

Pharmacist and Physician Satisfaction and Rates of Switching to Preferred Medications Associated with an Instant Prior Authorization Program for Proton Pump Inhibitors in the North Carolina Medicaid Program

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ABSTRACT

BACKGROUND: Proton pump inhibitors (PPIs) are among the highest expenditure drugs covered by health care plans. During fiscal year 2001-2002, Medicaid programs nationwide spent nearly \$2 billion on PPIs. Although the costs of individual PPIs vary widely, there is little variation in therapeutic effectiveness. On June 1, 2007, the North Carolina Medicaid program implemented an "instant approval" option simultaneously with a prior authorization (PA) program for PPIs with the goal of managing costs and maintaining high-quality care. Preferred PPIs included generic omeprazole and Prilosec OTC. This instant approval process (IAP) was expected to impose less administrative burden than is typically associated with PA programs by permitting physician and nonphysician prescribers to either write the PA criteria directly on a prescription form or use "MD Easy," a preprinted form that could be faxed by the prescriber to the dispensing pharmacy. A previous study found that from the prescriber's perspective the IAP reduced practice-related administrative burden and was associated with a reduced gap in PPI therapy when compared with traditional PA.

OBJECTIVE: To evaluate the acceptability and effectiveness of this IAP for PPIs as assessed by the outcome measures of (a) pharmacist satisfaction with the IAP; (b) physician and pharmacist satisfaction with the MD Easy form; and (c) utilization rates for preferred PPIs, comparing medical practices that used the MD Easy form with practices that did not.

METHODS: A cross-sectional design was used to assess pharmacist and physician satisfaction. A stratified random sample of 240 pharmacies was selected from 1,561 North Carolina pharmacies with claims in the Medicaid claims data file during state fiscal year 2006. Additionally, a stratified random sample of 240 medical practices was selected from 1,045 primary care practices serving Medicaid beneficiaries during 2006. Surveys were administered to pharmacists using either in-person interviews or self-administered questionnaires and to physicians using a mailed questionnaire with follow-up to nonrespondents. An interrupted time series analysis was used to evaluate the effect of the MD Easy form on switching to preferred PPIs using paid Medicaid claims of surveyed practices from calendar year 2007. Practices that reported both using the IAP and receiving the MD Easy form were defined as MD Easy users. Monthly market share data were analyzed using log negative binomial regression models to account for autocorrelation in the time series data.

RESULTS: The pharmacy survey was completed by 202 (84.2%) pharmacies selected for participation. Of 198 permanently employed pharmacists, 140 (70.7%) reported experience with the IAP for PPIs. More than two-thirds (68.6%) of the pharmacist respondents with IAP experience indicated that the IAP is better (34.3%) or much better (34.3%) than traditional PA with

respect to overall administrative burden of phone calls, faxes, patient interactions, and doctor contacts. Surveys were completed by 171 (71.3%) of selected physician practices, of which 56 (32.7%) reported experience with the MD Easy forms. Of practices that recalled receiving the MD Easy forms, 52 of 56 (92.9%) reported that the forms "very much" or "somewhat" helped prevent gaps in PPI therapy; 54 of 55 (98.2%) reported that they helped identify patients affected by Medicaid PPI PA; and 100% reported that they helped physicians to follow PA requirements. Immediately after implementation of the IAP and MD Easy form, the observed market share of preferred PPIs increased by 4.1 times (95% CI=3.57-4.62). From May to June 2007, the preferred PPI market share increased by 64.0 percentage points, from 19.3% to 83.3% ($P<0.001$), for practices that reported using the IAP and receiving the MD Easy form ($n=56$) and by 55.4 percentage points, from 21.8% to 77.2% ($P<0.001$), for practices that either (a) reported not receiving the MD Easy form ($n=25$) or (b) reported not using the IAP ($n=84$) or (c) did not respond to the survey item asking about the MD Easy form ($n=4$). The overall increase in preferred PPI market share after implementation of the IAP was 1.29 times higher for practices that used the MD Easy form than for those that did not based on negative binomial regression modeling; this difference approached statistical significance (95% CI=1.00-1.68; $P=0.053$).

CONCLUSION: This study suggests that an IAP for PPIs using either handwritten prescriptions or a preprinted form is an effective alternative to traditional PA. The IAP was associated with an increase in market share for preferred PPIs and was perceived by pharmacists as less administratively burdensome than traditional PA. Additional studies are needed to determine sustainability and the applicability to other prescription drugs.

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What is already known about this subject

- Prior authorization (PA) programs for prescription drugs can effectively reduce use of higher-cost medications when other equally effective and lower-cost alternatives are available. In a study of Medicaid enrollees, Delate et al. (2005) found a 90.9% decrease in per member per month (PMPM) expenditures for proton pump inhibitors (PPIs) accompanied by a 223.2% increase in PMPM expenditures for lower-cost histamine-₂-receptor antagonists following implementation of a PA process for PPIs. PMPM expenditures for antisecretory drugs decreased by 49.9%, from \$3.44 to \$1.74.

What is already known about this subject (*continued*)

- Traditional PA programs may be costly and burdensome to prescribers and pharmacists. Bukstein et al. (2006) found that physicians and nurses in an allergy practice averaged 1.9 and 5.6 phone calls per day, respectively, for PA, resulting in an average cost of \$17.77 per PA. The specific costs of PA to pharmacies have not been identified in published literature.
- Alternatives to traditional PA, such as instant approval mechanisms, electronic PA, and web-based PA, are increasing and include the Missouri Medicaid automated electronic PA system (SmartPA) for cyclooxygenase-2 (COX-2) inhibitors, implemented in 2002, and a Medical Mutual of Ohio automated PA process (Smart Rules) for determining patient qualification for COX-2 inhibitors and antidepressants.
- Limited existing evidence suggests that alternative PA strategies may be effective and perceived as less burdensome to physicians than traditional PA. The automated electronic PA system in the Missouri Medicaid program was credited with reducing expenditures for COX-2 inhibitors by \$131 per patient per year (PPPY) in 2003 compared with an increase of \$59 PPPY in a comparison state without PA for COX-2 inhibitors.
- A previously published study of the North Carolina Medicaid instant approval process (IAP) for PPIs reported that the market share for preferred PPIs increased from 17% to 19% in the pre-IAP period to 76% in the first month after IAP implementation. Although market share changes were similar for practices using IAP and traditional PA, the median gap in PPI therapy for patients whose prescribers used traditional PA was approximately twice the gap for the IAP (26 days vs. 12 days, respectively, $P < 0.001$). Of the physician practices using IAP, 81.1% believed it reduced practice-related administrative burden.

What this study adds

- This study builds on the previously published study of IAP for PPIs by focusing on the perceived administrative burden of traditional PA compared with IAP from the perspective of the pharmacist. Of responding pharmacists familiar with the IAP, 68.6% rated the IAP as being better or much better than traditional PA with respect to administrative burden to the pharmacy. Pharmacists reported that the IAP saved an estimated 21 work minutes per patient, on average, when compared with traditional PA.
- The use of a unique preprinted “MD Easy” PA form that could be faxed by prescribers to dispensing pharmacies was introduced despite concerns that the MD Easy form may make it easier to prescribe nonpreferred PPIs. However, in the first month after implementation of the IAP, the increase in preferred PPI market share was similar in practices using the MD Easy form and practices not using the MD Easy form (64.0 percentage points vs. 55.4 percentage points). In negative binomial regression modeling, the overall increase in preferred PPI market share after implementation of the IAP was 1.29 times higher for practices that used the MD Easy form than for those that did not; this difference approached statistical significance (95% CI = 1.00-1.68; $P = 0.053$).
- Of the pharmacies who rated the usefulness of the MD Easy form for expediting the PA form, most (95.5%) rated it good to excellent. One-third of physician practices recalled receiving the MD Easy forms, and these practices reported that the MD Easy form helped to prevent gaps in therapy (92.9%) and follow PA requirements for PPI (100%).

