

Determinants of HMO Formulary Adoption Decisions

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Objective: To identify economic and organizational characteristics affect the likelihood that HMOs include new drugs on their formularies

Data Sources: We administered an original survey to directors of pharmacy at 75 HMOs, of which 41 returned usable responses. We obtained drug-specific data from an industry trade journal.

Study Design: We perform multivariate logistic regression analysis, adjusting for fixed-drug effects and random-HMO effects. We use factor analysis to limit the number of predictors.

Data Collection Methods: We held initial focus groups to help with survey design. We administered the survey in two waves. We asked respondents to report on seven popular new drugs, and describe a variety of HMO organizational characteristics.

Principal Findings: Several HMO organizational characteristics, including nonprofit status, the incentives facing the Director of the Pharmacy, size and make-up of the pharmacy and therapeutics committee, and relationships with drugs makers, all affect formulary adoption.

Conclusions: There are many organizational factors that may cause HMOs to make different formulary adoption decisions for certain prescription drugs.

Key Words: Formulary, Managed Care, Pharmacoeconomics

Organizational Determinants of HMO Formulary Adoption Decisions

A drug formulary is a list of approved drugs.¹ The term is historically associated with hospitals; a hospital pharmacy stocks those drugs on the hospital formulary and some non-formulary items.² Today, formularies are an essential component of managed care.³ Most health maintenance organizations (HMOs) provide greater coverage to patients who obtain drugs listed on their formularies.⁴ Some HMOs design their own formularies while others rely on third parties for formulary design. Regardless of how HMOs design their formularies, there is variation across HMOs in how they make adoption decisions for a given set of drugs. Some formularies are relatively "open" and include almost all FDA-approved drugs.⁵ Others are more restrictive, so that their HMOs pay for only one or two out of a class of competing drugs. This variation in formulary adoption decisions are, needless to say, important to pharmaceutical executives who are at a loss to explain why some HMOs adopt their drugs while others do not.

Lyles et al. (1997) examines some of the factors influencing formulary adoption decisions by HMOs and other managed care organizations (MCOs). The 51 organizations that respond to their survey all report that they use formularies to contain costs and assure appropriate drug use. All respondents state that they assess the clinical effectiveness and cost effectiveness of drugs, while about half also assess the impact of drugs on quality of life. While this study sheds light on the goals of formulary makers, it does not identify sources of variation

1 Ito and Blackburn (1995) define a managed care formulary as "a listing of prescription medications which are preferred for use by a health plan".

2 Goldberg (1997) discusses the origins of formularies and describes different types currently in use. See Sloan et al. (1993) for a discussion of the effectiveness of hospital formularies.

3 According to one report, in 1997 formularies were a component of over 90 percent of all managed care plans. See Sax (1999). All of the managed care plans studied by Lyles et al. (1997) report that they use a formulary.

4 A 2000 survey by the Kaiser Family Foundation and the Health Research and Educational Trust reports that 58 percent of workers in HMOs face a formulary that restricts which drugs are covered.

5 Goldberg (1997)

in adoption decisions. For example, the study does not address the relative importance of cost versus quality goals. Nor does the study assess how organizational characteristics affect specific adoption decisions.

Lyles et al. show that when making formulary adoption decisions, MCOs examine a variety of criteria, including cost and quality. While all MCOs may weigh similar criteria, they may not reach the same conclusions. This can occur for at least three reasons. First, drug adoption decisions may vary because MCOs may pursue different objectives (or strategies for value creation) and may draw different conclusions about the available evidence on drug performance. Variation can also result from the organization-specific characteristics of MCOs. These could include incentives, controls, and practices that are incomplete or else inconsistent with the economic objectives for cost and quality that the MCO formally espouses. Organizational idiosyncrasies can thus bias adoption decisions away from those outcomes that would be most consistent with the MCO's objectives. Lastly, variation in adoption decisions may stem from different relationships between MCOs and the drug manufacturers.

In this study, we report the results of a survey of the Directors of Pharmacy at over 40 HMOs. We identify economic and organizational factors that influence formulary adoption decisions for seven of the largest selling drugs.⁶ Our intent is to clarify the decision processes that occur at this critical institutional linkage between pharmaceutical firms and HMOs. Knowledge of these processes becomes more important as the share of pharmaceutical sales that occurs through HMOs continues to grow.

⁶ Concerns about response rates limited our analysis to seven drugs. We chose large selling drugs because of the heightened interest among pharmaceutical companies and HMOs about the adoption of such drugs.

Background on Pharmacy Benefits Management

Pharmacy benefits management emerged during the 1980s when HMOs sought to extend the practice of selective contracting to prescription drugs. Under selective contracting, HMOs and other managed care organizations obtain discounts directly from providers such as hospitals and physicians by threatening to exclude high price providers from their provider network. Providers are willing to grant the discounts because they realize that HMOs have the ability to move market share.⁷

The same principles that enable HMOs to obtain discounts from providers apply to the purchase of prescription drugs. The early group and staff model HMOs established their own formularies. During the 1980s, IPAs outsourced pharmacy benefits management to independent pharmacy benefit management firms (PBMs) such as Medco, DPS, PCS, and Value Rx.⁸ Through the use of formularies, HMOs obtain substantial rebates by threatening to exclude high price drugs. These rebates may be obtained by excluding the drug entirely from the formulary or including it, but denying it “preferred status”; i.e. requiring enrollees to make a differential copayment.

