Intended and Unintended Consequences of HMO Cost-Containment Strategies: Results from the Managed Care Outcomes Project

Susan D. Horn, PhD; Phoebe D. Sharkey, PhD; Diane M. Tracy, PhD; Corinne E. Horn; Blair James; and Frederick Goodwin, MD

Managed Care Outcomes Project: Study Design, Baseline Patient Characteristics, and Outcome Measures

Susan D. Horn, PhD; Phoebe D. Sharkey, PhD; and Julie Gassaway, RN, MS
Intended and Unintended Consequences of HMO Cost-Containment Strategies: Results from the Managed Care Outcomes Project

Susan D. Horn, PhD; Phoebe D. Sharkey, PhD; Diane M. Tracy, PhD; Corinne E. Horn; Blair James; and Frederick Goodwin, MD

Abstract
The objective of the Managed Care Outcomes Project was to examine the relationship of various health maintenance organization cost-containment strategies with the utilization of ambulatory care visits, hospital admissions, and prescription drugs. In this longitudinal, prospective study, we compared utilization of ambulatory services for patients having at least one of five diseases (arthritis, asthma, epigastric pain-ulcer, hypertension, and otitis media) in HMO settings with various levels of cost-control measures, including visit copayment and limitations on drugs to treat these diseases. We used multivariate regression to control for other variables, including severity of illness, provider count, age, gender, and time in the study. The study setting was six health maintenance organizations in six states (three in the eastern United States; three in the western United States). Between 1,309 and 3,938 patients were available for analysis for each disease studied. A total of 12,997 patients were assessed for severity of illness at every encounter for 1 year, accounting for more than 99,000 office visits, 480 emergency department visits, 1,000 hospitalizations, and 240,000 prescriptions. This was a prospective observational study. Outcome measures were prescription count, prescription cost, office visit count, emergency department visit count, and hospital admissions. The study found healthcare utilization to be strongly associated with severity of illness; all analyses took this finding into account. For all conditions except otitis media, formulary limitations on drug availability were significantly positively related to higher rates of emergency department visits and hospital admissions and positively, but not always significantly, related to drug cost, drug count, and office visits. Ratios of utilization between the site with the unrestricted formulary and the one with the most restricted formulary for a disease ranged up to more than twice as great. Use of multisource drugs was strongly positively related with drug use for all conditions but was less consistently related to visit frequency, emergency department visits, or hospital admissions. Stricter second-opinion requirements, salaried physicians, and strictness of case management had mixed, mostly nonsignificant associations with drug and other resource utilization. Visit copayment was not associated with lower drug utilization but was mixed in its association with office visits, emergency department visits, and hospitalizations. As expected, "strictness of gatekeeper" was associated with lower drug utilization, emergency department visits, and hospitalizations and had a mixed effect on office visits. In this study, we found some expected and some unexpected associations of common health maintenance organization cost-containment practices with utilization of healthcare services. In the case of limited formularies, we found the unintended consequence of increased utilization of healthcare resources. 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.

(Am J Man Care 1996;2:253-264)
information on the impact of cost-containment initiatives by managed care organizations and insurers. Most of this research has focused on a single component of healthcare, that which the intervention was intended to affect. Some investigations, recognizing that unintended utilization effects may occur in other components of healthcare, have taken a more global approach to analyses of the impact of interventions on healthcare utilization. This study builds on the latter approach by incorporating patient-level data from six managed care organizations into a single analysis and controlling for the influence of patient characteristics and disease severity.

Great care must be taken to examine the total patient-care picture when seeking effective cost-control practices. Individual medical services and costs are part of an interrelated system and must be viewed as such; changes in one area may be reflected in utilization changes in other areas. This integrated approach to assessing healthcare utilization includes development of a comprehensive database linking patient characteristics, disease characteristics, medical processes, outcomes, and costs in order to examine all the factors that influence utilization simultaneously.

The Rand Health Insurance Experiment (HIE) comprehensively examined the impact of cost-sharing, including copayments and deductibles. The HIE was a large-scale, randomized, controlled trial of alternative forms of healthcare financing that investigated the effect of cost-sharing on the use of outpatient medical care. Cost-sharing both reduced the probability of any medical contact during the year across a wide spectrum of ambulatory care diagnoses and was associated with fewer visits and a lower utilization of tests and medications. Moreover, free care reduced the severity of hypertension. In a study by Anderson et al, cost-sharing reduced the use of outpatient services by pediatric patients. These researchers found cost-sharing had a significant impact on three measures of utilization: (1) the probability of having at least one episode of care; (2) the total number of episodes of care; and (3) total charges for professional services. Because all our study sites made use of visit and drug copayments, we expected that the copayment level would be an important determinant of utilization at the sites.

Increases in the cost of drug therapy have led to scrutiny of the clinical and economic outcomes of prescribing; in many practice settings, management techniques designed to lower drug costs have reduced physicians' prescribing autonomy. Restrictive formularies, required use of multisource (generic) drugs, drug-category exclusions, and cost-sharing by patients are a few of the strategies designed to achieve pharmaceutical cost containment. Many health maintenance organizations (HMOs) have established limited formularies (ie, lists of pharmaceutical agents that are eligible for reimbursement) and often require prior authorization for nonlisted drugs or therapeutic substitution of a listed agent when a nonlisted drug has been prescribed. Sloan et al suggest that the rationale for formularies is based on three potential sources of cost reductions: (1) purchasing drugs at discounted prices; (2) substitution of clinically similar, less-expensive drugs; and (3) reductions in inventories. In addition, many HMOs offer financial incentives to both pharmacists and enrollees to use multisource rather than sole-source products.

