

Impact of a Medicare MTM Program: Evaluating Clinical and Economic Outcomes

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Medicare Part D (MPD) is a prescription drug benefit for seniors and individuals with disabilities, which began in 2006 after enactment of the 2004 Medicare Modernization Act.¹ Along with the establishment of MPD, there was a mandate for the participating plans to provide medication therapy management (MTM) services to MPD beneficiaries who met specific eligibility requirements.² The goal of the Medicare MTM program is to improve health outcomes. Although MTM services can be provided by a variety of healthcare professionals, pharmacists—with their extensive knowledge of medications—are the most common providers.³⁻⁵

The Centers for Medicare & Medicaid Services (CMS) mandates provision of MTM services, targeted at MPD beneficiaries with multiple chronic conditions who are taking multiple Part D medications and likely to exceed a preset annual cost for covered Part D medications.² The eligibility criteria for MTM services have changed since the inception of the program for MPD beneficiaries, with the most significant updates imposed by CMS in 2010. The major changes included: (1) standardizing the minimum number of chronic conditions and Part D medications required; (2) decreasing the annual threshold for medication costs from \$4000 in 2006 to \$3000 in 2010; and (3) requiring all participating plans to enroll eligible Part D beneficiaries in an opt-out manner, versus the previous opt-in or opt-out option that MTM programs could offer at their discretion between 2006 and 2009. These changes resulted in a substantial increase in eligible beneficiaries for MTM programs in 2010.

Several small studies have evaluated various outcomes of MTM services in various settings.⁶⁻¹⁹ These studies were limited in that they were either limited to specific disease states, lacked a comparison group or used patients who opted out of MTM services as the comparison group. The purpose of our study was to evaluate the impact of pharmacist-run telephone based Medicare MTM services on health-related outcomes for enrolled patients compared with a matched control group from January 2006 to December 2010 in the Kaiser Permanente (KP) California Regions. Our aim was to evaluate if there was any impact that our

MTM program had on hospitalization utilization, emergency department (ED) visits, change in daily prescription costs, and mortality rate.

In this article

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Objectives: To assess the impact of a Medicare Medication Therapy Management (MTM) program in a large integrated health plan on patient mortality, hospitalization and emergency department (ED) utilization, and daily prescription costs.

Study Design: Retrospective matched cohort study.

Methods: Patients who received MTM services between 2006 and 2010 were matched to control patients who were enrolled in Medicare but did not receive MTM services. They were matched in a 1:4 ratio based on age, gender, geographic location, and prospective diagnostic-cost-group (DxCG) risk score. Multivariate regressions were used to analyze the outcomes. Subgroup analyses were conducted for patients enrolled in 2010 because the Centers for Medicare & Medicaid Services lowered the drug-cost threshold for MTM eligibility and changed from opt-in to opt-out participation.

Results: We identified 34,532 members who received MTM services and 138,128 control members. The MTM group was found to have a significantly reduced mortality (hazard ratio 0.86, 95% confidence interval [CI], 0.84-0.88; $P < .001$), lower odds for hospitalization (odds ratio [OR] = 0.97, 95% CI, 0.94-0.99; $P = .018$), higher odds for emergency department visits (OR = 1.17, 95% CI, 1.14-1.20; $P < .001$), and no differences in change in daily medication costs when compared to the matched group. The subgroup analysis of the 2010 cohort found similar results with better outcomes than the overall cohort.

Conclusions: Medicare MTM services resulted in lower mortality and odds for hospitalization for enrolled patients compared with matched controls. This study observed an increase in ED visits and no differences in change in daily medication costs in MTM services.

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For author information and disclosures,
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Take-Away Points

- Medicare Medication Therapy Management (MTM) programs are mandated by the Centers for Medicare & Medicaid Services to be provided by any health plans that have a Medicare Part D (MPD) drug plan.
- A pharmacy-led MTM program is useful in improving clinical outcomes in Medicare beneficiaries but it may not decrease medication costs.

and interventions made by the MTM staff were documented in each patient's electronic medical record.

