Preparing Pharmacists to Provide Medication Therapy Management Services: Evaluating Agreement between a Novice Pharmacist Guided Interview and Experienced Clinical Pharmacist Judgment in Identifying Drug Therapy Problems

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Abstract (312 words)

Purpose

This research determined agreement between student pharmacists using a guided interview tool and experienced clinical pharmacists using usual clinical judgment to identify drug therapy problems (DTPs) in community-dwelling elderly patients. Students' and patients' perceptions of the interview were also evaluated.

Methods

Patients participated in live medication therapy management reviews independently performed by a fourth professional year student pharmacist and an experienced clinical pharmacist during a single office visit. Students interviewed patients using a guided interview tool. Clinical pharmacist interviews followed their usual practices. Student-pharmacist agreement concerning the DTPs identified was evaluated using the kappa statistic (k) with 95% confidence interval (CI). Four statements with a five-point Likert-type agreement scale were used to assess student pharmacist perceptions about the tool's usefulness, practicality and recommendations for use. Similarly, four statements were used to assess patient satisfaction with the interview process.

Results

Fair to moderate agreement was observed on four DTPs. Actual agreement was significantly higher than chance for three DTPs [adverse drug reaction (k=0.342, 95% CI: 0.051 – 0.632), dosage too high (k=0.417, 95% CI: 0.143 – 0.691), needs additional drug therapy (k=0.310, 95% CI: 0.072 – 0.547)] and not statistically significant on the fourth [unnecessary drug therapy (k=0.214, 95% CI: -0.004 – 0.431)]. Students reported the interview tool was easy to use (3.73/5) and useful in the practice environment (3.43/5), but were less enthusiastic with respect to its practicality (3.07/5) and recommendation for use in community pharmacies (3.10/5). Patients strongly agreed the pharmacist's efforts

will help improve or maintain their health (4.78/5), assure that their medications do what they are supposed to do (4.80/5), manage their medications (4.77/5), and solve problems with their medications (4.82/5).

Conclusions

The guided interview tool may be useful for assisting inexperienced practitioners in identifying complex DTPs. Although students did not find the guided interview tool practical for routine use, patients were satisfied with the level of care received throughout the interview process.

Introduction (3033 words exclusive of references and tables)

To provide high quality medication therapy management services, pharmacists must competently gather patient-specific medical and drug histories, evaluate the data collected, identify and prioritize a patient's drug therapy problem(s), develop and implement a care plan and monitor the outcomes achieved.[1] However, not all practicing pharmacists have received training in these skills during their professional education and may lack the confidence to perform them. As a result, a number of practice tools have been developed to assist pharmacists as they transition to a more patient-focused practice. One common practice aid is a guided data collection form that pharmacists can use to gather patient histories.

Strand et al. have published a detailed commentary on data collection forms and their uses.[2] They note that different forms have different functions. Some forms are summative in nature and are used to document a pharmacist's activities to support administrative decision making. Other forms are formative in nature and are used to provide direct patient care and to guide the pharmacist's clinical thought processes while assessing the patient.

A wide variety of data collection forms have been published in both the peer-reviewed and non-reviewed literature.[1,2,3,4,5,6,7,8,9,10,11,12] Collectively, these instruments are widely variable in their design and intended uses. Many are simply tools that provide a space to document important information in a complete and organized fashion. Others are intended to be used as screening tools to identify problems that may occur in certain disease states or patient groups. Regardless of intent or format, as noted by van Mil et al., it is concerning that few of these tools have ever been validated for use. [13] Neither do they have a consistent taxonomy for the problems they are intended to identify. Instead, they have been published with the belief that they are useful practice aids although this has rarely been demonstrated. Forms described in the peer-reviewed literature are not typically included in their entirety in such papers. Textbooks, however, are more likely to

provide a full text copy of the forms they discuss. Readers who wish to receive a copy of the tool discussed in this study may contact the first author (JPR).

