Effects of Restrictive Formularies in the Ambulatory Care Setting

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Objective: To determine the consequences of restrictive formularies in the ambulatory care setting in 4 areas: overall drug expenditures, overall healthcare spending, changes in the quality of prescribing, and health outcomes.

Study Design: A MEDLINE search was conducted for English and French language articles, published between 1977-1999, that presented results in quantitative terms. Only articles from industrialized countries were used.

Methods: Information was extracted from each article in the following areas: time period of the study, geographic location and group of patients involved, outcome measurement(s), intervention, study design, and results.

Results: Poor methodologic quality made definitive conclusions difficult to draw in most areas. Prior authorization may be effective in controlling drug costs without increasing costs in other areas. Both desirable and undesirable therapeutic substitutions may take place when drugs are delisted from formularies.

Conclusions: The use of restrictive formularies in the ambulatory care setting requires more rigorous research. Before changes are made in formularies, money needs to be set aside for research into short-term and long-term consequences of using restrictive formularies.

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Rising drug costs are a reality in nearly all industrialized countries. In Canada, spending on pharmaceuticals increased from 0.6% of gross domestic product in 1980 to almost 1.2% in 1996.[1] A similar trend has been reported for the United States,[1] and the Health Care Financing Administration has projected a prescription drug spending increase of 11.2% between 1999 and 2001.[2] In an attempt to control costs in the outpatient sector, public and private payers have resorted to a number of measures, of which the most common is to use a restrictive formulary or cover only a limited range of drugs. Restrictive formularies are used in the public drug programs in all Canadian provinces, Australia, and New Zealand and in almost 50% of health maintenance organizations (HMOs) in the United States.[1]

Proponents justify restrictive formularies on the grounds of cost containment, whereas critics charge that such formularies curtail patient and prescriber choice and that any cost savings are illusory because this type of formulary increases physician visits, hospitalizations, and physicians' nonreimbursed administrative costs. This article presents the findings from a literature review of studies that addressed the effects of restrictive formularies on 4 specific areas of ambulatory healthcare—overall drug expenditure, overall healthcare spending, physicians' prescribing habits, and health outcomes. Policy implications of the findings are also discussed.

···METHODS···

English and French language reports of original studies on the effects of any form of formulary restriction in the ambulatory care setting were identified through a MEDLINE search (search terms: budgets, cost control, drug costs, drug utilization, formularies, health benefit plans, and prescription drugs). Only results obtained from research in countries belonging to the Organization for Economic Cooperation and Development were considered. Studies published from the start of 1977 to the end of 1999 were included, regardless of methodology. All included studies assessed actual changes in prescribing behavior, drug costs or utilization, overall

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Table. Synopsis of Studies on Effect of Restrictive Formularies

