Quality Assessment of a Collaborative Approach for Decreasing Drug-Related Morbidity and Achieving Therapeutic Goals

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Comments
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Quality Assessment of a Collaborative Approach for Decreasing Drug-Related Morbidity and Achieving Therapeutic Goals

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Background: Collaboration between physicians and pharmacists is one approach to address drug-related morbidity and achieve therapeutic goals. A collaborative practice of pharmaceutical care has been used in the Fairview Clinics System of Minneapolis-St Paul since 1999.

Methods: The quality of therapeutic determinations made by pharmacists within this collaborative practice of pharmaceutical care was studied by a 12-member panel of physicians and pharmacists who used randomly selected patient records. This was a quality improvement and care process validation component of a study evaluating the effects of drug therapy management in patients receiving prepaid medical assistance. An implicit review process was used to evaluate the clinical credibility of therapeutic determinations made by pharmaceutical care practitioners.

Results: A total of 5780 drug therapy problems were resolved for 2524 patients receiving pharmaceutical care. The rate of therapeutic goals achieved increased from 74% at the time of patients’ initial pharmaceutical care encounters to 89% at patients’ latest encounters. In this quality assessment analysis panel members performed a total of 4779 evaluations of clinical decisions. Panelists indicated agreement with the evaluations in 94.2% of cases, expressed a neutral opinion in 3.6% of cases, and disagreed in 2.2% of cases. Intraclass correlation coefficients ranged from 0.73 to 0.85.

Conclusions: The decisions made by pharmaceutical care practitioners working in collaboration with physicians to provide drug therapy management services are clinically credible based on the evaluations and comments of a peer review panel. This study provides information on the quality of care provided by pharmacists when collaborating with physicians to provide drug therapy management services.

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Patient safety and quality improvement in the US health care system have been the focus of national reports.1,2 These reports have called for redesigning the health care system from the perspective of optimizing responsiveness to patients’ needs. When the needs are related to the use of medications, patients benefit from collaborative efforts between physicians and pharmacists toward achieving intended goals of drug therapy while avoiding or minimizing adverse consequences. Several methods of effective collaboration in drug therapy management have been described.3-5

The collaboration between physicians and pharmacists addresses undesirable and ineffective consequences of medication use. “Drug misadventuring” and “drug-related morbidity and mortality” have been used to describe such consequences.5-8 Studies of drug-related morbidity and mortality have focused on the incidence of adverse drug events and drug complications.9,12 Characteristics of hospital readmissions,13 and preventability.9,14 In 1995, the cost impact of these drug therapy problems in the US health care system was estimated at $76 billion, and updated to $177 billion for 2000.8,13 Causes of drug-related morbidity and mortality include acts of commission (ie, prescribing and dispensing drugs, and administering errors), idiosyncratic causes (ie, unpredictable medication consequences), and acts of omission (ie, absence of systems designed to consistently help patients achieve desired therapeutic goals while avoiding or minimizing the adverse consequences of medication use). Although various risk factors have been associated with complications from drug therapy,16-19 the predictive validity of risk factors for such problems needs further study. Undesirable medication-related consequences are not necessarily the fault of

From the College of Pharmacy, University of Minnesota, Minneapolis (Drs Isetts, Brown, and Schondelmeyer), and the Fairview Clinics System, Minneapolis-St Paul (Dr Lenarz). The authors have no relevant financial interest in this article.
any individual, and they do not constitute a special field of medicine. Rather, they represent a need to apply theories and approaches already used in other fields to minimize adverse consequences and improve reliability.  

Pharmacists working in collaboration with physicians through a redesigned approach to medication use can prevent errors and reduce drug costs.  

One of 4 recent suggestions for improving the quality of medication use in elderly patients includes a call for enhanced collaboration between those who prescribe drugs and those who know drugs best, ie, clinical pharmacists.  

In a 2-year study of 397 patients with low- or high-risk coronary heart disease whose pharmacists and physicians worked persistently and collaboratively to promote adherence with prescribed dyslipidemic therapy, it was found that, at their last full lipid profile, 62.5% of patients were at or below the low-density lipoprotein cholesterol target levels specified by the National Cholesterol Education Program.  