A review of this literature suggests the standards for data collection instruments are variable and, in general, not very rigorous. Accordingly, in this study we describe and evaluate a guided interview tool intended to lead the pharmacist through the data collection process to find drug therapy problems in a primary care setting. The guided interview tool was designed but not evaluated in a previous study.[14] It was designed to support a pharmacy practice wherein the pharmacist collects the patient's history in order to find and resolve the seven drug therapy problems originally identified by Strand et al.[15] These drug therapy problems include: no indication for drug therapy, dosage too high, dosage too low, wrong drug, adverse drug reaction, inappropriate compliance, and needs additional drug therapy. We also investigated the situation of no drug therapy problem found.

For each drug therapy problem assessed using the guided interview tool, screening questions to determine the presence/absence of the problem were provided. For example, to evaluate if the drug therapy problem of inappropriate compliance existed, the pharmacist is guided to ask questions such as if the patient finds it difficult to pay for medications, ever refills his/her prescriptions late or has ever considered stopping taking the medication. For most questions, the pharmacist then documents their answer as yes, no or unsure. Questions answered yes or no suggest the presence/absence of the problem respectively. In such cases, the pharmacist can document on the included checklist whether the problem does not exist or choose from several suggested interventions to resolve the problem (e.g. "Tell your doctor why you prefer not to take this medication."). Questions answered as unsure were intended to trigger the pharmacist to probe with follow-up questions to more accurately identify the presence/absence of a given drug therapy problem.

Research Objectives

To address a gap in the literature with respect to medication therapy management data collection tools, this research sought to assess:

1. agreement between student pharmacists using a guided interview tool and experienced clinical pharmacists using usual clinical judgment in identifying the presence of drug therapy problems in community-dwelling, older patients;
2. student pharmacists' perceptions of the guided interview process; and
3. patients' perceptions of the guided interview process.

Methods

Design. Consenting patients participated in live medication therapy management reviews independently performed by a student pharmacist in the second half of their advanced experiential rotations and an experienced clinical pharmacist during a single office visit. Interviews by student pharmacists were performed using a previously developed guided interview tool[14]; whereas, clinical pharmacist interviews were based on their usual practices and served as the reference standard for clinical practice. During the guided interview, student pharmacists initially completed a medication history, a review of general medication safety (e.g., allergies, etc.) and determined the need for additional therapy. After completing the initial assessment, student pharmacists reviewed the indication, safety, compliance, efficacy and cost using questions in the guided interview tool for the four medications that they determined to be of highest priority. With the exception of the medication history, general medication safety and determination of need for additional therapy sections, the complete guided interview tool was used for each medication reviewed by the student pharmacist and the number reviewed was capped at four to reduce patient fatigue in the elderly study sample. The order of the student and clinical pharmacist interviews was randomly assigned to minimize sequencing bias. Both interviews were completed within two hours. Agreement between student and clinical pharmacists regarding the number and type of drug therapy problems was evaluated and reported. Student pharmacist perceptions of the guided interview tool and patient

perceptions of the interview process were also assessed. The study was approved by the Drake University Institutional Review Board.

Participants. Patients were recruited from a community dwelling patient population at three ambulatory care practice sites in Polk County, IA. Specifically, patients $\geq$ 65 years of age who were taking at least four medications and having no conditions precluding them from effectively communicating with study personnel in English were targeted for participation. Patients were offered a $50 grocery store gift card for participating in the interviews.

Measurements. Separate study data collection case report forms were used for each interview to ensure independent data collection. Patient demographics (age, sex, race/ethnicity), a medical problem list, drug therapy problem list, the number, type and priority of drug therapy problems and a medication list associated with the highest priority drug therapy problem based on the previously described taxonomy of drug therapy problems were recorded by the first interviewer. With the exception of patient demographics, the second interviewer recorded all clinical information identical to the first interviewer. Each interviewer identified themselves as a student or clinical pharmacist (CK, SH, KH) on their respective data collection forms. All data collection forms were placed in sealed envelopes and returned to the principal investigators (JPR, MJM) for data entry and analysis. Subsequent to completing all data collection forms, student and clinical pharmacists met to discuss the case and adjudicate drug therapy problems consistent with accepted clinical practice.