Author	Dates	Study Population	Measurement
Bloom and Jacobs[3]	1981-1983	West Virgina Medicaid recipients	Expenditures for peptic ulcers
Cromwell et al[4]	1989-1993	Florida Medicaid recipients	Outpatient anti-ulcer drug utilization and rate of hospitalization
Dranove[5]	1983, 1984	Illinois Medicaid recipients	Outpatient and drug expenditures
Ferrando et al[6]	1980-1984	Irish low-income population and General Medical Services patients (40% of population)	Drug utilization
Hefner[7]	1976, 1977	Louisiana Medicaid recipients	Change in expenditure for drug and nondrug products; incidence of specific diseases
Hefner[8]	1976, 1977	Louisiana and Texas Medicaid recipients	Change in expenditure for drug and nondrug products; incidence of specific diseases
Horn et al[9]	1992	Patients in 6 HMOs	Ambulatory care visits; hospital admissions; utilization of prescription drugs
Horn et al[10]	1992	Elderly (65+ years) and nonelderly (0-64 years) patients in 6 HMOs	Ambulatory care visits; hospital admissions; utilization of prescription drugs
Kotzan et al[11]	1989, 1990	Georgia Medicaid recipients	Drug costs; medical costs
Kotzan et al[12]	1989, 1990	Georgia Medicaid recipients	Drug costs; medical costs
Kozma et al[13]	1983-1985	South Carolina Medicaid recipients	Drug costs; physician costs; outpatient costs; hospitalization costs
Kreling et al[14]	1984, 1985	Wisconsin Medicaid recipients	Analgesic costs
Lingle et al[15]	1983-1985	South Carolina Medicaid recipients	Utilization of prescription services; physician visits; outpatient services; inpatient services
McCombs and Nichol[16]	1983-1988	California Medicaid recipients	Overall healthcare expenditures per episode of lower respiratory tract infection
Moore and Newman[17]	1983-1989	Medicaid recipients in states with restrictive formularies	Prescription drug and total program expenditures
Schweitzer et al[18]	1970-1980	Medicaid recipients in states with restrictive formularies	Prescription drug and total program expenditures
Smalley et al[19]	1988-1991	Tennessee Medicaid recipients	NSAID costs; total program expenditures
Smith and McKercher[20]	1981-1982	Michigan Medicaid recipients	Change in prescribing behavior; out-of-pocket payments
Smith and Simmons[21]	1973-1980	Medicaid recipients in states with restrictive formularies	Overall drug expenditures
Soumerai et al[22]	1980-1983	New Jersey Medicaid recipients	Overall drug expenditures; appropriateness of substitutions
Yule et al[23]	1984-1985	Residents of Grampian, Scotland	Change in cost per prescription; use of private prescriptions; over-the-counter purchases
Zechnich et al[24]	1992-1994	Oregon Medicaid recipients	Drug costs; substitution effects

NSAIDs = nonsteroidal anti-inflammatory drugs; NHS = National Health Service.

Event/Comparison	Design	Results
Imposition of restrictive formulary	Before-after; no control	↓78.9% pharmaceutical costs ↑3.1% physician payments ↑23.6% hospital costs
Restrictions on payment for anti-ulcer drugs	Time series; no control	↓33% number of doses of antiulcer drugs reimbursed No change in hospitalization rates for ulcer disease
Restrictive to open formulary for anti-infectives	Before-after; no control	↑ outpatient costs ↑drug costs
Imposition of limited list	Repeated measures; no control	Switch to drugs with higher ingredient costs
Elimination of selective drug categories from reimbursement	Before-after; no control	↓11.4% prescription expenditures ↑7.3% total program expenditures Adverse health outcomes
Elimination of selective drug categories from reimbursement	Before-after; controlled	↑$23.69 total health expenditure per Louisiana recipient ↑$4.08 per Texas recipient Adverse health outcomes in Louisiana recipients
Degree of restrictiveness of HMO formularies	Prospective; cross-sectional; after only	Increased utilization of healthcare resources correlated with restrictiveness of formulary
Degree of restrictiveness of HMO formularies	Prospective; cross-sectional; after only	Increased utilization of healthcare resources correlated with restrictiveness of formulary Associations often significantly greater for the elderly
Maintenance dosage program for H_2 antagonist products (prior authorization)	Time series; no control	↓$1.4 million in drug costs in 5 months ↔medical costs
Prior authorization for single-source NSAIDs	Time series; no control	↓$3 million in NSAID costs in 7 months ↑$0.19 million in analgesic costs in 7 months ↔medical costs
Restrictive to open formulary	Time series; no control	↑12.5% drug costs ↑17.7% physician costs ↑2.6% outpatient costs ↓8.6% hospitalization costs
Removal of propoxyphene napsylate products from formulary	Before-after; no control	↑0.23% analgesic costs
Switch from restrictive to open formulary	Time series; no control	↑use of prescription services, physician visits, and outpatient visits ↓inpatient services
Pharmacy-enforced treatment protocol for cefaclor	Time series; no control	↓$388 in overall costs per episode of lower respiratory tract infection after addition of cefaclor to formulary
Restrictive vs open formularies	Pooled cross-sectional time series; post only	↓14.8% drug expenditures ↑expenditures on physician services and inpatient mental healthcare ↔total program expenditures
Lag in approval of new drugs in states with restrictive formularies	Pooled cross-sectional; post only	Restrictiveness of formulary not associated with drug costs Total Medicaid expenditures lower in states with more restrictive formularies
Prior authorization for NSAIDs	Time series; no control	↓53% expenditures on NSAIDs, ↔total program expenditures
Delisting of less-than-effective drug products from formulary	Before-after; no control	46% of recipients discontinued therapy, 23% received other drugs still covered, 30% continued therapy at own expense
Restrictive vs open formulary	Pooled cross-sectional time series	Drug expenditures increased in some states with formulary restrictions but not in others
Delisting of less-than-effective drug products from formulary	Time series; no control	↔drug expenditures More as well as less desirable drugs substituted for ones removed
Delisting of drug products from NHS list	Before-after; no control	↓£0.66 per prescription ↑ private prescriptions and over-the-counter purchases
Delisting of over-the-counter products	Time series; no control	↓6.0% medication cost per eligible recipient per month Limited evidence of substitution of prescription drug products