Medicaid expenditures for prescription drugs have increased over time at alarming rates.¹ After adjusting for inflation, total U.S. Medicaid expenditures for prescription drugs more than doubled from \$11.6 billion to \$23.7 billion from the fiscal years 1996-1997 to 2001-2002.² The North Carolina Medicaid program experienced an estimated 88% increase in prescription drug reimbursement between 2000 and 2005, from \$795 million to \$1.49 billion.³ Between fiscal years 1996-1997 and 2001-2002, similar trends in expenditure increases nationwide were observed for the broad class of drugs that treat gastrointestinal (GI) disorders. Medicaid expenditures nationwide for GI drugs increased from \$1.02 billion in 1996-1997 to \$1.83 billion in 2001-2002,² driven in large part by proton pump inhibitors (PPIs). These increases were attributed to increases in the cost per user as well as growth in the number of people using GI drugs.²

PPIs are a subclass of GI drugs that are indicated for short-term therapy of acute upper GI disorders (e.g., peptic ulcers and esophagitis), pathologic gastric hypersecretory conditions (e.g., Zollinger-Ellison syndrome), and maintenance therapy for persons with healed ulcers and erosive esophagitis.⁴⁻⁶ PPIs are among the costliest drugs covered by health care plans.⁴ Although the costs of individual PPIs vary widely, there is little variation in therapeutic effectiveness among the PPIs.⁶

State Medicaid programs and other payers have developed and implemented a number of strategies to attempt to curb rising prescription drug expenditures while ensuring appropriate access to prescription medications.⁷⁻¹⁶ Existing evidence has shown that prior authorization (PA) is one approach that can be effective at reducing use of higher-cost medications when other equally effective and lower-cost alternatives are available.^{4,14,17-23} PA has been defined as a process that “restricts the use of specific medications by requiring an advance approval by the Medicaid program or its agent for the drug before dispensing to qualify for reimbursement.”⁴ The benefit of PA to a payer is the ability to stop inappropriate utilization before it takes place. Although concerns about patient access exist, a number of published studies demonstrate safety and effectiveness of PA programs.^{4,14,17,20} Yet, studies of PA programs have not completely dispelled lingering criticisms. For example, high administrative costs are a major criticism of U.S. health care systems.²⁴⁻²⁷ In 1999, U.S. health care administrative costs were estimated at \$294.3 billion or \$1,059 per capita.²⁶ PA-related activities and other interactions between pharmacies, prescribers, and health insurance programs contribute to these administrative costs.^{13,24} Using data from a national survey, Casalino et al. (2009) estimated that the cost for the time spent by U.S. health care providers to interact with health insurance plans ranges from \$23 to \$31 billion annually.²⁴ They reported that the average amount of time spent weekly on authorizations was 13.1 hours by nursing staff for each physician in the practice, 1 hour per physician, and 6.3 hours for clerical staff.²⁴ Bukstein et al.

(2006) found that the cost per PA of physician and nursing time within an allergy practice was \$17.77.²⁸ Administrative costs of PA are also incurred by third-party payers. For example, one Medicaid program paid an administrative fee of \$20 for each PA request for PPIs.⁴

Less attention has been devoted to the administrative burden to pharmacies. Although pharmacists are not typically asked to submit written PA documentation to payers, they are nonetheless thrust into the middle of coverage determination activity. Traditional pharmacy PA typically involves a multi-step process in which the physician or other prescriber writes a prescription, the patient takes the prescription to the local pharmacist, the prescription is denied through the electronic claims system, the pharmacist contacts the prescriber by telephone to indicate the need for PA, the prescriber contacts the PA center to initiate the PA, the prescription is approved or denied based on clinical criteria established by the payer, and potentially the prescriber notifies the pharmacy of the PA decision. If the pharmacy is not notified of the PA decision, the pharmacy may call the PA center to inquire about the status, periodically re-run the prescription in the electronic claims system to see if it is approved, or leave the process incomplete. Often acting as a messenger from patient to prescriber to payer and back, it is ultimately the pharmacist's responsibility to ensure that a drug is covered before dispensing it or risk denial of reimbursement for the dispensed prescription. In an era of multiple hundreds of prescriptions filled by a single pharmacist in a day, stopping the workflow to address a PA for a patient can be disruptive, even if the activity takes as little as 5 or 10 minutes to address with the patient and prescriber, mostly because of the sheer volume of PAs that a pharmacist may encounter on any given day.

Alternatives to traditional PA programs, including electronic PA and web-based PA, are beginning to emerge with the intent of improving administrative efficiency and reducing burden on providers, patients, and pharmacists while achieving cost-containment and quality of care goals.^{17,29,30} However, limited empirical evidence exists on whether the alternative mechanisms actually achieve these administrative and cost-related goals. A study of a "SmartPA" system for cyclooxygenase-2 (COX-2) inhibitors in the Missouri Medicaid program, conducted by Carroll et al. (2006), involved use of an automated electronic PA system that used clinical rules and queries of drug and medical claims data at the point of service.¹⁷ This study reported reduced expenditures for COX-2 inhibitors as well as significant administrative cost avoidance over traditional PA based on a decrease in PA-related calls.

The instant approval process (IAP) is another alternative to traditional PA for managing access to specific types of prescription drugs. The IAP permits physician and nonphysician prescribers to document the patient-specific approval criteria directly on a written prescription so that the pharmacist can

dispense the drug without delay at the pharmacy. A previously published study assessed 2 objectives of the North Carolina Medicaid IAP for PPIs: (a) contain drug costs and (b) avoid clinical and service problems, such as gaps in therapy and clinician dissatisfaction.³¹ The previous study reported that the market share for the preferred PPIs, generic omeprazole and Prilosec OTC, increased from 17% to 19% in the pre-IAP period to 76% in the first month after IAP implementation.³¹ Although market share changes were similar for practices using the IAP and traditional PA, the median gap in PPI therapy for patients whose prescribers used traditional PA was approximately twice the gap for the IAP (26 days vs. 12 days, respectively, $P < 0.001$). Of the physician practices using IAP, 81.1% believed it reduced practice-related administrative burden.

The present study built on the previous study by including an assessment of the pharmacy experience and examining the use of pre-printed prescriptions. Specifically, the present study examined (a) pharmacist satisfaction with the IAP, (b) prescriber and pharmacist satisfaction with MD Easy, a pre-printed prescription form, and (c) whether the rate of switching to preferred PPIs varied between those practices that used the MD Easy form compared with those practices that did not.