The findings of several studies of the impact of pharmaceutical cost-containment strategies have been mixed, regardless of whether the outcome was utilization or costs of drugs or other medical resources. These inconclusive findings may have been due to limitations in the analyses. The analyses were performed at the aggregate, rather than the patient, level; measured only an isolated portion of healthcare costs (eg, drug costs); did not assess health outcomes; did not control for the severity of the patients' illnesses; or used only a binary representation for the presence of a formulary. We attempted to address these limitations in our study design.

Ownership status of an HMO theoretically is associated with productivity of the organization. The role of profit incentives in the delivery of healthcare has been studied carefully. The research has assumed that the incentives to maximize profits are less strong in not-for-profit organizations serving multiple constituencies and attempting to balance multiple goals than they are in for-profit HMOs. Some of these goals (ie, community service, charity care, and enhanced quality) may not always be consistent with an organizational strategy to maximize profit. Because managers in both for-profit and not-for-profit firms may pursue objectives that affect utilization and efficiency, we controlled for ownership status in all of our models.

The Managed Care Outcomes Project (MCOP) is a multisite study that examined healthcare utilization by patients at six HMO sites and that assessed clinical changes by measuring levels of patients' physiologic and psychosocial severity at each visit. The six sites varied in cost-containment policies and ownership status. The purpose of the study was to understand clearly the association of these factors with healthcare service utilization.
Managed Care Outcomes Project

The MCOP was a longitudinal prospective study that examined variations in clinical and resource-use outcome measures among HMO patients over a 1-year period. We present a detailed description of the study design and various baseline statistics and correlations among the variables in a paper that appears in this journal.24

Study Sites

Six HMO sites participated in the MCOP study: three in the eastern United States (New England, Mid-Atlantic, and South Atlantic regions) and three in the western part of the country (one in the Mountain and two in the Southwest regions). Three were for-profit; three were not-for-profit. Enrollments ranged from about 32,000 to 310,000 members.

Formulary limitation varied from no formulary in one site (0% limitation) to a site in which only 24% of the drugs available in the US that are indicated (FDA approved) for the treatment of asthma (ie, 22 of 92 possible asthma drugs) were on the formulary. Other cost-containment/management techniques included various visit copayment amounts (from $2 to $10 per visit); various levels of gatekeeper strictness, case management, and requirements for a second opinion; and various physician-reimbursement methods (Table 1).25

Site Formulary Information

The director of pharmacy and individual medical specialists at each site were surveyed to obtain specific information about formulary content, the latitude given physicians to prescribe formulary versus nonformulary drugs, and other organizational practice patterns. At all sites, reimbursement for nonformulary drugs was authorized only after approval of the prescribing physician's requests to the pharmacy (prior authorization). Because physician compliance in prescribing formulary drugs was very high (95%), the identity of formulary drugs closely corresponded to the identity of drugs dispensed.

Drug-Utilization Information

All information on patient drug utilization was obtained from computerized pharmacy claims records. Variables in the pharmacy claims database included name, dose, and amount of drug dispensed; number of days' supply; date prescription was filled; therapeutic category; National Drug Code numbers; copayment amount; and whether a drug was a multisource (generic) drug. Although we could not obtain data on out-of-plan drug use, all the sites informed us that they believed such use was minimal because drugs were a covered benefit for all study enrollees. Nonprescription-drug costs were not covered by any of the study sites.

Data on drug claims at site 2 could not be matched with the patient-visit data. This site therefore was dropped from analyses of drug counts and costs. It was included in analyses of number of office and emergency department (ED) visits and hospitalizations.

Study Diseases

Five diseases that often require pharmaceutical-intensive treatment and that typically are managed on an outpatient basis were studied at each site. They were selected by the participating HMOs. Selection criteria were their high prevalence and variation among patients in disease severity, number of office visits, and drug utilization. The five disease groups (with ICD-9-CM codes in parentheses) were: (1) otitis media (381.00-382.9); (2) arthralgia of joint or arthritis (710.0-710.9, 711.1-716.9, 720.0-720.9, 721.0-721.6, 721.8-721.9, 724.1-724.2, 724.5); (3) epigastric pain or ulcers (530.0-530.3, 530.5-530.6, 531.0-535.6, 536.0-536.9, 537.81, 787.0-787.3); (4) hypertension (401.0-401.9); (5) and asthma (493.0-493.9). A disease group was assigned to each patient on the basis of the study disease for which the largest number of that

<table>
<thead>
<tr>
<th>Site</th>
<th>Formulary Limitation Rank</th>
<th>Visit Copayment</th>
<th>Gatekeeper</th>
<th>Case Management</th>
<th>Second Opinion</th>
<th>Physician Affiliation</th>
<th>For Profit/Not for Profit</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td>6</td>
<td>$5.00 (2.5)</td>
<td>Strict (5)</td>
<td>Loose (1)</td>
<td>None (2)</td>
<td>Salaried</td>
<td>+</td>
</tr>
<tr>
<td>5</td>
<td>5</td>
<td>$5.00 (2.5)</td>
<td>Moderate (2)</td>
<td>Medium (3.5)</td>
<td>None (2)</td>
<td>Salaried</td>
<td>-</td>
</tr>
<tr>
<td>2</td>
<td>4</td>
<td>$8.50 (4)</td>
<td>Moderate (2)</td>
<td>Medium (3.5)</td>
<td>Moderate (5.5)</td>
<td>Contracted</td>
<td>+</td>
</tr>
<tr>
<td>6</td>
<td>3</td>
<td>$10.00 (5.5)</td>
<td>Strict (5)</td>
<td>Medium (3.5)</td>
<td>None (2)</td>
<td>Contracted</td>
<td>+</td>
</tr>
<tr>
<td>1</td>
<td>2</td>
<td>$2.00 (1)</td>
<td>Strict (5)</td>
<td>Strict (6)</td>
<td>Loose (4)</td>
<td>Salaried</td>
<td>-</td>
</tr>
<tr>
<td>4</td>
<td>1</td>
<td>$10.00 (3.5)</td>
<td>Moderate (2)</td>
<td>Medium (3.5)</td>
<td>Moderate (5.5)</td>
<td>Contracted</td>
<td>-</td>
</tr>
</tbody>
</table>

Data on organization characteristics are found in reference 25.
The sites are listed in order of formulary limitation, from most limited (rank 6) to least limited (no formulary) (rank 1). Ranks are given in parentheses.
patient's visits occurred during the year, taking into account all the diagnosis codes at each visit.

