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Title:

Promoting safe use of medications: Providing medication education to seniors receiving Meals on Wheels

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Key words: Geriatric, Meals on Wheels, Medication adherence, Medication-related harm, Medication safety, Patient counseling

Abbreviations: MAR = Medication adherence ratio, MOW = Means on Wheels, OTC = Over-the-counter.

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Abstract:

Study Objectives: To assess whether pharmacist-provided medication education and counseling to Meals on Wheels (MOW) participants decreases medication-related preventable harm and improves adherence.

Design: Prospective, quasi-experiment.

Setting: Ambulatory congregate dining centers. **PATIENTS:** Persons 60 years of age and older participating in MOW receiving prescription, nonprescription, or complementary products were eligible. In total, 42 patients consented. Five patients did not complete the first visit, and 13 patients did not complete the six-month follow-up visit. **INTERVENTIONS:** Pharmacists provided comprehensive medication education about prescription, nonprescription, and complementary products at baseline. Additional resources to enhance adherence and avoid medication-related preventable harm were provided and discussed.

Main Outcome Measures: Medication-related preventable harm and medication adherence were assessed before pharmacist intervention and six months after intervention. Adherence was assessed and compared with baseline using the Morisky scale and pill counts.

Results: Women constituted the majority of participants (94.4%) with an average age of 74.5 ± 8.2 years. Mean difference in Morisky score from baseline to six months was 0.28 (-0.11 to 0.56). After adjustment for age and living situation, the change in Morisky score was associated with a 14% improvement in adherence. Mean differences in drug-drug and drug-supplement interactions, and medication-related harm were not significantly reduced from baseline to study end.

Conclusion: Pharmacist intervention with MOW participants appeared to improve medication adherence rates but had limited effect on medication-related preventable harm. No findings reached statistical significance as the sample size was inadequate. Larger studies are needed to confirm these findings.

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Introduction

Drug-related morbidity and mortality is common, with an estimated 100,000 deaths annually and a quarter of drug-related injuries being preventable.¹ When the Institute of Medicine released *To Err Is Human: Building a Safer Health System*, a much-needed focus was placed on patient safety within the United States health care system. The initial focus after publication was on medication errors in a hospital setting; however, medication errors cause 1 of every 854 deaths in a hospital as opposed to 1 of every 131 deaths in the outpatient setting.² The starkly higher risk of death from a medication error in the outpatient setting clearly indicates the need for preventing harm from medications in the ambulatory population.

Medication-related preventable harm occurs for a variety of reasons. Medication errors are usually multifactorial in origin and are more likely to occur in patients receiving multiple medications.³ Seniors are more likely to suffer medication-related problems because of their chronic conditions and polypharmacy. Polypharmacy has important health consequences because adherence becomes more difficult, and the risk for adverse drug reactions, cognitive impairment, falls, and mortality increases with increasing numbers of medications while activities of daily living decline.⁴⁻¹⁰ Previous research indicates that inappropriate medication use occurs in 12% to 40% of seniors living in the community and that inappropriate use increases as the number of medications used increases.^{11,12} Additionally, up to 30% of hospital admissions are caused by drug-related problems or side effects of medications.¹³

While many strategies are available to improve the safe and effective use of drugs, collaboration among organizations that already have established trust and reliability among seniors, such as Meals on Wheels (MOW), may help pharmacists position themselves to enhance patient education and reduce medication misadventures. Because MOW services seniors, a population at high risk for preventable harm from medications, we hypothesized that pharmacist-provided medication education and counseling to MOW participants would decrease medication-related preventable harm and improve adherence.

Methodology

The study was a prospective, open-label, quasi-experiment designed to evaluate whether medication education and counseling provided to seniors receiving MOW would decrease preventable harm from medications and improve medication adherence. MOW is provided in two ways in Rhode Island: 1) delivered to the seniors at home or 2) delivered to a congregate dining site, usually a community senior center. To maximize the potential number of participants, presentations about the study were made at congregate dining sites for MOW throughout the state to recruit study participants.

Any person older than 60 years of age receiving MOW, also taking prescription, nonprescription, or complementary products, was eligible to participate. Interested and eligible participants provided informed consent as required by The University of Rhode Island Institutional Review Board. At the baseline and six month visits, participants were instructed to bring all their prescription medications, over-the-counter (OTC) medications, and complementary products.