HMO use of formularies has grown rapidly since the 1980s. Today, 92 percent of HMOs use a formulary.⁹ All of the HMOs that responded to our survey constructed their own formularies. (We excluded from our sample those that reported otherwise.) We focus on these HMOs because they make their own decisions and would be best able to respond to our survey. But even those HMOs that outsource formulary design can have custom-designed formularies.

⁷ There are many articles describing selective contracting in more detail. For example, see Glied (2000) and Phelps (1997).

While independent PBMs have an “off-the-shelf” formulary that they offer to all clients, they will also tailor-make formularies to meet the needs of specific clients. Therefore, there is every reason to believe that there is wide variation in all HMO formularies, not just those that we study.

Note that while formularies are important tools for drug use control, HMOs also may use other mechanisms such as disease management.¹⁰ We asked our respondents if they used disease management in the relevant therapeutic categories. When we included this measure in our models, our results were unchanged.

Factors Affecting Adoption Decisions

As a starting point for considering formulary adoption decisions, we would expect an HMO to add a drug to its formulary if the expected benefits, which may be economic, medical, or both, exceed the additional expected costs. To the extent that HMOs follow this rational choice model, then adoption decisions for specific drugs should be highly correlated across HMOs. In other words, there should be considerable inter-drug variation in adoption probabilities, where this variation depends on each drug’s commonly perceived benefit/cost ratio. For example, we might expect most HMOs to adopt a breakthrough therapeutic drug such as Proscar (for the treatment of prostate cancer). At the same time, we expect that fewer HMOs would adopt a drug with less obvious benefits and/or substantial side effects, such as Meridia (for the treatment of obesity).

In this study, we do find considerable inter-drug variation in adoption rates. We study

8 Taniguchi (1995)

9 Aventis (2000).

seven drugs, for which the probability of adoption among our sample of HMOs ranges from .35 (Amerge and Viagra) to .80 (Allegra). To control for this inter-drug variation in adoption probabilities, we estimate drug fixed-effects (i.e., we include separate indicator variables for each drug). This allows us to focus on the factors affecting the adoption of individual drugs across HMOs. However, in one specification, we replace fixed-effects with limited drug-specific measures of potential benefits and costs, such as the extent of competition within the drug's therapeutic category.

In addition to inter-drug variation in adoption probabilities, there is considerable inter-HMO variation (i.e., variation across HMOs for specific drugs). Otherwise, the probabilities of adoption would all be 0 or 1. We infer that objective benefit/cost criteria are not the only determinants of drug adoption. One reason is that such criteria do not, in general, exist. Each organization is therefore free to interpret the available evidence. Organizational factors specific to each HMO can also influence adoption by affecting (a) how that HMO conducts its benefit/cost analysis and (b) how it weighs the benefit/cost ratio against other considerations.

For example, consider that each HMO with a formulary has a Pharmacy and Therapeutics (P&T) committee whose charge is to construct and update that formulary. The P&T committee is usually made up of between 10 and 20 medical and managerial personnel; a few HMOs include one or more individuals from outside the organization, such as an independent consultant, consumer, or ethicist. A physician specialist or the HMO's Director of Pharmacy will often chair the committee. Regardless of who chairs the committee, the Pharmacy Director has the ultimate responsibility for managing the HMO's drug benefit.

It stands to reason that adoption decisions are influenced by the individuals on the P&T

committee and by organizational factors affecting the committee as a whole. The individuals on P&T committees vary in their training, experience, and perspective.¹¹ The data on which they must base decisions are often incomplete and unclear. In addition, the firms seeking to have their products adopted provide much of the data, and each committee has different experiences to guide their interpretation of this data.¹² P&T committee structures, which determine how members of the committee work together to make decisions, can vary by HMO, as can the incentives facing Pharmacy Directors to control the pharmacy budget. These variations may be only loosely linked to the goals or markets served by the HMOs.¹³ Some key decision-makers, including physicians, may have little incentive to consider costs at all. This variation in decision-makers, decision processes, and information may cause considerable inter-HMO variation in adoption decisions.

HMO Characteristics and the Evaluation of Benefits and Costs

All HMOs, for-profit and non-profit alike, will value the pecuniary benefits that arise if a generous formulary enhances the overall demand for the HMO, especially among relatively healthy individuals. To our knowledge, there are no studies that demonstrate a link between formularies and HMO demand. However, we conjecture that healthy employees will prefer HMOs with more generous formularies, all else equal. One reason is that at the time they select a health plan, all individuals have "option demand" for a range of treatments.¹⁴ In other words, they want the security of knowing that their HMO will cover whatever medical needs may arise.

11 Sarpong (1999) documents substantial variation in the training of P&T committee members.

12 Lyles et al. (1997) report that 80 percent of plans responding to their survey relied on industry evaluations when making formulary adoption decisions. However, they tend to place relatively little weight on these evaluations, when compared with other sources of information such as publications in peer reviewed literature.