**Study Population**

Patients became eligible for the study if they had an ambulatory visit for any one of the five study diseases during a 4-month enrollment period. All patients meeting the eligibility requirement were accepted. Patient healthcare utilization was followed up for the remainder of the 12-month data collection period (approximately calendar year 1992). Three percent of patients dropped out before the end of the study.

For each disease studied, from 1,309 to 3,938 patients were available for analysis across the six HMOs, for a total of 12,997 patients across all five diseases. These patients accounted for more than 99,000 office visits, 480 ED visits, 1,000 hospital admissions, and 240,000 prescriptions during the year. Further description of the HMOs and their patients is presented elsewhere in this journal.24

**Variables**

The primary hypothesis of the study was that specified cost-containment strategies would be associated with healthcare utilization measures that were directly or indirectly related to cost. The healthcare utilization (dependent) variables were number of outpatient office visits, number of ED visits, number of hospital admissions, total prescription count, disease-group prescription count, total prescription cost, and disease-group prescription cost; the cost-containment (independent) variables were level of formulary limitation, extent of multisource-drug use, copayment for visits and/or drugs, strictness of gatekeeper, intensity of case management, and second-opinion requirements. In addition, in the analyses, it was necessary to control for two types of potential confounding independent variables: (1) patient characteristics—severity of illness, demographics, number of providers seen, and time in study; and (2) HMO characteristics—physician affiliation (salaried or contracted), ownership status (for profit or not for profit), and geographic location.

**Dependent Variables.** Visit Count per Patient per Year represents total visits during the study period for all reasons, not just visits for the disease group assigned to that patient. Emergency Department Visits per Patient per Year are the total number of ED visits for all reasons. Hospital Admissions per Patient per Year represents the total number of admissions during the study period for all reasons.

**Prescription Count per Patient per Year (script count)** is the number of prescriptions filled by a given patient over the course of the study period and includes new and refilled prescriptions. Every study site had a 30-day supply limit on prescriptions. Antibiotics, which usually are prescribed in 7- to 10-day courses, were the only drugs for the study diseases that were not normally prescribed in 30-day regimens. The same drug dispensed n times during the year counted as n prescriptions. Two methods were used to analyze prescription count: (1) prescription count for all drugs; and (2) prescription count specifically for the study-disease drugs.

**Prescription Cost per Patient per Year (script cost)** was determined by assigning the cost on the 1992 Average Wholesale Price (AWP) list to each prescription. We used the AWP because four of the study sites were forbidden by their contracts to reveal whether they received discounts from pharmaceutical manufacturers. Although usually not the actual price paid, the AWP nevertheless is valid as a relative value unit that allows comparisons of weighted drug costs across sites. Prescription cost was analyzed in two ways: (1) for all prescriptions; and (2) for prescriptions specific to the study disease.

**Independent Variables.** All variables with the exception of formulary limitation and HMO site characteristics were defined at the patient level.

To define the variable Formulary Limitation, we obtained written formulary lists for 1991 and 1992 from each HMO. Two years of lists permitted determination of the extent of any changes in the lists. The few changes that occurred usually were within a drug category (i.e., one drug was added and another was removed). However, because more drugs were added in 1992 than were removed, there was slightly greater availability in 1992 than in 1991.

We defined the independent variable Availability to be the ratio (for 1992):

\[
\frac{\text{Number of Chemical Entities Available on the Formulary for Specified Disease}}{\text{Total Number of Chemical Entities Indicated for Specified Disease}}
\]

"Indicated" means FDA approved for treatment of the specified disease (i.e., the drug has been shown to be effective for that disease). In cases in which a chemical identity was available in formulations giving an altered pharmacokinetic profile (e.g., sustained release), such formulations were scored as a separate chemical entity. The independent variable Formulary Limitation, as used in subsequent tables and regression equations, is defined as:

\[
\text{Formulary Limitation} = 1 - \text{Availability}
\]

Thus, high formulary limitation is equivalent to low availability (i.e., a lower proportion of indicated chemical entities available on formulary). Examples
of how the formulary-limitation variable was calculated for each of the six sites for hypertension and arthritis are presented in Table 2. The definition of formulary limitation assumes that each indicated chemical entity for a disease has the same weight (= 1), as this definition counts the number of chemical entities on the formulary for a diagnosis, compared with the total number of chemical entities indicated for the diagnosis.

Use of multisource (generic) drugs is an important aspect of drug-budget management. Formularies in the study sites contained both multisource agents and sourcesource agents still protected under patent. Multisource drugs contain the same active ingredients in the same dosage form as do the original patented drugs but their bioavailability may vary. They are less expensive and represent an older generation of drugs. For agents available as multisource drugs, the original patented drug is considered multisource in our definition. To describe the extent of use of multisource drugs for each patient, we calculated Percent Multisource as follows:

\[
\text{Percent Multisource} = \frac{\text{Number of Prescriptions for Drugs that Are Multisource for a Patient}}{\text{Total Number of Prescriptions for a Patient}}
\]

Percent Multisource is a patient-level variable and is based on all drugs prescribed for a patient during the study period, rather than on the drugs for the patient’s disease group.

