Iowa Medicaid Pharmaceutical Case Management Program

Report of the Program Evaluation

December 2002

Submitted by The PCM Evaluation Team from The University of Iowa Colleges of Public Health and Pharmacy:

Elizabeth A. Chrischilles	Principal Investigator
Barry Carter	Co-Principal Investigator
Margaret Voelker	Project Coordinator
Shari Chen-Hardee	Database Analyst
Linda Rubenstein	Statistician
Tae-Ryong Park	Database Analyst
Brian Lund	Clinical Pharmacist
Gary Rosenthal	Medical Investigator

External Advisor

Joseph T. Hanlon	University of Minnesota

With special thanks for assistance provided by affiliated College of Pharmacy faculty:

Randy McDonough
Karen Farris
William Doucette
William Miller
Michael Ernst
Jay Currie

Table of Contents

Table of Tables

Table of Figures

Executive Summary

Background

The ultimate aim of the Iowa Medicaid Pharmaceutical Case Management (PCM) Program is to avoid adverse drug events (or side effects) and the health system costs associated with these side effects. The means to accomplish this is by more optimal, lower risk medication regimens. Adverse drug events are one of the most frequent and costly consequences of medical errors.[1]

The number one risk factor for adverse drug events is the number of drugs that a patient is taking.[2] For example, whereas 10% of older Iowans will experience adverse drug events during a one year period of time,[2] this figure rises to 40% among those taking 5 or more medications.[3] Seventy-five percent of adverse drug events are considered avoidable, that is they are a known consequence of the pharmacologic properties of the drug. However, disease state management is complicated when a patient has multiple medical conditions. This is because medications that are desirable for one condition may be contraindicated or require dose modification for patients with another condition at the same time.

Pharmaceutical case management is an opportunity for physicians and pharmacists to closely scrutinize the total drug regimens of their complex patients – to look across disease states and find the best combination of drugs and doses for that particular, complex patient. There is strong published evidence to suggest that this will work.[3-18]

During the past 35 years there have been numerous examples of innovative practice models in community pharmacy.[4] Studies in community pharmacies have demonstrated that interventions and management by pharmacists can improve the control of blood pressure,[5-8] asthma,[9] and hyperlipidemia.[10] A multi-center study also demonstrated that lipid control was significantly improved when community pharmacists assisted with management of patients with

hyperlipidemia.[11] Pharmaceutical care training has been shown to result in increased resolution of medication problems.[12,13] Community pharmacists throughout the United States have been trained and certified to provide immunizations and this service is clearly improving patient access to influenza and other vaccinations.[14,15] Studies have reported costs savings ranging from $122[16] to $856[17] per recommendation made by a community pharmacist and accepted by a physician.

Two randomized controlled trials of physician-pharmacist care teams are of particular significance.[3,18] Both studies documented the effectiveness of physician-pharmacist team care for complex patients attending Veterans Administration outpatient clinics. One found that pharmacist consultation with physicians for patients taking five or more medications reduced the prevalence of adverse drug events from 40% to 30% and significantly reduced the rate of unnecessary drug use.[3] The other study found that pharmacist consultation for complex patients resulted in better lipid control, even though the study was not specific to hyperlipidemia.[18]

Iowa has been the location of several research and demonstration projects regarding advances in community pharmacy practice.[12,13,19,20] Through these prior efforts, the foundation has been established for the Iowa Medicaid Pharmaceutical Case Management program by training over 200 pharmacists in strategies to re-engineer their practices to identify and resolve drug-related problems;[20] demonstrating the effectiveness of the training program;[12,13] and engaging a large number of Iowa pharmacists in practice-based research.[19] The Iowa Medicaid Pharmaceutical Case Management program is the first attempt to implement and reimburse physician/pharmacist team delivery of medication management services for high-risk patients in the community setting.

The primary study objective was to determine whether PCM services resulted in improved medication use quality. Also described are patient-reported adverse drug reactions, patient perceptions of their care, and health status.

Program Description

Patients were considered high-risk and thus eligible for PCM based on the number of drugs they were taking. Non-institutionalize patients taking 4 or more medications including at least one medication representing one of 12 disease states were eligible. The Iowa Medicaid PCM project was implemented with 117 participating pharmacies on October 1, 2000. Eligible patients are identified quarterly from pharmacy claims data from participating pharmacies. Patients who became eligible for PCM services during the first calendar year of the project were studied. The PCM program was described in detail in the State Plan Amendment It is reproduced in Appendix A. An advisory board designed the program and a half-day training program explained the features of the program to eligible pharmacists.

Advisory Board

A peer review advisory committee was established to oversee development of the program. The committee consists of pharmacists and physicians in the state and is attended by staff from the Department of Human Services, Iowa Medical Society, Iowa Osteopathic Society and Iowa Pharmacists Society. Specific responsibilities of the committee have been to: (1) draft the State Plan Amendment for PCM which establishes all details of the program (Appendix A); (2) establish eligibility requirements for participating providers; (3) determine eligibility of individual pharmacies/sts; and (4) review and approve the program evaluation plan.

Training Program

All participating pharmacists were required to participate in a training program. A live half-day training program instructed pharmacists on the services covered under the PCM program and the reimbursement process. Two live sessions were held in September, 2000 and a videotape training was also available. Training to physicians consisted of a manual of operations mailed by the fiscal intermediary (Consultec). A website provides answers to frequently asked questions and general information about the PCM project (www.public-health.uiowa.edu/pcm).

Program Evaluation

Summary of Evaluation Design

The evaluation of the PCM program was designed to detail the experience with eligible patients who were identified during the first four calendar quarters of the program, each followed for one year. Hence, the evaluation timeline includes patients who became eligible for PCM from October 1, 2000 through July 1, 2001 and followed-up through July 1, 2002. Thus, the evaluation reports mainly on the start-up of the PCM program. As such, an important component of the evaluation has also been to collect information about the difficulties experienced in attempting to implement the new service and innovative solutions that distinguish providers who successfully implement the services.

Pharmacies were classified according to the intensity with which they adopted the PCM services during the first program year. Some pharmacies that were eligible and were receiving lists of eligible patients did not provide PCM services and thus formed a natural comparison group (zero intensity). Other pharmacies varied in the proportion of patients for whom they provided PCM services.

The primary hypothesis of the PCM evaluation is that PCM services will be associated with an improvement in medication appropriateness as measured by the modified Medication Appropriateness Index[21-23] (MAI) score. The evaluation described the change in medication appropriateness among patients who received PCM services. In addition, the evaluation tested the relationship between intensity of PCM services (from none to moderate to high intensity) and the program goal of improving medication appropriateness, and decreasing risk for adverse drug reactions. Changes in Medicaid pharmacy, medical and institutional costs were also described among patients who received PCM services.

Data Collection

Monitoring of submitted claims for reimbursement for PCM services, quarterly fax surveys of all participating pharmacies, review of problem-oriented patient records kept in pharmacies for recipients of the service, surveys of eligible patients, analysis of Medicaid eligibility and claims files, and questionnaires and discussions with participating pharmacists and physicians constituted the main data collection activities.

Claims for PCM Services

Each month the evaluators receive a file containing PCM claims. The number of claims per pharmacy and per physician is then tabulated by type of claim, date of service, and quarter of initial patient eligibility.

Quarterly Fax Surveys

At the conclusion of each calendar quarter a survey was faxed to each participating pharmacy to ascertain the status of each patient identified to the pharmacy at the beginning of that quarter. Pharmacists were asked to indicate for each patient whether they: (a) met with the

patient; (b) worked up (evaluated) the patient's medication-related information; (c) sent a recommendation to the patient's physician; and (d) received a reply from the physician. When a pharmacist indicated being unable to provide the service to a patient s/he was asked to provide a reason.

Review of Problem-oriented Patient Records

Pharmacists are required to maintain documentation of all PCM services provided. The training program provided a recommended patient record format, including medication list, medical problem list, and problem-oriented notes in the S.O.A.P. format (Subjective, Objective, Assessment, Plan) commonly used by physicians. Copies of these records were obtained one year after each patient's initial PCM eligibility date. A random sample of these were abstracted to describe the action plans developed by the care teams. In addition, these records served as the source of detailed information about medical diagnoses and medication purpose and dosage which were required for construction of a complete Medication Appropriateness Index (MAI) score.

Medication Appropriateness Evaluations

The MAI[21,22] rates each medication using 10 weighted explicit criteria that are classified by the reviewer as either "appropriate," " marginally appropriate," or "inappropriate," on the basis of strict operational definitions for each criterion. The 10 criteria that contribute to the MAI score are:

- Indication (1)
- Effectiveness (2)
- Correct Dosage (3)
- Correct Directions (4)
- Practical Directions (5)
- Drug-Drug Interaction (6)
- Drug-Disease Interaction (7)
- Duplication (8)

- Duration of treatment (9)
- Cost (10)

The MAI score for a medication can range from 0 to 18 (higher is more inappropriate). Patient-specific summary scores have also been calculated by summing MAI medication scores for all prescribed medications.[22] However, patient-specific scores are thus dependent on the number of medications rated so both the summed MAI score and the mean MAI score (i.e., the average MAI rating for all medications prescribed) were examined. MAI scores were determined by a clinical pharmacist blinded to PCM intensity who reviewed patients' medication profiles and problem-oriented patient records maintained by pharmacists. Individual items in the MAI have demonstrated excellent inter-rater reliability in previous work (kappa = 0.83 for physician/internist agreement; kappa = 0.64 for two pharmacists)[21] and high inter-rater reliability has also been obtained for the MAI scores (intraclass correlation coefficient = 0.74).[22] Intra-rater reliability of individual items was also high (kappa = 0.92) In its initial development, content validity of the items and their weights was established via surveys of 10 academic physicians and clinical pharmacists.[22]

The developers of the MAI have used it as a primary measure of the effectiveness of physician/pharmacist care teams in a VA outpatient clinic setting where there is ready access to patient medical records. One of the PCM study investigators has reported on her use of the MAI in a study of community physician/pharmacist care delivery. In that study, the MAI was calculated from problem-oriented patient records kept by *pharmacists* and was demonstrated to be reliable in that setting.[23]

Several components of the MAI were identified that could potentially be adequately identified from pharmacy claims data alone and were therefore available for *all* patients who

were eligible for PCM services, regardless of whether they received the services. The items include: drugs considered absolutely contraindicated in the elderly, drugs considered ineffective (DESI drugs), potentially interacting drugs, apparent duplications of therapy, and whether the daily dose is too high for patient age. The availability of this information for patients who did not receive PCM services but who met the eligibility criteria (i.e. four or more medications including medications representing at least one of 12 disease states) provided a comparison group against which the effectiveness of PCM services could be judged.

Other MAI items require the kinds of detailed information that can only be found in the detailed records of patients who actually receive the PCM service. These additional items such as whether there is an indication for each drug, whether doses are within the approved range for the indication, the presence of drug-disease interactions, and the correctness and practicality of the prescribed directions, allowed a much more detailed analysis of medication appropriateness and calculation of a full MAI score. The change in full MAI score from before PCM to nine months after initial eligibility for PCM services was evaluated for all patients who received the service.

Patient Questionnaires

Patients were mailed questionnaires on the first day of the calendar quarter in which they first become eligible for PCM services (called the "Baseline Questionnaire") and again twelve months later. The questionnaire asked patients to report their perceptions and expectations of pharmacy services, whether during the past 12 months they have experienced any unwanted or side effects from a medication, their satisfaction with their health care, and questions about their health status.

Medical and Institutional Claims Analysis

Medicaid medical and institutional claims were used to determine whether there was any change in healthcare utilization. Because the majority of those who are eligible for PCM services are also eligible for Medicare, these claims do not provide a complete picture of the reasons for healthcare utilization (Medicare claims would be needed). However, the descriptive information provides an estimate of the impact on the Medicaid program per se.

Pharmacist Interviews and Large-group Discussion

An independent investigator, not involved with the design phase of the project, conducted in-person pharmacist interviews with a stratified random sample of one dozen pharmacies selected from the 117 participating pharmacies. Strata were defined by number of PCM claims received during the first quarter of the program so as to insure a spectrum of PCM intensity. The interviews were qualitative in nature and used a semi-structured format with open-ended questions. The primary goal of the interviews was to identify obstacles to PCM services and solutions devised to these obstacles.

Two other independent researchers lead a large-group discussion among PCM pharmacists attending the January 2002 annual continuing education Expo sponsored by the Iowa Pharmacy Association.

Pharmacist and Physician Surveys

Participating pharmacists and physicians received questionnaires to elicit their attitudes about the PCM program.

Statistical Methods

Results

Description of Eligible Patients

A total of 3,037 patients were eligible for PCM services during the study enrollment year. Table 1 displays the age distribution of patients by quarter of initial eligibility for PCM services. The mean age was 52 years and almost two-thirds of eligible patients were age 45 or older; 6.7% were children. Overall, 70% of patients were women. Of 117 eligible pharmacies, 109 had eligible patients in quarter 1, 76 had more eligible patients assigned in quarter 2, 71 in quarter 3, and 81 in quarter 4 (Table 1). Of the 117 eligible, 114 pharmacies had eligible patients assigned in at least one quarter.

Table 1. Age Distribution of Patients Eligible for PCM Services.

Age Group	Quarter Beginning 10/1/2000	Quarter Beginning 1/1/2001	Quarter Beginning 4/1/2001	Quarter Beginning 7/1/2001	Total
<10	17 (1.1)	17 (3.0)	27(6.2)	20 (4.2)	81 (2.7)
10-17	38 (2.4)	31 (5.5)	28 (6.4)	24 (5.0)	121 (4.0)
18-29	76 (4.9)	38 (6.8)	30 (6.9)	55 (11.5)	199 (6.6)
30-44	313 (20.1)	141 (25.0)	111 (25.5)	132 (27.6)	697 (23.0)
45-54	312 (20.0)	94 (16.7)	68 (15.6)	81 (17.0)	555 (18.3)
55-64	324 (20.8)	68 (12.1)	72 (16.6)	66 (13.8)	530 (17.5)
65+	481 (30.8)	174 (30.9)	99 (22.8)	100 (20.9)	854 (28.1)
All ages	1561 (100.0)	563 (100.0)	435 (100.0)	478 (100.0)	3037 (100.0)
Pharmacies with patients	109	76	71	81	114

Description of PCM Service Delivery

Intensity of Pharmacist Service Delivery

Fax surveys were sent to pharmacies querying the status of 2,931 eligible patients. Fax surveys were returned for 2,834 patients (96.7%). Table 2 displays the number of surveys

returned and results of the quarterly fax surveys. These represent the actions taken by pharmacists and physicians during the first quarter after a patient was identified as eligible. Within three months of receiving a list of newly eligible patients, pharmacists on average met with 31.7% of new patients in quarter 1, 42.2% of new patients in quarter 2, 28.3% of new patients in quarter 3 and 32.2% in quarter 4. From 25.5% to 34.6% of patients (depending on quarter of enrollment) were "worked-up" by pharmacists and recommendations were sent to physicians for 15.7% to 23.1% of new patients in various quarters. Pharmacists received physician replies for 9.9% to 13.7% of new patients in various quarters.

Table 2. Patient status three months after initial eligibility for PCM services, according to pharmacy fax surveys, by quarter of patient initial eligibility.

Quarter of Eligibility Beginning:	Pharmacist Met With Patient	"Worked Up" Patient	Sent Recommendation to Physician	Physician Replied	Unable to Meet with Patient
October 1, 2000 (n=1,566)	497 (31.7%)	400 (25.5%)	246 (15.8%)	172 (11.0%)	1069 (68.3%)
January 1, 2001 (n=540)	228 (42.2%)	187 (34.6%)	125 (23.1%)	74 (13.7%)	312 (57.8%)
April 1, 2001 (n=424)	120 (28.3%)	98 (23.1%)	66 (15.6%)	42 (9.9%)	304 (71.7%)
July 1, 2001 (n=304)	98 (32.2%)	78 (25.7%)	62 (20.4%)	39 (12.8%)	206 (67.8%)
TOTAL (n=2,384	943 (33.3%)	763 (26.9%)	500 (17.6%)	327 (11.5%)	1891 (66.7%)

When pharmacists reported being unable as yet to provide PCM services to a patient, the reason was requested. Table 3 lists the reasons pharmacists gave. For the entire sample, no reason was reported for 575 patients (30.4%). Pharmacy start-up difficulties accounted for about 22% of reasons provided. Reasons having to do with inability to gain access to patients increased in frequency from 14.9% in quarter 1 to 44.6% in quarter 2, with an overall percentage

of 23.2%. Patient outright refusal accounted for less than 10% of reasons and physicians declining to participate for less than 4%.