13 Aldrich, 1999.

Another reason is that healthy patients might view a generous formulary as a signal of overall HMO quality. Sick individuals will likely also prefer a generous formulary, not always to the liking of the HMO.

It is important to note that the benefits of boosting demand may vary according to the HMO's target population and that population's willingness to pay for treatments and drugs. For example, an HMO that serves mostly privately insured patients should be able to boost its premium if it offers a generous formulary. An HMO that serves mostly Medicare or Medicaid patients may be more constrained in its pricing.

Many drugs provide HMOs with another pecuniary "benefit" by substituting for other therapies, sometimes at much lower cost. The anti-ulcer medications Zantac and Tagamet, which greatly reduce the need for costly ulcer surgery, are good examples. Although all of the drugs in our sample, with the exception of Viagra, substitute for other drugs or therapies, there is no systematic evidence on the extent to which they reduce costs through this substitution effect. Consequently, we are unable to test directly whether the potential for substitution encourages formulary adoption, even though this potential often motivates pharmaceutical company arguments for the adoption of their products.

HMOs must weigh these benefits of including drugs on a formulary against the costs of doing so. An obvious cost is the direct cost of paying for the drugs. One factor that may affect this direct cost is the number of drugs in the therapeutic category. To the extent that the pricing of prescription drugs follows the predictions of oligopoly theory, we can expect HMOs to negotiate better discounts when there are therapeutically equivalent drugs available. The need to use a formulary to control costs may be tempered by the presence of other cost containment

¹⁴ See Dranove and White (1996)

mechanisms, such as the inclusion of pharmaceuticals within the capitated rate paid to primary care physicians. In this case, capitation may substitute for the formulary. However, some HMOs may use both formularies and capitation to reduce costs. In this case, formularies and capitation are complements. While the relationship between formularies and physician capitation is worth investigating, the predicted direction is ambiguous.

Lastly, we might expect for-profit HMOs to take a stricter view of the benefit-cost tradeoff than nonprofits. Weisbrod (1988) observes that when it comes to quality, nonprofits may offer more "hard to measure" attributes than for-profits. For example, Weisbrod argues that nurse training is hard for patients to measure, and documents that the nurses in nonprofit nursing homes are better trained than those in for-profit homes. From the perspective of a managed care enrollee selecting a plan, the exact makeup of the formulary may well be hard to measure. Not only is the formulary large and complex, but many enrollees will not know their exact drug needs at the time they select their health plan, and thus will not make specific inquiries about the formulary. This may lead for-profits to be less concerned about how enrollees to react to decisions to exclude specific drugs.

Organizational Factors Affecting Likelihood of Formulary Adoption

There are many organizational reasons why the individuals who participate in formulary adoption decisions may not collectively find the optimal balance of economic costs and benefits.¹⁵ P&T decision-makers must gather information about each drug, interpret the information, and negotiate with other decision-makers who may not share the same interpretation

¹⁵ For more on the influence of organizational characteristics on health care organizations, see Money, Gilfillan, and Duncan (1980).

of the data or the same values.

One way in which these factors can manifest themselves is in the relationship between HMO decision makers and the drug manufacturers. Drug manufacturers invest considerable resources in encouraging HMO decision makers to adopt their drugs. This includes supplying information to decision-makers about drug benefits, as well as developing personal relationships with decision makers. Thus, the attitudes of these decision makers toward drug manufacturers may influence their decisions. Drug manufacturers who contact an HMO more frequently and otherwise provide more “service” to the HMO may be perceived more favorably.

Adoption decisions may also depend on the characteristics of the P&T team.¹⁶ For example, up to some point, the participation of multiple individuals might lead to higher quality decision making, due to the need to assess complex information and incorporate multiple perspectives. Past that point, however, as a more diverse set of individuals participates in adoption decisions, it will be more costly and time-consuming to inform them all with appropriate data, reconcile differences in how data are interpreted, and forge a consensus out of the different goals and incentives that motivate them. With the spread of managed care, it is increasingly likely that conflicts may arise between management, physicians, and other personnel. Differences in goals and values among the involved parties will become more difficult to reconcile.

The size of an HMO may influence adoption decisions. Larger HMOs have greater opportunities for achieving scale and scope economies and exercising volume purchasing power than will smaller ones. At the same time, larger HMOs may have more layers of bureaucracy and face greater pressures to formalize their decision processes. Increased bureaucracy could

make adoption decisions more difficult and impede decision makers responding effectively to market pressures.

Even if decision-makers in different HMOs have the same information, draw the same conclusions, and face the same organizational pressures, they may face different incentives to act on their information. Some pharmacy directors report directly to the Chief Executive Officer or Chief Operating Officer, whereas others report to the Chief Medical Officer. These reporting relationships may affect the pharmacy directors' decisions.

Pharmacy directors may even face direct financial incentives that influence their decisions. All pharmacy directors in our sample undergo an annual performance evaluation. The performance criteria for these evaluations, however, vary across HMOs. Some pharmacy directors are evaluated based on a comparison of the pharmacy budget relative to plan. Others are evaluated based on member satisfaction with the pharmacy. These different evaluation criteria have important implications for formulary adoption decisions, since individuals may be biased towards decisions consistent with the incentive scheme under which they work.¹⁷ For example, a director evaluated on pharmacy budget relative to plan may be biased against including higher cost drugs on the formulary, even if those drugs offer offsetting cost savings that may boost HMO profitability. Conversely, a director evaluated on firm profitability or patient satisfaction will be biased towards including such drugs.