Strictness of Gatekeeper was defined using data from a Scour-Levin survey. Our study sites had either moderate or strict gatekeeper policies, as shown in Table 1.

Visit Co-Pay was the copayment charged for each visit. It was obtained directly from the sites. Mean Drug Co-Pay, a patient-level variable, was the average drug copayment paid by a patient over the course of the year.

To determine Severity of Illness, a patient characteristic, trained raters abstracted data on patient severity of illness for each ambulatory visit, using the Ambulatory Patient Severity (APS) index, and for each inpatient admission (for patients hospitalized at any time during the study period), using the Computerized Severity Index (CSI). These measures are described in more detail in the accompanying baseline paper and elsewhere.

All APS criteria were reviewed by the physicians in each participating HMO prior to data collection. We requested that the physicians document all relevant patient criteria as completely as possible for subsequent abstraction into the APS software, as poor documentation could result in inaccurate severity scores.

A continuous APS score, based on the biophysical and behavioral derangement scores, was produced for each patient visit in this study. The severity sum for a patient was defined as the sum of the continuous APS scores for all of a patient’s visits over the year. In addition, a mean severity score per patient over the study year was computed by dividing the severity sum by the number of visits during the year. We used the severity sum score as an independent variable to

--- MANAGED CARE OUTCOMES PROJECT: RESULTS ---

Table 2. Number of Chemical Entities Available on Formulary Within Drug Class for Hypertension and Arthritis, by Site

<table>
<thead>
<tr>
<th>Drug Class</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hypertension</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ACE inhibitors</td>
<td>3</td>
<td>3</td>
<td>4</td>
<td>7</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>Calcium channel blockers</td>
<td>7</td>
<td>6</td>
<td>7</td>
<td>13</td>
<td>6</td>
<td>6</td>
</tr>
<tr>
<td>Beta-agonist blockers</td>
<td>9</td>
<td>9</td>
<td>6</td>
<td>17</td>
<td>6</td>
<td>5</td>
</tr>
<tr>
<td>Antihypertensive blockers (peripheral)</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>6</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>Antihypertensive blockers (central)</td>
<td>3</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Thiazides</td>
<td>4</td>
<td>4</td>
<td>3</td>
<td>14</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>Loop diuretics</td>
<td>2</td>
<td>3</td>
<td>1</td>
<td>3</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>Potassium-sparing agents</td>
<td>3</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Diuretic combinations</td>
<td>2</td>
<td>2</td>
<td>3</td>
<td>3</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Total Available</td>
<td>37</td>
<td>34</td>
<td>32</td>
<td>71</td>
<td>27</td>
<td>29</td>
</tr>
<tr>
<td>Formulary Limitation (FL1)</td>
<td>47.9%</td>
<td>52.1%</td>
<td>54.9%</td>
<td>0%</td>
<td>62.0%</td>
<td>59.2%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Arthritis Drug Class</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propionic acids</td>
<td>7</td>
<td>3</td>
<td>5</td>
<td>8</td>
<td>3</td>
<td>5</td>
</tr>
<tr>
<td>Acetic acids</td>
<td>5</td>
<td>6</td>
<td>4</td>
<td>12</td>
<td>6</td>
<td>3</td>
</tr>
<tr>
<td>Fenamates</td>
<td>2</td>
<td>1</td>
<td>0</td>
<td>7</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Propranolol</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Salicylates</td>
<td>3</td>
<td>1</td>
<td>2</td>
<td>8</td>
<td>4</td>
<td>6</td>
</tr>
<tr>
<td>Anthem inohemotoic agents</td>
<td>2</td>
<td>1</td>
<td>0</td>
<td>3</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Gold compounds</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>3</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Miscellaneous</td>
<td>2</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>Total Available</td>
<td>23</td>
<td>17</td>
<td>15</td>
<td>40</td>
<td>18</td>
<td>21</td>
</tr>
<tr>
<td>Formulary Limitation (FL1)</td>
<td>42.5%</td>
<td>57.5%</td>
<td>62.5%</td>
<td>0%</td>
<td>55%</td>
<td>47.5%</td>
</tr>
</tbody>
</table>

ACE = angiotensin converting enzyme.

*Seventy-one separate chemical entities were available in the US market with an indication for hypertension.

Forty separate chemical entities were available in the US market with an indication for arthritis.

VOL. II, NO. 3  THE AMERICAN JOURNAL OF MANAGED CARE 257
control for severity over the year in analyses in which the dependent variable was based on a year's utilization. The average severity score was not a significant variable when the severity sum was included, so it was deleted in the analyses presented here. We accounted for patient variation not controlled for in previous studies by taking into account global severity of illness, including psychosocial and physiologic criteria.

Compared with other patients, a patient who remained sicker longer or whose adverse reactions were the result of restrictions in drug therapies or of controls on visits by the use of a strict gatekeeper, strict second-opinion requirements, or a higher visit copayment, would be considered a sicker patient. Therefore, the use of the severity sum score in subsequent regression equations biases the analyses against finding significant effects for the cost-containment strategies used. The more deranged a patient’s findings at each visit, the higher severity sum score. Simply having a greater number of visits will not raise the severity sum score if the patient does not present with deranged signs and symptoms at those visits.

First-visit severity is the continuous APS score at the first visit. It was used as an alternative to the severity sum in our regression analyses.

Reliability testing of APS scores for data abstractors was performed using case scenarios and by re-rating a random sample of 25 patient charts per rater to ensure accurate abstraction of APS data. If raters were found to have less than 95% agreement on the APS questions, further training was performed until their reliability achieved 95%.

