Evaluation of an Automated System for Prior Authorization: A COX-2 Inhibitor Example

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Objective: To evaluate the effectiveness of an automated prior authorization (PA) system (SmartPA) in reducing use of and expenditures for cyclooxygenase-2 (COX-2) inhibitors.

Study Design: Before and after with control group.

Methods: After implementation of SmartPA in Missouri, changes in use of and expenditures for COX-2 inhibitors, COX-2 substitutes (traditional nonsteroidal anti-inflammatory drugs [NSAIDs] and other products for pain), and gastrointestinal (GI) protective agents were compared between the Medicaid program of Missouri and that of a state with no PA program for COX-2 inhibitors. Subjects were continuously enrolled for the 24-month study period and had a claim for a COX-2 inhibitor in the 12-month baseline period. Analyses included comparison of means and linear regression. Regressions controlled for age, sex, risk for GI complications, severity of illness, and the interaction between state and risk.

Results: Changes in expenditures for COX-2 inhibitors, NSAIDs, other pain drugs, and GI-protective drugs were $256 higher, $56 lower, $21 higher, and $198 higher, respectively, in the control state among low-risk patients. Changes in expenditures were $102 higher, $12 lower, $21 lower, and $185 higher, respectively, in the control state among high-risk patients. Results were similar for drug utilization.

Conclusion: Implementation of SmartPA resulted in reduced use of and expenditures for COX-2 inhibitors and reduced net expenditures for all pain and GI-protective medications. These effects were greatest for patients at low risk for GI complications.

(Am J Manag Care. 2006;12:501-508)

State Medicaid prescription drug expenditures continue to grow at an alarming rate. Expenditures grew by more than 15% in 2003, the latest year for which data were available.[1] Increases in expenditures in the prior 3 years exceeded 19%.[2-4] As one means of controlling growing prescription expenditures, 49 state Medicaid programs have implemented prior authorization (PA) programs.[2]

A number of studies have indicated that PA programs can produce significant savings. Smalley and colleagues documented a 53% decrease in expenditures on nonsteroidal anti-inflammatory drugs (NSAIDs) after imposition of a PA program for brand name NSAIDs in the Tennessee Medicaid program.[5] Kotzan et al also documented substantial savings after introduction of a PA program for single-source NSAIDs in the Georgia Medicaid program.[6] Neither program found that medical or hospital costs increased after imposition of the PA program. Phillips and Larson examined PA programs for NSAIDs, benzodiazepines, histamine-2 receptor antagonists (H2RAs), and nonsedating antihistamines in the Iowa Medicaid program.[7] They estimated savings of between $2.5 million and $3.8 million net of administrative expenses. Fischer and colleagues examined the effects of Medicaid PA programs on the use of cyclooxygenase-2 (COX-2) inhibitors in a national sample of Medicaid programs.[8] The results indicated savings of about $10 per NSAID prescription dispensed. The savings resulted from a 15% decrease in the proportion of NSAID doses represented by COX-2 inhibitors. Hartung et al[9] and Gleason et al[10] also found evidence of PA-related cost savings on COX-2 inhibitors. Delate et al found that PA was effective in reducing expenditures on proton pump inhibitors in a state Medicaid program.[11] Their analyses also indicated no offsetting increases in other medical expenses.

ACS Heritage has developed an automated electronic PA system (SmartPA) that works as an enhanced point-of-sale (POS) processing tool. It uses a clinical rules system that queries both drug and medical claims data at the POS in addition to incorporating provider-supplied information within a call center. At the pharmacy POS level, pharmacists enter the patient's prescription into their computer system and submit the claim electronically as they normally would. The claim then is processed through clinical and fiscal edits specific to the medication. The POS system automatically queries the administrative databases (drug claims, medical claims, encounters) and determines whether the PA criteria have been met. (The criteria used in the SmartPA program for COX-2 inhibitors are shown in **Table 1**.) If PA criteria are

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This study was funded by ACS Heritage.

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met, the pharmacist is sent a message that the prescription is approved. If the prescription is not approved, then the patient and physician have the option of submitting the PA request manually for additional review. The physician may contact the call center and possibly provide new information that was not available in the electronic database, and the request will be reevaluated.

