NOTES

Medication therapy management


Effect on health outcomes of a community-based medication therapy management program for seniors with limited incomes

SCOTT R. SMITH, DIANE J. CATELLIER, ELIZABETH A. CONLISK, AND GINA A. UPCHURCH

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Aging is closely linked to a broad array of risk factors that are associated with chronic disease and declining health. With increasing age, most individuals will have a growing and sustained need for a variety of prescription drug therapies. In a survey of noninstitutionalized adults, 94% of women age 65 years or older had taken at least one medication in the preceding week, and 57% took at least five.1 In many cases, therapies are complex and costly and involve the services of multiple health care providers. Factors such as these enhance the potential for the occurrence of drug-related problems, including adverse drug events, drug interactions, and poor adherence to treatment plans.2,3

While the majority of older adults receive health care in ambulatory care settings, many experience challenges in managing their medications. These challenges are compounded in populations living on limited incomes. Nearly one-third of Medicare beneficiaries and many non-Medicare beneficiaries are at risk for medication-related problems.4

Scott R. Smith, B.S.PHARM., M.S.P.H., Pharm.D., is Senior Service Fellow and Director of Pharmaceutical Outcomes Research, Agen-

Address correspondence to Scott R. Smith at the Center for Outcomes and Evidence, Agency for Healthcare Research and Quality, 540 Gaither Road, Rockville, MD 20850 (ssmith@ahrq.gov).

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of adverse events. Gwirtz et al. examined the frequency of adverse drug events among 27,617 Medicare beneficiaries receiving ambulatory care services and found the incidence was 50.1 adverse drug events per 1000 person-years of observation; 27.6% of these were classified as preventable. The results of the study suggest that new approaches are needed to improve the quality of care and health outcomes of older adults, especially in ambulatory care settings.

The need of the elderly for drug therapy also places an increasing burden on seniors to continuously garner the resources needed to access medications over extended periods. Despite this need, it is estimated that 25% or more of seniors do not have prescription drug coverage. The recent enactment of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) is an important national milestone that holds potential to increase seniors’ access to medications and improve their quality of care. Beginning in January 2006, MMA expands the Medicare entitlement program to offer seniors and people living with disabilities the option of purchasing a prescription drug plan (PDP) through a benefit designated as Part D or as part of the Medicare Advantage program in Part C (MA-PD). An important provision of MMA is that PDPs and MA-PDs establish a medication therapy management (MTM) program that may be furnished by a pharmacist and that is designed to ensure, with respect to targeted beneficiaries, that covered drugs are appropriately used to optimize therapeutic outcomes and reduce the risk of adverse events.

Nevertheless, MMA broadly defines MTM and does not currently mandate the involvement of pharmacists. Consequently, there is an important need to identify successful models of MTM that are practical in the community settings where most Medicare beneficiaries reside. We evaluated the effects of a novel, comprehensive, community-based program that integrates MTM services by pharmacists with prescription drug assistance for seniors with limited incomes. Although the program was developed prior to the enactment of MMA, it serves as a potential model for delivering effective MTM services in community settings. The objectives of this evaluation were to assess (1) whether a model of providing medication payment assistance, MTM, and tailored community referral improves health outcomes for seniors with limited incomes and (2) the sustained effects of enrollment after 24 months in the program.

Methods. Community residents age 65 years or older in Durham County, North Carolina, who had incomes at or below 150% of the federal poverty level and who either did not have supplemental health insurance (including Medicaid) or had insurance that did not include prescription drug coverage were eligible for participation in the Senior PHARMAssist program (appendix). Briefly, the program includes financial assistance through pharmacy reimbursement for medications on a geriatric drug formulary using a special prescription drug card, periodic review of participants’ medications by a program pharmacist (including screening for drug interactions or adverse effects, tailored health education, and monitoring of adherence), staff communication with prescribers and dispensing pharmacies, and tailored referrals to community and governmental programs. The key goals of the program are to assist seniors with obtaining and managing prescribed medications, as well as maintaining their health and functional status. Formulary medications are dispensed at local community pharmacies, where participants may also receive additional and customary services provided by dispensing pharmacists.

