P R A C T I C E  R E P O R T

The Iowa Continuity of Care study: Background and methods

BARRY L. CARTER, KAREN B. FARRIS, PAUL W. ABRAMOWITZ, DAVID B. WEETMAN, PETER J. KABOLI, JEFFREY D. DAWSON, PAUL A. JAMES, ALAN J. CHRISTENSEN, AND JOHN M. BROOKS

Purpose. The background and methods of an ongoing study to determine the effects of hospital pharmacists’ enhanced communication with patients and their community providers are described.

Summary. The Iowa Continuity of Care study is a randomized, prospective trial enrolling 1000 patients with selected medical conditions admitted to one large Midwest hospital. Patients will be randomized to a control group (usual care), minimal intervention, or enhanced intervention. For the intervention groups, a pharmacist case manager (PCM) will provide admission medication verification with the patients’ community pharmacists, medication teaching, and discharge counseling. Patients in the enhanced intervention group will have a discharge care plan faxed to their outpatient physician and community pharmacist and will receive a follow-up phone call from the PCM three to five days after discharge; the PCM will continue to facilitate communication between the patient and community providers until all medication problems are resolved. A blinded research nurse will collect data, including adverse drug event (ADE) data, at admission and 30 and 90 days after discharge. The primary outcome measures include medication appropriateness, ADEs, emergency department visits, unscheduled office visits, and rehospitalizations. Data will be collected from the inpatient electronic medical record, outpatient physician medical records, and community pharmacist records and directly from patients. A cost-effectiveness analysis will be performed.

Conclusion. This study will address the value of a PCM in improving communication of care plans between the inpatient and community settings and thereby optimizing medication use.

Index terms: Communication; Errors, medication; Hospitals; Patient care; Pharmaceutical services; Pharmacists, hospital; Pharmacy, institutional, hospital; Professional relations

Am J Health-Syst Pharm. 2008; 65:1631-42

Poor communication among health care providers and settings and lack of shared information about patients are common causes of undertreatment, suboptimal therapy, adverse drug events (ADEs), and hospital admissions. Discharge from a hospital can be a chaotic event, and several types of errors can occur during or after discharge. Multiple medications may be changed during hospitalization,
leading to confusion of patients and potential discrepancies in drug lists between hospital and community care providers. Community pharmacists and primary care physicians are often unaware of the complete list of medications for a discharged patient. Furthermore, many patients do not fill all of their discharge prescriptions; one study showed that 32% of prescribed medications were not being taken by elderly patients two days after discharge.3,4

Poor communication with community physicians and patients’ confusion after discharge may jeopardize proper therapy and increase the risk of ADEs. No consistently effective approach to these problems has been found. The Joint Commission’s 2008 national patient safety goals are designed to address these issues.5 Goal 8 is to “accurately and completely reconcile medications across the continuum of care.” The first requirement for meeting this goal is having “a process for comparing the patient’s current medications with those ordered for the patient while under the care of the organization.” The second requirement is that “a complete list of the patient’s medications is communicated to the next provider of service when a patient is referred or transferred to another setting, service, practitioner, or level of care within or outside the organization.” The Joint Commission states that “patients are most at risk during transitions in care (hand-off) across settings, services, providers, or levels of care. The development, reconciliation, and communication of an accurate medication list throughout the continuum of care is essential in the reduction of transition-related adverse drug events.”

Schnipper et al.4 found medication discrepancies for 49% of 178 hospital patients at discharge. These investigators found that discharge counseling and telephone follow-up by a clinical pharmacist reduced preventable ADEs (1% intervention group versus 11% usual care, p = 0.01) and preventable emergency department (ED) visits or readmissions (1% intervention group versus 8% usual care, p = 0.03). Another study evaluated the effect of a telephone call by a pharmacist two days after discharge.7 Fewer patients in the intervention group (n = 110) than in the control group (n = 111) had a visit to the ED (10% versus 24%, p = 0.005), and there was a trend toward fewer hospitalizations (15% versus 25%, p = 0.07). Both studies were relatively small and had short follow-up (four to six weeks); in addition, data were not provided to community physicians and community pharmacists, and neither study included complete identification of ADEs through the use of multiple sources such as the community pharmacy or outpatient physician. These limitations must be addressed in order to identify all ADEs and determine the extent to which ADEs can be prevented by sharing information.

