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ABOUT NPC

The National Pharmaceutical Council is an education association supported by the leading research-based pharmaceutical companies. NPC conducts research on the appropriate use of pharmaceuticals and the clinical and economic aspects of pharmaceutical care. The Council prepares education and information resources for public and private payers and health care policy makers.
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Executive Summary

The second edition of *Component Management Fails to Save Health Care System Costs: The Case of Restrictive Formularies* reviews a total of 37 research studies on the effects of limitations of pharmaceuticals. These studies represent diverse methodological approaches, academic disciplines, patient populations, types and locations of health care organizations and categories of restricted drugs. Taken together, these studies indicate that restrictive formularies and other limitations often fail to achieve their fundamental goals and frequently have negative, unintended effects on overall costs and quality of care.

Also reviewed in this report are surveys, commentaries, editorials, letters and news items by individual practitioners and various professional groups that reveal widespread dissatisfaction by physicians and pharmacists with formulary and substitution practices and a lack of communication between the professions.

The general failure of formularies and other limitations to contain total costs and improve outcomes has important implications for health care policy and the design of the health care delivery and reimbursement systems of the next millennium. The reviewed literature shows that component management, in the form of restrictions on pharmaceuticals, does not result in overall savings and that a system-wide, population-based approach integrating all components of health care is needed to control health care spending and maintain quality of care.

The research challenge is to document the effectiveness of integrated approaches to care in well-characterized groups of patients. With the data sets now becoming available, researchers will be better able to design and conduct rigorous studies to provide more detailed information on the complex interrelations between pharmaceutical therapy and overall treatment costs and outcomes. The knowledge derived from these studies can guide future policy decisions that will promote optimal therapy.

Studies Show Formularies Associated with Higher Overall Costs

Table 1 displays the results of 20 research studies on the association between restrictions on pharmaceuticals and overall treatment costs and costs of other services. The researchers, who represent numerous academic disciplines, used a variety of methodological approaches. The studies involved a wide range of patient populations, health care organizations and delivery settings. The range of restrictions included limits on all drugs, various pharmacological classes, and drugs for specific diseases. Thirteen of the 20 studies reported an associated shift in costs due to increased utilization of other health care services. Three studies showed a decrease in overall costs, due primarily to reduced costs in the pharmacy budget, with either no change or, in one case, an increase in costs for other
services. Four studies showed either no change in overall costs or some redistribution of costs across services or diseases. None of the studies showed a clear association between drug restriction and reduced costs in other health service categories.

Table 1. Results of 20 Studies Relating Access to Pharmaceuticals and Costs

<table>
<thead>
<tr>
<th>Overall Costs or Costs of Other Services</th>
<th>Increased</th>
<th>Decreased*</th>
<th>Mixed**</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of Studies</td>
<td>13</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

* Decreased: The decrease in overall costs was due primarily to a decrease in drug costs.
** Mixed: Either no change in overall costs was observed or a decrease in costs of some services or diseases was offset by an increase in others.


Seventeen additional studies examined the effects of drug restrictions on drug use or costs only, and not on other services. Eight of these studies found restriction to be associated with increased use of non-restricted drugs (Green 1989; Rifenberg et al. 1996; Smith and McLayton 1977; Smith and McKercher 1984; Smith and Simmonds 1982; Soumerai et al. 1990; Strandberg et al. 1992; Taubman 1982). The remaining nine studies showed some decrease in drug costs, at least for the categories examined (Cantrell et al. 1999; Harr and LoGerfo 1977; Hazlet and Hu 1992; Krantz et al. 1996; Macario et al. 1995; Martin and McMillan 1996; Murray et al. 1998; Phillips and Larson 1997; Smith et al. 1989).

Major Research Raises Questions About Formularies

One of the major studies reviewed in this monograph is research by Horn et al. (1996) on the relationship between formularies and service utilization in six health maintenance organizations (HMOs). They observed that the more restrictive the formulary, the higher the rates of drug use, office visits, emergency room visits and hospital admissions. Using the same database in a later study, the researchers found that formulary limitations for certain drug classes were linked to increased resource utiliza-
tion by elderly patients (Horn et al. 1998).

In their study of the economic effects of prescription drug restrictions in 47 state Medicaid programs, Moore and Newman (1993) found that restrictive formularies were associated with reduction in pharmaceutical expenses by 13 percent on average. However, these savings “appear to be completely offset by increased expenditures elsewhere in the system.” The effect was seen most notably on physician services and inpatient mental hospital care. “Our results cast considerable doubt on the effectiveness of formularies in achieving their ultimate goal, that is, cost savings with no reduction in the quality of health care benefits,” the authors said.

Looking at the Illinois Medicaid program, Dranove (1989) studied the effect of easing the formulary’s restrictions to allow all forms of anti-infective therapy, including both old and newly introduced drugs. Dranove’s results show that the availability of new pharmaceutical technologies does not significantly affect the total costs of treatment associated with bacterial infectious diseases, and this availability improves the quality of care for Medicaid patients.

Other seminal research on this issue includes studies by Soumerai et al. (1991) on the impact of the New Hampshire Medicaid program’s policy to limit Medicaid patients’ coverage of prescription drugs to three per month. The estimated statewide savings on drug reimbursements were largely offset by payments for excess nursing home admissions and other incremental costs. Later Soumerai and colleagues (1994) examined the impact of the prescription cap on patients with chronic mental illness. Implementation of the policy was found to substantially reduce the use of drugs for mental health disorders. However, increased use of community health centers, emergency mental health services, and partial hospitalization was also observed. The increase in mental health services costs was 17 times higher than the savings in drug costs.

Overall, the literature cited in these chapters demonstrates that component management, in the form of restrictions on pharmaceuticals, does not result in overall savings and that a system-wide approach integrating all aspects of health care is needed to maintain quality of care while controlling health care spending.
Like the first edition published in 1996, the review of the literature in the second edition of Component Management Fails to Save Health Care System Costs: The Case of Restrictive Formularies concludes that the use of restrictive formularies does not produce overall cost savings. Many of the 11 more recent research studies summarized in the second edition, like earlier studies, find that restrictive formularies are often associated with higher overall health care costs and with suboptimal clinical outcomes (Horn et al. 1998; Pestotnik et al. 1996).

The new studies and commentaries, published between 1996 and mid 1999, also suggest the emergence of two opposing trends. One is a movement toward increasingly restrictive formularies in both private and public plans despite the paucity of evidence supporting their net value (Novartis 1998; Wyeth-Ayerst 1998; Department of Veterans Affairs 1997). The driving force seems to be the rising cost of the plans’ pharmacy benefit. But few studies have explored the extent to which the increased use of pharmaceuticals may actually reduce the escalation of costs for other health care services. As formularies have become more restrictive, the quality of the formulary process has become a growing area of concern. Notably, the National Committee for Quality Assurance (NCQA) has added standards on drug formularies to its quality criteria for accreditation of those health plans having formularies (National Committee for Quality Assurance 1998).

The second trend, running counter to the first, is exemplified by those leading managed care plans and pharmacy benefit management companies (PBMs) that are moving away from more restrictive formularies (IN VIVO 1998). This movement is spurred in part by rising consumer demands for greater access and choice of medicines (McCarthy 1998a) and for full disclosure of plan limitations. An additional impetus for relaxing restrictions is a broader managerial perspective involving a growing acceptance of the value of coordinated, systems-based approaches to enhancing care (Cunningham 1997; Talley 1996).

The second edition of this monograph updates the extensive body of literature presented in the first edition on the effects of formularies. This new edition is organized so that the reader can examine the impact of formularies on various patient populations, and in various care settings. The studies cited above and those summarized in the following chapters show how restrictions on prescription drugs often shift costs from the pharmaceutical component to other areas of the health care system, resulting in increases in total health care spending. Research included here also examines the effect of restrictive prescription policies on the quality of care.
A number of studies are cited and summarized in more than one chapter in this monograph; these are studies whose findings reflect the themes of several different chapters, such as the use of formularies in managed care plans as well as the issue of quality of health care.

Chapter I presents an overview of the unintended consequences of component management, citing core studies on the economic effects of pharmaceutical restrictions in five health care settings: Medicaid, nursing homes, mental health organizations, health maintenance organizations and hospitals. Chapter II focuses on the movement toward disease management and integration of pharmaceutical care, especially for patients with chronic illness and disability.

The studies in Chapter III describe how restrictive formularies in managed care plans can result in overall health care cost increases while those in Chapter IV show that Medicaid formularies are often associated with increased overall health spending. Chapter V includes summaries of research documenting the detrimental effect of formulary restrictions on the quality of care, including the effects of therapeutic substitution and restrictions on antibiotics.

In Chapter VI the studies show how physician authority may be restricted by drug formularies. Finally, Chapter VII looks at the use of formularies in the Department of Veterans Affairs’ health care system, hospitals, nursing homes and mental health organizations.
Chapter I.
The Economics of Restricting Resource Allocation in Health Care

In the field of economics, it is well recognized that changes in the interaction of the various elements that make up an economic system or structure can cause significant unintended effects. These unknown consequences can occur on both the demand and supply sides of the economic structure. This section summarizes the studies that primarily focus on the economic significance of restrictive formularies. These studies are important because they span a spectrum of health care delivery organizations, including Medicaid, nursing homes, mental health centers, hospitals, health maintenance organizations (HMOs) and third-party payers. What is striking about these studies is that they show a consistent pattern of the effects of restriction—increased restrictions are associated with increased total costs.

The revolution in the U.S. health care system in recent years has been driven by the concern over rapidly rising costs. The health care market has responded to this rise in costs through organizational shifts and the significant rise in the number of managed care organizations, hospital systems and hospital mergers.

These new organizations are all trying to address the problem of rapidly rising costs. A seemingly rational solution is to manage health care resource allocation on a component or, in accounting terms, a line item basis. Component management is based on the notion that the costs of health care are the specific “inputs” or activities that comprise health care spending. Thus, line item management generally specifies budget targets within a particular organization and attempts to manage those targets independent of the total health care organization or system.

Economists have long recognized the perils of this component approach to resource allocation. Von Hayek (1984) is one of the most well known economists to elucidate the “law of unintended effects”:

“The …problem of a rational economic order is… that the knowledge…never exists in [a] concentrated or integrated form but solely as the dispersed bits of incomplete and frequently contradictory knowledge... The economic problem of society is …how to secure the best use of resources known to any of the members of society, for ends whose relative importance only these individuals know.

This monograph reviews one body of literature that addresses the issue of how restricting one component of health resources can cause unintended consequences in the allocation of other health care resources. Specifically, the focus will be on the restrictions that have been applied to
pharmaceuticals and the resulting resource reallocations. Several recent studies that directly analyze the economic effects of restrictions on pharmaceuticals are summarized below. The remainder of the monograph provides brief summaries of other studies that have directly or indirectly assessed the unintended consequences of pharmaceutical restrictions.

**Medicaid**

There are two core studies of the economic effects of formulary restrictiveness relative to the Medicaid program. Dranove (1989) looked at formulary restrictiveness in one state’s Medicaid program. He examined the effect of easing the restrictiveness of a Medicaid formulary by allowing access to all forms of anti-infective therapy, including both older and newly introduced drugs. Dranove’s results show that the availability of new antibiotic technologies does not affect the total costs of treatment associated with bacterial infectious diseases, and this availability improves the quality of care for Medicaid patients.

The second Medicaid study is a “macro” assessment of the effects of formulary restrictiveness in these programs. The specific types of formulary restriction and the drug classes restricted vary by state. Moore and Newman (1993) looked at the Medicaid program as a whole in the context of formulary restrictions by assessing the restrictiveness of 47 state Medicaid programs. They used a regression model to analyze pooled cross-sectional data for 1985-89. Moore and Newman concluded:

“In this study of expenditure effects of restricted drug formularies in state Medicaid programs, we find that a restricted formulary may reduce prescription drug expenditures by approximately 13 percent, on average. Because of service substitution, however, such a policy does not translate into reductions in total program expenditures. Savings in the drug budget appear to be completely offset by increased expenditures elsewhere in the system.

“With respect to particular substitute services, we find that restricted formularies tend to increase expenditures on physician services and inpatient mental hospital care. It appears that the increased expenditures in these two areas arise from the increased utilization by Medicaid recipients whose drug of choice may be excluded from the state’s formulary.

“Our results cast considerable doubt on the effectiveness of formularies in achieving their ultimate goal, that is, cost savings with no reduction in the quality of health care benefits.”

**Nursing Homes**

Soumerai et al. (1991) studied the effects of pharmaceutical restrictions on admissions to nursing homes. In particular, they looked at the Medicaid policy of restricting to three the number of prescriptions a Medicaid patient could receive per month. This restriction had the same cost-reducing purpose as a formulary. When a cap of three prescriptions
was instituted in the New Hampshire program, there was a 35 percent decline in drug usage, but a significant increase in the number of nursing home admissions also occurred. After the cap was eliminated, the amount of drug use and the number of nursing home admissions returned to previous levels. They concluded:

“Limiting reimbursement for effective drugs puts frail, low-income, elderly patients at increased risk of institutionalization in nursing homes and may increase Medicaid costs.”

Mental Health Organizations

In another study, Soumerai et al. (1994) looked at the effects of pharmaceutical restrictions on patients with schizophrenia. Like the nursing home study, the restrictive policy by Medicaid limited prescriptions to three per month. They compared the New Hampshire prescription cap policy with a no-limits policy in New Jersey and found the cap was linked to a substantial reduction in the number of drugs to treat schizophrenia with a concomitant increase in the use of community mental health centers. There was also a significant increase in the use of emergency mental health services and partial hospitalization. After the cap was removed in New Hampshire, drug and mental health services use returned to normal levels. During the time of the cap, the increase in mental health services costs was 17 times higher than the savings in drug costs. They concluded:

“Limits on coverage for the costs of prescription drugs can increase the use of acute mental health services among low-income patients with chronic mental illnesses and increase costs to the government even aside from the increases caused in pain and suffering on the part of patients.”

Hospitals

The effects of formulary restrictions have also been studied in the hospital setting. Sloan et al. (1993) found that hospitals restricting the choice of pharmaceuticals can have unintended effects, and the effect on drug costs and overall costs can vary from disease to disease. This study concluded:

“Limiting the number of drugs in particular therapeutic categories reduced total charges incurred for gastrointestinal disease and asthma patients, increased total charges for cardiovascular disease patients, and had no effect on charges for infectious diseases patients. Restricting availability of drugs reduced pharmacy charges, but these savings tended to be offset by increases in other charges. Combining the categories, we found that restricting availability of drugs did not affect charges. We conclude that across-the-board restrictions do not result in cost savings, although savings may be realized for particular drug categories.”
In recent years, managed care organizations and other third-party payers have used a variety of programs to contain costs, some involving prescription medications. One of the most common cost containment strategies was restrictive formularies. Horn et al. (1996) investigated the relationship between cost containment strategies, such as restrictiveness of formularies, copayment amounts, strictness of gatekeeper and second opinion requirements, and intensity of case management, on the use of health care services in managed care organizations. The objective of this research was to explore the potential impact of limiting access to prescription drugs and other cost containment practices on health care utilization. Obviously, the use of health care services has important implications for the quality of patient care and health care costs. The study looked at data from six geographically dispersed HMOs and was the first study to analyze data for individual patients.

The results of Horn’s research indicate that for patients with similar severity of illness, there is a common pattern for each of the HMO sites studied. In general, as physicians’ choice of prescription medications was limited, the use of health care services increased. In other words, with increased formulary restrictions, the researchers found more patient visits to physicians, more emergency room visits and more hospitalizations, all of which would increase health care costs. The research showed that greater formulary restrictions were even associated with an increased number of prescriptions.

These six studies represent a core of research that shows the economic effects of restricting choice in the allocation of health care resources. Although the focus of these core studies has been pharmaceuticals, it is likely that the principle is universal, that is, in addressing the allocation of resources in treating specific diseases, as well as looking at health generally, a systems approach is necessary. The Horn et al. research puts it succinctly:

“It is important to assess combinations of cost containment strategies, because the individual strategies do not function independently, and the results of changing one component may not be easily predictable. A systems approach to cost containment, rather than individual component management techniques, is needed.”
Chapter II.
Integrated Pharmaceutical Care

Introduction

The rapid growth of multi-organizational health care systems in recent years has been accompanied by an interest in adopting a more holistic, patient-centered approach to health care delivery. The intent is to provide comprehensive, individualized treatment plans that address all of a patient’s medical conditions as they change over time and as the patient receives treatment from different providers across delivery settings. This approach not only benefits patients, it also is more cost-effective for purchasers because it aligns financial incentives for treatment choices to take into account the total costs of care over a period of time instead of trying to control the cost of separate components of care. Evidence to date indicates that component management — particularly the individual management of pharmaceuticals through formularies and other restrictions — tends to increase the use of other more expensive services.