Participants or their caregivers were seen by program staff, including a pharmacist in the program office or in their homes at entry into the program and at 6, 12, and 24 months after enrollment. Basic descriptive information, such as age, sex, years of education, race, income, insurance status, and medical history, was obtained at baseline. At each visit, data on medication knowledge, adherence, health services use, and health and functional status were collected through interviews with the participant or a caregiver. These data were used to derive variables to evaluate the effects of program participation. A preliminary evaluation of the program based on data after 12 months of enrollment was previously published.

The study was approved by the institutional review board of the University of North Carolina at Chapel Hill.

Conceptual framework. The PRECEDE-PROCEED model provided the framework for development of the Senior PHARMAssist program. PRECEDE is an acronym for predisposing, reinforcing, and enabling characteristics that represent the antecedent and supportive factors for initiating and sustaining change in behavioral factors, which in turn have an influence on general health and functional status. PROCEED is an acronym for policy, regulatory, and organizational actions that make environments more conducive to physical, mental, and social well-being.

Predisposing, enabling, reinforcing, and behavioral variables. Predisposing factors include knowledge, beliefs, readiness to change, and attitudes. In the program these factors were represented by the participant’s knowledge of the medication pur-
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pose and the prescriber’s knowledge of appropriate and low-cost medications included on the program’s geriatric formulary. A cadre of community clinicians (many formally trained in geriatric medicine and affiliated with local academic medical centers) developed the formulary based on professional knowledge of medication safety and effectiveness in the elderly and cost-effectiveness within medication classes. In general, the formulary excluded medications considered inappropriate for the elderly by expert consensus.11,12

Enabling factors are those that allow a motivation or aspiration to be realized. Enabling factors include the availability and accessibility of resources, supportive policies, and assistance. Senior PHARM Assist provides financial assistance for medications, home visits by a program pharmacist when necessary, and referrals to community and government programs, including home-delivered meals and Medicare Savings Plans (Medicaid programs that assist Medicare beneficiaries with limited incomes with Part B cost sharing).

Reinforcing factors (e.g., social support, praise, and reassurance from family or a health provider) develop after a behavior has begun and contribute to persistence or extinction of the behavior. Reinforcers in the program include the provision of ongoing medication assistance, the use of medication reminder aids (e.g., pill boxes, medication calendars), and MTM by a pharmacist (e.g., participant and prescriber education, adherence monitoring).

Medication knowledge was evaluated as the proportion of prescribed medications for which clients could correctly identify the therapeutic purpose during a Senior PHARM Assist visit. Likewise, adherence was assessed by comparing participants’ reported medication use with instructions printed on the labels of prescription containers. For each medication in a participant’s record, the pharmacist asked the participant how the medication was used. For analyses, adherence was subsequently calculated as the proportion of all prescriptions taken as prescribed on the label.

Behaviors targeted for change during a visit to Senior PHARM Assist included the use of unnecessary or inappropriate medications, the underprescribing of medications that might be useful to participants, inappropriate nonadherence (some nonadherence, say due to adverse reactions, was considered appropriate), incorrect administration of medications, unnecessary utilization of costly health services, and the use of medications not included on the geriatric formulary.

General health and functional status variables. Participants were also asked at each visit to rate their general health as poor, fair, good, very good, or excellent, and their responses were dichotomized into poor–fair or good–very good–excellent. Functional status was assessed with the activities of daily living (ADLs) and the instrumental activities of daily living (IADLs) scales from the Duke Older Americans Resources and Services strategy.13 The participants indicated the degree to which they needed assistance with activities such as bathing, dressing, toileting, and eating or instrumental activities such as performing housework, managing money, and taking medications on their own. The number of activities the participant was fully able to carry out on his or her own ranged from zero to six ADLs and zero to eight IADLs. In addition, participants were asked, “During the last three months, did you ever stay in bed all or most of the day because of illness or injury?” The proportion of bed-bound episodes was subsequently calculated based on the number of participants who responded yes to this question. Finally, health services use was determined by asking clients or caregivers how many times they had gone to the emergency room or been hospitalized during the past 12 months. The continuous number of emergency department (ED) visits or hospitalizations in the preceding year and dichotomous none versus any ED visit or hospitalization variables were used in the analysis.

