassium. However, all patients receiving diuretics certainly do not need potassium supplements. With most computerized databases, there is no way to identify patients who should have received potassium supplement but did not, and thus there is no direct way to identify physicians whose prescribing in this area is substandard.

Educational drug utilization review creates a better environment for both the patient and the physician. The changes that are created in the physician's knowledge base will have wider effects than the specific program in which he or she is involved. For those reasons, educational drug utilization review should be a very large part of drug utilization review programming. It has been proven to work in a research setting. The challenge now is to find out how to implement it in the real world — the world of Medicaid programs run by people who have quite a few pressures on what they do in the realm of health maintenance organizations.

The DUR provisions of the Catastrophic Care statute placed too much emphasis on a very limited display of a few prescriptions in a pharmacist's office and the idea that from that one would be able to markedly improve prescribing. The emphasis could have been shifted more to educational drug utilization review. There may be a role for computerized-based screening, but it should not be the centerpiece of a DUR program. In screening for drug interactions, there are a lot of programs out there that generate many false positives.

In the proposed implementation stage of the Catastrophic Care drug benefit, HCFA took a very mechanized approach. The intent of the law might have been that DUR should occur at the pharmacist level, as well as other points in the process. The use of computerized screens to identify "prescribing problems" was not written into the Catastrophic Care Act; rather, it was HCFA's proposed method of complying with its view of Congressional intent. However, most pharmacists in the country have computerized profiling systems in place now that are far more sophisticated than the system HCFA proposed.

Following Dr. Ray's presentation, participants noted that while the educational approach is good, for the individual patient at the time the patient is beginning therapy, the educational approach may be too late. The combination of the pharmacist providing pharmaceutical care and collaborating with the physician could offer something immediate for the patient, while

the educational approach is designed to make longer-term changes in physicians' prescribing behavior. Physician education and pharmaceutical care don't compete, but there has been tension in this debate throughout the last year over the relative value of each approach.

The Catastrophic Care Act clearly called for prospective review and also called for an educational program. What is needed is a comprehensive and systematic review of therapy — not just what can be seen from a profile. The patient needs to be consulted and the professional must get integrated into the medical database in order to prevent drug-related morbidity. Although the law did attempt to speak to educational programs, it was in the implementation phase that problems arose.

There is a major deficit in medical education in therapeutics, and this deficit is amplified in the area of geriatrics. What can be done in the wake of this deficit is to catch the errors and clean up after them every time they occur, or since the same people are making the errors over and over it would be better in the long run to try to educate them to do it right.

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### ■ Policy And Practice Recommendations For Drug Utilization Review

On day two, the symposium participants re-convened for a panel discussion with active involvement of all attendees. The panel was given a twofold task by Dr. Avorn, who chaired the discussion:

- Part one — Given that in the coming decade there will be more governmental payment for medications used by the elderly; given that there already is such payment at the non-Federal level through various State programs; given that even if there weren't such payment, extensive medication use by the elderly would still present major questions of health care delivery and medical care expenditures; as we gear up for the next set of bills and programs and consider those already in place, what would be the model DUR system those around the table would like to see?
- Part two — What research needs must be addressed in order for us to know more about DUR and how it ought to be performed, and how do we want to guide those efforts in the next several years?

There are many aspects of how DUR systems work about which we do not know. The list of research issues is extensive:

- We know that educational drug utilization review programs work in small-scale settings run by academically oriented groups. Will they work as well when they are run on a larger scale?

- We need to study educational drug utilization review in more difficult settings and for more difficult clinical problems, such as the nursing home and the use of psychotropic drugs.
- Does the widely promoted computerized feedback DUR model actually work?
- What is the role of the pharmacist in the outpatient setting?

Participants noted that peer review organizations (PROs) could prove to be one mechanism for addressing drug utilization review. However, this would be appropriate only if the Government is willing to allocate funds and resources to the task. PROs could argue that, although this is very important, there are other parts of the mandate that they cannot fully complete at this point because they do not have enough resources.

GAO has done a series of studies looking at the activity of the PROs with respect to drug utilization review. Two questions emerged: (1) Do PROs have the expertise, manpower, and access to data that would permit them to do appropriate drug utilization reviews? (2) What is the advantage? This could come to a head in some years ahead as the PROs are required to move into outpatient care. Suddenly, PROs could find themselves heavily involved with the appropriateness of prescribing practices.