Provider Count is the number of different providers seen by the patient during the study year. It includes primary care and specialist physicians, as well as non-physician providers.

Patient Age and Patient Gender (female, with male the omitted reference group) were included in the regression analyses. Because data on patient race were missing for more than half the patients, race was not included in the analyses.

Time in Study was defined as the number of months that the patient participated in the study, beginning with the first visit within the 4-month enrollment period and ending at the study end date or disenrollment date, whichever was earlier. “Year” means “time in study” for all variables defined over a year. The actual time enrolled in the study was measured for each patient and was used as an independent variable in all regression analyses.

HMO characteristics are additional variables used to control for other potential influences on resource utilization. From the sites, we learned their geographic location and profit status. We obtained the following additional variables from a survey of HMOs: intensity of case management (strict, moderate, or loose); second-opinion requirements (moderate, loose, or none); and physician affiliation (salaried or contract). The more highly “managed” or restrictive HMO sites would be expected to have lower resource utilization (Table 1).

Because only six HMOs were included in the study, entering all these HMO-characteristic variables into the regression analyses at once would have resulted in collinear variables. Therefore, for each study disease, we examined both the correlations among the HMO-characteristic variables and each of their correlations with the dependent variables. Principal component factor analyses were used to examine the relationships among the independent variables and to reduce the number of variables in the regression analyses.

Analyses

Each disease was analyzed separately, so that the effects of cost-containment practices would not be confounded across diseases. In the analyses, we first assessed the frequencies and means for the dependent variable measures within each site and within each disease to determine the extent of variation in the data set. We then examined the relationship between formula-limitation levels and resource use while controlling for severity of illness. Finally, regression analyses assessed whether the effects of various cost-containment practices on the dependent variables would remain after other variables were taken into account. (The omitted reference categories were: not-for-profit, moderate gatekeeper, moderate case management, no second opinion, and contract physician affiliation, respectively.) Both untransformed and log-transformed dependent variable values were analyzed. The results were consistent; therefore, with the exception of ED visit count and hospital admissions (the numbers were small), only the log results are reported here. Because drug copayment information was missing for 28% to 35% of the patients by disease group (and all drug copayment data were missing from one site), we analyzed the data both with and without the drug copayment variable.

Factor Analyses

Using principal component factor analysis, we identified four independent variables, within three
principal components, for use in the regression analyses. The three principal components can be interpreted as measures of concepts relating to pharmaceutical controls, overall management strategies, and demand-reduction strategies. The components provided a good summary of the HMO characteristics, explaining 95% of the standardized variance overall and from 85% to 97% of the variance, by study disease.

Within the pharmaceutical-controls component, formulary limitation had the highest positive loading and was therefore chosen. The overall management-strategies component included the variables salaried, contract, ownership, case management, and gatekeeper strictness. Ownership status and gatekeeper strictness were chosen as they had the highest loadings on this factor. From the demand-reduction component, we chose visit copayment, as it exhibited a high negative loading value. Geographic location was not significant on any component. All the selected variables had factor loadings greater than .60; most were greater than .80. The Cronbach's alphas ranged between .74 and .93 for each disease, with the exception of asthma, for which it was .43.

Correlations

The correlations among the HMO characteristics and the dependent variables indicated that formulary limitation was one of the strongest predictors of the dependent variables. Higher formulary limitation was associated with greater healthcare utilization for all study diseases. Case management often was the least highly correlated with the dependent variables. The other HMO characteristics fell between formulary limitation and case management, with correlations ranging from -.37 to .41.

The variables formulary limitation and visit co-pay were negatively correlated with each other for each study disease (r = -0.29, P < 0.0001). Therefore, sites with higher visit copayments to control healthcare utilization tended to have less-restrictive formulary policies. Finally, for-profit status was positively correlated with formulary limitation (r = 0.66); the for-profit HMOs were associated with greater formulary limitation.

Variability

The substantial variation in formulary limitation is illustrated in Table 2. Between 27 and 71 drugs were available across the sites for hypertension treatment, and between 15 and 40 drugs were available for arthritis treatment. Small differences in total availability can obscure major differences in drugs that are available within a particular drug class. In addition, formu-

Correlations Between Formulary Limitations and Resource Utilization

A similar pattern was found for each of the diseases studied. Both in general and for patients with similar levels of disease severity, the more limited the formulary, the higher the patient prescription count and costs (as measured by AWP) per year, and the higher the number of ambulatory office visits. ED visits, and hospitalizations per patient per year. As examples, we

Figure 1. Mean Prescription Cost per Patient per Year, by Formulary Limitation Percent and Severity Level

![Figure 1. Mean Prescription Cost per Patient per Year, by Formulary Limitation Percent and Severity Level](image1)

Figure 2. Mean Office Visit Count per Patient per Year, by Formulary Limitation Percent and Severity Level

![Figure 2. Mean Office Visit Count per Patient per Year, by Formulary Limitation Percent and Severity Level](image2)
show details for total prescription costs for patients with arthritis (Figure 1) and for office visits for patients with hypertension (Figure 2).

To simplify these presentations, the continuous severity sum over the year per patient was categorized as low (bottom 30%), medium (middle 40%), or high (upper 30%) for patients with the study disease. Each site was labeled by formulary-limitation level; a larger limitation number indicates fewer drugs available for the disease on that site’s formulary.