A recent study showed that many recommended workups or treatment plans were not completed after discharge, especially when primary care physicians did not have access to discharge summaries.4 A report by the Agency for Healthcare Research and Quality stated that the transfer of information between inpatient and community pharmacies is likely to be beneficial, with “medium” implementation cost and complexity.9,10 Two randomized, controlled studies have evaluated information transfer between hospitals and outpatient pharmacies.11,12 Kuehl et al.12 found that facsimile transmissions of patient information at discharge from a community hospital to the community pharmacy resulted in significantly more pharmacist interventions either in the hospital (47%, p < 0.001) or in the community (42%, p < 0.05) than for patients whose information was not transferred (14% and 0%, respectively). Other studies have shown that information sharing reduces medication problems.6,7,13

Study background

The Iowa Continuity of Care (COC) study, whose background and methods are described here, builds upon this previous research. It will evaluate an intervention to improve continuity of pharmacy care and will target patients with specific cardiovascular diseases, pulmonary diseases, or diabetes who are at high risk for ADEs. This intervention is designed to improve medication appropriateness, reduce ADEs associated with suboptimal therapy, and reduce costs due to hospitalizations or unscheduled office visits. The primary goal is to determine whether using a pharmacist case manager (PCM) to improve communication and continuity of care can result in more appropriate medication therapy.

Two PCMs (33% full-time equivalent each) will be devoted to this study to ensure proper coverage and timely performance of all interventions. Each PCM has a Doctor of Pharmacy (Pharm.D.) degree and at least one year of residency or clinical practice experience that includes conducting admission medication histories, discharge education, medical team rounding, and chronic disease management.

Previous studies have described the value of medication reconciliation, and studies have shown that increased collaboration between pharmacists and physicians improved therapy, improved disease control, and reduced ADEs.14-31 The proposed intervention is supported by small studies.10-12 The investigators conducted a pilot study, funded by the ASHP Research and Education Foundation, that helped establish the electronic communication links for the present study. The present study is a five-year, randomized, controlled clinical trial, funded by the National Heart, Lung, and Blood Institute.
(NHLBI), to evaluate the success of a comprehensive COC model.

The study has three testable hypotheses, stated here in the positive form:

1. Medication appropriateness during and after hospitalization will be improved in patients who receive the enhanced intervention from a PCM, compared with usual care.
2. The rate of preventable ADEs during and after hospitalization will be lower for patients who receive the enhanced intervention than for patients who receive usual care or minimal intervention.
3. The number of hospital readmissions, ED visits, and unscheduled office visits—and specifically the number of visits attributed to poor medication adherence—will be lower for patients who receive the enhanced intervention, compared with usual care or minimal intervention.

This trial will enroll 1000 patients at the University of Iowa Hospitals and Clinics (UIHC), a tertiary academic health sciences center. The study has been approved by the University of Iowa committee on protection of human subjects. The overall study design is displayed in Figure 1.

Inclusion and exclusion criteria

To be eligible for enrollment in the study, a patient must be an English or Spanish speaker 18 years of age or older who is admitted to UIHC with a diagnosis of hypertension, hyperlipidemia, heart failure, coronary artery disease, myocardial infarction, stroke, transient ischemic attack, asthma, chronic obstructive pulmonary disease, or diabetes or is receiving oral anticoagulation. The patient must be admitted to the general medicine, family medicine, cardiology, or orthopedics service; patients initially admitted to an intensive care unit will qualify only if they are later transferred to one of these services. The patients must receive their medical care in the community and their prescriptions from a community pharmacy.

Patients will be excluded from the study if they receive their primary medical care from any UIHC clinic with electronic medical records connected to the hospital. They will also be excluded if they receive their long-term prescriptions from the UIHC outpatient pharmacies. Patients will be excluded if they do not have a working telephone or have a hearing impairment that does not allow them to use a telephone; if they have a life expectancy estimated at less than six months, dementia or cognitive impairment, or severe psychiatric or psychosocial factors, including substance abuse, that may impair their desire or ability to complete all aspects of the study; or if they are admitted to the psychiatric, surgery, or hematology/oncology services.