After completing their interviews, each student pharmacist was asked to complete a brief survey about their experience with using the guided interview tool. Four statements with a five-point Likert-type agreement scale, where 1 = Strongly Disagree and 5 = Strongly Agree, were used for student pharmacists to express their perceptions about the interview tool's ease of use, usefulness in practice, practicality and recommendation for use in community pharmacy practice.

Four statements with a five-point Likert-type agreement scale, where 1 = Strongly Disagree and 5 = Strongly Agree, were also used to assess patient participants' perceptions of the interview process. Statements were derived and adapted from a previously validated questionnaire related to patient satisfaction with pharmaceutical care.[16] Items were specifically related to the pharmacist's effort to: (1) improve or maintain health (2) assure medications do what they are supposed to do; (3) help in managing medications; and (4) solve problems with medications.

Analysis. Descriptive statistics were used to profile the study patient participants with respect to demographic characteristics, most important medical problem identified, number of medications (including prescription, OTC, vitamins, herbals, samples, etc.) used and the number and type of drug therapy problems identified. To address the first research objective, the proportion of patients classified by student and clinical pharmacists as having each of the drug therapy problems was described. Agreement between the student and clinical pharmacists' classification of the presence of each of the drug therapy problems was evaluated by describing the proportion of cases with observed agreement and calculating the kappa statistic[17,18] with 95% confidence interval. Confidence intervals containing zero were interpreted as not statistically significant. The kappa statistic is represented as a fraction (i.e., actual agreement beyond chance/potential agreement beyond chance) and falls between -1 and 1. Kappa is interpreted according to common guidelines as poor ($\leq$0), slight (>0 – 0.2), fair (>0.2 – 0.4), moderate (>0.4 – 0.6), substantial (>0.6 – 0.8), and almost perfect (>0.8 – 1). To address research objectives two and three, student pharmacists' perceptions about the use of the guided interview tool and study patient participants' perceptions about their interview experience were profiled using descriptive statistics.

Results

Study Demographics. Data from completed case report forms were entered into a relational database and exported to Stata Version 10.1[19] for analysis. Sixty-four patients were recruited and consented to participate in the study. Of those, 62 had complete data

and were included in the analysis. The study sample was predominantly White and evenly divided by sex (see Table 1). Participants' mean age was 74.6 years and ranged from 62.9 to 87.9 years. Two participants less than 65 years of age were enrolled in the study and retained for analysis given their close proximity to 65 years of age. Clinical pharmacists reported a higher median number of medications (12 vs. 11) and drug therapy problems (3 vs. 2) compared to student pharmacists.

Agreement between Student and Clinical Pharmacists. The types of drug therapy problems identified by the student and clinical pharmacists as well as observed agreement are reported in Table 2. Compared to the clinical pharmacists, student pharmacists were more likely to report no drug therapy problem, wrong drug, adverse drug reaction and inappropriate compliance. Whereas, clinical pharmacists were more likely to report unnecessary drug therapy, dosage too low, dosage too high and the need for additional therapy than the student pharmacists.

The highest observed agreement between the student and clinical pharmacists was related to no drug therapy problem (87.1%), followed by adverse drug reaction (80.7%), dosage too high (80.7%) and needs additional drug therapy (66.1%). With the exception of no drug therapy problem, the observed agreement for each of these problems was significantly higher than the expected agreement. Kappa statistics ranged from slight for inappropriate compliance to fair for needs additional drug therapy to moderate for dosage too high (Table 2).

Student Perceptions of the Interview. Thirty student pharmacists completed the assessment of their experience with the interview tool. The student pharmacists reported the highest level of agreement with the statement that the interview tool was easy to use (3.73), followed by the statement that the interview tool was useful in the practice environment in which it was used (3.43) using the five-point scale. The student pharmacists had less agreement that the interview tool was practical in the practice environment in which it was used (3.07) and whether they would recommend its use in a

community pharmacy practice setting (3.10). The observed alpha reliability of the four-item student perceptions scale was 0.88.

