THE UNIVERSITY OF IOWA

December 26, 2002

To: Iowa legislators, the Iowa Department of Human Services, and interested others
Subject: The Iowa Medicaid Pharmaceutical Case Management Program Evaluation

The final report for the Iowa Medicaid Pharmaceutical Case Management (PCM) Program Evaluation is enclosed. The Iowa PCM program began with funds appropriated during the 2000 Iowa Legislative session. The program was designed to benefit a subset of individuals at very high risk to experience adverse effects from their medications.

High-risk medication use among Medicaid patients taking four or more medications is a public health issue of significant import. Thirty percent self-reported an adverse drug reaction in the previous year, 35% had drug-drug interactions, and, among those age 60 or older, 35% were taking medications considered to have a poor risk-benefit balance and to be inappropriate for use among older adults.

In a relatively short period of time, the PCM program improved medication safety. It is anticipated that if the program can be maintained and nurtured into maturity, improvements in longer-term health outcomes will be achieved.

Sincerely,

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Iowa Medicaid Pharmaceutical Case Management Program

Report of the Program Evaluation

December 2002

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4 Executive Summary

4.1 Background

The Iowa Medicaid Pharmaceutical Case Management (PCM) program was designed to benefit a subset of individuals at very high risk to experience adverse effects from their medications. The Iowa PCM program began with funds appropriated during the 2000 Iowa Legislative session. The innovative care delivered through this program is based on a model of care known to improve medication safety in hospital and clinic settings where pharmacists and physician are under the same roof and have ready access to the patient medical record. To deliver this model of care in a *community* setting, Iowa pharmacists and physicians who participated in the PCM program did so without benefit of a shared practice location or common access to a patient medical record. By most measures, they did so successfully.

Pharmaceutical case management provides an opportunity for physicians and pharmacists to closely scrutinize the total drug regimens of their most complex patients. Working together, they can find the best combination of medications and doses for a particular, complex patient with multiple disease states.

Under this initiative, pharmacists and physicians may provide and be reimbursed for one Initial Assessment, up to four Problem Follow-up Assessments per 12 months, up to two New Problem Assessments per 12 months, and up to one Preventive Follow-up Assessment every six months. Eligible patients are those taking at least four medications and with one of 12 disease states. Eligible patients who participate in the program receive an Initial Assessment by the pharmacist who then makes written recommendations to the patient's physician. Recommendations that are accepted or modified by the physician are considered an action plan. Pharmacists make Problem Follow-up Assessments until all problems are resolved, communicating with the physician in each case. Once problems are resolved, Preventive Follow-up Assessments can occur every six months and new problems that arise episodically can trigger a New Problem Assessment and a new action plan.

The primary objectives of the PCM evaluation were to describe the extent and content of PCM services and determine the effect of the PCM program on medication safety. Secondary objectives included describing the health of eligible patients, determining whether there was an

impact on healthcare utilization, and compiling the responses of physicians and pharmacists who participated in the program.

4.2 Findings

There were four major findings:

1. Those who are eligible for PCM are at very high risk for adverse medication effects:
    - Standardized health status measures found that this population is much less healthy than a typical sample of the US population.
    - Alarmingly, 30% self-reported an adverse drug reaction in the previous year. This is three times the rate observed in a different population of elderly Iowans not on Medicaid.
    - Approximately 35% of PCM-eligible patients had drug-drug interactions. More alarming was the finding that, among those age 60 and over who were taking antihypertensive medications, approximately 75% had a drug-drug interaction.
    - 35% of adults aged 60 and older who received PCM services had been taking at least one medication considered to have a poor risk-benefit balance and to be inappropriate for use among older adults.
2. PCM services were provided to many eligible patients:
    - A total of 117 pharmacies participated in the program from all areas of the state.
    - Of 3,037 patients eligible during the first year of the program, pharmacists had met with 943, sent recommendations to physicians for 500 of these patients, and received replies from the physician for 327 within the first three months of patient eligibility.
    - The mean patient age was 52.5 years, two-thirds were age 45 or older, and 6.4% were children.
    - Pharmacists chose to provide care first to those at highest risk for medication-related problems (patients who received care were older, took more medication, and were taking more high risk medications than those who were eligible for PCM but who did not receive it).
    - Pharmacists detected an average of 2.6 medication-related problems per patient.

- The most common recommendation made by pharmacists (52% of patients) was to start a new medication. This finding confirms numerous other studies of pharmacist interventions indicating that many patients have untreated conditions. Examples included failure to received life-saving medications like aspirin or beta blockers following a heart attack. Pharmacists recommended a change in medication 36% of the time indicating a more appropriate therapy might be available. Pharmacists also recommended discontinuation of medications 33% of the time.

3. The PCM program significantly improved medication safety and did not measurably affect Medicaid expenditures.
    - Those who received PCM services had a statistically significant 12.5% improvement in the Medication Appropriateness Index, a detailed, structured measure of ten domains of prescribing quality.
    - Among PCM recipients age 60 or older, the percent using medications considered inappropriate for use among the elderly decreased by 24%, a statistically significant decrease relative to those who did not receive PCM services.
    - Medicaid paid a total of $94,170 for PCM services through May 31, 2002.
    - Even after including the amount paid for PCM services, there was no net increase in healthcare utilization or charges among patients who received PCM relative to those who were eligible but did not receive the services.
    - The data suggested that emergency room and outpatient facility utilization may have decreased for patients of pharmacies who adopted PCM most intensely.
4. The PCM program can be extremely effective if obstacles to success can be miminized:
    - Some pharmacists were more successful in completing all PCM functions and included more patients in the program. It is assumed that these pharmacists overcame challenges and obstacles that daunted other pharmacists. The pharmacists who achieved a higher intensity of PCM service provision yielded the greatest improvement in medication safety (e.g. Medication Appropriateness Index scores).
    - Many patients presented a challenge because they were difficult to contact or schedule, many missed appointments or declined the service.

- Even though these patients were at extremely high risk for medication-related problems and drug interactions, physicians did not accept half of pharmacists' recommendations, and most of these were ignored rather than actively rejected. Frequently physicians did not respond to repeated requests for information and communication.
- Physicians who responded to a questionnaire about the program exhibited largely positive attitudes toward the collaboration with a pharmacist, but 17% indicated they would not cooperate with pharmacists. Physicians on average reported not having knowledge about what services were reimbursable under the PCM program.
- Pharmacists and physicians who responded to surveys agreed on average that physician-pharmacist discussions led to better quality of care, better health outcomes, and increased continuity of care.
- Unlike physician offices, pharmacies lack support staff to obtain medical records, schedule patients, follow-up when patients miss appointments and keep records. Therefore, participating pharmacists were doing most of this work themselves and found it difficult to incorporate these activities into their other responsibilities.

4.3 Recommendations

As it matures, the fledgling PCM program has the potential to achieve greater benefits to more patients eligible for the program. In order for this to happen, the program should be actively nurtured. Action is recommended on the part of the Iowa Department of Human Services (DHS), the state and local professional organizations, and pharmacy colleges:

1. The Iowa DHS, Colleges of Pharmacy and Iowa Pharmacy Association should develop and deliver pharmacist training to address the obstacles identified in this report and to involve more pharmacists in the delivery of these services.
2. The Iowa DHS and professional societies should facilitate development and maturation of pharmacist-physician care teams by actively fostering training and dialogue.
3. Medical societies and the Iowa DHS should develop and implement training programs for physicians about the potential crisis of high-risk medication use among patients eligible for PCM and about specific mechanisms for integrating PCM services in their practices.

4. The Iowa DHS should maintain the eligibility screening process but increase its flexibility so that not only the DHS but also individual physicians and pharmacists may identify patients in need of PCM.
5. The Iowa DHS should notify all PCM-eligible patients about their eligibility and inform them about how to obtain these services.

4.4 Conclusion

High-risk medication use among Medicaid patients taking four or more medications is a public health issue of significant import. In a relatively short period of time, the PCM program has achieved numerous successes. It is anticipated that if the program can be maintained and nurtured into maturity, greater collegiality among providers will develop and improvements in longer-term health outcomes will be achieved.

5 Background

During the 2000 Iowa Legislative session, funds were appropriated to reimburse physicians and pharmacists up to $75 per assessment for services provided through the Iowa Medicaid Pharmaceutical Case Management initiative. This initiative provided the means for Iowa Medicaid recipients at high risk for adverse medication practices to receive assessments, action plans, and follow-up to improve their medication use. The program was implemented as a State Plan Amendment.

The ultimate goal 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 method to accomplish this is to have patients use more optimal, lower risk medication regimens. Adverse drug events are one of the most frequent and costly consequences of medical errors.[1]

The predominant 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 five or more medications.[3] Disease state management is particularly 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 and find the best combination of drugs and doses. There is strong published evidence to suggest that pharmacist-physician teams can increase medication safety.[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] 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] Moreover, pharmaceutical care training has been shown to result in increased resolution of medication problems.[12,13] 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] These prior efforts established a foundation for the Iowa Medicaid Pharmaceutical Case Management program by training over 200 pharmacists in strategies 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 in the United States to implement and reimburse physician/pharmacist team delivery of medication management services for high-risk patients in the community setting.

6 Program Description

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

Pharmacists and physicians may provide and be reimbursed for one Initial Assessment, up to four Problem Follow-up Assessments per 12 months, up to two New Problem Assessments per 12 months, and up to one Preventive Follow-up Assessment every six months. Eligible patients who participate in the program receive an Initial Assessment by the pharmacist who then makes written recommendations to the patient's physician (Appendix B). Recommendations that are accepted or modified by the physician are considered an action plan. Pharmacists make Problem Follow-up Assessments to determine progress with the action plan and communicate this with the physician, which may result in a modified action plan. Once all problems have been resolved, the patient is eligible for a Preventive Follow-up Assessment every six months.

New Problem Assessments occur when a new problem arises episodically in this process. A New Problem Assessment may result in a new action plan.

6.1 Advisory Board

A peer review advisory committee was established to oversee program development and evaluation. The committee consists of four pharmacists and four physicians working in the state. Staff from the Department of Human Services, Iowa Medical Society, Iowa Osteopathic Medical Association, Iowa Academy of Family Physicians, and Iowa Pharmacy Association provided input. Specific responsibilities of the committee were to: (1) draft the State Plan Amendment for PCM which established all details of the program (Appendix A); (2) establish eligibility requirements for participating providers; (3) determine eligibility of individual pharmacies and pharmacists; and (4) review and approve the program evaluation plan.

6.2 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. Physician training consisted of a manual of operations mailed to them by the fiscal intermediary (Consultec). A website provided answers to frequently asked questions and general information about PCM services (www.public-health.uiowa.edu/pcm).

7 Program Evaluation

7.1 Objectives

The primary objectives of the Evaluation were to:

1. describe the extent and content of PCM services and
2. determine the effect of the PCM program on medication safety.

Secondary objectives of the Evaluation were to:

3. compare the change in prevalence of adverse drug reactions between baseline and follow-up for those who received PCM services and those who did not;
4. compare the change in health status between baseline and follow-up for those who received PCM services and those who did not;
5. compare patient-perceived quality of care between baseline and follow-up for those who received PCM services and those who did not;
6. compare the healthcare resource use and related Medicaid charges between baseline and follow-up for those who received PCM services and those who did not; and
7. describe the attitudes of providers who participated extensively in the program.

7.2 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. Patients from each of these quarters were 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 phase of the PCM

program. An important component of the evaluation was to collect information about the challenges experienced and innovative solutions that distinguish providers who successfully implemented the services.