healthcare costs or utilization, or changes in health status and expressed their results quantitatively. In the case of duplicate publication, the more comprehensive report was chosen. Studies that examined the effects of user fees or reference-based pricing were not included. Reviews were excluded from the analysis, but additional material was identified from reference lists in reviews and original studies.

The following information was extracted from each article: time period of the study, geographic location and group of patients involved, outcome measurement(s), intervention, study design, and results. No attempt was made to blind the studies and the information in all studies was abstracted by the same reviewer.

··· RESULTS ···

The search process identified 22 studies on restrictive formularies and their effect on drug and healthcare costs, prescribing patterns, and health outcomes.[3-24] The **Table** summarizes the findings from these studies.

Methodologic Limitations of the Studies

Most of the studies lacked methodologic rigor; many were before and after studies,[5,7,8,14,20] or cross-sectional analyses.[17,18,21] Only 1 study used a control group[8] and only 1 was prospective.[9,10]

All studies were performed in Medicaid populations, with the exception of 3,[6,9,10,23] and all were studies conducted in a single state, except for 3 that were multistate.[17,18,21] Studies from single states may suffer from at least 4 drawbacks. First, because Medicaid populations include a disproportionate number of the elderly and children, results cannot be generalized to the rest of the population. Second, the results would reflect not only the idiosyncrasies of formulary restrictions in a particular state, but also other policy changes in the state and other unspecified environmental factors, such as the state's medical inflation rate. Of note, none of the Medicaid studies provided details as to how the formularies were constructed. Third, the studies compared costs before and after a change in the formulary policy and attributed any changes in behavior or expenditure to differences in the formulary, ignoring any environmental changes that may have coincided with changes to the formulary. Finally, these studies focused only on the short-term effects of formulary restrictions and did not consider downstream effects such as changes in other healthcare expenditures, emergency department visits, and hospital admissions or changes in the quality of prescribing or in health outcomes.[25]

Effect of Formulary Restrictions on Overall Drug Expenditures

The effects of restrictive formularies on drug costs from the point of view of the payer (public-administered plans or private HMOs) varied considerably. Methodologic problems rendered any conclusions highly tentative. None of the studies were controlled and most employed a before-after design. One paper reported lower costs with a restrictive formulary, but this study was a pooled cross-sectional time-series study with only posttest results.[17] Two studies showed that a move from a restrictive to an open formulary led to higher drug costs, but neither was a controlled study.[5,13]

Schweitzer and coworkers[18] examined additions to restrictive formularies in 7 states and found no correlation between degree of restriction and drug costs; more restrictive formularies were not associated with lower drug costs. However, the strength of their conclusion was limited by their use of only posttest data. Similar conclusions were reached by Smith and Simmons[21] in their multistate study; these authors argued that states would be better off without restrictive formularies through avoiding administrative costs associated with formularies. Their conclusions, however, need to be interpreted with caution, as they were based on 14 statistically significant comparisons out of 624, of which approximately 30 would expectedly be statistically significant by chance alone.[26]