Table 3. Reasons pharmacists gave for being unable to meet with patients during the first three months after patients' initial eligibility for PCM services, by calendar quarter of initial patient eligibility.

Reason patient not yet seen:	Quarter 1 N = 1069	Quarter 2 N = 312	Quarter 3 N = 304	Quarter 4 N = 206	Total N = 1891
• Patient refusal	98 (9.2%)	27 (8.7%)	28 (9.2%)	26 (12.6%)	179 (9.5%)
• Patient access problem*	159 (14.9%)	139 (44.6%)	95 (31.2%)	45 (21.8%)	438 (23.2%)
• Visit scheduling issues	44 (4.1%)	20 (6.4%)	9 (3.0%)	0	73 (3.9%)
• Pharmacy staffing/start-up delay	216 (20.2%)	53 (17.0%)	59 (19.4%)	91 (44.2%)	419 (22.2%)
• Physician participation issues	61 (5.7%)	0 (0.0%	3 (1.0%)	2 (1.0%)	66 (3.5%)
• Other patient issues	42 (3.9%)	35 (11.2%)	41 (13.5%)	23 (11.2%)	141 (7.5%)
• No reason specified	449 (42.0%)	38 (12.2%)	69 (22.7%)	19 (9.2%)	575 (30.4%)

*Patient moved/changed pharmacy/deceased/nursing or group home/other patient access problem

The intensity of pharmacist service delivery was summarized in two ways (Table 4). The percent complete indicates those cases in which the pharmacist met with the patient, prepared a written assessment and provided recommendations to the physician within the first 3 months after receiving that quarter's list of eligible patients. In the first quarter list, 16.5% of the pharmacies had completed all these steps for at least half of their eligible patients within three months.

Table 4 also displays the intensity score. Approximately 17% of pharmacies during the first quarter were considered "high intensity" indicating that they worked up and completed a large

number of their first quarter patients. Only 1-3 pharmacies (out of 117) provided a high intensity of service to patients on the quarter 2-4 lists.

Table 4. Intensity Scores Among Participating Pharmacies

	Quarter 1 (n=109 Pharmacies) N (%)	Quarter 2 (N = 76 Pharmacies) N (%)	Quarter 3 (N = 73 Pharmacies) N (%)	Quarter 4 (N = 81 Pharmacies) N (%)
Percent Complete:*				
≥ 50%	18 (16.5%)	15 (19.7%)	9 (12.3%)	8 (9.9%)
25-49.9%	14 (12.8%)	7 (9.2%)	10 (13.7%)	8 (9.9%)
1-24%	17 (15.6%)	6 (7.9%)	3 (4.1%)	4 (4.9%)
0%	60 (55.0%)	48 (63.2%)	51 (69.9%)	61 (75.3%)
Total Intensity Score:**				
≥ 50	19 (17.4%)	3 (3.9%)	1 (1.4%)	3 (3.7%)
25-49.99	20 (18.3%)	4 (5.3%)	1 (1.4%)	4 (4.9%)
0.01-24.99	42 (38.5%)	21 (27.6%)	20 (27.4%)	13 (16.0%)
0	28 (25.7%)	48 (63.2%)	51 (69.9%)	61 (75.3%)

* - percent of patients who had the following services: "met with patient", "worked-up patient", and"sent recommendation to physician".

** - Intensity score was the summation of the following for each patient: Met with patient = 1 point, work-up patient = 3 points, sent recommendation to the physician = 6 points, physician replied = 1 point.

Claims Received by Provider and Claim Type

For patients who became eligible for PCM services during the four study calendar quarters beginning October 1, 2000, January 1, 2001, April 1, 2001, and July 1, 2001, PCM claims had been submitted by May 31, 2002 for 690 patients (22.7% of 3037 eligible patients; Table 5) and 1599 services. Of the 1599 PCM services reimbursed, 90% (n=1440) were submitted on claims from pharmacists (Table 5) and only 159 were from physicians. The PCM services are tabulated by the quarter when patients were assigned/enrolled (Table 5), by the quarter when claims were submitted (Table 6), and by the quarter when services occurred (Table 7).

Table 5. PCM patients and PCM Services by Quarter of Enrollment, Beginning October 1, 2000 (Quarter #1).

	Quarter #1	Quarter #2	Quarter #3	Quarter #4	Total
#Patients Enrolled	1,561	563	435	478	3,037
#Pharmacy Services (#Patients receiving)	827 (376)	360 (175)	119 (74)	134 (95)	1440 (690)
#Physician Services (#Patients receiving)	112 (77)	31 (25)	13 (9)	3 (3)	159 (114)

Table 6. PCM Claims by Quarter of Submission (According to Claim Transaction Dates), Beginning October 1, 2000 (Quarter #1), through May 31, 2002.

	Quarter of Submission							
	1	2	3	4	5	6	7	Total
PCM Claims Submitted	109	178	309	357	278	246	135	1,612 [a]

[a] Includes 47 services for 38 patients enrolled in the post-study period

Table 7. PCM Services by Quarter of Services (According to Date of Service), Beginning October 1, 2000 (Quarter #1), through May 31, 2002.

	Quarter of Services							
	1	2	3	4	5	6	7	Total
#Pharmacy Services within Quarters (756 patients)	220	244	306	257	224	197	38	1,486 [a,b]
#Physician Services within Quarters (114 patients)	47	36	40	24	8	4	0	159 [c]

[a] Includes 47 services for 38 patients enrolled in the post-study period
[b] Sixty-one Pharmacies had submitted PCM bills before the end of May 2002
[c] Forty Physicians had submitted PCM bills before the end of May 2002.

Table 8 cross-tabulates claims received by quarter of enrollment and quarter of service. From Table 8, and supported by the start-up statistics in Tables 2 and 3, it is clear that PCM services continued to be provided for patients over time. For example, among the patients

enrolled on October 1, 2000 (Quarter #1), a total of 827 claims were filed throughout the ensuing 20 months (Table 8). Only 27% of these claims (n=220) had dates of service during the first three months of eligibility for PCM services.

Table 9 displays various types of service. The most common type of service by pharmacists was an Initial Assessment (W4100; n=741) followed by a Problem Follow-up Assessment (W4400; n=468). New Problem Assessments (W4300; n=194) and Preventive Follow-up Assessments (W4200; n=84) occurred less commonly. Physician Initial Assessment (W3100) and Problem Follow-up Assessment (W3400) claims occurred most frequently (n=107 and 38, respectively).

Table 8. Quarter of Enrollment and Quarter of Services (on Pharmacy Claims) for PCM Claims Submitted Through May 31, 2002.

Service Quarter	Enrollment Quarter					
Frequency Percent Row Percent Column Percent	1	2	3	4	Outside Study Period	Total
1	220 14.80 100.00 26.60	0 0.00 0.00 0.00	0 0.00 0.00 0.00	0 0.00 0.00 0.00	0 0.00 0.00 0.00	220 14.80
2	142 9.56 58.20 17.17	101 6.80 41.39 28.13	0 0.00 0.00 0.00	0 0.00 0.00 0.00	1 0.07 0.41 2.13	244 16.42
3	157 10.57 51.31 18.98	97 6.53 31.70 27.02	50 3.36 16.34 42.02	1 0.07 0.33 0.75	1 0.07 0.33 2.13	306 20.59
4	122 8.21 47.47 14.75	57 3.84 22.18 15.88	20 1.35 7.78 16.81	56 3.77 21.79 41.79	2 0.13 0.78 4.26	257 17.29
5	79 5.32 35.27 9.55	60 4.04 26.79 16.71	23 1.55 10.27 19.33	47 3.16 20.98 35.07	15 1.01 6.70 31.91	224 15.07
6	87 5.85 44.16 10.52	36 2.42 18.27 10.03	22 1.48 11.17 18.49	25 1.68 12.69 18.66	27 1.82 13.7 57.45	197 13.26
7	20 1.35 52.63 2.42	8 0.54 21.05 2.23	4 0.27 10.53 3.36	5 0.34 13.16 3.73	1 0.07 2.63 2.13	38 2.56
Total	827 55.65	359 24.16	119 8.01	134 9.02	47 3.16	1,486 100.00

Table 9. Pharmacy PCM claims reimbursed by service type code, through May 31, 2002.

PCM SERVICES (61 pharmacies, 756 patients; 40 physicians, 114 patients)					
Code	W4100[a]	W4200	W4300	W4400	TOTAL
N of Pharmacist Services	741	84	194	468	**1,487** [b]
Code	W3100	W3200	W3300	W3400	TOTAL
N of Physician Services	107	6	8	38	**159**

[a] W4100 - Initial Assessment - Pharmacist
W3100 - Initial Assessment - Physician
W4200 - Preventive Follow-up Assessment - Pharmacist
W3200 - Preventive Follow-up Assessment - Physician
W4300 - New Problem Assessment - Pharmacist
W3300 - New Problem Assessment - Physician
W4400 - Problem Follow-up Assessment - Pharmacist
W3400 - Problem Follow-up Assessment - Physician
[b] Includes 47 services for 38 patients enrolled outside the study period.

Description of Patients Who Received PCM Services

We further studied patients for whom a PCM claim was received. Among the 3,037 patients who were eligible for PCM, we analyzed only those who remained continuously eligible for Medicaid from six months before through 12 months after the date at which they became eligible for PCM services (n=2211; 72.8%).

Age was strongly associated with the number and types of drugs taken and was also associated with receiving PCM services (data not shown). Older patients took more medications, were more likely to received PCM services, and had poorer medication appropriateness scores. They were also much more likely to be taking cardiovascular, endocrine, and antidepressant medications. Younger patients were more likely to be taking antipsychotic, respiratory, and anticonvulsant drugs.

Table 10 displays the baseline (before PCM) sociodemographic and medication characteristics of patients of those who received PCM services compared to those who were

eligible for PCM services and continuously eligible for Medicaid, but who did not receive PCM services, adjusted for differences between these two groups in patient age and gender. After adjusting for age differences, those who received PCM still took a higher number of medications and were more likely to be female. The types of drugs taken by those who did and did not receive PCM services were similar. Regardless of whether they received PCM services, about two-thirds of PCM eligible patients had at least one indicator of inappropriate medication use.

Table 10. Baseline sociodemographic and medication characteristics of PCM-eligible patients according to whether they received versus did not receive PCM services, adjusted for age and gender.

	Received PCM (n=524)		No PCM (n=1687)	
Mean age (S.E.) (adjusted for gender)*	54.1	(0.9)	48.6	(0.5)
Number (%) female*	419	(80.0)	1169	(69.3)
Number (%) male*	105	(20.0)	518	(30.7)
Number (%) ethnic background:				
White	467	(89.1)	1519	(90.0)
Black	31	(5.4)	93	(5.5)
Indian	0	(0)	2	(0.1)
Oriental	1	(0.2)	20	(1.2)
Other	4	(0.8)	13	(0.8)
Unknown	21	(4.0)	40	(2.4)
Mean (S.E.) number of drug products *	7.5	(0.2)	6.9	(0.1)
Mean (S.E.) number of ingredients	8.3	(0.2)	7.7	(0.1)
Categories of Baseline Drugs (N (%) greater than 2.0% of total)				
(CN101) Non-opioid analgesics	190	(4.6)	642	(5.4)
(CN300) Sedative/Hypnotics	141	(26.9)	427	(25.3)
(CN400)Anticonvulsant	157	(3.8)	483	(3.9)
(CN400)Antidepressants	202	(38.6)	692	(41.0)
(CN500) Antiparkinson	??	??	??	??
(CV100) Beta blockers	138	(3.3)	335	(2.8)
(CV250) Antanginals	56	(10.7)	133	(7.9)
(CV350) Bile acid sequestrants	5	(1.0)	2	(0.1)
(CV350) HMG COA inhibitors *	33	(6.3)	69	(4.1)
(CV350) Other antilipemics	13	(2.5)	30	(1.8)
(CV702) Loop diuretics	130	(3.1)	302	(2.5)
(CV800) ACE inhibitors	126	(3.1)	315	(2.6)
(GA300) Antiulcer agents	68	(13.0)	170	(10.1)
(GA301) Histamine antagonists	125	(3.0)	351	(2.9)
(GA900) Other gastric medications	79	(1.9)	243	(2.0)
(HS501) Insulin	79	(1.9)	240	(2.0)
(HS502) Oral hypoglycemics	165	(4.0)	441	(3.7)
(HS851) Thyroid supplements	99	(2.4)	248	(2.1)
(MS102) Nonsteroidal anti-inflammatory agents (non-salicylate)	129	(3.1)	418	(3.5)
(RE100) Respiratory	27	(5.2)	86	(5.1)
Baseline medication appropriateness by patient:				
a. N (%) with drug-drug-interactions	186	(35.5)	581	(34.4)
b. N (%) with therapeutic duplications	210	(40.1)	686	(40.7)
c. N (%) with contraindicated/ineffective drugs	76	(14.5)	131	(7.8)
d. N (%) with high dosage error	88	(16.8)	231	(13.7)
e. N (%) with any of the above	333	(63.6)	1053	(62.4)
* p-value <= 0.05 for difference between received PCM and no PCM, all means adjusted for age and gender.				

Table 11 displays the baseline health status characteristics of patients of those who received PCM services compared to those who were eligible but who did not receive PCM services, adjusted for differences between these two groups in patient age and gender. After adjusting for age and gender, those who received PCM services were similar to those who did not in overall, physical, and mental health, prior use of urgent care services, health behaviors (tobacco and alcohol use), and prevalence of adverse drug reactions. At 30%, the reported rate of adverse drug reactions in the prior year was quite high among PCM eligible patients. This rate is three times the rate observed using the same question in a survey of a population-based sample of elderly Iowans.[2]

Table 11. Baseline health status characteristics of PCM-eligible patients according to whether they received versus did not receive PCM services, adjusted for age and gender.

	Received PCM		No PCM	
Baseline Health Status (available only for survey responders):	N=119 survey respondents		N=308 survey respondents	
SF-36 mean physical health score (scale 0 to 100) (S.E.)	34.1	(1.1)	34.4	(0.7)
SF-36 mean mental health score (scale 0 to 100) (S.E.)	43.6	(1.2)	42.5	(0.9)
Mean overall health status score (scale 0 to 1.0) (S.E.)	62.3	(2.2)	58.6	(1.4)
Tobacco (current smoker), n (% of survey respondents)	27	(23.1)	79	(27.4)
Alcohol (moderate/heavy drinker), n (% of survey respondents)	5	(4.2)	15	(5.1)
Had adverse drug reaction in past 12 months, n (% of survey respondents)	32	(27.6)	92	(30.0)
Hospitalized in past year, n (% of 524 patients)	47	9.0	202	12.0
Percent with ER in past year, n (% of 1687 patients)	105	20.0	423	25.1

* p-value <= 0.05 indicating statistical difference adjusted for age and gender

Categorizing Pharmacists Recommendations

We photocopied the problem-oriented patient records maintained by pharmacies for the continuously eligible patients who did receive PCM services. A random sample of 203 patient pharmacy charts were reviewed in order to characterize the nature of the problems identified, recommendations made by pharmacists, and physician acceptance of these recommendations. The communication form between the pharmacist and the physician was the source used to identify recommendations.

The 203 charts contained a total of 771 pharmacist recommendations. Table 12 displays the average number of different problem types, number of recommendations made, number of accepted recommendations, and time until recommendation acceptance. Table 13 displays the types of problems identified and types of recommendation appear in Table 14..

Table 12. Mean problems identified and recommendations made and accepted for a random sample of 203 patients who received PCM services.

Characteristic	Mean	SD	Median	Range
Number of different problem types per person	2.6	1.6	2.0	1-9
Number of recommendations per person	3.8	3.0	3.0	1-15
Number of accepted recommendations per person	1.9	2.0	2.0	0-15
Time to recommendation acceptance (days)	8.9	14.9	4.0	0-112

On average, pharmacists made several recommendations for each patient (Table 12; mean 3.8 recommendations per patient). Of the 771 recommendations made by pharmacists, a total of 379 (49.2%) were accepted by physicians. It took a mean of 8.9 days (median, 4.0 days) for physicians to confirm their acceptance of a pharmacist's recommendation. The most common type of recommendation made was to start a new medication (Table 14; 51.7% of patients, 24.5% of all recommendations). Other common recommendations were to change the dose of a medication, change a medication to an alternate therapy, monitor the medicine or a disease state (e.g. monitor drug levels or blood pressure), or to discontinue a medication.