Patient selection and randomization

Electronic medical records will be reviewed daily by the research nurse or project manager for all new patients admitted to each of the four medical services included in this study. In order to meet NHLBI goals for minority recruitment, we will overenroll African Americans and Hispanics. The research nurse will first determine if the patient meets the inclusion criteria; then, if the patient is a member of a minority group, he or she will be approached to participate. Nonminority patients will then be screened and enrolled.

Once patients have given written, informed consent, randomization will occur. The study biostatistician created a blinded randomization scheme to stratify for the medical services and for minority versus nonminority patients. The randomization was developed by using pseudorandom number generation via SAS statistical software to ensure that the probabilities of assignment to each treatment group are equal.

Once the patient has signed a consent form, the project manager will open a sealed envelope to determine the group to which that patient will be randomized. Patients will be randomized equally to one of three groups: enhanced intervention, minimal intervention, or control.

Next, a research nurse, who will be blinded to the group randomization, will collect demographic information, including the patient’s ability to pay for medications. The nurse will also administer baseline surveys of ADEs, health status, and self-reported adherence; the Pfeiffer32 mental status questionnaire; and the Katz et al.33,34 index of activities of daily living. Medication management skills will be evaluated: the ability to read a prescription label, ability to remove two tablets from a 7-dram prescription vial, ability to interpret directions, and ability to differentiate tablet colors35; these are important predictors of adherence and ADEs. The research nurse will read aloud all questions on each survey for all study patients, whether English- or Spanish-speaking. For Spanish-speaking patients, a translator will read each question and obtain the responses from the patient.

Once the research nurse has completed collection of all baseline information, one of the two PCMs assigned to the study will be informed if the patient is randomized to one of the two intervention groups. However, to maintain blinding, the pharmacists will not be told at this time whether the patient is in the minimal or enhanced intervention group.

Admission medication reconciliation

In alignment with recent Joint Commission national patient safety goals, “usual care” at UIHC now includes medication reconciliation within 24 hours of admission to the hospital for all patients. Hospital pharmacists obtain a list of medications the patient was taking prior to
hospital admission from the patient or caregiver. The patient’s medication list is then reconciled with the previous, possibly outdated, medication list found in the electronic medical record. When a current medication list cannot be obtained from the patient or caregiver, one is obtained by calling the patient’s community pharmacy. The pharmacist then reconciles the newly obtained medication history with the hospital admission orders. If a change is deemed appropriate, consultation with the inpatient team occurs. This process will continue in the control (usual care) group. For all patients randomized to the minimal or enhanced intervention group, the PCMs will augment usual care by calling the patient’s com-

---

**Figure 1.** Overall study design. UIHC = University of Iowa Hospitals and Clinics, ADE = adverse drug event.
munity pharmacy to verify the complete medication list. When possible, discrepancies will be clarified with the patient.

Medication teaching and discharge counseling

Patients in the minimal and enhanced intervention groups will receive medication teaching throughout hospitalization. The PCM will visit the patient every two to three days to discuss probable discharge medications and their purpose, goals of therapy, dosages, administration, duration required for the medication, potential adverse effects, potential barriers to adherence, strategies to improve adherence, and what to expect for future dosage changes and monitoring. The PCM will perform extensive patient medication teaching throughout hospitalization to allow patients a chance to ask follow-up questions. This approach helps minimize the negative effect of a hurried discharge counseling session that might overwhelm the patient. The PCM will track the patient throughout the hospital stay to monitor for medication problems and will regularly contact the medical service in charge of the patient’s care or the unit hospital pharmacist in order to determine the timing of discharge and identify a potential discharge care plan. On the day the patient is to be discharged from the hospital, the PCM will complete medication teaching about the patient’s discharge medications. The patient will receive a discharge medication list and a wallet card listing all discharge medications.

Patients in the control group will not receive medication teaching from the PCM but will receive a discharge medication list and oral information from a hospital nurse according to usual care in our hospital. After a patient in an intervention group is discharged from the hospital, the PCM will contact the project manager, who will then inform the pharmacist if the patient is in the enhanced intervention group. Patients in the minimal intervention group will receive no further contact or intervention from the PCM.

For patients in the enhanced intervention group, the PCM will compile a care plan containing the patient’s discharge medication list and including the purpose of all medications, plans for dosage adjustment, duration of therapy, a plan for monitoring, recommendations for preventing ADEs, and anticipated timing of refills if applicable. The care plan will also highlight important points from discharge teaching (e.g., medication adherence issues, cost issues, patient anxiety about new diagnosis). The discharge care plan will be faxed to the patient’s community physician and community pharmacist.