A prospective study by Horn of 6 HMOs across the United States found a correlation between formulary restrictiveness and drug cost increases, especially in the elderly.[9,10] Again, the conclusions were questionable because of weaknesses in methodology. The study provided only posttest data, with nonequivalent groups, and also failed to control for preexisting variability among the HMOs, which were geographically widespread; consequently, differences in medical care cost and utilization, member demographics, and compensation methods for physicians and other providers could have significantly influenced total medical care costs and utilization. Details of patient selection were not provided.[27]

Three studies reported that delisting both prescription and nonprescription drugs from formularies[7,23,24] resulted in lower drug costs, but 2 others found that drug costs actually increased because of

a switch to drugs with higher ingredient costs.[6,14] In some cases, a decrease in drug costs was probably at the expense of shifting costs to individuals.[20,23] None of these studies was controlled, and all employed a before-after design. In a time-series analysis, Soumerai et al found no overall change in drug costs to New Jersey's Medicaid plan when they examined the consequences of stopping payment for ineffective products in the plan formulary.[22]

Prior authorization is a cost-control policy that restricts the use of services by requiring pharmacies to obtain advance approval before dispensing certain drugs, usually effective drugs for which there are less costly therapeutic alternatives. Three studies looked at the effects of prior authorization, and although none of the studies was controlled, all used a time-series analysis and showed that Medicaid drug costs declined in all cases.[11,12,19] The Florida decision to impose limitations on the use of antiulcer medications can also be considered a variation on prior authorization. In this instance, Medicaid prescribing costs decreased initially, but after 1 year, utilization and reimbursement were noted to be rebounding to prepolicy levels.[4]

Effect of Formulary Limitations on Spending in Other Healthcare Sectors

All studies of the effects of formulary restriction on other healthcare spending were performed in Medicaid recipients and all, except for 3 studies,[8,17,18] were performed in single states in the United States. Only 1 study from Hefner et al,[8] in Louisiana and Texas Medicaid recipients, was controlled.

Studies by Hefner et al found that delisting drugs from formularies increased total Medicaid spending.[7,8] Whether there was a cause and effect is doubtful because changes in health outcomes could not be ascribed to the drugs delisted (see below). Similarly, Moore and Newman observed that restrictive formularies increased Medicaid expenditures for physician services and inpatient mental healthcare.[17] Using data from the Medicaid programs in 47 states, these investigators claimed that any savings from restrictive formularies were offset by increases in other healthcare expenditures. However, their analysis had serious weaknesses. As noted by Soumerai et al,[26] the study was based largely on posttest, cross-sectional regression analysis of 4 years of aggregate Medicaid expenditures. No adjustments were made for preexisting differences in Medicaid program characteristics between formulary and nonformulary states. The analysis also did not include enough time points to adequately adjust for differences in previous trends in expenditures among states with and without formularies.

The findings of Moore and Newman were contradicted by the results of Schweitzer and colleagues who demonstrated that total spending was actually lower in states with more restrictive formularies.[18] Again, apart from weak methodology, there were confounding effects of other cost-containing measures in states with lower Medicaid expenditures.

Prior authorization programs[11,12,19] and pharmacy-enforced treatment protocols[16] did not lead to overall increases in healthcare spending. Open formularies usually translated into higher outpatient costs[5,13,15] and lower inpatient costs.[15]

Physician Prescribing Patterns After Removal of Drugs from a Formulary

Soumerai et al[22] examined the choices made by physicians when substituting for drugs removed from formularies. In January 1982, New Jersey stopped Medicaid payment for 12 categories of drugs found to be of low effectiveness by panels from the National Academy of Sciences/National Research Council. In some cases, physicians responded by substituting products that represented a probable improvement in therapy, whereas in other instances, the substituted drugs were just as inappropriate as the original medications. An example of a therapeutic improvement was the switching of patients who were receiving a bronchodilator-sedative combination to nonsedative-containing theophylline preparations. An inappropriate substitution was the use of drugs such as papaverine and ergoloid mesylates in place of peripheral and cerebral vasodilators.