To achieve a truly integrated approach to patient management, pharmaceutical services must be woven into the system of care. This can help reduce overall treatment costs as well as improve the coordination and quality of care for patients across treatment settings. An example of the trend toward more systematic approaches to pharmaceutical management is the antibiotics program at LDS Hospital in Utah. Here, a patient-focused approach and wide latitude in prescribing is supported by a computer-based decision support system. The program has been successful in reducing adverse reactions, mortality, resistance to antibiotics, and costs (Burke 1998; Burke and Pestotnik 1996; Evans et al. 1998).

One area where an integrated approach to pharmaceutical management is particularly beneficial – to patients, purchasers and providers – is the treatment of chronic conditions, such as diabetes or cardiovascular disease. Chronic conditions are the leading cause of illness, disability and death in the U.S. and account for 70 percent of total personal health care spending. Prescription drug therapy is the major form of treatment for people with chronic disease or disability. Because of the nature of these conditions and the characteristics of the patients, often elderly, there is increased potential for adverse drug reactions and drug interactions, duplicate prescriptions, noncompliance with medication regimens, suboptimal prescribing, overtreatment and undertreatment. The problems associated with chronic conditions are “systemic and intertwined”; only “an integrated, system-wide, and longitudinal approach to care,” including pharmaceutical care, can address these problems, according to a concept paper developed by the National Chronic Care Consortium and the National Pharmaceutical Council (1999).
Pharmacists have a growing role to play in the development and implementation of formularies as part of the move toward integrated health care. In such integrated systems, as Talley (1996) pointed out, the focus of formulary drug selection shifts from drug product cost to overall disease management costs. Mehl (1989) sees the pharmacist’s expanded role in the disease management approach as “a positive step towards the pharmacist’s relationship with the patient and interaction with the physician.”

Until we have health plans where outcomes and evidence-based medicine drive treatment decisions, pharmacists must continue to deal with the often burdensome aspects of formulary administration. According to a 1991 survey by American Druggist, many pharmacists practicing outside of hospitals have problems with various aspects of restrictive formularies. For example, the majority of those responding said that financial incentives to substitute generic or formulary drugs “compromise professionalism in pharmacy”; most also complained that restrictive formularies lead to burdensome “nonpatient-centered” work to check on varying formulary requirements of different plans and to call physicians about substitutions.

Citations

Following are summaries of major articles on the advantages of systems-based pharmaceutical care.

INTEGRATED PHARMACEUTICAL CARE NEEDED FOR OPTIMAL TREATMENT OF CHRONIC CONDITIONS

Optimal treatment of chronic conditions, which affect over 100 million Americans and cause the most illness, disability and death in the U.S., requires an integrated approach to care, including the delivery of pharmaceutical care. Chronic conditions are multi-dimensional, interdependent, disabling, interpersonal and ongoing. “Since pharmaceuticals play such a large role in the treatment of chronic care patients, the organization of pharmacy services in keeping with these characteristics is especially important in serving their needs,” according to an NPC/NCCC concept paper.

The characteristics of chronic illness and disability “call for a systems solution. Simply changing practice guidelines or creating new protocols will not achieve the desired results in patient care. The problems are systemic and intertwined – therefore, reform needs to occur in the infrastructure and organization of the health care delivery system, as well as in clinical practice and service provision.” The solutions recommended by NCCC and NPC include: redefining the governance and management of the health care system; changing care management to provide for “seamless continuums of care, including the full spectrum of primary, acute and long-term services; establishing coordinated data systems to allow tracking of patients across the system; and realigning financial incentives for providers “to manage pharmaceuticals across settings and over time. . . .” Finally, federal and state policy must be formulated to support “an integrated, system-wide and longitudinal approach to care” (National Chronic Care Consortium and National Pharmaceutical Council 1999).
FORMULARY FOCUS SHIFTS TO DISEASE MANAGEMENT

C. Richard Talley, editor of the *American Journal of Health-System Pharmacy*, wrote that “Factors considered important in drug product selection are changing...from medication acquisition cost to the more encompassing disease management cost.” This needed change in perspective has been brought about by the managerial integration of inpatient and ambulatory patient services in integrated health systems.

The major shortcoming of drug cost-based formulary control is that “medication costs per se do not necessarily correlate well with overall disease prevention and disease management costs,” Talley said. An example is the selection of an antihypertensive medication for inpatient hospital use based on its lower acquisition cost. In an integrated system, the medication may not be preferable for long-term, outpatient use. “Suppose...the adverse effects of this antihypertensive for this patient, or the frequency at which it must be taken, become so bothersome that the patient chooses not to continue taking it long-term. Ultimately, the patient may suffer severe consequences of untreated hypertension and the health system may incur substantial expense in the patient’s treatment. “[C]hoosing medications tailored to specific patient needs looks to be far more important than jockeying for best purchase price,” he concluded.

Another formulary problem arises when different sites in a multi-organization system maintain different formularies. This can “create havoc for pharmacists,” who are faced with telling physicians that the medication approved for ambulatory use is not on the hospital formulary. Talley also questioned the role of pharmacists as “formulary police.” Since drug acquisition costs may have little effect on overall treatment costs, “perhaps it would make more sense for pharmacists to pick their physician confrontations with greater emphasis on important outcome issues,” he said.

“Some believe that treatment guidelines and other forms of disease management will render current styles of formulary creation and control obsolete. Future medication purchase decisions are likely to depend heavily on pharmacoeconomic analyses. . . . Whatever evolves, it is bound to demonstrate greater attention to clinical, economic, and humanistic concerns than does the traditional formulary focus on medication acquisition costs” (Talley 1996).

HOLISTIC APPROACH TO DRUG SELECTION RECOMMENDED

Formularies represent an old, component focused and very inefficient management technique that will soon be superseded by approaches based on health outcomes, according to Harry DeMonaco, pharmacy director, Massachusetts General Hospital, Boston. “In the near future, hospitals will not rely on formularies as an instrument of health care; newer and more reliable technologies will permit more appropriate and cost-effective medication selection. With the arrival of health outcomes assessment, restricting access to drugs and therapies will become counter-intuitive and nonscientific,” he told a roundtable discussion.
“Major questions still exist regarding the role of the formulary and antibiotic-associated resistance. Perhaps more important is the increasing concern about the unknown impact that formularies have on the quality of care of our patients. Although many pharmacy administrators have used formularies for the past 20 years, it is now time to explore another basis for product selection: outcomes measures. Restriction policies should only be used when restriction makes clinical sense, not as a method of reducing cost.”

He recommended that pharmacists “look at the whole process of health care; drug therapy is just one component of that process. Unfortunately, formularies look at drug therapy as an independent item, without regard to the other components of care. This situation can lead to very poor decision-making; in some cases, using an expensive drug can, in fact, lower the cost of care, improve outcome, and improve patient satisfaction. These issues need to be modeled” (DeMonaco 1996).

**Some Plans Moving Away from Restrictive Formularies**

Despite the trend toward increasing formulary controls (McCarthy 1998), some health plans are implementing a broader approach to pharmacy management based on an integrated approach to care. HealthNet, a 1.4 million member California HMO, is “moving ... to a data-intensive, computer-supported decision model for its providers which allows them wide latitude in prescribing as long as their choices are evidence-based.” The strategy is based on options rather than limits to pharmacy management.

HealthNet began reevaluating its formulary policies when comparison of data from different sites in California showed no correlation between formulary compliance and pharmacy costs. Using company-wide patient care data, HealthNet now analyzes and provides feedback to all its medical groups on treatment patterns in 13 disease groups, accounting for 50 percent of pharmacy utilization. HealthNet has reported cost savings and quality improvement by investing in new drugs that are often more expensive than older agents.

In another example of the movement away from restrictive formularies, United Healthcare recently reversed its long-standing policy of making formularies more restrictive by reducing the number of non-reimbursable drugs on its formulary as well as the number of drugs requiring prior authorization (Cunningham 1997).

**Formularies in Health Care Delivery Systems Should Support Disease Management**

Many health care delivery systems are now providing hospital care as well as ambulatory care services such as routine dispensing and sophisticated home care (Penna 1996). Although formularies are currently the foundation for managing pharmaceuticals in these systems (Penna 1996), they are increasingly being evaluated based on their impact on supporting overall disease management and not just on drug budget costs (Talley 1996). Some integrated systems are establishing a single uniform formula-
ry (at least for oral medications) applicable to patients in all settings. Under such arrangements it is vital that “all formulary decisions should be made with a full understanding of the clinical and financial impact across the continuum of care” (Cano 1996).

CLOSED FORMULARIES LESS LIKELY WITH DISEASE MANAGEMENT PROGRAMS

A survey of a representative sample of 51 large managed care organizations reported that their main reasons for having a formulary were to decrease cost, reduce duplication, provide information, control drug use and ensure appropriate therapy. Primary motivations for having a disease management program were “to improve the quality of care” and “cost containment.” Notably, plans without a disease management program were twice as likely to have a closed formulary as those with a disease management program (56 percent compared to 25 percent). Since the goals of formularies and disease management were similar, the authors suggested that disease management programs may be substituting for direct formulary controls (Lyles et al. 1997).

AN INTEGRATED APPROACH TO ANTIBIOTICS MANAGEMENT

In 1988 the Latter Day Saints (LDS) Hospital in Salt Lake City implemented a process-of-care approach to the management of antibiotics and other anti-infective agents. The program uses local clinician-derived consensus guidelines imbedded in computer assisted decision report programs, with a focus on the entire continuum of care. The practice guidelines were programmed into a hospital information system as rules, algorithms, and predictive models. The LDS antibiotic management process extends far beyond initial product selection and includes choosing the correct dose and the correct route and timing of administration for the individual patient. It also takes into account such factors as current physiological functional status, decisions to obtain cell cultures, laboratory tests, and duration of therapy.

Seven years after program implementation, adverse drug events associated with antibiotics were reduced by 30% and mortality declined. In addition, expenditures for antibiotics decreased from 25 percent of total pharmacy costs in 1988 to 13 percent, although the number of patients receiving antibiotics increased from 32 percent to 53 percent. “Trend analysis showed that antimicrobial resistance patterns have been stable, possibly as a result of improved use of antibiotics with an unrestricted drug formulary that encouraged a random use,” the authors said (Burke and Pestotnik 1996; Pestotnik et al. 1996). Additional outcomes of the program are provided in Table 2.
Table 2. Outcomes of patients who received antiinfective agents prior to and during a computerized anti-infectives management program (adapted from Evans et al 1998)

<table>
<thead>
<tr>
<th>Variable</th>
<th>Pre-intervention period</th>
<th>Intervention period</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of different anti-infectives ordered</td>
<td>2.2</td>
<td>1.6</td>
</tr>
<tr>
<td>Duration of anti-infective therapy (hours)</td>
<td>263</td>
<td>128</td>
</tr>
<tr>
<td>No. of anti-infective doses</td>
<td>28.7</td>
<td>14.0</td>
</tr>
<tr>
<td>Days of excess anti-infective dosage</td>
<td>5.7</td>
<td>1.3</td>
</tr>
<tr>
<td>Cost of anti-infective agents ($)</td>
<td>412</td>
<td>134</td>
</tr>
<tr>
<td>No. of microbiology cultures</td>
<td>8.2</td>
<td>3.7</td>
</tr>
<tr>
<td>Length of stay in ICU (days)</td>
<td>6.3</td>
<td>3.3</td>
</tr>
<tr>
<td>Days from ICU admission to hospital discharge</td>
<td>14.1</td>
<td>9.7</td>
</tr>
<tr>
<td>Total length of hospital stay (days)</td>
<td>15.9</td>
<td>11.5</td>
</tr>
<tr>
<td>Total cost of hospitalization ($)</td>
<td>40,290</td>
<td>29,515</td>
</tr>
<tr>
<td>Mortality (%)</td>
<td>22</td>
<td>18</td>
</tr>
</tbody>
</table>
Chapter III.
Formularies in Managed Care Plans

Introduction

In recent years, managed care organizations and other third-party payers have established an array of programs to control their expenditures, including the cost of prescription medicines. One of the most common cost containment strategies implemented by managed care plans is the use of restrictive formularies. But research shows that such efforts have produced unintended effects.

Looking at data from six health maintenance organizations (HMOs), Horn et al. (1996) explored the impact of limitations on access to prescription drugs and other cost containment practices on health care utilization. Their study found that the tighter the formulary restrictions, the higher the increase in the use of health services, including more visits to physicians and emergency rooms and more hospitalizations, as well as an increase in the number of prescriptions.

In a later study, the authors used the same database to examine the relationship between restrictive formularies and the use of health care services by the elderly enrolled in the six plans. For certain major drug classes, they found a significant correlation between limitations and increases in resource utilization by the elderly patients, but not by younger patients (Horn et al. 1998).

Despite the findings of Horn et al. and other researchers that restrictive formularies are associated with increases in health service utilization, many managed care plans, as well as employers, are adding even more restrictions to their pharmacy benefits. Recent surveys show that over 37 percent of HMOs and almost 19 percent of employers have either implemented or expect to implement a closed formulary in 1999 (Novartis Pharmaceuticals 1998; Wyeth-Ayerst Laboratories 1998). A 1995 report by the General Accounting Office also predicted that health plans will increasingly rely on restrictive formularies “because of their potential to help reduce a plan’s drug costs.”

On the other hand, some managed care organizations are moving away from restrictive formularies to more systems-based approaches to pharmaceutical treatment. For example, California’s HealthNet now uses “a data-intensive, computer-supported decision model” that gives providers prescribing options that are based on scientific evidence (Cunningham 1997).
Another alternative to restrictive formularies that is becoming popular among managed care plans and pharmacy benefit management companies (PBMs) is the concept of “managed formularies.” In response to patients’ desire for open access, such formularies don’t exclude drugs from coverage. Instead, prescribers are directly involved in the management of patients. The trend is toward managing individual patients and away from managing the cost of the drug component of care (Kreling et al. 1996). Often managed formularies include a tiered copayment system to encourage patients to use lower cost, preferred drug products (IN VIVO 1998, Kreling et al. 1996). In a three-tiered system the patient would pay, for example, $5 for a generic drug, $15 for a preferred brand and $25 or more for a non-preferred brand. Such a system allows prescribers to select any “medically necessary” drug within a class while giving patients some choice about how much they want to spend out-of-pocket.

With the growth of health care systems which provide hospital and ambulatory care services as well as pharmacy services, formularies are increasingly being evaluated based on their impact on overall disease management, not just on drug expenditures (Talley 1996).

Citations

Following are summaries of major articles that discuss the effects of restrictive formularies in managed care plans.

HMO Formulary Restrictions Linked to Increased Service Use

Horn et al. investigated the relationship between cost containment strategies, such as restrictiveness of formularies, copayment amounts for office visits, strictness of gatekeeper and second opinion requirements and intensity of case management, to the use of health care services in six geographically dispersed HMOs. The results of the research indicate a common pattern for patients with arthritis, asthma, hypertension, otitis media, or ulcer. Specifically, as formulary restrictions increased across study sites, there was an increase in the number of patient visits to physicians, emergency room visits, and hospitalizations. The study even showed that the more limited formularies were associated with greater numbers of prescriptions written (Horn et al. 1996).

Formulary Limits Tied to Greater Service Use by Elderly

Using the database developed for the 1996 study, Horn et al. examined the relationships between restrictive formularies and service use in 2,306 patients aged 65 years and older. They found a positive correlation between formulary limitations in some important drug classes (NSAIDs, theophyllines, loop diuretics, peripheral anti-adrenergics) and the utilization of drugs, outpatient visits and hospitalizations. These associations were sometimes significantly greater for elderly than for younger patients, after controlling for severity of illness and other variables (Horn et al. 1998).
HORN METHODOLOGICAL DEBATE IN PERSPECTIVE

In a letter to the editor of the *American Journal of Health-System Pharmacy*, entitled “Where is the evidence for formulary effectiveness?” Charles Hepler provided a different perspective on the Horn study:

“None of the studies [on evidence for formulary effectiveness] would meet the high standards for scientific rigor that [critics] seem to demand. Few (if any) even come close to the rigor of the Horn et al. [1996] study, flawed as it may be. Although managed care executives may mean well, they would be irresponsible if they pretend to have scientific evidence to support what are really subjective decisions. It adds insult to injury when they hold ‘disagreeable’ results to a higher standard of scientific rigor than the standard for their own untested assumptions” (Hepler 1997).

STUDY METHODOLOGY ON PRESCRIPTION RESTRICTIONS EVALUATED

Soumerai et al. reviewed 19 studies that looked at the effects of patient cost sharing or the effects of administrative restrictions on the prescribing of specific drugs. In addressing the administrative restrictions issues, the authors found two basic methodological approaches—time series with comparison series and pre-post (or in some cases post only) with comparison group. After reviewing the 12 studies that looked at administrative restrictions, the authors concluded that the time series with comparison series, as opposed to the pre-post approach, is the superior method. Their primary reason is: “The potential bias that may result from inadequate control for preexisting differences and trends can be understood by examining pre-intervention changes in drug use documented in the more rigorous time series studies.”