Drug therapy management and drug management are terms used in proposed federal legislation and in federal government reports to describe contemporary models in which pharmacists and physicians work together to manage the complex medication needs of Medicare beneficiaries. A report released by the Medicare Payment Advisory Commission states that “drug management is an evolving approach to care in which therapy decisions are coordinated collaboratively by physicians, pharmacists and other health professionals together with the patient.” The Medicare Payment Advisory Commission report also recommends that the Secretary of the US Department of Health and Human Services assess models for collaborative drug therapy management services in outpatient settings.  

The impact of pharmacists’ contributions to drug therapy decision making is found in the literature evaluating the effectiveness of clinical pharmacy services.  

A Cochrane database review examining the effects of expanding the roles of ambulatory pharmacists on patient outcomes and health care use suggests that pharmacist intervention can improve patient behavior and adherence and improve physician prescribing.  

Studies of pharmacists’ performance in clinical decision making related to the use of medications include a description of decision-making models, factors influencing drug therapy decision making by pharmacists, and decision analysis applied to clinical pharmacy.  

The term pharmaceutical care was described in the literature in 1975 as pertaining to the care that a given patient requires and receives which assures safe and rational drug usage.  

A article published in 1990 articulated the responsibilities of a pharmaceutical care practitioner desiring to expand beneficial drug therapy management services, including the creation of a covenantal bond or therapeutic relationship between patient and pharmacist. The practice of pharmaceutical care is now defined as “a practice in which the practitioner takes responsibility for all of a patient’s drug-related needs and is held accountable for this commitment.”  

A consistent and systematic pharmaceutical care process is used to (1) assess all of a patient’s drug-related needs, identify drug therapy problems, and establish therapeutic goals; (2) design a pharmaceutical care plan to help the patient achieve the established goals and resolve or prevent drug therapy problems; and (3) conduct follow-up evaluations with the patient to determine progress toward these goals.  

A drug therapy problem is defined as “any aspect of a patient’s drug therapy that is interfering with a desired, positive patient outcome.”  

A classification of drug therapy problems is presented in Table 1. The practice of pharmaceutical care outlined in this article encompasses drug therapy management described in proposed federal legislation as well as federal government reports; therefore, the term drug therapy management is used synonymously with pharmaceutical care.  

<table>
<thead>
<tr>
<th>Table 1. Classification of Drug Therapy Problems*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indication</td>
</tr>
<tr>
<td>1. Additional drug therapy needed</td>
</tr>
<tr>
<td>2. Unnecessary drug therapy being used</td>
</tr>
<tr>
<td>Effectiveness</td>
</tr>
<tr>
<td>3. Ineffective drug therapy</td>
</tr>
<tr>
<td>4. Dosage too low</td>
</tr>
<tr>
<td>Safety</td>
</tr>
<tr>
<td>5. Adverse drug reaction</td>
</tr>
<tr>
<td>6. Dosage too high</td>
</tr>
<tr>
<td>Convenience</td>
</tr>
<tr>
<td>7. Adherence to therapy</td>
</tr>
</tbody>
</table>

*Adapted from Cipolle et al.  

PEER REVIEW

Peer review has been used as a quality improvement strategy in medicine and nursing. In contrast to explicit review, which requires strict predetermined criteria that ignore extenuating circumstances, implicit review integrates all available information about each patient. Researchers working in conjunction with the RAND Corporation created a structured implicit review (SIR) process for assessing the quality of medical care delivered in the hospital and ambulatory care settings. The SIR process guides the reviewer through medical records information and allows for a more consistent review of care delivered.

A SIR process relevant to the practice of pharmaceutical care was used for this analysis based upon the RAND SIR process. The use of SIR has been central to Medicare quality management and for reviewing care delivered by physicians. Reviewers apply their professional expertise to provide implicit judgments about the quality of care delivered by individual clinicians. Although implicit review often has high face validity, poor interrater reliability is often a drawback. Assessments based on medical record reviews, especially when implicit and not guided by objective criteria, can produce disagreement among physicians on the appropriateness and quality of care delivered to specific patients.

