Pharmacist Response to Alerts Generated From Medicaid Pharmacy Claims in a Long-term Care Setting: Results From the North Carolina Polypharmacy Initiative

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ABSTRACT

OBJECTIVE: In response to burgeoning drug costs, North Carolina (NC) Medicaid encouraged pharmacists and prescribers to develop collaborative programs to reduce drug expenditures. One of these programs, the North Carolina Polypharmacy Initiative, was a focused drug therapy management intervention aimed at reducing polypharmacy in nursing homes. This intervention targeted patients with more than 18 prescription fills in 90 days, beginning in November 2002. These patients were believed to have a high likelihood of experiencing potential drug therapy problems (PDTPs). Consultant pharmacists were asked to utilize profiles displaying alerts generated from pharmacy claims to guide interventions in addition to usual-care drug regimen reviews. The pharmacists documented their reviews, recommendations, and resulting changes in drug therapy. Our objectives were to determine (1) the persistence of PDTP alerts following interventions by consultant pharmacists and (2) the impact of these interventions on patient drug costs from a payer perspective.

METHODS: A before-after study with comparison group design was used. Medicaid prescription claims data were compared for the 90-day periods prior to the intervention (June-August 2002) and following the intervention (March-June 2003). The 90-day postintervention period allowed for 2 to 3 follow-up prescriptions and reduced the drop-out rate. The 5 categories of potential problem alerts included potentially inappropriate medications (Beers criteria), substitution opportunity for a lower-cost drug, 16 drugs or drug classes with specific quality improvement opportunities (Clinical Initiatives list), therapeutic duplication, and length of drug therapy evaluation.

RESULTS: A total of 253 nursing homes, involving 110 consultant pharmacists and 6,344 patients, were in the intervention arm, with 5,160 patients (81.3%) remaining at the end of the follow-up period. At baseline, study-group patients used an average of 9.7 prescriptions per month, costing the NC Medicaid program $517 per patient per month (PPPM). There were 6,360 recommendations offered for 3,400 patients, or an average of 1.87 recommendations per patient. Physicians concurred with 59.8% (3,801 of 6,360) of all recommendations to change drug therapy, about half involving a switch to a lower-cost drug. Two of 5 alert categories had significant ($P < 0.01$) reductions in alert persistence: -10.8% for the study group versus -0.7% for the comparison group for the Clinical Initiatives list and -29.7% for the study group versus -14.1% in the comparison group for the drug substitution opportunity. Median drug costs per patient in the study group decreased by $12.14 (-0.92%), from $1,329.46 to $1,317.32, and increased in the comparison group by $44.98 (3.35%), from $1,341.25 to $1,386.23, creating a relative cost reduction of $57.12 per patient in the 3-month follow-up period, or $19.04 PPPM.

CONCLUSION: A supplemental program of medication reviews for nursing home patients targeted by high drug utilization resulted in a reduction in the persistence of PDTP alerts and was cost beneficial based solely on drug cost savings. This intervention may be a model for future medication therapy management services provided by prescription drug plans under Medicare Part D for patients in long-term-care settings and possibly ambulatory patients.

KEYWORDS: Nursing homes, Pharmaceutical care, Medication therapy management, Drug use review, Polypharmacy, Drug regimen review

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Note: An editorial on the subject of this article appears on pages 586-87 of this issue.

The passage of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) and the ensuing rollout of the outpatient drug benefit in January 2006 have focused attention on ensuring elderly patient access and cost-effective prescribing and use of drugs. Those responsible for Part D program administration within the Centers for Medicare and Medicaid Services (CMS) and prescription drug program sponsors share the formidable task of managing both the cost and quality of drug regimens for more than 40 million Medicare beneficiaries. Medicare will become the largest single payer of drug benefits in the United States, with a projected $70 billion in expenditures in 2006.[1]