Pharmacists detected several types of problems for each patient (Table 12; mean 2.6, median 2.0). Each type of problem includes many sub-types so this underestimates the total number of problems detected per person. "Medication/Indication Issues" were the most common types of problem detected, including medications being used without a reason or for an unclear reason, untreated conditions, under-treated conditions, and medications that are not the best choice among available alternatives (Table13). "Pharmaceutical Issues" were the next most common type of problem, including inappropriate dose, route of administration, or schedule of a medication, therapy duplication, and need for therapy monitoring.

Table 13. Types of problem identified for a random sample of 203 patients who received PCM services.

	Patients		Recommendations	
	N	%	N	%
PROBLEM TYPE				
Pharmaceutical Issues:	111	54.7	201	26.1
Inappropriate/Suboptimal Dose	29	26.1	44	21.9
Inappropriate/Suboptimal Schedule	17	15.3	19	9.5
Inappropriate/Suboptimal Route	0	0	0	0
Therapeutic Duplication	9	8.1	9	4.5
Non-Formulary Request	0	0	0	0
Therapeutic Monitoring	85	76.6	129	64.2
Risk to Patient	55	27.1	81	10.5
Allergy	2	3.6	3	3.7
Actual ADE/ADR	15	27.3	23	28.4
Potential ADE/ADR	42	76.4	52	64.2
Medication Error	2	3.6	3	3.7
Medication/Indication Issues	156	76.8	365	47.3
Med Use Without Indication/Unclear Indication	22	14.1	29	7.9
Untreated Condition	82	52.6	136	37.3
Undertreated Condition	75	48.1	110	30.1
Alternative Therapy	52	33.3	90	24.7
Efficacy Issues	62	30.5	87	11.3
Min/No Evidence of Therapeutic Effectiveness.	8	12.9	8	9.2
Compliance or Drug Administration Issue/Convenience	58	93.5	79	90.8
Cost	9	4.4	9	1.2
Record Update	11	5.4	24	3.1
Unspecified Type	2	1.0	4	0.5
OVERALL TOTAL	203	100	771	100

Table 14. Types of recommendation made for a random sample of 203 patients who received PCM services.

Recommendation Type				
Discontinue Medication	67	33.0	106	13.7
Start Medication	105	51.7	189	24.5
Change Medication	73	36.0	105	13.6
Change Dose	83	40.9	125	16.2
Change Route	0	0	0	0
Change Schedule	28	13.8	35	4.5
Change Dosage Strength	4	2.0	4	0.5
Change Dosage Form	5	2.5	5	0.7
Change Treatment Duration	0	0	0	0
Therapeutic/Disease State Monitoring	78	38.4	117	15.2
Enhance Compliance	2	1.0	2	0.3
Patient Education	40	19.7	59	7.7
Provider Education	14	6.9	19	2.5
Unspecified	3	1.5	5	0.6
TOTAL	**203**	**100**	**771**	**100**
Total Accepted Recommendations	129	100	379	100

Effect of PCM Services on Medication Appropriateness

Medication appropriateness was rated by a clinical pharmacist using the problem-oriented patient charts compiled by PCM pharmacists and an active drug list constructed from Medicaid pharmacy claims. Medication appropriateness was rated using the protocol and instrument for the Medication Appropriateness Index (MAI) of Hanlon et al.[3, 21-23] Only patients continuously eligible for Medicaid from 6 months before their initial PCM eligibility through 12 months after their initial PCM eligibility date were included in these analyses.

Table 15 displays the MAI scores the day the patient became eligible for PCM (baseline) and nine months later (follow-up). All medications that were active on the date the patient

became eligible for PCM were evaluated to arrive at the baseline MAI measures. All medications that were active nine months later (including any new medications) were evaluated to arrive at the follow-up measures. Technical Appendix 1 provides the detailed methodology for determining the baseline and follow-up active drug lists. Technical Appendix 2 provides the detailed methodology for evaluating medication appropriateness using the MAI. Table 16 lists the ten MAI questions that were evaluated for each drug and the weight each question is given when scoring the MAI.

Table 15 presents the proportion of medications with inappropriate ratings for each MAI criterion at each of the two time points for the intervention group. In the intervention group (those who received PCM services), by closeout, the percentage of inappropriate ratings decreased in all 10 MAI dimensions.

Overall, the summated MAI score at baseline was 10.4. The intervention resulted in a 12.5% improvement in MAI score from a mean of 10.4 to a mean score of 9.1. The difference in total MAI scores was statistically significant ($p<0.001$). These results indicate that the appropriateness of medications improved significantly from before to nine months after patients received PCM services. This was in spite of an increase in number of active ingredients in the from baseline to follow-up.

Overall, nearly half of medications and 92.9% of patients had at least one sign of inappropriate medication use. The mean number of ingredients increased from 7.9 to 9.0 and the mean MAI score improved (decreased) from 10.4 to 9.1, a 12.5% improvement. After receiving PCM services, patients were significantly less likely to be taking a drug that: had no reason (indication) for use; was considered ineffective; interacted with a patient disease state; was duplicative with another drug; or had an inappropriate duration of use. Though not statistically

significant, there was a trend for directions to become more correct and practical, for fewer drug-drug interactions to be detected, and for the cost of the medications to be more appropriate.

Table 15. Medication Appropriateness Index (MAI) ratings the day the patient became eligible for PCM (baseline) and nine months later (follow-up) (p-value is for difference between baseline and follow-up).

	Medications N=8142					Patients				
	Baseline N=4001		Follow-up N=4141		p-value	Baseline N=507		Follow-up N=507		p-value
MAI Questions (weight)	Total	N (%)	Total	N (%)		Total	N (%)	Total	N (%)	
Indication (3)	3465	113 (3.3)	3622	89 (2.5)	0.042	478	89 (18.6)	472	68 (14.4)	0.002
Effectiveness (3)	3481	235 (6.8)	3638	185 (5.1)	0.003	478	166 (34.7)	472	141 (29.9)	<0.001
Correct Dosage (2)	3454	339 (9.8)	3587	261 (7.3)	<0.001	478	222 (46.4)	472	192 (40.7)	<0.001
Correct Directions (2)	3412	348 (10.2)	3515	315 (9.0)	0.079	473	228 (48.2)	470	210 (44.7)	0.061
Practical Directions (1)	3412	234 (6.9)	3520	206 (5.9)	0.086	473	159 (33.6)	470	156 (33.2)	0.901
Drug-Drug Interaction (2)	3661	278 (7.6)	3808	259 (6.8)	0.189	493	179 (36.3)	484	172 (35.5)	0.735
Drug-Disease Interaction (2)	3477	236 (6.8)	3637	212 (5.8)	0.096	478	173 (36.1)	472	156 (33.1)	0.013
Duplication (1)	3476	391 (11.2)	3637	357 (9.8)	0.049	478	250 (52.3)	472	233 (49.4)	0.120
Duration of treatment (1)	3473	332 (9.6)	3630	289 (8.0)	0.017	478	205 (42.9)	472	184 (39.0)	0.005
Cost (1)	3476	581 (16.7)	3630	576 (15.9)	0.338	478	321 (67.2)	472	307 (65.4)	0.310
At least one of the above	3636	1767 (48.6)	3784	1637 (43.3)	<0.001	478	444 (92.9)	472	423 (89.6)	0.004
MAI Descriptive Statistics	Total	Statistic	Total	Statistic		Total	Statistic	Total	Statistic	
Mean (STD) ingredients[a]	Not applicable					507	7.9 (4.3)	505	9.0 (4.4)	<.001
Median ingredients[a]						507	8.0	505	8	
Range in ingredients[a]						507	1-28	505	1-24	
Mean (STD) MAI score[b]	4001	1.3 (1.9)	4141	1.1 (1.7)	<0.001	471	10.4 (8.4)	469	9.1 (7.8)	<.001
Median MAI score	4001	0	4141	0		471	9.0	469	7.0	
Range in MAI score	4001	0-11	4141	0-14		471	0-48	469	0-45	

[a] Ingredients are the active components of drug products. Some combination products contain multiple active ingredients.

[b] The MAI score was calculated by summing the weight for each MAI question that was violated for each active ingredient. The mean MAI score per medication was the total of the summated MAI scores divided by the total number of active ingredients rated (n=4001 baseline, n=469 follow-up). The mean MAI score per patient was the total of the summated MAI scores (excluding patients with missing data for any MAI question) divided by the number of patients (n=471 baseline, n=460 follow-up).

Table 16. The Medication Appropriateness Index.

Appropriateness Question	Relative Weight Applied to Inappropriate Ratings
Is there an indication for the drug?	3
Is the medication effective for the condition?	3
Is the dosage correct?	2
Are the directions correct?	2
Are there clinically significant drug-drug interactions?	2
Are there clinically significant drug-disease interactions?	2
Are the directions practical?	1
Is this drug the least expensive alternative compared to others of equal utility?	1
Is there unnecessary duplication with other drugs?	1
Is the duration of therapy acceptable?	1

Because problem-oriented pharmacy charts were available only for patients who received PCM services, these detailed clinical pharmacist MAI ratings were not possible for those who did not receive PCM services. Instead, we attempted to construct measures of medication appropriateness based only on pharmacy claims (which were available for all patients). We called the latter "automated medication appropriateness measures." Sufficient information was available in Medicaid pharmacy claims to allow construction of automated measures corresponding to four of the ten MAI questions: effectiveness, dosage, drug-drug interaction, and duplications. Once constructed, we compared the automated measures with the corresponding clinical pharmacist MAI measures to evaluate the reliability and validity of the automated measures. Only the automated "effectiveness" question performed adequately (kappa coefficient=0.76 at baseline and kappa=0.69 at follow-up; kappa is a measure of agreement with 1.0 reflecting perfect agreement and kappa > 0.7 considered good agreement). The kappa statistics for dosage and duplication were quite low (0.28 or less) suggesting considerable measurement error with the automated questions. For dosage, the clinical pharmacist was able to evaluate whether dose was appropriate for the concurrent disease states and could consider

whether dose was being gradually titrated, whereas the automated measures could not. For therapeutic duplication, the clinical pharmacist could determine if a drug had been discontinued and a different drug substituted and could identify duplications that involved two different categories of drugs. The clinical pharmacist MAI rating for drug-drug interactions was created directly by the automated system so "agreement" wa 100% by definition. The end result was that only the automated "effectiveness" measure has known and acceptable measurement characteristics. The other measures were either too imprecise (dosage and duplications) or have not been validated by comparison with clinical pharmacist review.

To answer the question "is the medication effective for the condition?" the clinical pharmacist and the automated measure both compared the patient's active drug list to a list of drugs either (1) considered less than effective by the FDA or (2) considered to be too risky for use among those age 60 or over, i.e. the risks outweighed the benefits. Because Medicaid does not reimburse for drugs that the FDA considers less than effective (designated DESI drugs; http://www.cms.gov/medicaid/drugs/drug11.htm), none of these drugs were found. The "effectiveness" measure is thus in reality a measure of using medications deemed too risky for use among those aged 60 and over. This list of drugs whose potential risks outweigh their potential benefits among older adults was created by consensus (Beers MH Arch Intern Med 1997;157:1531-6) and the list of included drugs is included in Table 17.

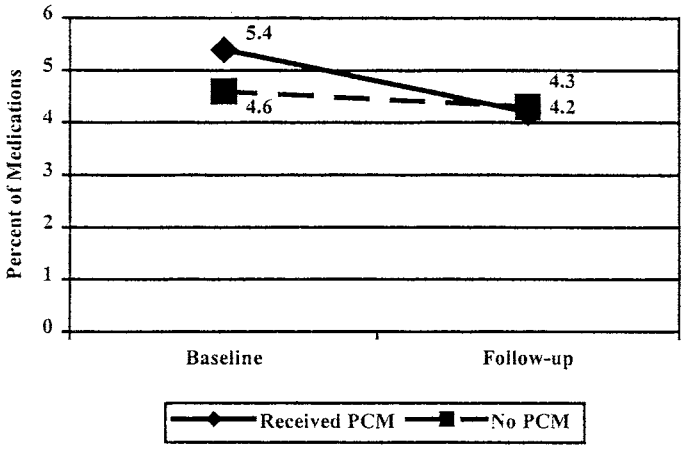
Table 17.Medications whose potential risks outweigh their potential benefits (Beers MH. Arch Intern Med 1997;157:1531-6).

amitriptyline	diazepam	methocarbamol
amobarbital	dicyclomine	methyldopa
atropine	diphenhydramine	oxybutynin
belladonna	dipyridamole	pentazocine
butabarbital	disopyramide	pentobarbital
carisoprodol	doxepin	phenylbutazone
chlordiazepoxide	ergot mesyloids	promethazine
chlorpheniramine	flurazepam	propantheline
chlorpropamide	hydroxyzine	propoxyphene
chlorzoxazone	hyoscyamine	reserpine
clidinium	indomethacin	scopolamine
cyclobenzaprine	meperidine	secobarbital
cyproheptadine	mephobarbital	ticlopidine
dexchlorpheniramine	meprobamate	trimethobenzamide
	metaxalone	tripelennamine

Figures 1 and 2 display the effect of PCM services on use of risky medications among PCM-eligible patients aged 60 and older. As illustrated in Figure 2, before receiving PCM services 35% of patients aged 60 and over who received PCM services had at least one active drug considered to have a poor risk-benefit balance and to be inappropriate for use among older adults. For patients who received PCM services, the percent with risky drug use decreased from 34.8% to 26.5 %, representing a clinically substantial and statistically significant 23.8% improvement in this measure from baseline to follow-up. In contrast, those who did not receive PCM services showed no significant change in risky medication use. Interestingly, patients who received PCM services had a higher baseline prevalence of risky drug use than did patients who did not receive PCM services.

Figure 1. Percent of medications used by PCM eligible patients aged 60 and over, that are considered risky, i.e. potential risk outweighs potential benefits.

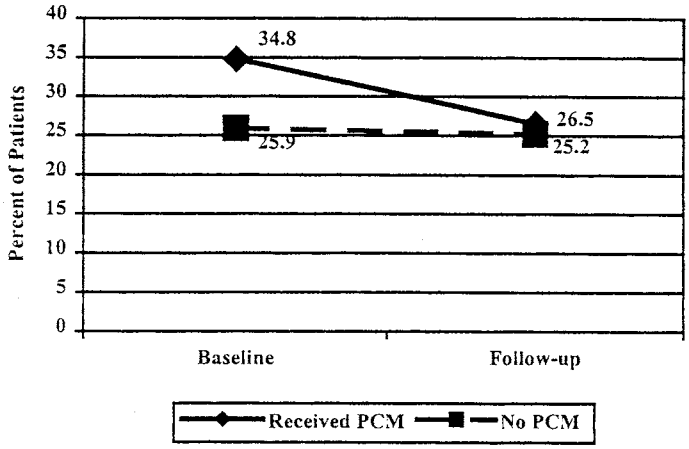
Total baseline medications for those who received PCM services were 4,138 and for those who did not receive PCM services were 11,936.



Patients who received PCM had a significant decrease (p=0.003) in percent of medications considered risky (from 5.4 to 4.2) whereas those who did not receive PCM did not have a significant decrease (p=0.175).

Figure 2. Percent of PCM eligible patients aged 60 and over taking medications that are considered risky, i.e. potential risk outweighs potential benefits.

A total of 218 patients age 60+ received PCM services and 505 did not.



Significant intervention (PCM) by time interaction ($p<0.05$) indicates that PCM resulted in a significant decrease in percent of patients using risky medications (from 34.8% to 26.5%) compared with no PCM (from 25.9% to 25.2%)..