Patients in the enhanced intervention group will receive a follow-up phone call from the PCM three to five days after hospital discharge. The purpose of the call is to determine whether and why the patient failed to fill any discharge medications; evaluate any administration difficulties or problems taking discharge medications; evaluate patient understanding of each medication; inquire about specific ADEs since discharge; reinforce patient education on medication purpose, administration, and monitoring; encourage follow-up with the community physician; and encourage communication of ADEs or poor treatment response to the patient’s community physician and community pharmacist. Any problems identified during the follow-up phone call will be communicated to the patient’s community physician or to the inpatient medical team if the patient has not yet seen the community physician. In addition, a report of the follow-up call will be faxed to the community physician and community pharmacist. The PCM will continue to communicate with the patient and the patient’s community health care providers at least weekly until all identified problems are resolved.

Follow-up surveys

Patient questionnaires. The research nurse will contact all patients by telephone to administer the ADE survey and questionnaires on self-reported adherence and overall health status by 30 and 90 days after discharge. The patients will be asked structured questions to determine whether they have had any readmissions or ED or urgent care visits.

Pharmacist and physician surveys. For each patient in the study, we will survey community physicians and community pharmacists, using a survey instrument that was previously piloted and subsequently modified.36 Physicians will be surveyed to determine how much they value the interactions with the pharmacist. Physicians with a patient in the enhanced intervention group will receive questions about both the community pharmacist and the PCM (appendix). Physicians with a patient in the usual care or minimal intervention group will respond only to the questions about the community pharmacist.

Community pharmacists with patients in the control and minimal intervention groups will receive a patient-specific survey to determine whether they valued interactions with physicians for each specific patient in the study. For patients in the enhanced intervention group, community pharmacists will receive the same questionnaire plus a second part that asks their opinion on the value of data, information, and recommendations communicated by the PCM. Community physicians and pharmacists will be compensated $50 per patient for the time and resources they use to prepare copies of medical or pharmacy records and to complete questionnaires.

Data collection and analysis

Data abstraction. For each pa-
tient, a blinded research assistant will obtain data from community pharmacy refill and inpatient records, outpatient physician records, and billing records for days 1–90 following discharge. The research assistant will compile the data into a structured report for each patient. The intervention endpoints, data sources, and timing of data collection are displayed in Table 1. Discharge summaries, ED summaries, and billing information will be obtained for any admission to the community hospital or clinic or UIHC. A structured, blinded case abstract will be created for each patient, using methods developed by the principal investigator. The case abstract will include any medication list available in the progress notes, the goals of therapy for each medication, and whether there is a monitoring plan documented. We will determine whether this information is available on the following dates: admission and discharge (hospital records) and 30 and 90 days after discharge (community pharmacy and outpatient physician records).

**Medication appropriateness.** Blinded evaluators will score case abstracts using a modified Medication Appropriateness Index (mMAI). The evaluators are all board-certified clinical pharmacy specialists and faculty. The mMAI will be scored for each patient at discharge, 30 days, and 90 days to evaluate changes in

<table>
<thead>
<tr>
<th>Table 1. Study Endpoints, Data Sources, and Timing of Data Collectiona</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Item</strong></td>
</tr>
<tr>
<td>---</td>
</tr>
<tr>
<td><strong>Primary Endpoints</strong></td>
</tr>
<tr>
<td>Medication appropriateness, guideline adherence</td>
</tr>
<tr>
<td>Documented serious or life-threatening ADEs</td>
</tr>
<tr>
<td>Self-reported ADEs</td>
</tr>
<tr>
<td>Hospital readmissions (university and local hospitals)</td>
</tr>
<tr>
<td>ED visits, all scheduled and unscheduled office visits (university, local hospital, clinics)</td>
</tr>
<tr>
<td>Billing records for university and community hospital admissions, physician office visits</td>
</tr>
<tr>
<td>All prescription costs</td>
</tr>
<tr>
<td><strong>Secondary Endpoints</strong></td>
</tr>
<tr>
<td>Adherence to medications (refill records)</td>
</tr>
<tr>
<td>Self-reported adherence to medications</td>
</tr>
<tr>
<td>Value of pharmacist recommendations</td>
</tr>
<tr>
<td>Inappropriate medications in elderly</td>
</tr>
<tr>
<td>Up-to-date medication list in chart</td>
</tr>
<tr>
<td><strong>Covariates</strong></td>
</tr>
<tr>
<td>Number of active medications</td>
</tr>
<tr>
<td>Demographics</td>
</tr>
<tr>
<td>Comorbidity</td>
</tr>
<tr>
<td>Pfeiffer mental status, Katz index, medication management skills</td>
</tr>
<tr>
<td>Patient insurance and pharmacy benefit</td>
</tr>
<tr>
<td>Source of discharge medications (hospital, community pharmacy, or both)</td>
</tr>
<tr>
<td>Inpatient service</td>
</tr>
<tr>
<td>Community physician</td>
</tr>
<tr>
<td>Level of community pharmacy services</td>
</tr>
</tbody>
</table>