A loose notion of managed care is becoming prominent in health care. It is implemented in very different ways in different systems. What is needed is a standard, whether it is formulated by the Government or a public-minded private non-profit. We need a model of drug utilization review that takes into account all the operational aspects of making a DUR system work. The marketplace does not necessarily come up with the right sort of utilization management tools. If we are to have strategies for the dissemination of this kind of innovation, they have to be multi-pronged. They have to include some Government demonstrations and conferences with public and private providers who are doing DUR in an intelligent and scientific way.

The whole intent of DUR should not be seen merely as “error pick-ups,” but as an educational activity. However, in a managed care environment, where there are finite resources, the bottom line is always a factor. In the for-profit sector money is ultimately the priority, and there is concern that in some managed care organizations, money will be the entire focus. There is an additional problem to consider when examining the question of managed care: the group that probably deserves the greatest priority is the debilitated elderly, who are receiving the most medication and are probably the most at risk for adverse drug effects. The debilitated elderly are not moving into these managed care situations in large numbers.

The Feedback DUR Model, which is based on retrospective reviews of pharmaceutical interventions, was not represented at the symposium. It has been dismissed as not being rigorous, although it is possibly the most common kind of DUR. The Feedback DUR Model is not represented in the body of well done, well controlled studies. There appears to be no study

that meets the standards of scientific research which shows that it works. However, since it seems to be such a popular model, it should be tested more extensively.

Dr. Avorn presented three models to illustrate the limitations and strengths of the way academia operates, the way the private sector does things, and the Government approach. Because each has problems, consideration should be given to taking the best parts of each and bringing them together in future studies of DUR:

- Academic approach — There is enormous attention to methods. This prolongs the time necessary to perform and evaluate a project, and it is done on a small scale because that is the only way one can do something that carefully. Often the intervention is performed without attention to its cost-effectiveness. Detailed evaluations eventually emerge.
- Government approach — For political reasons it is very difficult to do a randomized controlled trial: one cannot say that some States or that some older people are going to get DUR and some are not. Programs are implemented on a massive scale, but program conceptualization, design, and evaluation are often the imperfect products of consensus and political necessity.
- Private sector approach — Interventions are brought to market rapidly, but the evaluation component is often neglected, and in the case of some of the examples presented, more than neglected. In some instances, it may even be scrupulously avoided for reasons that have to do with commercial interests. Efficiency and cost-effectiveness are well tracked, but “bottom line” considerations may overwhelm those of quality if the two conflict.

A question which needs to be examined is: “Is there a way that we could take the carefulness of the academic approach and couple it with the operational abilities of the Government approach and the zeal of the private sector approach to produce a well-evaluated public or private product — a product that lends itself to a definition of what it actually does and what its outcome is?” There is a real opportunity here to marry some of the academic and the operational in DUR with the data open to everybody. There now exists a window of time and opportunity. Knowing that DUR will come up again in a few years, decisions should be made on how best to take advantage of this window.

Much can also be done in terms of participation by pharmacists. There are some things that the community pharmacist could do as an individual, drawing on an extensive body of knowledge in pharmacy. Pharmacy students generally start out wanting to perform patient-related services. They are taught that in school but when they enter the real world, they frequently are shocked by policies and procedures of places where they go to work, and they cannot implement much of what they have learned. One of the ways to empower pharmacists is for them to have their own pharmacy practices, which are likely to be patient-oriented.

An avenue available through Medicaid for DUR is claims data. They have been used for research in the past. Yet claims data are often available with a very long lead-time, which could result in retrospective review two or three years later. There are real research possibilities with data which can be used as a key into the system once it is determined what those claims data mean and how they can best be used.

It will be unfortunate if Government doesn't take some leadership on DUR issues, because without some initiative coming from the center, other forces will make DUR less significant. One has to wonder why the knowledge base which has been developed in hospitals with Pharmacy and Therapeutics Committees cannot be brought into some type of educational intervention committee on an outpatient basis, where physicians and pharmacists get together for ongoing DUR discussions.

It is possible to consider other laboratories to try out drug utilization review and education. The Public Health Service supports some 600 community and migrant health centers around the country. One of the advantages of doing research in the system is having a complete and long-term profile of drug use. Resources are built into the system for continuing education. Another is the Indian Health Service, which provides a billion dollars a year in health care coverage. They are atypical because of the population served, but again it is essentially a closed provider system.