The elderly have more chronic illnesses and use more prescription drugs than any other age segment, increasing the likelihood of adverse drug events, many of which are avoidable.[2-4] In an attempt to ameliorate the cost burden and ensure rationale and optimal drug use, Congress took the novel approach of requiring prescription drug plans (PDPs) and Medicare Advantage PDPs to offer a Medication Therapy Management Program (MTMP) as part of their drug benefit. Despite considerable variations in strategy and implementation, prior MTMP-like programs have demonstrated significant cost savings and reductions in drug therapy problems for other targeted patient populations.[5-7]
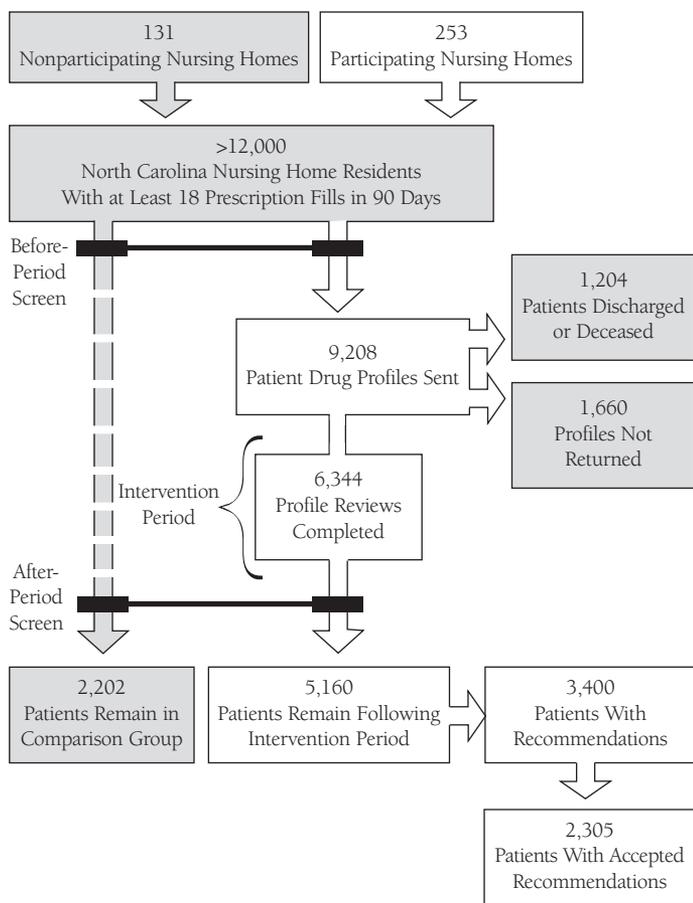
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FIGURE 1 Inclusion Criteria and Cohort Development

used in long-term-care settings. While such reviews have resulted in improved care since first mandated,[12] there is room for improvement, and a more holistic approach based upon the optimization of both the type and use of all drugs taken by Medicare Part D recipients seems prudent.[13]

Medicaid recipients are also subject to drug reviews through OBRA '90 regulations that require ongoing statewide drug utilization review (DUR) activities. These programs typically focus on drug use by ambulatory Medicaid recipients. The legislation compelled states to establish committees and systems to review patterns of drug use believed to be problematic but did not go as far as MMA to allow for explicit compensation of pharmacists as providers of care.

MMA legislation effectively shifts the burden of drug costs incurred by elderly Medicaid recipients from the state-federal program to the federal government. Prior to the passage of MMA, states were burdened with Medicaid drug expenditures that were ballooning at unsustainable rates despite the federal sharing of Medicaid costs. North Carolina (NC) Medicaid spent more than $1.2 billion on drugs in 2003, with the elderly accounting for 11% of recipients but 32% of all prescription drug costs.[14,15] In response to these trends, NC Medicaid introduced a program that combined the state-level, top-down administration characteristic of DUR activities with patient-level, pharmacist-driven activities typical of DRRs. This program was titled the North Carolina Polypharmacy (NCPP) Initiative.

Following a successful pilot study, the NCPP Initiative was launched in 253 nursing homes in North Carolina with emphasis on elderly Medicaid recipients. In addition to mandated DRRs, the initiative provided a targeted drug therapy management consultation provided by a pharmacist with the treating physician. In these targeted drug therapy management consultations, pharmacists were to (1) review a drug profile generated from Medicaid pharmacy claims with potential drug therapy problem (PDTP) alerts and medical records of Medicaid patients in nursing homes, (2) determine if a drug therapy problem existed, (3) recommend a change if needed, and (4) perform a follow-up to determine if the change was implemented.

The NCPP Initiative was organized as a collaborative activity that incorporated a physician primary care practice network (AccessCare of North Carolina), a pharmacy consultant coalition, and a network of nursing home medical directors. The nature of the NCPP Initiative and its organization was described in an earlier paper that reported the type and frequency of pharmacist interventions and estimated the cost impact of drug therapy changes by type of PDTP.[16] Intervention documents submitted by pharmacists were used as a single data source. For the 6,344 patients with reviews, pharmacists responded to approximately 20,000 drugs with alerts by making 6,520 recommendations, resulting in changes in drug therapy 58% of the time.[16] These changes were projected to save NC Medicaid $30.33 per patient per month (PPPM).[16]

Defining the nature and scope of MTMP services within Medicare Part D continues to be a dynamic and ongoing endeavor. A consortium of pharmacy trade and professional associations published a working definition in July 2004.[8] This definition was expanded by the American Pharmacists Association and the National Association of Chain Drug Stores in April 2005.[9] However, CMS's final rules pertaining to MTMP services remain broadly defined, leaving the operational details to PDP sponsors.[10]

MMA was not the first federal legislation to require pharmacist involvement in the drug-use process. Beginning in the 1970s, federal regulations imposed a requirement that monthly drug regimen reviews (DRRs) be conducted in long-term-care facilities by consultant pharmacists.[11] Subsequent Omnibus Reconciliation Act legislation (OBRA '87) required that this review be accomplished in collaboration with the attending physician. These regulations contained explicit requirements for reviewing therapy for targeted drugs and drug classes deemed to be over-