a ADE = adverse drug event, ED = emergency department.
medication appropriateness. The evaluators will also (1) determine if there is a complete medication list at 30 and 90 days, (2) categorize medication errors at admission, discharge, and 30 and 90 days, and (3) determine the severity and significance of each medication error.

**Identification of ADEs.** We will combine several previously developed methods of identifying ADEs. We use the method of Bates et al. to identify inpatient ADEs. We will use other methods to identify ADEs during the outpatient period. ADEs will be detected by examining (1) the patient self-reported survey done on admission, (2) free text from the inpatient electronic medical record, (3) the physician discharge summary, (4) the free text from the PCM’s electronic discharge summary, (5) community pharmacy records, (6) patient self-report following discharge, and (7) outpatient physicians’ records. We have chosen to use ambulatory care medical records because they yield many more ADEs than electronic indicators. We will also use patient self-report because it identifies ADEs not detected by other methods and has been used in other recent studies of ADEs in ambulatory care. One study in ambulatory care found that patient self-report resulted in a fivefold greater frequency of ADEs than clinician report, computerized indicators, and computerized searching of electronic notes. Multiple methods, including patient and clinician reports and chart review, are complementary and most likely to result in more complete identification of ADEs. We expect that this combined approach will identify a higher rate of ADEs than found in other studies.

**Classification of possible ADEs.** We will use blinded expert panels to separate serious and life-threatening ADEs from minor events and then determine whether the ADEs could have been prevented. Serious ADEs will be evaluated on admission, on discharge, and at 90 days (includes any event that occurs from 1 to 90 days after discharge). The clinical pharmacy evaluators will blindly evaluate each case abstract. The evaluators will review each reported ADE and determine whether it is potentially related to one of the patient’s medications by using the U.S. Pharmacopeia and the AHFS Drug Information. This strategy was used at our institution to evaluate ADEs in elderly patients, and these ADEs were found to lead to greater health care utilization. All potential ADEs will be presented to pairs of investigators that include one physician and one clinical pharmacy investigator; these investigators will be blinded to the intervention or control group and will independently classify each ADE through a structured implicit review using the following criteria: whether an ADE was present, the severity of the event, whether the event was preventable, and the effects the event had on the patient. The investigators will determine the probability that the event was related to the drug (the Naranjo et al. probability scale). Next, severity of an ADE will be categorized as significant, serious, life-threatening, or fatal. For the purpose of hypothesis testing, the primary outcomes of interest are serious, life-threatening, or fatal ADEs classified into type A (predictable, dose-dependent, or exaggerated pharmacologic effect of a drug) or type B (idiosyncratic or due to an allergic reaction that is not predictable). ADEs will be considered preventable if they were due to an error that could have been prevented by any means, including physician ordering, transcribing, dispensing (pharmacy), administration (nursing or patient in the home), monitoring, and adherence. ADEs will be classified by the pair of investigators as preventable, probably preventable, probably not preventable, or absolutely not preventable. The effects of the ADE will be classified as abnormal laboratory results without signs or symptoms, symptoms of less than one day in duration, symptoms of one day and longer in duration, nonpermanent disability, permanent disability, and death. Previous studies that used these techniques found good to excellent interrater agreement (kappa statistic, 0.66–0.89). Differences between the two reviewers’ classifications will be resolved by discussion to achieve consensus for each ADE.