■ Methods

Description of the PA Intervention

Prior to June 2007, North Carolina Medicaid placed no coverage restrictions on PPIs. On June 1, 2007, North Carolina Division of Medical Assistance (DMA) implemented a PA program for PPIs for Medicaid beneficiaries. Out of concern for the potential burden that a PA program would place on prescribers and pharmacists, Community Care of North Carolina (CCNC), the state's Medicaid managed care program, requested that the PA process include an IAP as an alternative option to the traditional PA system. The new PA program included 3 options for patient access to PPIs. In option 1, prescriptions for the 2 preferred medications, generic omeprazole and Prilosec OTC, were exempt from PA. Option 2 was the traditional PA process for nonpreferred PPI medications. Option 3 included a unique IAP for nonpreferred PPIs that permitted prescribers to document the patient-specific approval criteria directly on the written prescription or use a pre-printed prescription form, MD Easy. Approval criteria for nonpreferred PPIs included (a) failure with a 30-day trial of no less than 40 milligrams (mg) of omeprazole during a 12-month period; (b) use of esomeprazole magnesium (Nexium) 40 mg for diagnosis of erosive esophagitis Grade C or D; or (c) inability to swallow tablets or capsules (use of brand name solutab and liquid dosage formulations). The PA policy excluded Medicaid beneficiaries who were aged 6 years or younger, those in an eligibility category indicating pregnancy, and dual eligible beneficiaries with Medicare Part D coverage.

As part of the IAP effort, CCNC created pre-printed

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FIGURE 1 MD Easy Form: Pre-Printed Prescription Form for Proton Pump Inhibitors


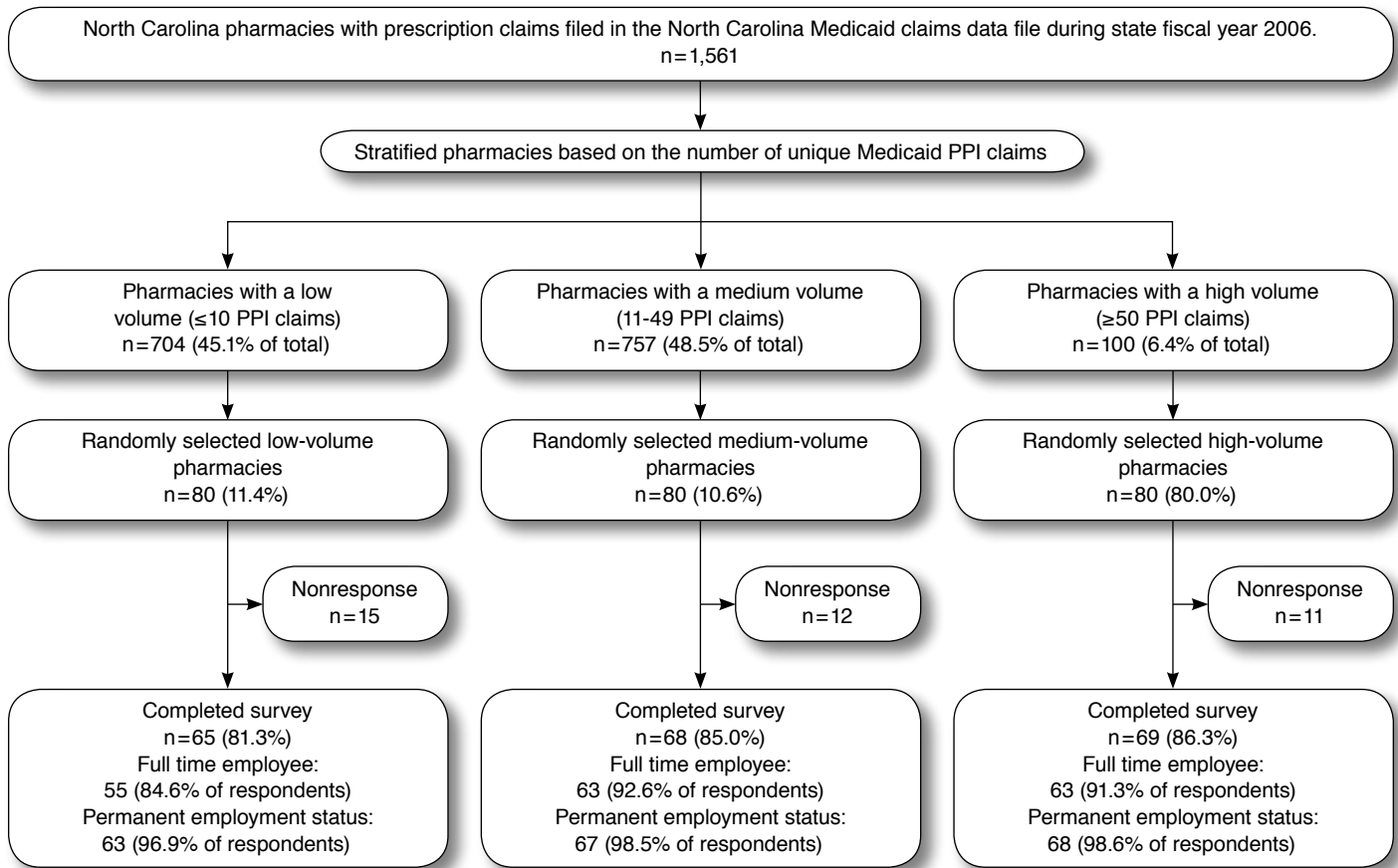
 <h2 style="margin: 0;">Community Care of North Carolina</h2> <p style="margin: 0;">MD Easy™ Form for “Instant Approval”</p>			
Practice Information		Request Date / /	
Practice Name		Pharmacy Information	
Practice Address		Pharmacy Name	
Practice City, State, Zip		Pharmacy Phone	Pharmacy Fax
Practice Phone	Practice Fax		
Patient Information			
Patient Name		Patient DOB	Patient Address
Please select <u>one</u> of the following three options and fax to pharmacy.			
1) Please switch patient to (select one):			
<input type="checkbox"/> Omeprazole 20mg Cap Circle one: 1QD 1BID 2QD 2BID Other _____ Dispense # _____ Refill # _____		<input type="checkbox"/> OTC Prilosec 20mg Tab Circle one: 1QD 1BID 2QD 2BID Other _____ Dispense # (circle one): 42 84 126 168 Refill # _____	
2) <input type="checkbox"/> Prescribers: <i>In your own handwriting</i>, please indicate one of the following applicable exemption criteria for override in the space provided below for the medication:			
Originally Prescribed PPI		Quantity	
Directions for use & route of administration			
<ul style="list-style-type: none"> “Failed Omeprazole 40mg for 30 days” (within the last 12 months) Erosive “Esophagitis grade C” or “Esophagitis grade D” (Esomeprazole (Nexium) only) “Cannot swallow tablets” or “Cannot swallow capsules” 			
Note: “Dispense as written” or “Brand medically necessary” is only applicable for Prilosec 20mg or 40mg, and can only be used after the above criteria have been documented on the face of the prescription.			
Exemption Criteria (<i>write exactly as shown</i>) _____		Refill # _____	
(Pharmacist– For exemption criteria, use override code 1 in PA field or 2 in submission clarification field. If patient pregnant or breastfeeding, indicate 2 in the pregnancy indicator field or V22 or V23 in the diagnosis field Override begins Jun 1, 2007.)			
3) <input type="checkbox"/> On or after June 1, 2007, I will initiate PA process and contact ACS at 866-246-8505 (phone) or 866-246-8507 (fax).			
Prescriber Signature _____		Date _____	
Prescriber Name (please print) _____		DEA _____	
Note: By signing this document and 1) checking the OTC Prilosec/Omeprazole substitution or 2) checking the brand name exemption criteria box above you are consenting to this being a legal prescription and the pharmacy should fill it as such. DMA policy requires documentation of exemption criteria in the patient’s chart for auditing purposes if option 2 is selected.			