FIGURE 2 Patient Profile Generated From Medicaid Pharmacy Claims—
With Potential Drug Therapy Problem Alerts

Nursing Home PolyPharmacy Project - Patient Profile   Patient Name   Medicaid ID   Page 1 of 4   5/7/2003

Nursing Home Practice: Nursing Home Name and Number

Patient ID: XXXXXX   **Last Name:** XXXXXX   **First Name:** XXXXXX

Gender: F   **Age:** 82   **DOB:** xx/xx/xxxx   **Avg # of Drugs/month:** 7.67   **Avg monthly drug $:** $625.85

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Fill Date	Drug Class	Medication	Amount Paid	Prescriber	PAL	Potential Theraputic Duplication	Clinical Initiatives	Consider Length of treatment*	Beers List ≥ 65	Problem Type	Results Type	New Drug and Strength
7/30/02	ANALGESICS, NARCOTIC	ULTRACET TABLET *d*	$164.96	Prescriber Name						A B C D E F G	1 2 3 4 5 6	
8/16/02	ANTINAUSEANTS	METOCLOPRAMIDE 10MG TABLET	$11.81	Prescriber Name						A B C D E F G	1 2 3 4 5 6	
6/5/02	ANTISPASMODIC-ANTICHOLINERGIC	HYOSCYAMINE 0.375MG TAB SA	$16.04	Prescriber Name					X	A B C D E F G	1 2 3 4 5 6	
8/7/02	ANTI-ULCER	NEXIUM 40MG CAPSULE	$131.32	Prescriber Name	PAL 3 Prefer Protonix		X			A B C D E F G	1 2 3 4 5 6	
8/9/02	BRONCHIAL DILATORS	ALBUTEROL .83MG/ML SOLUTION	$16.70	Prescriber Name	PAL 1					A B C D E F G	1 2 3 4 5 6	
8/29/02	DIURETICS	FUROSEMIDE 40MG TABLET *a*	$7.52	Prescriber Name						A B C D E F G	1 2 3 4 5 6	

*Please refer to toolkit for further explanation.

Problem Type (Circle all that apply)
A. Unnecessary Drug Therapy
B. More Cost Effective Drug Available
C. Wrong Dose or Strength
D. Drug has High Potential for ADRs
E. Needs Additional Therapy
F. Not a problem at this time
G. Other - Any other problem not listed above

Results Type (Circle all that apply)
1. Dose/Delivery Changed - Dosage or administration was changed
2. Drug Added - New drug was added for previously untreated indication.
3. Drug Change - Drug was changed from one to another.
4. Drug Discontinued - Drug was discontinued or was changed to PRN.
5. No Change - Physician Responded but did not make any changes.
6. Other - Any result not listed above.

Medication Superscripts
a. Recommended check for K+ need
b. Recommended use with Ca+ supplement.
c. Recommended check for FE+ need
d. Recommended check for Stool Softener need
e. Recommend check for Folic Acid therapy.
f. Recommend check for supplemental calcium need..
g. TB test needed?
h. Does patient have BPH and HTN? Consider Cardura.
i. Consider dose reduction/excessive dose.

PAL Codes
PAL Code 1 - Preferred Drug
PAL Code 2 - No Preference
PAL Code 3 - Avoid
PA   - Prior Authorization
Required

In the present article, we reconcile the projected drug cost impact of pharmacist intervention activities with actual Medicaid claims data spanning a 6-month period. We describe the nature of PDTP alerts, drugs involved, recommendations, and actions taken after physician consultation. We also assess changes in drug therapy from a qualitative and economic perspective using a before-after study design with a comparison group.

Our working hypothesis was that a systematic program of pharmacist-directed DUR that supplements requisite OBRA '87 DRRs in nursing homes would produce drug therapy changes that maintain or improve the quality of care while decreasing drug costs. The specific objectives of the current study were to determine (1) the persistence of PDTP alerts following interventions by consultant pharmacists and (2) the impact of these interventions on patient drug costs from a payer perspective. This study received approval from the Institutional Review Board at the University of North Carolina at Chapel Hill.

■ Methods

Setting and Participants

Phase 1 of the NCPP Initiative was conducted by 110 pharmacists in 253 nursing homes, representing approximately 70% of all nursing homes in North Carolina (Figure 1). Participation in the intervention was solicited through the North Carolina Long Term Care Pharmacy Alliance, a representative group of pharmacists serving nursing homes throughout the state. Exempted were 13 homes that contracted with a single pharmacy provider and were involved in a separate, ongoing intervention project. All Medicaid residents of the participating facilities who had 18 or more prescription fills in the 90-day period prior to the start of the study were eligible for an on-site profile review by a consultant pharmacist. This time horizon was chosen to capture, on average, 3 monthly supplies of medications while limiting the dropout rate as much as possible.

Pharmacist Responsibilities

Participating pharmacists were introduced to the project, toolkit, and documentation form during two 1-hour group meetings and one 1-hour conference call. Other professional interactions took place throughout the course of the project, including informational meetings with geriatric associations, nursing home medical directors, and network physicians, as well as the use of telephone follow-ups. The toolkit contained instructions for documenting interventions and explained the screening criteria used to select (flag) drugs for attention.