The MTM pharmacists worked under collaborative practice agreements with physicians from the Permanente Medical Group and Southern California Permanente Medical Group. Interventions may

have included: performing or obtaining necessary assessments of the patient's health status; initiating and adjusting doses of medications and ordering medication-associated laboratory tests; reviewing and adjusting medications to reduce the likelihood of adverse drug events, interactions, or duplication of therapy; ensuring optimal dosing; improving medication adherence; providing education to enhance each patient's understanding and to encourage appropriate use of medications; simplifying drug therapy and reducing drug therapy costs; and ensuring therapies are in concordance with clinical practice guidelines. Any recommendations falling outside of the protocol were communicated to the primary care physician for approval. Coordination of services was performed with local population care management services, as well as ambulatory care pharmacist-managed services (eg, anticoagulation, oncology, etc).

MATERIALS AND METHODS

Setting

KP California is an integrated healthcare delivery system caring for 6.6 million members in California. Medicare beneficiaries comprise approximately 10% of the total membership, with over 90% of those members having purchased the MPD benefit. Over 40% of our MPD beneficiaries have employer-sponsored retiree benefits. KP California's Medicare MTM program started in 2006 and was initially staffed by 16 full time (FT) clinical pharmacists and 10 FT support staff. By 2010, the number had grown to approximately 40 FT pharmacists and 22 FT support staff to meet the increased demand for services.

Intervention

From 2006 to 2009, the KP California MTM program identified members that were likely to incur annual drug costs of \$4000 or more, who were taking at least 2 medications covered by MPD and had at least 2 or more chronic conditions, such as diabetes, cardiovascular diseases, hypertension, hyperlipidemia, or stroke. MTM services were offered to these patients, and participation in the program was voluntary. In 2010, in addition to the changes in eligible requirements made by CMS, KP California MTM increased the number of chronic conditions from 2 to 3 and the number of required medications from 2 to 5. It was estimated that approximately 3% of MPD enrollees were eligible for the MTM program during the period from 2006 to 2009, while 5% of the MPD enrollees were eligible for MTM program during 2010.

Potential participants meeting the above criteria were identified several times per year during the study period by a computerized system and letters outlining the MTM program were mailed to the members. During 2006 to 2009, only patients who agreed to participate were contacted by the MTM staff, while in 2010, all patients who did not opt out were contacted by the MTM staff. All contacts were made by phone. The initial encounter consisted of the pharmacist or a support staff member obtaining a list of current medications, followed by the pharmacist performing a comprehensive medication review. Follow-up encounters generally focused on identifying opportunities to improve medication therapy. All encounters

STUDY DESIGN

This study was a retrospective, matched-control cohort study. The study group consisted of KP members participating in the Medicare MTM program who had a comprehensive medication review and as-needed follow-ups conducted by an MTM pharmacist. The matched-control group consisted of KP members who were Medicare beneficiaries, who may or may not have been enrolled in MPD, and were not eligible for MTM. Since patients that qualified for MTM (1) were enrolled in MPD, (2) had higher medication costs, and (3) had high disease burden, a likely control patient did not have all 3 conditions and hence may have had less spending in medications and less disease burden. Both the study and the control groups received the usual care, with scheduled visits with their primary care physician or other healthcare providers. Each study group member was matched to 4 control group members based on geographic location, age (same birth year), gender, and prospective diagnostic-cost-group (DxCg) score (within ± 0.01).²⁰ The DxCg score predicts an individual's total healthcare cost in the next year relative to the population mean using a model based on age, gender, diagnoses, and drug codes. This relative score is calculated at the individual level. DxCg scores for Medicare beneficiaries ranged from .05 to 15.59 in the national population. Individuals with a score of 1.0 have a

relative risk that is equivalent to that of the national Medicare reference population.