The purpose of this study was to evaluate the effectiveness of the SmartPA system in controlling use of and expenditures for COX-2 inhibitors. COX-2 inhibitors, a subclass of NSAIDs, were, at the time of the study, widely prescribed for relief of chronic arthritis pain. These agents were as effective as, but substantially more expensive than, nonselective NSAIDs. However, COX-2 inhibitors were believed to have substantially lower gastrointestinal (GI) toxicity than nonselective NSAIDs.[12-19] Although COX-2 inhibitors were indicated in patients at high risk for GI problems, many patients who were prescribed COX-2 inhibitors lacked these risk factors and could have been treated just as effectively and safely, but at much lower expense, with nonselective NSAIDs. Because of this, traditional PA programs for COX-2 inhibitors have been shown to generate substantial savings. However, the effects of an automated electronic PA system have not been previously reported.

This study had 3 specific objectives:

- To compare changes in use of and expenditures for COX-2 inhibitors as well as products that may have been used as substitutes for COX-2 inhibitors after implementation of the SmartPA program in the Missouri Medicaid program. If COX-2 therapy is denied for a specific patient, his or her physician may use alternative therapies such as nonselective NSAIDs or other pain medications (eg, narcotic analgesics, pentazocine, propoxyphene). Additionally, because COX-2 inhibitors have lower GI toxicity than nonselective NSAIDs, use of products for the prevention or treatment of ulcers (eg, H2RAs, misoprostol, proton pump inhibitors) may increase when COX-2 therapy is denied. If utilization of COX-2 inhibitors is controlled, it is reasonable to expect an increase in the utilization of substitute or adjunct products.
- To compare changes in use of and expenditures for COX-2 inhibitors and substitute products between patients at high risk and low risk for GI problems. If the SmartPA system works as designed, there should be a greater decrease in utilization and expenditures of COX-2 inhibitors in the low-risk group than in the high-risk group.
- To estimate net savings on drug costs attributable to SmartPA-related decreases in COX-2 expenditures, taking into account increases in expenditures for substitute products.

METHODS

We examined changes in use of and expenditures for COX-2 inhibitors and potential substitutes using a before-and-after study design with a control group. The intervention group consisted of fee-for-service patients enrolled in the Missouri Medicaid program. Missouri Medicaid implemented the SmartPA program for COX-2 inhibitors on December 16, 2002. The baseline period for the study was the 12 months immediately preceding the date of implementation, and the post intervention period was the 12 months immediately after the date of implementation. The control group consisted of fee-for-service patients enrolled in the Medicaid program of a large eastern state that did not have a PA program for

Table 1. SmartPA COX-2 Inhibitor Approval Criteria

Patients were approved to receive COX-2 inhibitors if they met *any* of the following criteria:

1. Age 65 years or older at the time of the request.
2. Pharmacy claims history for any of the following:
   - High-dose (>75% of the recommended daily maximum) NSAIDs in the 180 days preceding the COX-2 request.
   - >35 days of oral steroid* therapy in the 90 days preceding the COX-2 request.
   - Warfarin in the 45 days preceding the COX-2 request.
   - Two different nonselective NSAIDs† in the 180 days preceding the COX-2 request.
   - Adalimumab, anakinra, gold compounds, etanercept, hydroxychloroquine, infliximab, leflunomide, oral methotrexate, or penicillamine (inferred rheumatoid arthritis diagnosis).
3. Medical/encounter claims history for any of the following in the 2 years preceding the COX-2 request:
   - Peptic ulcer disease (*ICD-9* codes 531.xx–534.xx).
   - Gastrointestinal bleed (*ICD-9* code 578.xx).
   - Rheumatoid arthritis (*ICD-9* codes 7140.x–7148.x).
   - Osteoarthritis (*ICD-9* code 715.xx).
   - Familial adenomatous polyposis (*ICD-9* code 211.3) for celecoxib requests only.

*Oral steroids included paramethasone, prednisone, betamethasone, cortisone, dexamethasone, hydrocortisone, methylprednisolone, prednisolone, and triamcinolone.
†Different nonselective NSAIDs were defined by using the unique First DataBank Hierarchical Ingredient Code List.
COX-2 indicates cyclooxygenase-2; NSAIDs, nonsteroidal anti-inflammatory drugs; *ICD-9, International Classification of Diseases, Ninth Revision.*

COX-2 inhibitors. The baseline and postintervention periods for the control group were the same as for the intervention group. The analysis included all patients who were continuously eligible for Medicaid over the 24-month study period and who had at least 1 claim for a COX-2 in the baseline period.