Adherence to medications for chronic conditions (defined as conditions that persist three months or more) was assessed using the Morisky scale and pill counts.¹⁴ The Morisky scale is a four-question binary response questionnaire that is reported as a scale from 0 (adherent) to 4 (nonadherent).¹⁵ Pill counts were performed at baseline and six months for each medication used to treat a chronic condition; dates of prescription filling and the number of days supply were also recorded. Medication adherence ratio (MAR) was used to calculate adherence. MAR is a ratio of the number of pills absent in a given time period and the total number of pills prescribed (received) in a given time period, which is then multiplied by 100 to convert to percentage.¹⁶ Patients were dichotomized to adherent or nonadherent based on attainment of 80% adherence or better.¹⁶

A comprehensive review of the participant's medication list (i.e., prescription, nonprescription, and dietary supplements), pertinent medical history, and other health information was performed to ascertain sources of potentially preventable harm. Preventable harm was defined as an adverse drug event (an injury resulting from medical intervention related to a drug) arising from a medication error (i.e., errors of prescribing, omission, wrong time, unauthorized drug, improper dose, wrong dosage form, wrong drug preparation, wrong administration technique, deteriorated drug, monitoring, or compliance).^{17,18} Presence of preventable harm was assessed using the Beers list of medications to quantify and characterize potentially inappropriate medication use, proprietary drug interaction software (Drug Interaction Facts; eAnswers by Facts and Comparisons) to quantify drug-drug and drug-dietary supplement interactions, and participant interview.¹⁹ Identification of any medication error or drug interaction (with a significance rating of 1 or 2, which corresponds to major or moderate severity), prompted a study pharmacist to contact the prescriber.

Medication education and counseling were performed by both the study investigators and advanced pharmacy practice students in their fourth professional year. The Teach-Back Method and Indian Health Service interactive counseling techniques were used.²⁰ Since many patients had less than high school education, pictures, colors of medications, and other techniques were used to enhance patient education. Patients were allotted approximately an hour to review medications—nonprescription, prescription, and dietary supplements. Often patients would ask for additional information, and students or study pharmacists would follow up with pamphlets, medication information, or disease-state information.

Because a large number of medication errors identified on hospital admission originate in medication histories, the use of a pocket card may minimize medication histories as a potential source of harm.²¹ Therefore, along with medication education, patients were provided with a pocket card to list all medications, including prescription and nonprescription, and dietary supplements as well as their doses and frequencies. The pharmacist completed the pocket card based on the medication vials provided (for prescription products) and by participant report (for nonprescription products and dietary supplements) during the study visits. Pill boxes capable of organizing 28 days of medications (divided by day and week) were provided at the initial study visit. The pharmacist discussed with each participant how to use the pill box. A medication alarm clock (MedCenter 4 Alarm Talking Reminder Clock) was also provided to each participant. The

medication alarm clock was programmed during the study visits to alarm at the times of day when medications were scheduled for administration, up to four alarms per day.

Statistical Analysis

Because this was a pilot study, 100 participants were targeted for inclusion, which allowed for a 20% attrition rate. Based on recent work in a similar population, the baseline adherence rate was expected to be $66\% \pm 14\%$.²² We assumed an improvement of 0% if the intervention did not occur, as adherence is not expected to improve or decline in the absence of intervention. Setting alpha at 0.05 and beta at 0.2, the resultant power would be 80% to detect a change in the adherence rate of 9.5% or greater from baseline, with a 15% standard deviation.

Student's t-tests were used to compare normally distributed continuous data. Wilcoxon-signed rank tests were used to examine the differences in the Morisky scores from baseline to six-month follow-up. Categorical data were analyzed using χ^2 or Fisher's exact test. Medication adherence was also assessed using Morisky scale change as improvement in adherence (decreased Morisky score) or no change or decreased adherence (increased Morisky score).

Results

In total, 42 patients gave their consent, 5 patients never completed the initial visit, 1 patient died after initial visit, and 12 patients did not complete the six-month follow-up visit. Of the patients who completed the initial visit, most (94.4%) were women, with an average age of 74.5 ± 8.2 years. The congregate sites were located in underserved minority population areas in Providence, Rhode Island; 88.6% were nonwhite and 37.1% had less than a high school education. Most patients lived alone (68.6%), managed medications on their own (91.4%), ordered refills on their own (88.6%), and used 7.9 ± 2.9 chronic medications. Combined never-users or former users of tobacco comprised the majority of study patients. A small number of participants reported current alcohol use. Additional baseline characteristics are shown in Table 1.