The intraclass correlation coefficient (ICC) has been used to measure interrater reliability within the implicit review process. Six different intraclass correlation models have been delineated based on the selection of patients and reviewers, and on whether the goal is to com-
pare individual raters with other raters or with the mean rating of all raters.\textsuperscript{37} Coefficients above 0.75 indicate excellent agreement, those from 0.40 to 0.75 indicate fair to good agreement, and those below 0.40 indicate poor agreement.\textsuperscript{38}

One study on the quality of medical care found that, when using SIRs, outcome measures had higher inter-rater reliability than process measures.\textsuperscript{39} In pharmacy, peer review has been applied primarily in the institutional setting as part of continuous quality improvement efforts to evaluate, validate, and improve the appropriateness of pharmacists’ clinical interventions.\textsuperscript{40} In this study, peer review by physicians and pharmacists was performed to evaluate interventions of pharmaceutical care practitioners intending to identify and resolve drug therapy problems and achieve the therapeutic goals of patients in an ambulatory health care setting.

**PROGRAM ORGANIZATION**

Collaboration to provide drug therapy management services exists at 6 of the largest clinics within the Fairview Clinics System of Minneapolis-St Paul, Minn, and more than 3000 patients have received drug therapy management services since the program inception in 1999. There were 3195 patients in active pharmaceutical care plans through February 2003. Drug therapy management within the Fairview system is defined as “a practice in which a credentialed pharmaceutical care practitioner, working in collaboration with physicians and other care-givers, takes responsibility for all of a patient’s drug-related needs and is held accountable for this commitment.”

Pharmacists complete a 120-hour, 8-week, 50-patient certificate preparation program in pharmaceutical care provided by the Peters Institute of Pharmaceutical Care at the University of Minnesota. This program represents a paradigm shift for pharmacists. It focuses on a unique philosophy of practice and process of care, and prepares generalist practitioners to identify, resolve, and prevent drug therapy problems. This preparation program contrasts with continuing education programs on disease state management or certification programs by the Board of Pharmaceutical Specialties, because the emphasis of these latter programs is on content areas or clinical knowledge. Three pharmaceutical care practitioners in the Fairview system hold doctorate degrees in pharmacy, 3 others hold bachelors’ degrees in pharmacy, and their total experience as pharmacists ranges between 3 and 21 years (mean, 12 years). Two pharmacists completed postgraduate residency programs, and 1 is a Board-Certified Pharmacotherapy Specialist.

The Fairview Credentialing Committee comprises 9 physicians and 1 pharmaceutical care practitioner who accredit pharmaceutical care practitioners to provide care in the Fairview system. Physicians and pharmaceutical care practitioners use a collaborative practice agreement to enhance cooperation in the delivery of drug therapy management services. Patients schedule pharmaceutical care appointments pursuant to physician referrals, informational mailings, self-referrals, and health insurance company notifications. Pharmaceutical care practitioners conduct patient assessments in a clinic examination room or in a semiprivate pharmacy consultation area.

Fairview’s pharmaceutical care practitioners assess and document actual therapeutic outcomes at every patient encounter using a pharmaceutical care software documentation program (Assurance Pharmaceutical Care; licensed by the University of Minnesota, Minneapolis). Consistent with the collaborative practice agreement, a set of therapeutic goals are established for each of a patient’s medical conditions during the initial stage of care plan development. These are clinical goals established in the literature, combined with realistic, observable, and measurable patient-specific goals. Occasionally, prescriber, pharmacist, and patient may confer to discuss patient expectations or goals of therapy.

After each encounter, a pharmaceutical care documentation note is entered into the patient’s medical record. The note includes the intended use and dose of all active prescription and over-the-counter medications, plus a summary of the outcome of therapy. If the patient is experiencing a potentially harmful or urgent drug therapy problem, the pharmaceutical care practitioners intervene immediately through consultation with the patient’s physician(s).

All patients seen in the 6 Fairview clinics affiliated with a pharmaceutical care practitioner are eligible to receive pharmaceutical care services regardless of ability to pay or health insurance status. Patients in the Fairview system receive these services through various research grants, demonstration projects, and third-party payer pilot programs, or as part of a central Fairview Department of Pharmacy health system budget.