We examined the cost and use of COX-2 inhibitors, nonselective NSAIDs, other medications used for treatment of pain, proton pump inhibitors, H2RAs, and misoprostol. The Medicaid agencies in both states covered both prescription and nonprescription products for these drug classes. Comparisons were made on a per-patient per-year basis. For purposes of the analysis, patients in each state were categorized into high-risk and low-risk groups. The categorization was based on data from the baseline period. Patients in the high-risk group were those who met the criteria shown in Table 1. Unadjusted means and standard deviations were calculated for changes in expenditures and utilization for each class of drugs after implementation of SmartPA and for both high-risk and low-risk patients in each state. Ordinary least squares linear regressions were run to compare changes in expenditures and utilization after controlling for between-group differences in age, sex, risk for GI problems, the interaction between risk for GI problems and state of residence, and severity of illness. Severity of illness was measured with the Charlson Comorbidity Index.[20] The index is a weighted measure of a patient's risk of mortality. It is based on the number and severity of diseases from which the patient suffers. The index was adapted so that *International Classification of Diseases, Ninth Revision* scores from administrative databases can be used to calculate it.[21] If the SmartPA program worked as intended, there should have been a major effect on patients at low risk for GI complications and little effect on patients at high risk. There should be little effect on either group in the control state. We modeled this hypothesis by including a term for the interaction between state and risk in the regression models. GI-protective agents were subject to traditional PA in Missouri in the baseline period and were subject to SmartPA afterwards. GI-protective agents were not covered by either type of PA in the control state in either period.

We estimated unadjusted aggregate drug cost savings related to the SmartPA on COX-2 inhibitors as:

> [(Mean change in COX-2 expenditures in Missouri – mean change in COX-2 expenditures in control state) – (mean change in expenditures for COX-2 substitutes in Missouri – mean change in expenditures for COX-2 substitutes in control state)] × Number of COX-2 users in Missouri

We also calculated aggregate drug savings controlling for age, sex, risk for GI problems, severity of illness, and the interaction between risk for GI problems and state. Regression coefficients were used to calculate the predicted means for changes in expenditures for COX-2 inhibitors, nonselective NSAIDs, and other products for pain. The differences in means between the control state and Missouri were then calculated for each level of risk. Each difference was then multiplied by the number of Missouri patients in the risk group to give aggregate estimates. The sum of the aggregate measures over both risk groups gave estimated aggregate savings on drug costs in Missouri for the first year after implementation of the SmartPA program.

Finally, we gathered statistics on call center volume for COX-2 inhibitors in Missouri's Medicaid program after implementation of the SmartPA system. We compared these with the call center volume that would have been expected in a traditional PA program. Both estimates were based on the entire Medicaid fee-for-service population in Missouri.

The identifiers used for patients in this study were randomly assigned. No key was maintained that would allow the identifiers to be matched to individual patient names or identities. Consequently, the project did not fall under the regulatory definition of human subjects research and did not require review by an institutional review board.

RESULTS

Baseline characteristics of the sample are shown in **Table 2**. The sample of patients from Missouri was younger, had greater use of and expenditures for prescription drugs, included a smaller proportion of patients at high risk for GI toxicity, and had a higher severity of illness as measured by the Charlson Comorbidity Index. The 2 samples were similar in terms of sex and mean number of different medications per patient.

A comparison of unadjusted means indicated that the SmartPA program was effective in reducing expenditures on COX-2 inhibitors (**Table 3**). Expenditures for these agents in Missouri declined by $131 per patient per year while expenditures in the control state increased by $59 per patient per year. As shown in the **Figure**, a major decrease in COX-2 expenditures occurred around the time of implementation of the SmartPA program.