Although the authors faulted the majority of studies addressing the relationship between administrative restriction and outcomes, they did find that the strongest studies supported the notion that restricting access to medications results in cost shifting to other service areas (Soumerai et al. 1993).

NCQA STANDARDS FOR DRUG FORMULARIES AND BENEFITS

The National Committee for Quality Assurance (NCQA) for the first time in 1998 incorporated into its accreditation program a number of standards for the management of drug benefits and formularies. Effective July 1, 1999, plans or PBMs using drug formularies are required to have procedures in place to incorporate NCQA’s new standards. Starting in 2000, NCQA will review actual denials of requests for off-formulary drugs and make determinations as to whether formulary policies were followed. Among the new standards and actions are:

- Processes must be established to ensure that a drug formulary is based on sound clinical evidence and is reviewed and updated at specified intervals.
• The formulary must be developed with input from actively practicing practitioners and be made available to practitioners.
• Those managed care organizations with a closed formulary must have in place an exceptions policy for off-formulary use that is similar to their general appeals process.
• The organization must specify how to apply the formulary based on the needs of individual patients.
• The formulary must be reviewed annually and updated as necessary.
• Subscribers must be provided with written information about drug benefit charges and limitations, including copayments.

The NCQA standards require that a plan specify if there is a formulary, how to obtain the list of covered drugs, the extent to which non-formulary drugs are covered and any exceptions policy (National Committee for Quality Assurance 1998).

**Trend Toward Increasing Restrictiveness**

Despite considerable evidence that limited formularies and other tactics designed to reduce drug use may not lower overall treatment costs, many employers and plans continue to increase restrictions in the hope of reducing the cost of the pharmacy benefit. Recent surveys reveal that 37.2 percent of HMOs and 18.8 percent of employers have either implemented or expect to implement a closed formulary in 1999. Although benefit sponsors rated cost as the primary factor in selecting a health plan, for consumers, cost was fourth in importance, after choice of physicians, the plan’s quality reputation and the availability of a pharmacy benefit.

Figure 1 presents the percentage increases between 1995 and 1998 in employers’ use of drug cost control measures:

**Figure 1.** Percentage Increase Between 1995 & 1998 in Employers’ Use of Tactics to Control the Drug Budget (source: surveys by Novartis and Wyeth-Ayerst)
About 20 percent of HMOs now cap the pharmacy benefit at $2,000 to $3,000 per member per year (PMPY) for commercial/group members, and at $500 to $1,000 PMPY for individual coverage. Nearly 70 percent of employer-sponsored plans now feature variable copayments. Differential copayments are also common: the average copayment among HMOs for a brand-name drug in 1997 was nearly $10; the average for a generic was $5.50. About 26 percent of employers have introduced a deductible to the pharmacy benefit. These data are derived from two surveys: the Novartis Pharmacy Benefit Report: Trends and Forecasts (1998), and Latest Trends in Prescription Benefit Cost and Design, published by Wyeth-Ayerst Laboratories, the Pharmacy Benefit Management Institute (Novartis Pharmaceuticals Corporation 1998; Wyeth-Ayerst Laboratories 1998).

**Effects of Drug Copayments on Managed Care Patients**

Hillman and colleagues studied the effects of patient cost sharing for prescription drugs in 135,000 middle-income persons, aged 18 to 64, enrolled in five IPA and four network model managed care plans. These patients paid varying levels of copayments, ranging from zero to $10 per prescription. It was found that higher copayments were associated with lower drug spending in IPA models, where physicians are not at risk for drug costs. However, drug copayments had little effect in network models, where physicians assume financial risk for all prescribing behavior. Thus, there was an interaction between financial incentives directed at patients and those directed at physicians. The effect of the copayments on outcomes of care was not measured, but the authors speculate that effects of modest copayments (under $10) on outcomes could be large (Hillman et al. 1999).

**Increasing Use of Tiered Copayments**

Differential patient copayments are increasingly being used as an incentive for patients to use lower cost, preferred drugs (IN VIVO 1998). Three-tiered copayment systems are a common feature of managed formularies (Kreling et al. 1996). Under this approach the core drug benefit requires copayments of $5 for generics, $15 for a preferred brand, and $25 or higher for a nonpreferred brand. The managed care organization does not incur expenses for authorization overrides and other administrative activities. Under a tiered copayment system, prescribers can select any drug in a class that they believe to be medically necessary; and patients have some choice in drug product selection, based on perceived value for the additional cost.

Some believe that tiered formularies may be preferable to closed formularies, especially for open access health plans that offer more physicians and limited feedback mechanisms (Formulary 1998). Although consumption of medicine by consumers is usually inversely related to price, the extent to which this occurs is unclear (Burstall 1994). There is no agreement in the literature about the price sensitivity of essential medicines as opposed to medicines that just relieve symptoms; and little is known about variations in price sensitivity and patients’ income.
The elderly, poor, and/or chronically ill may be at greater risk of not filling their prescriptions due to real or perceived expense (Burstall 1994). Most importantly, the effects of copayments on use of other services and on treatment outcomes have not been adequately studied (Kreling et al. 1996). Large changes in drug copayments especially need further examination (Johnson et al. 1997). One study of elderly HMO patients reported that larger copayments may reduce the use of drugs essential to maintaining health and that health status may be diminished (Johnson et al. 1997).

**High Copayments May Increase Total Costs and Reduce Employee Productivity**

The primary purpose of copayments and deductibles is to save money and manage demand by shifting some of the expense to patients. This may yield considerable cost savings, especially if patients with high copayments decide not to fill the prescription. In some cases, however, higher copayments may deter sicker patients from filling their prescriptions leading to higher overall treatment costs and contributing to an overall reduction in employee productivity, according to McCarthy.

Many managed care organizations, especially those with disease management programs, are attempting to improve patient compliance with drug regimens. This will lead to at least short-term increases in drug use and expenditures, but also possibly to a “compliance/cost-shifting merry-go-round,” McCarthy predicted. As compliance efforts keep more patients on their medications, drug costs will rise. This will stimulate plans and employers to shift drug expenses to the patient, who may then decide that compliance is unaffordable. This dynamic then creates a new round of compliance worries. This conundrum constitutes “an interesting problem in logic and cost accounting” that must be addressed by managed care and benefit sponsors (McCarthy 1998).

**‘Managed Formulary’ as Alternative to Closed Drug List**

Some PBMs and managed care organizations are now changing their formulary policies and are seeking alternatives to restrictive formularies. This movement is a response to patients’ desire for open access. It also signals a shift to a broader managerial perspective. According to one PBM official surveyed, “Movement is toward managing the patient and away from managing the unit cost of drugs as a total management principle.” Another said that “Formularies will be considered plan design features, rather than primarily cost reduction measures.”

There is a growing interest in “managed formularies” as an alternative to restrictive formularies. Such formularies do not exclude drugs from coverage, but involve active management and intervention with prescribers. In addition, the benefit design includes incentives, such as differential copayments, for patients to choose preferred products (Kreling et al. 1996).
Most PBM Formularies Relatively Inclusive

A 1995 survey of pharmacy benefit management companies indicated that over 60 percent of employers, covering 137 million beneficiaries, utilized some form of PBM services (Grabowski and Mullins 1997). PBMs provide basic services (e.g., electronic claims processing, mail order services, benefit design) as well as services designed to influence drug use, including the development and implementation of formularies. The formulary instruments developed by PBMs range from open, preferred lists, to closed lists, with the client firm deciding how aggressive and restricted the formulary will be. Employers, whose health benefits contracts have recently evolved from fee-for-service to preferred provider organizations or gatekeeper models of managed care, generally select an open formulary, with the main objective of educating prescribers and patients on the different costs of alternative medications. Over time, employers usually move to “preferred” formularies with differential copayments, drug utilization reviews, and therapeutic substitution. Closed formularies, which reimburse only for listed drugs, are chosen primarily by staff-model HMOs and are unusual in employer plans.

Although the survey found the formularies of the leading PBMs to be relatively inclusive, they also tended to have stronger enforcement measures, such as differential copayments.

PBMs thus far have achieved drug budget savings, but the management of drug benefits as a separate component isolated from other health care activities is limited and the PBM cannot capture the larger cost efficiencies potentially available from an integrated treatment approach. Accordingly, many PBMs see disease management as a major growth area, especially for high-cost chronic diseases, and are participating in the movement by managed care organizations toward a more coordinated systems-based approach to care (Grabowski and Mullins 1997).

Well-managed Formularies Based on Outcomes

A November 1995 study from the General Accounting Office (GAO) cited evidence of a growing shift from open to closed or incentive-based formularies. GAO noted that a “greater number of health plan sponsors” will adopt more restricted programs in the future “because of their potential to help reduce a plan’s drug costs.” The danger in this trend, said John Santell, director of the Center on Pharmacy Practice Management at the American Society of Health Systems Pharmacists, “is that plans may remove from their lists drugs that could keep people out of the hospital. A closed formulary can help plans ratchet down costs, although they also can be less cost effective overall, if that’s all they do.”

Mike Barberi, principal with William M. Mercer Consulting, believes that to be successful in better managing care, plans will need “outcomes-based formularies that measure medical and drug costs related to medical events, severity of illness, patient satisfaction/quality of life, plus worker
productivity. The well-managed drug plan also will have special drug management programs for prevalent diseases such as diabetes, asthma and cancer. These plans may spend more on prescription drugs, but that is all right if the expenditures help reduce medical costs” (Wechsler 1996).

HMO FORMULARIES LAG IN LISTING NEW DRUGS

Examining the formularies of 29 HMOs, Chinburapa and Larson assessed the availability of 38 drugs that had entered the market in the last five years. The most restrictive formularies were found to have less than one-third of the new drugs available without limit, while in the least restrictive formularies, more than 95 percent of the drugs were available without restriction. Drugs of higher therapeutic significance (Food and Drug Administration rating of 1A) were no more likely to be available without restriction than drugs judged to be less therapeutically advanced. Fewer new drugs were available in those plans where the pharmacy and therapeutics committee made the final decision (Chinburapa and Larson 1991).
Chapter IV.
Medicaid Formularies

Introduction

In an effort to reduce overall health care costs, state Medicaid programs have established various restrictions on pharmaceuticals prescribed for Medicaid-covered patients. But research has shown that Medicaid savings from the use of formularies may be deceptive.

An assessment by Moore and Newman (1993) of formulary restrictions in 47 Medicaid programs found that while average prescription drug costs declined between 1985 and 1989, program expenditures increased in other service areas, specifically physician services and inpatient mental hospital care. “It appears,” the authors concluded, “that the increased expenditures in these two areas arise from the increased utilization by Medicaid recipients whose drug of choice may be excluded from the state’s formulary.”

Similarly, in a 1988 review of 14 studies of Medicaid formularies, Jang found that the authors were “unanimous in concluding that restricted formularies did not save money when their total impact on the Medicaid program was considered, and they had significant potential for reducing the quality of life.” His review “affirms that Medicaid drug programs do not exist in a vacuum. Restricted drug lists appear to save money, but the savings are illusory. They come at the cost of other service components or represent a reduction in benefit to participants” (Jang 1988).

In another key study, Soumerai et al. looked at a New Hampshire program’s policy of restricting the number of prescriptions for Medicaid recipients to three per month. Although drug use declined significantly when the cap was instituted, the number of nursing home admissions substantially increased, the authors found (1991). A later study of the New Hampshire Medicaid monthly prescription cap focused on mental health care and came to similar conclusions: a decrease in the use of psychotropic drugs by noninstitutionalized Medicaid patients with schizophrenia was accompanied by increases in the number of patient visits to community mental health centers and in the use of emergency mental health services and partial hospitalizations (Soumerai et al. 1994). In both studies drug use and utilization of the other services returned to normal levels after the cap was eliminated.

Cost containment efforts such as the New Hampshire Medicaid program’s policy not only fail to accomplish the goal of saving Medicaid costs, they may also be harmful to Medicaid patients. As Schroeder and Cantor (1991) of the Robert Wood Johnson Foundation pointed out, such restrictive policies apply constraints “to the most vulnerable patients—that is, to those with both low incomes and complex illnesses . . . with ‘disturbing’ results.”
If a drug formulary is to work, it must balance cost, access, and quality, Eugene Reeder of the University of South Carolina College of Pharmacy concluded at a conference (Reeder 1995). The formulary should not be designed with only the cost of drugs in mind. Because of the impact of the formulary on other health services, its effect on patient health should also be considered. A formulary "only becomes valuable when the list of drugs is embedded within a context that includes systems for product evaluation and selection, as well as procedures for product usage and quality assurance," he said.

Citations

The following are summaries of studies on the effects of formularies and other restrictions on Medicaid. General and state-specific studies are included.

Hospitalization Rates Unaffected by Limits on Anti-ulcer Prescriptions, but Elderly Not Studied

Cromwell et al. studied the impact of payment restrictions on the use of anti-ulcer medications implemented by the Florida Medicaid program in 1992. Under the policy, patients could receive only one anti-ulcer prescription at a time and only one refill per written prescription; in addition, high-dose treatment for acute disorders was limited to 60 days. These three restrictions were rather mild because the dosing and duration limits were consistent with clinical recommendations and selection of any of the six anti-ulcer drugs available at the time was not restricted. The authors examined the effect of the policy on ulcer drug use in all ulcer patients in the study group and on ulcer-related hospitalizations in patients under 64 years old.

Following the policy’s implementation, the reimbursement rate for anti-ulcer drugs decreased by 33 percent, a $6 million saving to the Medicaid drug budget, the authors found; they did, however, observe some reversal of these effects beginning one year after the policy was implemented. No associated increase occurred in hospitalization rates. When the authors adjusted for trends in non-Medicaid hospitalization rates for ulcer-related conditions, however, they estimated that postrestriction hospitalization rates would have increased up to 35 percent depending on the type and severity of the condition. They did not examine the policy’s impact on ambulatory health care services since these data were not available.

The authors cautioned that the results of their study should not be extrapolated to other states that may have more or less restrictive policies. They further indicated that elimination of the elderly from the patient sample may have reduced the sensitivity of their methods for finding an unintended association between the policy and an increase in ulcer-related hospitalizations (Cromwell et al. 1999).
**Drug Savings Under Medicaid Formularies Offset by Added Costs Elsewhere**

Moore and Newman (1993) studied varying formulary restrictions in 47 Medicaid programs. Using a regression model to analyze pooled cross-sectional data for 1985-89, they concluded that: “[A] restricted formulary may reduce prescription drug expenditures by approximately 13 percent, on average. Because of service substitution, however, such a policy does not translate into reductions in total program expenditures. Savings in the drug budget appear to be completely offset by increased expenditures elsewhere in the system.” The added costs, seen particularly in physician services and inpatient mental hospital care, appeared to be due to the formulary exclusion of the Medicaid recipients’ drugs of choice.

“Our results cast considerable doubt on the effectiveness of formularies in achieving their ultimate goal, that is, cost savings with no reduction in the quality of health care benefits,” they concluded (Moore and Newman 1993).

**New Hampshire Medicaid Restrictions Increase Nursing Home Utilization**

A 1991 study by Soumerai and colleagues of the Harvard Medical School revealed that New Hampshire’s attempt to save money on drugs in its Medicaid program unexpectedly resulted in increased nursing home admissions. For a period of 11 months, Medicaid benefits were limited to a maximum of three prescribed drugs per month. Compared to previous figures, and compared to a control cohort of New Jersey residents, New Hampshire Medicaid recipients used fewer prescriptions, but were admitted to nursing homes at a higher rate (Soumerai et al. 1991). An accompanying editorial commented that “[A]lthough piecemeal efforts at cost containment may accomplish their narrow goals, this achievement may come at the considerable price of diminished access, decreased quality, or excessively intrusive (and even expensive) bureaucracy” (Schroeder and Cantor 1991).

**Mental Health Care Costs Also Rose in New Hampshire**

In a later study, Soumerai et al. evaluated the effects of the New Hampshire Medicaid policy on the use of psychotropic drugs and acute mental health care by noninstitutionalized patients with schizophrenia. After institution of the cap, there was an immediate reduction in the use of antipsychotics, anxiolytics, hypnotics, antidepressants and lithium. But this decline in drug use was accompanied by increases in patient visits to community mental health centers and sharp increases in the use of emergency mental health services and partial hospitalizations. The estimated average increase in mental health care costs per patient during the cap ($1,530) exceeded the savings in drug costs to Medicaid by a factor of 17. After the cap was discontinued, the use of medications and most mental health services reverted to baseline levels (Soumerai et al. 1994).
SAVINGS FROM MEDICAID FORMULARIES FOUND ILLUSORY

In Medicaid programs, researchers have often found that increased restrictions in the formulary initially appear to save money, but this initial impression does not withstand scrutiny. A 1988 review by Jang of 11 studies of the impact of formularies on prescription drug use and cost in various Medicaid programs found that the authors were “unanimous in concluding that restricted formularies did not save money when their total impact on the Medicaid program was considered and they had significant potential for reducing the quality of life.”