A patient was considered to have received PCM services if at least one claim for PCM reimbursement was filed within nine months of the date the patient was identified to be eligible for PCM. Pharmacies were classified according to the intensity with which they adopted the PCM services during the first program year.

To determine the effects of the PCM program on the primary study objective of improving medication safety, three types of comparison were made:

1. Among patients who received PCM services, medication safety on the day a patient became eligible for PCM was compared with safety of their medications nine months after becoming eligible.
2. Changes in use of high-risk medications, number of active drugs, and medication cost were compared for PCM-eligible patients who actually received PCM services vs. those who were PCM-eligible but who did not receive PCM services.
3. PCM-eligible patients of high intensity pharmacies were compared with those of low intensity pharmacies with respect to change in use of high-risk medications.

7.3 Data Collection

Data collection activities included: monitoring submitted claims for PCM services reimbursement, faxed surveys of participating pharmacies to monitor the status of all eligible patients, 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. These data sources

are detailed in Table 1 along with the measures constructed from them and the specific study objectives each measure addressed. The detailed measurement methods are described below.

Table 1. Data collected according to study objectives

Study Objective	Measure	Data Source
1) Describe the extent and content of PCM services.	Intensity of pharmacies' participation in PCM activities	Fax surveys to participating pharmacies; PCM claims by provider and claim type; categorizing pharmacists' recommendations
2) Determine the effect of the PCM program on medication safety.	Medication Appropriateness Index	Clinical pharmacist review of patients' pharmacy records using Medication Appropriateness Index instrument
	Use of High-Risk Medications	Medicaid pharmacy claims file
	Number of Medications	Medicaid pharmacy claims file
	Medication Costs	Medicaid pharmacy claims file
3) Compare the change in prevalence of adverse drug reactions between baseline and follow-up for those who received PCM services and those who did not.	Patient-reported experience of unwanted of side effects from medication in a 12 month period.	Mailed questionnaire to PCM-eligible Medicaid recipients at baseline (pre-PCM) and 12 months later (follow-up).
4) Compare the change in health status between baseline and follow-up for those who received PCM services and those who did not.	Functional Status	Mailed questionnaire to PCM-eligible Medicaid recipients at baseline (pre-PCM) and 12 months later (follow-up).
	Perceived Health and Overall Quality of Life	Mailed questionnaire to PCM-eligible Medicaid recipients at baseline (pre-PCM) and 12 months later (follow-up).
5) Compare patient-perceived quality of care between baseline and follow-up for those who received PCM services and those who did not.	Patient Perception of Quality of Care (satisfaction with physicians, satisfaction with pharmacists, expectations about pharmacist care)	Mailed questionnaire to PCM-eligible Medicaid recipients at baseline (pre-PCM) and 12 months later (follow-up).
6) Compare the health care resource use and related Medicaid charges between baseline and follow-up for those who received PCM services and those who did not	Health Care Utilization	Iowa Medicaid institutional and medical claims files
7) Describe the attitudes of providers who participated in the program	Attitudes of Care Team Members	Pharmacist and physician surveys; pharmacist qualitative interviews; pharmacist large-group discussions.

7.3.1 Objective 1: Description of PCM Service Delivery

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 eligible 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.

7.3.2 Objective 2: Effect of PCM on Medication Safety

Measures of medication safety included: 1) clinical pharmacist review of patients' pharmacy records using a structured protocol for rating medication appropriateness; 2) Use of medications considered to be inappropriate for use by those age 60 and over, i.e. potential risks outweigh potential benefits; 3) number of active medications; and 4) cost of active medications.

7.3.2.1 Clinical Pharmacist Review of Patients' Pharmacy 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 for those who received PCM services. 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. In addition, a random sample of these were abstracted to

describe the recommendations made by pharmacists and action plans developed by the care teams.

The MAI[21,22] rates each medication using ten 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 ten 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 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. A clinical pharmacist, blinded to PCM intensity, reviewed each patient's medication profile and problem-oriented patient record determined MAI scores. 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 ten 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] 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.

7.3.2.2 Use of High-risk Medications

Several components of the MAI were identified that could potentially be adequately identified from pharmacy claims data alone and were therefore available for *all* eligible patients, regardless of whether they received PCM. These items included: drugs considered inappropriate for use (high-risk) among 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 other MAI items require detailed information only available from the records of patients who actually received the PCM service.

Use of high-risk medications among the elderly was the only one of these items that had suitable validity upon further evaluation. This measure was constructed from Medicaid pharmacy claims thus allowing patients who received PCM to be compared with patients who were eligible but did not receive PCM services.

7.3.2.3 Construction of Active Drug Lists from Medicaid Pharmacy Claims

A computer algorithm was developed to construct a list of drugs considered "active" on the date a patient became eligible for PCM (the "index" or "baseline" date). A drug was considered active on a date if a claim for that drug met any one of three criteria. Criterion 1 was that the index date fell within the period from the fill date of the prescription through the fill date plus the number of days the supply would last (days supply). The days supply field in administrative pharmacy claims is the field used by the pharmacist who submits the electronic drug claim to indicate the number of days the prescription is expected to last, based on the prescription directions and quantity dispensed. Criterion 2 required one fill prior to the index date and one fill after the index date, with the gap between fills being ≤ 90 days. Criterion 3 was designed to identify drugs used on an as-needed basis. A list of 816 drug products that were most commonly used as-needed was adapted by the investigators. Criterion 3 required a fill for an as-needed drug in the 90 days prior to the index date. The rationale for this criterion was that the likelihood for potential use within 90 days after the fill was high. In a sample of 100 patients, who received 1476 potentially active medications, the computer algorithm had a sensitivity of 93.8% and specificity of 91.7% using pharmacist reviewers of a one year refill history as the gold standard. The National Drug Code for each active drug product was linked to the ingredients in the drug product (some products are combination products containing more than one drug). Unique drug ingredients were counted to calculate the number of active drugs on the index date. This same process was conducted 9 months later (follow-up date). The amount billed to Medicaid for each active drug product was also tallied at each date.

7.3.3 Objectives 3-5: Effect of PCM on Patient Perceptions

Patients were mailed questionnaires on the first day of the calendar quarter in which they became 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, and their satisfaction with their health care. They were also asked a number of questions about their health status. Baseline and follow-up responses were compared for those who received PCM services and those who did not.

7.3.4 Objective 6: Effect of PCM on Healthcare Utilization

Medicaid medical and institutional claims were used to determine whether there was any change in healthcare utilization during the program evaluation period. Because the majority of individuals eligible for PCM services are also eligible for Medicare, these Medicaid claims do not provide a complete picture of healthcare utilization (Medicare claims would be needed). Nonetheless, Medicaid claims provide an estimate of the short-run impact on the Medicaid program.

7.3.5 Objective 7: Effects of PCM on Physician and Pharmacist Attitudes

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 overcome 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. Participating pharmacists and a random sample of physicians whose patients received PCM received mailed or faxed questionnaires to elicit their attitudes about and experiences with the PCM program.

7.4 Statistical Methods

The relationships of continuous variables at baseline with receipt of PCM were assessed using t-tests, ANOVA, ANCOVA (when controlling for age and gender), and non-parametric procedures. Correlation analyses used Pearson or Spearman methods. Comparisons between categorical variables were assessed using chi-square statistics or exact non-parametric methods for small sample sizes. Cochran-Mantel-Haenszel Methods were used when controlling for age, gender, and other characteristics. The relationship of continuous and categorical variables were assessed with Wilcoxon/Kruskall-Wallis methods, ANOVA, and ANCOVA (when controlling for age and gender).

Longitudinal analyses of change in measures over time (e.g. from pre-PCM to 9 months after PCM eligibility) utilized one of the most widely used current methods for data analysis of correlated, normal and non-normal data distributions, Generalized Estimating Equations (GEE). GEE is a form of generalized linear modeling that accommodates data that can be modeled as a generalized linear model except for the correlation among responses. A traditional linear model is of the form $y_i = x_i'\beta + \varepsilon$. The generalized linear model extends the traditional linear model and is therefore applicable to a wider range of data analysis problems. GEE methods can be used for

Poisson, logistic, gamma, and normal distribution analyses. These regression models can include main effects, interactions, and quadratic or cubic terms just as in regression without correlated dated.

Repeated measures analyses (for repeated observations over time on either the same patient or the same pharmacy) used the patient ID or the pharmacy ID as the unit of repetition. Results were similar for both types of repetition (only patient results are shown).

8 Results

8.1 Description of Eligible Patients

A total of 3,037 patients were eligible for PCM services during the study year. Table 2 displays the age distribution of patients by quarter of initial eligibility for PCM services. The mean age was 52.5 (±20.2) years and almost two-thirds of eligible patients were age 45 or older; 6.7% were children. Adults ranged from 18 years to 101 years of age. Overall, 71.4% of patients were women. Of 117 participating pharmacies, 109 had eligible patients in quarter 1, 76 had additional eligible patients assigned in quarter 2, 71 in quarter 3, and 81 in quarter 4 (Table 2). Of the 117 eligible pharmacies, 114 had eligible patients assigned in at least one quarter.

Table 2. 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

8.2 Objective 1: Description of PCM Service Delivery

8.2.1 Intensity of Pharmacist Service Delivery

Three months after receiving their list of eligible patients, fax surveys were sent to pharmacies querying the status of 2,931 eligible patients (106 patients were inadvertently omitted from these mailings). Fax surveys were returned for 2,834 patients (96.7%). Table 3 displays the number of surveys returned and results of the fax surveys. These represent the actions taken by pharmacists and physicians during the three months after a patient was identified as eligible. These findings were recently published.[24] Within three months of receiving a list of newly eligible patients, pharmacists 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 first eligibility) were "worked-up" by pharmacists and recommendations were sent to physicians for 15.6% 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 3. 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%)	247 (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=2,834)	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 4 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 4. Reasons pharmacists gave for not meeting with patients during the first three months after patients' initial eligibility for PCM services, by quarter of 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 PCM service delivery was summarized in two ways (Table 5). The percent complete indicates the proportion of eligible patients for whom 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. In the first quarter list, 16.5% of the pharmacies had completed all these steps within three months for at least half of their eligible patients.

Table 5 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. For patients on the quarter 2 through 4 lists, few pharmacies provided a high intensity of service.

Table 5. 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%)
25-50	20 (18.3%)	4 (5.3%)	1 (1.4%)	4 (4.9%)
1-24	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.

8.2.2 Claims for PCM Services Received by Provider and Claim Type

Charges for PCM services through May 31, 2002 totaled $94,170. Two-thirds of this amount was billed for Initial Assessments and 21.5% was billed for Problem Follow-up Assessments.

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, claims for PCM services had been submitted by May 31, 2002 for 690 patients (22.7% of 3037 eligible patients; Table 6) and 1599 services. Of the 1599 PCM services reimbursed, 90% (n=1440) were submitted on claims from pharmacists (Table 6) and only 159 were from physicians. The PCM services are tabulated by the quarter when patients were assigned/enrolled (Table 6), by the quarter when claims were submitted (Table 7), and by the quarter when services occurred (Table 8).

Table 6. Number of PCM patients and PCM services by quarter of first eligibility, 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 7. Number of 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 8. Number of 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 (excludes one claim with a service date before 10/1/00)
[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 9 cross-tabulates claims received by quarter of first eligibility and quarter of service. From Table 9, and supported by the start-up statistics in Tables 3 and 4, 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 had service dates throughout the ensuing 20 months (Table 9). Only 27% of these claims (n=220) had dates of service during the first three months of eligibility for PCM services.

Table 10 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 9. Number of pharmacy PCM claims according to quarter of patient first eligibility and quarter of service, for PCM claims submitted through May 31, 2002.