Within each severity level, the differences in mean utilization by formulary limitation represented in the figures were statistically significant (one way analysis of variance, \( P<0.001 \)). The average increase in utilization between the site with no formulary and the site with the most limited formulary for that disease, adjusted for low, medium, and high severity, was 160%±78% (SD) for prescription count, 83%±29% (SD) for visit count, 161%±76% (SD) for drug cost, and 184%±88% (SD) for study-disease drug cost. In addition, as formulary limitation increased, from the site without limitation to the site with greatest limitation, a large increase in ED visits was observed. A 100% increase in utilization represents a twofold difference in magnitude of utilization. Unfortunately, percentage increase could not be computed, as the number of ED visits at the site with no formulary limitation was zero for most diseases.

**Regression Analyses**

Regression analyses (controlling for patient and HMO variables) were used to determine the significance of the relationships between the cost-containment practices and resource utilization, controlling for other variables. For each dependent variable, all regression analyses included the formulary limitation variable, ownership status, all the patient independent variables, and two other HMO site variables. Because five sites were available for the drug analyses, we could only use four site variables. To maximize the sample size available to address this paper’s primary research question concerning relationships between HMO cost-containment strategies and resource utilization, we first ran the regressions omitting the mean drug co-pay variable, which was missing in 28% to 35% of the patients, by disease group.

The independent variables had various effects on resource use. Some of these were expected; some were unexpected.

**Control Variables**

Yearly severity sum was highly significant and positive, indicating that sicker patients used more resources (more drugs, office visits, ED visits, and hospitalizations) than did patients who were less sick. As expected, age, time in study, and number of providers generally correlated positively with utilization of healthcare resources. For-profit status also was positively associated with drug use but was mixed and mostly not significant in its association with office visits, ED visits, and hospitalizations.

**Cost-Containment Variables**

Percent multisource was strongly associated with drug count and drug cost. For all five diseases, it correlated positively and significantly (\( P<0.001 \)) with total drug count, total drug cost, disease-group drug count, and disease-group drug cost. This correlation indicated that greater use of multisource drugs was associated with higher yearly drug costs and drug counts. Percent multisource was not significant in predicting ED visits and hospitalizations (except for hospitalized ulcer patients). It was positive and significant in predicting office visits for hypertension, otitis media, and arthritis, and hospitalizations for ulcer patients, and was negative but not significant for office visits for ulcer and asthma patients.

Visit co-pay was negative and significant for total drug cost, total drug count, and disease-group drug count; it was negative but not always significant for disease-group drug cost. Visit co-pay was mixed in its effect on visit count, ED visit count, and hospitalizations. Thus, a higher visit copayment was associated with lower total drug costs and counts but did not have a consistent effect on the number of office visits, ED visits, or hospitalizations (Table 3).

Strict gatekeeper (relative to moderate gatekeeper) was negative and highly significant (\( P<0.001 \)) for the four drug-use dependent variables, indicating that a strict-gatekeeper policy was associated with lower drug costs and counts. For the dependent variable office visit count, it was negative but not significant for ulcer and asthma, negative and significant for hypertension, and positive and significant for otitis media and arthritis. For the dependent variable ED visit count, it was consistently negative and significant (\( P<0.01 \)). For the dependent variable hospitalizations, strict gatekeeper was negative and significant for otitis media, arthritis, and ulcers (\( P<0.05 \)) and was negative but not significant for hypertension and asthma. Thus, a stricter gatekeeper generally was associated with lower drug, ED, and hospital utilization but had a mixed effect on office visits (Table 3).

Controlling for yearly severity sum, age, gender, provider count, months in study, and the other HMO characteristics, the effect of formulary limitation on
ED visit count and hospital admissions was positive and significant (P<0.01) except for otitis media, for which it was negative and significant (Table 3). Its effect on office visits was positive except for otitis media but was significant only for ulcers. In general, we found that greater limitations on drugs available were associated with greater office, ED, and hospital utilization. The effect of formulary limitation on the four drug-use variables was positive but not always significant.

To determine whether the variable drug co-pay was associated with resource utilization, we analyzed regression models using the subset of patients for whom data on copayments were available (68% of the study population). In these models, when all independent variables were the same, drug co-pay was not significantly associated with utilization for 24 of the 35 equation types listed in Table 3. For the dependent variables for which patient drug co-pay was statistically significant, its effect on resource utilization was positive 10 out of 11 times.

Severity sum was selected as our measure of severity of illness because it captures patients’ total illness profile across all visits over the year. However, if patients became sicker as a result of cost-control measures, severity sum may have interacted with the cost-control independent variables. This confounding of severity sum may have biased the results against finding an effect of these cost-containment measures on resource use. To assess this possible bias, we ran the regression analyses using first-visit severity in the place of severity sum. The predominant effects on

<table>
<thead>
<tr>
<th>Independent Variable</th>
<th>Dependent Variable</th>
<th>Hypertension</th>
<th>Otitis Media</th>
<th>Arthritis</th>
<th>Epigastric Pain/Ulcer</th>
<th>Asthma</th>
</tr>
</thead>
<tbody>
<tr>
<td>Visit Co-Pay</td>
<td>RxCount</td>
<td>-.12***</td>
<td>-.12***</td>
<td>-.04 (0.04)</td>
<td>-.14***</td>
<td></td>
</tr>
<tr>
<td></td>
<td>DisGrRxCount</td>
<td>-.13***</td>
<td>-.057**</td>
<td>-.075**</td>
<td>-.13**</td>
<td>-.16**</td>
</tr>
<tr>
<td></td>
<td>RxCost</td>
<td>-.205***</td>
<td>-.13*</td>
<td>-.15***</td>
<td>-.23***</td>
<td>-.28**</td>
</tr>
<tr>
<td></td>
<td>DisGrRxCost</td>
<td>-.19***</td>
<td>-.077 (0.15)</td>
<td>-.05 (0.33)</td>
<td>-.24**</td>
<td>-.52**</td>
</tr>
<tr>
<td></td>
<td>Visits</td>
<td>-.112***</td>
<td>-.079 (0.21)</td>
<td>+.014 (0.82)</td>
<td>-.047 (0.31)</td>
<td>+.017 (0.87)</td>
</tr>
<tr>
<td></td>
<td>ED Visits</td>
<td>+.002 (0.24)</td>
<td>-.043***</td>
<td>+.011**</td>
<td>-.001 (0.74)</td>
<td>+.008 (0.33)</td>
</tr>
<tr>
<td></td>
<td>Hosp Adms</td>
<td>+.020***</td>
<td>-.072***</td>
<td>+.053***</td>
<td>+.007 (0.40)</td>
<td>+.029 (0.06)</td>
</tr>
</tbody>
</table>