Each consultant pharmacist was provided with drug profiles computer-generated from Medicaid pharmacy claims that displayed flags for patients and suggestions for modifications of drugs and classes of drugs. Pharmacists were asked to record both the result of the review (i.e., the intervention) and the result of the consultation with the prescribing physician (i.e., the outcome) on a documentation form (Figure 2). Recording the result of the intervention required awaiting the prescriber's response to the recommendation. Pharmacists were required to conduct these assessments during their regularly scheduled visits to each home. Consultant pharmacists employed their usual methods of communicating with physicians (fax, phone, or written notation in the medical record) to make recommendations and to learn the outcome of the change recommendation. We categorized the drug therapy flags as (1) unnecessary drug therapy, (2) more cost-effective drug available, (3) wrong dose/delivery, (4) potential for adverse drug reaction, (5) needs additional therapy, and (6) other problem. We coded intervention results as (1) dose/delivery changed, (2) drug added, (3) drug changed (from one to another), (4) drug discontinued, (5) no change, and (6) other intervention.

If an intervention resulted in a drug therapy change of any type, the new drug, dose, and quantity were noted. Drug, dose, and quantity were also reported for each new drug added for previously untreated indications. Pharmacists were compensated $12.50 for each comprehensive profile review for which results were clearly documented on the forms provided (i.e., the patient profile). This compensation amount was based on our estimate of the additional time required for these focused reviews above and beyond normal review activities and a customary rate of pay of $50 per hour. Pharmacists were compensated regardless of problem determination and/or the offering of a recommendation.

Drug Profiles and PDTP Alert Criteria

Patient drug profiles were generated from Medicaid claims data and contained, for each listed drug, a space for all alert categories, marked with the appropriate flag/alert if a PDTP was determined by matching claims data with drug lists generated from alert categories. The profiles were a compilation of all drugs for which a claim was paid in the 90 days prior to generation, regardless of the presence of an alert. The first alert criterion was receipt of a drug widely considered to be inappropriate for use in the elderly (Beers drug list).[17] In order to engender participation and maximize the quality of the PDTP alerts, program administrators also elicited input from local physicians and consultant pharmacists. Thus, the second criterion was receipt of a drug on the Community Care of North Carolina Prescription Advantage List (PAL), which encourages substitution of less expensive drugs within a therapeutic class. This voluntary preferred drug list was conceived and is maintained by a committee of practicing physicians in North Carolina specifically for NC Medicaid. There are 3 categories of PAL drug alerts. PAL-3 drugs are considered to incur "significant cost" to the Medicaid program (e.g., Nexium, Prilosec, Zestril, Prinivil, as of November 2002), while PAL-2 drugs offered "no clear cost advantage" (e.g., Prevacid, Aciphex, Accupril, Monopril, Lotensin, Altace, as of November 2002), and PAL-1 drugs offer "significant cost savings" to the Medicaid program (e.g., Protonix, lisinopril, enalapril, captopril, as of November 2002). The third criterion was the appearance of a drug on a "Clinical Initiatives" list. The Clinical Initiatives list was developed by consultant pharmacists participating in the NCPP Initiative and included 16 drugs and/or drug classes (e.g., COX-2 inhibitors, statin drugs, sleep aids, low-sedating antihistamines) that had the potential for quality improvement and cost savings. Program administrators offered 2 additional alerts: therapeutic duplication and a "consider length of therapy" alert that was derived from classes of drugs considered appropriate only for short-term use (e.g., antibiotics, injectable enoxaparin).

Research Design

We first evaluated pharmacist action and reporting by reconciling the response to alerts with downstream prescribing activity using the Medicaid dispensed prescription claims database. Using a before-after, study-comparison-group design, we compared prescription use during the 3 months before intervention (June-August 2002) with a period of equal length at the end of Phase 1 (March-June 2003). Second, we assessed whether or not PDTP alerts were reduced during the follow-up period compared with usual-care controls (nonrandomized comparison group). Third, we describe the economic consequences of pharmacist activities in terms of changes in drug cost using pharmacy paid claims data.

Study-group patients were Medicaid recipients residing in participating nursing homes who received a completed profile review by a consultant pharmacist. The comparison group consisted of patients in nursing homes not responding to the invitation for inclusion in Phase 1 of the intervention. Inclusion of patients in comparison-group homes was determined by criteria identical to study-group patients (i.e., more than 18 prescription fills in 90 days, Figure 1). Several of the nursing homes in the comparison group became participants in later phases of the project, but only after the 6-month study window in this

TABLE 1 Baseline Characteristics of Continuously Enrolled Patients by Treatment Group