FIGURE 2 Selection, Enrollment, and Characteristics of North Carolina Medicaid Pharmacies



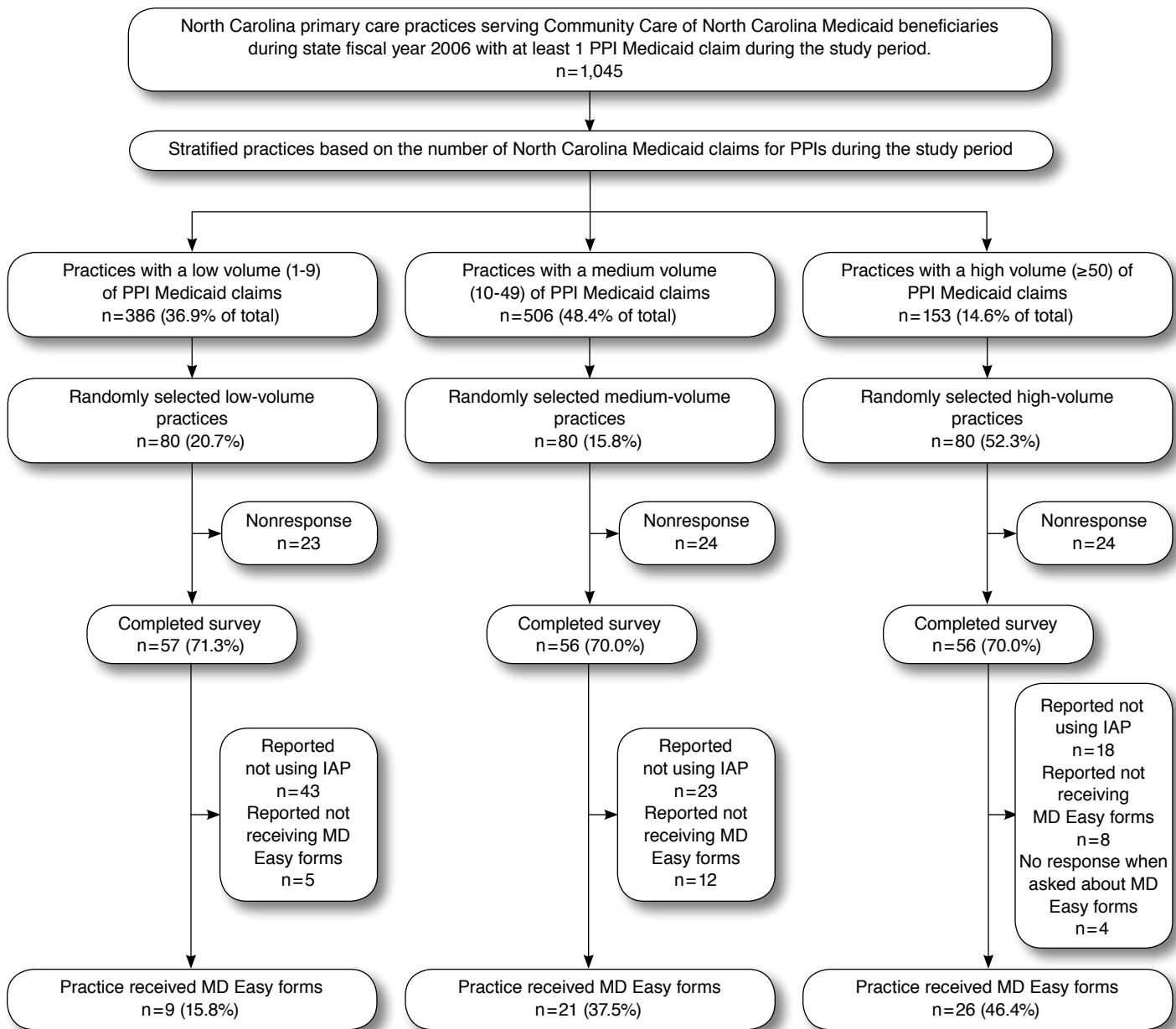
PPI = proton pump inhibitor.

prescriptions, called MD Easy forms (Figure 1). Approximately 35,000 MD Easy forms were printed, 1 for each enrolled North Carolina Medicaid recipient who had a nonpreferred PPI claim during the previous year. The MD Easy forms were pre-populated with patient name, date of birth, address, prescribing practice, pharmacy, the nonpreferred drugs that the patient was currently taking, and instructions to select 1 of the 3 prescribing options. These forms were provided to each of the 14 CCNC networks to be sent to their respective primary care practices during May 2007. The new PA program with an IAP option and the deployment of MD Easy forms was intended to contain costs of PPIs, while maintaining high-quality care and reducing the administrative burden typically associated with traditional PA. The MD Easy form was also expected to facilitate patient access to a prescription through a preemptive PA process that occurs before the patient arrives at the pharmacy when picking up the next PPI refill.

Study Design and Participants

Cross-sectional and interrupted time series designs were used in this study. A cross-sectional design with a descriptive data analysis was used to assess pharmacist and prescriber satisfaction with the IAP and MD Easy form as alternatives to traditional PA for PPIs. A stratified simple random sample of 240 pharmacies was selected from 1,561 North Carolina pharmacies with claims in the North Carolina Medicaid claims data file during state fiscal year 2006 (Figure 2). Random number generation was used in each stratum to select the final sample using SAS PROC SURVEYSELECT (SAS Institute Inc., Cary, NC). Pharmacies were stratified based on the number of unique Medicaid PPI pharmacy claims as a proxy measure for pharmacy size. Three strata were defined as (a) 10 or fewer PPI prescription claims (low volume, 80 of 704 pharmacies); (b) 11 to 49 PPI claims (medium volume, 80 of 757 pharmacies); and (c) 50 or more PPI claims (high volume, 80 of 100 pharmacies; Figure 2). Both rural and urban pharmacies were represented

FIGURE 3 Selection and Enrollment of North Carolina Primary Care Practices



IAP=instant approval process; PPI=proton pump inhibitor.

in the sample, based on a review of the distribution of Rural-Urban Commuting Area (RUCA) scores for eligible pharmacies.³² For each eligible pharmacy, 1 pharmacist was selected for interview or self-administered survey based on availability at the time of an on-site visit. Although there were no sampling exclusions, survey responses of 4 temporarily employed pharmacists were excluded from the survey results because these

employees may be less likely to have the experience to compare traditional PA and IAP.

A stratified simple random sample of 240 medical primary care practices was selected to participate in the PPI provider survey. These practices were selected from 1,045 primary care practices serving CCNC Medicaid beneficiaries with at least 1 PPI Medicaid claim during the state's fiscal year 2006 (Figure

3). Random number generation was used in each stratum to select the final sample using SAS PROC SURVEYSELECT. Strata for provider practices were defined similarly to the pharmacies and were based on practice-level PPI prescribing patterns during the year: (a) low volume of PPI claims (80 of 386 practices); (b) medium volume (80 of 506 practices); and (c) high volume (80 of 153 practices; Figure 3). The sample size of 240 practices was selected with an expectation of a 60% response rate, that is, an expected sample size of 144. This sample size would allow estimation of survey outcomes with 95% confidence intervals (CI) of +/- 8 percentage points.