| Gatekeeper Strict    | RxCount            | -1.15***     | -.70***      | -.57***   | -.169***             | -1.04*** |
|                      | DisGrRxCount       | -1.39***     | -.59***      | -.657***  | -.13***              | -1.05*** |
|                      | RxCost             | -1.65***     | -1.05***     | -.078***  | -.170***             | -1.63*** |
|                      | DisGrRxCost        | -1.96***     | -1.23***     | -.60***   | -.192***             | -2.69*** |
|                      | Visits             | -.27*        | -.30*        | +1.42***  | -.032 (0.90)         | -.120 (0.47) |
|                      | ED Visits          | -.033***     | -.138***     | -.063***  | -.054***             | -.336*** |
|                      | Hosp Adms          | -.019 (0.38) | -.173***     | -.114***  | -.090***             | -.065 (0.31) |

| Formulary Limitation | RxCount            | +.28 (0.15)  | +.27 (0.79)  | +1.46***  | +1.60***             | +.80*   |
|                      | DisGrRxCount       | +.27 (0.19)  | +.239***     | +1.125*** | +1.06 (0.09)         | +.55 (0.17) |
|                      | RxCost             | +.78*        | +.259 (0.16) | +1.42*    | +2.28*               | +.42 (0.49) |
|                      | DisGrRxCost        | +.284***     | +.265 (0.84) | +4.80***  | +3.79***             | +.53 (0.55) |
|                      | Visits             | +.32 (0.35)  | -.574 (0.09) | +.74 (0.39) | +2.13***             | +1.11 (0.31) |
|                      | ED Visits          | +.125***     | -.028***     | +.29***   | +.287***             | +.289*** |
|                      | Hosp Adms          | +.519***     | -2.12***     | +1.02***  | +1.90***             | +.431*** |

| R²                   | RxCount            | .36          | .57          | .42       | .39                  |        |
|                      | DisGrRxCount       | .29          | .53          | .31       | .26                  | .41     |
|                      | RxCost             | .30          | .47          | .35       | .27                  | .35     |
|                      | DisGrRxCost        | .18          | .46          | .16       | .19                  | .24     |
|                      | Visits             | .74          | .74          | .74       | .72                  | .66     |
|                      | ED Visits          | .04          | .06          | .07       | .06                  | .06     |
|                      | Hosp Adms          | .11          | .08          | .12       | .10                  | .10     |

*** indicates P<0.001; ** indicates .001<P<0.01; * indicates .01<P<0.05
+ indicates increased utilization with increased limitation; - indicates decreased utilization with increased limitation.
The dependent variables (except for ED visits and hospital admissions) were expressed in natural log form and the explanatory variables in linear form. Thus the coefficient of the continuous variable, formulary limitation, represents the percentage change in the dependent variable from changing the independent variable one unit. The effects of formulary limitation, gatekeeper, and visit co-pay only are presented. However, each of the regression equations upon which these results are based also included the following independent variables: sum severity score, % multisource drugs, age, gender, provider count, for-profit/not-for-profit status, and length of time in study.
resource use of the variables described remained the same.

--- DISCUSSION ---

Our results must be interpreted within the constraints of the study design. The apparent effects of the HMO cost-containment practices on utilization of healthcare resources may have been caused by some unmeasured factor or factors at the sites other than, or in addition to, the site variables included in the analyses. Possible causative or confounding factors are other pharmacy-management practices, patterns of prescribing, and the culture or quality of medical practice unique to the managed care organization, all of which are difficult to measure directly. The variable for-profit status may be such a measure of culture. This variable is measurable and was controlled for in all of our analyses. The cost-containment variable visit co-pay had a lowering (negative) effect on drug use, as expected and as observed in the Rand HIE; however, it had a mixed effect on office and ED visits and generally had the unexpected effect of association with more hospital admissions. The cost-containment variable strict gatekeeper had a lowering (negative) effect on all healthcare utilization. The only variables with consistent unexpected effects were multisource and formulary limitation.

The formulary-management process varied across the study sites, differing in such aspects as composition of the Pharmacy and Therapeutics Committee, conduct of formal drug reviews, frequency of formulary changes, and policies for communicating formulary changes to clinicians. However, the common endpoint of the process at all sites was the formulary list. In general, there was a positive association between formulary limitation and utilization of drugs and other services, suggesting that, independent of differences in the formulary process, formulary limitation is an important correlate of outcomes across a group of patients with a given disease.

Because four of the five formularies in the study year had been operating for 3 to 12 years, the relationship between formulary limitations and utilization should have stabilized. Formularies at all sites that originally had been instituted to reduce drug utilization, and that were successful in doing so, should have reduced utilization as limitations increased, after controlling for severity and site-specific factors. Therefore, because we found that drug utilization tended to increase with greater limitations, formularies either are causing higher utilization or are ineffective in reducing utilization to the levels of sites with fewer limitations. From the patient’s perspective, increased utilization means greater inconvenience and longer periods of illness and discomfort.