Characteristic	Study Group (n = 5,160)	Study Group (With Recommendation*) (n = 3,400)	Study Group† (With Acceptance) (n = 2,305)	Comparison Group (n = 2,202)
Sex, no. (%)				
Male	1,289 (24.98)	820 (24.12)	533 (23.99)	484 (21.98)
Female	3,871 (75.02)	2,580 (75.88)	1,752 (76.01)	1,718 (78.02)
Race, no. (%)				
White	3,533‡ (68.47)	2,325‡ (68.38)	1,588‡ (68.89)	1,667 (75.70)
Other	1,627 (31.53)	1,075 (31.62)	717 (31.11)	535 (24.30)
Age, years, mean ± SD	77.57 ± 12.72	77.63 ± 12.42	77.67 ± 12.44	78.65 ± 12.46
(median)	(80.0)	(80.0)	(80.0)	(81.0)
No. of prescription fills, 3 month period, mean ± SD	29.04 ± 9.92	29.86 ± 10.27	30.19 ± 10.53	28.18 ± 10.74
(median)	(27.0)	(28.0)	(28.0)	(26.0)
Amount of paid claim ($), 3-month period, mean ± SD	$1,549.89 ± 1,652.49	$586.91 ± 919.17	$1,610.02‡ ± 926.77	$1,543.67 ± 921.98
(median)	($1,329.46)	($1,392.14)	($1,427.13)	($1,341.25)

Note: Difference of proportions tests were used to determine differences in sex and race. T-testing was used to determine differences in age, number of prescription fills, and amount of paid claims.

* Study group (with recommendation) = those patients having a recommendation resulting from pharmacist consultation, regardless of outcome.

† Study group (with acceptance) = those patients having a recommendation and a change in therapy as a result of a recommendation provided by a pharmacist.

‡ Denotes significantly different from comparison group at P <0.01.

analysis. For study-group patients, we linked prescription drug use elicited through claims data to pharmacist-reported interventions (or lack thereof) on patient profiles. We examined 2 study subgroups: (1) patients whose drug use received pharmacist recommendations and (2) patients for whom recommendations were accepted.

Studies in the long-term-care arena are often burdened by a high attrition rate. Using a combination of claims data and pharmacist report, we estimated an annual nursing home resident attrition rate of 36% due to death or discharge in North Carolina. Since we were not able to verify dropout from prescription claims with certainty, only residents having claims in the last 35 days of the 90-day follow-up period were included in both the study and comparison groups.

Statistical testing was performed using SAS statistical software, version 8.2 (1999-2001, SAS Institute Inc., Cary, NC). We used nonparametric statistical testing to account for possible skewness in the data.

■ Results

Prescription profiles were generated and sent to consultant pharmacists for 9,208 patients. Pharmacists returned 7,548 (82%) of all profiles sent to them (Figure 1). After excluding 1,204 patients (13%) who were discharged or deceased, 6,344 patients were subjected to profile reviews. This number diminished to 5,160 patients who remained in the Medicaid population throughout the follow-up period, constituting an 18% dropout rate over 6 months due to death or discharge. This is consistent with historical dropout rates for Medicaid recipients. Remaining patients had received an average of 9.7 prescription fills (median

9) per month during the 3-month period prior to profile generation. Exclusive of manufacturer rebates, the average PPPM drug cost to NC Medicaid was $517, with a median of $443.

The comparison group consisted of 2,202 patients selected in the same manner as study-group patients (having 18 or more prescription fills in a 90-day period). We compared study and comparison groups based on age, gender, race, baseline prescription use, and dropout rates (Table 1). The groups differed with respect to race, with a lower proportion of whites in study nursing homes versus comparison-group homes (69% vs. 76%, respectively, P <0.01). At baseline, drug usage and costs were similar for study and comparison-group patients with one exception: the study subgroup with changes resulting from recommendations had higher baseline prescription costs. Dropout rates from the original cohorts were also similar across the groups (at 18% to 19%).

Among study group patients, the most common PDTP alert was for a drug with a potential therapeutic duplication with an average of 5.11 alerts (Table 2). Therapeutic duplication alerts were common because a single potential duplication triggered at least 2 alerts. Clinical Initiative alerts averaged 2.77 alerts per patient. This was followed by PAL-2 or PAL-3 drugs (1.58 per patient) and Beers list drugs (0.78 per patient). A total of 6,360 interventions were offered for 3,400 patients in the study group, an average of 1.87 per patient with intervention. Based on pharmacist reporting, physicians concurred with 59.8% (3,801 of 6,360) of all interventions to change drug therapy (Table 3). Pharmacist suggestion for a more cost-effective drug was the most popular recommendation (3,327) with the greatest frequency of success (2,088, 62.8%). A recommendation for a

TABLE 2 Comparison of Potential Drug Problem Alert Rates Before and After a Single Retrospective Intervention