Statistical analysis. The primary objectives were to estimate the average (within-subject) change in outcome measures over the course of two years and to determine whether the changes were best approximated by linear or quadratic trends. Where significant, a quadratic term with a sign opposite to the linear term indicates slowing of the rate of change over time, while the same sign indicates acceleration of the rate of change. To be eligible for analysis, participants had to have a baseline measurement and at least one follow-up measurement. To determine whether patterns of change over time differed according to the duration of follow-up, the trajectory of change was graphed separately for individuals whose last office visit occurred at 6, 12, and 24 months; the composite trajectory, which makes use of all available data, is referred to in the graphs as observed data. Analyses for continuous repeated measures (e.g., number of impaired ADLs) used linear mixed models, and analyses of binary outcomes (e.g., one or more ED visits) used generalized linear mixed models with a logit link function.14 All models included a random intercept for each participant to account for the natural variation in responses between participants and assumed that the correlations between pairs of measurements for the same individual followed an autoregressive pattern in which correlations became weaker as the time interval between the measurements increased. Model variables were estimated by using the MIXED and NLMIXED procedures in SAS version 8.15 The a priori level
of significance was 0.05. Assuming a two-sided \( \alpha \) of 0.05, power was estimated to be 90% or better for detecting annual rates of change (increase or decline) of 0.10 hospitalization and ED visit per year.

These procedures produce valid results if the probability of incomplete follow-up is unrelated to the (unobserved) value of responses after dropout. Since this missing-at-random assumption cannot be verified from the observed data, sensitivity analyses were performed in which estimated longitudinal trends were compared for each response pattern.

**Results.** Of the 794 seniors enrolled in Senior PHARMassist between June 1994 and December 2001, 279 (35%) were excluded from analysis because only baseline program data were available and consequently the effect of program participation could not be assessed. Reasons for discontinuing participation in the program were diverse and included becoming ineligible due to other prescription coverage (primarily due to statewide Medicaid eligibility changes), increased savings or income, or lack of prescription medication use \((n = 129)\); death between the first and second waves \((n = 56)\); and moving (many into a nursing home or adult care home), loss to follow-up, or dropout \((n = 62)\). Thirty participants had not been in the program long enough to have six-month data. The small number of participants who were neither black nor white \((n = 9)\) would not allow inferences to be made about this subgroup and were therefore excluded, leaving 506 (64%) in the study sample. The number of individuals with complete assessments at 12 and 24 months were 384 (48%) and 234 (29%), respectively. Regression analysis showed that participants who completed a greater number of follow-up interviews were more likely to be female \((p < 0.001)\). Duration of follow-up was not significantly associated with baseline age, sex, perceived health, ADLs or IADLs, number of prescription medications, or medical insurance coverage.

The sample comprised 88 men and 418 women; mean ± S.D. age was 76 ± 6.9 years. Approximately half of the cohort was African American, 52% lived alone, and 21% had completed high school. On average, participants reported nearly six medical conditions, the most frequent being arthritis or gout (79%), hypertension (79%), heart disease (60%), anxiety or depression (35%), and diabetes (35%). The mean ± S.D. number of prescription medications at baseline was 5.5 ± 2.85. A more comprehensive description of participants at baseline has been published.

The effects of the program on measured predisposing, enabling, and reinforcing factors are shown in Table 1. The proportion of participants knowing the purpose of their medications increased during the first six months, with no further gains incurred over the remainder of follow-up. This was demonstrated by a significant positive linear coefficient and a significant negative quadratic coefficient. The acceptance of referrals to other programs and services also increased across all time points, as evidenced by a gradual significant increase in the use of subsidized medical transportation from 13% at baseline to 26% in year 2. Use of medication reminder aids increased significantly, with 42% of participants reporting use at baseline, compared with 53% in year 2. The average number of prescription medications and adherence remained stable throughout the follow-up period. However, the proportion of these medications that were included on the formulary increased significantly from 68% at baseline to 82% after two years. The rate of improvement in this measure was most marked in the first six months of participation and declined over time.

At baseline, the 506 participants reported a total of 409 hospital admissions in the previous year \((0.81 ± 1.18\) admission per person-year\) (Table 2). The rate of hospitalizations decreased across all time points. When results were calculated in terms of the probability of any hospitalization, a similar decline from 47% at baseline to 23% at the end of follow-up was observed. The rate of ED visits during the previous year decreased during the first 12 months and then increased, although the rate at 24 months remained lower than at baseline. A similar decline in any ED visit in the past year was found, with 56% of participants reporting at least one ED visit during the previous year at baseline, compared with lower values at follow-up. Sensitivity analyses were consistent with these findings in showing that, regardless of the duration of follow-up, measures of service utilization declined during the first year and then appeared to stabilize (Figure 1).