An interrupted time series analysis was used to evaluate the effect of the MD Easy form on channeling to preferred PPIs. Paid PPI claims for calendar year 2007 were selected for North Carolina Medicaid beneficiaries who were subject to the PA policy and linked in the CCNC Medicaid program with primary care practices that completed the physician survey. The study was approved by the University of North Carolina School of Medicine Institutional Review Board.

Study Procedures, Data Sources, and Measurement

Medicaid Claims for Sample Identification and Measurement of Preferred PPI Market Share. North Carolina Medicaid claims for PPIs were obtained from the North Carolina Division of Medical Assistance for 2 time periods for distinct purposes. First, Medicaid claims from state fiscal year 2006 were used to identify potentially eligible pharmacies and physician practices and obtain contact information for the provider surveys. Second, pharmacy claims for calendar year 2007 were obtained for time series analyses.

To construct the data file for the time series analysis, the FirstDataBank (FirstDataBank, San Francisco, CA) Specific Therapeutic Class (GC3) code "D4J" was used to select the pharmacy claims for PPI drug products. Physician survey responses were matched with calendar year 2007 pharmacy claims using CCNC practice identifier codes and Medicaid beneficiary primary care provider designations. The PPI claims were then assigned to 1 of 2 groups based on the practice survey results: (a) used the MD Easy form (i.e., reported using the IAP and receiving the MD Easy form [n=56]) or (b) did not use the MD Easy form (n=113, including 25 practices that answered "no" to the question "Did your practice receive any pre-populated MD Easy forms?" and 88 practices that either reported not using the IAP [n=84] or reported using the IAP but did not reply to the question about receipt of the MD Easy forms [n=4]). Preferred PPI market share was computed for each of the 2 groups for each month as the number of preferred PPI prescription claims divided by the total number of preferred and nonpreferred PPI prescription claims. The preferred market share percentages were plotted for 12 sequential months for calendar year 2007 separately for those practices

that used the MD Easy form versus those practices that did not use the MD Easy form. This period included 5 months immediately prior to and 7 months following implementation of the PA program.

Measurement of Pharmacist Satisfaction. A team of investigators and pharmacists developed a brief structured interview tool to be administered to eligible pharmacists. A slightly modified version of the interview tool was developed as a self-administered questionnaire for those pharmacists not available to complete an in-person interview. The interview tool and questionnaire inquired about the pharmacist's employment status, pharmacy experience with the PPI IAP and MD Easy form, perceived administrative burden of IAP for the pharmacist and patient compared with traditional PA, perceived usefulness of the IAP training, and overall comparison between traditional PA and IAP. The survey was pilot tested with 3 pharmacists; estimated completion time was approximately 5 minutes.

Prior to implementing data collection, 2 graduate pharmacy students completed interviewer training. In-person interviews were performed between mid-August and mid-December 2007 by these students at most pharmacy sites. For 7 pharmacies in more distant locations, regional CCNC network pharmacists performed the interviews, 6 in person and 1 by mailed questionnaire. Interviewers made initial contact in person at the eligible pharmacies and asked to conduct the brief structured interview at that time. If an interview could not be completed, a survey formatted for self-completion and a pre-addressed stamped survey return envelope were provided to the pharmacist. No attempts were made to re-contact nonresponding pharmacists. Interviewers assigned and documented unique study identification numbers on survey forms and master eligibility lists at the time of interviews. Completed interview and questionnaire responses were entered in Microsoft Excel (version 2003; Microsoft Corporation, Redmond, WA).

Measurement of Physician Satisfaction. The investigative team also developed a brief survey to assess the perceived usefulness and adoption of PPI IAP and MD Easy among physicians. The survey was pilot tested with 4 primary care physicians. Survey packets were sent from the North Carolina Physician Advisory Group to community case managers during August 2007. Case managers delivered cover letters, PPI practice surveys, and postage-paid pre-addressed survey return envelopes to eligible practices. Cover letters explained that only 1 primary care provider per practice should complete the form, ideally the physician with the most experience with PPI IAP. Community case managers provided a second copy of the survey to nonresponding practices approximately 6 weeks after the initial distribution. Completed survey responses were entered in Microsoft Excel (version 2003).

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TABLE 1 Pharmacist and Physician Satisfaction with the PPI Instant Approval Process and the MD Easy Form