There is evidence that eliminating relatively inexpensive drug treatments leads to increased use of other, often more costly, services. Patient health may be adversely affected by restrictions as well. Drugs that are removed from the list of reimbursable products may be replaced by more expensive drugs, more numerous drugs, too few drugs, or simply the stripping away of benefits, as patients assume the costs of their treatment in order for it to continue. Those patients who lose access to a treatment that was keeping them functional may eventually turn up in the hospital, presumably to their detriment and to the detriment of a program’s budget (Jang 1988).

MEDICAID RESTRICTIONS ON NEW AIDS DRUGS INCREASE HOSPITAL COSTS

Presentations given at the September 1998 Disease Management Congress and experts interviewed by Healthcare Demand and Disease Management magazine are in agreement that restricting coverage of new AIDS drugs is like “robbing Peter to pay Paul.” Despite National Institutes of Health guidelines recommending early aggressive treatment of HIV-infected patients, current Medicaid eligibility rules provide coverage to such patients only after they exhibit signs of full-blown disease. Thus, the new highly active antiretroviral therapy (HAART) is not reimbursed until there is an AIDS-defining illness or the CD-4 count declines to below 200. Many private pay insurers have established similar coverage criteria.

But early HAART therapy has been shown to delay the onset of AIDS symptoms, while only slightly increasing medical care costs over the first five years ($241 per patient per year). A Department of Veterans Affairs study of 59,000 patients reported a 37 percent decrease in hospital admissions and a 41 percent decrease in hospital days after one year of HAART therapy. Although there was a 38 percent increase in clinic visits, an overall annual savings of $18 million occurred. Based on these findings, one expert said “The cost of 10 years of the new drug therapies will pale in comparison to one prolonged hospital stay for a serious infection” (National Health Information 1998).

OBRA LIMIT ON RESTRICTIVE MEDICAID FORMULARIES PRODUCED MIXED EFFECTS

The Omnibus Budget Reconciliation Act of 1990 (OBRA ’90) disallowed restrictive formularies in all state Medicaid programs. Although
subsequently repealed, the act provided a natural experiment for examin-
ing some of the effects of increased coverage for previously restricted
medications. Opening the formularies had the potential benefit of making
available some agents whose frequent exclusion prior to OBRA ‘90 may
have been “clinically unjustified” — for example, loperamide, ery-
thromycin, and naproxen sodium. The pre-OBRA ’90 exclusion of other
drugs, especially benzodiazepines, may reflect negative public percep-
tions of these agents, despite their clinical value in patients with panic dis-
orders, convulsions, febrile seizures, alcohol detoxification and short-term
reactive insomnia.

The study by Walser et al. considered the clinical benefits of making
available 18 of the 200 top-selling medications in at least four states where
they had been unavailable before OBRA ’90. Physician panels judged that
seven of these agents provided a net therapeutic advantage; in the case of
five, the panelists concluded either that the agents have “questionable
therapeutic benefit” or they could not agree and determined that six have
“no additional therapeutic benefit.”

Disallowing formularies may have both intended and unintended
effects, the authors said. Of special importance are the positive clinical and
economic effects associated with increased availability of agents with ther-
apeutic advantage. In addition, increased spending on high-priced, high-
benefit drugs may offset total health care costs. Large new expenditures
on widely prescribed drugs with little therapeutic advantage, however,
would not be offset by reductions in other health care spending.

Although the authors did not assess the net clinical and economic con-
sequences of eliminating formularies, they note that definitive conclusions
about the implications of such policies should be based on analysis of
quality and total cost of care (Walser et al. 1996).

**Small Copayments May Prevent Vulnerable Medicaid Beneficiaries from Acquiring Needed Therapies**

Stuart and Zacker examined the impact of Medicaid prescription drug
copayment policies in thirty-eight states using survey data from the 1992
Medicare Current Beneficiary Survey. Elderly and disabled Medicaid
recipients residing in states with copay provisions were found to have sig-
nificantly lower rates of drug use than their counterparts in states without
copayments. After controlling for other factors, the researchers found that
the primary effect of copayments is to reduce prescription-filling behavior.
They state that: “Apparently, even very small [$3 or less] Medicaid copay-
ments deter drug use, and the primary effect is to reduce the likelihood
that recipients will fill any prescriptions at all during the year.” Although
effects on health were not measured directly, reduced drug use due to
copay was proportionately greater in recipients in fair or poor health.
Thus, the deterrent to fill prescriptions was disproportionately more effec-
tive for the sickest patients (Stuart and Zacker 1999).
**Study in 19 States Finds No Cost Differences Between Open and Closed Formularies**

In 1972, in one of the first studies of its kind, Hammel analyzed public assistance medical care expenditure data supplied to the Department of Health, Education, and Welfare from 19 states. Expenses in states with no formulary or with an open formulary were compared to expenses in states with closed formularies. “Contrary to popular expectation, no relationship was found between formulary status and expenditures,” according to the author. In southern states, the average health expenditure per recipient was lower in states that had no formularies or open formularies than in states with closed formularies. In the west, the opposite was true: the average expenditure per recipient in states with open or no formularies exceeded those in states with closed formularies (Hammel 1972).

**Restricted Drugs Prescribed Anyway and Paid for by Medicaid Patients**

In a 1984 study funded in part by the Michigan Pharmacists Association Pharmacy Data Center, Smith and McKercher found that 30.7 percent of Medicaid patients for whom disallowed drugs were prescribed simply paid for these drugs themselves. Michigan Medicaid eliminated 32 drugs termed “marginally effective;” the authors theorized that if more significant agents had been involved, the residual prescribing effect and patients’ desire for their medications would have been even stronger (Smith and McKercher 1984).

**Shift of Costs Rather Than Savings Documented**

Based on his 1998 review of Medicaid formularies, Jang made the following observations: “The assumption that restriction of specific drugs results in savings in the drug costs proportional to prior usage was shown to be questionable…. There was a tendency for alternate drugs to be more expensive…. Little information exists as to the incremental administrative costs of restricted formularies or the therapeutic appropriateness of substituted drugs” (Jang 1988).

**Citations—State Medicaid Experience with Formulary Restrictions**

The following citations describe the impact of restrictive prescription policies in individual Medicaid programs.

**California and Texas: Medicaid Administrative Costs Compared**

Sudovar and Rein compared California’s Medicaid program to the less restrictive Texas system. After adjusting for differences in patient population characteristics and patterns of utilization, the authors estimated that California could have saved more than $14 million if it had run its Medicaid system the way Texas operated its system in the year studied. More than $5 million of the projected savings would have resulted from reduced administrative overhead (Sudovar and Rein 1978).
FLORIDA: HOSPITALIZATIONS NOT AFFECTED BY LIMITS ON
ANTI-ULCER PRESCRIPTIONS, BUT ELDERLY NOT STUDIED

After the Florida Medicaid program implemented certain payment restrictions on the use of anti-ulcer drugs in 1992, the reimbursement rate for these drugs declined by 33 percent, creating a savings of $6 million, according to a study by Cromwell et al. The authors observed some reversal of this effect one year after the policy was put into place. The restrictions did not appear to cause an increase in hospitalization rates. But when the authors adjusted for trends in non-Medicaid hospitalization rates for ulcer-related conditions, they estimated that post-restrictions hospitalization rates would have increased up to 35 percent, depending on the type and severity of the condition. The authors cautioned that their findings should not be extrapolated to other states where prescription payment policies may be more or less restrictive. They also noted that the omission of the elderly from the patient sample may have reduced the sensitivity of their methods for finding an unintended increase in ulcer-related hospitalizations (Cromwell et al. 1999).

GEORGIA: MEDICAID DRUG LIMITS AND DRUG USE AMONG SENIORS

In 1991, Georgia Medicaid reduced the maximum number of reimbursable prescriptions from six per month to five. Martin and McMillan studied the impact of this further limitation in 743 ambulatory patients, 53 percent of whom were over age 65 and were high prescription users. They did not look at the effects of this restriction on overall costs or outcomes.

The new limit was associated with a 6.6 percent decline in total prescriptions, a 9.9 percent drop in prescriptions reimbursed by Medicaid and a temporary 9.7 percent increase in prescriptions paid for out-of-pocket. Abrupt, permanent decreases in prescription use were observed for some major therapeutic drug categories — cardiovascular, miscellaneous, pulmonary and palliative — but no change was seen in other categories, such as gastrointestinal, chemotherapy, hormone/insulin and central nervous system.

Overall Medicaid drug savings of about $69 per patient per year were “modest when compared with the potential consequences of noncompliance with cardiovascular and other medicines considered essential to preventing and controlling many life-threatening conditions such as stroke and myocardial infarction.” In discussing their findings, the authors stated:

“The implementation of a more restrictive limit alters prescription regimens potentially predisposing elderly Medicaid recipients to clinical consequences” (Martin and McMillan 1996).
ILLINOIS: RELAXING RESTRICTIONS REDUCED UTILIZATION

In a study of the Illinois Medicaid program’s formulary restrictions, Dranove found that after the limits were relaxed in 1984, utilization of medical and surgical services declined, “but not by enough to offset markedly higher drug costs. Once possible non-pecuniary benefits to patients are accounted for, however, it appears that the benefits of an unrestricted formulary may equal or exceed the costs” (Dranove 1989).

IOWA: PRIOR AUTHORIZATION REDUCED PRESCRIPTION VOLUME

The Iowa Medicaid prior authorization (PA) program, implemented in 1992 and expanded in 1993, restricted access to four main categories of drugs: single-source anti-arthritis, single-source benzodiazepines, nonsedating antihistamines and high-dose chronic therapy with anti-ulcer medications. A 1995 study of the restrictions, which did not use a control group, assessed the potential effects of the program on drug use and drug expenditures. The study found that prescription volume for agents in all four categories was markedly reduced. The total net drug budget savings in 1995 was estimated at $2.51 million to $3.83 million, representing 2 percent to 3 percent of drug vendor payments.

As the authors pointed out, the study did not measure the perceptions of prescribers, pharmacists and patients as to the ease of administration of the PA program and its effects on quality of care, patient satisfaction, and overall treatment costs. Also, since the study relied on program-wide data, assessment of effects on the individual patients, especially the effects of denial of PA requests, was not possible (Phillips and Larson 1997).

LOUISIANA: FORMULARY RESTRICTIONS INCREASED TOTAL PROGRAM OUTLAYS

Hefner’s study (1979) of the Louisiana Medicaid system revealed that following the implementation of formulary restrictions in 1976 there was a reduction in the number of prescriptions by 11.4 percent, a savings of $4.1 million. Total program expenditures, however, increased 7.3 percent to $15.1 million. “[J]udicious use of prescription drug products is an inexpensive form of medical treatment that often can reduce the demand for more expensive forms of treatment,” he concluded (Hefner 1979). Based on the Louisiana data, Hefner later asserted that “Medicaid administrators should avoid making ad hoc changes in program benefits without first considering the implications for the entire Medicaid program” (Hefner 1980).

LOUISIANA: HEFNER’S STUDY OF MEDICAID FORMULARY CRITICIZED

The Hefner study of the Louisiana Medicaid formulary was criticized by Rucker and Morse, who claimed that the state’s drug restrictions were too minor to have caused such a substantial rise in costs. The study’s significance should also be discounted, the authors said, because it was sponsored and disseminated by an interested party, the National Pharmaceutical Council (Rucker and Morse 1980).
Notwithstanding his criticism of the Hefner study, Rucker is on record with his own concerns about restricted formularies: “If price considerations are applied rigorously (i.e., products priced significantly above the true economic cost of production and distribution are actually excluded from the formulary), many first and second choice drugs may not be available for patient treatment. Under such conditions, program expenses could actually rise as treatment is prolonged due to the fact that drugs of second choice or last resort may often be substituted for the medication of choice” (Rucker 1971).

Although the Hefner study has been criticized on methodological grounds (Soumerai and Ross-Degnan 1990), a study published in a respected health services research journal accepted the results of the report without question (Kreling et al. 1989). Soumerai and Ross-Degnan state there is clearly “a need for more rigorous examination of both the intended and unintended economic and quality of care effects of negative drug lists before their widespread implementation in drug benefits programs” (Soumerai and Ross-Degnan 1990).

MICHIGAN: FORMULARY RESTRICTIONS CORRELATED WITH RISE IN DRUG COSTS

In their study of the Michigan Medicaid formulary, Smith and McKercher found that the process of prescribing alternative, approved drugs in place of originally prescribed, disallowed drugs, drove up costs. “Average daily acquisition cost for the alternate prescription was 111 percent higher than the original prescription ($0.18 versus $0.38). Average cost per dose for the alternate prescription was 70 percent higher than the original prescription ($0.07 versus $0.12). Although not statistically significant, the total average prescription price was $5.91 for the original versus $7.59 for the alternate. The total average acquisition cost was $3.26 for original therapy versus $4.94 for alternate therapy” (Smith and McKercher 1984).

MISSISSIPPI: LIMITS ON MINOR TRANQUILIZERS LED TO INCREASE IN MORE POTENT, RISKIER DRUGS

When minor tranquilizers were restricted in the Mississippi Medicaid formulary, overall drug prescribing increased by 11 percent, according to a study by Smith and Simmons (1982). More importantly, prescriptions for psychostimulants rose by 103 percent, barbiturates by 74 percent, combination drugs by 71 percent and major tranquilizers by 43 percent. Not only were more prescriptions written, but apparently minor tranquilizers may have been replaced by more potent medications, presumably an undesirable shift in prescribing in terms of additional costs and potential for side effects (See Table 3) (Smith and Simmons 1982).
Restriction drives up prescribing. When minor tranquilizers were restricted in the Mississippi Medicaid formulary, the following changes in prescribing occurred:

<table>
<thead>
<tr>
<th>Increases</th>
<th>Decreases</th>
</tr>
</thead>
<tbody>
<tr>
<td>11% all categories</td>
<td>100% minor tranquilizers</td>
</tr>
<tr>
<td>103% psychostimulants</td>
<td></td>
</tr>
<tr>
<td>74% barbiturates</td>
<td></td>
</tr>
<tr>
<td>71% combination drugs</td>
<td></td>
</tr>
<tr>
<td>43% major tranquilizers</td>
<td></td>
</tr>
</tbody>
</table>

**MISSISSIPPI: REMOVAL OF ANALGESICS RAISED MEDICAID COSTS**

A comparison of prescribing patterns and costs within the Mississippi Medicaid program, before and after its formulary was restricted, led Smith and McLayton to conclude that although formulary limitations appear to offer simple solutions for saving money, detrimental medical and economic effects may follow. They found that after the state disallowed reimbursement for certain analgesics, analgesic prescribing rose 25 percent in a sixmonth period, while prescribing on the whole rose only 11 percent. The authors estimated that removing the analgesics from the formulary cost the state more than $120,000 in six months (Smith and McLayton 1977).

**NEW HAMPSHIRE: RX LIMITS LINKED TO INCREASED NURSING HOMES AND MENTAL HEALTH CARE USE**

The New Hampshire Medicaid program’s policy of limiting prescriptions to three per month led to a significant increase in nursing home admissions, although it did achieve its purpose of reducing Medicaid drug expenditures, according to a study by Soumerai et al. (1991). In a later study (1994) the authors looked at the effect of the policy on patients with schizophrenia and found that the cap resulted in an increase in the use of community mental health centers, emergency mental health services and partial hospitalizations. The additional cost of mental health care services was 17 times higher than the savings in drug costs, they concluded. In both studies drug use and service utilization returned to previous levels after the prescription cap was eliminated (Soumerai et al. 1991, 1994).

**NEW JERSEY: WITHDRAWAL OF CERTAIN DRUGS NETS NO COST SAVINGS**

Soumerai and colleagues reviewed prescription records of more than 390,000 New Jersey Medicaid patients for the period of 1980 to 1983. They found that after New Jersey Medicaid stopped paying for 12 categories of scientifically unsubstantiated drugs—which accounted for 7 percent of prescriptions dispensed in the base year—there was no measurable reduction in programwide drug use or expenditures. Reductions in use of withdrawn drugs were offset by increases in substitute drugs, which varied substantially in cost and efficacy. Although patients switched from fixed-ratio combinations of theophylline and barbiturates to bronchodilators...
without sedatives represent a likely improvement in therapy, patients on cerebral vasodilators were often switched to poorly effective and costly substitutes, such as papaverine or ergoloid mesylates (Soumerai et al. 1990).