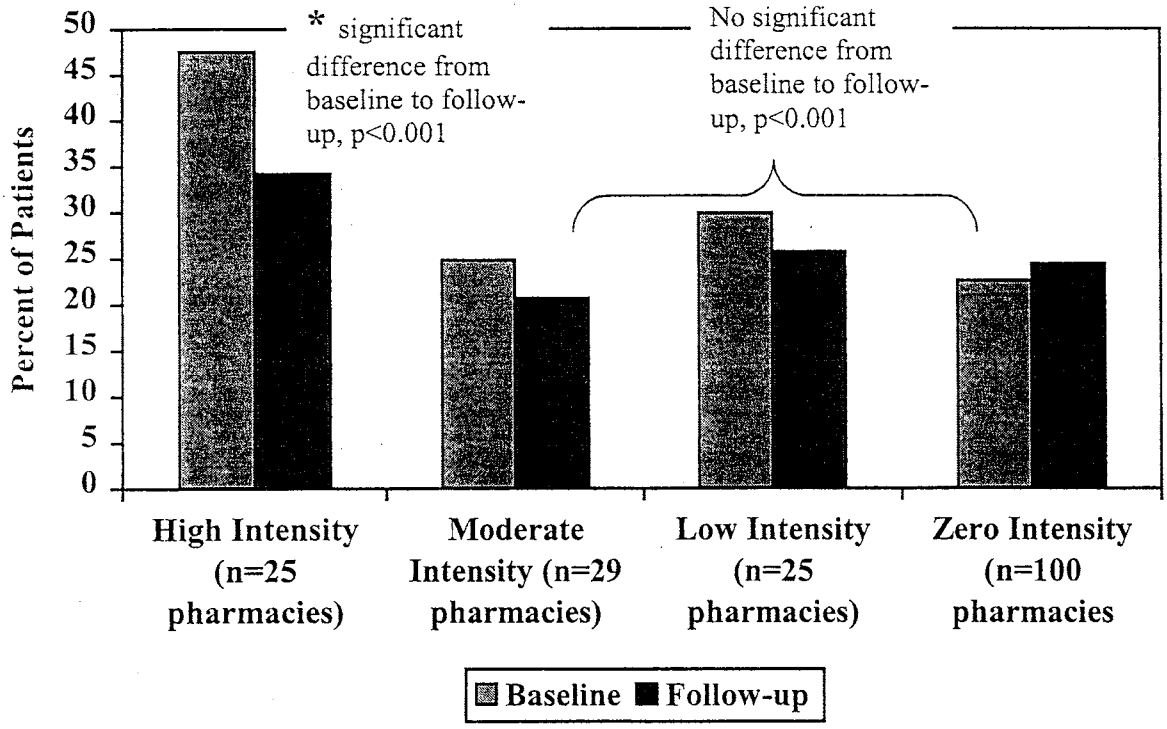
Effect of Intensity of PCM Services on Medication Appropriateness of A Pharmacy's Total Patient Population.

Another way to examine the effect of PCM services on medication appropriateness is to examine the change in medication appropriateness over time for all of the PCM eligible patients. Because low intensity pharmacies provided PCM to so few patients the effect of PCM should not be detectable in the patient population of these pharmacies (i.e., the intervention effect will be swamped by the large number of patients who did not receive the intervention). In contrast, for high intensity pharmacies where the majority of PCM eligible patients actually received the service, the effect of PCM should be detectable. We therefore hypothesized that there would be a significant time by pharmacy intensity interaction, specifically that medication appropriateness would improve in high intensity pharmacies to a greater extent than it would in low intensity pharmacies. As displayed in Figure 3, this hypothesis was supported. The decrease over time among high intensity pharmacies was significantly greater than for zero intensity pharmacies ($p=0.037$). Furthermore, only in high intensity pharmacies was a statistically significant change

over time observed ($p<0.001$). It was observed that patients filling prescriptions at high intensity pharmacies had a higher baseline prevalence of risky medication use than did patients receiving prescriptions from lower intensity pharmacies.

Figure 3. Percent of PCM eligible patients aged 60 and over taking medications that are considered risky, i.e. potential risk outweighs potential benefits, by pharmacy intensity score (time by group interaction p-value for high vs zero intensity = 0.037).

A total of 122 age 60+ PCM eligible patients were patients of high intensity pharmacies, 141 were patients of moderate intensity pharmacies, 137 were patients of low intensity pharmacies, and 323 were patients of zero intensity pharmacies.



Effect of PCM Services on Number of Active Drugs and on Medicaid Pharmacy Costs.

Adjusted for age and gender differences, when compared with PCM-eligible patients who did not receive PCM, PCM services had no significant effect on the net number of medications or medication charges (Table 18). The number of drugs and charges tended to increase both for those who did and who did not receive PCM services. Because pharmacists frequently recommended both discontinuation of drugs and initiation of new drugs, the net effect of these recommendations may have been neutral.

Table 18. Mean active drugs and mean Medicaid charges for active drugs the day the patient became eligible for PCM (baseline) and nine months later (follow-up), by whether PCM services were received, adjusted for age and gender.

	Patients Who Received PCM Services (n= ????)			Eligible But Did Not Receive PCM Services (n=????)		
	Baseline	Follow-up	p-value	Baseline	Follow-up	p-value
Mean number of (SD) active drugs	7.5 (0.1)	7.8 (0.2)	0.006	6.8 (0.2)	7.0 (0.1)	0.003
Median number active drugs	7.0	8.0	0.241	6.0	6.0	0.235
Range in number of of active drugs	0-25	0-22		0-27	0-26	
By drug						
Mean (SD) amount billed per drug for active drugs, $	65.47	68.54	0.069	65.1	69.2	<0.001
Median (SD) amount billed per drug for active drugs, $	37.48	40.22	0.024	35.14	38.40	<0.001
By patient						
Mean (SD) amount billed per patient for active drugs	488.4 (20.76)	525.01 (22.11)	0.003	441.94 (14.46)	477.60 (15.48)	<0.001
Median (SD) amount billed per patient for active drugs	378.64	420.73	0.052	327.12	376.47	<0.001

** No significant results for time by PCM interaction for any variables. This indicates that the change over time in these variables was the same for those who received and those who did not receive PCM services.

Effect of PCM Services on Patient Perceptions (Survey Respondents Only)

There were no significant changes over time in patient perceptions either for those who received PCM services or those who did not. Neither health status nor satisfaction with pharmacists or physicians was observed to change.

In contrast, patient expectations about the degree of collaboration between pharmacists and physicians was significantly associated with receipt of PCM services. Those who received PCM services expected a higher degree of collaboration between their pharmacist and physician. Because this was measured only in the follow-up survey, it is not clear whether receipt of PCM services caused patients to have higher expectations or whether patients with higher expectations were more likely to participate in PCM. However, among those who received PCM, expectations tended to decrease among patients of higher intensity pharmacies, suggesting that the lower intensity pharmacies provided care to patients with relatively more favorable attitudes whereas the highest intensity pharmacies managed to provide PCM even to patients with less favorable attitudes. There was no association between pharmacy intensity and patient attitudes toward collaboration among the group of patients who did not receive PCM services.

Table 19. Assessment of changes in patient health status, attitudes, and self-reported healthcare utilization from the baseline (before PCM) to the follow-up survey (one year later).

	Patients Who Received PCM Services (n=????)			Eligible But Did Not Receive PCM Services (n=????)		
	Baseline	Follow-up	p-value	Baseline	Follow-up	p-value
						0.137
SF-36 mean physical health score (S.E??)	34.2 (1.2)	34.4 (1.2)	0.841	34.0 (1.0)	35.7 (1.0)	0.059
SF-36 mean mental health score	43.6 (1.2)	43.3 (1.3)	0.248	42.3 (1.1)	41.9 (1.0)	0.525
Mean general health status score	62.7 (2.2)	61.4 (2.3)	0.470	57.5 (2.0)	58.7 (2.0)	0.999
Self-reported hospitalization in past year, n (%)	10 (7.8)	10 (7.8)	0.999	29 (8.9)	28 (8.5)	0.999
Self-reported ER visits in past year, n (%)	18 (14.1)	18 (14.1)	0.999	63 (19.1)	62 (18.8)	0.725
Current tobacco use, n (%)	27 (23.1)	28 (23.1)	0.729	79 (27.4)	81 (27.1)	0.9990.
Percent drinking alcohol more than ???	5 (4.1)	5 (4.2)	0.9220.	15 (5.1)	17 (5.6)	0.681
Mean pharmacist satisfaction score (higher score is more satisfaction, possible range 4-28) Linda did you remember to recode a and e. I just noticed that c is a duplicate of h so c is not included in any score.	16.6 (0.3)	16.6 (0.3)	0.857	16.9 (0.2)	17.3 (0.2)	0.268
Mean expectations of pharmacist score (higher score is more positive expectation, possible range is from 12 to 84) Linda this includes f-q and not c. f, h, k, n, q need to be recoded, not sure you caught this.	48.1 (0.9)	48.6 (0.9)	0.554	48.4 (0.8)	47.7 (0.7)	0.094
Mean physician satisfaction score (higher score is more satisfaction, possible range is from 3 to 15)	5.3 (0.2)	5.4 (0.2)	0.840	5.2 (0.2)	5.5 (09.2)	0.050
Self-reported adverse drug reaction in past 12 months, n	32 (27.6)	26 (22.8)	0.319	92 (30.0)	75 (24.4)	0.092

(%)						
Mean score on view of pharmacist- physician relationship (at follow-up only), higher score is more favorable attitude toward collaboration, possible range is 4 to 28		*24.1*			*22.8*	0.050
By Intensity:						0.092
Zero		*25.7*			*23.1*	
Low		*24.5*			*22.8*	
Moderate		*24.1*			*23.8*	
High		*23.0*			*22.3*	

Results of Pharmacist Interviews

Pharmacist opinions about PCM services were obtained in three ways. Qualitative in-person interviews were conducted of a sample of pharmacists. A large-group discussion was held among PCM pharmacists attending an annual meeting of the Iowa Pharmacy Association. Finally, questionnaires were mailed to all PCM pharmacists.

In-person Interviews

The purpose of the in-person pharmacist interviews was to describe the obstacles faced by the pharmacists during their provision of PCM services and to identify strategies that these pharmacists used to overcome these obstacles. The interviewer did not know the level of the pharmacist's PCM performance. The interviews were audio-taped and transcribed verbatim. The transcripts were analyzed using a grounded theory approach to identify major themes and to connect these themes to an underlying core issue. Data saturation (i.e., no new issues identified) was achieved after completion of nine interviews. The detailed methods are available in a technical report by the independent investigator (K. Farris) that is available upon request.

Many obstacles to providing PCM were identified in these interviews. However, those obstacles that were recurrent themes are identified as shaded entries in Table 18. All of the obstacles were categorized into four main categories (processes, systems, information, and people/organizations). Processes refers to the actual behaviors or activities that pharmacists had to do to provide PCM. Systems refers to the environment in which pharmacists provided PCM. Information is the data necessary to do PCM in a

high quality manner. People/organization refers to those people/organizations directly affected by PCM.

Process obstacles ranged from perceived problems with the lists of eligible patients to determining who the primary physician was for a patient (especially when there were multiple physicians) to the considerable effort the pharmacists had to expend to educate physicians and patients about the new program and difficulties developing a physician-pharmacist team approach. Systems obstacles included substantial complexities of implementing a brand new service and care concept into an existing dispensing system and some uncertainty about the billing process. Information obstacles included low physician awareness about the PCM program and difficulty obtaining patient information from physicians and laboratories that is needed to complete a high quality assessment. People and organizations such as patients and physicians were associated with some obstacles, such as perceived apathy and antipathy by physicians and some patients who were confused by the service or did not expect this kind of care from their pharmacist. One pharmacist summarized the complex array of obstacles to providing PCM in this way:

"...they [pharmacists] have enough to worry about just trying to figure out the care, because these patients are complicated. Not just because of their social situation and being on Medicaid and not having the financial resources um, but they're on a lot of different medications as well, too...So you've got a lot of physical and emotional components that we have to deal with. So, I think just dealing on that level is hard enough from a pharmacist's viewpoint and then having to set up the whole thing within your own practice I think could have been just overwhelming."

Table 20. Recurrent themes that high and low-providing pharmacists of PCM identified as obstacles (designated in shaded text)

Processes	Systems	Information	People/Organizations
PCM Project Requirements	**Pharmacy Obstacles**	**Valuable SOAP note**	**Physicians' response**
Review patient lists Identify primary care provider Recruit all participants Methods to tell about PCM	Lack of staff Parts of process too time-consuming Time needed for PCM External facilitators or obstacles Privacy for interviews Requires administrative support 1 pharmacist to cover 2 pharmacies 1 to 100 patients Too few patients & no priority	Lack of information is greatest obstacle Obtain laboratory information Obtain physicians input/notes Conduct research to identify DRPs	Physicians ignore requests for info Physician refusal Responsive physicians Role of office nurse
Providing PCM	**Overcoming pharmacy obstacles**	**Unaware of PCM**	**Patients**
Multiple contacts to get lab & MD info Prepare and fax SOAP to > 1 physician Little collaboration Patients break appointments Interview patients – general comments Obtain medical release of info form Complete follow-ups re DRP status	Using others to make PCM happen Time allotted for PCM Can't "fit it in" dispensing unless 2 pharmacists	Study leaders publicity of PCM Physicians unaware	Complex patients Home interviews Reasons for patient refusal Patient acceptance PCM in theory – for patients
Billing for PCM	**Pharmacy Facilitators**		**Pharmacists**
Billing process Number of claims billed	Scheduling system Organized charting system Adaptable, computerized forms Level of reimbursement		Pharmacist personal characteristics make PCM happen PCM cuts into pharmacist personal time Positive outcomes for pharmacists Negative emotions for pharmacists PCM in theory – for pharmacists & pharmacies
Figuring out a PCM process	**Billing confusion**		**Study leaders**
Process figured out Success stories	When to bill? Physician billing		Study leaders provided no feedback Study leaders unsure how to help

Figure 4 outlines the behaviors required by patients, pharmacists and physicians in the PCM project. It highlights that new behaviors have been required by individuals besides pharmacists in order to deliver high quality PCM services. For example, physicians were often asked to provide pharmacists with laboratory or progress note information about patients. This is not a typical request from pharmacists. In addition, patients had to meet with pharmacists for a medication history interview. Many patients have not experienced this before. When PCM is considered in this light, it is not surprising that the adoption or provision of PCM has been variable among pharmacies. As evidenced in these surveys with pharmacists, there is considerable variation in physician and patient response. When two important actors in the PCM process are unaware of PCM or fail to understand its potential value, then participation will require time, i.e., greater than one year, to fully develop.

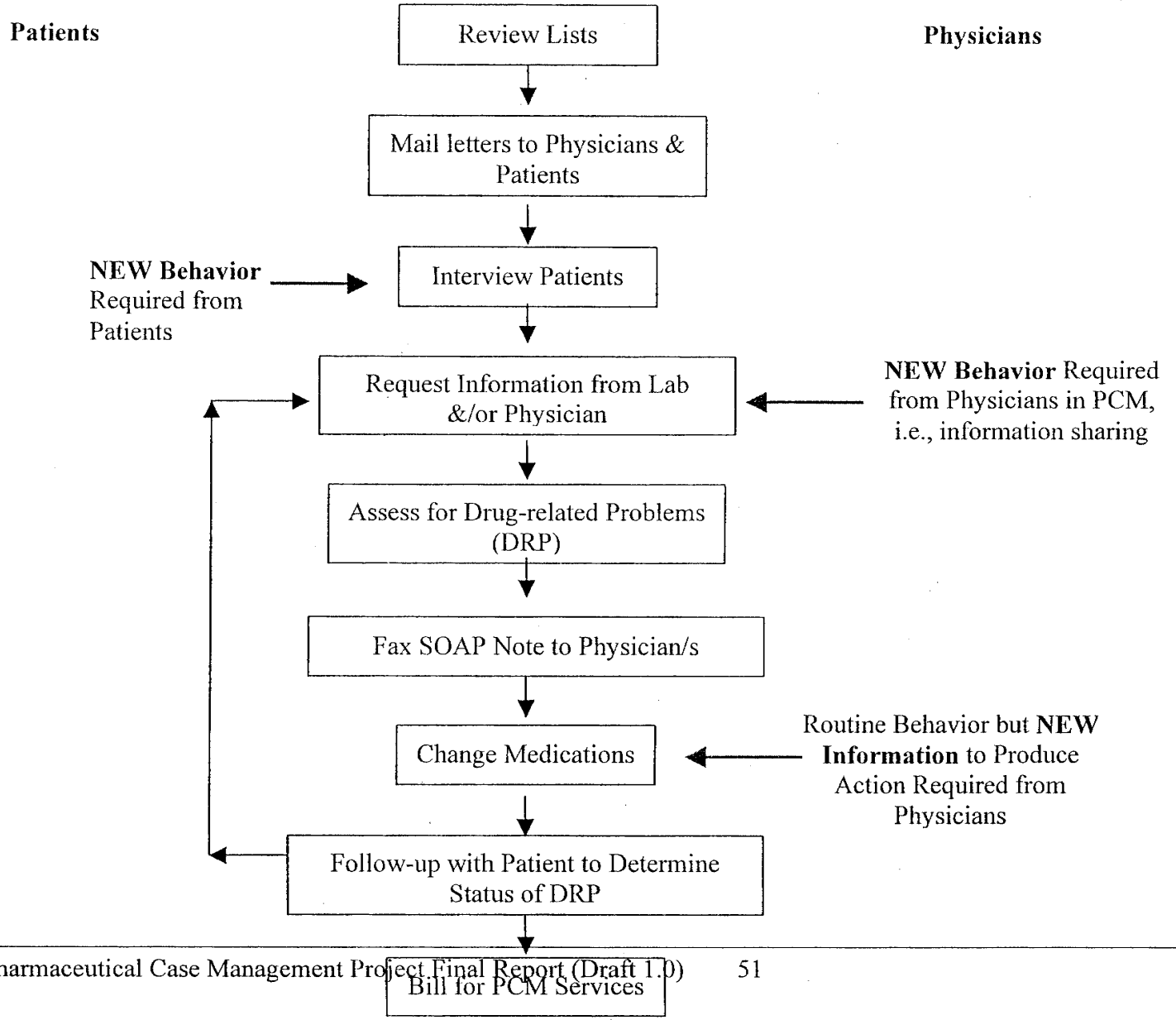
What is not conveyed in Figure 1 is the pharmacy environment in which pharmacists provide PCM. Time remains a significant obstacle for pharmacists. Simply paying either pharmacists or physicians is not sufficient to change their behavior. Behavior change has to be easy and supported by the systems in which they work. Having all providers faxing communication forms back and forth over a span of several days does not fit efficiently into existing, busy systems of practice. Changes in processes of care, systems, information sharing/accessibility, and attitudes of people/organizations will be necessary to facilitate the expansion of PCM services for high risk patients.