Table 1 summarizes the various factors that we have identified that may affect formulary decision-making. In the data section, we describe the specific variables that we use to measure these factors.

¹⁶ For the characteristics of high performance decision-making teams, see Mohrman, Cohen, and Mohrman (1995).

¹⁷ See Cyert and March (1963).

Table 1 about here

Survey Methods

Prior to administering the survey, we conducted a one-day focus group with leading representatives from HMOs, drug manufacturers, and academia.¹⁸ The group made important contributions to both the theory and methods and made especially helpful suggestions for designing and administering the survey. For example, group participants clearly indicated that Directors of Pharmacy were the decision makers who should be surveyed. The focus group also stressed that an instrument that required less than ten minutes to complete would enhance the response rate, and that it would be necessary to compensate survey respondents for their time.¹⁹ These suggestions limited the scope of our research. Lastly, the group helped us select terminology to use in the survey.

We conducted the survey in two waves, three months apart. We initially sent the survey to randomly selected Directors of Pharmacy (or the equivalent title) at 30 HMOs that reported they constructed and maintained their own formularies.²⁰ We made follow-up calls to nonrespondents and ultimately received 13 responses. Of these, three were missing responses to more than one key variable, leaving us with 10 usable responses.²¹ We sent the second wave to Directors of Pharmacy at 45 more HMOs that also constructed their own formularies. After follow-ups with nonrespondents, we ultimately received 35 more responses. One response was

¹⁸ The focus group included several economists from pharmaceutical companies and academia, as well as individuals from HMOs with responsibility for formulary design.

¹⁹ We paid respondents to the first survey wave \$50 for completing the survey. Respondents to the second wave received \$100.

²⁰ These were chosen from the *Directory of Managed Care Pharmacy* of the Academy of Managed Care Pharmacy, 1998 edition. We excluded HMOs that reported that they largely used “off the shelf” formularies prepared by other firms.

²¹ We considered surveys to be incomplete if the respondent failed to complete three or more questions that were used in the final empirical analysis.

incomplete. One responding HMO serviced Veterans Administration patients only. We believed that formulary decisions at this HMO might be driven by different factors than at other HMOs, and deleted it from the sample. Two HMOs serviced Medicaid patients only. Consistent with our earlier discussion, these Medicaid-only HMOs did not include any of our study drugs on their formularies. Because of this "perfect fit", we omitted these HMOs from further analysis.²² This left us 31 usable responses from the second wave, for a total of 41 responses.

It is difficult to say to what extent our sample is representative of all HMOs. Owing to the brevity of the instrument, we were unable to ask detailed questions about many HMO characteristics. Our HMOs represent a cross-section of sizes from under 100,000 enrollees to over 1 million, with a larger percentage of large HMOs than in the general population. Our sample also included a roughly equal mix of nonprofits and for-profits, compared with 66 percent for-profits in the general population.²³

Drug Selection and Measurement of the Dependent Variable

We asked our focus group to identify drugs for our study. We asked them to select drugs with the following characteristics:

- 1) The drugs must be relatively new (approved for marketing in the last five years). We restricted our attention to new drugs because these are generally of greater interest to drug makers.
- 2) The drugs must be in relatively high demand. This criterion again reflects the interests of drug makers.

²² Including these Medicaid-only HMOs does not change our results, but artificially improves our goodness of fit.

²³ Source: Health Care Investment Analysts Inc.

3) The drugs are not universally included or excluded from formularies.²⁴ Given the constraints on survey size, we wanted to maximize the inter-HMO variation in adoption decisions.

Note that the third criterion implies that the variation that we find in adoption decisions across HMOs may exceed the overall variation for all drugs. For instance, there may be some drugs that appear on the vast majority of formularies. By focusing on those drugs for which there is disagreement, however, we can do a better job of explaining the sources of that disagreement.

Table 2 lists the seven drugs included in our study, along with their manufacturers and their principle clinical indications. The list includes some drugs commonly prescribed at the time of the survey. For instance, Lipitor, Viagra, and Allegra were among the top 100 selling drugs in the world. The table also includes the year in which each drug was approved for marketing in the United States and 1998 worldwide drug sales, as reported in *MedAdNews*, an industry trade journal.

Table 2 about here

We asked respondents to state whether each drug was included on their formulary. All respondents gave unambiguous “yes/no” responses for every drug. Based on the responses, we constructed a dichotomous dependent variable that equaled 1 if the HMO included the drug on the formulary and 0 if they did not. The final column of Table 1 reports the fraction of HMOs that reported including these drugs on their formularies. In our empirical analysis, we used logistic regression to estimate models of formulary inclusion.²⁵

²⁴ The drugs we study are not the only ones for which there is substantial disagreement. Sax (1999) documents substantial variation in adoption rates of several cholesterol-lowering agents drugs, including Lescol, Mevacor, Pravachol, and Zocor.

²⁵ Logistic regression is identical to logit, except that the reported coefficients indicate how a one unit change in the predictor variable affect the "odds ratio" — the relatively probability of inclusion versus exclusion.