Service Quarter Beginning Date	Quarter of First Eligibility Beginning Date					
	10/1/00	1/1/01	4/1/01	7/1/01	Outside Study Period	Total
10/1/00	220	0	0	0	0	220 14.80
1/1/01	142	101	0	0	1	244 16.42
4/1/01	157	97	50	1	1	306 20.59
7/1/01	122	57	20	56	2	257 17.29
10/1/01	79	60	23	47	15	224 15.07
1/1/02	87	36	22	25	27	197 13.26
4/1/02	20	8	4	5	1	38 2.56
Total	827 55.65	359 24.16	119 8.01	134 9.02	47 3.16	1,486[a] 100.00

[a]Excludes one claim with a service date before 10/1/00.

Table 10. Number of 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.

8.2.3 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 were 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 with whether PCM services were received (data not shown). Older patients took more medications, were more likely to receive 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 11 displays the baseline (before PCM) sociodemographic and medication characteristics of patients 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 later received PCM services, about two-thirds of PCM eligible patients had at least one indicator of inappropriate medication use during the baseline (pre-PCM) period.

Approximately 35% of PCM-eligible patients had drug-drug interactions at the time they became eligible for the service. When we examined interactions with antihypertensive medications,[25] approximately 75% of adults over age 60 who were taking antihypertensive

medications had a drug-drug interaction and approximately 53% of these were considered to be of high clinical significance requiring attention by care providers.[26]

Table 11. Baseline sociodemographic and medication characteristics of PCM-eligible patients by whether they received PCM services, adjusted for age and gender.

	Received PCM (n=524)		No PCM (n=1687)	
Mean age (S.E.) (adjusted for gender)*	54.1	(0.8)	48.4	(0.5)
Number (%) female*	419	(80.0)	1169	(69.3)
Number (%) ethnic background:				
White	467	(89.1)	1519	(90.0)
Black	31	(5.4)	93	(5.5)
Other	5	(1.0)	35	(2.1)
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)
(CN600)Antidepressants	202	(38.6)	692	(41.0)
(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, adjusted for age and gender.				

Table 12 displays the baseline health status characteristics of those who received PCM services compared to those who were eligible but who did not receive PCM services, adjusted for differences 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 12. Baseline health status characteristics of PCM-eligible patients by whether they received PCM services, adjusted for age and gender.

	Received PCM		No PCM	
Baseline Health Status (available only for survey respondents):	N=128 survey respondents		N=330 survey respondents	
SF-36 mean summary physical health score (scale 0 to 100) (S.E.)	34.1	(1.1)	34.4	(0.7)
SF-36 mean summary 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 100) (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)
Baseline Urgent Care Use (available for all with continuous PCM eligibility):	N=524		N=1687	
Hospitalized in past year, n (%)	47	(9.0)	202	(12.0)
Percent with ER in past year, n (%)	105	(20.0)	423	(25.1)

8.2.4 Categorizing Pharmacists Recommendations

We photocopied the problem-oriented patient records maintained by pharmacies for the continuously eligible patients who received 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 13 displays the average number of different problem types, number of recommendations made, number of accepted recommendations, and time until recommendation acceptance. Table 14 displays the types of problems identified and types of recommendation appear in Table 15.

Table 13. 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 13; 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 15; 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 13; mean 2.6, median 2.0). The most common types of problem detected were: therapeutic monitoring needed (41.9% of patients, 16.7% of recommendations), untreated conditions (40.4% of patients, 17.6%

of recommendations), and under-treated conditions (37.0% of patients, 14.3% of recommendations) (Table14).

Table 14. Types of problem identified for a random sample of 203 patients who received PCM services.

	Patients (n=203)*		Recommendations (n=771)	
	N	%	N	%
PROBLEM TYPE				
Inappropriate/Suboptimal Dose	29	14.3	44	5.7
Inappropriate/Suboptimal Schedule	17	8.3	19	2.5
Inappropriate/Suboptimal Route	0	0	0	0
Therapeutic Duplication	9	4.4	9	1.2
Non-Formulary Request	0	0	0	0
Therapeutic Monitoring	85	41.9	129	16.7
Allergy	2	1.0	3	0.4
Actual ADE/ADR	15	7.4	23	3.0
Potential ADE/ADR	42	20.7	52	6.7
Medication Error	2	1.0	3	0.4
Med Use Without Indication/Unclear Indication	22	10.8	29	3.8
Untreated Condition	82	40.4	136	17.6
Undertreated Condition	75	37.0	110	14.3
Alternative Therapy	52	25.6	90	11.7
Min/No Evidence of Therapeutic Effectiveness.	8	3.9	8	1.0
Compliance or Drug Administration Issue/Convenience	58	28.6	79	10.2
Cost	9	4.4	9	1.2
Record Update	1	5.4	24	3.1
Unspecified Type	2	1.0	4	0.5

* There were several recommendations made per patient so column does not total 203.

Table 15. Types of recommendation made for a random sample of 203 patients who received PCM services.

	Patients (n=203)*		Recommendations (n=771)	
RECOMMENDATION TYPE	N	%	N	%
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 Accepted Recommendations			379	49.2

* There were several recommendations made per patient so column does not total 203.

8.3 Objective 2: Effect of PCM on Medication Safety

There were four methods used to determine the effect of PCM services on medication safety:

1. clinical pharmacist structured review of patients' pharmacy records (available only for those who received PCM services) to determine change in medication appropriateness from the day of first PCM eligibility to 9 months later;
2. evaluating change over nine months in use of high-risk medications for patients aged 60 and older who received PCM vs. those who did not;

3. evaluating the association of pharmacy PCM service intensity with change over nine months in use of high-risk medications for all PCM-eligible patients; and
4. evaluating change in number of active drugs and drug charges for those who received PCM vs. those who did not.

8.3.1 Medication Appropriateness: Structured Clinical Pharmacist Review For Those Who Received PCM Services

A clinical pharmacist rated medication appropriateness using the problem-oriented patient charts compiled by PCM pharmacists and active baseline and follow-up drug lists 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 six months before their initial PCM eligibility through 12 months after their initial PCM eligibility date and who received PCM services (n=507) were included in these analyses. Table 16 lists the ten MAI components that were evaluated for each drug and the weight each component was given when scoring the MAI.

Table 16. The Medication Appropriateness Index.

Appropriateness Component	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

Table 17 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.

Table 17 presents the proportion of medications with inappropriate ratings for each MAI criterion at each of the two time points for those who received PCM services. At follow-up, the percentage of inappropriate ratings decreased in all 10 MAI dimensions.

Overall, nearly half of medications and 92.9% of patients had at least one sign of inappropriate medication use in the baseline period (pre-PCM). The mean number of ingredients increased significantly from 7.9 to 9.0 among those who received PCM and the mean MAI score improved (decreased) significantly 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. These results indicate that, among participants receiving PCM services, the appropriateness of medications improved significantly from before to nine months after they became eligible for the services. This was in spite of an increase in mean number of active ingredients from baseline to follow-up (Table 17).

Table 17. Medication Appropriateness Index (MAI) ratings the day the patient became eligible for PCM (baseline) and nine months later (follow-up), adjusted for age and gender (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 Medi-cations Evaluated	N (%) Inappropriate	Total Medi-cations Evaluated	N (%) Inappropriate		Total People Evaluated	N (%) With Inappropriate Rating	Total People Evaluated	N (%) With Inappropriate Rating	
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=4141 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).

8.3.2 Change in Use of High-risk Medications: Those Who Received PCM vs. Those Who Did Not.

Because problem-oriented pharmacy charts were available only for patients who received PCM services, the detailed clinical pharmacist MAI ratings were not possible for those who did not receive PCM services. Instead, we attempted to construct measures of medication safety based only on pharmacy claims (which were available for all patients). Sufficient information was available in Medicaid pharmacy claims to allow construction of measures corresponding to four of the ten MAI components: effectiveness, dosage, drug-drug interaction, and duplications. Once constructed, we compared the claims-based measures with the corresponding clinical pharmacist MAI measures to evaluate their reliability and validity. Only the claims-based "effectiveness" measure 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 is considered good agreement). The kappa statistics for dosage and duplication were quite low (0.28 or less) suggesting considerable measurement error with the claims-based measures. 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 claims-based 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 from the claims-based measure so "agreement" was 100% by definition. The end result was that only the claims-based "effectiveness" measure had known and acceptable measurement properties. The other measures were either too imprecise (dosage and duplications) or have not been validated by comparison with clinical pharmacist review (drug-drug interactions).

To answer the question "is the medication effective for the condition?" the clinical pharmacist and the claims-based 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 inappropriate for use among those age 60 or over because the risks outweigh 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 high-risk medication use by 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 high-risk drugs is included in Table 18.

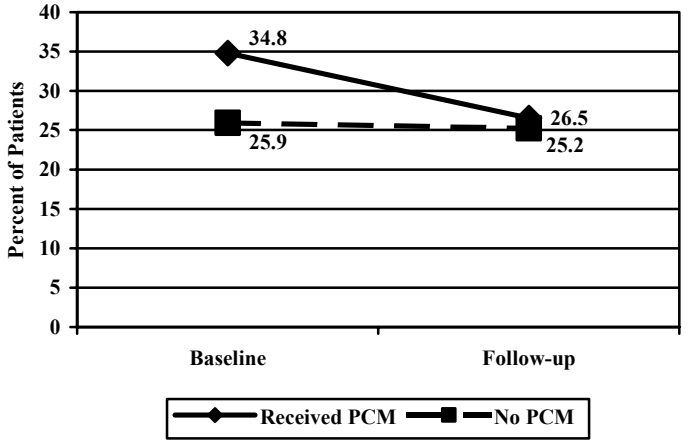
Table 18.High-risk medications whose potential risks outweigh their potential benefits (Beers MH. Arch Intern Med 1997;157:1531-6).

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

Figure 1 displays the effect of PCM services on use of these medications among PCM-eligible patients aged 60 and older. As illustrated in Figure 1, before receiving PCM services 34.8% of patients aged 60 and over who later 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 these patients, after receiving PCM services, the percent with high-risk 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 use of high-risk medications. Interestingly, patients who received PCM services had a higher baseline prevalence of high-risk drug use than did patients who did not receive PCM services. Patients selected because of extreme values on any measure are known to "regress toward the mean" of the distribution upon repeat measurement. Hence, some of the decline in use of high-risk medications may be due to the regression phenomenon.

Figure 1. Percent of PCM eligible patients aged 60 and over taking medications that are considered high-risk, i.e. potential risk outweighs potential benefits, by whether PCM was received.

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



After adjusting for age and gender, the significant intervention (PCM) by time interaction ($p<0.05$) indicates that PCM was associated with a significant decrease in percent of patients using high-risk medications (from 34.8% to 26.5%) compared with no PCM (from 25.9% to 25.2%).