Morisky scores (a score of "0" is adherent, a score of "4" is nonadherent) were calculated at the initial visit and the six-month follow-up visit. Morisky scores were ranked according to low/high adherence (score of "0"), medium adherence (score of "1" or "2"), or low adherence (score of "3" or "4"). At baseline, Morisky score of high adherence was 42.8%, medium adherence was 51.4%, and low adherence was 5.8%. At the six-month follow-up visit, scores for the high adherence improved to 52.2%, while medium adherence was 43.4%, and low adherence was 4.3%. Wilcoxon-signed rank test showed $P = 0.317$, an insignificant change, although trended improvement. Adherence as measured by pill counts at the initial visit was $68.5 \pm 42.4\%$, compared with pill counts at six-month follow-up of $87.9 \pm 67.5\%$ with a nonsignificant mean difference of 19.5% (95% confidence interval [CI] -34.5% to 68.6%; $P = 0.92$).

The mean difference from baseline in drug-drug interactions and drug-supplement interactions determined by the pharmacists and pharmacy students was reduced by 0.11 (95% CI -0.18 to

0.40; $P = 0.43$) and 0.06 (95% CI -0.06 to 0.17; $P = 0.33$), respectively. Medication-related preventable harm had a nonstatistically significant decreased mean difference of 0.06 (95% CI -0.34 to 0.46). (Table 2)

Discussion

A classification scheme for medication errors is available; however, all potential sources of preventable harm when medications are used in the ambulatory population are not addressed.¹⁷ While initiatives to target causes of medication errors such as prescribing (e.g., computerized prescriber order entry) and dispensing (e.g., robots, dispensing machines) are ongoing, potentially preventable medication-related harm arising from inappropriate or incorrect medication use by patients has been more difficult to address.

Adherence to prescribed medication regimens continues to pose challenges. Medication adherence diminishes over time and with increasing numbers of prescribed medications.^{22,24} Seniors are at risk for nonadherence and medication-related preventable harm because many are prescribed multiple medications based on the presence of chronic diseases; community-dwelling seniors take between two and nine prescription medications.⁴

Although pharmacists have the legal duty to offer medication counseling at the time of dispensing, barriers exist. First, participants receiving MOW services have limited access to transportation. As a result, interactions with the pharmacy usually occur with the participant caregiver and conveyance of information provided by the pharmacist may not be reliable. Some participants may take advantage of home delivery or mailing of medications, which also prevents face-to-face interaction with a pharmacist. Second, a brief medication information sheet is provided with dispensing that discusses how to take the medication, common side effects, and potential adverse effects that require immediate follow-up with a health care provider. The most commonly used pharmacy database to provide written summaries uses a sixth- to eighth-grade reading level. However, label comprehension studies required by the Food and Drug Administration for manufacturers of OTC products request a target of fourth- to fifth-grade reading level.²⁵ Third, seniors may have difficulty reading the written summaries and prescription vials because of the small font used and visual problems. Finally, inadequate health literacy is common in the general and Medicare populations, making education about medications challenging.^{26,27} Our study attempted to address these barriers by having face-to-face interaction with participants to directly convey information about medications and providing medication education verbally rather than in written form to avoid difficulties with varying reading levels. The medication alarm clocks had large print numbers; however, we were otherwise unable to address visual barriers. We attempted to provide medication education to participants of all health-literacy levels; however, we did not formally assess health literacy.

Persistence of medication adherence is improved with pharmacist intervention. One study showed a difference of almost 25%; 69.1% vs. 95.5% of patients achieved persistence of adherence in the usual-care group and the pharmacist-care group, respectively; ($P < 0.001$).²² In another randomized, controlled study of an ambulatory population, medication adherence

was greater in the pharmacist-intervention group after nine months.²⁸ However, the effect dissipated after cessation of the pharmacist intervention, suggesting a continued need for reinforcement to maintain high levels of medication adherence.