The core category (the one related to all issues in the data) was identified to be "implementing a valuable SOAP note." Where a SOAP note is defined as the Subjective, Objective, Assessment, Plan ingredients of a pharmacist's assessment and where *implementation* of the assessment is in the form of a collaborative action plan. If pharmacists are not able to

implement a valuable SOAP note, then physicians have not responded and patients have not been helped. Generating a SOAP note is a process within PCM, but its value is determined by the combination of factors included in processes, systems, information, and people/organization. For example, a SOAP note's value will be determined in part by (1) systems allowing pharmacists time to collect information and make assessments of drug-related problems, (2) information constraints when pharmacists cannot obtain laboratory or progress notes from labs or physicians, (3) physicians' responses for information requests, (4) patient's participation in providing information, and (5) pharmacists' personal characteristics such as tenacity in providing PCM in the face of obstacles.

In summary, the experiences of these nine pharmacists suggest that (1) pharmacists faced obstacles in processes, systems, information and people/organization and payment alone was not sufficient to fully overcome these obstacles; (2) single physician-single pharmacist teams were not an adequate definition of collaboration when patients had numerous prescribing physicians; and (3) "implementing a valuable SOAP note" is the central theme in the pharmacists' experiences with PCM.

Figure 4. Behaviors Required In Order To Provide Pharmaceutical Case Management



Pharmacist Large-group Discussion

Below is summarized discussion held by attendees of the session "PCM Project – Making it Happen," held on January 20, 2002 during the Iowa Pharmacy Association Continuing Education Expo. This report was submitted to the evaluators by the discussion leaders (R McDonough and W Doucette).

Some Obstacles to PCM

Inadequate time and staffing – Staffing levels may not allow time to perform PCM, which can take considerable time (during initial work-up).

Interface between dispensing and PCM – The average service episode for dispensing is much shorter than PCM service episodes. Differences in workflow and necessary time blocks can make it difficult to mesh dispensing and other services such as PCM.

Insufficient pharmacist confidence and knowledge – PCM may require new clinical knowledge for pharmacists. In addition, the PCM process itself can create uncertainty for pharmacists and other staff.

Limited patient information for PCM – PCM may require a pharmacist to try to collect patient information not normally collected, such as latest lab test results. Figuring out how to get this information is a challenge and takes time.

Absence of automated follow-up – The PCM process is longitudinal, and requires follow-up. A pharmacy needs some way of triggering follow-up activities. This is in contrast to dispensing which is triggered when most of a medication in a vial has been taken by a patient.

Lack of patient acceptance – Patients may not recognize value from PCM. They may view PCM as unwanted interference.

Physician resistance or unawareness – Physicians may not recognize value from PCM. They may view PCM as unwanted interference.

Ambiguity in billing process – Since PCM is new, it may not be clear to pharmacists what is a billable activity.

Some Suggestions for Making PCM Happen

Dedicate pharmacist time to PCM activities. Free up pharmacists from other duties. Students can help free up pharmacists

Clearly identify patients as PCM patients. After the initial work-up, link follow-up to dispensing by focusing on refill medications. Can use this to perform monitoring (e.g. BP monitoring).

Be persistent when working with patients, physicians, and own staff.

Develop a working relationship with local labs. CLIA-wavered labs can be done in the pharmacy.

Be specific in how you describe PCM. Don't frame it as a new program, but rather as a part of normal care.

Be creative in communicating with patients. Make home visits if needed.

Use a variety of triggers for PCM activities. These can include new medications, refills, physician phone calls, patient reports of problems, pharmacy-initiated calls. Some computer systems have electronic calendar features that will notify pharmacists when a follow-up activity is due.

Avoid asking physicians for information that is difficult for them to gather. Be selective in which information is requested.

Visit a physician's office to discuss the needs of the patients and how PCM helps to meet them. Discuss preferred modes of communication.

Pharmacist Questionnaires

A total of 228 pharmacist surveys were mailed to 146 pharmacists in 101 participating pharmacies (34 pharmacists received more than one survey because they worked in more than one participating pharmacy). The two page survey was preceded by a one-page cover letter with instructions, including the fax number for return of the survey. A return-addressed postage paid envelope was enclosed with each survey. A copy of the questionnaire is provided in the Technical Appendix. The questionnaires were mailed out in late November and are not yet available for analysis.

Physician Surveys

A two-page survey was faxed to a random sample of physicians known to have received recommendations from PCM pharmacists. These were the physicians identified on the fax

communication forms in the random sample of patient charts that were reviewed in order to summarize the nature of these recommendations. The purpose of the physician survey was to elicit the attitudes of physicians about the PCM program and about the pharmacists they had worked with to provide PCM. A copy of the questionnaire materials is provided in the Technical Appendices.

A total of 62 surveys were faxed. Each fax was preceded by a telephone call to the physician's office to notify them of the purpose for the fax that would follow and to request their attention to the survey. Two weeks after these surveys were faxed, eight completed surveys had been received. Follow-up phone calls to the physician's office are scheduled to obtain a higher response rate.

Medicaid Claims Analysis

Pharmacy, medical, inpatient, emergency room, other outpatient, and long-term care claims were analyzed over time. Medicaid claims data were available through May, 2002. Charges to the Medicaid program and number of claims of each type are displayed for those who received PCM and those who did not in the following graphs (Figures 5-16). In the graphs, month 1 represents six months *before* PCM eligibility; month 7 represents the beginning of PCM eligibility; month 17 represents 11 months *after* PCM eligibility.

There was a significant PCM by time interaction for mean Medicaid pharmacy charges, indicating that those who received PCM had a greater increase in pharmacy mean monthly charges than did patients who did not receive PCM (Figure 5). However, when Figure 5 is examined closely, it can be seen that the difference in rate of change between the two groups was already happening before PCM was initiated in month 7. There was no significant difference between patients who received PCM and those who did not in the change in number of pharmacy

claims over time (interaction p-value 0.184; Figure 6). Although there was an increase in number of pharmacy claims over time, this increase occurred also among those who did not receive the intervention. There were no other significant PCM by time interactions for the other healthcare claims variables, indicating that there was no significant effect of PCM services on other healthcare utilization. Interestingly, the PCM claims were included in the medical claims analysis (because they are submitted on a HCFA 1500 claim form they reside in this file). In spite of including the cost of PCM, there was no significant effect of PCM on the net number of medical claims or medical claims-related charges. Checking on this to be sure. Tae-Ryong or Linda may have thought to exclude PCM claims from the analysis file.

There were significant time intensity by time interactions for the number of emergency room claims, and the number and charges for outpatient facility claims (Figures 17-19). In all three cases, patients of high PCM intensity pharmacies had lower claims and/or charges than did patients of lower PCM intensity pharmacies.

Figure 5. Mean amount billed per month to Medicaid for medications, according to whether PCM services were received, data through May 31, 2002, n=2,211 continuously eligible patients.

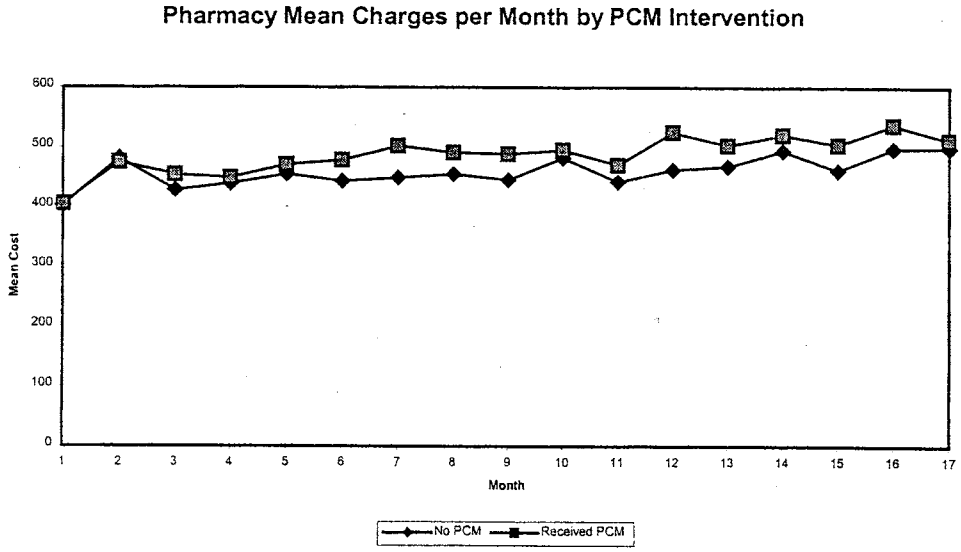


Figure 6. Mean number of claims paid per month for medications, according to whether PCM services were received, data through May 31, 2002, n=2,211 continuously eligible patients.

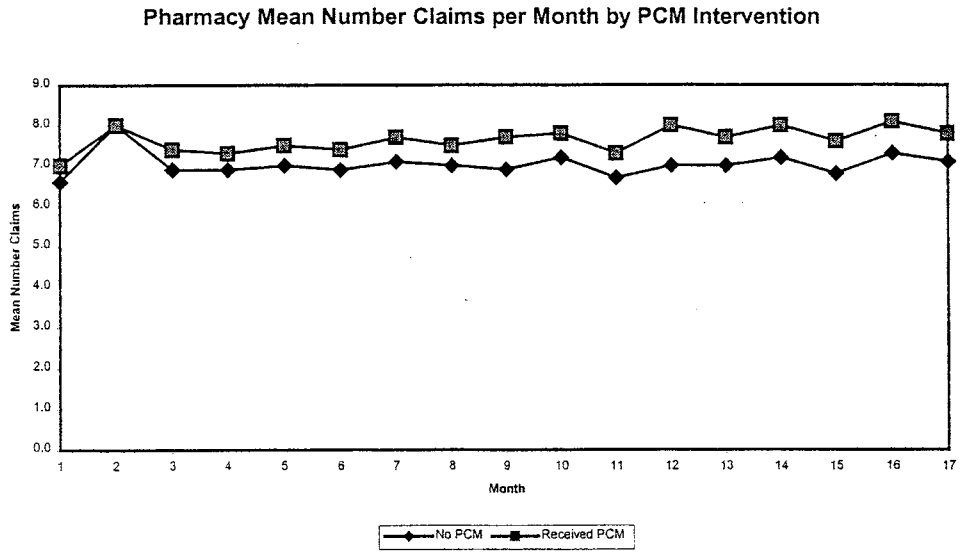


Figure 7. Mean amount billed per month to Medicaid for medical services (i.e. services billed on a HCFA1500 form), according to whether PCM services were received, data through May 31, 2002, n=2,211 continuously eligible patients.

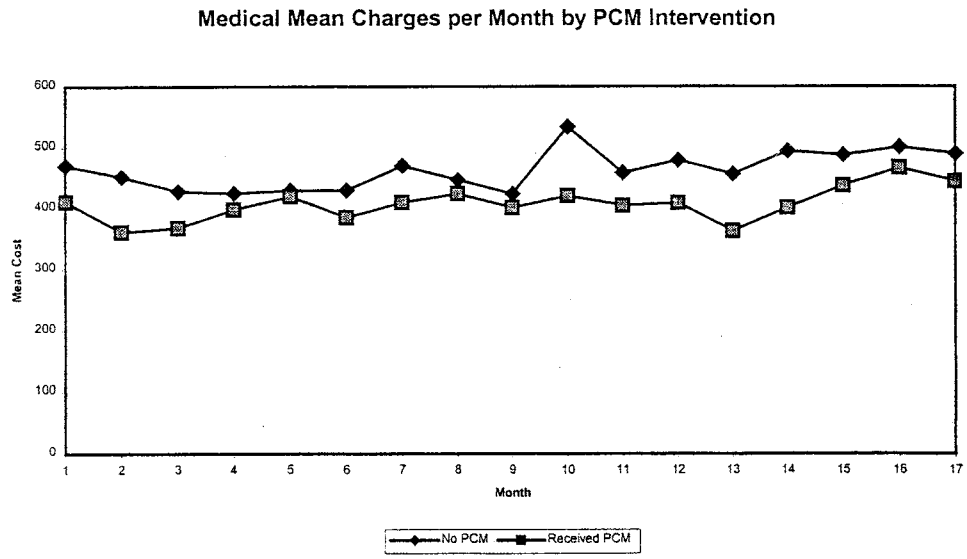


Figure 8. Mean number of claims paid per month for services billed on HCFA1500 forms, according to whether PCM services were received, data through May 31, 2002, n=2,211 continuously eligible patients.

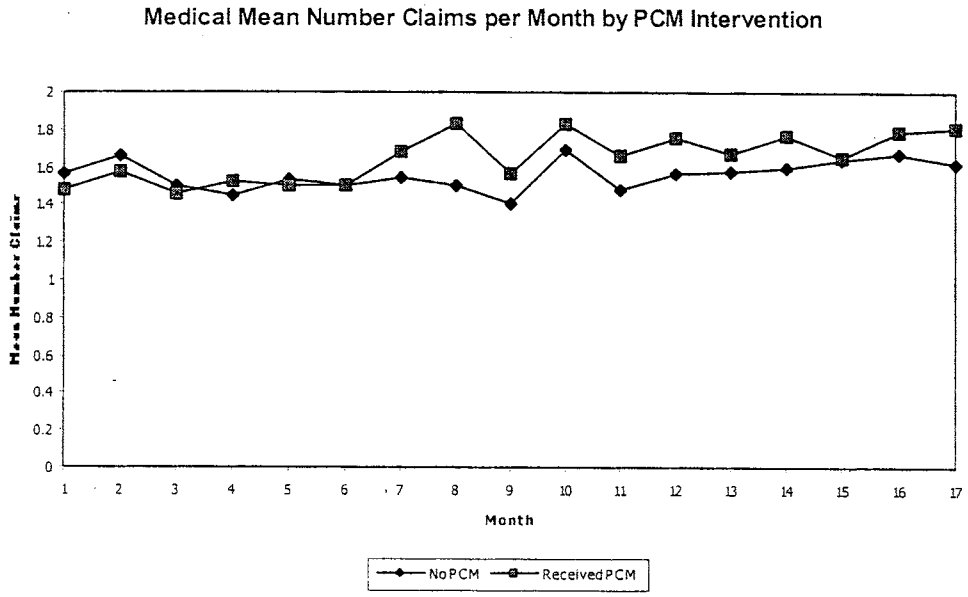


Figure 9. Mean amount billed per month to Medicaid for acute inpatient facility care, according to whether PCM services were received, data through May 31, 2002, n=2,211 continuously eligible patients.