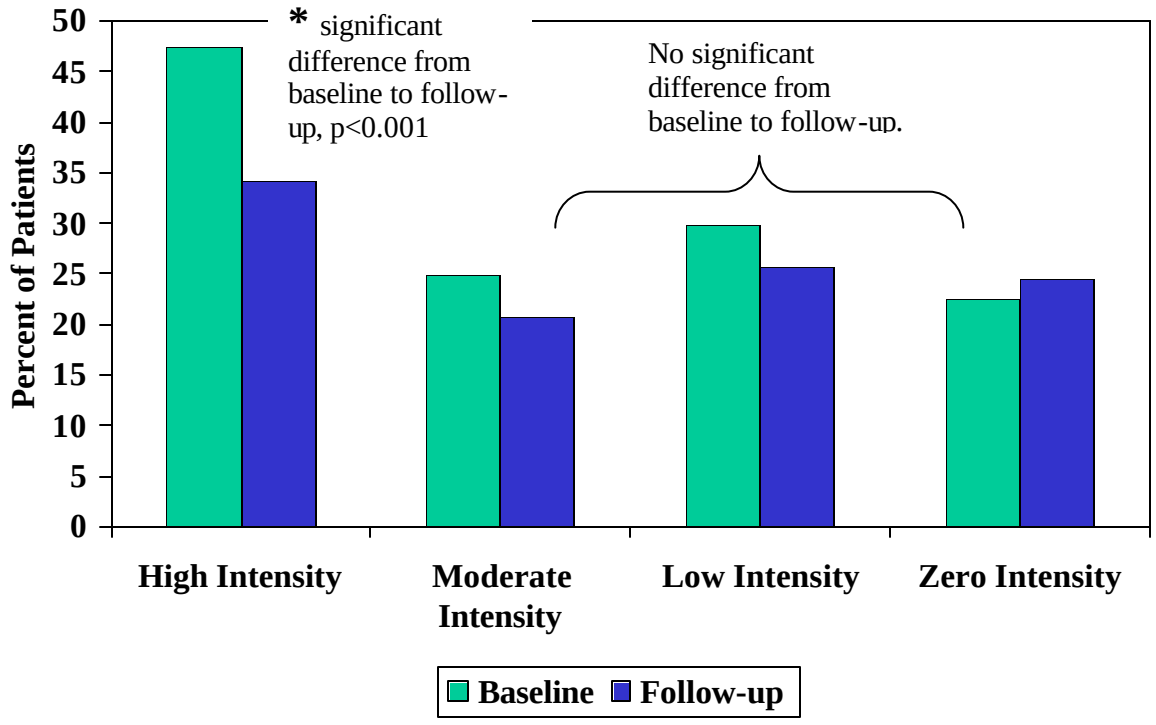
8.3.3 Effect of PCM Service Intensity on Use of High-risk Medications Among All PCM-eligible Patients

Another way to examine the effect of PCM services on medication appropriateness is to examine the change in use of high-risk medications over time for all of the PCM eligible patients. Because low intensity pharmacies provided PCM to few patients, the effect of PCM is likely not detectable in their patient populations (i.e., any intervention effect would be obscured 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 safety 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 also observed that PCM-eligible patients filling prescriptions at high intensity pharmacies had a higher baseline prevalence of high-risk medication use than did patients receiving prescriptions from lower intensity pharmacies.

Figure 2. Percent of PCM eligible patients aged 60 and over taking medications that are considered high-risk, i.e. potential risk outweighs potential benefits, by pharmacy intensity score.

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. The time by group interaction p-value (adjusted for age and gender) for high vs. zero intensity was statistically significant at p=0.037.



8.3.4 Effect of PCM Services on Number of and Charges for Active Drugs.

After adjusting for age and gender, PCM services had no significant effect on the net number of medications or medication charges (Table 19). The number of drugs and charges tended to increase both for eligible patients 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 on number of and charges for active drugs among patients receiving PCM services may have been neutral.

Table 19. Mean number of active drugs and mean Medicaid charges for active drugs the day of initial PCM eligibility (baseline) and nine months later (follow-up), by whether PCM services were received, adjusted for age and gender.

	Patients Who Received PCM Services (n= 524)			Eligible But Did Not Receive PCM Services (n=1,687)		
	Baseline	Follow-up	p-value	Baseline	Follow-up	p-value
Mean number of (SE) 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 (SE) amount billed per drug for active drugs, $	65.47	68.54	0.069	65.1	69.2	<0.001
Median (SE) amount billed per drug for active drugs, $	37.48	40.22	0.024	35.14	38.40	<0.001
By patient:						
Mean (SE) 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 (SE) 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.

8.4 Objectives 3-5: Effects of PCM 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. As shown in Table 20, neither health status nor satisfaction with pharmacists or physicians was observed to change. Patient expectations about the degree of collaboration between pharmacists and physicians were not associated with receipt of PCM services.

Table 20. 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=128)			Eligible But Did Not Receive PCM Services (n=330)		
	Baseline	Follow-up	p-value	Baseline	Follow-up	p-value
SF-36 mean summary 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 summary 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 2-3 days/week or more and having >= 3 drinks per occasion	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)	19.3 (0.3)	19.4 (0.3)	0.691	18.9 (0.2)	19.2 (0.2)	0.797
Mean expectations of pharmacist score (higher score is better, possible range is from 12 to 84)	65.4 (1.1)	64.8 (1.1)	0.421	63.2 (0.7)	62.8 (0.7)	0.378
Mean physician satisfaction score (higher score is better, 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 better, possible range 4 -28		24.0 (0.6)			23.(0.4)	0.168
By Intensity:			0.536			0.808
Zero		25.7			23.1	
Low		24.5			22.8	
Moderate		24.1			23.8	
High		23.0			22.3	

8.5 Objective 6: Effects of PCM on Healthcare Utilization

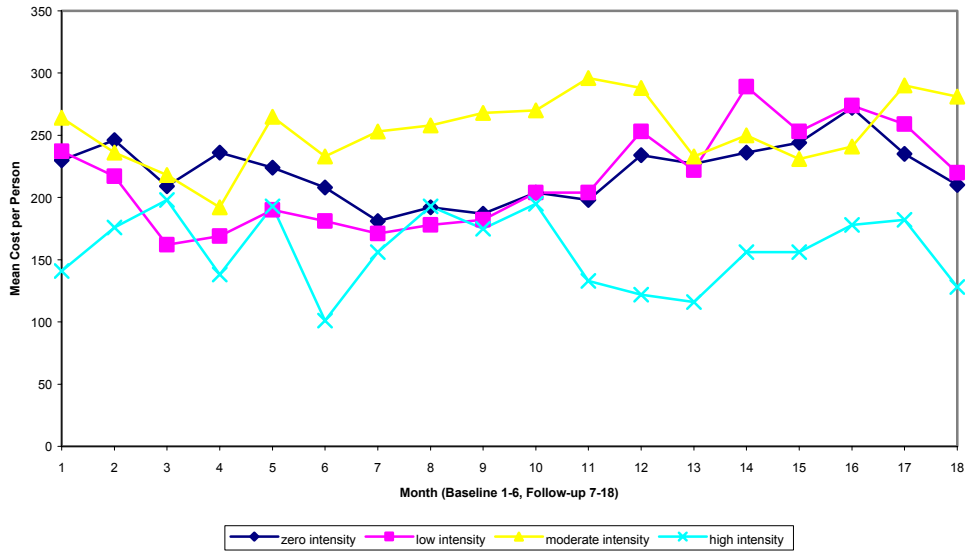
A secondary objective of the PCM evaluation was to examine the short-term effects of PCM on healthcare utilization. Measures included numbers of claims and charges to Medicaid for pharmacy, institutional, and medical services. Four analytical methods were used and several comparisons were made.

First, the age- and gender-adjusted mean number of monthly claims and mean monthly charges were plotted for those who received PCM services and for those who were eligible for PCM services but did not receive them. Included in these analyses were all PCM-eligible patients who were continuously eligible for Medicaid from six months before PCM eligibility through 12 months after. Patterns of change over time were compared using a type of repeated measures analysis. This method tested whether the two groups (PCM vs. no PCM) differed in their rate of change in monthly claims or monthly charges from 6 months before through 12 months after becoming eligible for PCM. A significant time by group (PCM/noPCM) interaction would have indicated that the rate of change in mean claims or charges differed between groups. These analyses were performed for each claim type. For all six claim types (pharmacy, medical, hospital, emergency room, other outpatient facility, and long-term care) analyses consistently found no significant difference in change in mean number of monthly claims or mean monthly charges between PCM eligible patients who received the service and those who did not (see charts in Appendix C). The "medical claims file" actually is a file of all types of healthcare providers who bill for their services on a HCFA 1500 claim form. Of considerable interest was that the PCM claims from both pharmacies and physicians are included in the "medical" claims analysis (because they are submitted on a HCFA 1500 claim form so they reside in the medical claims file). In spite of including the charges for PCM services in these analyses, there was no

significant effect of PCM on charges for services billed on a HCFA 1500 form (i.e. claims in the Medicaid medical claims file).

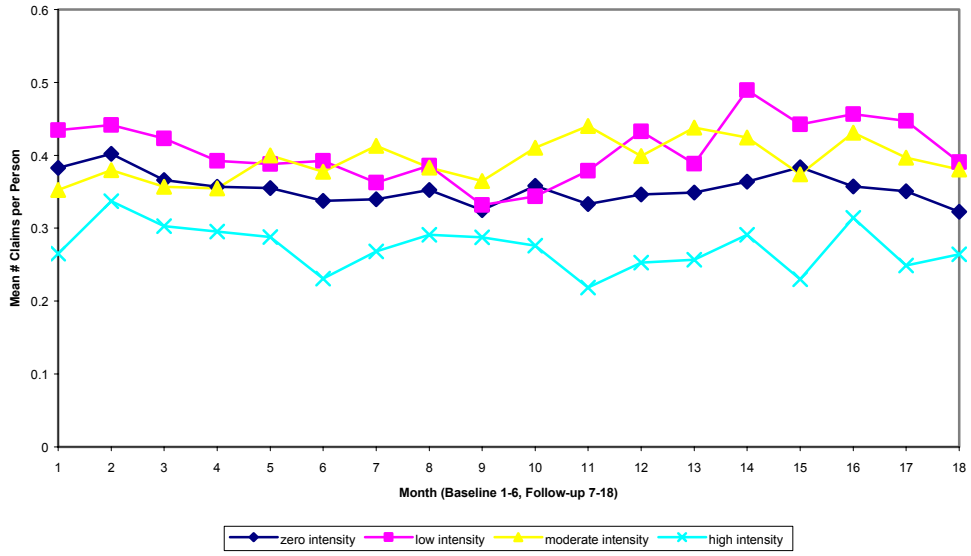
Second, we compared change in utilization over time across the four PCM service intensity groupings of pharmacies, including all PCM-eligible patients. There were significant intensity by time interactions for the number of emergency room claims, and the number and charges for outpatient facility claims (Figures 3-5). In all three cases, patients of high PCM intensity pharmacies had lower claims and/or charges than did patients of lower PCM intensity pharmacies. This suggests that a higher intensity of PCM services may have reduced ER and Outpatient facility visits.

Figure 3. Mean amount billed per month to Medicaid for outpatient facility care (excluding emergency room), by pharmacy PCM service intensity, data through May 31, 2002, n=2,211 continuously eligible patients.