The current study looked at the effect of comprehensive medication education and counseling on medication-related preventable harm and adherence to prescribed medications for chronic conditions. The study differs from other studies because participants in a MOW program were specifically targeted for pharmacist intervention to assess medication-related preventable harm and medication adherence. Other studies have evaluated medication education to seniors in assisted living facilities; however, medication adherence and preventable medication-related harm were not the primary study objectives.²⁹⁻³¹ In the current study, the enrolled population was nonwhite women who lived alone, managed their own medications, and ordered their own refills, which could present opportunities for difficulties with medication adherence and preventable harm. However, alcohol use, a potential indicator for unreliability, was low. Former smokers and those who never smoked represented the majority of the population, which might suggest a population with a strong interest in their health. A number of patients at our congregate sites had no relationship with their pharmacist and felt that their providers were more equipped to provide medication information and education. Our interactions at the congregate sites with the patients will hopefully improve the likelihood that they would seek a relationship with their local pharmacist.

The primary study limitation was the investigators' inability to recruit enough study participants to meet sample size requirements. This occurred because of an unanticipated cessation of MOW service to adult day care programs in Rhode Island, which limited the number of potential eligible participants. As a result, the sample size was inadequate to detect differences in baseline and endpoint Morisky scores assessing medication adherence, differences in pill counts for adherence, or medication-related preventable harm.

Conclusion

Although not statistically significant, pharmacist intervention with MOW participants appeared to improve medication adherence rates, but had limited effect on medication-related preventable harm; larger studies with adequate sample size are needed to confirm these findings.

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Table 1. Baseline Characteristics	
Characteristics	Value (Mean \pm SD or %)
Age in years (n = 35)	74.5 \pm 8.2
Gender (n = 36)	
Female	34 (94.4%)
Male	2 (5.6%)
Race (n = 35)	
White	4 (11.4%)
Black/African American	18 (51.4%)
Hispanic	5 (14.3%)
Asian/Pacific Islander	4 (11.4%)
Other	4 (11.4%)
Highest education level (n = 35)	
Less than high school	13 (37.1%)
High school Some college	13 (37.1%)
Associate's degree	4 (11.4%)
Bachelor's degree	1 (2.9%)
Advanced degree	3 (8.6%)
degree	1 (2.9%)
Smoking history (n = 35)	
Never smoked	11 (32.4%)
Former smoker	19 (55.9%)
Current smoker	4 (11.8%)
Alcohol use (n = 35)	
Never	22 (62.9%)
Past alcohol use	9 (25.7%)
Present alcohol use	4 (11.4%)
Illicit drug use	1 (2.9%)
Housing (n = 35)	
Lives alone	24 (68.6%)
Lives with spouse/significant other	0
Lives with children	9 (25.7%)
Lives with other, nonrelative	2 (5.7%)
System for refills; yes/no (n = 35)	
Orders on own	25 (71.4%)
Child assists	31 (88.6%)
Paid caregiver assists	2 (5.7%)
Paid caregiver assists	2 (5.7%)
Method of managing medications (n = 35)	
Take from vials	12 (34.3%)
Use pill box	20 (57.1%)
Reminder system	3 (8.6%)
Abbreviation: SD = Standard deviation.	

Table 2. Intervention Results

Value	Initial Visit (Mean ± SD)	Six-Month Follow-Up	Mean Difference (95% CI)	P-value
Morisky score ^a	0.91 ± 0.81	0.68 ± 0.89	0.28 (-0.11 to 0.56)	0.17
Drug-drug interactions, mean	0.22 ± 0.55	0.11 ± 0.32	0.11 (-0.18 to 0.40)	0.43
Drug-supplement interactions, mean	0.11 ± 0.32	0.06 ± 0.24	0.06 (-0.06 to 0.17)	0.33
Beers criteria medications, mean	0.28 ± 0.58	0.28 ± 0.58	0.00 (-0.17 to 0.17)	1.00
Medication-related preventable harm, ^b mean	0.50 ± 0.79	0.44 ± 0.71	0.06 (-0.34 to 0.46)	0.77

^a Morisky scale is reported as a scale from 0 (adherent) to 4 (nonadherent).¹⁵

^b Medication-related preventable harm was calculated by adding significant drug-drug interactions, Beers criteria medications, and medication errors identified during participant interview.

Abbreviation: CI = Confidence interval, SD = Standard deviation.