When over-the-counter products were delisted from the Oregon Medicaid formulary, physicians did not respond by prescribing prescription-only products,[24] possibly indicating that physicians felt that most of the delisted OTC items were not medically essential.

Effect of Formulary Restrictions on Health Outcomes

Studies that have directly or indirectly examined the impact of restricted formularies on healthcare outcomes all show a deleterious effect on health as a result of restrictive formularies.[7-10]

The study by Horn and colleagues assessed emergency department visits and hospital admissions for patients with 5 conditions (arthritis, asthma, epigastric pain/ulcer, hypertension, or otitis media) in 6 HMOs in 6 states and graded the formularies in these HMOs.[9] For all conditions except otitis media, formu-

lary limitations on drug availability were significantly related to higher rates of emergency department visits and hospitalization, which suggested that the more restrictive the formulary, the poorer was the health outcome. In addition, these changes were more significant for the elderly (65 years and older) than the nonelderly (younger than 65).[10] The limitations of this paper were discussed earlier.

Hefner reported 2 studies that examined outcomes directly.[7,8] The first study was an uncontrolled assessment of health outcomes when Louisiana delisted a group of drugs from its formulary.[7] The 3 disease categories thought to be most affected by the products removed from the formulary exhibited a significant increase in reporting on submitted claims during the period following implementation of the restricted formulary. The second paper compared health outcomes in Louisiana with those in Texas, which had an open formulary, and found poorer health outcomes in Louisiana.[8] However, 80% of the patients in this study had diagnoses that were not treated with the delisted drugs (cough/cold preparations, minor tranquilizers, multiple-ingredient anti-anemia preparations, and certain gastrointestinal drugs, vitamins or vitamin-containing products, enzymes, and anorexics). Because of the discrepancy between the formulary changes and the medical problems of the population sample, it is unlikely that the former contributed to the observed increase in hospital days among the Louisiana elderly. Furthermore, Hefner did not control for diagnosis, other relevant medical history, or time trend, all of which were factors that could have accounted for the reported changes in health outcomes.

In the previously mentioned study of Florida Medicaid recipients, restricting the use of ulcer medications to medically justifiable indications did not lead to any increase in hospitalizations for ulcers or their complications.[4] However, the authors had no data on ambulatory healthcare claims and could not rule out the possibility that the restrictive policy led to increased use of ambulatory healthcare services for ulcer-related disorders.

··· DISCUSSION ···

The quality of the literature on the effect of restrictive formularies on ambulatory healthcare is generally poor and hence limits the ability to draw any definitive conclusions in most areas.[25-28] There are no convincing data that restrictive formularies limit drug costs, nor that open formularies increase drug costs. The effects of delisting drugs from formularies is also not clear. The study by Soumerai et al,[22] with the strongest methodology, showed that when drugs are delisted, other products are substituted, the costs of which determine whether payers will realize any savings. Such a move may actually lead to a cost increase, as demonstrated by the experience in Ireland.[6]

A decrease in drug costs in the public sector as a result of delisting drugs may simply represent a transfer of costs to individuals. Patients may elect to pay the costs of prescription medications out of pocket or may replace withdrawn drugs with over-the-counter purchases. Whether patients follow the latter course of action is currently not known. Research performed in the United. Kingdom is contradictory on this point[29,30]; however, in a study of Michigan Medicaid recipients, Smith and McKercher reported that 30% of their sample continued drug therapy at their own expense, with at least some of these purchases being nonprescription items.[20]

A substitution effect could have serious negative economic consequences for the lowest-income population. Lexchin analyzed out-of-pocket expenses for drugs in low- and high-income populations for the period 1964 to 1990.[31] He showed that per capita spending, as percentage of total family expenditure, in the low-income group was 7 times that in the high-income group and that in absolute dollars, the low-income group was spending more than the high-income group.

Prior-authorization plans seem to have some success in slowing cost increases for certain drug categories. However, this approach has been reported for only 2 classes of drugs—nonsteroidal anti-inflammatory drugs and H_2 antagonists—and none of the studies have documented the administrative costs associated with a prior-authorization program.