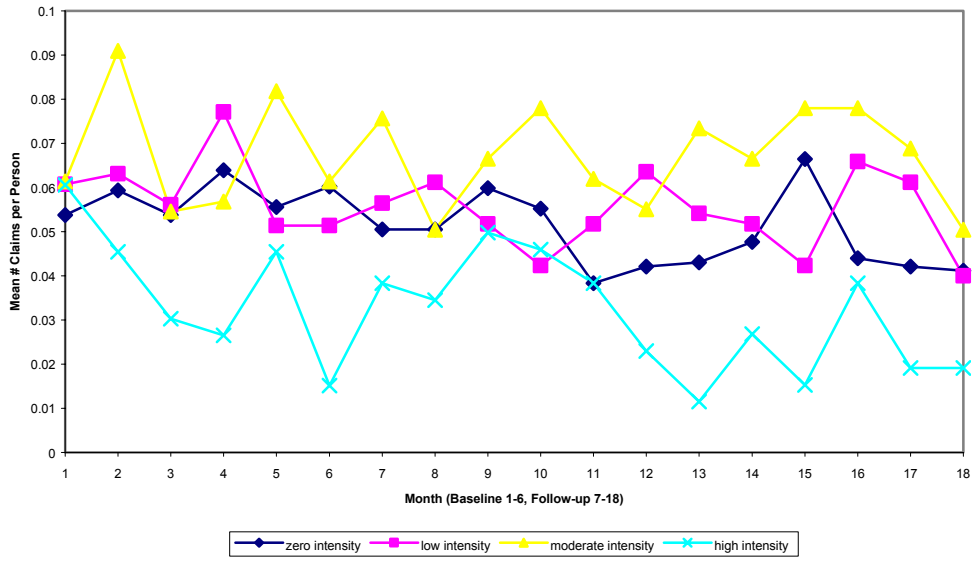
Adjusted for age and gender, the significant intensity by time interaction ($p<0.05$) indicates that higher intensity of PCM was associated with significantly less increase in outpatient facility charges.

Figure 4. Mean number of outpatient facility claims paid per month (excluding emergency room), by pharmacy PCM service intensity, data through May 31, 2002, n=2,211 continuously eligible patients.



Adjusted for age and gender, the significant intensity by time interaction ($p<0.05$) indicates that higher intensity of PCM was associated with significantly less increase in outpatient facility use.

Figure 5. Mean number of emergency room claims paid per month, by pharmacy PCM service intensity, data through May 31, 2002, n=2,211 continuously eligible patients.



Adjusted for age and gender, the significant intensity by time interaction ($p<0.05$) indicates that higher intensity of PCM was associated with a significant decrease in emergency room use.

Third, because PCM claims were included in the HCFA 1500 claims file we continued our investigation of the effect of PCM on HCFA 1500 claims and charges. We tested whether there were PCM participation effects in subgroups of patients. Patients were grouped according

to characteristics known to influence receipt of PCM (age, gender, and number of medications). We then compared subgroups of patients to determine whether those who received PCM differed from those who did not receive PCM in their rate of change in monthly HCFA 1500 charges. Table 21 displays the results of these analyses. The table represents the cross-tabulation of four age categories (<18, 18-44, 45-64, 65+), three categories of number of drugs (1-6, 7-9, 10+), and two gender categories, together yielding 24 combinations of these variables. Of the 24 combinations, 18 had a sufficient number of patients with which to conduct statistical tests. Of the 18 groups of patients, in no group was there a statistically significant difference between those who received PCM vs. those who did not in the pattern of monthly HCFA 1500 charges over time.

Table 21. Change in charges billed through HCFA 1500 forms from Baseline to Follow-up, PCM vs. No PCM comparisons within subgroups defined by age, number of drugs, and gender.

There were no statistically significant time by intervention interactions indicating that the pattern of change within these subgroups was the same for those receiving PCM as for no PCM.

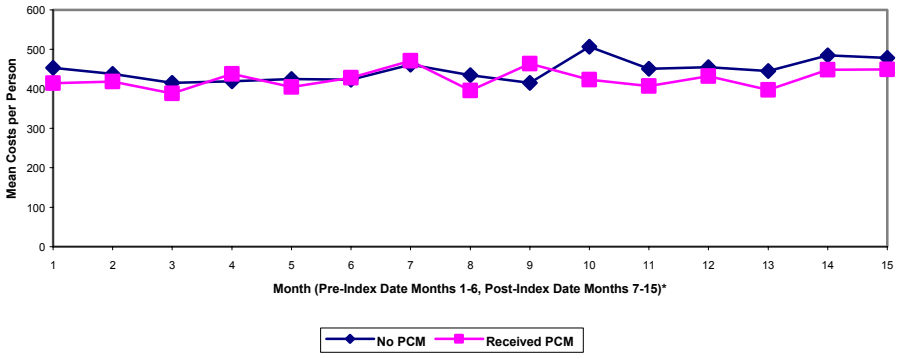
Age Group	# of Drugs	Gender	Intervention	N	Mean Baseline	Stderr	Mean Followup	Stderr	Mean Difference	Stderr
Age <18	1-6 drugs	F	No PCM	35	1132	356	2192	788	1060	515
Age <18	1-6 drugs	F	PCM	10	7729	5695	6176	3151	-1553	2791
Age <18	1-6 drugs	M	No PCM	71	1359	299	3039	705	1680	513
Age <18	1-6 drugs	M	PCM	9	1382	815	3563	1873	2181	1124
Age <18	7-9 drugs	F	No PCM	12	7214	2678	13440	3672	6226	1890
Age <18	7-9 drugs	F	PCM	3	9143	8954	17679	16508	8536	7562
Age <18	7-9 drugs	M	No PCM	13	3179	1110	11070	3199	7891	2882
Age <18	7-9 drugs	M	PCM	0						
Age <18	10+ drugs	F	No PCM	3	9570	6603	30677	15513	21107	14594
Age <18	10+ drugs	F	PCM	0						
Age <18	10+ drugs	M	No PCM	1	2567		875		-1692	
Age <18	10+ drugs	M	PCM	0						
Age 18-44	1-6 drugs	F	No PCM	198	2355	384	4968	762	2612	422
Age 18-44	1-6 drugs	F	PCM	41	3946	1392	6984	2625	3037	1359
Age 18-44	1-6 drugs	M	No PCM	118	4425	788	9152	1608	4727	947
Age 18-44	1-6 drugs	M	PCM	18	2352	1465	4302	3057	1950	1765
Age 18-44	7-9 drugs	F	No PCM	91	5209	871	9587	1654	4378	921
Age 18-44	7-9 drugs	F	PCM	21	1014	292	4146	1243	3132	1169
Age 18-44	7-9 drugs	M	No PCM	26	8613	2190	16779	4225	8167	2230
Age 18-44	7-9 drugs	M	PCM	7	4278	3613	10052	5982	5774	2995
Age 18-44	10+ drugs	F	No PCM	62	3306	838	6581	2034	3275	1300
Age 18-44	10+ drugs	F	PCM	21	3245	1386	8368	3580	5123	2442
Age 18-44	10+ drugs	M	No PCM	18	3382	1729	5383	3521	2001	2033
Age 18-44	10+ drugs	M	PCM	3	13634	10964	26938	22393	13304	11432
Age 45-64	1-6 drugs	F	No PCM	167	1946	377	4284	746	2338	468
Age 45-64 (continued)	1-6 drugs	F	PCM	61	3773	1011	7888	1993	4116	1116

Age Group	# of Drugs	Gender	Intervention	N	Mean Baseline	Stderr	Mean Followup	Stderr	Mean Difference	Stderr
Age 45-64	1-6 drugs	M	No PCM	105	4154	836	9303	1832	5149	1066
Age 45-64	1-6 drugs	M	PCM	19	2300	1303	4911	2853	2611	1665
Age 45-64	7-9 drugs	F	No PCM	152	1878	304	4880	841	3002	684
Age 45-64	7-9 drugs	F	PCM	50	2735	797	5095	1502	2360	871
Age 45-64	7-9 drugs	M	No PCM	54	3069	747	6399	1709	3330	1166
Age 45-64	7-9 drugs	M	PCM	12	1653	993	2634	1108	981	1095
Age 45-64	10+ drugs	F	No PCM	158	2500	282	5211	578	2710	437
Age 45-64	10+ drugs	F	PCM	61	2008	358	4213	679	2205	481
Age 45-64	10+ drugs	M	No PCM	39	1851	424	7612	2194	5762	2074
Age 45-64	10+ drugs	M	PCM	14	3357	1144	7022	2019	3665	1060
Age 65+	1-6 drugs	F	No PCM	140	1172	224	2393	381	1221	205
Age 65+	1-6 drugs	F	PCM	54	643	186	1823	366	1180	221
Age 65+	1-6 drugs	M	No PCM	40	1440	607	2996	1260	1556	659
Age 65+	1-6 drugs	M	PCM	10	1501	1143	956	487	-545	1121
Age 65+	7-9 drugs	F	No PCM	79	1352	306	2763	641	1410	352
Age 65+	7-9 drugs	F	PCM	52	953	212	2293	438	1340	277
Age 65+	7-9 drugs	M	No PCM	18	881	248	2157	460	1277	332
Age 65+	7-9 drugs	M	PCM	9	2853	2408	7171	5204	4318	2804
Age 65+	10+ drugs	F	No PCM	72	1921	560	4453	1143	2532	632
Age 65+	10+ drugs	F	PCM	45	1334	238	3237	514	1903	345
Age 65+	10+ drugs	M	No PCM	15	2177	517	4135	1015	1958	570
Age 65+	10+ drugs	M	PCM	4	387	280	827	548	440	277

Fourth, because PCM services were not provided instantaneously at the time a patient became eligible for PCM (21% of PCM services occurred more than six months after eligibility and 10% occurred more than nine months after eligibility), some patients had very little time after receipt of PCM and to the end of the 12 month follow-up. To equalize the available follow-up time after first receiving PCM, we further analyzed HCFA1500 billed charges by re-setting the index date for those who received PCM to the patient's first PCM claim service date. We included only PCM recipients who had continuous Medicaid eligibility from six months before through nine months after their first PCM service date. The index date for the comparison group (those who did not receive PCM) remained the date of PCM eligibility. There was no significant difference in change over time of mean monthly HCFA 1500 billed charges between PCM eligible patients who received the service and those who did not (Figure 6).

Figure 6. Mean HCFA 1500 billed charges per person, from 6 months before the index date* through 9 months after the index date, n=2,211**

There was no significant time by intervention interaction, indicating no difference between groups in the pattern of these charges over time.



* Index Date for the no PCM group was the date first eligible for PCM;
Index Date for the group that received PCM was the date of first PCM service

** Patients continuously eligible for Medicaid from 6 months before through 9 months after the index date, n=2211

8.6 Objective 7: Effects of PCM on Physician and Pharmacist Attitudes

Provider opinions about PCM services were obtained in several 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. Questionnaires were also faxed to a random sample of physicians known to have received PCM recommendations from participating pharmacists.

8.6.1 In-person Pharmacist Interviews

The purpose of the in-person pharmacist interviews was to ascertain the obstacles faced by the pharmacists during their provision of PCM services and to identify strategies that 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 22. 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.