**South Carolina: Formulary Expansion Results in Savings**

When the South Carolina Medicaid formulary was expanded, the number of prescriptions, physician office visits and outpatient hospital visits per person increased, according to a 1990 study by Kozma et al. But the authors also found a decline in the number of inpatient hospital admissions per person and average total expenditures per person. They noted that “[A]s the average expenditure per hospital claim is large, a small decrease in hospital utilization can offset the costs of a substantial increase in prescription claims.” This association between expanded coverage for drugs and a reduction in inpatient services “support[s] the thesis that medical care services should not be viewed in isolation but rather as a system of interrelated activities.” They concluded (Kozma et al. 1990).

**Tennessee: Restrictions Prevent Effective Treatment, Doctors Say**

Many physicians participating in the TennCare Medicaid managed care program believe that formulary restrictions prevent them from treating their patients effectively. In a 1996 survey of 200 participating physicians, 98 percent of respondents said they have been unable to prescribe the drugs of their choice and 95 percent said they have been advised to change a patient’s prescription because the drug was not covered. The poll was conducted by Yankelovich Partners at the request of the Tennessee Medical Association.

These restrictions often have serious consequences. Two-thirds of the physicians who were forced to switch their patients’ prescriptions reported serious adverse consequences, including death or near death, strokes, gastrointestinal bleeding and drug interactions. In addition, they said switching drugs also resulted in patient suffering, prolonged illness and drug side effects (Yankelovich 1996).

**Tennessee: Decrease in NSAID Costs May Not Apply to Other Drugs**

In a study by Smalley et al. of the effect of the TennCare formulary, restriction of single source nonsteroidal anti-inflammatory agents (NSAIDs) through mandatory advance approval was successful in shifting the prescribing of NSAIDs toward generic agents of this class. As a result, NSAID expenditures decreased by 53 percent. The authors found no concomitant increase in Medicaid expenditures for other medical care. They cautioned, however, that these findings may not be applicable to other drug classes. Restriction of other therapeutic classes, such as antidepressant or antihypertensive agents, with greater pharmacological diversity among individual agents may have adverse consequences, they point-
ed out. Changing medications of patients with well-controlled major depression or hypertension might entail substantial hazards due to the lesser efficacy of the alternative medications. “Even if such changes could be made without risk to the patient, the additional visits to the physician could cancel out any savings in the cost of the medication,” they conclud- ed (Smalley et al. 1995).

**WEST VIRGINIA: REDUCED DRUG BENEFITS LED TO MORE SURGERY**

Bloom and Jacobs compared West Virginia Medicaid data for peptic ulcer patients for nine months before and nine months after cimetidine was removed from the formulary. Pharmaceutical expenditures decreased 78.9 percent, but hospital payments increased 23.6 percent. The number of peptic ulcer patients receiving pharmaceutical benefits fell from 71.4 percent to 23.6 percent after the formulary restriction, but the rate of gastrointestinal surgical procedures rose. Reduced drug benefits might result in patients avoiding expenses at first, but that this probably results in more severe illness and, ultimately, greater expenses, the authors con- cluded. “The small, short-term savings may be negated by increased expenditures in the near future when sicker patients, previously denied peptic ulcer drug treatment, may reenter the Medicaid system in need of expensive in-hospital treatment,” they said (Bloom and Jacobs 1985).
Chapter V.
Effect of Restrictions on Quality of Care and Costs

Introduction

Aside from the potentially adverse economic consequences of restrictive formularies, research has shown that such restrictions may also seriously affect the quality of patient care, including limiting access to services, reducing patient satisfaction, and adversely affecting clinical outcomes. According to a survey by American Druggist (1991), the majority of pharmacists polled said that formularies significantly or slightly diminished the quality of care.

Several studies have concluded that formulary restrictions are often associated with increases in institutionalization or medical procedures, subjecting patients to additional risks. For example, Soumerai et al. (1991) found that the New Hampshire Medicaid’s policy of limiting prescriptions to three per month led to a significant increase in the number of nursing home admissions. Their later study (1994) of patients with schizophrenia showed that the prescription cap also resulted in increases in mental health service use. A study of the Louisiana Medicaid program discovered a marked increase in the hospitalization of the elderly and disabled when the formulary was restricted (Hefner 1979). Looking at the West Virginia Medicaid program, Bloom and Jacobs (1985) found that the rate of gastrointestinal surgical procedures for peptic ulcer patients rose when the drug cimetidine was deleted from the formulary.

As these and other studies show, some patients are more vulnerable to the effects of restrictive formularies, particularly the elderly, those with disabilities or complex illnesses and the poor. Levy (1993) also reported that due to the special needs and drug responses of different ethnic and racial groups, formularies may compromise care in minority patients.

A number of studies of the effects of formulary changes on patients stabilized on certain drugs have shown modest overall cost savings, but in some cases there may have been a decline in quality of care due to an increase in medical encounters and side effects (Cantrell et al. 1999, Stock and Kofoed 1994, Hilleman et al. 1997). Others have found that patients sometimes do not have access to state-of-the-art therapies because formularies delay the introduction of new technologies.

Another problem arising from the use of restrictive formularies is the practice of therapeutic substitution, used widely in hospitals and managed care plans. Therapeutic substitution or interchange involves the replacement of a prescribed drug with a similar but not identical agent of the same pharmacologic or therapeutic class.
The section on therapeutic substitution includes some studies focusing on the impact of substitution and formulary changes on the quality of care. According to a 1989 Gallup survey of physicians commissioned by the American Medical Association (AMA), an estimated 1.2 million patients across the country have been adversely affected by drug substitution. Several studies of formulary changes in patients stabilized on medications in selected drug classes, including ACE inhibitors, calcium-channel blockers and lipid-lowering agents, have provided some evidence for modest overall savings, primarily through lower drug costs with no substantial changes in treatment outcome. In some cases, quality of care may have been reduced for individual patients due to increased frequency of side effects or medical encounters (Hilleman et al. 1997). Treatment outcomes were marginally improved in one case involving the unintended administration of a more effective dose when the medications were switched (Pettita et al. 1997).

Some studies have looked specifically at how formulary restrictions on antibiotics and antibiotic substitutions affect quality of care, as well as health care costs. One major unexpected consequence is increased antibiotic resistance, according to research by Burke (1998). In a study by DeTorres and White (1984), antibiotic formulary restrictions were associated with increased nephrotoxicity. These studies are summarized in the section on antibiotic substitution below.

In response to these concerns about quality, the AMA and the National Committee for Quality Assurance (NCQA) have separately adopted standards for managed care formularies. The AMA’s 1997 policy stresses a physician’s responsibility to insist on the best drug for the individual patient, the importance of quality considerations over cost issues and full disclosure to patients of any drug benefit restrictions. Starting in 1999, NCQA will include accreditation standards to assure the quality of the formulary process in managed care. NCQA’s proposed standards for accreditation in 2000 will also apply to procedures for implementing the formulary, including prior authorization, differential or “tiered” copayments, and substitution.

Citations

Following are summaries of major articles that discuss the often deleterious effect of restrictive formularies on quality of care.

**PRESCRIPTION CAP LINKED TO RISE IN NURSING HOME ADMISSIONS**

In a 1991 study of the effect of Medicaid prescription limits, Soumerai et al. found that after the New Hampshire program instituted a cap of three prescriptions per month, drug usage declined by 35 percent. But that decrease was accompanied by a significant increase in the number of nursing home admissions. When the cap was later eliminated, the amount of drug use and the number of nursing home admissions returned to normal. They concluded that “Limiting reimbursement for effective drugs puts frail, low-income, elderly patients at increased risk of institutionalization
in nursing homes and may increase Medicaid costs” (Soumerai et al. 1991).

**LIMITS ON PRESCRIPTIONS ALSO TIED TO INCREASED USE OF MENTAL HEALTH SERVICES**

Later Soumerai et al. studied the effect of the New Hampshire Medicaid prescription cap on the use of psychotropic drugs and acute mental health care by noninstitutionalized patients with schizophrenia. They found that immediately after the policy was implemented, the use of antipsychotics, anxiolytics, hypnotics, antidepressants and lithium decreased. At the same time patient visits to community mental health centers rose and the use of emergency mental health services and partial hospitalizations increased significantly. The use of medications and most mental health care services returned to normal levels when the cap was discontinued (Soumerai et al. 1994).

**MEDICAID FORMULARIES LAG IN LISTING NEW DRUGS**

A study of Medicaid formularies in six states showed significant time lags in getting new drugs listed on state formularies, even beyond the delays imposed by the Food and Drug Administration (FDA) approval process. Such delays deny Medicaid patients access to the latest medical technology (Grabowski 1988).

**FEWER NEW DRUGS ON MOST RESTRICTIVE HMO FORMULARIES**

In a study on the availability of new drugs on the formularies of 29 HMOs, the authors found that the plans with the most restrictive formularies applied restrictions to less than one-third of 38 drugs that entered the market in the last five years. By contrast, HMOs with the least restrictive formularies covered more than 95 percent of the drugs without limit. Drugs of higher therapeutic significance (FDA rating of 1A) were no more likely to be available without restriction than drugs judged to be less therapeutically advanced. Fewer new drugs were available in those plans where the pharmacy and therapeutics committee made the final decision about drug selection (Chinburapa and Larson 1991).

**LOW-INCOME AND SICKER PATIENTS MOST VULNERABLE**

Schroeder and Cantor of the Robert Wood Johnson Foundation noted the hazards of cost containment efforts in public assistance programs, such as the New Hampshire Medicaid prescription limit policy (see Soumerai et al. above). “In this instance, constraints were applied to the most vulnerable patients—that is, to those with both low incomes and complex illnesses—and the effects were particularly disturbing…. Perhaps the most important lesson from the New Hampshire experiment is that although the poor are a tempting target for cost containment efforts, those who seek a quick and politically painless solution may be deceiving themselves, as well as harming others” (Schroeder and Cantor 1991).

**VARIETY OF AGENTS NEEDED TO TREAT VARIETY OF PATIENTS**

A 1989 study published in *The Journal of Rheumatology* reported that 75 percent of private rheumatology practices surveyed used at least 10
preparations in the course of their normal work with patients and that the use of 10 preparations reportedly met the therapeutic needs of 80 percent of patients (Pincus and Callahan 1989). Citing the study, Janice Zoeller, editor of American Druggist, noted that “it is fairly well accepted that individual response to NSAIDs can vary, perhaps in relation to varying drug effects on immune processes” (Zoeller 1991).

**FORMULARIES MAY COMPROMISE CARE IN MINORITY PATIENTS**

Environmental, cultural and genetic factors underlie varying responses to medications among different ethnic and racial minority groups, such as African-Americans, Asians and Hispanics. The special needs and drug responses of these groups have traditionally been undervalued or ignored in the design of formularies and other pharmacy management programs. The published information reviewed in Levy’s article suggests that these patients may be subject to greater risks if they are prescribed or switched to an “equivalent” drug because the agent may not be as effective, or substantial dosage adjustments may be necessary to avoid over- or under-dosing.

The factors involved in determining response to a medication in different ethnic groups are complex. Environmental factors, such as age, diurnal rhythms, sex, multiple disease states, fever, diet, chronic alcohol ingestion or cigarette smoking, presence of other drugs, pregnancy, stress and menstrual cycle, may have a profound effect on drug metabolism and disposition. Cultural or psychosocial factors may affect the efficacy of or compliance with a particular drug therapy. Genetic factors, which cause variations in drug response due to inherited metabolic defects or enzyme deficiencies, are a major determinant of the variability in drug effects. These factors underlie the significant differences reported in the effects of cardiovascular and central nervous system agents across different ethnic and racial populations (Levy 1993).

**AMA SETS STANDARDS FOR MANAGED CARE FORMULARIES**

The September 1997 Report of the AMA Board of Trustees reaffirmed AMA’s policies on standards and ethics regarding formularies in managed care plans. The policies stress physicians’ responsibility to insist on the best drug for the individual patient, the importance of quality care over cost savings and financial incentives, and full disclosure to patients of drug benefit limitations. Key principles include:

- “Physicians . . . should maintain awareness of plan decisions about drug selection by staying informed about P&T Committee actions and by ongoing personal review of formulary composition. P&T Committee members should include independent physician representatives. Mechanisms should be established for ongoing peer review of formulary policy.

- “Physicians should be particularly vigilant to ensure that formulary decisions adequately reflect the needs of indi-
vidual patients and that individual needs are not unfairly sacrificed by decisions based on the needs of the average patient. Physicians are ethically required to advocate for additions to the formulary when they think patients would benefit materially and for exceptions to the formulary on a case-by-case basis when justified by the health care needs of particular patients. Mechanisms to appeal formulary exclusions should be established. Other cost-containment mechanisms, including prescription caps and prior authorization, should not unduly burden physicians or patients in accessing optimal drug therapy.

- “Financial incentives (to lower drug costs) are permissible when they promote cost-effectiveness, not when they require withholding medically necessary care. Physicians must not be made to feel that they jeopardize their compensation or participation in a managed care plan if they prescribe drugs that are necessary for their patients but that also may be costly. There should be limits on the magnitude of financial incentives, incentives should be calculated according to the practices of a sizable group of physicians rather than on an individual basis, and incentives based on quality of care rather than cost of care should be used. Prescriptions should not be changed without physicians having a chance to discuss the change with the patient.

- “Patients must fully understand the methods used by their managed care plans to limit prescription drug costs. During enrollment, the plan must disclose the existence of formularies, the provisions for cases in which the physician prescribes a drug that is not included in the formulary, and the incentives or other mechanisms used to encourage physicians to consider cost when prescribing drugs. In addition, plans should disclose any relationships with PBMs or pharmaceutical companies that could influence the composition of the formulary. If physicians exhaust all avenues to secure a formulary exception for a significantly advantageous drug, they are still obligated to disclose the option of the more beneficial, more costly drug to the patient so that the patient can decide whether to pay out-of-pocket.

- “Research is encouraged to access the impact of restrictive formularies, therapeutic interchange and other approaches to containing prescription drug costs on patient welfare and health outcomes” (American Medical Association 1997).
NCQA FOCUS ON FORMULARIES AND BENEFIT LIMITATIONS

The National Committee for Quality Assurance (NCQA), which provides accreditation for managed care organizations, developed its first standards for the management of drug formularies and benefits in 1988. These initial standards, taking effect in July 1999, are summarized as follows:

“The managed care organization has processes to ensure that its drug formulary, if any, is based on sound clinical evidence and is reviewed and updated at specified intervals. The managed care organization develops its formulary with input from actively practicing practitioners and makes the formulary available to its practitioners. The managed care organization with a closed formulary has an exceptions policy in place.”

These standards also require that subscribers be provided with written information about benefit limitations and charges, including co-payments (National Committee for Quality Assurance 1998).

NCQA realizes that limitations on pharmaceuticals other than restrictive formularies can potentially affect the quality of pharmaceutical care in managed care plans. In its proposed 2000 accreditation standards, the NCQA accounts for this by extending its definition of formularies to include any accompanying procedures for implementation, including prior authorization, differential or “tiered” copayments, coinsurance, and substitution. NCQA defines an open formulary as a recommended list of drugs without requirements regarding its use. A closed formulary is defined as any system that includes either: 1) higher copayments or coinsurance for specific name-brand drugs on a preferred list than for specific name-brand drugs not on the list; or 2) no reimbursement for drugs not on the preferred list (National Committee for Quality Assurance 1999).

RESTRICTIVE FORMULARIES DIMINISH QUALITY, PHARMACISTS SAY

A survey published by American Druggist in 1991 asked independent and chain pharmacists about their experiences with third-party formularies. A significant majority stated that third-party formularies either significantly or slightly diminished the quality of care. Slightly less than half of these pharmacists said that plans offered them financial incentives to switch patients to generics or to formulary approved drugs, and more than half said they believed that financial incentives to change prescriptions compromised the quality of care (American Druggist 1991). The same survey found that 47 percent of independent pharmacists and 41 percent of chain pharmacists reported that their third-party plans give them financial incentives to switch patients to generic or formulary approved drugs. Most pharmacists, however, reported spurning these incentives. According to the survey, about 63 percent of independent pharmacists and almost 70 percent of chain pharmacists said they believe such incentives compromise professionalism (American Druggist 1991).
EMPLOYERS’ GROUP RAISES LIABILITY AND QUALITY QUESTIONS

Ruth Stack, president of the National Association of Employers on Health Care Action, says that “[E]mployers should be questioning what effect these restrictive policies have on quality health care and what liability issues they raise.” This organization warns that the use of restrictive drug policies could compromise quality of care and expose employers to increased liability—unless enrollees are made aware of restrictions in advance (Kenkel 1990).