Missouri also had greater increases in expenditures on NSAIDs and other medications for pain. Expenditures on GI-protective medications declined in Missouri while increasing substantially in the control state. Changes in the sum of expenditures for all 4 types of agents (COX-

Table 2. Characteristics of Sample Patients During Baseline Year

Characteristic	Mean (SD)	
	Missouri (n = 42 262)	Control (n = 62 306)
Age, y	56.9 (18.3)	64.8 (16.3)*
No. of different medications for the year†	12.5 (6.5)	12.4 (5.9)*
No. of pharmacy claims for the year	84.5 (51.3)	65.8 (34.8)*
Per-patient per-year pharmacy expenditure, $	400.0 (774.5)	339.6 (428.6)*
Female, %	75.5	75.8
High risk for GI complications, %‡	44.6	61.3*
Charlson Comorbidity Index§	0.82 (1.06)	0.40 (0.96)*

*$P < .001$.
†The number of different medications was determined by using the unique First DataBank Hierarchical Ingredient Code List (HICL). The HICL identifies drugs at the ingredient level.
‡Patients were classified as high risk if they met any of the criteria shown in Table 1.
§Possible scores on the Charlson Comorbidity Index range from 0 to 37. However, most scores are in the 0-5 range.[20,21]
GI indicates gastrointestinal.

Table 3. Changes in Expenditures and Prescription Claims for Pain Medications and GI-protective Medications After Implementation of the SmartPA Program for COX-2 Inhibitors in Missouri

Change	Mean (SD)	
	Missouri (n = 42 262)	Control (n = 62 306)
In expenditures per patient per year, $		
COX-2 inhibitors	−131 (445)	59 (354)*
Nonselective NSAIDs	45 (196)	9 (112)*
Other pain medications	106 (746)	81 (747)*
GI-protective medications	−6 (297)	181 (401)*
In number of paid prescription claims per patient per year		
COX-2 inhibitors	−1.6 (4.2)	0.4 (3.6)*
Nonselective NSAIDs	0.7 (3.2)	0.2 (2.1)*
Other pain medications	0.7 (5.8)	1.0 (4.4)*
GI-protective medications	0.4 (1.4)	1.4 (3.3)*

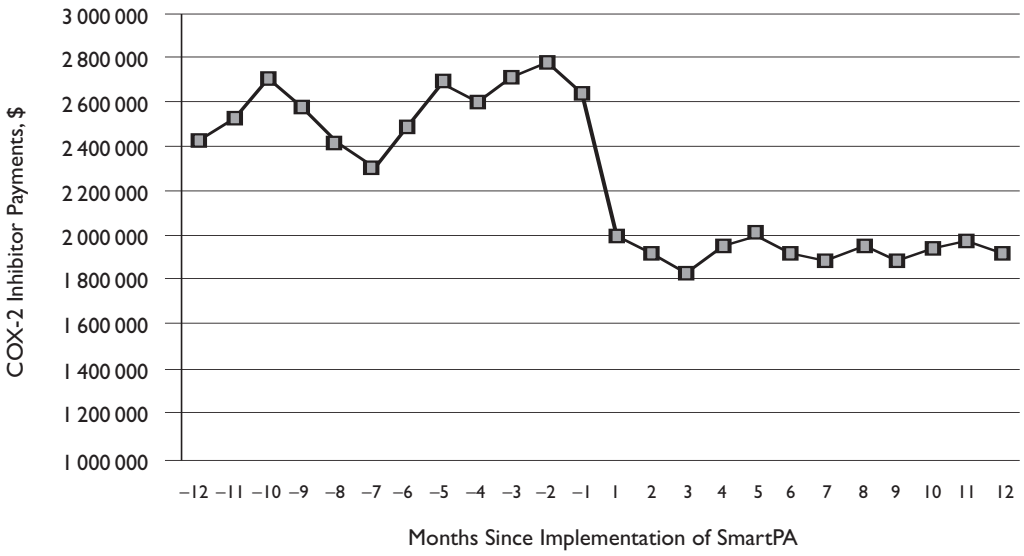
*All between-state differences were significant at $P < .001$.
GI indicates gastrointestinal; COX-2, cyclooxygenase-2; NSAIDs, nonsteroidal anti-inflammatory drugs.

2 inhibitors, nonselective NSAIDs, GI-protective medications, and other medications for pain) were substantially less in Missouri than in the control state. A comparison of changes in claims for these agents showed similar results (Table 3).

Mean comparisons indicated that the effects of SmartPA in Missouri were substantially greater for low-risk patients than for high-risk patients (**Table 4**). Expenditures for and use of COX-2 inhibitors decreased in Missouri in both the low-risk and the high-risk groups. However, the decrease was 2 to 3 times greater in the low-risk group. By comparison, expenditures and utilization increased by similar amounts in the low-risk and high-risk groups in the control state. In addition, increases in the use of and expenditures for nonselective NSAIDs and other pain medications were greater in the low-risk group than the high-risk group in Missouri, and were greater in Missouri than in the control state. These findings indicate that SmartPA was selective for patients at low risk of GI problems. Increases in use of and expenditures for GI-protective products were much larger in the control state, but little difference was seen between high-risk and low-risk groups within either state.