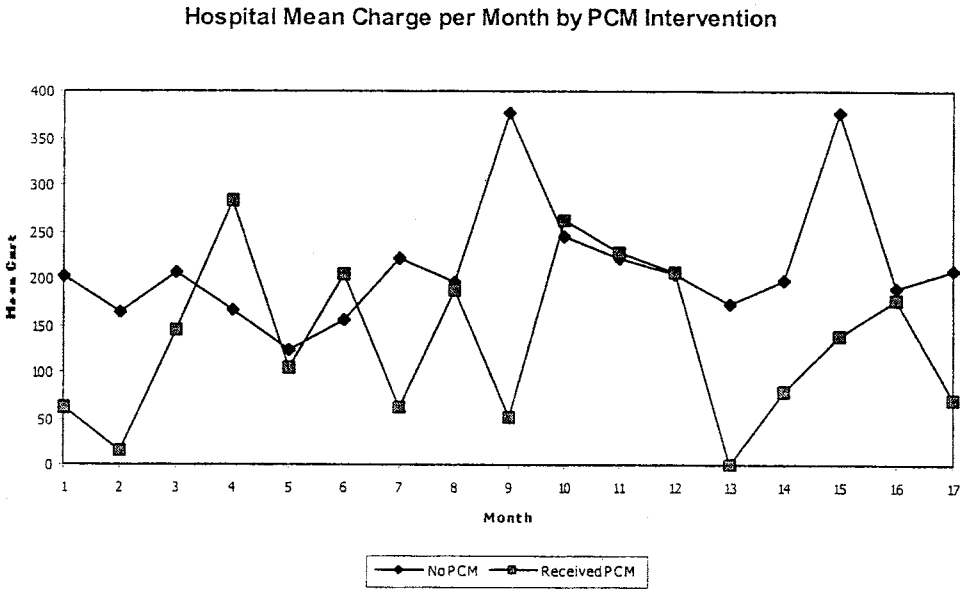


Figure 10. Mean number of claims paid per month for acute inpatient facility care, according to whether PCM services were received, data through May 31, 2002, n=2,211 continuously eligible patients.

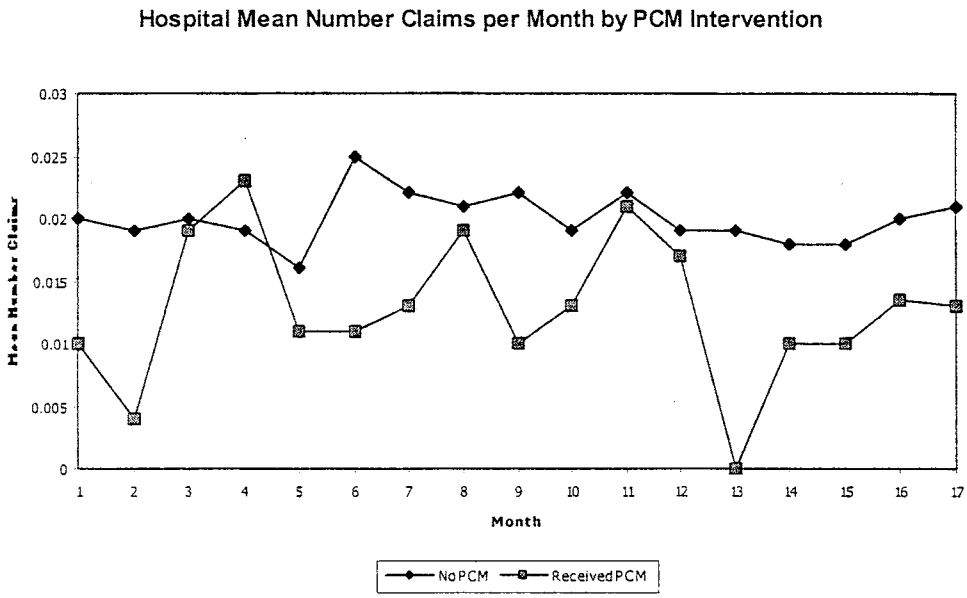


Figure 11. Mean amount billed per month to Medicaid for emergency room visits, according to whether PCM services were received, data through May 31, 2002, n=2,211 continuously eligible patients.

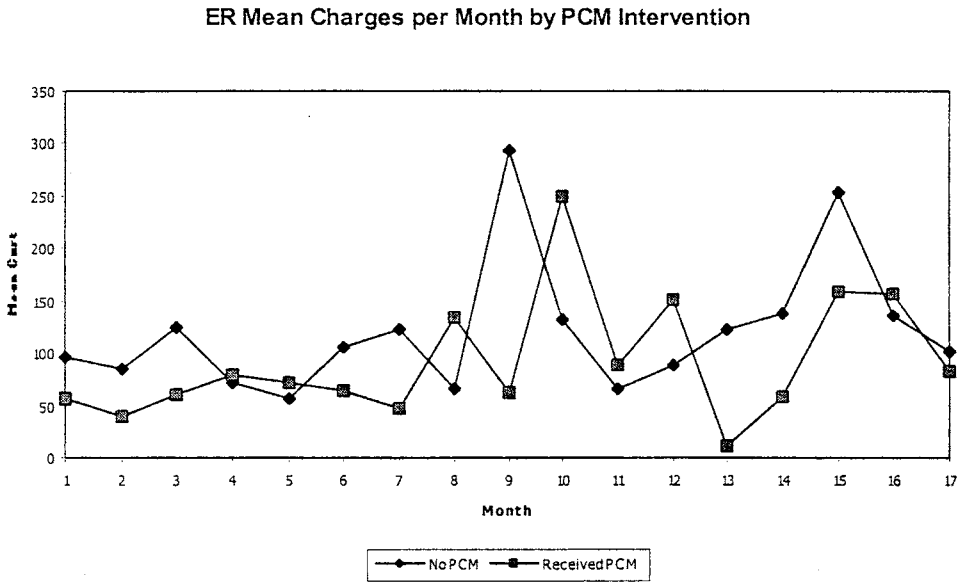


Figure 12. Mean number of emergency room claims paid per month, according to whether PCM services were received, data through May 31, 2002, n=2,211 continuously eligible patients.

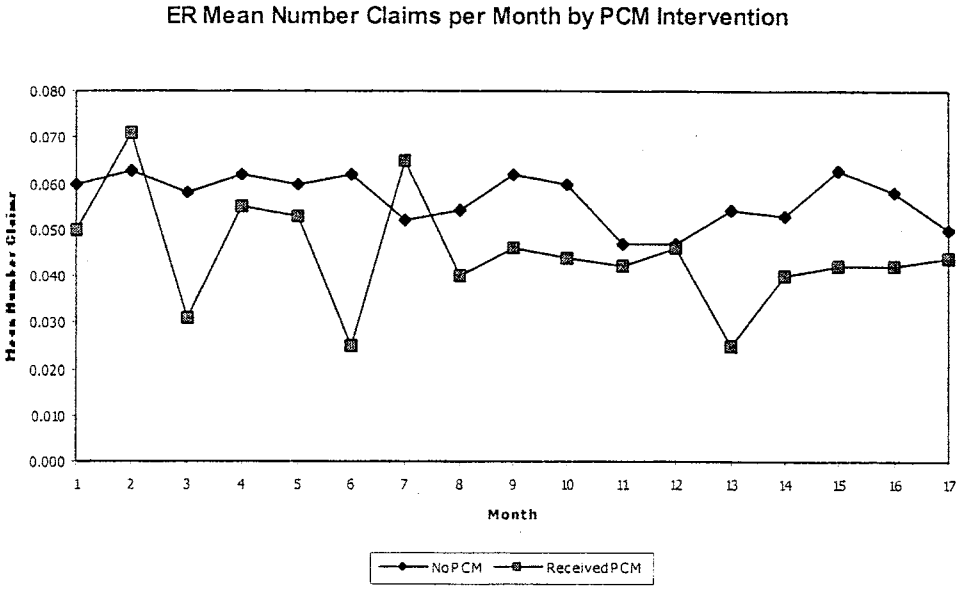


Figure 13. Mean amount billed per month to Medicaid for outpatient facility care (not including emergency room), according to whether PCM services were received, data through May 31, 2002, n=2,211 continuously eligible patients.

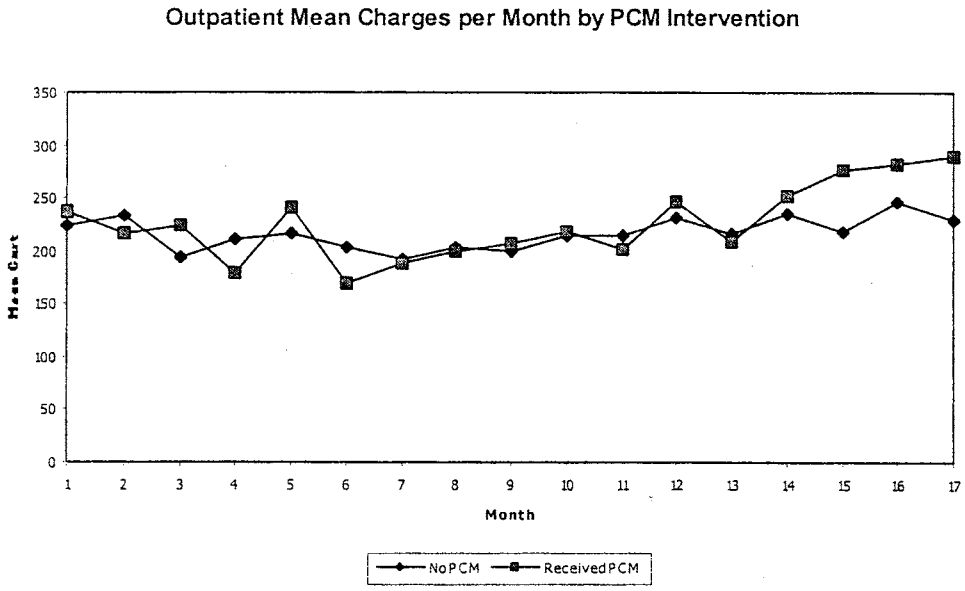


Figure 14. Mean number of claims paid per month for outpatient facility care, according to whether PCM services were received, data through May 31, 2002, n=2,211 continuously eligible patients.

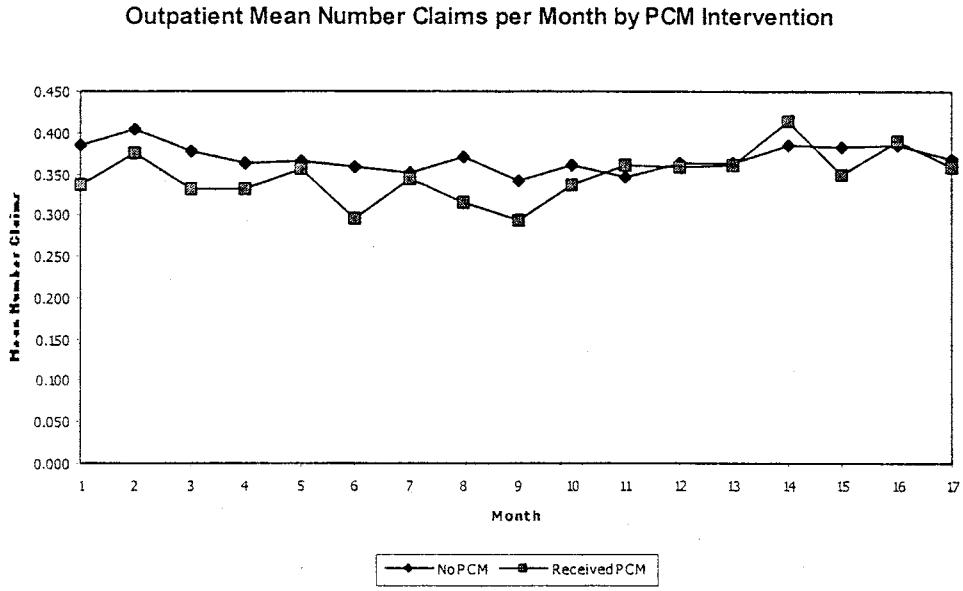


Figure 15. Mean amount billed per month to Medicaid for long-term institutional care, according to whether PCM services were received, data through May 31, 2002, n=2,211 continuously eligible patients.

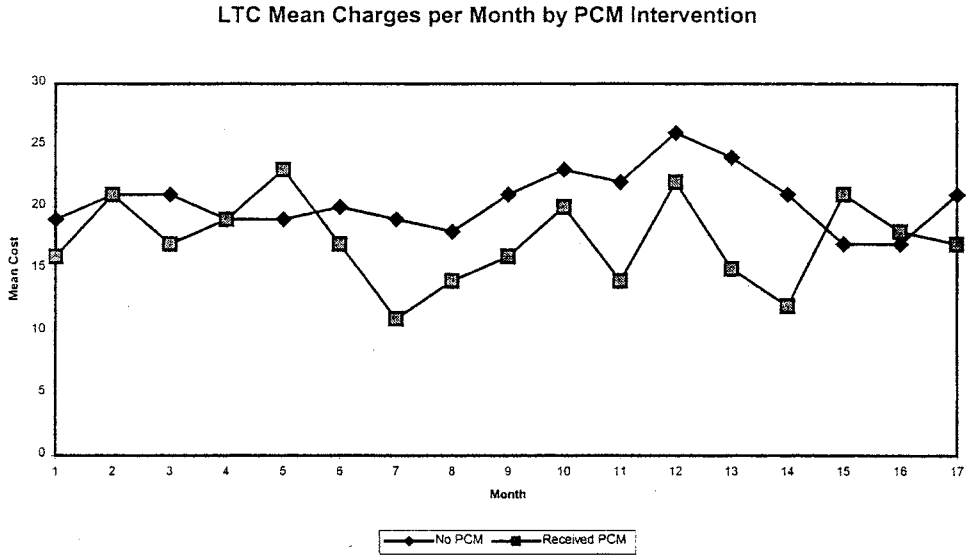


Figure 16. Mean number of long-term institutional care claims paid, according to whether PCM services were received, data through May 31, 2002, n=2,211 continuously eligible patients.

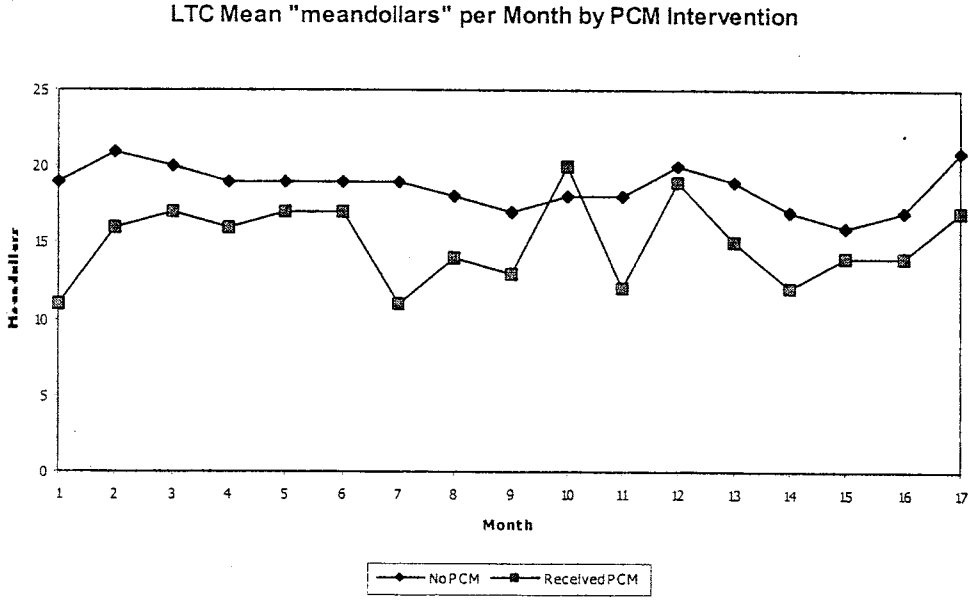


Figure 17. Mean amount billed per month to Medicaid for outpatient facility care (not including emergency room), according to pharmacy PCM service intensity, data through May 31, 2002, n=2,211 continuously eligible patients.