NATIONAL HEALTH COUNCIL CALLS FOR FULL DISCLOSURE ON DRUG COVERAGE POLICIES

An area of growing concern is that managed care systems may deny patients full access to needed care, particularly in regard to prescription drugs and experimental treatments. The National Health Council has issued a statement on “Principles of Patients’ Rights and Responsibilities,” which highlights the need for managed care plans to fully reveal benefits and coverage policies.

In announcing the statement, Jacqueline McLead, president of the American Lung Association, emphasized her concern about full disclosure regarding access to pharmaceutical products. “Can the lung disease patient receive any drug prescribed or does the managed care system use a formulary to restrict access? Are there limits on the number of prescriptions or dollar amounts spent? If so, the patient may receive decades-old therapy instead of the latest, more effective technology” (Wechsler 1996).

AN EFFECTIVE FORMULARY MUST CONSIDER PATIENT OUTCOMES

Eugene Reeder, professor and assistant dean, University of South Carolina College of Pharmacy, told a 1995 conference that formularies should not be evaluated in isolation from other health services. “Formularies have a systemic impact upon other health services,” he said. “When designing a formulary, it is wholly irrational to focus solely on the cost of inputs (drugs). You must also weigh the cost of outputs (patient health). The cheapest formulary would probably be one composed solely of OTCs [over-the-counter drugs]. But such a formulary would almost certainly result in costs ballooning on the outputs side, because patients being treated with such a limited formulary would experience relatively poor outcomes.”

Reeder said that a workable formulary must balance cost, access and quality. To reduce costs, formularies restrict access to pharmaceuticals. But if restrictions are too aggressively applied, quality of care suffers and overall health care costs increase. “Thus, considered in isolation, a formulary is perfectly useless; it only becomes valuable when the list of drugs is embedded within a context that includes systems for product evaluation and selection, as well as procedures for product usage and quality assurance,” he stressed.

At the heart of the formulary question is patient outcomes. It is immaterial that a formulary lowers drug costs; it is essential that a formulary...
contributes to better patient outcomes since that is what really reduces costs in the system and addresses the quality of care issue. “The best formulary drug is the one that is most efficient,” he said. “Choose the drug that most surely and most expeditiously delivers the best outcome. If increasing the dollars spent on certain pharmaceuticals decreases the dollars expended on inpatient and outpatient care, then those drugs at those prices are a bargain — and should be on the formulary.”

Reeder also addressed the issue of formularies in the context of the emerging concepts of disease management and best-practice therapeutic guidelines: “Disease management is just another specification of an economic production process. For a selected disease state, you determine what needs to be done to produce the best outcome, by the most cost-effective means. . . . If we continue along the current disease management trend line, formularies as presently constituted may cease to exist. They will have been made redundant; they will have been folded into disease management therapy protocols. If you properly specify a disease management protocol, why will you need a formulary? Part of the treatment protocol will simply include the optimal drug products,” he concluded (Reeder 1995).

Restrictions on Psychiatric Drugs Raise Ethical Issues

Writing in the “Ethics” column in Hospital and Community Psychiatry, psychiatrist Walter Van Vort explored some of the ethical considerations that arise when prescribing restrictions are imposed in the practice of psychiatry. Although monitoring the prescribing of nonformulary drugs can promote effective and economical drug use, he said, in psychiatry, confidentiality is a major foundation of treatment, and nonformulary review may intrude on confidentiality of both psychiatrist and patient. “Choice and implementation of methods are ethically tinged because of the impact on the psychiatrist’s autonomy and on the doctorpatient relationship.” He advocated “[a] common sense approach in which enforcement of the formulary system is combined with tact, neutrality, transmission of up-to-date information, and flexibility” (Van Vort 1988).

Whether decisions about the availability of drugs in hospitals are intended to benefit patients or control costs, “the result is considerable ethical controversy,” said Spencer Eth, the journal editor, in an introduction to Van Vort’s column (Eth 1988).

Restrictions on Pharmacy Benefit Cause Consumer Dissatisfaction

A 1998 survey by CareData Reports, a consumer health care research company, showed that 20 percent of plan members requesting a specific drug from the doctor did not get it. As a result, they were twice as unhappy with the plan as members receiving requested drugs, and wanted to disenroll. When requested medications were denied, the percentage of members rating their care as excellent declined from 85 percent to 50 percent. Respondents also reported dissatisfaction when a generic equivalent or other brand was given. Fewer plan members were satisfied with the
pharmacy benefit in 1998 compared with 1996 when the previous survey was done (69 percent vs. 76 percent).

These results suggest that plan member dissatisfaction and disenrollment are likely to worsen if further restrictions and/or changes in drug benefit design are implemented (McCarthy 1998a).

**Formulary Restrictions Increase Hospitalizations**

In his study of the Louisiana Medicaid program, Hefner noted that hospitalization of the elderly and the disabled increased markedly during the period when the formulary was restricted, thus subjecting this vulnerable population to increased risks associated with institutionalization. The rise in the rate of hospitalization may have been one of the forces driving up overall costs in the program, he said (Hefner 1979).

**Restrictive Formularies Trigger Surgeries**

Bloom and Jacobs compared West Virginia Medicaid data for peptic ulcer patients for nine months before and nine months after cimetidine was removed from the formulary. Pharmaceutical expenditures per patient month decreased 78.9 percent, but hospital payments increased 23.6 percent. The number of peptic ulcer patients receiving pharmaceutical benefits fell from 71.4 percent to 23.6 percent after the formulary restriction, but the rate of gastrointestinal surgical procedures increased. Although a reduction in drug benefits might result in lower costs at first, it also probably leads to more severe illness later and ultimately to greater expenses. “The small, short-term savings may be negated by increased expenditures in the near future when sicker patients, previously denied peptic ulcer drug treatment, may reenter the Medicaid system in need of expensive in-hospital treatment,” they concluded (Bloom and Jacobs 1985).

**Cost, Not Clinical Preference, Is Major Factor In Some Prescribing Decisions**

A study of the use of two thrombolytic agents, streptokinase and tissue plasminogen activator (tPA), revealed that economic considerations have a substantial impact on the decision-making process where these two agents are concerned. The majority of physicians who use streptokinase cited economic factors as the reason for their choice, while the majority of those prescribing tPA based their decision on clinical preference. The authors of this 1991 study pointed out that clinical preference of either of these agents over the other has yet to be conclusively shown, which calls into question the clinical preference rationale on the part of tPA users. “Our study was not designed to settle these questions but rather to show the extent to which clinical decisions are currently being made primarily on the basis of economic considerations…. Our data clearly show that in the case of thrombolytic therapy, consideration of cost as the major determinant for an important clinical decision is already widespread in American medicine” (Brody et al. 1991).
Geriatric Psychiatrists See Risks of Formulary Limitations

In a September 1997 position paper, the American Association for Geriatric Psychiatry (AAGP) stated that closed or restricted formularies “discriminate against geriatric patients when they limit access to the most appropriate, individualized treatment.” Their rationale is that the elderly have biologic and psychological characteristics differing from those in younger people, which can alter both the therapeutic and adverse effects of drugs. Restricting choice may lead to a disproportionate risk of adverse effects. The paper also pointed out that mentally ill older patients have greater differences in their responsiveness to treatment with different psychotherapeutic drugs.

The AAGP believes that formulary limitations run the risk of prolonging suffering, decreasing social, occupational, emotional and physical functioning, increasing morbidity, increasing mortality, and increasing costs to both patients and the community. In addition, formulary limitations may result in delays in initiation of treatment when nonformulary requests are required and in changes to alternative medications, possibly leading to withdrawal syndromes, relapse or other undesirable effects.

The position paper further stated that “formulary choices should not be driven primarily by claims of...lower product cost.” Formulary decisions must emphasize safety and tolerability, as well as therapeutic efficacy and treatment effectiveness, and, especially in the elderly, considerations of compliance and outcomes (American Association for Geriatric Psychiatry 1997).

Individual Patient Needs Should Drive Therapy Selection

Pharmacist J. Lyle Bootman of the Center for Pharmaceutical Economics at the University of Arizona College of Pharmacy and Richard J. Milne, former editor of the journal Pharmacoeconomics, believe that “pharmacoeconomics may herald the end of drug formularies as we know them.” They further stated:

“There are very few, if any, drugs that are cost effective in every situation and patient group, even within one indication. The cost effectiveness of each drug must be evaluated in specific indications and patient subgroups to achieve maximal cost effectiveness for that indication. One goal of pharmacists must be to determine the appropriate mix of drugs for particular patients, especially those with several coexisting medical conditions, and thereby to maximize the cost effectiveness of drug therapy in the treatment of each disease” (Bootman and Milne 1996).
Citations—Therapeutic Substitution

The following summaries describe some of the adverse effects associated with therapeutic substitution, especially on stabilized patients. Some of the studies suggest modest savings in the drug budget but others report that favorable treatment outcomes can be jeopardized.

**ACE INHIBITOR SWITCH LOWERS OVERALL COSTS BUT MAY ADVERSELY AFFECT QUALITY OF CARE**

A study by Hilleman et al. followed 36 patients with mild to moderate hypertension who were stabilized on one of three ACE (angiotensin converting enzyme) inhibitors and then were switched to a fourth ACE inhibitor having similar clinical profiles. Only one of these patients failed to maintain blood pressure control, but over the one-year study period, there were increases in laboratory services, clinic visits and side-effects management. Despite these service substitutions, an average net cost savings of $138 per patient was projected due to the large differential in drug costs. These results indicate that manipulation of formularies can result in overall cost savings and can maintain health status, but the observed increases in clinic visits, laboratory monitoring and side effects suggest a decrease in the quality of patient care (Hilleman et al. 1997).

**MORE OFFICE VISITS AFTER SWITCH IN ACE INHIBITOR MEDICATION**

In a study of the economic effects of switching between two ACE inhibitors in a staff model HMO, McDonough et al. compared the drug, laboratory, administrative, and clinical costs and the costs associated with adverse effects in 75 patients switched to lisinopril and costs associated with treating 52 patients remaining on enalapril. The converted patients had more office visits over a 12-month period (4.5 compared to 2.6). In addition, seven of the converted patients had mild adverse effects and had to be switched back to enalapril. Although the increase in office visits, adverse effects, and administrative activities led to higher costs, lower drug acquisition costs resulted in an overall cost savings within the first year (McDonough et al. 1992).

**ACE INHIBITOR SWITCH PRODUCES SAVINGS IN DRUG EXPENDITURES**

Cantrell et al. (1999) studied the effects of switching between two ACE inhibitors on blood pressure and on levels of serum creatinine and potassium in elderly male patients at a Veterans Affairs Medical Center. They found no difference in blood pressure control or in the incidence of hyperkalemia following conversion of patients stabilized on lisinopril to benazepril. Serum creatinine levels declined, but not to a clinically significant extent. Since the study population was not limited to patients receiving ACE inhibitors exclusively for hypertension, the effect of the switch on therapeutic response was not determined for conditions such as diabetic nephropathy and congestive heart failure. The switch saved the institution $50,000 in annual drug costs for ACE inhibitors. The study did not assess changes in adverse effects, frequency of clinic visits and laboratory monitoring, or the utilization of other services for hypertension or other conditions (Cantrell et al. 1999).
SAVINGS FROM SWITCH TO LOW COST ACE INHIBITOR OFFSET BY ADMINISTRATIVE COSTS

A study from the University of Illinois pointed out that the process of switching patients from enalapril to lisinopril, which involved retitration, clinic visits and lab work, increased costs such that “a patient would have to receive 15, 17, or 27 months of therapy with 5, 10, or 20 mg tablets of lisinopril, respectively, before a net savings would be realized” (Lindgren-Furmaga et al. 1991).

COST SAVINGS RESULT FROM SUBSTITUTION OF LIPID-LOWERING AGENT

In 1994 the Henry Ford Medical Group Formulary Committee conducted a prescription medication class review of the HMG-CoA reductase inhibitors for patients with coronary heart disease (CHD) and selected one of the four agents then available for its formulary based on relative efficacy and lower cost. Petitta et al. estimated the economic and health effects of this formulary limitation by modeling them from risk factor and drug efficacy data. The researchers obtained CHD risk factor data from a random sample of 150 patients and derived the relative efficacy of the four drugs from the clinical literature and FDA-approved labeling. Outcomes until age 80 were modeled using the risk factor data and results from the Framingham Heart Study and the Scandinavian Survival Study. When the authors extrapolated to the full cohort of 3,500 patients with CHD, they found that 154 life years were gained and the estimated cost per life-year gained was reduced by $8,100. Most of these savings resulted from drug cost savings of 16 percent, plus a small reduction in hospitalizations stemming from dosage increases. Savings were derived mainly through favorable pricing from the manufacturer (Petitta et al. 1997).

INCREASE IN SIDE EFFECTS SEEN AFTER HEALTH PLAN CHANGES CALCIUM-CHANNEL BLOCKERS

In 1992 Humana Health Care Plans changed the only long-acting type of calcium-channel blocker on its formulary to the other available agent in this class. A study of the switch in 246 stabilized patients (Krantz et al. 1996) found that the new agent was at least as effective in controlling blood pressure. In addition, the monthly cost per patient for this class of medication was reduced by 15 percent, resulting in a medication cost savings of more than $150,000 per year. There were no significant differences in the overall frequency of adverse effects potentially related to medication use, but the frequency of certain side effects did increase, in accordance with the pharmacological properties of the new agent. During the three-month study period, nine patients discontinued therapy due to side effects which generally were more frequent in patients taking the new agent. Hilleman et al. (1997) suggested that a three-month follow-up of a switch program for chronic medications (ACE inhibitors) may be too short to detect late-onset side effects or treatment failures.
TREATMENT FAILURE SEEN IN SOME PATIENTS AFTER SWITCH OF SSRI AGENTS

The therapeutic interchange of SSRI (selective serotonin reuptake inhibitor) antidepressants in the mental hygiene clinic of a Department of Veterans Affairs medical center led to treatment failure in some patients. In 1992, 54 patients who were established on one SSRI agent were switched to another without a washout period. Although deemed successful in 34 patients, the substitution was judged by clinicians to be unsuccessful in the other 20 because of intolerable side effects, interrupted treatments soon after the change and lack of effectiveness.

The chief of psychiatry and the pharmacy service staff decided to make the switch in order to save costs, believing that the then available SSRI agents were equally effective and that the interchange of equivalent dosages was unlikely to cause untoward clinical effects. But the published dosage-equivalence ratio they used proved to be inaccurate. In addition, some patients experienced acute drug interactions after the abrupt switch. The interchange did not even result in significant savings in drug acquisition costs. The authors concluded that “Interchange policies should be implemented cautiously and evaluated systematically.” A review of the data from this study led eventually to the inclusion of both drugs on the hospital formulary (Stock and Kofoed 1994).

ANTICOAGULANT SWITCH LEADS TO HIGHER COSTS AND MORBIDITY

When Boston City Hospital’s pharmacy department substituted a different brand of the anticoagulant warfarin, which differed from the brand previously stocked, in an effort to save money, there was a noticeable increase in the number of patients with poorly controlled anticoagulation and in the number of clinic visits. A retrospective analysis of the medical and economic consequences showed that “a significant increase in morbidity and overall health care costs resulted from this attempt to economize by changing brands of medication” (Richton-Hewett et al. 1988).

AMERICAN COLLEGE OF PHYSICIANS CONDITIONS FOR THERAPEUTIC SUBSTITUTION

In a 1990 position paper the ACP supported hospital formularies as an educational resource when the available drugs are selected and evaluated according to detailed methods and criteria. The paper states that:

“[T]herapeutic substitution is appropriate only in hospitals with an effectively functioning formulary system and Pharmacy and Therapeutics Committee…. An effective formulary system provides detailed methods and criteria for the selection and objective evaluation of available pharmaceuticals; policies for the dissemination, maintenance, and comprehensive review of formulary drugs; protocols for the procurement, storage, distribution and safe use of formulary and non-formulary drug products; active surveillance mechanisms to regularly monitor compliance with these standards and to intercede where indicated; and enough spe-
cially qualified medical staff, pharmacists, and other professionals to carry out these activities [emphasis added]” (American College of Physicians 1990).

**Therapeutic Substitution Undercuts Coordinated Care**

Responding to the ongoing debate over therapeutic interchange, Donald McLeod stated in a 1988 editorial for *Drug Intelligence and Clinical Pharmacy*: “In my opinion, legislative approaches and organizational power plays by pharmacy, medicine, or the drug industry will create patient care problems…. In a well-operated hospital, with a P&T committee and a well-defined formulary, a non-formulary order is not simply substituted with a different chemical entity. The physician is contacted, his consent for change is sought, and proper notation is made in the medical record so that nurses and others can carry out orders correctly…. When therapeutic substitution is attempted unilaterally, the patient is not receiving the optimal benefits of the professions’ coordinated care” (McLeod 1988).