**METHODS**

**PHARMACEUTICAL CASE SIR**

A SIR process was developed as a component in the assessment of the quality improvement of Fairview’s pharmaceutical care, and to provide information on the validity of therapeutic determinations made by pharmaceutical care practitioners. Information was obtained on the reliability of this pharmaceutical care SIR process. Validity in this analysis refers to the face validity, or clinical credibility, of the determinations made when collaborating to provide drug therapy management services.

Records for panel review were drawn from those of a group of patients receiving pharmaceutical care as part of a grant designed to study the effects of providing drug therapy management services to prepaid medical assistance program (PMAP) patients. A total of 142 PMAP patients had at least 2 visits with a pharmaceutical care practitioner between January 1, 2000, and December 31, 2000. The University of Minnesota’s Research Subjects Protection Program reviewed and approved this study.

**REVIEW PANEL PROCESS**

Fifteen of the 142 PMAP patient records were randomly selected for peer review as case records. A 12-member peer review panel was assembled, consisting of 4 physicians with patients in pharmaceutical care plans, 4 physicians with no patients in pharmaceutical care plans (they were practicing at a Fairview clinic that had no pharmaceutical care practitioner), and 4 pharmaceutical care practitioners. Physician panel members
A total of 5897 drug therapy problems were identified and resolved among the 2524 patients in Fairview's Pharmaceutical Care Program. For a problem to be considered resolved, therapy had to be changed based on the pharmaceutical care practitioner's recommendation, as evidenced by a change in the physician's order or in the patient's behavior. The distribution of the 5897 resolved drug therapy problems is presented in Table 3. 71% of them were resolved without the direct involvement of the patient's physician(s) while 29% were resolved with the active involvement of the patients' physician(s).

A total of 259 drug therapy problems were reviewed by 15 peer-reviewed patients in active pharmaceutical care plans from January 1999 through March 2002, or an average of 2.3 visits per patient. The patients ranged in age from 3 to 97 years, 48% of them were older than 65 years, and 66% were women. These 2524 patients had among them a total of 16406 medical conditions (an average of 6.5 medical conditions per patient) present at both their initial and latest pharmaceutical care encounters. They were taking, on average, 8.2 active medications (Table 2). Demographic characteristics of the 142 PMAP patients receiving pharmaceutical care and the 15 peer-reviewed patients are also presented in Table 2.

### RESULTS

#### PATIENT DEMOGRAPHICS

There were 5810 documented encounters with 2524 patients in active pharmaceutical care plans from January 1999 through March 2002, or an average of 2.3 visits per patient. The patients ranged in age from 3 to 97 years, 48% of them were older than 65 years, and 66% were women. These 2524 patients had among them a total of 16406 medical conditions (an average of 6.5 medical conditions per patient) present at both their initial and latest pharmaceutical care encounters. They were taking, on average, 8.2 active medications (Table 2). Demographic characteristics of the 142 PMAP patients receiving pharmaceutical care and the 15 peer-reviewed patients are also presented in Table 2.

### RESOLVED DRUG THERAPY PROBLEMS

A total of 5897 drug therapy problems were identified and resolved among the 2524 patients in Fairview's Pharmaceutical Care Program. For a problem to be considered resolved, therapy had to be changed based on the pharmaceutical care practitioner's recommendation, as evidenced by a change in the physician's order or in the patient's behavior. The distribution of the 5897 resolved drug therapy problems is presented in Table 3. 71% of them were resolved without the direct involvement of the patient's physician(s) while 29% were resolved with the active involvement of the patients' physician(s).