Table 22. 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

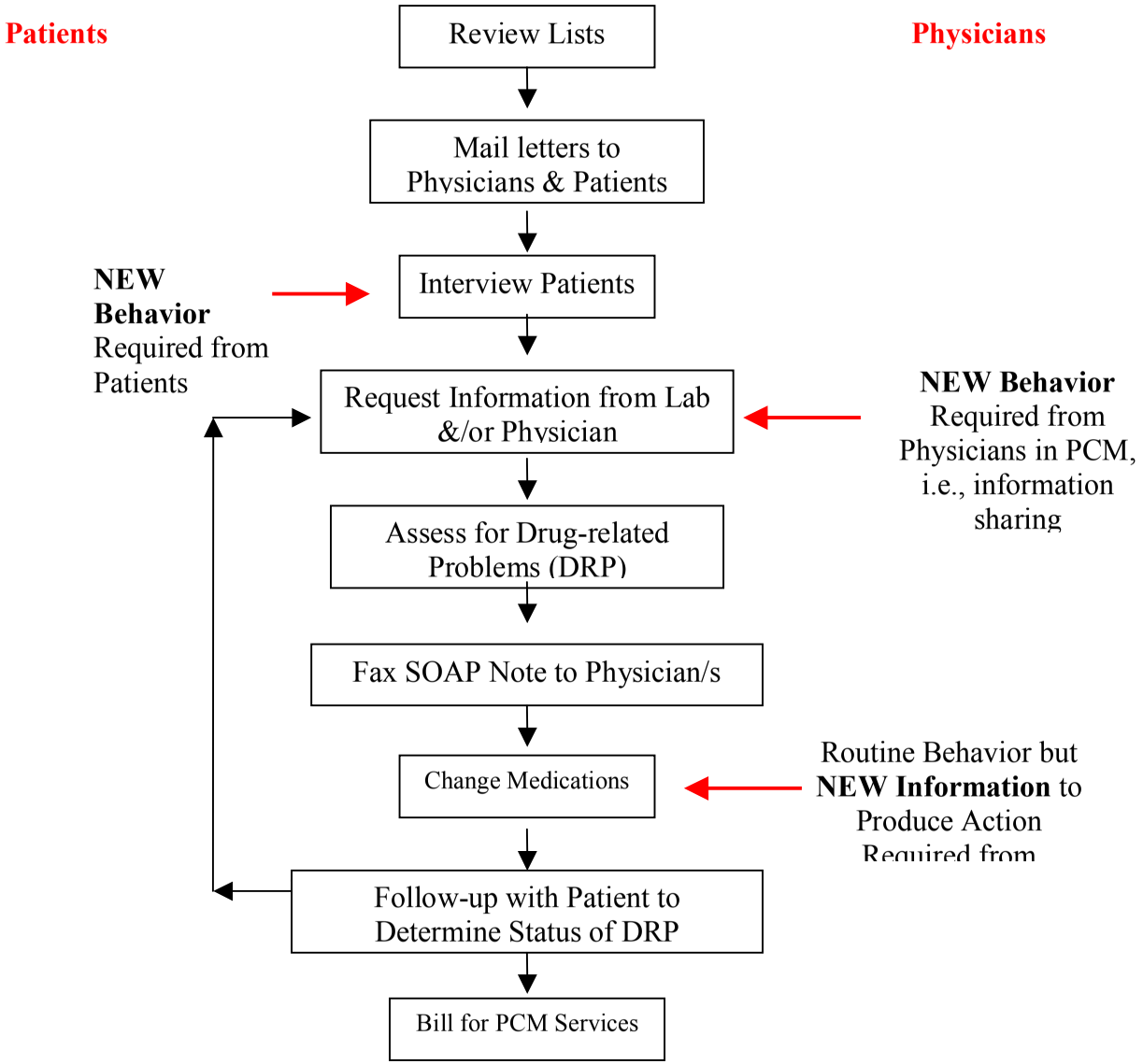
Figure 7 outlines the behaviors required by patients, pharmacists and physicians in the PCM program. It highlights that new behaviors have been required by individuals besides pharmacists in order to deliver high quality PCM services. For example, physicians were often asked to provide pharmacists with 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 interviews with pharmacists, there is considerable variation in physician and patient response. When two important participants 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 7 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 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). 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 information from laboratories and 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.

Figure 7. Behaviors required in order to provide Pharmaceutical Case Management.



8.6.2 Pharmacist Large-group Discussion

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

8.6.2.1 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.

8.6.2.2 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 laboratories. CLIA-wavered laboratory tests 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.

8.6.3 Pharmacist Surveys

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. To date, 61 pharmacist surveys have been returned from a total of 51 pharmacists.

The mean age of pharmacists who responded was 39.6 years (range; 25-61 years; n=49). Twenty-one (42.9%) were male. Thirty-seven (74.0%) practiced in an independent retail setting, 8 (16.0%) practiced in a chain retail setting, and the remainder practiced in a clinic or hospital setting. Twenty-five pharmacists (51.0%) were owners or managers in their practice settings, and the remainder were staff pharmacists (two did not specify). One-third of pharmacists possessed

the Doctor of Pharmacy degree; the remainder possessed the Bachelor of Science degree (three pharmacists did not specify). Respondents had practiced pharmacy an average of 14.4 years (range, 1-38 years; n=49). Thirty-six (72.0%) of pharmacists worked in a pharmacy that filled more than 125 prescriptions a day. The mean number of full-time pharmacist equivalents per pharmacy was 2.8 (range, 1-11; n=49), and the mean number of full-time pharmacy technician equivalents per pharmacy was 3.8 (range, 1-18; n=49)

Pharmacists were first asked to consider a physician with whom they had communicated the most about case management patients. They were then presented with a series of statements regarding these communications, to which they indicated their level of agreement using a Likert-type scale ranging from 1 (very strongly disagree) to 7 (very strongly agree).

Pharmacists agreed that there was cooperation between physicians and themselves in managing the drug therapy of case management patients (mean score 5.1; n=57), and that agreement on the pharmacist's role in managing drug therapy is reached by working together (mean score 4.9; n=57). They also expected to continue collaborating with the physician (mean score 5.5; n=57), and agreed that the physician could be counted on to do what he/she says (mean score 5.3; n=57). They agreed slightly that open communications with the physician took place as decisions about patient care were made (mean score 4.8; n=57). Four pharmacists (7.0%) agreed that they did NOT cooperate with the physician in making decisions about care of case management patients. Overall, pharmacists agreed that communications with the physician about drug therapy led to better quality of care, better health outcomes, and increased continuity of care for case management patients (mean scores 5.6, 5.5, and 5.6, respectively; n=57). Pharmacists agreed that providing pharmaceutical case management services is an important part of their job responsibility (mean score 5.2; n=57).

Slightly less than half (25 of 57) of pharmacists agreed that providing pharmaceutical case management services is frustrating, and one-fourth (14 of 57) felt that the rules and procedures for case management were confusing. Half (29 of 57) reported that it was hard to get physicians to send clinical information about case management patients.

Pharmacists agreed that pharmaceutical case management strengthened their relations with physicians (mean score 4.9; n=57) and that physicians were willing to consider case management recommendations made by them (mean score 5.3; n=57). They also agreed that patients appreciated the services (mean score 5.3; n=56) and that it strengthened their relations with patients (mean score 5.6; n=57). They agreed that most patients who were eligible for pharmaceutical case management really needed the service (mean score 5.4; n=57) and that many patients who were NOT eligible for case management really needed the service (mean score 5.6; n=57).

Using the same Likert scale, pharmacists were asked about payment for their role in Pharmaceutical Case Management. In general, pharmacists indicated strong agreement that they understood that they could bill for collaborating with physicians about case management patients (mean score 5.9; n=56). They also indicated agreement regarding knowledge of which case management activities were billable (mean score 5.4; n=56). They agreed slightly that case management billing procedures were convenient (mean score 4.6; n=56) and easy to understand (mean score 4.8; n=55).

8.6.4 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 203 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 total of 70 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. To date, responses have been received from 25 physicians.

The mean age for physicians who responded was 48.4 years (range, 27-78 years). Sixteen (73%) were male (three did not indicate a gender). Nineteen physicians specialized in Family Medicine, and one in internal medicine (5 did not indicate a specialty). Seventeen of the physicians were Board Certified. The physicians had an average of 18.8 years experience practicing medicine (range, 2-53 years). The majority (65%) of physicians practiced in a private, non-HMO or non-academic setting. Two physicians saw more than 125 patients per week on average, 14 physicians saw between 76-125 patients per week, and 6 saw less than 76 patients per week (3 physicians did not respond).

Physicians were first asked to consider a pharmacist with whom they had communicated the most about case management patients. They were then presented with a series of statements regarding these communications, to which they indicated their level of agreement using a Likert-type scale ranging from 1 (very strongly disagree) to 7 (very strongly agree).

Physicians agreed that there was cooperation between the pharmacist and themselves in managing drug therapy of patients (mean score 5.0; n=23). They strongly agreed that the pharmacist was credible, and that they could count on the pharmacist to do what he/she said (mean score 6.0; n=23). They agreed that they would continue to collaborate with this pharmacist (mean score 5.5; n=23). Four physicians (17.4%) indicated that they did NOT cooperate with the

pharmacist in making decisions about care of case management patients, and that working with this pharmacist is a 'waste of time' . Overall, physicians agreed slightly that discussions with the pharmacist about drug therapy led to better quality of care, better health outcomes, and increased continuity of care for case management patients (mean scores 4.7, 4.5, and 4.9, respectively; n=22).

Using the same Likert scale, physicians were asked about payment for their role in Pharmaceutical Case Management. They were neutral about the statement "I understand that I may bill for collaborating with pharmacists about case management patients" (mean score 4.0; n=22). They disagreed with the statement "I know which case management activities are billable" (mean score 3.0; n=22), and did not agree that they understood the process of submitting a bill for providing case management services (mean score 3.1; n=22).

9 Discussion

Iowa Medicaid PCM services were founded on a solid body of evidence which demonstrates 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 three months of a patient's eligibility for PCM, 146 pharmacists in 114 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 these services 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 made by pharmacists 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. In addition, this was necessarily an evaluation of short-term effects of PCM. Health status and healthcare utilization benefits likely require a longer time to be realized.

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 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.[3,28,29]

Previous studies have used the MAI to evaluate interdisciplinary team interventions in institutional settings involving a small number of care providers. 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.[27] 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 the use of high risk medications. Provision of PCM services was associated with a decrease in use of high-risk 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 percentage of these patients taking high-risk 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 full service (22.7%). The effort to start up this new service rested largely with the pharmacist. When a pharmacy received its list of eligible patients, a pharmacist contacted the patients, scheduled appointments, met with them, obtained additional information from their physician if necessary, completed their assessment, and forwarded a written recommendation to the physician. Unlike the typical doctor's office with staff to perform these

types of duties, pharmacies lack such staff. 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, many pharmacists were still attempting to meet with patients or complete work-ups when they received the three-month fax survey. 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.

Even though 49.2% of physicians accepted pharmacist recommendations when PCM was provided, 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) sometimes after 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.[12,30-38] 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.[30] 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[37] 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.[38] 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.[31] 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 the PCM program 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.[32-35] 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.[35]

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 and lack of knowledge about billing procedures from the physician survey. 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 time they had to expend required reimbursement.

A major priority for expanding PCM service rates will be outreach from the Iowa Department of Human Services (DHS) 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, other community pharmacy-based 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 have a high probability of inappropriate therapy. However, pharmacists, physicians, and patients should be encouraged to begin PCM for patients with multiple medications who desire the service, without waiting for the patient's name to appear on a list for a particular pharmacy. In particular, all patients who are eligible to receive PCM should be informed about their eligibility by the DHS. 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.

10 Conclusion

PCM services were delivered to Iowa Medicaid 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. Despite a reasonable payment, 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 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 call for efforts to develop these services in a higher percentage of community pharmacies.

11 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. Annals of Pharmacotherapy (forthcoming).
24. Carter BL, Chrischilles EA, Scholz D, Hayase N, Bell N. Extent of services provided by pharmacists in the Iowa Medicaid Pharmaceutical Case Management program. J Am Pharm Assoc 2002;42 (6):
25. Carter BL, Lund BC, Hayase N, Chrischilles E. The extent of potential antihypertensive drug interactions in a Medicaid population. Am J Hypertens 2002;15:953-7.
26. Tatro DS (ed): Drug Interaction Facts. St. Louis, Missouri, Facts and Comparisons, 2001, 1-776.

27. 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.
28. 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.
29. 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.
30. Rupp MT. Value of community pharmacists' interventions to correct prescribing errors. Ann Pharmacother 1992;26:1580-4.
31. Barnette DJ, Murphy CM, Carter BL. Clinical skill development for community pharmacists. J Amer Pharm Assoc 1996;36:573-81.
32. 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.
33. 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.
34. 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.