**Substitution Adversely Affects 1.2 Million Patients**

A 1989 Gallup organization survey of 814 physicians, commissioned by the American Medical Association, asked physicians about their involvement in cases where generic or therapeutic drug substitution impaired or delayed a patient’s recovery. Some 60 percent of those surveyed indicated they had seen no such cases or were unsure of the number or they refused to answer. But for the remaining 40 percent, the total number of adverse experiences was 4,641. Based on the total population of physicians and specialties represented in its survey, Gallup estimated that 1.2 million patients across the country have been adversely affected by drug substitution (AMA Gallup Poll 1989).

**Therapeutic Interchange Risks Undetermined Legal Liability**

According to a 1988 survey of 200 HMOs by Doering et al., “therapeutic substitution is being practiced by 30.5 percent of the responding HMO programs,” and this practice is associated with having significantly fewer drugs on the formulary. “The willingness of plans to engage in this practice is of interest in view of the lack of state laws that specifically address the legality of therapeutic substitution. Apparently, many plan administrators feel that the cost saving benefits of therapeutic substitution exceed the risk of engaging in a practice of undetermined legality.” But 36.2 percent of nonsubstituting HMOs cited concerns about violating state and/or federal laws and 21.6 percent mentioned risk of civil liability as reasons why they do not practice therapeutic substitution. The most common reason given for not practicing substitution was that “[I]t would not be accepted by the physician providers” (Doering et al. 1988).

**Wisconsin Recognizes Liability Risk of Therapeutic Substitution**

In 1986, after Maxicare Milwaukee began requiring physicians to sign a prior authorization for generic and therapeutic substitutions, the state medical society complained that the HMO was unfairly opening physicians up to liability by treating their patients with drugs the doctors had
The following year Wisconsin eliminated its state pharmacy board’s rules allowing therapeutic substitution and passed a law limiting therapeutic substitution to hospital patients (Schutte 1989).

**Ten Hospitals with Therapeutic Interchange Programs Failed to Consider Liability**

A Boston-based study of therapeutic substitution programs in 10 hospitals found that none had considered liability issues. “One obvious gap in the process at the P&T level in all 10 hospitals was the apparent inattention to legal and risk management consideration,” the authors said. Since only Washington and Wisconsin allow therapeutic substitution, and states that allow generic substitution often require prior consent of the practitioner, the authors advised hospitals to obtain legal opinions on any substitution practices they may have in place. This study also found that about 75 percent of 230 responding physicians rated themselves as either somewhat informed or not informed about the prescription drug policies and procedures in their hospitals, suggesting that these doctors may be exposed to liability without even knowing it (Shulman et al. 1992).

**Citations—Antibiotic Restrictions**

Following are summaries of articles on how formulary restrictions on antibiotics and antibiotic substitution affect quality of care.

**Antibiotic Restriction Lowered Drug Costs, But Implementation Costs Not Considered**

Switching all orders for cefoxitin to cefotetan (with appropriate dosage modifications) for one year saved a large teaching hospital almost $125,000, according to a study by Smith et al. (1989). The hospital’s P&T committee recommended the policy of substitution “based on data reported in the literature regarding antimicrobial activity, pharmacokinetic profile, and adverse reactions.” The authors noted that “[A]t the time of the evaluation, there were few clinical trials directly comparing the two drugs; however, sufficient clinical data were available to suggest that they were similar with respect to clinical efficacies and toxicities.”

But the savings calculation failed to take into account the costs of implementing the switch, including making, disseminating and enforcing the policy. Before the policy was fully implemented, the hospital instituted “an intense education program,... including in-service presentations to medical and nursing staff by [infectious disease] specialists and clinical pharmacists, and distribution of a therapeutic newsletter and a pocket guideline brochure.” The labor cost savings reported reflect only the less frequent dosing required with cefotetan, which led the authors to conclude: “Savings due to reduction in labor may not be realized by the institution unless pharmacy or nursing positions are actually eliminated” (Smith et al. 1989).
ANTIBIOTIC RESTRICTION AND UNEXPECTED DRUG RESISTANCE

Attempts to reduce antibiotic resistance by limiting the use of a class of compounds may be offset by changes in prescribing and drug resistance that are “even more ominous,” according to Burke (1998). He identified this offset as an unexpected type of adverse drug event. For example, Rahal et al. (1998) reported that restriction of cephalosporin use in a hospital was followed by the positive result of reduced resistance to beta-lactam antibiotics by *Klebsiella* species of bacteria. An unintended consequence of the hospital’s restriction program, however, was an increase in the prescribing of imipenem and a concomitant increase in imipenem-resistant *Pseudomonas aeruginosa*.

Although quality improvement has become synonymous with decreased variation in medical practice, in this case standardization could lead to “homogenous” prescribing patterns and the development of resistance, Burke cautioned. The extensive use of single classes of antibiotics has often been associated with marked increases in resistance. Antibiotic restriction programs may heighten the potential for misuse of unrestricted drugs, he stated.

Burke believes that efforts to encourage heterogeneity and individualization of drug selection might offer the best hope of managing resistance. Any method that brings more information to the selection decision will encourage heterogeneity. For example, computer-assisted decision support systems, incorporating a flexible and dynamic medical informatics system can inform and improve drug selection decisions, rather than enforce them (Pestotnik et al. 1996). This and other patient-centered strategies may reduce the total amount of antibiotic use, promote the unintentional random use of specific agents, and thereby stabilize antibiotic resistance (Burke 1998).

FORMULARIES AND RESISTANCE TO ANTIBIOTICS, A LOOMING PUBLIC HEALTH ISSUE

Jerome Shentag, PharmD, Director of the Pharmacokinetics Laboratory at the Millard Fillmore Health System (MFHS), Buffalo, New York, asserted that hospital formularies have contributed substantially to resistance by repeatedly exposing bacteria to the same antibiotic. The problem of antibiotic resistance is a major public health issue. By the year 2000, infections may be the third leading cause of death, following cardiovascular disease and cancer.

The costs to managed care organizations of this self-induced problem of antibiotic resistance could be enormous for capitated provider organizations, Shentag said. Resistance to antibiotics accounts for 10 percent of overall treatment cost throughout MFHS, he estimated. “Formularies were created to save money and they are unnecessarily costing us millions of dollars a year,” he said (Genesis Report 1996).
Hospital Physicians Fight Formulary’s Antibiotic Restrictions

Nickman et al. reported that the urologists in their 575-bed facility, United Hospitals, Inc., of St. Paul, refused to comply with hospital-wide antibiotic restrictions agreed upon by the P&T and surgery committees. The surgery committee was reluctant to instruct the urologists to change their use of antibiotics and recommended instead that the urologists be exempted. “The P&T committee did not totally agree with this recommendation, but approved it anyway” (Nickman et al. 1984).

At Northwest Texas Hospital in Amarillo, the substitution of cefuroxime for cefamandole met with unexpected resistance from one sector of the medical staff. “Physicians in the department of surgery would not propose or support a change to cefuroxime use for surgical prophylaxis. They maintained that cefamandole was superior to cefuroxime for surgical prophylaxis. Most of the studies documenting the use of cefuroxime were conducted in Europe rather than in the United States, and they maintained that in their clinical experience, cefamandole was a superior agent.” The proposal was tabled, to be reviewed at subsequent meetings (Dzierba et al. 1986).

Hospital Pharmacists and Physicians Disagree Over Antibiotic Restrictions

Based on their survey of hospital pharmacists, Johnson and Jeffrey, a drug information specialist and a director of pharmacy services, have questioned the wisdom of restricting drugs in spite of doctors’ objections: “Beginning, or continuing efforts to restrict the number of cephalosporins on a hospital formulary may not be worth the attendant aggravation and hostility engendered…. We can sympathize with one of our correspondents who wrote: ‘One of the worst experiences we’ve ever had was when we tried to delete a cephalosporin from our formulary’” (Johnson and Jeffrey 1981).

Thorough Evaluation of Formulary Candidates Helps Tailor Antibiotic Drug Use

Thorough evaluations of pharmaceutical products by hospitals and social service programs ideally would identify marginally effective drugs, as well as inferior versions of established drugs. Researchers at the Zablocki VA Medical Center in Milwaukee, Wisconsin, tested 549 isolates of gram-negative organisms present in their institution for susceptibility to 17 antimicrobial drugs and compared the results with published reports of the sensitivity of those organisms to the agents. Seven of the drugs exerted unexpectedly suboptimal activity against institutional pathogens. In 34 of 77 drug-organism pairs tested, the cumulative susceptibility seen in actual testing differed by more than 10 percent from published values. The authors suggested using institution-specific in vitro testing as one criterion for formulary inclusion. “Clinical efficacy studies, pharmacokinetic features, potential synergistic activity with other agents, toxicity, and cost factors pertaining to each drug deserve strong consideration in the evaluation process. However, in vitro testing is a very useful and objective
means by which to identify and clarify one component of local needs, and it should receive appropriate attention” (Franson et al. 1987).

**Hospital’s Data-based Guidelines Cut Antibiotics Costs, Adverse Effects, Mortality**

After the Latter Day Saints (LDS) Hospital in Salt Lake City implemented a “flexible, patient-specific, clinician-friendly, and data-intensive program” in 1988, adverse drug events and mortality declined, Burke and Pestotnik reported. In addition, expenditures for antibiotics decreased from 25 percent of total pharmacy costs in 1988 to 13 percent in 1994, although the number of patients receiving antibiotics went up from 32 percent to 53 percent. “Trend analysis showed that antimicrobial resistance patterns have been stable, possibly as a result of improved use of antibiotics with an unrestricted drug formulary that encouraged a random use,” the authors said. Conversely, they believe that restrictions and controls on antibiotic use could increase resistance (Burke and Pestotnik 1996).

**Antibiotics Formularies May Result in Cost Shifting, Not Cost Savings**

A survey of 88 U.S. and Canadian hospitals found that formulary changes within a class of antimicrobial agents, such as from one third-generation cephalosporin to another, seldom produced significant reductions in the hospitals’ total antimicrobial expenditures between 1993 and 1994. Although intended to save costs, the changes instead often resulted in the use of more expensive antimicrobials from other classes. In some cases, equally expensive antibiotics replaced restricted drugs. Sometimes the formulary changes increased the use of combinations of less expensive agents, the total cost of which “might easily exceed the cost of the single agents that were targeted for restriction,” the authors said. Replacement of a high-priced drug with a less expensive agent in the same class lowered expenditures for that particular category but did not alter total antimicrobial expenditures.

In contrast to the surveyed hospitals, the authors’ own institution, the Millard Fillmore Health System hospital in Buffalo achieved substantial overall savings in antimicrobial expenditures by using a wider array of agents at first and then modifying treatment based on culture and susceptibility test results (Rifenburg et al. 1996).

**Kidney Toxicity Rose Following Formulary Restrictions**

DeTorres and White’s 300-bed hospital achieved total savings of $42,000 over the course of three years after the P&T committee removed tobramycin from its formulary and restricted amikacin use. As a result, gentamicin use increased in place of the restricted drugs. But nephrotoxicity also rose from 0 percent in the first year of restricted prescribing to 4.5 percent in the second and 6.5 percent in the third. The authors noted that nephrotoxic effects “are almost always reversible,” but they did not speculate as to monetary and other costs that would accompany these adverse effects (DeTorres and White 1984).
Chapter VI.
Physician Authority Curtailed by Formularies

Introduction

Many physicians are concerned that restrictive formularies limit their control over what drugs their patients receive. For example, according to a 1989 Gallup survey, most doctors approve of the use of hospital formularies, which they see as being easy to override. But the survey showed that doctors are much less enthusiastic about HMO formularies where the plan administrators rather than the physicians tend to control formulary decisions. The respondents’ approval of HMO formularies also varied according to patient status and for certain classes of drugs.

Other studies have shown that physicians are increasingly protesting formulary restrictions, both in HMOs and in hospitals.

Many doctors also worry about possible adverse effects if their patients are given a drug other than the specific one prescribed. A 1996 survey of 200 doctors participating in TennCare, conducted by Yankelovich Partners, found that two-thirds of those who were required to switch their patients’ prescriptions reported that their patients often suffered serious consequences, including death or near death, strokes, gastrointestinal bleeding and drug interactions.

Citations

Following are summaries of articles that assess how physician authority may be restricted by formularies.

TENNESSEE PHYSICIANS SAY TENNCARE FORMULARIES COMPROMISE CARE

TennCare, which replaced Tennessee’s Medicaid program in 1994, provides medical care, including prescription services, to enrollees through 12 managed care organizations. A 1996 survey of 200 physicians participating in TennCare, conducted by Yankelovich Partners, questioned physicians about their experiences with TennCare’s restrictive drug formularies, established to minimize prescription drug costs. The survey was requested by the Tennessee Medical Association.

According to the survey, physicians participating in TennCare felt that the restrictive drug formularies prevented them from treating their patients effectively. Fully 98 percent of respondents said they couldn’t always prescribe the drugs of their choice because they were not included in the formularies and 95 percent said they had been advised to change a patient’s prescription because the drug was not covered.
These restrictions often have serious consequences. Two-thirds of the physicians who were forced to switch their patients’ prescriptions reported that many patients later suffered severe problems, including death or near death, strokes, gastrointestinal bleeding and drug interactions. Two of the most frequently cited problems were ineffective medications that exacerbated health conditions such as diabetes or congestive heart failure and continuation of symptoms. The doctors said that forcing patients to switch to covered drugs most often resulted in patient suffering and prolonged illness.

Drug side effects were another commonly mentioned problem reported by physicians. When patients were forced to switch drugs, the physicians reported, they frequently had such side effects as drug addiction, nausea, vomiting and ulcers—problems they did not experience when using the uncovered drugs.

Tennessee Medical Association President Robert Bowers, MD, summarized the survey findings in a press conference, stating that inability to prescribe doctors’ first choice of medicines is causing serious consequences for patients and is driving up the overall cost of TennCare (Yankelovich 1996).

**MOST DOCTORS SUPPORT FORMULARIES IN HOSPITALS BUT NOT IN HMOs**

A 1989 AMA-sponsored Gallup survey found that 78 percent of hospital physicians polled approve or strongly approve of their hospital’s use of a formulary. Two-thirds, however, said that their hospital’s formulary system is easy to override and that the pharmacist calls to check with the doctor before making any substitution.

But approval of the use of formularies was less widespread and enthusiastic among physicians who practiced in HMOs. In contrast to hospital formularies, which are almost always controlled by a pharmacy and therapeutics committee, HMO formularies appear to be controlled to a greater degree by HMO administrators. Some 22 percent of HMO physicians reported that their formulary is controlled by the administration, and 43 percent reported that physicians are “not very” or “not at all” involved in formulary decision-making. Only about one-third of HMO physicians reported that their HMO pharmacists routinely check with them before making substitutions. These results suggest that physician approval of the use of formularies corresponds to physicians’ perceived control over the final choice of what drug a patient will receive.

Physician approval of formulary use in HMOs also depends on the extent of physician reliance on HMO patients; the more patients derived from the HMO, the greater the approval (AMA 1989).
APPROVAL OF HMO FORMULARY VARIES BY PATIENT STATUS, DRUG CLASS

Opinion about which patients may be subjected to formulary regulations varies widely. The Gallup survey found that physicians were less likely to support formulary interference in the treatment of geriatric and pediatric patients and least likely to accept the formulary’s authority when treating patients with kidney disease (AMA 1989).

According to the survey, physicians’ approval of HMO formularies also varies by the class of drug prescribed (Figure 2). The majority of physicians disapproved of formulary intercession for four of eight drug classes specified in the survey. Physicians were least opposed to HMO formulary regulation of bronchodilators and orally administered antibiotics and most opposed to formulary rules for anti-hypertensives and anti-psychotics. In between, in descending order of acceptance, were injectable antibiotics, anti-diabetics, anti-arthritics and anti-depressants. These incremental differences in approval levels seem to suggest that doctors lack confidence in substitutes for their drugs of choice, especially for more vulnerable patients (AMA 1989).

Figure 2. Doctor Approval of Formularies in HMOs Depend on Drug Class

The length and direction of each bar indicate the net combined approval and disapproval responses.
DIFFERING PLAN FORMULARIES DIFFICULT TO MANAGE

Because their patients are enrolled in plans each with different formulary restrictions, physicians find it difficult to keep track of which drugs are covered for a given patient. For example, in Nashville, Tennessee, the angiotensin-converting enzyme (ACE) inhibitors listed by three health plans were captopril, quinapril and ramipril, but two listed benazepril and lisinopril while one included only fosinopril and another, only enalapril, according to a study by Stein et al.

The frequent revision of formularies makes the matching of drugs to formularies for a given patient even more difficult, the authors said. “The continuing instability of formularies is of great importance because formulary changes result in a large number of patients having to change medications.”