As mentioned earlier, an HMO may approve several drugs in a therapeutic category but encourage physicians and patients to use a subset of them, perhaps by use of differential copayments. To capture this possibility, we asked respondents to state whether drugs received preferential status. Preferential status was granted in about 20 percent of the cases. We recomputed the dependent variable by creating ordered categories of formulary inclusion; for example, we scored "on formulary-preferred" higher than "on formulary-not preferred." We then re-estimated our models of formulary inclusion using ordered probit, but obtained qualitatively similar findings to the logistic regression estimates. Specifically, the predictors that are statistically significant in the logistic regression remain statistically significant in the ordered probit regression, and the magnitudes of their effects on the probability of adoption are largely unchanged.

There is another meaningful distinction between drugs on the formulary that are exclusive within their therapeutic class and those that share formulary status (even preferred status) with substitutes. Many of the factors that we consider might affect decisions about whether to grant exclusivity to a drug and which drug to select. We did not collect information about exclusivity, however, and leave this issue to future research.

Predictor Variables

We asked the pharmacy directors to provide general descriptive information about their HMOs, as well as specific information about various organizational characteristics that might influence formulary adoption decisions. We also obtained information about each drug from

MedAd News, an industry trade publication.²⁶ From this information, we constructed variables that correspond to the various factors that potentially drive formulary adoption decisions. Table 3 lists and describes these variables, and indicates whether they are HMO-specific, drug-specific, or HMO/drug-specific.

Table 3 About Here

Several variables may be more meaningful when expressed in relation to others. For example, variable A2a, the "importance of pharmacy budget relative to plan", is reported on a scale of 1-5. But this may be more meaningful when measured in comparison with the importance of other elements of performance evaluation, A2b-A2d. Thus, we measured "relative importance of pharmacy budget" as equaling A2a divided by the average of A2a-A2d. Similarly, we computed relative importance of opinions for questions A4a-A4d. Lastly, we measured R1 and R2 (relationships with drug manufacturers) for each HMO as follows. We asked the HMO to report the number of visits by representatives from each drug maker. We then computed the nominal difference between the number of visits by each drug maker and the average across all drug makers. Table 4 reports summary statistics for key predictor variables.

Empirical Issues and Data Reduction

As described above, 41 of the 75 surveyed HMOs returned usable responses. Although we nominally have 287 observations (seven drugs and 41 HMOs), we effectively have far fewer degrees of freedom, because an HMO's adoption decision for one drug is likely to be correlated with that HMO's decision for other drugs. In other words, our observations are not necessarily

²⁶ In an unreported regression, we considered whether the drug was rated as having high therapeutic potential by the FDA. (Three drugs did: Evista, Lipitor, Rezulin, and Viagra). This was not a significant predictor of adoption.

independent within HMOs. We adjust our standard errors to account for this intra-HMO correlation in adoption decisions.²⁷

Correcting for intra-HMO correlation reduces the effective degrees of freedom, thereby limiting the number of predictor variables that we may include in our model. To maximize the information contained in predictor variables while minimizing the number of predictors, we performed a factor analysis of two sets of predictors, thereby reducing them to two composite scores. Specifically, we computed factor scores from a varimax factor analysis of the variables measuring the composition of the P&T committee and the extent to which the P&T committee relied on different sources of information inside and outside the firm. We selected three factors with eigenvalues greater than one. These factors were heavily loaded (loadings greater than 0.5) on the following underlying variables:

Factor 1: Extent to which P&T committee relies on input from management as opposed to published literature

Factor 2: Medical personnel on the P&T committee

Factor 3: Non-medical personnel on the P&T committee

Based on these factors, we constructed composite variables to reflect the principal contributing variables for each factor. The variable "Percentage Medical personnel on the P&T committee" equals the total number of physicians on the committee divided by the total size of the committee. The variable "Reliance on management rather than published literature" equals the difference between the relative importance ratings of these two information sources (i.e., A3a minus A3c).

²⁷ We use the `logistic,cluster` option in Stata.

Results

Table 5 reports the results of our logistic regression models. Model 1 in Table 5 includes HMO-specific economic factors that might affect formulary adoption decisions. Models 2-4 add various administrative factors and the measure of visits by company representatives. Model 5 includes two drug-specific measures. The first four models include drug-fixed effects, which directly account for differences across drugs in the benefit/cost ratios that influence the likelihood of adoption. The last model includes drug-specific variables and so excludes drug-fixed effects. We experimented with many other specifications. Our principle findings are robust to other specifications.

To better understand the logistic regression coefficients, it is useful to think about a drug that is included on 60 percent of all formularies. For this drug, the "odds ratio" — the relative probability of inclusion versus exclusion — is 1.5 (which equals $60/40$). If a logistic regression coefficient is 1, then the predictor variable has no effect on the probability of formulary inclusion. If the coefficient is 1.10, then a one unit increase in the predictor variable causes the odds ratio to increase by a factor of 1.10, in this case to 1.65. This would imply that the drug would be included on 62.3 percent of formularies (because $62.3/57.7 = 1.65$).