Alert Type	No. of Alerts Per Patient		Difference (%)
	Before (3 months)	After (3 months)	
Beers List§			
Study	0.78	0.70	-0.08 (-10.8)
Study (w/recommendation*)	0.82	0.72	-0.10 (-12.2)
Study (w/acceptance†)	0.83	0.71	-0.12 (-14.5)
Comparison	0.83	0.74	-0.09 (-10.8)
PAL List (2 or 3)‖			
Study	1.58	1.11	-0.47‡(-29.7)
Study (w/recommendation*)	1.76	1.16	-0.60‡(-34.1)
Study (w/acceptance†)	1.82	1.10	-0.72‡(-39.6)
Comparison	1.63	1.40	-0.23 (-14.1)
Clinical Initiatives List¶			
Study	2.77	2.47	-0.30‡(-10.8)
Study (w/recommendation*)	3.00	2.67	-0.33‡(-11.0)
Study (w/acceptance†)	3.09	2.68	-0.41‡(-13.3)
Comparison	2.73	2.71	-0.02 (-0.7)
Consider Duration Flag#			
Study	0.16	0.15	-0.01 (-6.3)
Study (w/recommendation*)	0.15	0.15	0.00 (0.0)
Study (w/acceptance†)	0.14	0.14	0.00 (0.0)
Comparison	0.18	0.15	-0.03 (16.7)
Therapeutic Duplication**			
Study	5.11	4.63	-0.48 (-9.4)
Study (w/recommendation*)	5.15	4.78	-0.37 (-7.2)
Study (w/acceptance†)	5.22	4.75	-0.47 (-9.0)
Comparison	5.00	4.56	-0.44 (-8.8)

Note: The Wilcoxon 2-sample test was used to assess differences in alert rates between the comparison group and study.
Sample sizes:
  Study group: n=5,160
  Study group with recommendations: n=3,400
  Study group with accepted recommendations: n=2,305
  Comparison group: n=2,202
* *Study group (with recommendation)=those patients having a recommendation resulting from pharmacist consultation, regardless of outcome.*
† *Study group (with acceptance)=those patients having a recommendation and a change in therapy as a result of a recommendation provided by a pharmacist.*
‡ *Denotes significantly different from comparison group at P <0.01.*
§ *The Beers List is a list of drugs generally considered to be inappropriate in the elderly.[17]*
‖ *PAL = Prescription Advantage List, a categorization of drug alerts proposed by practicing physicians in North Carolina. PAL 3 drugs are considered to "incur significant cost." PAL 2 drugs are considered to offer "no clear cost advantage." PAL 1 drugs are considered to offer "significant cost savings." The rates of PAL 2 and 3 drug alerts are shown in this table.*
¶ *Clinical Initiatives List refers to potential drug therapy problem alerts proposed by consultant pharmacists in North Carolina.*
# *Consider Duration alerts were derived from classes of drugs considered appropriate only for short-term use.*
** *Therapeutic Duplication alerts were generated based upon duplications within hierarchical drug class codings.*

TABLE 3 Frequency of Recommendation by Type With Resultant Success* (n=3,400)

Recommendation Type	Frequency	Success, No. (%)
Wrong dose or strength	545	444 (81.5)
More cost-effective drug available	3,327	2,088 (62.8)
Drug has potential for ADRs	632	328 (51.9)
Needs additional therapy	167	69 (41.3)
Other (not specified)	432	146 (33.8)
Total	6,360	3,801 (59.8)

* *Recommendations were considered successful when a change in therapy occurred subsequent to a recommendation by the clinical pharmacist.*
ADRs=adverse drug reactions.

different dose garnered the highest rate of success (444 of 545, 81.5%). For Clinical Initiatives and PAL-2 or PAL-3 flags, pharmacists made interventions for change in 46.2% (2,271 of 4,916) of patients; physicians endorsed 60.2% (1,939 of 3,222) of the recommendations. Beers drugs and "consider length" (of drug therapy) categories garnered considerably fewer recommendations.

We next examined persistence of computer-generated alerts in the drugs received by patients before and after intervention. Our working hypothesis was that, if the intervention program was successful, there should be a decrease in the number of PDTP alerts on subsequent patient drug profiles using the same computer-screening process employed in the before-intervention period. We found statistically significant declines in the number of alerts per patient for both PAL and Clinical Initiatives flags ($P < 0.01$) for all study groups (-29.7% and -10.8%, respectively) compared with the comparison group (-14.1% and -0.7%, respectively) using the Wilcoxon 2-sample test (Table 2). As expected, even greater declines in alert rates were observed in the study subgroup that received intervention (-34.1% and -11.0%) and in the subgroup that had drug therapy changes as a result of dispensing pharmacist recommendations (-39.6% and -13.3%). When compared with baseline drug use, all flag categories in all study groups had statistically significant reductions ($P <0.01$; Wilcoxon signed rank test), with the exception of the "consider length" (of drug therapy) flag.

Finally, we examined before-after changes in the amount paid for prescriptions (Table 4). Median drug costs per patient in the intervention group decreased by $12.14 (-0.92%) from $1,329.46 to $1,317.32 and increased in the comparison group by $44.98 (3.35%) from $1,341.25 to $1,386.23, creating a relative cost reduction of $57.12 per patient in the 3-month follow-up period, or $19.04 PPPM. Even larger reductions in drug costs were observed in the study subgroups with (1) documented profile reviews and with recommendations for change, where a median decline of $25.83 per patient was observed and (2) in the subgroup for which drug therapy changes occurred as a result of the recommendations, where a decline of $61.68 per patient was observed.