**Evaluation of readmissions and unscheduled office visits.** Schnipper et al. found a rate of readmissions or ED visits in 1% of the intervention group and 8% of patients receiving usual care (p = 0.03). Other studies have found higher rates. Readmissions and unscheduled visits to EDs or urgent care facilities will be identified by the research nurse through patient self-report, outpatient physician notes, and hospital records for readmissions. During the telephone survey conducted at 30 and 90 days, patients will be questioned about any health care visits. Patients who have visited any facility will be asked to describe the reason for the visit, the date, and the outcome of the visit. The research nurse will attempt to confirm each visit by comparing the patient’s report with hospital, ED, clinic, or physician records. Only visits related to an ADE or medication problem (including underuse) as determined through adjudication by the senior investigators will be counted as outcomes, and only one outcome will be counted per unscheduled office visit or hospitalization. The adjudication process will also determine whether the ADE was preventable. If the patient subsequently has a different event during the study, the second event will also be counted.

**Cost-effectiveness.** A cost-effectiveness analysis (CEA) will be performed. We assume that the deci-
sion to reimburse for our intervention in practice will be at the discretion of third-party payers, so we will use this perspective as the basis for our CEA.

We will focus on the differences in direct resource costs across the three study arms, using two distinct CEAs. The first analysis will contrast the control and minimal intervention arms. The cost-effectiveness of the enhanced intervention arm will be assessed in the second analysis. The comparison intervention (either control or minimal intervention) used in the second analysis will depend on the results found in the first analysis. The enhanced intervention will be compared with a single intervention if a clear best choice emerges in the first analysis. If the choice is not clear in the first analysis, the enhanced intervention will be compared with both.

Secondary measures

Number of medications. Use of a greater number of medications has been shown to increase the risk for ADEs and drug interactions. The intervention might reduce the number of unnecessary medications; but it might increase total medications if there are untreated indications, as observed in several other studies. It will be important to categorize the total number of medications and their association with the primary outcome variables (mMAI score, medication errors, ADEs, and visits to health care facilities). The number of active medications will be determined at admission, discharge, and 30 and 90 days following discharge. Only nontopical medications will be counted. The number of regularly scheduled medications will be recorded separately from “as needed” medications. We have found that community pharmacists are more likely to provide an intervention for patients who are receiving greater numbers of medications. Therefore, the number of medications will be used as a covariate in the multiple regression model that examines the influence of the intervention on ADEs, readmissions, and ED and urgent care facility visits.

Complete medication list. The documentation of a complete medication list has been shown to reduce the risk of ADEs. Therefore, the peer review panel form will include a section that asks whether there was a complete medication list at the following index dates and locations: admission, discharge, and 30 and 90 days after discharge. The outpatient medication lists will be determined from the community pharmacy and community physician records. The standard for comparison will be the medication list that has been generated by the PCMs.

Use of inappropriate medications in elderly subjects. Many studies have found frequent use of inappropriate medications in the elderly as defined by the Beers criteria. We found that 40% of elderly patients receiving Medicaid in the Iowa pharmaceutical case management program were receiving an inappropriate medication. We expect to find that the intervention will reduce the number of inappropriate medications in the subgroup of patients over 65 years of age. These data will be used for descriptive purposes.

Barriers to adherence. The research nurse will administer baseline questionnaires concerning ADE symptoms, adherence, self-efficacy, cognitive impairment, activities of daily living, and medication management skills. We have selected to survey these factors because they may be barriers to medication administration.

Medication adherence. Gurwitz et al. found that 21% of preventable ADEs were due to errors in patient adherence. Two methods for evaluating adherence are preferable to a single assessment. We will estimate adherence by both refill history and self-report. Adherence scores from refill histories have been widely used in studies of adherence, including studies we conducted. We will determine the timing of refills and calculate possession ratios. This evaluation will be performed at baseline and during the study at 30 and 90 days after discharge. Patient adherence will be defined as a score of 0.80 or greater; nonadherence will be a score below 0.80, which has been used by other investigators. We will test adherence as a predictor of ADEs and visits to health care facilities as both a dichotomous and a continuous variable. The other method will be a self-reported adherence tool developed by Morisky et al. This tool had item-to-total correlations of 0.48–0.56 and a Cronbach alpha of 0.61. When the tool was evaluated in patients with hypertension, the sensitivity was 0.81 and specificity was 0.44.