In Table 6, we use the coefficients from model 4 to report how representative changes in predictor variables affect the likelihood of formulary inclusion for different baseline inclusion probabilities. We summarize these findings below. In all cases below, we consider a drug that would normally be included on 60 percent of formularies. (This is the mean probability of formulary adoption, averaged across all the drugs and HMOs.)

Many HMO-specific economic factors, including size, drug expenditures, and whether or

not the PCPs are at financial risk for drug costs, have no effect on adoption. Other factors do predict adoption. For-profits have lower adoption rates, though the difference is only significant in the richest model specifications. Based on the coefficient on for-profit status in model 4, we conclude that a drug that is included in 60 percent of nonprofit formularies would only be included in 44 percent of for-profit formularies. HMOs serving large Medicaid and Medicare populations also have more restrictive formularies. If the Medicare and Medicaid share of HMO enrollment increases by 20 percentage points (approximately one standard deviation in the sample), then the likelihood of adoption falls to 52 percent.

Several organizational factors significantly affect formulary decisions. In each example below, we compute the effect of a roughly one standard deviation increase in the value of the predictor on the probability of formulary inclusion. Larger P&T committees tend to approve fewer drugs. Adding five members to the P&T committee reduces the inclusion probability to just 33 percent. The incentives inherent in the performance evaluation of the pharmacy director have a substantial impact on adoption decisions. An 0.8 increase in the relative importance of the criterion "importance of meeting Rx budget" reduces the probability of adoption to 44 percent. In contrast, if the relative importance of the overall HMO budget increases by 0.8 percent, the chances of adoption increase to 71 percent. Lastly, if the relative importance of member satisfaction increases by 0.8 percent, then the chances of adoption increase to 78 percent.

HMOs tend to favor manufacturers whose representatives pay more visits. If representatives make four additional annual visits, the probability of formulary inclusion increases to 77 percent. This result could reflect endogeneity; i.e., drug manufacturer representatives might make more visits to HMOs when they have products with a higher

potential for adoption. However, the manufacturers of the drugs that we study sell many drugs besides those we analyze. Thus, we can take the number of visits as exogenous, and we interpret causality as running from visits to adoption. The makeup of the P&T committee and the sources of information that it relies upon also matter. Increasing the relative importance of management opinion versus the published literature by .25 increases the probability of adoption to 73 percent. Replacing two medical personnel on the P&T committee with two non-medical personnel reduces the likelihood of adoption to 50 percent. This latter finding may reflect Fuchs' "therapeutic imperative"; i.e., specialty physicians may argue for the full complement of therapeutic modalities in their specialty available on the formulary regardless of cost.²⁸

Lastly, we find that drug sales do not affect adoption decisions, but that drugs with more direct competitors have a greater chance of adoption. The addition of two direct competitors boosts the adoption probability to 69 percent. This is consistent with competition forcing manufacturers to give larger rebates to encourage adoption.

Discussion

Prior to the growth of managed care, pharmaceutical companies directed their marketing efforts at physicians and hospitals. With managed care, pharmaceutical companies found that this was not sufficient. Now, they must convince MCOs to include their drugs on their formularies. Pharmaceutical companies have taken a number of steps to market their products to MCOs, including (1) MCO-specific sales forces, (2) disease-management programs, and (3) the establishment of in-house pharmacoeconomic programs. Managed care has also played a critical role in the development of direct-to-consumer (DTC) advertising. According to some

28 Fuchs (1974)

pharmaceutical executives with whom we have spoken, one of the goals of DTC advertising is to get MCO enrollees to pressure their physicians to prescribe, and therein, their MCOs, to pay for advertised drugs. Despite these efforts, pharmaceutical companies have had mixed success promoting their drugs to MCOs. The fact that some HMOs are willing to pay for drugs while others are not is a challenge for pharmaceutical companies. It is also a concern to patients, albeit not always a perceived one, because their access to drugs may depend on their choice of HMO. To the extent that MCOs believe that they use purely objective cost-benefit analyses to guide adoption decisions, the importance of organizational factors should be a concern.

In this paper, we have attempted to identify organizational factors that cause inter-HMO variation in formulary adoption decisions. We studied seven drugs that were not universally adopted upon initial launch. By estimating a fixed drug effects model, we controlled for the overall propensity of HMOs to adopt each drug and examined why there is inter-HMO variation in adoption probabilities for each drug. Our key finding is that organizational characteristics do matter. The ways in which HMOs structure their review process, how they reward their key decision makers, and their relationships with manufacturers all affect adoption decisions. As a result, two seemingly similar HMOs (same size, nonprofit status) will often make different decisions about drug adoption. For example, HMOs with large P&T committees are much less likely to adopt drugs, whereas HMOs that reward their pharmacy directors on the basis of overall medical costs, rather than just pharmacy costs, are more likely to adopt drugs.