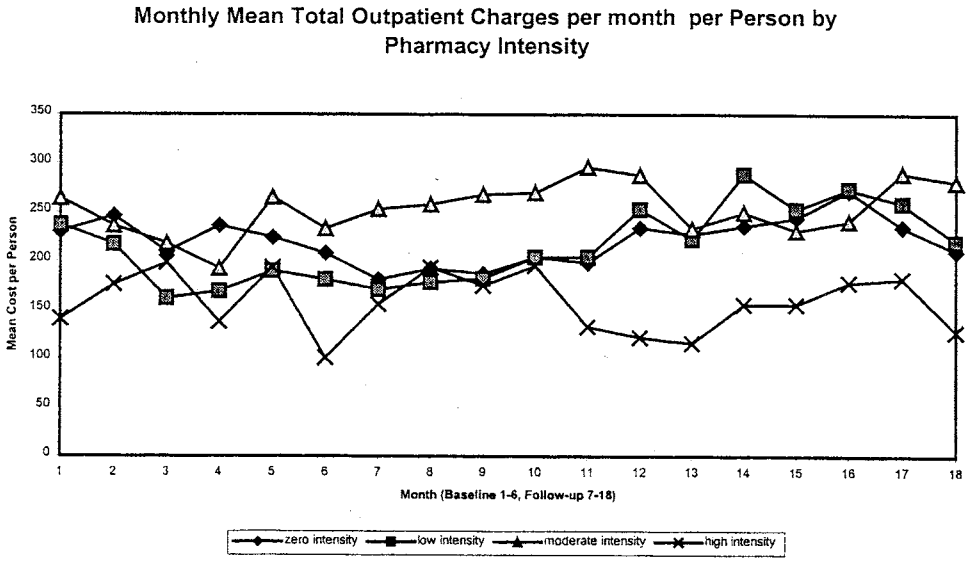


Figure 18. Mean number of outpatient facility claims paid per month (not including emergency room), according to pharmacy PCM service intensity, data through May 31, 2002, n=2,211 continuously eligible patients.

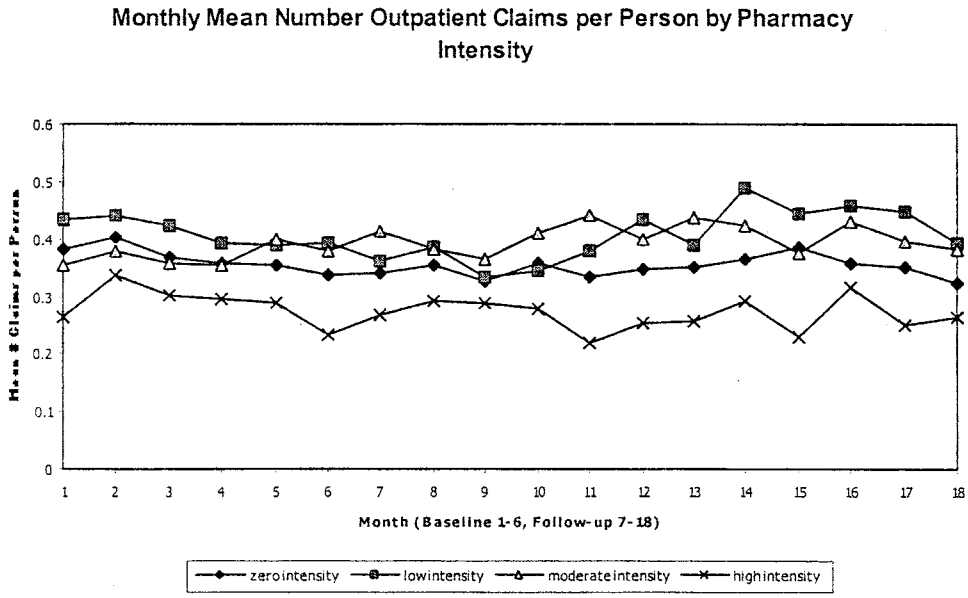
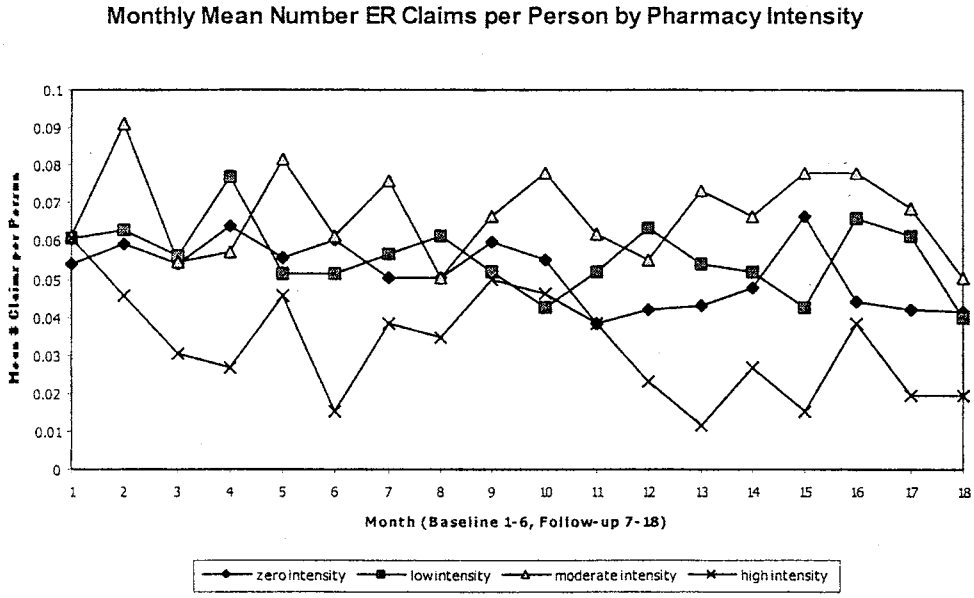


Figure 19. Mean number of emergency room claims paid per month, according to pharmacy PCM service intensity, data through May 31, 2002, n=2,211 continuously eligible patients.



Discussion

Iowa Medicaid PCM services were founded on a solid body of evidence demonstrating that pharmacists and physicians working together improves medication safety.[3-18] In this evaluation we found a relatively high delivery of PCM services compared to other intervention studies in community pharmacies. Within 3 months of a patient's eligibility for PCM, 146 pharmacists in 115 participating pharmacies had already met with nearly 1000 patients, prepared a written assessment for over 760 patients and sent recommendations to 500 physicians. Pharmacists continued their efforts to provide the care to eligible patients throughout the two-year evaluation period, culminating in 1440 billed services for 690 patients. Physicians accepted 49.2% of pharmacist recommendations and patients who received PCM services experienced significant improvements in medication appropriateness. The most common recommendation was to start a medication and the most common reason was an untreated or under-treated condition. Discontinuation, changes in drug dose, and switches to alternate drugs also were common recommendations. Health status, measured in a small subgroup of patients, remained stable over the period indicating no adverse effects of pharmacist actions. Similarly, patients' satisfaction with their pharmacists and physicians was not affected adversely. Healthcare utilization patterns for patients who received PCM services were similar to those of patients who did not receive PCM services. Health status, healthcare utilization, and patient satisfaction were secondary endpoints in this study. They were measured for descriptive purposes only and it was known that the study would have insufficient power to detect small improvements in these measures. Small improvements can translate into significant health and economic benefits.

This is one of the first studies using a reliable and valid instrument to measure prescribing quality that demonstrated that a pharmaceutical care or pharmaceutical case management intervention in community pharmacies results in improvement. It appears that the

improvement involved all 10 aspects of the medication appropriateness measure (the MAI). This is comparable to results found in a study by Hanlon et al.[3] who, in their intervention group, by closeout, found that the percentage of inappropriate ratings decreased in only seven of the 10 MAI dimensions. Also of interest is that the inappropriate ratings *in*creased in five of the 10 dimensions in the control group of that study. Our mean baseline MAI rating of 10.4 was comparable to those in other studies of pharmacist interventions for high-risk patients for whom mean MAI scores have ranged from about 10 to 15.[3,25,26]

Previous studies have used the MAI to evaluate interdisciplinary team interventions in institutional settings involving a small number of care providers. No studies have used the MAI to study pharmacist interventions in the context of a busy dispensing pharmacy. The typical change in MAI score in prior studies has been approximately 4 or 5 points. The Iowa Medicaid PCM program intervention, which resulted in a mean change in MAI score of 1.3 points, thus appears to be less potent than the studies of institutional interdisciplinary team care. Though smaller, the mean change in MAI score following PCM is probably clinically significant. Schmader et al.[24] found that changes in total MAI scores of 2-2.5 points were correlated with emergency room and hospital use and that a change of 1.7 points for cardiac medications was associated with improved blood pressure control.

This is also the first study to examine the effect of a community pharmacy intervention on risky medication use practices. Provision of PCM services was associated with a decrease in use of risky medications from 34.8% to 26.5 %, representing a clinically substantial and statistically significant 23.8% improvement. This was in contrast to PCM-eligible patients who did not receive PCM. The risky-ness of these patients' medications did not change.

In spite of these impressive results, it is clear that this program experienced similar start-up challenges as those experienced by other pharmaceutical care studies conducted in community pharmacies. There were 3037 patients who were eligible for PCM but only 690 patients received the service (22.7%). The effort to start up this new service rests largely with the pharmacist. When a pharmacy receives its list of eligible patients, a pharmacist contacts the patients, schedules appointments, meets with them, obtains additional information from their physician if necessary, completes their assessment, and forwards a written recommendation to the physician. Because of the time needed to complete all of these steps, it may take several months to finalize an action plan for a patient, and, in fact, some pharmacists were still attempting to meet with patients or complete work-ups when they received the three-month fax survey. This lag would mean that some steps may not have been completed when the survey was faxed to the pharmacy. However, because pharmacies continued to receive lists each quarter of patients newly eligible for the service, it is unknown whether or when pharmacists would catch up. In many pharmacies, catching up could require hiring additional staff. In the face of uncertainty about the longevity of the PCM program and the effects of staffing changes on pharmacy finances, managers would be understandably reluctant to make such changes during the initial year of the program.

Main obstacles to establishing PCM services were related to patient access, pharmacist issues, physician awareness, and changing the existing systems of care. Patients moving, losing Medicaid eligibility and related problems meant that the pharmacy's list of eligible patients wasn't always accurate. Furthermore, pharmacists reported identifying patients that they thought should qualify for the service but who were not on their list. The pharmacists also had significant challenges with pharmacist staffing, including insufficient staff to expand the service

and difficulties scheduling patient visits. In some cases this may have been related to the pharmacist shortage or problems hiring qualified technicians.

The need to devise solutions to obstacles can be expected to result in a slow start-up for any new program. All the pharmacists received PCM training and indicated their desire to participate and it was hoped that this enthusiasm would be sufficient to sustain pharmacists through problem-solving activities needed to integrate PCM into their individual environments. The finding that between 40 and 60% of the pharmacies were providing very little, or no, PCM services in various study quarters underscores the need for policy makers and professional organizations to assist pharmacist and physician providers to form effective care teams.

Interestingly, patient and physician refusal was an uncommon reason given for inability to provide PCM services to some patients. It is possible, however, that patient or physician refusal accounted for some instances when pharmacists did not list a reason for their inability to provide the service. In addition, when PCM was provided, even though 49.2% of physicians accepted pharmacist recommendations, often lack of acceptance was not direct disapproval of the recommendation. Rather, physicians often ignored these communications entirely, failing to respond (to either approve or disapprove) after sometimes repeated communications. Clearly, however, some of the pharmacists and physicians were very effective in working together.

Several papers have described training methods for community pharmacists that were designed to implement pharmaceutical care.[12,27-35] Currie et al[12] found that patients seen by pharmacists who had received such training were seven times more likely than a control group of patients to have problems identified (21% vs 3%). Additionally, study patients were more than eight times as likely to have an intervention performed on their behalf as patients receiving traditional pharmacy services. Rupp et al.[27] found that, of 623 prescriptions identified as

problematic by pharmacists, their interventions may have avoided otherwise likely adverse consequences in 128 (21%). Pharmacists' interventions were judged to have resulted in an estimated savings of $122 per intervention. Dobie and Rascati[34] reported that community pharmacists' interventions saved $3.50 per prescription processed, but the intervention rate was only 0.78% of all prescriptions. Finally, in a study of 31 pharmacies, Knapp et al.[35] reported an intervention rate of 0.7% of all prescriptions (range across pharmacies was 0 to 4%).

In the Florida Therapeutic Outcomes Monitoring (TOM) study community pharmacists were trained to provide pharmaceutical care for patients with asthma.[28] Of the twelve participating pharmacies, seven successfully implemented the program, but only 49 patients were recruited, and only 22 remained throughout its duration. Pharmacists did not expand this service, and stated that their main problem was the lack of time to provide and document the service.[16] While our PCM project has enrolled far more patients, the main obstacles have also been problems including start-up, difficulty sustaining the program, and lack of time.

Miller and Scott reported the results of providing drug information and pharmaceutical care training to pharmacists from five rural pharmacies.[17] The 878 interventions made during a two month period were initiated by pharmacists (57%), physicians (18%), patients (17%) or other professionals (8%). The pharmacist recommended seeing a physician 21% of the time or nonprescription therapy 47% of the time. These authors estimated that these interventions saved $752,391 in costs to the healthcare system.

The Washington State Cognitive Activities and Reimbursement Effectiveness (CARE) Project evaluated 110 treatment pharmacies and 90 control (nonpaid) pharmacies.[29-32] Treatment pharmacies billed Medicaid for each intervention for a drug-related problem. Pharmacists were paid $4.00 for each intervention requiring less than 6 minutes and $6.00 for

those requiring 6 minutes or more. During a 12-month period, 3,333 interventions (average of 2.5 per pharmacy per month) led to a drug change in the paid pharmacies compared with 2,084 (average of 1.9 per pharmacy per month) in the non-paid pharmacies. The majority of these involved "change in drug of choice" (37%), "change dose or dosage regimen" (32%) or "do not dispense" (11%). The cost savings for each drug change averaged $13. In the CARE study, pharmacists in medical centers or rural areas, those with lower prescription volumes and those with more Medicaid patients performed and documented more interventions. The researchers also found that this payment rate did not have a dramatic effect on the frequency of interventions.[32]

Comparing our findings with those of the studies cited above is somewhat difficult. Most of the previous intervention programs in community pharmacy have had to do with problem prescriptions or single disease states. The Iowa Medicaid PCM program is different in that it is an opportunity for physicians and pharmacists to closely evaluate the entire patient care plan. The program is initiated by pharmacists, but physicians must be closely involved as the plan is implemented and followed. Although some physicians have been eager partners, physicians in general have limited awareness and, perhaps, apathy about the program as indicated by the very small number of PCM bills submitted by physicians. Physicians submitted only 159 PCM bills even though they actively responded to 49.2% of pharmacists recommendations and could have billed for this activity. It is also possible that physicians did not believe that the amount of they had to expend required reimbursement.

A major priority for expanding PCM service rates will be outreach from the Iowa Department of Human Services (CHS) and state professional organizations to nonparticipating physicians, pharmacists, and patients. Clarification is needed from the DHS about the

consequences for physicians of failing to respond to pharmacist requests for records and failing to respond to pharmacist recommendations (to approve or disapprove them). Protocols, forms, and systems are needed for pharmacists to use to efficiently gather patient information in ways that are acceptable to patients and their physicians. These processes are likely to be somewhat unique to the individual pharmacist/physician/patient relationship, but commonalities should be sought. Lastly, patients clearly expect collaboration between their pharmacists and physicians as measured by the high expectations ratings. However, pharmacists commonly perceived that this did not always translate into the behaviors needed by patients in order to use these services (i.e. keeping appointments). Education by DHS counselors about this service and what it entails should be a priority for expanding use of the service.

The PCM program involves complex patients for whom the pharmacist looks at all disease states to find the best combination of drugs and doses. This makes the service complex and may, in part, explain some of the start-up difficulties. However, many of these programs have experienced difficulty starting and maintaining the service. We found that a small percentage of pharmacies in our sample were very active. The significant drop-off in intensity with time was probably related to the fact that the active pharmacies were still struggling to continue follow-up visits and physician communication with patients deemed eligible in previous quarters. They were, thus, less able to initiate the service for newly eligible patients in later quarters of the program. Refinement of the process for identifying patients in need of PCM could alleviate some of these problems. It is unlikely that administrative data alone are specific enough to precisely identify patients in need of PCM services. While the number of drugs is a strong predictor, as exemplified by the high adverse reaction history reported by these patients, behavioral, cognitive, and physical health are also important to consider and this information can

not come from administrative data. Administrative data are also not sensitive enough to identify all the patients who need the service and to assign them to their preferred primary physician and pharmacist. Patients who are taking many medications should continue to be eligible for PCM services because the evaluation has found these patients to be at high risk. However, pharmacists, physicians, and patients should be encouraged to begin PCM for patients with multiple medications who desire the service, without waiting to appear on a list for a particular pharmacy. Further, pharmacists, physicians and patients should be encouraged to determine themselves which eligible providers should deliver the care. To improve access of patients who need PCM, pharmacists, physicians, and patients should be encouraged to also consider other patient characteristics and request permission to provide the care to patients who may not be taking the threshold number of medications.