A total of 259 drug therapy problems were reviewed among the 142 PMAP patients enrolled in this study, and 37 drug therapy problems were resolved in
the 15 peer-reviewed patients (Table 3). The 5 most frequently encountered drug therapy problems by condition in the 142 PMAP patients were in the following order:

<table>
<thead>
<tr>
<th>Condition/Indication</th>
<th>Drug Therapy Problem</th>
</tr>
</thead>
<tbody>
<tr>
<td>Osteoporosis</td>
<td>Patient needs additional drug therapy</td>
</tr>
<tr>
<td>Asthma</td>
<td>Patient is using medication incorrectly</td>
</tr>
<tr>
<td>Nutritional supplementation</td>
<td>Patient needs additional drug therapy</td>
</tr>
<tr>
<td>Hypertension</td>
<td>Adverse drug reaction</td>
</tr>
<tr>
<td>Hypothyroidism</td>
<td>Dosage too low</td>
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The most frequently encountered drug therapy problems by condition in the 15 peer-reviewed patients were as follows:

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</table>

GOALS OF THERAPY ACHIEVED

At the time of the 2524 patients’ first pharmaceutical care visit, 74% of their therapeutic goals were being met. At the time of their final pharmaceutical care encounter, 89% of their therapeutic goals were met (Table 4). The goals of therapy achieved in the 142 PMAP patients and the 15 peer-reviewed patients are also presented in Table 4.

REVIEW PANEL RESULTS

The 15 patient records randomly selected for this quality assessment analysis presented a total of 300 situations. As already explained, on the research instrument each line item, or situation, consisted of a medical condition, a medication, directions for use of the medication, and the 4 therapeutic determinations. This analysis focused on the determinations made by the pharmaceutical care practitioner regarding each of these situations. Among the 300 situations, 37 showed a determination of an identified drug therapy problem and 263 showed a determination that there was no drug therapy problem present.

Table 4. Goals of Therapy Achieved Through Collaboration in Drug Therapy Management

<table>
<thead>
<tr>
<th>Total No. of Medical Conditions</th>
<th>Goals Met at Earliest DTM Encounter, No. (%)</th>
<th>Goals Met at Latest DTM Encounter, No. (%)</th>
<th>Percentage Point Increase in Goals Met, %</th>
</tr>
</thead>
<tbody>
<tr>
<td>16 406 (in all 2524 patients)</td>
<td>12 141 (74)</td>
<td>14 609 (89)</td>
<td>15</td>
</tr>
<tr>
<td>937 (in the 142 PMAP patients)</td>
<td>732 (78)</td>
<td>841 (90)</td>
<td>12</td>
</tr>
<tr>
<td>83 (in the 15 peer-reviewed patients)</td>
<td>63 (88)</td>
<td>78 (84)</td>
<td>16</td>
</tr>
</tbody>
</table>

Abbreviations: DTM, drug therapy management; PMAP, prepaid medical assistance program.

Ratings for 4500 of these evaluations (94.2%) agreed or strongly agreed with the pharmaceutical care practitioners’ therapeutic outcome determinations. A neutral opinion was expressed in 172 instances (3.6%), and there were 107 instances (2.2%) in which the panelists expressed disagreement.

Ratings were grouped to categorize the level of agreement as follows: “agree” (a rating of 5-7), “neutral” (a rating of 4), and “disagree” (a rating of 1-3). The number and distribution of agreement scores by type of determination made was compiled (Table 5). The level of agreement across reviewers and situations is presented in Table 6. A valid or clinically credible level of agreement was found for 97.9% (1175/1200) of the situations reviewed.

Panelists provided 300 comments describing the reasons for their ratings. Of this total, 119 were general supportive comments in conjunction with agreement ratings and 93 were offered in conjunction with neutral opinions. The panelists’ remaining 88 comments were offered in conjunction with disagreement ratings of 1 to 3 on the Likert scale. The disagreement scores and corresponding comments were fed back to the pharmaceutical care practitioners at monthly quality assurance case presentation meetings to foster continuous quality improvement in clinical care.

RELIABILITY MEASUREMENTS

To obtain information on the reliability of this pharmaceutical care SIR process, 3 sets of 2 patient cases were selected for review by the same 4 reviewers (ICC 3, 4). For set 1 (patients 3 and 4 reviewed by panelists 4, 6, 8, and 11), there was an ICC of 0.85. For set 2 (patients 7 and 8 reviewed by panelists 1, 6, 9, and 10), there was an ICC of 0.75. For set 3 (patients 13 and 14 reviewed by panelists 3, 5, 7, and 12), there was an ICC of 0.73.