Statistical analysis

The main goal of the data analyses will be to make comparisons among the three groups (two intervention and one control) on primary outcome variables. These primary outcome variables will be collected at enrollment (preintervention) and at 30 and 90 days, as displayed in Table 1. These three distinct outcomes include (1) mMAI scores, (2) the occurrence of preventable serious ADEs, and (3) readmissions, ED visits, and unscheduled office visits. For each outcome, a longitudinal random-effects model will be used to incorporate the repeated-measures aspect of the data and, if deemed necessary by the data, to control for the effects of pharmacy or physician cluster. This model will be used for numeric outcomes, such as mMAI scores.

Other outcomes are likely to be dichotomous in nature, such as whether a subject had at least one ADE or at least one hospital readmission. In these cases, the model above will be modified into a random-
effects logistic regression model. If we find it to be relatively common that subjects have more than one of these types of outcomes (e.g., multiple readmissions or ED visits), then those outcomes will be treated as being discrete counts, and we will modify the model to perform random-effect Poisson regression analysis. SAS Proc NLMIXED can be used to fit all three of these types of regression models (continuous, dichotomous, and counts), although it is more straightforward to use SAS PROC MIXED for continuous data.

For each model that we fit, we will examine the appropriateness of the modeling assumptions and modify our approach via transformations or non-parametric alternatives, if necessary.

Sample size approximations

For approximating the sample size necessary to achieve high power, we considered the following three distinct outcomes, each evaluated separately in determining sample size and power: mMAI score, serious ADE, and preventable hospitalization or ED visit. Although the actual analysis will incorporate random effects of subjects and physicians, we will consider pairwise comparisons of the three groups in order to facilitate power calculations. For mMAI, we will have 80% power to detect between-group effect sizes of 0.22 standard deviation and 90% power to detect between-group effect sizes of 0.25 standard deviation. Effect sizes of this order of magnitude are very small and allow considerable overlap in the distribution of the observed outcomes. For example, a 0.25 standard deviation effect size between two groups would occur if the 50th percentile (median) of one group is at the 40th percentile or at the 60th percentile of the other group. With 1000 patients, there should be excellent power to detect differences between the usual care group and the enhanced intervention group, both for ADEs and for preventable hospital or ED visits. We should also have reasonable power to distinguish the minimal intervention group from the usual care group or from the enhanced intervention group.

These sample size calculations assume a two-sided Type I error rate \( (\alpha) \) of 5%, with a Bonferroni correction for performing all three pairwise comparisons of proportions among groups. In the actual analyses, we will use more sophisticated statistical methods, including accommodating baseline patient characteristics and the clustering within physician and pharmacy (as described above). However, since these clusters are crossed with, rather than nested within, treatment groups, the effect of ignoring this issue for power calculations should be minimal (and perhaps even conservative).

Discussion

Patient safety is one of the most important issues for hospitals and for the American Society of Health-System Pharmacists. Medication reconciliation, shared information, and improved communication across levels of care are critical to improving patient safety and optimizing pharmacotherapy. Many hospitals are attempting to determine how to best implement these strategies, and the Joint Commission will continue to require such programs. Hospital pharmacy departments are examining ways to include pharmacists in these activities, and pharmacists are often the responsible individuals. The Iowa COC study is designed to evaluate the ability of a PCM to improve therapy and reduce ADEs, unscheduled office visits, and readmissions. This will be the first such study to include a comprehensive identification and assessment of ADEs and a cost-effectiveness evaluation. The study results are expected in 2012, and the knowledge gained will help hospital pharmacy departments to improve patient safety.

One limitation of the study is that findings in one tertiary hospital may not be generalizable to other tertiary hospitals or to smaller hospitals. Furthermore, the study results may not be generalizable to other geographic areas or different populations, especially large minority populations.

Conclusion

The study will address the value of a PCM in improving communication of care plans between the inpatient and community settings.

References

9. Kaushal R, Bates DW. The clinical pharmacist's role in preventing adverse drug events. In: Making health care...


Appendix—Survey questions for physicians with patients in the enhanced intervention group

Subject ID:________________  
Physician ID:________________

**Part 1:** First think about any interactions you had with the patient's local community pharmacy within 90 days of the patient's discharge from the hospital.