We should make several caveats about our findings. First, we only examine HMOs that develop their own formularies. The factors that influence their adoption decisions may differ from those in HMOs that outsource formulary development. Second, we examine a snapshot in time. It is possible that the adoption rates for drugs increase over time. This suggests that it

would be valuable to study adoption rates over time as well as in cross-section. Third, we intentionally study “controversial” drugs; i.e., commonly prescribed drugs with variable rates of adoption. Virtually all drugs are less controversial than those that we study, suggesting that there is substantial agreement among HMO formularies. Fourth, some of our predictor variables, such as the size of the P&T committee, may be endogenous to the overall goals of the HMO. Thus, an HMO that wishes to forestall drug adoption may enlarge its P&T committee. If so, then the observed negative effect of the size of the committee on adoption may be a reflection of the HMO’s overall objectives rather than a result of the size of the committee *per se*. Fifth, even though many of our predictor variables are statistically significant and have substantial magnitudes, our models fail to explain the majority of the variation among formulary adoption decisions. There are clearly additional sources of variation left to be identified. Finally, we note that since we performed our study, many HMOs have moved to more complex formulary structures, with multiple copayment levels that depend on different levels of “preferred” status. This might make it more difficult to predict whether drugs will be included on a formulary, and at what level of coverage.

What are the implications of our results for pharmacy directors and other participants in formulary adoption decisions? The upward pressure on pharmaceutical costs in managed care will only raise the stakes of formulary adoption decisions. Our findings suggest that many adoption decisions are based on organizational factors, rather than objective cost-benefit analyses. HMOs must review their internal systems to assure that they are making objective assessments of costs and benefits. The upward pressure on drug costs has also pressured some HMOs to adopt more complex drug benefits characterized by, for example, three or more tiers of copayments. At one level, the use of multiple tiers reduces the significance of the initial

formulary adoption decision. But, it ushers in more complexity, as pharmacy decision makers must determine both whether to include a drug on formulary and the appropriate tier.

It is reasonable to expect that some level of inter-HMO variation in adoption decisions will persist. HMOs are unlikely to become the same size, adopt identical objectives, or interpret of evidence on drug benefits and costs in the same way. Since variation across HMO formularies is likely to persist, the question arises of its consequences for consumers. Variation in adoption decisions for drugs that have close therapeutic substitutes is unlikely to have important clinical consequences, provided that at least one of the class of drugs is on the formulary. However, variation in adoption decisions for therapeutically unique products may adversely affect some patients, especially if patients are unaware of the drug's formulary status at the time they select their HMO, or are offered no choice of HMO by their employer. Research to determine the medical and economic impact of formulary variation would appear appropriate.

Our findings have relevance to pharmaceutical companies as well. We have shown that some HMOs are harder to “crack” than others, and may require greater sales and marketing effort. At the same time, individual sales personnel should not be penalized if they fail to get adoption at particular HMOs. Relationships between drug manufacturers and HMOs influence adoption decisions. Therefore, investing in these relationships can yield long-term benefits to pharmaceutical firms. Interestingly, by changing personal selling relationships between manufacturers and HMO, mergers within the pharmaceutical industry can affect adoption decisions.

Although we have not developed or tested a normative model, our findings do have some normative implications. To the extent that there is an “optimal” formulary based on objective benefit-cost data, our findings indicate that some HMOs do not achieve it. Over time, some

HMOs may move towards such a formulary by learning from their own experiences and the experiences of others about the effects of organizational factors on adoption decisions. More and better scientific information will also help HMOs develop formularies that best balance benefits and costs.

Table 1

Summary of Factors Potentially Affecting Formulary Adoption Decisions

Factor	Predicted Direction	Rationale
Nonprofit Status	More likely to adopt	Offer more "hard to observe" attributes of quality
Large Medicare/Medicaid Population	Less likely to adopt	Public payers less likely to boost rates for more generous formulary
Larger HMO	Ambiguous	Obtains purchasing discounts/ bureaucratic decision making
Capitated physicians	Ambiguous	Capitation may substitute for or complement use of a formulary
Pharmacy director rewarded for controlling drug costs	Less likely to adopt	Financial incentives
Pharmacy director rewarded for controlling total costs	More likely to adopt	Drugs may substitute for more costly interventions
Large P&T committee	Less likely to adopt	Harder to reach consensus; Composition of P&T committee may also affect adoption
Percentage physicians on P&T committee	More likely to adopt	Favor "quality" over "cost"
Frequent contacts with drug company representatives	More likely to adopt	Receive more favorable information and obtain better service
Number of drugs in the therapeutic category	Ambiguous	Less need to adopt, but potentially lower costs of adoption

Table 2
Drugs Studied

Drug	Manufacturer	Indicated for...	Year Approved ^a	Worldwide Sales (1998)	Formulary Inclusion Rate
Allegra	Hoechst AG	Allergies	1996	\$485 million	.80
Amerge	Glaxo	Migraine	1997	\$90m [*]	.25
Diovan	Novartis	Hypertension	1996	\$282m	.39
Evista	Eli Lilly	Osteoperosis	1997	\$144m	.51
Lipitor	Warner Lambert	Cholesterol Reduction	1996	\$2200m	.68
Rezulin	Warner Lambert	Type 2 Diabetes	1997	\$748m	.66
Viagra	Pfizer	Erectile Dysfunction	1998	\$1100m ^{**}	.39