Survey Item	Response Options	PPI Prescription Volume			P Value ^a	Total (unweighted)
		Low	Medium	High		
Pharmacy survey results						
Has this pharmacy had any experience with NC Medicaid's instant approval program for PPIs since June 1 of this year?	Yes ^b	33 (52.4)	50 (74.6)	57 (83.8)	<0.001	140 (70.7)
	No	30 (47.6)	17 (25.4)	11 (16.2)		58 (29.3)
Do you believe that the instant approval process causes less burden on your pharmacy than the traditional PA process? ^c	Yes	28 (84.8)	34 (68.0)	39 (68.4)	0.176	101 (72.1)
	No	5 (15.2)	16 (32.0)	18 (31.6)		39 (27.9)
[If yes] Estimate the total number of work minutes per patient, on average, that you believe are saved using the new instant approval versus the traditional PA process. Include all staff at your pharmacy in this estimate.		25.2	23.3	16.3	<0.001	21.1 minutes
Community Care of NC provided education before the roll-out of the IA program. This training included a description of the new program for PPIs, a sample MD Easy form, a list of criteria allowing instant approval, and gave an opportunity for people in your pharmacy to ask questions. Did your pharmacy receive any of the training described above?	Yes	12 (36.4)	24 (48.0)	25 (43.9)	0.578	61 (43.6)
	No	21 (63.6)	26 (52.0)	32 (56.1)		79 (56.4)
Did your pharmacy receive training on the MD Easy form?	Yes	11 (34.4)	20 (40.0)	22 (38.6)	0.873	53 (38.1)
	No	21 (65.6)	30 (60.0)	35 (61.4)		86 (61.9)
Has this pharmacy received any of the MD Easy forms for PPI prescriptions since June 1 of this year?	Yes	15 (48.4)	30 (61.2)	39 (69.6)	0.148	84 (61.8)
	No	16 (51.6)	19 (38.8)	17 (30.4)		52 (38.2)
Which answer best describes the overall administrative burden of phone calls, faxes, patient interactions, and doctor contacts with instant approval compared to traditional PA program? ^c	Traditional PA much better	0 (0.0)	2 (4.0)	2 (3.5)	0.819	4 (2.9)
	Traditional PA better	1 (3.0)	3 (6.0)	2 (3.5)		6 (4.3)
	No difference	7 (21.2)	11 (22.0)	16 (28.1)		34 (24.3)
	Instant approval better	11 (33.3)	17 (34.0)	20 (35.1)		48 (34.3)
	Instant approval much better	14 (42.4)	17 (34.0)	17 (29.8)		48 (34.3)
Next, use the same 5-level scale to compare your patients' satisfaction with the 2 PA processes.	Traditional PA much better	1 (3.2)	2 (4.0)	3 (5.3)	0.063	6 (4.3)
	Traditional PA better	0 (0.0)	3 (6.0)	3 (5.3)		6 (4.3)
	No difference	9 (29.0)	27 (54.0)	25 (43.9)		61 (44.2)
	Instant approval better	11 (35.5)	6 (12.0)	17 (29.8)		34 (24.6)
	Instant approval much better	10 (32.3)	12 (24.0)	9 (15.8)		31 (22.5)
Rate the usefulness of this training [using the scale provided].	Extremely	2 (16.7)	4 (16.7)	6 (24.0)	0.968	12 (19.7)
	Very	4 (33.3)	8 (33.3)	7 (28.0)		19 (31.1)
	Somewhat	6 (50.0)	12 (50.0)	12 (48.0)		30 (49.2)
	Not at all	0 (0.0)	0 (0.0)	0 (0.0)		0 (0.0)
Rate the usefulness of the MD Easy form for expediting the PA process [using the scale provided].	Excellent	2 (22.2)	5 (29.4)	8 (42.1)	NA ^d	15 (33.3)
	Very good	6 (66.7)	7 (41.2)	5 (26.3)		18 (40.0)
	Good	1 (11.1)	4 (23.5)	5 (26.3)		10 (22.2)
	Fair	0 (0.0)	1 (5.9)	0 (0.0)		1 (2.2)
	Poor	0 (0.0)	0 (0.0)	1 (5.3)		1 (2.2)
Taking all things into consideration and using the [scale], give us your overall comparison of the traditional PA and instant approval programs for Medicaid patients receiving PPIs.	Traditional PA much better	0 (0.0)	0 (0.0)	1 (1.8)	0.671	1 (0.7)
	Traditional PA better	1 (3.0)	4 (8.0)	3 (5.4)		8 (5.7)
	No difference	5 (15.2)	9 (18.0)	8 (14.3)		22 (15.7)
	Instant approval better	11 (33.3)	21 (42.0)	27 (48.2)		59 (42.1)
	Instant approval much better	16 (48.5)	16 (32.0)	17 (30.4)		50 (35.7)
Physician practice survey results^e						
Some practices received a pre-populated patient-specific MD Easy form. Did your practice receive any pre-populated MD Easy forms?	Yes	9 (64.3)	21 (63.6)	26 (76.5)	0.477	56 (69.1)
	No	5 (35.7)	12 (36.4)	8 (23.5)		25 (30.9)
To what degree did the pre-populated MD Easy forms help prevent gaps in therapy or days of missed therapy for your patients receiving PPIs?	Very much	5 (55.6)	10 (47.6)	15 (57.7)	0.782	30 (53.6)
	Somewhat	3 (33.3)	10 (47.6)	9 (34.6)		22 (39.3)
	Not at all	1 (11.1)	1 (4.8)	2 (7.7)		4 (7.1)

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TABLE 1 Pharmacist and Physician Satisfaction with the PPI Instant Approval Process and the MD Easy Form (continued)

Survey Item	Response Options	PPI Prescription Volume			P Value ^a	Total (unweighted)
		Low	Medium	High		
Physician practice survey results (continued)		n (%)	n (%)	n (%)		n (%)
To what degree did the pre-populated MD Easy forms help identify patients affected by Medicaid PPI prior authorization?	Very much	6 (66.7)	15 (71.4)	20 (80.0)	0.672	41 (74.5)
	Somewhat	3 (33.3)	6 (28.6)	4 (16.0)		13 (23.6)
	Not at all	0 (0.0)	0 (0.0)	1 (4.0)		1 (1.8)
To what degree did the information provided on pre-populated MD Easy forms help you follow requirements for PPI prior authorization?	Very much	7 (77.8)	14 (66.7)	17 (65.4)	0.782	38 (67.9)
	Somewhat	2 (22.2)	7 (33.3)	9 (34.6)		18 (32.1)
	Not at all	0 (0.0)	0 (0.0)	0 (0.0)		0 (0.0)
In general, how useful did you find the MD Easy form to be?	Extremely useful	4 (44.4)	8 (38.1)	13 (50.0)	0.782	25 (44.6)
	Very useful	4 (44.4)	7 (33.3)	8 (30.8)		19 (33.9)
	Somewhat useful	1 (11.1)	6 (28.6)	4 (15.4)		11 (19.6)
	Not at all useful	0 (0.0)	0 (0.0)	1 (3.8)		1 (1.8)

^aRepresents the level of statistical significance for comparisons among the 3 claims volume strata, using 1-way analysis of variance for the estimated number of work minutes saved and Pearson chi-square tests for all other comparisons.

^bOnly data from these respondents are included in the pharmacy responses below.

^c“Burden” was defined in the pharmacy survey as “phone calls, faxes, patient interactions, and doctor contacts.”

^dStatistical significance not calculated because of small counts in multiple cells.

^eEighty-eight physicians who either reported that they did not use the IA process (n=84) or did not respond to the question about the MD Easy forms (n=4) were not included in these analyses.

IA= instant approval; NA= not applicable; NC= North Carolina; PA= prior authorization; PPI= proton pump inhibitor.

Data Analysis

Pharmacist and Physician Satisfaction with IAP and the MD Easy Form. Survey responses were summarized as frequencies (number and percent) in aggregate, both unweighted and weighted to account for the stratified sampling procedure, and by sampling stratum based on annual volume of PPI prescription claims. Unweighted aggregate and stratified responses are presented. Pearson chi-square and Analysis of Variance (ANOVA) were used to test whether survey responses varied significantly by PPI claim volume strata. An a priori P value of 0.05 was used to indicate statistical significance.

Market Share of Preferred PPI Prescriptions. An interrupted time series analysis was used to assess overall pre-post changes in preferred PPI market share and compare practices that used the MD Easy form with those that did not, assessing (a) market share of preferred PPIs prior to implementing the IAP and (b) change in market share of preferred PPIs (percent of total) after implementation of the IAP. Market share data were analyzed within a log negative binomial regression model to account for the autocorrelation in the time series data. These tests were implemented using PROC GENMOD in SAS.³³ Question (a) was tested using 5 months of market share data immediately prior to IAP implementation. Question (b) was tested using the full 12 months of market share data.

Results

Pharmacist Satisfaction with IAP for PPIs

The pharmacy survey was completed by 202 of 240 (84.2%)

pharmacies selected for participation (Figure 2). Study results are restricted to 198 (82.5%) permanently employed pharmacists. Approximately two-thirds (65.2% weighted, 70.7% unweighted) of these pharmacies reported experience with North Carolina’s Medicaid’s IAP for PPIs (Table 1). In stratified analyses, higher PPI volume pharmacies were more likely to report experience with IAP than lower-volume pharmacies (83.8% vs. 52.4%, respectively, P<0.001). Of the 140 pharmacies with IAP experience, 68.6% indicated that the IAP is better (34.3%) or much better (34.3%) than traditional PA with respect to overall administrative burden of phone calls, faxes, patient interactions, and doctor contacts. Pharmacists estimated that the IAP saved 23.7 weighted work minutes per patient (unweighted, 21.1 minutes), on average, compared with the traditional PA process. Low-volume pharmacies reported greater mean time savings per patient than high-volume pharmacies (25.2 minutes vs. 16.3 minutes, P<0.001). Of the 45 pharmacists who rated the usefulness of the MD Easy Form for expediting the PA process, 95.5% indicated a rating of good to excellent. Differences by strata in responses to the remaining survey items were not statistically significant.