35. 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.

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

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

38. 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.

12 Appendices

12.1 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:

Initial Assessment

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.

New 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

12.2 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)

12.3 Appendix C. Medicaid Claims and Charges

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.

Figure 8. 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.

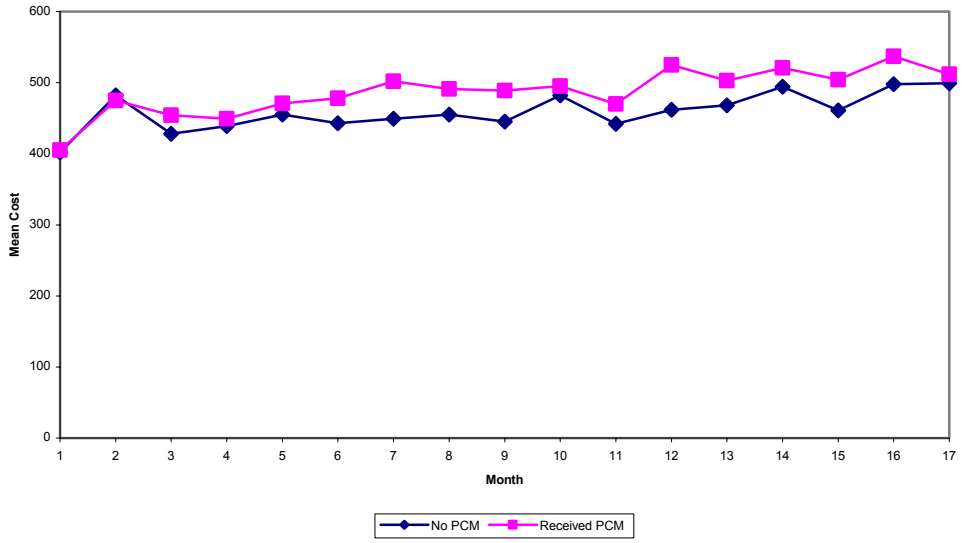


Figure 9. Mean number of claims paid per month for medications, according to whether PCM services were received, data through May 31, 2002, n=2,211 continuously eligible patients.

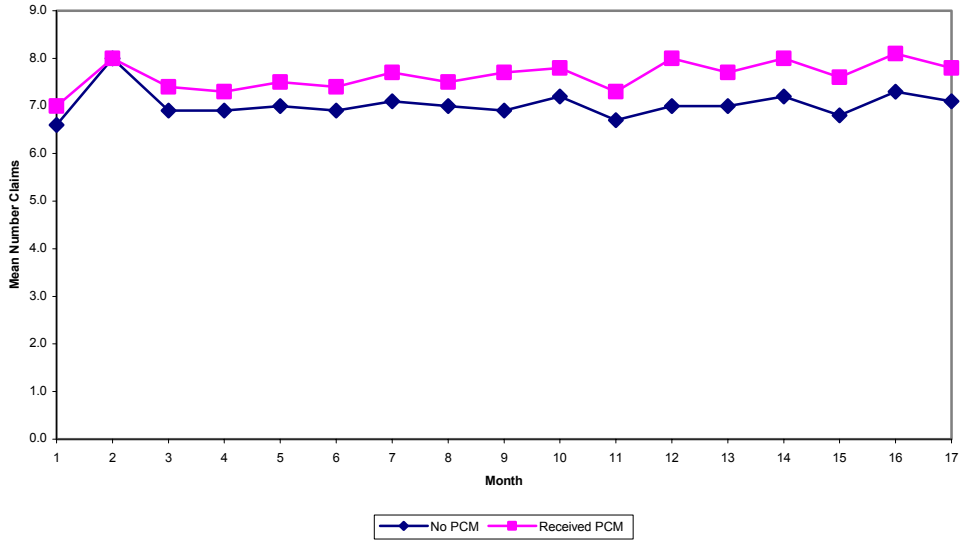


Figure 10. Mean amount billed per month to Medicaid for medical services (i.e. services billed on a HCFA1500 form), according to whether PCM services were received, data through May 31, 2002, n=2,211 continuously eligible patients.

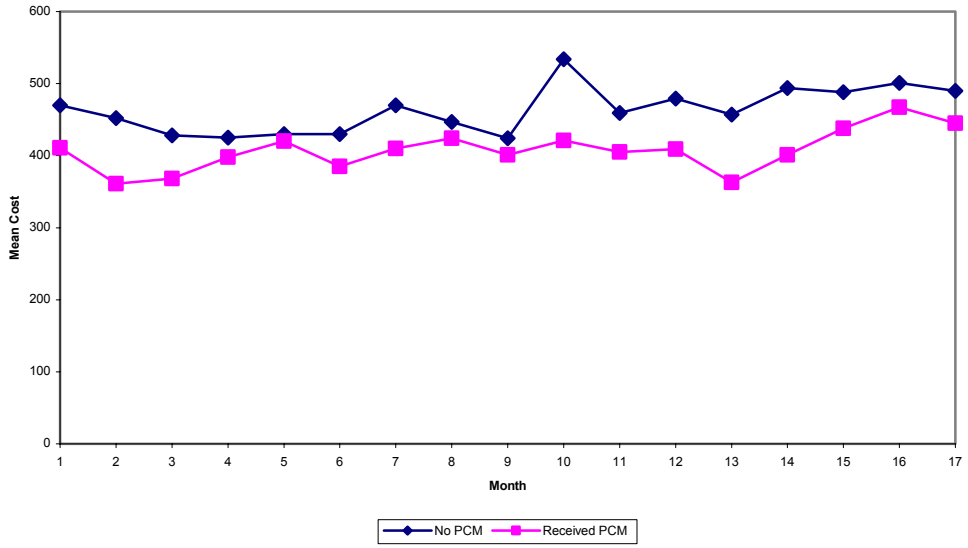


Figure 11. Mean number of claims paid per month for services billed on HCFA1500 forms, according to whether PCM services were received, data through May 31, 2002, n=2,211 continuously eligible patients.

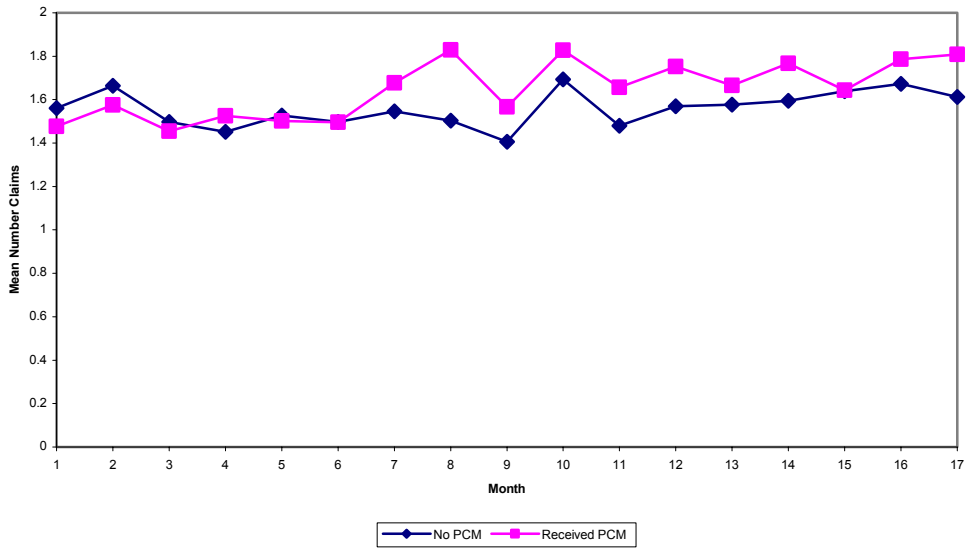


Figure 12. Mean amount billed per month to Medicaid for acute inpatient facility care, according to whether PCM services were received, data through May 31, 2002, n=2,211 continuously eligible patients.

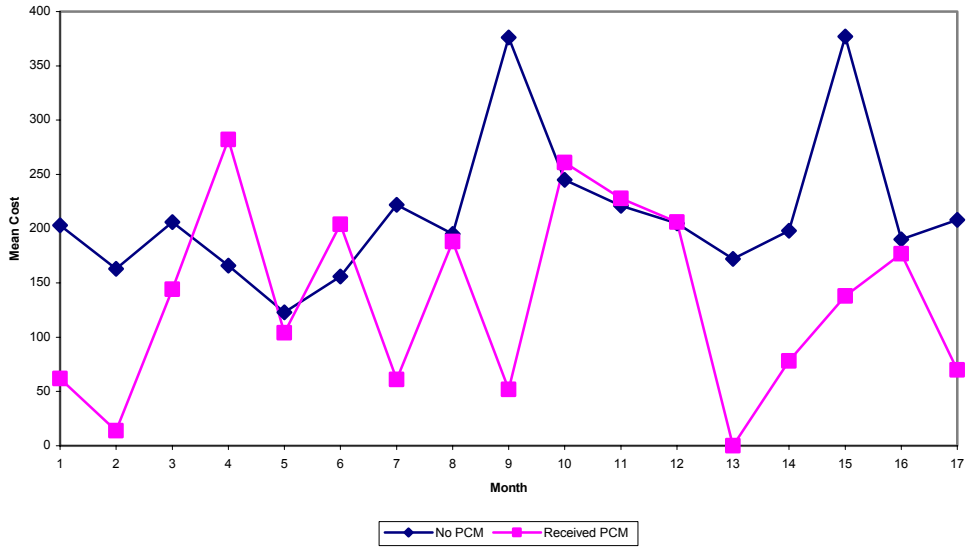


Figure 13. Mean number of claims paid per month for acute inpatient facility care, according to whether PCM services were received, data through May 31, 2002, n=2,211 continuously eligible patients.

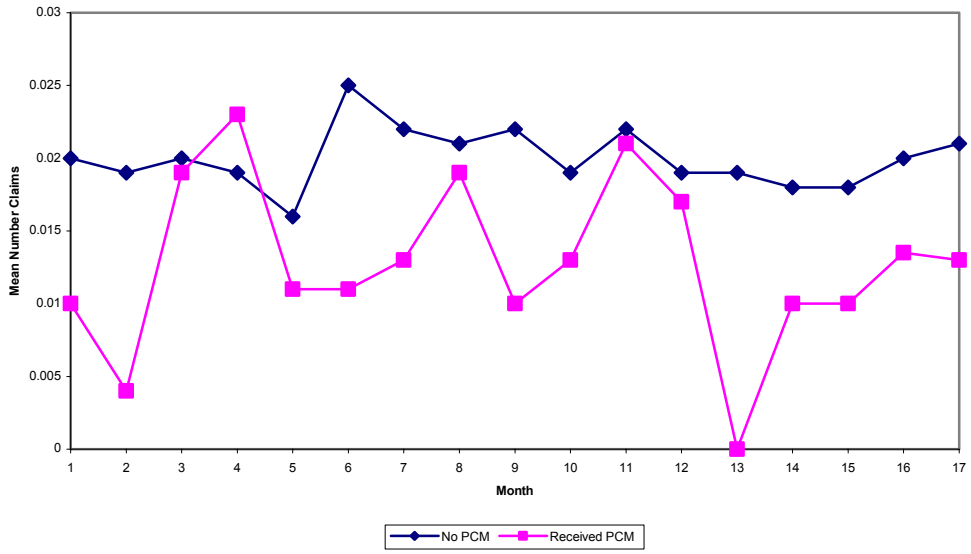


Figure 14. Mean amount billed per month to Medicaid for emergency room visits, according to whether PCM services were received, data through May 31, 2002, n=2,211 continuously eligible patients.