The experience in Canada with a form of prior authorization has not been as positive as in the United States. Some drugs in the Ontario formulary fall into the limited-use category. To prescribe drugs in this class, physicians must fill out forms documenting the need for these drugs, which patients then present to their pharmacist. A 1996 review by the Ontario Auditor General of the management of this category for drugs dispensed between January and June 1995, showed that expenditures for limited-use drugs totaled $38 million.[32] Thirteen percent of claims had "other" as a reason for the product being prescribed and an additional 21% ($6.6 million) of claims had a reason for use that did not apply for the drug dispensed. (The Ministry has now elimi-

nated the "other" category and modified the forms that doctors must complete.)

Prior-authorization programs do not seem to increase overall healthcare costs, but whether this conclusion applies to restrictive formularies in general is unknown. Similarly, no conclusions can be made about the health effects of restrictive formularies. In both cases the evidence is mixed and its quality lacks methodologic rigor.

Changes in prescribing patterns ensuing from delisting drugs from formularies can be either positive or negative, as demonstrated by Soumerai et al.[22] A survey of Ontario physicians after the delisting of over-the-counter and extended-dosage form drugs, such as all the antihistamines, from the provincial formulary found that physicians intended to substitute products remaining on the formulary for the deleted ones.[33] Whether these substitutions were therapeutically appropriate and whether delisting an entire group of products such as antihistamines can lead to unintended consequences remain unknown issues.

Many important areas of formulary management remain unexamined. The process by which drugs are selected and rejected for ambulatory care formularies has not been studied, and the impact of formulary restrictions that target clinically and economically important groups of drugs such as antipsychotic agents, oral hypoglycemics, and antidepressants remains a question.[26] A study of the Saskatchewan drug plan found the economic rationale for delisting some types of drugs to be questionable.[34] This plan proposed to remove several second-line antibiotics from its formulary for reasons of potential overuse and expense, but potential savings from such a move were very limited because the drugs were used in only 5% of all initial courses of therapy. By contrast, there is evidence that the majority of drugs excluded from Medicaid formularies in the United States offer questionable or no additional therapeutic benefit compared with listed drugs.[35] Finally, no study to date has examined the administrative cost burden to physicians and pharmacists as a result of restrictive formularies or changes in the status of drugs on formularies.

This review has a number of limitations. The search methods may have missed literature published in the social science field or unpublished studies. However, unless the missing literature is extensive and of high methodologic quality, the conclusions of this review are unlikely to change. The data from articles included in this review were abstracted by a single individual, which may have introduced unintended biases that could have affected the analysis. This, however, is unlikely because the conclusions from this review are similar to those from other analyses.[26,36]

Policy Recommendations

Before policy changes are made to public drug plans, plan administrators and relevant government departments should obtain independent policy advice from researchers. Physician and patient education must be included in future policy changes to prevent changes in drug prescribing that could result in inappropriate treatment decisions or lead to undue economic hardship on beneficiaries of formularies.

As part of any policy change, funds should be earmarked for research into the effects of changes such as delisting drugs. Studies should focus on downstream effects and should specifically target vulnerable subsectors of the population served by the plans, such as the frail elderly and social welfare recipients receiving multiple chronic medications. Research should examine not only short-term effects but also long-term consequences on quality of prescribing, spending in other areas of healthcare such as physicians and hospitals, and administrative costs to both payers and healthcare professionals such as doctors and pharmacists.

Currently existing formularies should be examined to determine whether there are cost-effective drugs that are not being covered. Policies such as prior approval and other restrictions on the use of listed drugs must be reevaluated to ascertain that such drugs are appropriately restricted to patients with a true medical need, but on the other hand, also ensure that patients are not denied necessary treatment.

With the alarmingly high cost of treatment for certain diseases, public and private payers will be confronted with increasingly difficult decisions regarding adoption of restrictive formularies and their composition. Because of the far-reaching impact of restrictive formularies on healthcare costs and outcomes, it is imperative that policy decisions be based on rigorous research. This article shows that current research suffers from several weaknesses and does not provide a quality evidence base to allow informed choices to be made.

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