Patient Perceptions of the Interview. Sixty study patient participants provided their perceptions of the guided interview process. Their responses demonstrated strong agreement that the pharmacist's effort will help: improve or maintain their health (4.78); assure that their medications do what they are supposed to do (4.80); manage their medications (4.77); and solve problems with their medications (4.82) on the five-point scale. The observed alpha reliability of the four-item patient perceptions scale was 0.95.

Discussion

This study reports the agreement between student pharmacists using a guided interview tool and experienced clinical pharmacists in identifying drug therapy problems in a sample of community-dwelling, older patients. We observed fair to moderate agreement, as shown by the kappa statistic on four of the seven drug therapy problems studied. Agreement was significantly higher than chance with three of the four drug therapy problems (adverse drug reaction; dosage too high; needs additional drug therapy). Although the kappa statistic suggested fair agreement, it was not significantly greater than chance for unnecessary drug therapy. For the four drug therapy problems in which kappa was poor (none, wrong drug, dosage too low, inappropriate compliance), no better than chance agreement between student pharmacists using the guided interview tool and clinical pharmacists' judgment was found.

There are distinct differences between the drug therapy problems for which the guided interview tool achieved greater than chance agreement (i.e. fair or moderate agreement) and those in which it did not (i.e. poor or slight agreement). Inappropriate compliance is usually easy to identify by simply asking the patient or reviewing their refill records. Identifying a dosage too low is similarly straightforward, as it only requires finding subjective or objective evidence that the medication is ineffective. Often, this can be done by simply asking the patient if a drug is working or is initiated by patient complaint.

Similarly, if a patient is on the wrong drug, there is usually ample evidence that the medication is not working well. Finally, patients who have no voiced complaints may be expected to be at a lower risk of having a drug therapy problem than those who voice problems with their medication.

Conversely, it can be fairly difficult to differentiate between an adverse drug reaction and a patient who has a problem caused by too high of a dose. The clinician must assess the temporality of the event, consider issues of re-challenge as well as the dose-response effects of the drug.[20] Determining if a patient actually requires drug therapy (i.e. identifying unnecessary drug therapy or need for additional drug therapy) are probably the most complex problems of all to identify. These two problems require the pharmacists to consider the totality of what they know about the patient's drug therapy, the patient's social history, as well as using considerable knowledge of pathophysiology and pharmacotherapeutics.

Given our results and the differences between the types of drug therapy problems for which greater than chance agreement was seen, we believe the guided interview tool studied is effective in assisting novice pharmacists to identify those drug therapy problems that require higher order clinical analysis and judgment. As pharmacists make the transition to medication therapy management, being able to identify patients with more complex or difficult to identify drug therapy problems will be a highly desirable skill for which the tool may be of assistance.

The time burden of using the guided interview must be balanced against the practicality for use. Since a new form must be used for every medication evaluated by the pharmacist, we had some concerns that the guided interview tool may not be practical for routine use, but may better serve as a training tool. Student pharmacists' perceptions of the tool suggest our concerns were well founded. We note that, although student pharmacists found the guided interview tool to be useful and easy to use, they were less likely to recommend the tool be adopted for routine use in a community pharmacy. Accordingly, we conclude the guided interview tool may be of particular value in

teaching student pharmacists how to identify drug therapy problems, especially complex ones. The guided interview tool may also be useful to include in training, residency and/or quality improvement programs for practitioners who lack the clinical experience to identify more complex drug therapy problems. Studies are currently underway to investigate the value of the tool as a teaching aid.

Patients expressed considerable satisfaction with the guided interview process. They felt that this interaction with the student and clinical pharmacist would improve or maintain their health, assure that their medications do what they are supposed to do, manage their medications and solve problems with their medications. For pharmacists who do find the form practical for routine clinical use, it appears to be helpful in maintaining or improving patients' satisfaction with the pharmacist's cognitive services.