We are in a primitive state concerning prospective DUR and we are not even sure what the name of it should be. That is because we are not yet in total agreement about what the process really is. One of the things that has been very helpful is all the new thoughts that were introduced in this symposium on exactly what the process is and what the goal is — the goal is taking better care of elderly people and not wasting anybody's money in the process. There are a lot of ways that can be done. Some of them may involve computers, some of them may not. Some of them may involve steps that happen before the dispensing and before the prescribing, but some of them don't.

Despite the nearly-implemented program that would have accompanied Catastrophic Coverage, we should not be so sure of ourselves that we know all there is to know about DUR. We will need to spend the next several years gearing up in as many different ways as possible. Dr. Avorn concluded the discussion by noting that whether or not one believes in the marketplace of commerce in shaping health care delivery, the marketplace of ideas works, even if it works slowly. If a given intervention or program isn't working, sooner or later, people are going to walk away from it. We need to try as many options as we can and then, perhaps, by mid-decade, we will have objective data on what works and what does not in DUR on which to base large-scale programs.

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## RESEARCH QUESTIONS IDENTIFIED IN THE SYMPOSIUM ON DRUG UTILIZATION REVIEW

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*Prepared by Jerry Avorn, M.D.*

The fact that the symposium brought together policymakers, regulators, geriatricians, pharmacists, health services researchers, and a number of other individuals from many sectors of the health care delivery system made it possible to approach the topic of drug utilization review for the elderly in a multidisciplinary way, and led to a number of provocative discussions that might otherwise never have taken place. A number of themes emerged as areas in need of further research for health policy planning and optimal patient care. These are summarized briefly below:

1. Several approaches exist to drug utilization review, but not all of them have been subjected to rigorous and methodologically acceptable evaluation. Systematic studies should be conducted of each of the modalities listed below considering outcomes that include both economic measures (cost of drugs as well as total cost of medical care) and clinical outcomes (quality of prescribing, frequency of adverse effects, and patient satisfaction). Because of the importance of the issue at hand, these must be conducted in a randomized controlled format if the results are to be of maximum utility.
  - a. *consultant pharmacist services, as currently mandated for long-term care facilities;*
  - b. *retrospective computer-based screening of prescriptions with feedback of the printouts thus generated to physicians;*
  - c. *proactive face-to-face education of physicians concerning proper medication use ("academic detailing");*
  - d. *concurrent computer screening of prescriptions at the pharmacy prior to dispensing.*

Of these, only (c) has been subjected to careful study in the recommended manner.

2. Is it feasible for the community-based pharmacist to engage in more effective drug utilization review, and if so how can this be facilitated? Much controversy exists concerning the actual and potential utility of having typical community-based pharmacists engage in evaluations of drug regimens, taking steps to improve them when necessary. In such studies, particular attention should be devoted to the issue of economic incentives, including both the need to fill large numbers of prescriptions in many commercial settings, as well as the question of what services are or should be provided in exchange for the currently automatic dispensing fee.

3. With the inevitable automation of prescription data and other health care claims data, what is the optimal approach to capturing and linking information in order to facilitate drug utilization review, particularly for the elderly? Specifically,
  - a. *What data elements should be collected?*
  - b. *What linkages between prescription data and clinical data are appropriate and feasible?*
  - c. *To whom should such information be made available?*
  - d. *What screening procedures should be used to identify cases in need of drug utilization review, and to what use should such information be put once it has been processed?*
4. The current U.S. health care system offers a large number of settings in which innovative drug utilization review strategies could be pilot tested in a careful manner before they are mandated nationally. These include the various State Medicaid programs, State pharmacy assistance for the elderly programs, health maintenance organizations, private insurers, professional review organizations, the Veterans Administration, the Department of Defense, health care systems, and numerous smaller HHS-supported health care delivery systems, among others. How can experimentation be encouraged in these settings to inform future policy decisions?
5. Considerable gaps still exist in our knowledge of the scientific basis for proper drug use in the elderly. While research continues in the areas of health care delivery outlined above, parallel research must be conducted, ideally through the National Institute on Aging, on the pharmacological basis of the recommendations that are to be implemented in any drug utilization review system. This would include more research on the pharmacokinetics and pharmacodynamics of commonly used medication in the aged, appropriate dosing adjusted for normal aging and for frail geriatric patients, and (through collaboration with the Food and Drug Administration) systematic post-market surveillance to help identify the magnitude of and risk factors for adverse effects of concern in an older population.