To better understand the positive association between formulary limitation and our outcome variables, we examined the number of drug entities used at each site. Formulary limitation generally did not result in absolute exclusion of unlisted entities from use. However, listed entities were prescribed much more frequently than nonlisted entities, and the breadth and composition of the formulary determined the identity and mix of the most frequently used drugs. The more limited the formulary, the fewer entities are available for patients who cannot be optimally managed with the formulary drugs. Suboptimal or failed therapy can result in increased prescription costs and increased office, ED, and hospital utilization. A review of the MCO patient-level data gives some insight into how formulary limitation might cause increased resource utilization. We examined the records of 50 patients with severe asthma who had been treated with steroids. In the case of patients for whom formulary limitation discouraged the use of inhaled steroids, we found fewer prescriptions for these agents, more prescriptions for oral steroids, an increased number of physician visits and ED visits, and persistence of severe asthma. Oral steroids provide a short burst of relief but may not improve long-term pulmonary function. According to current guidelines for asthma treatment, inhaled steroids are recommended for the chronic treatment of moderate and severe asthma. 31 Subsequent studies will explore additional linkages between formulary limitation and longitudinal patterns of asthma signs and symptoms and utilization.

A causal relationship between stricter HMO cost-containment practices and increased resource use also is supported by previous studies reporting shifts to more-expensive resources when restrictions are placed on the availability of drugs in Medicaid programs. 29,30-37,33-35 These shifts are not inconsistent with prevailing economic theory based on findings that greater choice enhances consumer satisfaction and economic efficiency. 34-35 Likewise, systems theory predicts that often unforeseen effects are found when complex systems (such as the healthcare system) are perturbed. 36-37 “Each individual action or each local intervention has a collective aspect that can result in quite unanticipated global changes...Often this response runs counter to our intuition.” 36

We do not know whether the formulary in each HMO actually changed physician prescribing behavior. Although we found 95% compliance with the
formulary, this figure could reflect either changed behavior or the evolution of formulary lists consonant with local physicians' prescribing patterns. The study does indicate that, for whatever reason, limited scope of prescribing (self-imposed or coerced) can be associated with greater office, ED, and hospital utilization, as well as with increased drug use.

The more-limited formularies sometimes were correlated with higher drug costs, based on the AWP. Although the assigned wholesale price of drugs (AWP) probably was not the actual price paid, the AWP represents a constant, benchmark value that is useful for comparisons across sites. The increased cost associated with a formulary limitation may be offset if buying power resulting from that limitation enables HMOs to negotiate lower drug prices. However, the increase in drug cost from our unrestricted formulary to our most restricted formulary sites often was greater than twofold, and hence would require more than a 50% reduction in AWP to offset the increased cost.

The percentage of multisource drugs that a patient received, while independent of formulary limitation, was itself directly correlated with increased drug utilization. Multisource drugs (including both generic and branded products) reflect older technology and can be associated with less specificity, lower overall efficacy, and characteristics related to reduced patient compliance, such as more side effects and less-convenient dosage forms. The consistent effect of this variable's association with greater drug utilization; more office visits for hypertension, otitis media, and arthritis; and more hospitalizations for ulcers requires further study.

Sensitivity Analyses

We checked sensitivity of the results in various ways. When we substituted first-visit severity for the severity sum, the effect of the other independent variables remained stable. When we tried various combinations of the HMO cost-containment practices in the regression equations, the effect of formulary limitation on drug use, office or ED visits, and hospital admissions became more significant.

Even though outliers for the dependent variables were not related to site, we analyzed the log of each dependent variable (except for ED visit count and hospital admissions) as well as the actual values. The study findings continued to hold.

CONCLUSIONS

The findings suggest that, for the five diseases studied, greater limitation in the scope of available medications may result in higher drug utilization, and higher office, ED, and hospital utilization. Greater reliance on multisource medications was associated with greater utilization of drugs. A stricter gatekeeper sometimes was associated with more office visits but was always associated with fewer ED visits and hospitalizations and with less drug use. Finally, a higher visit copayment was associated with less drug use but had a mixed association with office visits and ED visits. It generally was associated with more hospital admissions. These findings illustrate the difficulty of implementing cost-containment practices in the absence of severity-adjusted patient-level information about the associations that these restrictions will have on utilization and patient well-being.

In practice, the research suggests the need for an a priori assessment of cost-containment strategies, because the individual strategies do not function independently, and the results of changing one component may not be easily predictable. For example, restrictions in one area may be successful in decreasing utilization in that area but may cause increases in other areas. Our findings suggest the need for a systems or disease-case-management approach to cost containment, rather than individual component management techniques, which ignore the interactions among components of care. Each illness is associated with a unique set of therapies, interventions, cost elements, and cost patterns. Only by identifying and focusing on the important patient characteristics and process steps associated with better outcomes for a given disease can we hope to reduce costs substantially while ensuring quality care.

Acknowledgments

We thank the following individuals for many valuable suggestions and critique of the methodology, statistical approaches, and data interpretation: Ernst R. Berndt, PhD, Massachusetts Institute of Technology; Robert M. Goldberg, PhD, Brandeis University; Judith K. Jones, MD, PhD, The Degge Group, Ltd., Washington, DC; and George Washington University; Frank A. Sloan, PhD, Duke University; Gail Wilensky, PhD, Project HOPE, Washington, DC; David C. Hale, PharmD; and Peter P. Morgan, MD, DPH, consultant in controlled trials.

REFERENCES

3. Anderson G, Brook R, Williams A. A comparison of cost-sharing versus free care in children: Effects on the demand...