1. Did the community pharmacist contact you by fax, telephone, or other means about this patient?  
   - Yes  If yes, which method: Fax_______  Phone_______  Other (please specify) _________  
   - No (if no, go to question 13)

2. Did the community pharmacist discuss a medication problem following discharge that could have resulted in an adverse drug reaction or poor disease control?  
   - Yes (briefly describe)____________________________________________________  
   - No

Use the following scale for remaining questions concerning the patient's community pharmacist: 1 = strongly agree; 2 = agree; 3 = neutral; 4 = disagree; 5 = strongly disagree.

<table>
<thead>
<tr>
<th>Question</th>
<th>Strongly Agree</th>
<th>Strongly Disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>3. I approve of the pharmacist's recommendation.</td>
<td>1 2 3 4 5</td>
<td></td>
</tr>
<tr>
<td>4. This collaboration improved the quality of the patient's drug therapy.</td>
<td>1 2 3 4 5</td>
<td></td>
</tr>
<tr>
<td>5. The pharmacist's recommendation was helpful.</td>
<td>1 2 3 4 5</td>
<td></td>
</tr>
<tr>
<td>6. As a result of this study, my relationship with the pharmacist has improved.</td>
<td>1 2 3 4 5</td>
<td></td>
</tr>
<tr>
<td>7. As a result of this study, the pharmacist and I communicate more.</td>
<td>1 2 3 4 5</td>
<td></td>
</tr>
<tr>
<td>8. The contact procedure was satisfactory.</td>
<td>1 2 3 4 5</td>
<td></td>
</tr>
<tr>
<td>9. The communication was time-consuming.</td>
<td>1 2 3 4 5</td>
<td></td>
</tr>
<tr>
<td>10. The recommendation had a major positive impact on the patient's outcome.</td>
<td>1 2 3 4 5</td>
<td></td>
</tr>
<tr>
<td>11. The patient's adherence to therapy has improved with the recommendation.</td>
<td>1 2 3 4 5</td>
<td></td>
</tr>
<tr>
<td>12. As a result of the study, my relationship with the patient has improved.</td>
<td>1 2 3 4 5</td>
<td></td>
</tr>
</tbody>
</table>

**Part 2:** Now think about the interactions you had with the UIHC hospital pharmacist after the patient's discharge from the hospital.

13. Did the hospital pharmacist contact you by fax, telephone, or other means about this patient? (Check all that apply.)  
   - Yes  If yes, which method: Fax______________  Phone____________  Other (please specify)____________  
   - No

14. Did the hospital pharmacist discuss a medication problem following discharge that could have resulted in an adverse drug reaction or poor disease control?  
   - Yes (briefly describe)___________________________________________________  
   - No

Use the following scale for remaining questions concerning the UI hospital pharmacist: 1 = strongly agree; 2 = agree; 3 = neutral; 4 = disagree; 5 = strongly disagree.

<table>
<thead>
<tr>
<th>Question</th>
<th>Strongly Agree</th>
<th>Strongly Disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>15. I approve of the pharmacist's recommendation.</td>
<td>1 2 3 4 5</td>
<td></td>
</tr>
<tr>
<td>16. This collaboration improved the quality of the patient's drug therapy.</td>
<td>1 2 3 4 5</td>
<td></td>
</tr>
<tr>
<td>17. The pharmacist's recommendation was helpful.</td>
<td>1 2 3 4 5</td>
<td></td>
</tr>
<tr>
<td>18. As a result of this study, my relationship with the pharmacist has improved.</td>
<td>1 2 3 4 5</td>
<td></td>
</tr>
<tr>
<td>19. As a result of this study, the pharmacist and I communicate more.</td>
<td>1 2 3 4 5</td>
<td></td>
</tr>
<tr>
<td>20. The contact procedure was satisfactory.</td>
<td>1 2 3 4 5</td>
<td></td>
</tr>
<tr>
<td>21. The communication was time-consuming.</td>
<td>1 2 3 4 5</td>
<td></td>
</tr>
<tr>
<td>22. The recommendation had a major positive impact on the patient's outcome.</td>
<td>1 2 3 4 5</td>
<td></td>
</tr>
<tr>
<td>23. The patient's adherence to therapy has improved with the recommendation.</td>
<td>1 2 3 4 5</td>
<td></td>
</tr>
<tr>
<td>24. As a result of the study, my relationship with the patient has improved.</td>
<td>1 2 3 4 5</td>
<td></td>
</tr>
</tbody>
</table>