■ Discussion

The results indicate that the addition of PDTP alerts to usual-care DRRs was associated with more changes in drug therapy and a reduction in computer-generated drug therapy alerts during the follow-up period. Among drug problem alert categories, we found statistically significant differences between the study group and the comparison group in alert persistence for Clinical Initiatives and PAL drugs. These 2 categories were constructed by physician and pharmacist leaders, suggesting that practitioner involvement with a centralized DUR process aids in program response. Beers list and therapeutic duplication alerts decreased in all study groups and in the comparison

group, but persistence was not statistically different between study and comparison groups. This finding is consistent with the role of DRRs as outlined in OBRA '87.[11] These types of drugs and drug problems are explicitly mentioned as part of the guidelines for conducting customary mandated DRRs.

Residents in comparison homes were not subject to drug profile reviews with PDTP alerts generated from pharmacy claims as part of the NCPP Initiative. However, residents in both study and comparison homes were subject to requirements based on OBRA '87 and screening guidelines for the overuse of particular prescription drugs. This may explain the reduction in both groups. A *JMCP* article published in April 2005 demonstrated significant reductions in the use of Beers list drugs associated with an intervention involving letters to prescribers, pharmacist phone consultations, and written literature disseminated in a predominantly ambulatory population of Medicare + Choice (now Medicare Advantage) recipients.[18] It would seem prudent, given previous success, to attempt to replicate the NCCP Initiative in an ambulatory Medicare setting. Notably, few recommendations were made pursuant to the "consider length" (of therapy) flag category in all study and comparison groups. This length of therapy category generated only 205 alerts in total and did not contain drugs such as benzodiazepines or psychotropic medications customarily scrutinized for length of therapy during regularly scheduled DRRs.

This analysis of prescription claims data supports previous findings with regard to drug cost savings resulting from the NCPP Initiative as well as its pilot project. The NCPP Pilot Project was found to have generated an approximate 4% reduction in drug costs.[19] A previously published article utilizing primary data from pharmacist reports found that the NCPP Initiative produced savings of $30.33 PPPM savings in the month immediately following the intervention.[16] The resulting cost minimization ratio was determined to be 12:1.[16]

In the present study, we utilized Medicaid claims data to reconcile documented pharmacist interventions and to determine the downstream effects of those interventions. We also added a comparison group to further strengthen its internal validity. Using the results from Medicaid claims data in conjunction with comparison group findings, we observed a savings of $19.04 ($P$=0.06) PPPM for all patients receiving profile reviews, $23.60 for patients receiving interventions (P <0.01), and $35.55 ($P$ <0.01) for patients having at least 1 accepted intervention. The 3-month PPPM difference between the study group and comparison group of $57.12 remains substantial and justifies the implementation of the Polypharmacy Initiative on the basis of drug cost savings alone.

Previous projections based upon the first month immediately following the interventions did not allow us to consider the persistence of the intervention effect. An intervention may not have been carried out for reasons unknown to the consultant pharmacist. The intervention decision may have been reversed

TABLE 4	Total Amount Paid for Prescriptions in the Before and After Periods			
	Before Period (3 Months) (Median)	After Period (3 Months) (Median)	Difference (%)	P Value
Study group (n = 5,160)	$1,329.46	$1,317.32	-$12.14 (-0.92)	0.06
Study group (n = 3,400) (w/recommendation*)	$1,392.14	$1,366.31	-$25.83 (-1.86)	<0.01
Study group (n = 2,305) (w/acceptance†)	$1,427.13	$1,365.45	-$61.68 (-4.32)	<0.01
Comparison group (n = 2,202)	$1,341.25	$1,386.23	$44.98 (3.35)	n/a

Note: the Wilcoxon 2-sample test was used to assess differences in total amount of paid claims between the comparison and study groups.
* Study group (with recommendation) = those patients having a recommendation resulting from pharmacist consultation, regardless of outcome.
† Study group (with acceptance) = those patients having a recommendation and a change in therapy as a result of a recommendation provided by a pharmacist.
n/a = not applicable.

by the physician after the pharmacist documented acceptance in the report. Pharmacists may also have underreported new drugs found on the nursing home medical record but not appearing on the drug profile generated from Medicaid pharmacy claims due to lag time from profile receipt to regularly scheduled DRR activities. We noted an average difference of $15 per month between claims analysis and pharmacist-reported drug cost data ($516.63 in claims analysis versus $502.96 in pharmacist-reported data) in baseline costs between these studies. This difference illustrates the importance of reconciling pharmacist intervention reporting with administrative claims. Using both data sources, as we did in the present study, is advantageous since we can tie observed medication-level interventions derived from pharmacist reporting with actual costs incurred from claims data to validate pharmacist action.