Limitations

This study involved a small number of patients in three ambulatory clinic pharmacy settings in Polk County, IA. Efforts to study the guided interview tool in more diverse patient samples and settings are necessary. Given the median number of medications that patients were taking was between 11 and 12, the level of observed agreement is likely to be lower than expected as student pharmacists were restricted to using the guided interview tool for only four medications in the interest of time. If the guided interview tool was used for all medications, observed agreement would likely be higher. Student pharmacists' perceptions about the practicality of the guided interview tool may well be a function of the study methods rather than the guided interview tool. Student pharmacists were instructed to use the guided interview tool for each of the four medications reviewed. In effect, they were required to ask all medication assessment questions four times. Had students used the screening questions to evaluate all the patient's medications simultaneously, they may have found the guided interview tool to be more practical for routine use. However, the ability of a new practitioner to integrate all information simultaneously is limited and is developed over time with guided experience. Thus, the guided interview tool may assist with refining these skills. Finally, while the guided

interview tool is comprehensive, strict adherence to the script for purposes of the study may result in missed opportunities that may have been identified had additional questions been used off protocol.

Conclusions

We conclude that the guided interview tool may be useful to assist inexperienced practitioners to identify complex drug therapy problems more readily. Although student pharmacists did not find the guided interview tool practical for routine use, patients expressed considerable satisfaction at the level of care they received throughout the interview process. The guided interview tool may prove useful as a teaching aid.

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Table 1. Demographic Characteristics (n=62 patients)

Characteristic		Reported By:	
		Student Pharmacist	Clinical Pharmacist
	n (%)	n (%)	n (%)
Sex			
Male	28 (45.2)	-	-
Female	34 (54.8)	-	-
Race			
White	58 (93.6)	-	-
Black	3 (4.8)	-	-
Asian	1 (1.6)	-	-
Most Important Medical Problem Reported at the Interview			
Hypertension		10 (16.1)	20 (32.2)
Diabetes		11 (17.7)	17 (27.4)
Coronary Artery Disease / Hyperlipidemia		3 (4.8)	6 (9.7)
Atrial Fibrillation		6 (9.7)	4 (6.5)
Rheumatoid Arthritis or Osteoarthritis		3 (4.8)	3 (4.8)
Osteoporosis		4 (6.5)	3 (4.8)
Benign Prostatic Hypertrophy (BPH)		4 (6.5)	2 (3.2)
Pain (Chronic, Fibromyalgia, Neuralgia, Untreated)		4 (6.5)	0 (0)
Other		17 (27.4)	7 (11.3)

Medications Taken by Patient, Median (Range)   11 (4 – 21)   12 (4 – 25)

Drug Therapy Problems Identified, Median (Range)   2 (0 – 5)   3 (0 – 6)[a]

[a] n=61

Table 2. Drug Therapy Problem Agreement Between Student and Clinical Pharmacists
(n=62 patients)

Drug Therapy Problem	% of Student Pharmacists Reporting	% of Clinical Pharmacists Reporting	% Observed Agreement	Kappa (95% CI)[b]
None	11.3	1.6	87.1	-0.029 (-0.086 – 0.028)
Unnecessary Drug Therapy	25.8	48.4	61.3	0.214 (-0.004 – 0.431)
Wrong Drug	33.9	19.4	59.7	-0.005 (-0.237 – 0.226)
Dosage Too Low	24.2	37.1	64.5	0.181 (-0.063 – 0.426)
Adverse Drug Reaction	21.0	14.5	80.7	0.342 (0.051 – 0.632)
Dosage Too High	19.4	22.6	80.7	0.417 (0.143 – 0.691)
Inappropriate	50.0	40.3	58.1	0.161

Compliance   (-0.080 – 0.402)

Needs Additional   40.3   45.2   66.1   0.310

Drug Therapy   (0.072 – 0.547)

[b] Confidence intervals containing zero are considered not statistically significant.