Conclusion

The Iowa Medicaid PCM program was delivered to patients at high risk of adverse medication experiences. Indeed, 30% of these patients reported experiencing adverse drug reactions in the year before the program, a rate that is three times that in the general population of older Iowans, using the same survey instrument. In this report we have described the initial start-up experience with the Iowa Medicaid PCM program that was designed for these high-risk patients. A large number of patients received PCM services and medication use became more appropriate and less risky for these patients. Because of the complexity of the program, the complexity of the patient population and physicians' general unfamiliarity with the concept of pharmaceutical case management, the large number of patients who received care must be considered a success. In addition, the Iowa Medicaid PCM service provides both pharmacists

and physicians with a relatively high reimbursement rate compared with similar programs. Despite this, some pharmacies performed very little or no PCM services during the 12-month evaluation even though the pharmacists had been trained to provide the service and had agreed to implement the program. Interviews with pharmacists have suggested mechanisms for to increasing pharmacist, patient and physician participation. These mechanisms will require active involvement of the DHS, providers, and professional organizations to bring the full potential of PCM to fruition. It is clear that developing and sustaining pharmaceutical case management services in community pharmacy is a challenge. The beneficial effects observed among the large number of patients who received these services calls for efforts to develop these services in a higher percentage of community pharmacies.

References

1. Kohn LT, Corrigan JM, Donaldson MS (editors). To err is human: Building a safer health system. (Institute of Medicine Committee on Quality of Healthcare in America: National Academy Press, 1999).
2. Chrischilles EA, Segar ET, Wallace RB. Self-reported adverse drug reactions and related resource use. A study of community-dwelling persons 65 years of age and older. Ann Intern Med 1992; 117:634-640.
3. Hanlon JT, Weinberger M, Samsa GP et al. A randomized, controlled trial of a clinical pharmacist intervention to improve inappropriate prescribing in elderly outpatients with polypharmacy. *Am J Med* 1996;100(4):428-37.
4. Carter BL, Helling DK. Ambulatory care pharmacy services: Has the agenda changed? Ann Pharmacother 2000;34:772-87.

5. McKenney JM, Slining JM, Henderson HR, Devins D, Barr M. The effect of clinical pharmacy services on patients with essential hypertension. Circulation 1973;48:1104-11.
6. McKenney JM, Brown ED, Necsary R, Reavis HL. Effect of pharmacist drug monitoring and patient education on hypertensive patients. Contemp Pharm Pract 1978;1:50-6.
7. Park JJ, Kelly P, Carter BL, Burgess PP. Comprehensive pharmaceutical care in the chain setting. J Amer Pharm Assoc 1996;36:443-51.
8. Carter BL, Barnette DJ, Chrischilles E, Mazzotti GJ, Asali ZJ. Evaluation of hypertensive patients after care provided by community pharmacists in a rural setting. Pharmacother 1997;17:1274-85.
9. Rupp MT, McCallian DJ, Sheth KK. Developing and marketing a community pharmacy-based asthma management program. J Am Pharm Assoc 1997:37:694-9.
10. Shibley MCH, Pugh CB. Implementation of pharmaceutical care services for patients with hyperlipidemias by independent community pharmacy practitioners. Ann Pharmacother 1997;31:713-9.
11. Bluml BM, McKenney JM, Cziraky MJ, Elswick RK, Jr. Interim report from project ImPACT: Hyperlipidemia. J Am Pharm Assoc 1998;38:529-34.
12. Currie JD, Chrischilles EA, Kuehl AK, Buser RA. Effect of a training program on community pharmacists' detection of and intervention in drug-related problems. J Am Pharm Assoc 1997;37:182-91.
13. Kuehl AK, Chrischilles EA, Sorofman BA. System for exchanging information among pharmacists in different practice environments. *Consult Pharm* 1998;5:564-74.
14. Ernst ME, Charlstrom CV, Currie JD, Sorofman B. Implementation of a community pharmacy-based influenza vaccination program. J Am Pharm Assoc 1997;37:570-80.

15. Ernst ME, Bergus GR, Sorofman BA. Patients' acceptance of traditional and nontraditional immunization providers. J Am Pharm. Assoc 2001;41:53-9.

16. Hepler CD. Looking toward a market for pharmaceutical care. J Amer Pharm Assoc 1997;37:625-6.

17. Miller LG, Scott DM. Documenting indicators of pharmaceutical care in rural community pharmacies. J Managed Care Pharm 1996;2:659-66.

18. Ellis SL. **Carter** BL. Malone DC. Billups SJ. Okano GJ. Valuck RJ. Barnette DJ. Sintek CD. Covey D. Mason B. Jue S. Carmichael J. Guthrie K. Dombrowski R. Geraets DR. Amato M. Clinical and economic impact of ambulatory care clinical pharmacists in management of dyslipidemia in older adults: the IMPROVE study. Impact of Managed Pharmaceutical Care on Resource Utilization and Outcomes in Veterans Affairs Medical Centers. *Pharmacotherapy. 20(12):1508-16, 2000 Dec.*

19. Chrischilles E, Sorofman B, Zieglowsky MB et al. The Iowa on-line prospective drug utilization review (OPDUR) demonstration project: Study design, system design, and conceptual models. *Journal of Research in Pharmaceutical Economics* 1997;8(1):171-91.

20. Rovers JP, Currie JD, Hagel HP, McDonough RP, Sobotka JL. A practical guide to pharmaceutical care. American Pharmaceutical Association, Washington, DC, 1998; pages 1-242.

21. Samsa GP, Hanlon JT, Schmader KE et al. A summated score for the Medication Appropriateness Index: development and assessment of clinimetric properties including content validity. J Clin Epidemiol 1994;47:891-6.

22. Fitzgerald LS, Hanlon JT, Shelton PS et al. Reliability of a modified medication appropriateness index in ambulatory older persons. Ann Pharmacother 1997; 31:543-8.

23. Kassam R, Martin LG, Farris KB. Reliability of the Medication Appropriateness Index in the community pharmacy. (manuscript in review)

24. Schmader K, Hanlon JT, Landsman PM, Samsa GP, Lewis IK, Weinberger M. Inappropriate prescribing and health outcomes in the elderly in a pharmacist intervention trial. Ann Pharmacother 1997;31:529-33.

25. Jeffery S, Ruby CM, HanlonJT, Twersky J. The impact of an interdisciplinary team on suboptimal prescribing in a long-term care facility. Consult Pharm 1999;14:1386-9.

26. Hanlon JT, Schmader KE, Artz M, Pieper C, Cohen HJ. The Effect of Geriatric Evaluation and Management Units (GEMU) and Clinics (GEMC) on Drug-Related Problems (DRPs). (abstract) Gerontologist 2002; 42(S1):31-2.

27. Rupp MT. Value of community pharmacists' interventions to correct prescribing errors. Ann Pharmacother 1992;26:1580-4.

28. Barnette DJ, Murphy CM, Carter BL. Clinical skill development for community pharmacists. J Amer Pharm Assoc 1996;36:573-81.

29. Grainger-Rousseau TJ, Miralles MA, Hepler CD et al. Therapeutic outcomes monitoring: Application of pharmaceutical care guidelines to community pharmacy. J Amer Pharm Assoc 1997;37:647-61.

30. Christensen DB, Holmes, Fassett WE, Neil N, Andrilla CH, Smith DH, et al. Influence of a financial incentive on cognitive services: CARE project design/implementation. J Am Pharm Assoc 1999;39:629-39.

31. Christensen DB, Hansen RW. Characteristics of pharmacies and pharmacists associated with the provision of cognitive services in the community setting. J Am Pharm Assoc 1999;39:640-9.

32. Smith DH, Fassett WE, Christensen DB. Washington state CARE project: Downstream cost changes associated with the provision of cognitive services by pharmacists. J Am Pharm Assoc 1999;39:650-7.

33. Christensen DB. Lessens learned from the Washington state CARE project. J Am Pharm Assoc 1999;39:606-7.

34. Dobie RL, Rascati KL. Documenting the value of pharmacist interventions. Amer Pharm 1994;34:50-4.

35. Knapp KK, Katzman H, Hambright JS, Albrant DH. Community pharmacist interventions in a capitated pharmacy benefit contract. Am J Health-Syst Pharm 1998;55:1141-5.

Appendices

Appendix A. State Plan Amendment

ELIGIBLE MEDICAID PATIENTS

Patients are determined as eligible for these services through a two-step, computer-based algorithm under the direction of the Department of Human Services. Initial patient eligibility criteria include active prescriptions for four or more regularly scheduled non-topical medications and ambulatory care status. The second step of the eligibility process is the patient must also have at least one of the eligible disease states. Eligible disease states include congestive heart disease, ischemic heart disease, diabetes mellitus, hypertension, hyperlipidemia, asthma, depression, atrial fibrillation, osteoarthritis, gastroesophageal reflux, peptic ulcer disease, and chronic obstructive pulmonary disease.

ELIGIBLE PROVIDERS

Physicians and pharmacists on care teams must meet specific criteria to provide pharmaceutical case management services. Physicians must be licensed to practice medicine. Both physicians and pharmacists must complete an Iowa Medicaid provider agreement, have an Iowa Medicaid provider number, and receive training under the direction of the Department of Human Services regarding the provision of pharmaceutical case management services under the Iowa Medicaid program.

A copy of pharmaceutical case management records, including documentation of services provided, must be maintained on file in each provider's facility and be made available for audit by the Department of Human Services on request.

To become eligible to provide these services, pharmacists must present to the Department of Human Services evidence of competency including state licensure, submission of five (5) acceptable patient care plans, and successful completion of professional training regarding patient-oriented medication-related problem prevention and resolution. Acceptable professional training programs shall be approved by the Department of Human Services with input from a peer review advisory committee. A doctorate of pharmacy degree is considered acceptable professional training. The Iowa Center of Pharmaceutical Care (ICPC) training program, a cooperative training initiative of the University of Iowa College of Pharmacy, Drake University College of Pharmacy and Health Sciences, and the Iowa Pharmacy Foundation, is also an approved training program. Other programs containing similar didactic coursework and supplemental practice site evaluation and re-engineering will be considered for approval by the Department of Human Services. Pharmacists must also maintain problem-oriented patient records, provide a private patient consultation area, and submit a statement indicating the submitted patient care plans are representative of their usual patient care plans.

PCM SERVICES

Eligible patients may choose to receive services from any eligible provider care team (physician and pharmacist) of their choice. It is generally expected the members of the care team will be the patient's primary care providers. If either provider on the care team is not the patient's primary physician or pharmacy provider, the care team shall communicate its plan to the primary

physician and pharmacy providers. The care team shall not duplicate services performed by the primary care providers. Care team activities are intended to be value-added, complementary services to the basic medical services provided by the primary physician and pharmacist.

Once the patient/physician/pharmacist team has been established, the care team will provide the following services:

1. Patient evaluation by the pharmacist, including:
   a. Medication history;
   b. Assessment of indications, effectiveness, safety, and compliance of medication therapy;
   c. Assessment for the presence of untreated illness; and
   d. Identification of medication-related problems, such as:
      - unnecessary medication therapy
      - suboptimal medication selection
      - inappropriate compliance
      - adverse drug reactions, and
      - need for additional medication therapy
2. A written report and recommendation from the pharmacist to the physician.
3. A patient care action plan developed by the PCM team with the patient's agreement and implemented by the PCM team. Specific components of the action plan will vary based on patient needs and conditions but may include changes in medication regimen, focused patient or caregiver education, periodic assessment for changes in the patient's condition, periodic monitoring of the effectiveness of medication therapy, self-management training, provision of patient-specific educational and informational materials, compliance enhancement, and reinforcement of healthy lifestyles. An action plan must be completed for each initial assessment.

Problem Assessment

- May occur in the interim between other pharmaceutical case management services
- Initiated when a new medication-related problem is identified by the care team
- Care team assesses the patient, and develops and implements an action plan

Problem Follow-up Assessment

- Based on patient need or problem identified by a prior assessment
- Care team assesses the effectiveness of the agreed-upon action plan
- Care team evaluates the patient's status at an appropriate interval as determined by the team, and modifies action plan as necessary

Preventive Follow-up Assessment

- Follows an Initial Assessment when no medication-related problems were identified
- Occurs approximately six months following Initial Assessment
- Care team re-assesses the high-risk patient for newly developed medication-related problems
- Action plan is implemented to address any identified problems

An action plan is defined as a plan of patient care developed by and agreed upon by care team members. Specific activities vary based on patient needs and conditions. These activities may include:

- Changes in medication regimen
- Focused patient or caregiver education
- Periodic assessment for changes in the patient's condition

· Periodic monitoring of the effectiveness of medication therapy
· Patient self-management training
· Provision of patient-specific educational and informational materials
· Compliance enhancement
· Reinforcement of healthy lifestyles

A copy of pharmaceutical case management records, including documentation of services, shall remain on file in each provider's facility available for audit by the Department of Human Services.

REIMBURSEMENT

Pharmacist and physician team members shall be equally reimbursed for their participation in each of the four PCM services described above. Each team member shall be reimbursed the following amount for the services provided. The reimbursement structure was established after reviewing Medicaid's physician fee schedule and reimbursement methodologies and fees of other states and third party payers.

1. Initial Assessment	$75
2. New Problem Assessment	$40
3. Problem Follow-up Assessment	$40
4. Preventive Follow-up Assessment	$25

The maximum number of payments for each type of assessment per patient is listed below. Payment for services beyond this amount will be considered on an individual basis after peer review of submitted documentation of medical necessity.

1. Initial Assessment	One per patient
2. New Problem Assessment	Two per patient per 12 months
3. Problem Follow-up Assessment	Four per patient per 12 months
4. Preventive Follow-up Assessment	One per patient per 6 months

To bill for and be reimbursed for PCM services, there **MUST** be written communication between the pharmacist and physician. The **HCFA-1500** form will be used to file claims for both pharmacists and physcicians. The individual pharmacist provider number should be placed in **BOX 24K**. The following billing codes will be used in place of CPT codes for PCM services:

W4100 - Initial Assessment - Pharmacist
W3100 - Initial Assessment - Physician
W4200 - Preventive Follow-up Assessment - Pharmacist
W3200 - Preventive Follow-up Assessment - Physician
W4300 - New Problem Assessment - Pharmacist
W3300 - New Problem Assessment - Physician
W4400 - Problem Follow-up Assessment - Pharmacist
W3400 - Problem Follow-up Assessment - Physician

Appendix B. Sample Pharmacist-Physician Communication Form

See next page

Pharmaceutical Case Management Assessment Communication Form

Physician: _____ FAX : _____ Phone:_____

CONFIDENTIALITY WARNING: The information contained in this facsimile message is privileged and confidential information intended only for the review and use of the individual or entity named above. If the reader of this message is not the intended recipient, you are hereby notified that any disclosure, dissemination, distribution or copying of this communication or the information contained herein is strictly prohibited. If you have received this communication in error, please immediately notify sender by telephone, and destroy the original documents.

☐ Initial ☐ Follow-up ☐ New Problem ☐ Preventive

Patient Name:_____ Medicaid #:_____

Birthdate:_____ Sex:_____

Pharmacist: (print name) Date:

Subjective Findings:

Objective Findings:

Assessment:

Plan:

Recommended Pharmacist Follow-Up Assessment:

☐ 4 weeks ☐ 8 weeks ☐ 6 months Other_____

Signature:_____

(Complete, Sign, and Fax to Physician)

Pharmacist: _____ FAX: _____ Phone:_____

Physician: (print name) Date:

☐ Agree with Plan Recommended

☐ Proposed Modified Plan:

Pharmacist Follow Up: ☐ As recommended ☐ Other_____

Signature:_____

(Complete, Sign, and Fax to Pharmacist)

Technical Appendices

Technical Appendix 1. Methodology for Identifying Active Drug Lists

Available on request

Technical Appendix 2. Methodology for Medication Appropriateness Rating

Available on request

Technical Appendix 3. Pharmacist and Physician Survey Instruments

Available on request