ANALYSIS OF DRUG THERAPY PROBLEM DETERMINATIONS

An analysis of the level of agreement related to the 37 drug therapy problems identified in the 15 patients selected for inclusion in this peer review analysis was conducted to obtain information on the ability of pharmaceutical care practitioners to correctly identify a drug therapy problem that has been judged to exist. There was valid agreement for 100% (37/37) of the situations with drug therapy problems (Table 6). Unanimous agreement by all 4 panelists was present for 28 of 37 drug therapy problem cases. In 7 of the 9 remaining cases 1 panelist expressed a neutral rat-
and in the other 2 cases 1 reviewer disagreed. The 2 cases with disagreement were not related to the presence of a drug therapy problem but with the classification of a drug therapy problem (Table 1).

An analysis of the 263 situations determined to have no drug therapy problems was conducted to provide information on the practitioners’ accuracy in stating that no drug therapy problem exists (Table 6). There were
The results of this study suggest that decisions made by pharmaceutical care practitioners working in collaboration with physicians and other caregivers to provide drug therapy management services are clinically credible. The collaborative practice of pharmaceutical care may help to reduce drug-related morbidity and improve therapeutic outcomes by optimizing responsiveness to patient needs in their use of medication. Causes of suboptimal medication use outcomes include acts of commission, unpredictable events, and the absence of pharmaceutical care systems. The presence of a pharmaceutical care practitioner who is responsible for applying a systematic problem-solving process to the use of all of a patient’s medications can consistently ensure that the patients’ drug-related needs are met.

Recent studies and reviews suggest that pharmacists’ interventions can improve patient outcomes, reduce health expenditures, and prevent errors. The impact of pharmacists’ contributions in drug therapy decision making is found in the literature evaluating the effectiveness of clinical pharmacy services. Compared with studies of pharmacists’ performance in clinical decision making, this study provides information relating to the face validity or clinical credibility of collaborative drug therapy management services.

Although there are indications that the pharmaceutical care SIR process used in this analysis is reliable using the ICC in a subset of common patient cases, additional studies would help to corroborate these findings. This was discovery work, conducted to identify trends and patterns of agreement with pharmaceutical care practitioners’ therapeutic determinations using an implicit review process. Further studies in this area could be designed to have all panelists review the same patient cases to test the reliability of rater measurements and compare ratings between individual panelists.

The main responsibilities of pharmaceutical care practitioners are to identify, resolve, and prevent drug therapy problems that impede progress toward achieving intended therapeutic goals. A quality improvement analysis of drug therapy problem determinations was conducted to obtain information on practitioners’ abilities to identify a drug therapy problem when one is judged to exist, and to accurately state that no drug therapy problem exists. This analysis revealed estimates of 100% accuracy in identifying drug therapy problems and 97% in determining the absence of drug therapy problems.

Documenting patients’ actual therapeutic outcomes represents a desirable activity in any health care system. Therapeutic goals achieved increased from 74% at the time of patients’ initial pharmaceutical care encounters to 89% at their latest encounters. This study provides data demonstrating the clinical credibility of the therapeutic outcome determinations of pharmaceutical care practitioners when they collaborate with physicians to provide drug therapy management services. Patients, health care providers, employers, third-party payers, and policymakers can use these data to make better-informed decisions about the value and role of collaboration in reducing drug-related morbidity and achieving therapeutic goals.

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We thank Julie A. Bewick, Pharmaceutical Care Coordinator, Fairview Pharmacy Services, for support in coordinating the work of the Review Panel.

The Collaborative Practice Agreement for the provision of pharmaceutical care used in the Fairview Clinics System is available from the corresponding author.


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REFERENCES


Correction

Incorrect Name Order. In the Commentary by Goodnough et al titled “Ane- mia: Not Just an Innocent Bystander?” published in the June 23 issue of the Archives (2003;163:1400-1404), the authors should have appeared in the following order in the signature block on page 1403: Lawrence T. Goodnough MD; Robert W. Dubois, MD, PhD; and Allen R. Nissenson, MD. The journal regrets the error.