Self-reported rating of health improved over the measurement period. Thirty percent of participants reported their health to be good to excellent and 54% indicated that their health was “better now compared to a year ago” at baseline. After two years of participation in the program, the comparable figures were 42% and 70%. Similarly, the proportion of participants who reported at least one bed-bound episode in the previous three months declined from 43% at baseline to 28% at the end of follow-up. Functional status measures (ADLs and IADLs) did not improve over the study period, nor did they decline significantly.

**Discussion.** In this evaluation, we demonstrated the beneficial effects on health outcomes for seniors with limited incomes of participating in a comprehensive, community-based pharmaceutical care program. The program provided assistance with coordinating and managing drug therapy, access to a formulary of pre-
Table 1.
Program-Related Patient Characteristics and Behavioral Outcomes

<table>
<thead>
<tr>
<th>Variable</th>
<th>Baseline (n = 506)</th>
<th>6 mo (n = 506)</th>
<th>12 mo (n = 384)</th>
<th>24 mo (n = 234)</th>
<th>Value</th>
<th>Random Regression Coefficient (p)</th>
</tr>
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<tbody>
<tr>
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<td></td>
<td>Linear Quadratic</td>
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<tr>
<td>Predisposing factor</td>
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<tr>
<td>No. (%) pts. knowing purpose for ≥80% of medications</td>
<td>329 (65)</td>
<td>405 (80)</td>
<td>307 (80)</td>
<td>194 (83)</td>
<td>0.0005 (0.14)</td>
<td>-0.0005 (0.31)</td>
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<tr>
<td>Reinforcing factor</td>
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<tr>
<td>No. (%) pts. using medication reminder aids</td>
<td>213 (42)</td>
<td>258 (51)</td>
<td>215 (56)</td>
<td>124 (53)</td>
<td>0.0002 (&lt;0.001)</td>
<td>-0.0002 (&lt;0.001)</td>
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<tr>
<td>Enabling factor</td>
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<tr>
<td>No. (%) pts. using subsidized medical transportation</td>
<td>66 (13)</td>
<td>81 (16)</td>
<td>84 (22)</td>
<td>61 (26)</td>
<td>0.0019 (0.004)</td>
<td>-0.0012 (0.08)</td>
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<tr>
<td>Behavioral outcomes</td>
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<tr>
<td>Mean ± S.D. no. prescription drugs</td>
<td>5.5 ± 2.85</td>
<td>5.5 ± 2.73</td>
<td>5.6 ± 2.71</td>
<td>5.8 ± 2.98</td>
<td>0.0005 (0.57)</td>
<td>0.0005 (0.33)</td>
</tr>
<tr>
<td>No. (%) pts. with &gt;5 prescription drugs</td>
<td>233 (46)</td>
<td>248 (49)</td>
<td>192 (50)</td>
<td>115 (49)</td>
<td>0.0075 (0.13)</td>
<td>-0.0005 (0.31)</td>
</tr>
<tr>
<td>No. (%) pts. adherent to ≥80% of medications</td>
<td>283 (56)</td>
<td>273 (54)</td>
<td>234 (61)</td>
<td>142 (61)</td>
<td>0.0015 (0.53)</td>
<td>-0.0002 (0.98)</td>
</tr>
<tr>
<td>Mean ± S.D. proportion of medications on geriatric formulary</td>
<td>0.68 ± 0.26</td>
<td>0.77 ± 0.24</td>
<td>0.78 ± 0.24</td>
<td>0.82 ± 0.21</td>
<td>0.0138 (&lt;0.001)</td>
<td>-0.0004 (&lt;0.001)</td>
</tr>
</tbody>
</table>