Physician Perceptions and Satisfaction with the MD Easy Form

Surveys were completed and returned by 171 of the 240 (71.3%) selected physician practices (Figure 3). Responses are presented for the 56 of the 171 responding practices (32.7%) that reported receiving the pre-populated MD Easy forms (Table 1). Among physicians who recalled

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receiving the pre-populated MD Easy forms, 92.9% reported that these forms very much or somewhat helped prevent gaps in therapy or days of missed therapy for their patients receiving PPIs. The MD Easy forms also were reported to very much or somewhat help 98.2% of responding practices identify patients affected by Medicaid PPI PA, and 100% of respondents reported that the information on the forms very much or somewhat helped them to follow requirements for PPI PA. Almost all of the practices (98.2%) rated the MD Easy forms as somewhat to extremely useful (Table 1). Survey results did not vary significantly among the strata of physician practices.

Market Share of Preferred PPI Prescriptions

Immediately after implementation of the PA program for PPIs, including the IAP and use of MD Easy forms, the observed market share of preferred PPIs approximately quadrupled, from 20.0% in May 2007 to 81.6% in June 2007 (95% CI=3.57-4.62; Table 2). The increase in preferred market share between May and June was an absolute 64.0% (from 19.3% to 83.3%, $P < 0.001$) for practices using the MD Easy form and an absolute 55.4% (from 21.8% to 77.2%, $P < 0.001$) for practices not using the MD Easy form (Figure 4). The pre-IAP baseline market share of preferred PPIs in the group of practices that did not use the MD Easy form was 1.24 (95% CI=1.10-1.40) times as high or approximately 4 percentage points higher compared with the practices that used the MD Easy form ($P < 0.001$). The overall increase in preferred PPI market share after implementation of the IAP was 1.29 times higher in the group that used the MD Easy form than the group of practices that did not; this difference approached statistical significance (95% CI=1.00-1.68; $P = 0.053$).

Discussion

The trend to shift pharmacy management strategies from traditional PA programs to alternative strategies such as instant approval, electronic PA, and web-based PA is growing. Traditional PA programs have an established history of successfully moving market share to preferred drug products and limiting utilization of nonpreferred products. The downside to PA programs to date has been patient, prescriber, and pharmacy dissatisfaction, specifically the administrative costs of filling out paperwork, phoning, and faxing, as well as increased time between fills for patients seeking a medication that has a PA without immediate resolution. Third-party payers in Tennessee and New Jersey announced plans in early 2009 to launch a pilot electronic PA program.³⁴ Moreover, the American Medical Association's House of Delegates, at its June 2008 annual meeting, adopted a policy to support legislative efforts to mandate less administratively burdensome and costly pharmacy management strategies.³⁵

The current evaluation of the North Carolina Medicaid IAP for PPIs provides evidence to support the shift away from

TABLE 2 Monthly Market Share of PPI Prescriptions in Calendar Year 2007, Stratified by Physician Practice Report of Receiving MD Easy Forms

Month	No MD Easy ^a n = 113		MD Easy n = 56	
	Total PPI Prescriptions	% Preferred PPI ^b	Total PPI Prescriptions	% Preferred PPI ^b
January	830	19.6	1,739	15.0
February	761	20.1	1,661	16.9
March	846	19.6	1,765	15.6
April	747	20.9	1,606	16.3
May ^c	731	21.8	1,828	19.3
Pre-PA ^d	3,915	20.4	8,599	16.6
June ^e	540	77.2	1,381	83.3
July	596	77.0	1,424	80.8
August	644	75.0	1,546	77.2
September	581	72.8	1,370	76.1
October	585	72.3	1,571	73.3
November	608	72.7	1,567	74.6
December	579	70.3	1,437	73.9
Post-PA ^d	4,133	73.9	10,296	76.9

^a"No MD Easy" category includes practices that either (a) reported not using the IAP (n=84); (b) reported that they did not receive the MD Easy forms (n=25); or (c) reported using the IAP but did not respond to the question about MD Easy forms (n=4).

^bPreferred PPIs are generic omeprazole and Prilosec OTC.

^cFor both groups combined, total PPI claims count for May 2007 was 2,559, of which 512 (20.0%) were for preferred PPIs.

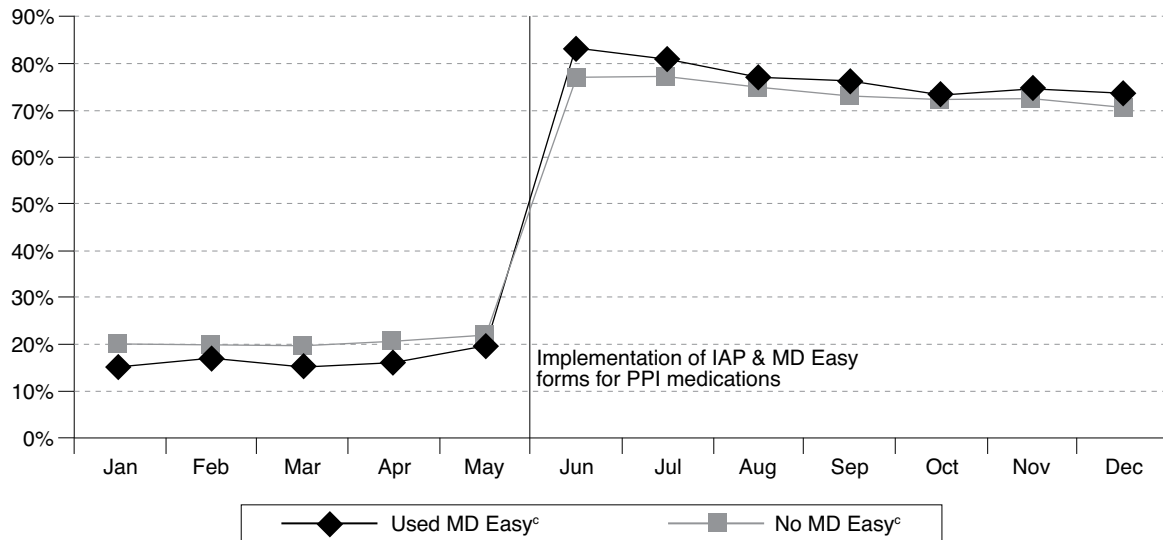
^dThe PA program and IAP were implemented on June 1, 2007. Results marked "pre-PA" and "post-PA" represent January through May and June through December, respectively.

^eFor both groups combined, total PPI claims count for June 2007 was 1,921, of which 1,567 (81.6%) were for preferred PPIs.

IAP= instant approval process; PA=prior authorization; PPI=proton pump inhibitor.

traditional PA for pharmacy benefits. The results of this study suggest that an IAP for prescription medications may be more administratively efficient for pharmacists than traditional PA processes while retaining the desired channeling effects. More than two-thirds of pharmacists in this study reported that the IAP was administratively less burdensome than traditional PA. This finding was consistent with the expectations and intent of investigators. The channeling to preferred PPI medications was similarly effective for practices that used the MD Easy form compared with those not using the MD Easy form. This finding was somewhat unexpected; the MD Easy form may make it easier for physicians to prescribe nonpreferred PPIs because the specific exemption criteria are listed directly on the form. One possible explanation for this result is the potential for a null effect of a barrier on prescribers' decision-making processes. That is, the level of difficulty of the PA override process may not affect the switching decision because patients who meet criteria or insist on using the nonpreferred medication

FIGURE 4 Market Share of Preferred PPI Medications^a Before and After Implementation of the IAP,^b by Provider Utilization of MD Easy Form, Calendar Year 2007



^aPercent of all PPI claims that were for the preferred PPIs, generic omeprazole and Prilosec OTC.