Formularies also cause inconveniences when a patient attempts to fill a nonformulary prescription and the pharmacist has to call the prescriber to discuss the appropriateness of alternate drugs. More importantly, the authors noted, these telephone discussions may pressure physicians to approve the use of drugs outside their “personal formularies” with which they may be less familiar and which may require dosage adjustment and monitoring (Stein et al. 1997).

MULTIPLE FORMULARIES CREATE PROBLEMS FOR PHARMACISTS, PHYSICIANS

William Bond, director of the Minnesota State Pharmaceutical Association, told the journal Drug Topics that the different formularies maintained by individual HMOs create problems for the retail pharmacist: “There is no question multiple formularies are extremely difficult to manage for health care providers generally and pharmacists specifically. Each HMO tends to generate its own formulary and that creates a tremendous information problem for pharmacists.” Not keeping up with this information means financial loss for the pharmacist, who will generally not be reimbursed for dispensing an unapproved item, but who may have to deal with 15 different HMO formularies. Bond also claimed that physicians who are not well informed about which drugs are on the approved list may simply pass the responsibility on to pharmacists. “They tend to defer to the pharmacists and say, ‘I don’t have my formulary book with me. Just follow the one that’s on the formulary,’” he said (Perrin 1989).
FORMULARY RESTRICTIONS MAY LIMIT ELDERLY’S ACCESS TO APPROPRIATE DRUGS

Restrictive formularies “discriminate against geriatric patients when they limit access to the most appropriate, individualized treatment,” according to a September 1997 position paper by the American Association for Geriatric Psychiatry (AAGP). The elderly’s biologic and psychological characteristics, which are different from younger people’s, may cause unexpected changes in the effects of drug treatment, the AAGP statement explained. In addition, limitations on choice may increase the risk of adverse reactions. The AAGP believes that restrictive formularies may prolong suffering, decrease social, occupational, emotional and physical functioning, increase morbidity and mortality, and raise costs to both patients and the community (American Association for Geriatric Psychiatry 1997).
Chapter VII.
The Use of Formularies by Hospitals and Other Providers

Introduction

Earlier chapters have focused on the increasing reliance of restrictive formularies by managed care organizations, other third-party payers and by state Medicaid programs. As the studies cited there indicate, drug formularies have often been associated with unexpected cost increases in other parts of the health care system and in overall health care spending. Research also shows that restrictions on prescription drugs have affected patients’ quality of care.

This chapter looks at the use of restrictive formularies in other health care settings, specifically within the Department of Veterans Affairs (VA) health care system and in hospitals. According to data compiled by the Pharmaceutical Research and Manufacturers of America (PhRMA), the limitations in the VA’s formulary are far stricter than those used by state Medicaid programs, thus giving veterans little or even no choice in certain drug categories.

According to Sloan’s 1995 survey of over 100 hospitals, the majority of hospitals have “very restrictive” formularies, with cost impact a prime factor in drug selection. Yet drug costs represent only a small part of total hospital expenditures, 2 to 8 percent of an institution’s budget, said Green (1986). Examining the effects of restrictive hospital formularies, several studies have found that strict limits on the availability of drugs may result in lower pharmacy costs, but may also lead to higher hospital costs overall. As Sloan et al. (1993) concluded, “across-the-board restrictions do not result in cost savings, although savings may be realized for particular drug categories.”

The use of formularies began in hospitals and then spread to ambulatory care settings and to other health care facilities. Studies by Soumerai et al. (1991 and 1994) demonstrated how restrictions on prescription drugs, in this case a monthly cap on the number of prescriptions a Medicaid patient could receive, can produce savings in drug spending but also increase expenditures for other health care services. In the first study the cap led to a significant decline in drug use along with a substantial rise in nursing home admissions. In the later study the restrictive policy resulted in lower drug utilization by patients with schizophrenia but considerably higher utilization of mental health care services.

Following are summaries of the major studies examining the use of formularies and other restrictions on prescription drugs in the VA system, hospitals and other settings.
The U.S. Department of Veterans Affairs (VA) implemented a national formulary in May 1997 (Department of Veterans Affairs 1997), to be used by all 12 Veterans Integrated Service Networks (VISNs) that provide health care services. As part of a continuing series of therapeutic category reviews, the VA has placed severe restrictions on six classes of medications within this formulary (Table 4). Only one brand name agent is available in each of four classes. For the other two classes, two of ten and two of five marketed brand name agents are available, respectively. This policy severely limits pharmaceutical choice among brand agents in these categories. The extent of restriction is much greater than in state Medicaid formularies. Only 13 states exclude drugs in at least one of these categories*, and no state restrictions are as severe as those in the VA formulary.

Each VISN is required to have a procedure for obtaining a non-formulary drug for those patients who experience side effects or fail to respond to the formulary product. Unlike Medicaid, the VA has no procedures such as approval process, response time for non-formulary requests or emergency supply while awaiting approval. The VA appears not to have

<table>
<thead>
<tr>
<th>Number of Products on Formulary by Class</th>
<th>ACE Inhibitors</th>
<th>Alpha Blockers</th>
<th>H$_2$ antagonists</th>
<th>Nitroglycerin Patches</th>
<th>Proton pump inhibitors</th>
<th>HMG-CoA reductase Inhibitors</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total in class</td>
<td>10</td>
<td>3</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>5</td>
</tr>
<tr>
<td>Median covered in 13 states with some restrictions*</td>
<td>10</td>
<td>3</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>5</td>
</tr>
<tr>
<td>Covered by VA formulary</td>
<td>2</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>2</td>
</tr>
</tbody>
</table>

ACE inhibitors are used to treat hypertension, congestive heart failure, post myocardial infarction, left ventricular dysfunction, and the treatment of diabetic nephropathy.

Alpha-blockers are used to treat hypertension and symptomatic benign prostatic hyperplasia.

H$_2$ antagonists are used in the treatment of ulcers.

Nitroglycerine patches are used to treat angina resulting from coronary artery disease.

Proton pump inhibitors are used to treat acid-related peptic disorders.

HMG-CoA reductase inhibitors aid in reducing cholesterol.

*CA, CO, HI, KY, MI, NE, NV, OH, OK, OR, PA, RI, WI

**Data compiled by PhRMA, based on analysis of state Medicaid data, DVA information, and data from First DataBank.
any plans to measure the impact of the restrictions in the six drug classes on treatment outcomes for this vulnerable group of patients (Pharmaceutical Research and Manufacturers of America 1998).

**Switch of SSRI Agents Led to Treatment Failure in Some VA Patients**

In 1992 the mental hygiene clinic of a Department of Veterans Affairs medical center switched 54 patients established on one SSRI (selective serotonin reuptake inhibitor) antidepressant to another SSRI agent, without a washout period. In 20 of the patients switched, clinicians judged the substitution unsuccessful due to intolerable side effects, interrupted treatment soon after the change and lack of efficacy.

Motivated by the desire to reduce costs, the chief of psychiatry and the pharmacy service staff agreed to the switch in the belief that the two agents were equally effective and that the interchange of equivalent dosages was not apt to cause negative clinical effects. But the dosage equivalence ratio they used, based on clinical studies, turned out to be inaccurate. There was also evidence that the abrupt switch led to acute drug interactions in some patients. In addition, drug acquisition costs did not decline substantially after the switch. After a review of these data, the decision was reversed, and the hospital formulary ended up including both drugs. “Interchange policies should be implemented cautiously and evaluated systematically,” the authors concluded (Stock and Kofoed 1994).

**Citations – Hospitals**

**Increase in Total Prescriptions Associated with Lower Hospital Spending**

Economist Frank Lichtenberg of the Columbia University Graduate School of Business analyzed the effect of changes in the quantity and type of pharmaceuticals prescribed in outpatient visits on rates of hospitalization, surgical procedures, mortality and related variables. This econometric analysis was performed on patient records for the period 1980-1992 across a range of diseases. The study showed that the number of hospital stays, inpatient days, and surgical procedures declined most rapidly for those diagnoses with the greatest increase in the total number of drugs prescribed and the greatest change in the kinds of drugs that became available through innovation during that time period. The estimates imply that an increase of 100 prescriptions is associated with 1.48 fewer hospital admissions, 16.3 fewer hospital days, and 3.36 fewer inpatient surgical procedures. A $1 increase in pharmaceutical expenditure is associated with a $3.65 reduction in hospital care expenditures, he concluded (Lichtenberg 1996).

**Restricting Anesthesia Drugs is a Poor Strategy for Management of Hospital Costs**

Analysis of treatment costs for 715 surgical inpatients at Stanford University Hospital revealed that total anesthesia costs accounted for only
5.6 percent of total procedure costs. An aggressive drug substitution program directed at the 10 most expensive anesthetic agents saved 23 percent of the anesthesia department’s drug budget, but this represented only a 0.7 percent decrease in total hospital costs. Although this could mean considerable dollar savings when multiplied by the thousands of surgical admissions annually in the U.S., the researchers calculated a far greater savings potential if cost containment were focused on operating room and hospital ward costs, which together accounted for 64 percent of the total cost of an inpatient surgical procedure. The authors concluded that rather than restricting anesthetic agents, supplies and equipment, greater cost savings may ensue through improved operating room efficiency and processes of care that shorten hospitalization (Macario et al. 1995).

Commenting on this study, Dr. Fredrick Orkin of Dartmouth Medical School said cost containment perspectives in anesthesia should not be limited to reducing costs of anesthetic drugs, “lest we become blind-sided to far greater cost savings opportunities.” In order to identify such opportunities one must consider the “entire surgical experience” (Orkin 1995).

SURVEY SHOWS SAVINGS IN HOSPITAL DRUG BUDGETS

A study of more than 500 hospitals across the country showed that hospitals using either closed formularies or therapeutic substitution spent 10.7 percent less on their pharmacy budget than did those hospitals using neither strategy. Hospitals employing both strategies had 13.4 percent lower pharmacy costs (Hazlet and Hu 1992).

CHANGE IN FORMULARY SAVED MONEY BUT INCURRED SOME LABOR COSTS

Michael Murray and associates at Wishard Memorial Hospital reported that deleting a fixed-ratio potassium-sparing diuretic from their formulary and converting more than 3,000 outpatients to another such agent resulted in an expected annual savings of almost $75,000. They cautioned, however, that “the first few weeks are particularly labor intensive for pharmacy staff because of the need to educate physicians with regard to the conversion process.” The authors estimated that the conversion campaign cost the hospital only $5,000 in labor, a cost that is only relevant for the initial conversion period (Murray et al. 1988).

ACROSS-THE-BOARD RESTRICTIONS DON’T LOWER COSTS

The impact of hospital formulary restrictions on costs varies by drug category, according to a study of Washington State hospitals by Sloan et al. The authors found that:

“Limiting the number of drugs in particular therapeutic categories reduced total charges incurred for gastrointestinal disease and asthma patients, increased total charges for cardiovascular disease patients, and had no effect on charges for infectious diseases patients. Restricting avail-
ability of drugs reduced pharmacy charges, but these savings tended to be offset by increases in other charges. Combining the categories, we found that restricting availability of drugs did not affect charges.”

While savings may be seen in particular drug categories, “across-the-board restrictions do not result in cost savings,” they concluded (Sloan et al 1993).

**FORMULARY SWITCH FROM PARENTERAL TO ORAL RX PRODUCED SAVINGS**

Pharmacists at Brigham and Women’s Hospital in Boston reported savings of $65,000 on H\textsubscript{2} receptor antagonists in the period from March 1988 through February 1989 after switching from the parenteral formulation of ranitidine to the oral formulation of famotidine. The pharmacy staff mounted an extensive educational effort, including newsletters and computer mailings, to explain the change in the drug formulary (Souney and Stoukides 1989).

**THOROUGHNESS OF HOSPITALS’ DRUG EVALUATIONS QUESTIONED**

When hospital pharmacy departments and drug information centers evaluate products for inclusion in the formulary, their reports typically may include comparative costs, advantages, disadvantages, therapeutic comparisons, drug interaction and adverse reaction information, and similarities to drugs already on the formulary. Administrators and pharmacy and therapeutics committees use this information in planning, in hopes of decreasing the number and cost of what are believed to be equivalent preparations. A study from the Medical College of Georgia, which examined drug evaluation reports from 80 hospital pharmacies or drug information centers (DICs), noted that none of the reports conformed completely to guidelines published by the American Society of Health-System Pharmacists. While most of the DIC or pharmacy-generated reports included more information than the manufacturer’s package insert, 20 percent of the reports actually provided less information than package inserts (Majercik et al. 1985).

**VALUE OF HOSPITAL FORMULARIES DEBATED**

When clinical pharmacist Jeffrey Green called the growing insistence upon restrictive formularies in hospitals a “con job” in his 1986 editorial (Green 1986), he spoke from experience; the editor of the *American Journal of Hospital Pharmacy* called Green’s editorial “a provocative piece of writing based on personal frustrations of trying to make a formulary system work” (Zellmer 1986). Green expressed skepticism about the value of a closed formulary as a cost-saving entity. “There has been a con job performed on institutional pharmacy; the culprits are the members of the profession itself, and the perpetuated deception is the formulary system. For at least 15 years, the powers who guide hospital pharmacy have pronounced, ‘thou shalt strive to maintain a formulary system.’”

“Given the negligible documentation of the success of [the formulary]
concept along with the variable inter-institutional definition of well-controlled, how can the profession promote widespread use of this system?” Green asked. “Therefore, with respect to formulary systems, institutional pharmacy is akin to the subjects of the fairy tale kingdom who stood in awe of their emperor’s beautiful new clothes,” he concluded (Green 1986).

**DRUG COSTS SMALL PART OF HOSPITAL BUDGET BUT INCITE CONTROVERSY**

Judging from some of the published remarks on the topic, debate over the institution of restricted formularies has become politicized and acrimonious. Green, a hospital pharmacist, stated: “The political risk-benefit ratio of enforcing a formulary system by whatever mechanism (therapeutic or generic product selection) can be high, given the fact that pharmaceutical expenditures represent only 2 to 8 percent of an institution’s total budget. Yet the emotional impact of this process on the medical staff may represent a concept of much greater magnitude and eventual ramifications,” he said (Green 1986).

**HOSPITAL’S RESTRICTIONS BROUGHT COST SHIFTS, NOT SAVINGS**

Pharmacy professor Elaine Green et al. reported that their 550-bed teaching hospital changed the formulary aminoglycoside from tobramycin to the less expensive gentamicin. The following year the cost of aminoglycoside prescribing decreased substantially; however, “most of these savings were offset by expenditures for third-generation cephalosporins” (Green et al. 1989).

**MOST HOSPITAL FORMULARIES ARE VERY RESTRICTIVE**

A 1995 survey of 103 hospitals revealed that the majority of hospitals self-rated their formulary policy as very restrictive. The degree of self-rated restrictiveness was unrelated to hospitals’ geographic location regarding penetration of managed care. Almost 90 percent of the hospitals did not generally stock non-formulary drugs and about three-fifths spent less than 5 percent of their drug budget on nonformulary products. About half of the hospitals monitored prescribers for excessive use of non-formulary drugs.

The vast majority of hospitals evaluated their formularies for ineffective or obsolete drugs, reviewed therapeutic categories with high risk or volume or expensive drugs, and considered the cost impact of drugs being considered for addition to the formulary. Most hospitals had also implemented some form of therapeutic interchange. At the time of the survey (1995), cost-effectiveness analysis was at most a minor tool in selecting drug products for the hospital formulary (Sloan et al. 1997).
Citations – Nursing Homes

Prescription Cap Results in Increased Nursing Home Admissions

Soumerai et al. (1991) studied the impact of the New Hampshire Medicaid policy of limiting to three the number of prescriptions Medicaid patients could receive per month. Like a formulary, this restriction was intended to reduce drug costs. The authors found that after the cap was instituted, drug usage declined by 35 percent, but there was at the same time a significant increase in the number of nursing home admissions. When the cap was later eliminated, the levels of drug use and nursing home admissions returned to normal. They concluded that “Limiting reimbursement for effective drugs puts frail, low-income, elderly patients at increased risk of institutionalization in nursing homes and may increase Medicaid costs” (Soumerai et al. 1991).

Citations – Mental Health Organizations

Cap on Prescriptions Tied to Rise in Mental Health Service Use

In a later study (1994) Soumerai et al. looked at the effects of the New Hampshire Medicaid prescription cap on patients with schizophrenia. As in the nursing home study, the restriction resulted in a significant decline in drug utilization among the patients in the study. But it also led to an increase in the use of community mental health centers, emergency mental health services and partial hospitalizations. Drug utilization and mental health services use reverted to their previous levels after the cap was eliminated. During the time of the cap, the increase in mental health services costs was 17 times higher than the savings in drug costs. The authors concluded: “Limits on coverage for the costs of prescription drugs can increase the use of acute mental health services among low-income patients with chronic mental illnesses and increase costs to the government, even aside from the increases caused in pain and suffering on the part of patients” (Soumerai et al. 1994).
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