Results of linear regressions on expenditures and utilization of COX-2 inhibitors are shown in **Table 5**. Results indicated that changes in expenditures for COX-2 inhibitors among low-risk patients were about $256 greater per patient per year in the control state than in Missouri. Among high-risk patients, expenditures were about $102 greater in the control state. The regression coefficients for state, GI risk, and the interaction of state and risk were statistically significant. This indicates that the observed differences in changes in expenditures between Missouri and the control state and between high-risk

Figure. Changes in COX-2 Payments After Implementation of an Automated Prior Authorization (PA) System SmartPA



COX-2 indicates cyclooxygenase-2.

Table 4. Expenditures and Prescription Claims for Pain Medications and GI-protective Medications by State and Risk of GI-related Complications After Implementation of SmartPA Program for COX-2 Inhibitors in Missouri

	Mean (SD)			
	Low Risk		High Risk*	
Change	Missouri (n = 23 427)	Control (n = 24 116)	Missouri (n = 18 835)	Control (n = 38 190)
In expenditures per patient per year, $				
COX-2 inhibitors	−190 (447)	70 (356)	−58 (431)	51 (351)
Nonselective NSAIDs	63 (213)	8 (98)	22 (171)	10 (120)
Other pain medications	127 (877)	140 (1095)	80 (538)	43 (387)
GI-protective medications	−6 (308)	192 (413)	−7 (282)	175 (393)
In number of paid prescription claims per patient per year				
COX-2 inhibitors	−2.2 (4.1)	0.5 (3.4)	−1.0 (4.2)	0.3 (3.6)
Nonselective NSAIDs	1.2 (3.3)	0.2 (2.0)	0.2 (2.7)	0.2 (2.1)
Other pain medications	0.7 (5.9)	1.4 (4.9)	0.6 (5.5)	0.7 (4.0)
GI-protective medications	0.3 (3.3)	1.3 (3.2)	0.4 (3.6)	1.4 (3.3)

*Patients were defined as high risk if they met any of the criteria shown in Table 1.
GI indicates gastrointestinal; COX-2, cyclooxygenase-2; NSAIDs, nonsteroidal anti-inflammatory drugs.

and low-risk groups were statistically significant. In addition, it indicates that the effect of state (or PA) was significantly different in the low-risk group than in the high-risk group. That is, the larger effect of the PA program in the low-risk group compared with the high-risk group was statistically significant. A regression on utilization of COX-2 inhibitors showed similar results (Table 5).

We also ran separate regressions on expenditures and utilization of nonselective NSAIDs, other pain medicines, and GI-protective agents (Table 5). The results indicated that expenditures on nonselective NSAIDs

Table 5. Regression Coefficients Indicating Changes in Expenditures and Prescription Claims for COX-2 Inhibitors and Potential COX-2 Substitutes After Implementation of SmartPA Program for COX-2 Inhibitors in Missouri*

Change	State	Age	Sex	Risk for GI Complications	Severity of Illness (Charlson Comorbidity Index)	Interaction of State and GI Risk	R^2
In expenditures per patient per year, $							
COX-2 inhibitors	256.3†	0.8†	–18.7†	110.7†	–6.1†	–153.9†	0.070
Nonselective NSAIDs	–55.8†	–0.1‡	1.3	–39.1†	–1.4§	43.2†	0.020
Other pain medications	21.1‡	–1.5†	26.0†	–11.1	16.9†	–42.5†	0.004
GI-protective medications	198.8†	–0.1	–8.2§	1.1	3.3§	–14.8§	0.060
In number of paid prescription claims per patient per year							
COX-2 inhibitors	2.59†	0.01†	–0.16†	0.97†	–0.05†	–1.35†	0.070
Nonselective NSAIDs	–0.92†	0.00	0.07†	–0.95†	–0.01	0.89†	0.024
Other pain medications	0.69†	–0.01†	–0.04	0.03	0.03‡	–0.53†	0.004
GI-protective medications	0.99†	0.01†	–0.06‡	–0.07	0.03‡	–0.01	0.024