Table 2.
Program-Related Changes in General Health and Functional Status

<table>
<thead>
<tr>
<th>Variable</th>
<th>Baseline (n = 506)</th>
<th>6 mo (n = 506)</th>
<th>12 mo (n = 384)</th>
<th>24 mo (n = 234)</th>
<th>Value</th>
<th>Random Regression Coefficient (p)</th>
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<td>Linear Quadratic</td>
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<td>Health services utilization</td>
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<tr>
<td>Mean ± S.D. no. hospitalizations in previous year</td>
<td>0.81 ± 1.18</td>
<td>0.72 ± 1.17</td>
<td>0.48 ± 0.97</td>
<td>0.39 ± 1.00</td>
<td>-0.0287 (&lt;0.001)</td>
<td>0.0005 (0.14)</td>
</tr>
<tr>
<td>No. (%) pts. with ≥1 hospital admission in previous year</td>
<td>238 (47)</td>
<td>213 (42)</td>
<td>111 (29)</td>
<td>54 (23)</td>
<td>-0.0619 (&lt;0.001)</td>
<td>0.0008 (0.21)</td>
</tr>
<tr>
<td>Mean ± S.D. no. ED visits in previous year</td>
<td>1.23 ± 1.89</td>
<td>0.97 ± 1.53</td>
<td>0.81 ± 1.52</td>
<td>0.88 ± 2.39</td>
<td>-0.0566 (&lt;0.001)</td>
<td>0.0017 (0.001)</td>
</tr>
<tr>
<td>No. (%) pts. with ≥1 ED visit in previous year</td>
<td>283 (56)</td>
<td>238 (47)</td>
<td>154 (40)</td>
<td>96 (41)</td>
<td>-0.0770 (&lt;0.001)</td>
<td>0.0022 (&lt;0.001)</td>
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<tr>
<td>Health status</td>
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<tr>
<td>No. (%) pts. with poor to fair perceived health</td>
<td>354 (70)</td>
<td>309 (61)</td>
<td>227 (59)</td>
<td>136 (58)</td>
<td>-0.0667 (&lt;0.001)</td>
<td>0.0019 (0.004)</td>
</tr>
<tr>
<td>No. (%) pts. with poorer health now than 1 yr ago</td>
<td>233 (46)</td>
<td>177 (35)</td>
<td>111 (29)</td>
<td>70 (30)</td>
<td>-0.0983 (&lt;0.001)</td>
<td>0.0029 (&lt;0.001)</td>
</tr>
<tr>
<td>No. (%) pts. with bed-bound episode in past 3 mo</td>
<td>218 (43)</td>
<td>177 (35)</td>
<td>127 (33)</td>
<td>66 (28)</td>
<td>-0.0534 (0.003)</td>
<td>0.0010 (0.18)</td>
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<tr>
<td>Functional status</td>
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<tr>
<td>Mean ± S.D. no. impaired ADLs</td>
<td>0.51 ± 1.15</td>
<td>0.47 ± 1.16</td>
<td>0.52 ± 1.28</td>
<td>0.52 ± 1.29</td>
<td>-0.0031 (0.67)</td>
<td>0.0003 (0.24)</td>
</tr>
<tr>
<td>No. (%) pts. with ≥1 impaired ADL</td>
<td>121 (24)</td>
<td>106 (21)</td>
<td>81 (21)</td>
<td>44 (19)</td>
<td>-0.0244 (0.14)</td>
<td>0.0007 (0.27)</td>
</tr>
<tr>
<td>Mean ± S.D. no. impaired IADLs</td>
<td>2.47 ± 2.54</td>
<td>2.54 ± 2.50</td>
<td>2.59 ± 2.50</td>
<td>2.56 ± 2.54</td>
<td>0.0189 (0.16)</td>
<td>-0.0002 (0.66)</td>
</tr>
<tr>
<td>No. (%) pts. with ≥5 impaired IADLs</td>
<td>127 (25)</td>
<td>121 (24)</td>
<td>88 (23)</td>
<td>56 (24)</td>
<td>-0.0093 (0.55)</td>
<td>0.0005 (0.36)</td>
</tr>
</tbody>
</table>

*ED = emergency department, ADLs = activities of daily living, IADLs = instrumental activities of daily living.
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The findings support a new model for delivering pharmaceutical services to older adults living in the community. By providing comprehensive and coordinated drug therapy management services that are not simply focused on dispensing prescriptions, the MTM model we have demonstrated is fundamentally different from most current drug assistance programs for older adults. While some existing federal, state, and industry-sponsored programs provide low-income elderly with various forms of drug benefits, most programs have few or no provisions for the supportive services that are equally important for assisting elders with managing their drug regimens appropriately. Although community pharmacists are legally and ethically responsible to screen for drug-related problems and to counsel patients on the appropriate use of medications, services in many community pharmacy settings are brief,
less comprehensive, and mainly provided at the time new medications are first dispensed.17 Thus, in some community settings, pharmaceutical care programs are less effective,18 particularly when technical services like dispensing prescriptions are the primary focus of the pharmacist–patient encounter.