The NCPP Initiative combines population-level, drug-specific surveillance of DUR programs with patient-level, comprehensive reviews characteristic of DRR activities. Alerts were generated by the payer, in this case NC Medicaid, and were provided to prescribing physicians to encourage change in targeted drugs and drug classes. In line with usual care in long-term-care settings, pharmacists were free to review and recommend therapy changes for any drug in a patient's profile for any problem they discovered. Beginning in 2006, Medicare PDP sponsors will take on a DUR role with differing approaches to MTMP under the MMA. Standard DUR approaches have offered little evidence, to date, of effectively improving patient outcomes for state Medicaid recipients despite the large budget outlays to these programs.[20-23] However, targeted, population-specific interventions such as the NCPP Initiative have shown some success.[24-26] Focused reviews based upon patient-specific

profiles generated from administrative pharmacy claims, in combination with collaborative activities that individualize care,[27] such as DRRs, may be a better strategy for PDPs to adopt through the MTMP service requirement.

This strategy is not limited to the long-term-care setting and may in fact be more effective in an ambulatory setting where less frequent review of drug use profiles takes place. The strategy is generally applicable to any group of beneficiaries that use online adjudication for processing pharmacy claims.

Limitations

It was not possible to draw a true random sample of patients, nursing homes, or pharmacist consultants due to the intermingling of providers. Our comparison group was not, by design, a randomized sample of patients. Due to clustering effects, it is difficult to construct a truly randomized patient-level sample within a nursing home because physicians often provide care to patients in more than one nursing home. Additionally, groups of pharmacists are often clustered through consulting organizations serving multiple nursing homes, and multiple nursing homes often operate under a common ownership structure. Fortunately, baseline demographic characteristics and prescription drug costs between the study group and the comparison group were remarkably similar ($516.63 in the study group versus $514.56 in the comparison group).

The study group, its subgroups, and the comparison group did not differ statistically with respect to gender, age, or number of prescriptions filled at baseline. There was a statistically significant difference with respect to race, with the study group and its subgroups having a greater proportion of nonwhite participants. We do not suspect that this difference confounded the results. Whatever unmeasured population differences existed, we believe our use of before-after comparisons within groups and the relatively large sample sizes enhance the validity of study results. We assume that contamination effects arising from sharing of pharmacist consultant firms between study and comparison facilities was trivial. While some pharmacist consulting firms served several different nursing homes, no individual pharmacist provided consulting services to both study and comparison group homes. Pharmacist turnover was not a problem since the time period was relatively short. To the extent that contamination effects were present, they would serve to diminish observed between-group differences. We do not know the effect of repeated interventions, the effects of continually evolving PDTP alerts criteria,[28] or intervention persistence beyond 6 months.

We cannot confidently project the long-term impact of these interventions. Our 3-month follow-up period reflected a balance in our approach. On the one hand, we wanted at least two 1-month follow-up periods to ensure that drug therapy changes were reflected in claims data and persisted. On the other hand, a longer follow-up period of 6 to 12 months would have incurred problems of patient attrition within the nursing homes, given the statewide average attrition rate of 36% per year. Yet another factor was the strong desire by the sponsor to finish the analysis of Phase 1 as soon as possible for public policy planning and budgeting purposes.

Using administrative claims data to measure differences in drug costs is not without limitations. Drugs may have been filled without submission of a claim, or nursing homes may have paid for products such as over-the-counter medications out of a separate budget. However, this study takes a payer perspective, and paid claims are the most meaningful measurement from this perspective. Administrative claims are also poor stand-alone proxies for measuring changes in quality, particularly in such areas as adverse effects or health status. On the other hand, the very large sample sizes involved in our study suggest that our findings are real and replicable.

As with any nonrandomized observational study, regression toward the mean must be considered. We chose our comparison group in the same way we chose study group patients; hence, both should have equally incurred this regression effect, and it is, in essence, neutralized for purposes of differential analysis.

Using a payer perspective, we assessed the impact of all drug claims not just those drugs flagged in profiles from preintervention screening. It is likely that our broader focus diluted our findings toward the null. Yet we found important drug cost differences on a PPPM basis.

■ Conclusions

A program of supplemental pharmacist review targeting patients with high drug use and the potential for multiple drug therapy problems was successful in generating changes in drug therapy. We believe that involving pharmacists and physicians in the creation of PDTP alerts was crucial to widespread adoption. The changes in drug therapy that resulted from a single (compensated) pharmacist retrospective review significantly reduced the number of PDTP alerts at follow-up. Currently, regulations governing DRRs do not explicitly focus on cost-effectiveness or cost reductions of pharmaceuticals received by patients, nor do they explicitly compensate reviewers for such services. Results from this study suggest that a program to encourage and compensate pharmacists for conducting focused reviews of drug therapy regimens for targeted high-risk patients as a supplement to usual mandated review activities can lower drug therapy costs and maintain or enhance the quality of drug therapy. Interventions by pharmacists were economically beneficial when labor costs and savings in drug costs are considered. Elements of this program can be applied to both ambulatory and long-term-care settings.

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