*Coding for dichotomous variables: state: 0 = Missouri, 1 = control; sex: 0 = female, 1 = male; risk for GI complications: 0 = low, 1 = high.
†$P < .001$.
‡$P < .05$.
§$P < .01$.
COX-2 indicates cyclooxygenase-2; GI, gastrointestinal; NSAIDs, nonsteroidal anti-inflammatory drugs.

increased $56 more in Missouri than in the control state for low-risk patients but only about $12 more in Missouri among high-risk patients. As with the regression on COX-2 expenditures, the regression coefficients for state, GI risk, and the interaction of state and risk were statistically significant. This indicates that the differences in changes in expenditures on nonselective NSAIDs were significantly different between states and between risk groups, and that the difference in the effects of PA between high-risk and low-risk groups was statistically significant.

Expenditures on other pain medicines were about $21 per patient per year lower in Missouri among low-risk patients but about $21 higher in Missouri for high-risk patients. Increases in both expenditures for and utilization of GI-protective agents were substantially higher in the control state than in Missouri, and changes in each state were similar for low-risk and high-risk groups. For both other pain medicines and GI-protective agents, the differences between states were significantly different, while differences in risk for GI complications were not.

Calculations based on the figures in Table 3 yielded an estimated $5 450 000 in unadjusted drug cost savings resulting from SmartPA. When the effects of age, sex, severity of illness, risk for GI complications, and the interaction between state and risk were statistically controlled, the resulting estimates indicated savings of about $6 440 000. This estimate was based on the regression coefficients in Table 5. (We did not include changes in spending on GI-protective agents in these estimates because, as discussed earlier, they were subject to PA in Missouri but not in the control state. Including the changes in spending on these agents would have resulted in larger savings estimates.)

DISCUSSION

The results of our study indicated that the SmartPA program was successful in controlling expenditures for and use of COX-2 inhibitors. The cost and utilization of these agents decreased in the SmartPA program while increasing substantially in the control state. These findings are consistent with past research on PA in state Medicaid programs.[5-11]

We expected to see greater increases in the use of COX-2 substitute products (nonselective NSAIDs, other pain products, GI-protective products) in Missouri than in the control state as a result of decreased use of COX-2 inhibitors. The results did indicate greater increases in the use of nonselective NSAIDs, but not in the use of GI-protective products. Part of the reason that use of GI-protective products did not increase in Missouri may have been that they were subject to SmartPA. However, they were subject to traditional PA before implementation of the SmartPA program, so any effects on the level of GI-protective product usage would have occurred

before the time of our study. Further, the SmartPA program decreased use of COX-2 inhibitors primarily in patients at low risk of GI problems. These patients would be less likely to need GI-protective agents when treated with nonselective NSAIDs. So the fact that the SmartPA program for COX-2 inhibitors did not result in large increases in the use of GI-protective agents may be reasonable. However, part of the difference in changes in usage between the states probably resulted from Missouri's PA program. Specifically, the PA program likely prevented increased use of these agents in Missouri, while use in the control state continued to increase. In any case, Missouri's increases in the sum of expenditures for and utilization of all pain products (COX-2 inhibitors, nonselective NSAIDs, and other products for pain) were much smaller than those in the control state after implementation of the SmartPA program.

Further, the results indicated that the SmartPA program controlled cost and use selectively. Cost and use of COX-2 inhibitors decreased to a much greater extent among patients at low risk for GI problems than among patients at high risk. Use of and expenditures for COX-2 inhibitors did decrease somewhat in the high-risk group. This may suggest that there is some spillover or learning effect among physicians as a result of the SmartPA program. That is, as prescriptions for COX-2 inhibitors for low-risk patients are denied by the SmartPA program, physicians learned that these agents were subject to administrative controls and responded by decreasing prescribing of COX-2 inhibitors for all patients. Another reason for the decrease in COX-2 use in the high-risk group may have been an artifact of the sample we selected. The analysis was conducted on all patients with at least 1 prescription for a COX-2 inhibitor in the baseline period. It seems likely that some patients would have stopped using COX-2 inhibitors even in the absence of a PA program, because of poor persistence, therapeutic failure, or remission of the underlying problem. A final reason for the decrease in COX-2 use in the high-risk group may be the time lag between when medical services are provided and when care is documented on the computer system. The time lag in Missouri averaged around 30 to 60 days but could have been as long as 5 months.