Our findings are also consistent with several other studies examining pharmaceutical services provided in clinical and institutionalized settings, such as academic medical clinics, nursing homes, and hospitals. In these settings, pharmacist involvement in patient care and medication management programs has been shown to positively affect health outcomes19,20 through reductions in inappropriate drug prescribing,21 preventable adverse drug events,22,23 and costs24,25; improvements in clinical outcomes26–28; and better patient adherence.29,31 Likewise, a growing number of randomized controlled trials have found intervention programs involving community-based pharmacists to have a beneficial effect on clinical outcomes and treatment adherence.32–34 Although not all medication review programs by pharmacists have shown positive effects on patient outcomes,35,36 the model presented in the current study shares many of the characteristics of validated medication management programs. Collectively, the findings of this evaluation and previous studies suggest that a coordinated system of care that is more comprehensive than the current standard may be needed to effectively care for older adults with limited incomes living in the community.

Our evaluation had some limitations. First, the MTM program was implemented by a few well-trained pharmacists in a sample drawn from a single geographic region. Thus, the findings may not be generalizable to all elderly populations and may depend on the interpersonal and technical skills of the pharmacists and affiliated staff. However, the magnitude of the impact of the program was so great that a substantial effect would probably be found elsewhere. Second, there was attrition from the program over time, and this potentially biased the results to favor individuals who began the program in better health. Attrition was due to a number of reasons, including dropout, switching to Medicaid or other prescription coverage, moving out of the service location, and admission into an adult care and nursing home. Nevertheless, sensitivity analyses showed relatively small differences in estimated program effects for partially observed groups versus the fully observed group. Third, some data were derived from self-reports, and therefore biases caused by poor recall or a desire to give socially desirable answers may have been introduced. Fourth, participation in the program relied on referrals, which may have influenced the composition of the sample. As a result, unmeasured factors related to referral patterns may have affected our observations. Finally, because we did not study a control population, it is possible that changes attributed to participation in the program were due to other, concurrent factors promoting health in the community. Future studies that include a control group and, ideally, randomization are needed to refine and potentially expand the MTM model we have presented.

**Conclusion.** An MTM program to assist seniors with limited income was associated with significant reductions in hospitalizations and ED visits and improvement in health status. The rate of change in these variables was greatest during the first six months of follow-up.

**References**


Appendix—Elements of Senior PHARMAssist

I. Activity of clinical pharmacist related to medication therapy
A. Patient monitoring
1. Blood pressure.
2. Blood glucose.
3. Height and weight.
4. Social drug use.
5. Depression.
6. Vaccinations and mammograms.
7. Medication allergies and adverse effects.
8. Medication administration and adherence.
10. Drug interactions and duplicate therapy.
B. Patient education
1. Smoking cessation.
2. Sleep hygiene.
3. Alcohol.
4. Aspirin use.
5. Calcium intake.
C. Interdisciplinary efforts
1. Collaborate with prescribers and community pharmacists.
2. Work closely with social service providers.

II. Payment
A. Prescription benefit card that can be used at any community pharmacy via contact with a pharmacy benefit manager.
B. Cost sharing: $5–$8 copayment for up to a 100-day supply of medications on a geriatric formulary, which is updated quarterly.
C. Tied to medication management (must have medication review and community referral to renew prescription card).
D. Local clinicians recommend medications for inclusion on the formulary based on safety and effectiveness in older adults and cost-effectiveness.

III. Medical and social referral
A. Connects participants with other resources.
B. Increases social connection and support system.
C. Common referrals: home-delivered meals, Medicare Qualified Beneficiary (partial Medicaid), senior centers, emergency assistance for bills, and subsidized medical transportation.
D. Nutrition counseling.
E. Diabetic supply information.
F. Drug manufacturer patient-assistance programs for nonformulary medications when there are no formulary alternatives.
G. Other resources that meet a variety of needs.

IV. Patient empowerment
A. Focused one-on-one attention for one to two hours every six months.
B. Participants are responsible for sharing their medication records with other health care providers.
C. Participants are responsible for their copayments at their community pharmacy.
D. Participants are asked to let their other health care providers know of their enrollment in Senior PHARMAssist.
E. Friendly, accessible staff.
F. Unintimidating environment.
G. Opportunity to ask questions and get them answered.
H. Increased control over health care due to medication access, knowledge.
I. Home visits for homebound participants.