a For U.S. Sales

* Not listed by *MedAdNews*. Sales estimated

** Twelve month sales estimate extropolated from nine months sales.

Table 3

Factors Affecting Likelihood of Formulary Adoption

<i>Economic and Organizational Factors</i>	
E1	Worldwide drug sales in 1998 (drug specific). Worldwide sales typically exceed U.S. HMO sales by a factor of four or more, so may be treated as exogenous to the decisions of U.S. HMOs.
E2	Number of direct competitors in 1998 (drug specific). These are drugs within the same therapeutic category and class as the drug in question.
E3	In the HMO nonprofit? (HMO specific)
E4	Percentage of HMO revenue derived from Medicare and Medicaid (HMO specific)
E5	Percentage of primary care practitioners at financial risk for pharmacy cost (HMO specific)
<i>Administrative Factors</i>	
A1	To whom does the Director of Pharmacy report? (HMO specific)
A2	Importance of the following elements of Director of Pharmacy's performance evaluation (HMO specific)
A2a	Pharmacy budget relative to plan
A2b	Overall profitability of HMO
A2c	Member satisfaction with pharmacy
A2d	NCQA accreditation
A3	Number and composition of the Pharmacy and Therapeutics committee ²⁹ (HMO specific)
A4	Extent to which P&T committee obtains information from the following sources (HMO specific)
A4a	HMO management
A4b	Other MDs in HMO
A4c	Published literature
A4d	Consulting firms
A4e	Specialty societies
A4f	Competing health plans
<i>Relationship with Pharmaceutical Companies</i>	
R1	Number of times company representative visited HMO in previous year (HMO/drug specific)
R2	Overall satisfaction with company (1=not satisfied; 5=very satisfied) (HMO/drug specific)
<i>Other characteristics not specified</i>	
O1	HMO size (1=smallest size class; 4 = largest size class) (HMO specific)
O2	Per member, per month pharmacy costs, and rate of PMPM increase (HMO specific)

²⁹ Five HMOs did not report this information. We set their P&T committee size and makeup equal to the average, so as to preserve degrees of freedom.

Table 4**Descriptive Statistics for Selected Key Variables**

Predictor Variable	Mean	Std. Dev.
For-Profit	.538	.486
Percentage Medicaid and Medicare	21.3	21.9
Per member per month Rx costs	\$19.00	6.50
% of PCP income at risk for drug costs	31.7	34.1
Size of PT committee	14.4	5.3
Does Dir. Of Pharmacy report to CEO or COO?	.414	.493
Importance of meeting Rx budget (1-5 scale)	4.17	.853
Importance of overall HMO budget (1-5 scale)	3.21	1.21
Importance of member satisfaction (1-5 scale)	3.64	.871
Visits by Rx company representatives	6.62	5.78
Mngt opinion versus published literature	-.345	.25
Percentage physicians on P&T committee	.57	.21
Number of direct competitors	2.5	2.12
Worldwide drug sales (in \$millions)	631	687

Table 5: Logistic Regression Results

(Coefficients indicate effect of one unit change in predictor variable on the odds ratio)

(Models 1-4 include unreported fixed drug effects)

Predictor	Model 1	Model 2	Model 3	Model 4	Model 5
For-Profit	.667	.640	.645	.520 ^c	.535 ^c
Percentage Medicaid and Medicare	.974 ^a	.976 ^a	.976 ^a	.985 ^c	.988 ^c
Size	1.033	--	--	--	--
Per member per month Rx costs	1.030	--	--	--	--
% of PCP income at risk for drug costs	.9978	--	--	--	--
Size of PT committee	--	.876 ^a	.858 ^a	.802 ^a	.831 ^a
Does Dir. Of Pharmacy report to CEO or COO?	--	1.27	--	--	--
Importance of meeting Rx budget	--	.535 ^a	.448 ^a	.455 ^a	.559 ^b
Importance of overall HMO budget	--	1.438	1.526	1.816 ^b	1.684 ^b
Importance of member satisfaction	--	2.180 ^a	2.249 ^a	3.048 ^a	2.644 ^b
Visits by Rx company representatives	--	--	1.201 ^a	1.223 ^a	1.146 ^a
Mngt opinion versus published literature	--	--	--	10.997 ^b	8.199 ^a
Percentage medical personnel on P&T committee	--	--	--	1.075	1.062
Number of direct competitors	--	--	--	--	1.214 ^a
Worldwide drug sales	--	--	--	--	1.000036
Pseudo R ²	.1512	.2275	.2714	.309	.218

a - Significantly different from 1 at p<.01 **b** -Sign at p < .05 **c**- Sign at p < .10

Table 6**Magnitudes of Estimated Effects**

Predictor	Change in Variable	Adoption Probability Changes from 60 percent to:
Ownership status	Going from Nonprofit to For-profit	44 percent
Percentage Medicare and Medicaid	Reduce by 20 percent	52 percent
P&T committee size	Adding 5 members	33 percent
Relative importance of meeting Rx budget	Increase score by 0.8	44 percent
Relative importance of overall HMO budget	Increase score by 0.8	71 percent
Relative importance of member satisfaction	Increase score by 0.8	78 percent
Visits by manufacturer reps	Four additional visits	77 percent
Importance of management opinion versus published literature	Increase by factor of 0.25	73 percent
Medical versus non-medical personnel on the P&T committee	Increase physician representation by 10 percent	Not significant
Number of direct competitors	Two additional competitors	69 percent

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