^bJune 1, 2007: implementation of the IAP and MD Easy Forms for PPI medications.

^cThe “Used MD Easy” trend line represents physician practices that received and rated the MD Easy form based on survey responses (n = 56). The “No MD Easy” trend line represents physician practices (n = 113) that reported (a) not using the IAP (n = 84); (b) not receiving the MD Easy forms (n = 25); or (c) using the IAP but did not respond to the question about MD Easy forms (n = 4).

IAP = instant approval process; PPI = proton pump inhibitor.

may ultimately receive the PA override, however difficult or easy to attain.

The results of this study are consistent with a limited body of published peer-reviewed literature on evaluations of automated or instant approval pharmaceutical PA programs. The evaluation of an automated PA system for COX-2 inhibitors in the Missouri Medicaid program demonstrated a shift in use of COX-2 inhibitors to less costly nonsteroidal anti-inflammatory drugs (NSAIDs).¹⁷ The automated PA system was credited with reducing expenditures for COX-2 inhibitors by \$131 per patient per year (PPPY) compared with an increase of \$59 PPPY in a comparison group without PA for COX-2 inhibitors.¹⁷ In addition, it was estimated that administrative costs were reduced by \$150,000 to \$925,000 per year based on an estimated drop in PA call center volume by 15,000 to 37,000 telephone calls per year at an estimated cost of \$10 to \$25 per PA request.¹⁷ A previously published study of the North Carolina Medicaid IAP for PPIs reported that the average monthly PPI drug costs dropped from approximately \$4 million to approximately \$1.5 million immediately after implementation of the PA program.³¹ The market share for preferred PPIs increased from 17% to 19% in the pre-IAP period to 76% in the first month after IAP implementation.³¹ Although market share changes were similar

for practices using traditional PA and IAP, the median gap in PPI therapy for patients whose prescribers used traditional PA was approximately twice the gap with the IAP (26 vs. 12 days, respectively, $P < 0.001$). And, of the physician practices using IAP, 81.1% believed it reduced practice-related administrative burden. The present study is the first report of which we are aware to focus on PA-related pharmacy burden and use of a pre-printed prescription form.

The North Carolina Medicaid PPI PA program had the advantage of the 14 CCNC networks, its pharmacists, and regular medical management meetings to educate providers and support the effort.³⁶ The ability to call on pharmacies and practices in person with existing human resources that already had established relationships was advantageous both for implementation and evaluation. One of the few drawbacks to the program was its limited scope with respect to a single drug class from a single payer. While pharmacists generally gave positive feedback about the IAP approach, it would likely be advantageous to patients, prescribers, and pharmacies if consistent phraseology for pharmacy claim PA override or procedures that cut across all drug classes and payers were developed. A more efficient IAP drug management program may be created through collaboration with other state Medicaid

programs and private payers, using universal override procedures and criteria.

The use of IAP can be applied across many drug classes and drug product types. A program similar to the PPI IAP has been in place in North Carolina Medicaid for palivizumab since 2004. Palivizumab is a humanized monoclonal antibody that has been shown to reduce the occurrence of respiratory syncytial virus-related hospitalizations in high-risk infants.³⁷ Within North Carolina Medicaid, generally only the specialty pharmacies have participated in dispensing palivizumab.³⁷ Palivizumab is both expensive and more time sensitive for administration than most other drug products, necessitating a PA program that is “user friendly” for patients, prescribers, and pharmacies. Although palivizumab requires PA in North Carolina, pharmacies can dispense the medication and be guaranteed reimbursement based on criteria and paperwork that can be submitted retroactively, allowing for the immediate delivery and administration of the drug product.³⁸

Unlike IAP for PPIs, use of MD Easy forms may not be feasible for all types of drug products. For the PPI program, there were logical and evidence-based therapeutic alternatives to nonpreferred products that provided prescribers an alternative to seeking an override. When the MD Easy form acts as a prescription for an alternative product, it allows the practice to quickly make switching and IAP decisions for all of its patients who would be affected by the PA prior to the policy taking effect. For PA policies other than therapeutic interchanges, such as limits on total daily dose, unit counts over time, or restrictions based on diagnosis with no “step therapy” or “fail first” component, the MD Easy form may act primarily as an educational tool or care alert because no new prescriptions for an alternative medication are expected.

Limitations

First, the IAP and the MD Easy form were compared with traditional PA using measurements of perceived burden. The actual administrative time and costs of each approach were not measured using direct observations and time studies. However, the perceived burden and relative acceptability of the PA approach are important considerations in efforts intended to reduce barriers to adoption of innovations.

Second, although the response rates to both the pharmacy (84.2%) and physician (71.3%) surveys were relatively high, only about one-third of responding physicians and two-thirds of responding pharmacists reported having had experience with IAP or the MD Easy form, thus limiting the sample size for this study. In addition, the survey results may be influenced by selection bias because only 1 pharmacist or physician was surveyed on behalf of each pharmacy or medical practice, and the pharmacist interviews were conducted based

on pharmacist availability. It is possible that experiences of those not surveyed may differ from those of survey respondents. An attempt was made to obtain the most informed respondents by requesting participation of the physician in each practice with the most experience with the IAP for PPIs. Yet, self-selection is likely to have occurred to some extent within each physician practice.

Third, many of the survey items asked the respondents to make relative comparisons to previous PA experiences. Prior to this PA program, the North Carolina Medicaid program had nearly complete open access, without a preferred drug list or any substantially disruptive PA policies affecting large numbers of prescribers or patients. It is possible that the addition of any PA requirement, even one that involves an IAP, may tend to bias the responses in the direction of understating satisfaction because historically North Carolina Medicaid has adopted less aggressive PA policies affecting small numbers of enrollees. However, given the widespread use of PA programs across payers, this potential source of bias is unlikely.

Fourth, the use of an interrupted time-series design for studying the effect of introducing a PA policy was a natural experiment without a comparison group and is not a strong design for controlling for threats to internal or external validity. The dramatic increase in the prescribing of preferred PPIs after the PA policy implementation could potentially be attributed to other factors. For example, physicians may be more likely to adhere to the PA policy when they are aware of being observed in an investigation. The sustainability of market share results over 7 months reduces this concern because physicians were directly involved in the study for only a brief time period, the time to complete a survey. Another potential explanation for successful channeling to preferred PPIs may be the involvement of early adopters or highly performing physicians in the study. Given that the PPI prescribing patterns were summarized for responding practices rather than individual responding physicians, this concern is unlikely to represent a major threat to study validity.

Conclusion

This study provides evidence that an IAP for PPIs is an effective alternative to traditional PA approaches for prescription drugs. The method, including use of the MD Easy form, was associated with an increase in market share of preferred PPIs and was reported to be less administratively burdensome to pharmacists than traditional PA. Additional studies are needed to determine sustainability and applicability to other prescription drugs.

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