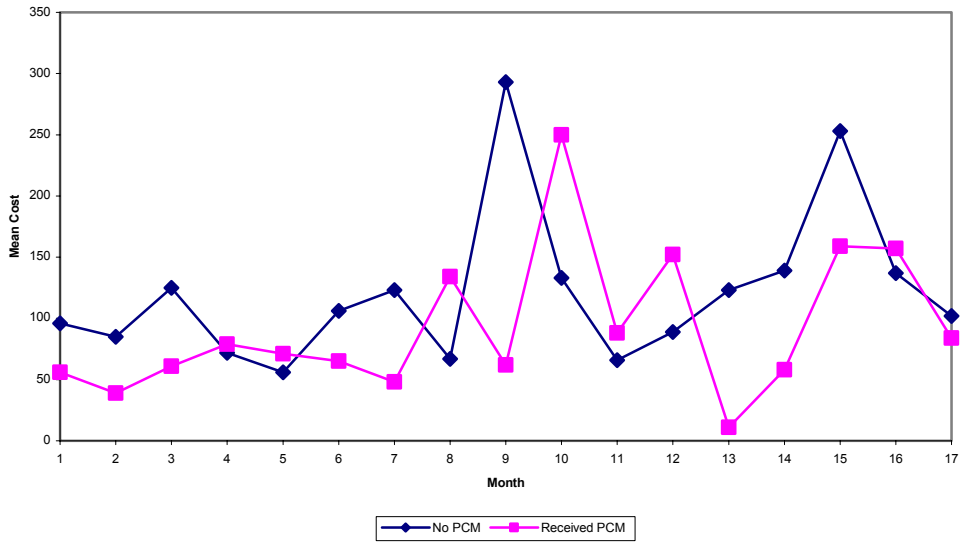


Figure 15. Mean number of emergency room claims paid per month, according to whether PCM services were received, data through May 31, 2002, n=2,211 continuously eligible patients.

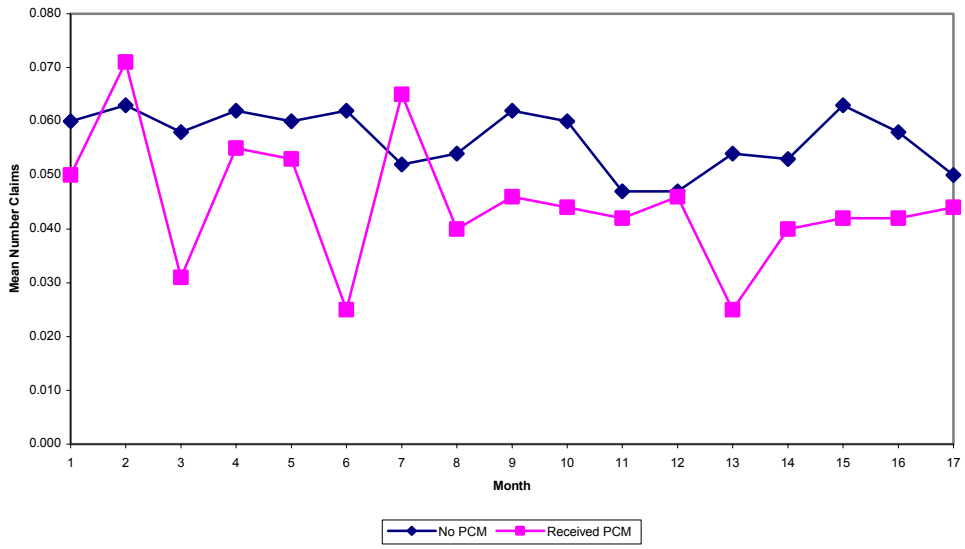


Figure 16. Mean amount billed per month to Medicaid for outpatient facility care (not including emergency room), according to whether PCM services were received, data through May 31, 2002, n=2,211 continuously eligible patients.

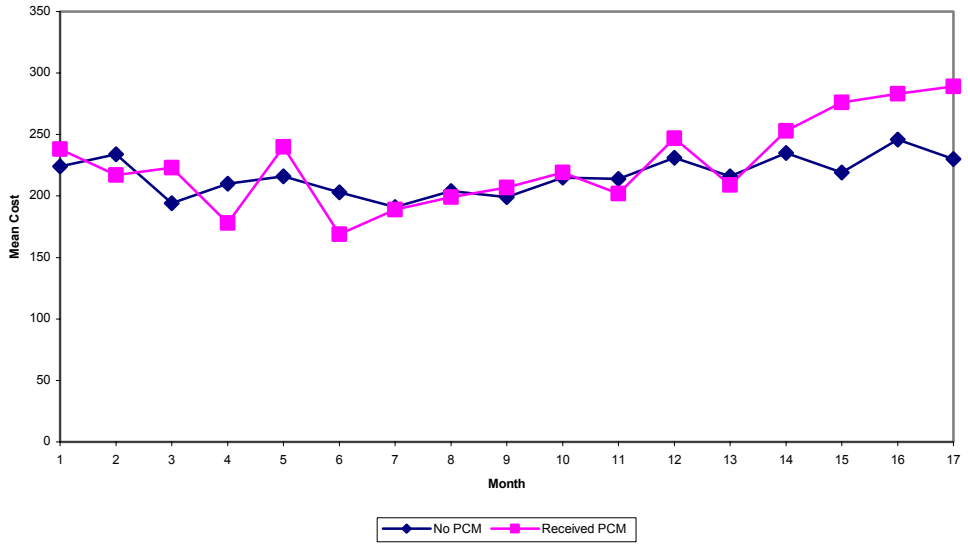


Figure 17. Mean number of claims paid per month for outpatient facility care, according to whether PCM services were received, data through May 31, 2002, n=2,211 continuously eligible patients.

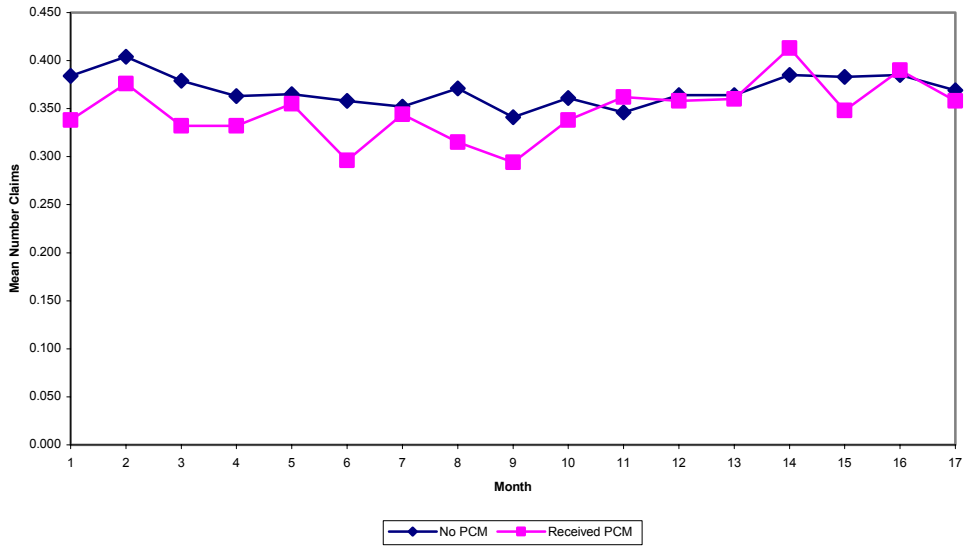


Figure 18. Mean amount billed per month to Medicaid for long-term institutional care, according to whether PCM services were received, data through May 31, 2002, n=2,211 continuously eligible patients.

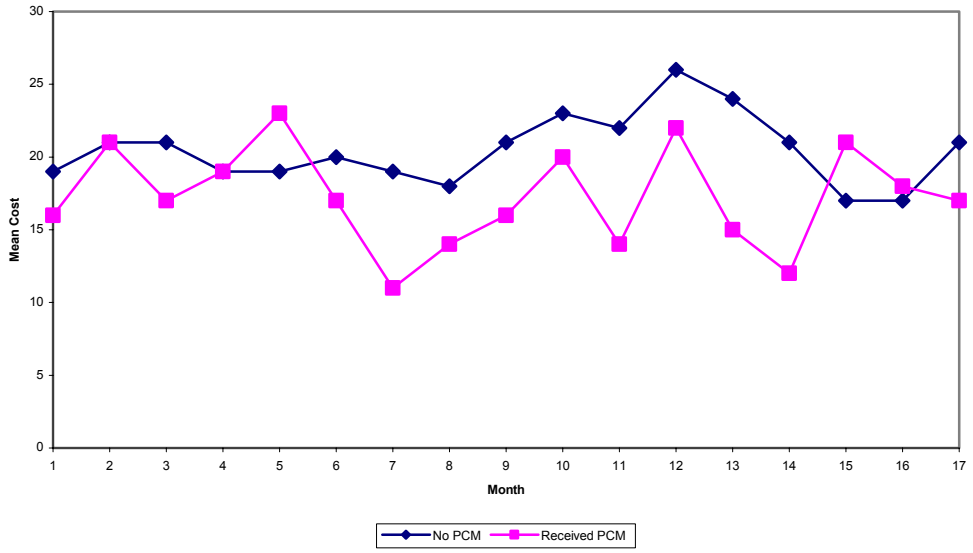
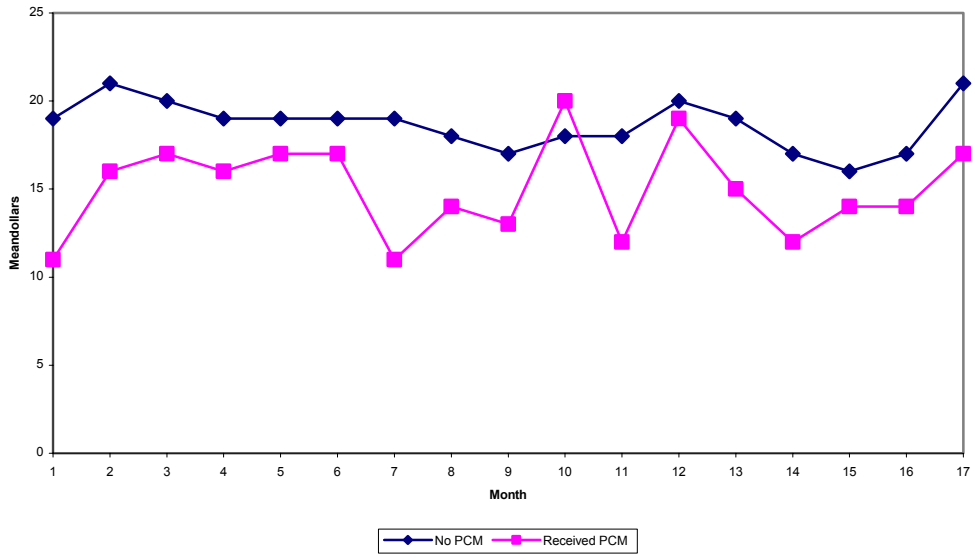


Figure 19. Mean number of long-term institutional care claims paid, according to whether PCM services were received, data through May 31, 2002, n=2,211 continuously eligible patients.



13 Technical Appendices – Available on Request:

13.1 Technical Appendix 1. Methodology for Identifying Active Drug Lists

13.2 Technical Appendix 2. Methodology for Medication Appropriateness Rating

13.3 Technical Appendix 3. Patient Survey

13.4 Technical Appendix 4. Pharmacist and Physician Survey Instruments