The following example illustrates how the time lag could contribute to a decrease in COX-2 inhibitor use in high-risk patients. Assume that a patient is diagnosed for the first time with rheumatoid arthritis and receives a COX-2 prescription at the same visit. The patient leaves the physician's office and attempts to have the prescription filled in the next week or so. When the prescription is submitted for adjudication, SmartPA would not classify the patient as high risk because the rheumatoid arthritis diagnosis would not yet be in the system. If the patient's physician then declined to pursue PA through the call center, the patient would not receive a COX-2 inhibitor. To the extent that these situations occurred, use of COX-2 inhibitors would have decreased in the high-risk group.

The results also suggested that the SmartPA program resulted in substantial savings, or cost avoidance, in administrative costs compared with what would have been expected in a traditional PA program. Savings resulted from the lower volume of call center use. We estimated that SmartPA resulted in between 15 000 and 37 000 fewer calls per year than would have occurred in a traditional PA program. Reports in the literature suggest costs of between $10 and $25 per PA request.[11,22,23] Thus, lower call volume yielded considerable administrative savings for the Missouri Medicaid program. In addition, it is likely that it led to major time savings for the patients, physicians, and pharmacists who would otherwise have had to contact the call center, reprocess prescriptions, or experience delays in therapy. These time savings probably resulted in actual dollar savings to the health professionals involved as well as greater acceptance of the SmartPA program. However, if SmartPA were not as effective as traditional PA, then these administrative cost savings would be offset by smaller savings from controlling drug use. Although we have no reason to believe that SmartPA would be less effective than traditional PA, we did not compare the 2 programs and therefore have no evidence about their relative effectiveness.

The new Medicare drug benefit has substantially expanded the number of patients subject to PA. This, in turn, has substantially increased PA-related administrative costs, time burden on pharmacists and physicians, and patient delays in receiving needed drug therapy. An automated PA system offers the promise of reducing administrative costs, lessening burden on pharmacists and physicians, and eliminating patient delays in receiving needed drug therapy for many of those patients for whom the therapy is indicated. The results of our study indicated that an automated PA system is effective at reducing drug costs and use. In addition, it is reasonable to assume, although it was not tested in this study, that an automated system would have lower administrative costs than a traditional PA system and that the time that physicians, pharmacists, and patients spent dealing with the PA system would be less than with a traditional system. If this is true, then automated PA systems have great potential to improve the efficiency of PA in Medicare drug programs.

Our results indicated that the SmartPA program was effective in reducing use of and expenditures for prior-

authorized products compared with no PA program. The next step in evaluating the effectiveness of the SmartPA program would be to compare it with a traditional PA program. This comparison would allow for an estimate of the relative effectiveness of SmartPA in reducing prescription use, as well as an estimate of administrative cost savings.

Several limitations of our study should be noted. First, there were demographic and drug utilization differences between patients in the intervention and control states. We statistically controlled for demographic differences and severity of illness using regression analysis. Second, we did not examine changes in the use of medical and hospital services for musculoskeletal and GI-related problems. It is possible that the decreases in use of COX-2 inhibitors in the intervention state resulted in increases in the use of these services. However, we believe that this is unlikely. Our results indicated that SmartPA acted selectively: it had a much greater effect in patients at low risk for GI problems. Thus, the patients most likely to increase their use of GI-related services as a result of a restriction on COX-2 use were the patients least likely to experience the restriction. Further, past studies have found that restrictions on nonselective NSAIDs[5,6] and COX-2 inhibitors[9,10] decreased use of those products without increasing use of other services.

There was a time lag that averaged 30 to 60 days, but could have been as much as 150 days, between the time that medical services were provided and the time they were documented on the computer system. As discussed earlier, this time lag could have resulted in some patients who were actually at high risk of GI problems being classified as low risk. That would have resulted in lower use of COX-2 inhibitors in Missouri in the post intervention period. The final limitation of our study is that it was based on administrative claims data and is therefore subject to all limitations associated with using such data.

CONCLUSIONS

An automated PA program (SmartPA) substantially reduced use of and expenditures for COX-2 inhibitors. Although use of and expenditures for COX-2 substitutes increased, the program yielded net savings on drug costs because the reduction in COX-2 expenditures was substantially greater than the increase in COX-2 substitute expenditures. The program's effects on utilization and expenditures were much more pronounced in those patients at low risk for GI complications.

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