The study group was enrolled in MTM during the 5-year period between January 2006 and December 2010. They were followed from their enrollment date for 365 days, or until death, or disenrollment from the health plan, whichever came first. If members were enrolled in the MTM program for multiple years, only the first year of enrollment was included in the study. The matched controls for each MTM member were assigned the same enrollment date as the MTM member and were followed in the same way as the patients enrolled in the study group. Each study and control group member was unique and was only used once in this study. All subjects must have had continuous health plan membership with drug benefits during the 12 months prior to the study period to ensure complete pre-period data.

Exclusions included subjects with a cancer diagnosis within 1 year of study entry and nursing home residents. This was because cancer patients were being followed by the specialized oncology team, which included physicians, pharmacists, nurses and social workers at KP and patients residing in the nursing homes did not obtain prescription drugs from our internal KP outpatient pharmacies.

All data were obtained from KP's integrated electronic medical, pharmacy, and administrative databases. Other covariables included: age, gender, Charlson Comorbidity Index (CCI),²¹ and pre-period utilization, including hospitalization, ED visits, and daily medication costs during the 12-month period prior to enrollment.

This study was approved by Kaiser Permanente Institutional Review Boards of both Northern and Southern California regions.

OUTCOMES

The primary outcome of this study was all-cause mortality within 365 days of study enrollment. Deaths were identified using several administrative and clinical data sources within KP, including records indicating discharge status after hospitalization. Deaths that occurred outside of the health plan were identified from California vital statistics death tapes. Secondary outcomes included percentage of hospitalization and ED visits within each group, and median change in prescription cost per day for the same period. Since some patients did not have 365 days of follow-up records due to death or termination of membership, prescription cost were assessed on a cost-per-day metric. Daily medication costs were calculated by dividing total medication costs by the length of follow up time during study period.

Data Analysis

Descriptive statistics, including χ^2 , *t* test, and Wilcoxon rank sum test, were used to compare baseline characteristics. In order to identify the direct impact MTM services had on the outcomes of interest, multiple logistic regressions were used to analyze proportion of patients who were hospitalized or who visited the ED; the Cox proportional hazards model was used to analyze death rate; and multiple ordinary least squares modeling was used to analyze changes in daily medication costs. Except for the Cox proportional hazards model, each model was adjusted for age, gender, region, CCI, and prior utilization of the same outcomes. All outcomes, except changes in daily medication costs, were analyzed as dichotomous variable. Changes in medication costs were analyzed as continuous variable. Test for proportional hazards assumption was assessed for the Cox proportional hazards models. Identical and separate analyses were done on study groups that were enrolled in 2010 because of the substantial changes in enrollment criteria. All analyses were performed using SAS 9.1.3 (SAS Institute, Cary, North Carolina).

RESULTS

During the study period from 2006 to 2010, a total of 46,734 MPD members had received an MTM comprehensive medication review. After applying the matching and exclusion criteria, 34,532 members receiving MTM services were identified and matched to 138,128 control members in a 1:4 ratio (Figure) based on age, gender, geographic location, and DxCG risk score. Over 81% of the members in both groups had a 1-year follow-up period. It represented 31,549 person-years in the study group and 124,546 person-years in the control group. Study enrollment rate was similar during 2006 to 2009, however, enrollment significantly increased in 2010, due to CMS-mandated changes, and these enrollees comprised 39% of the entire study cohort (MTM: 13,402; control: 53,608). The study population had a mean age of 75 ± 8 years, 58% were female, and the median DxCG score was 1.5 (IQR 0.8-2.5). Based on the 12-month data prior to enrollment to MTM services, the study group had a significantly higher CCI (a score that predicted the relative risk of death from prognostic clinical covariables), a higher rate of inpatient hospitalizations and ED usage, and higher daily medication costs than the matched controls (Table 1).

Unadjusted observed outcomes rates are presented in Table 2 for the entire cohort and in Table 3 for members that were enrolled in 2010. No differences were found in the unadjusted all-cause mortality rate between the 2 groups (5.7% in study group vs 5.6% in matched group), while the same mortality rate was significantly lower in the

MTM group for the cohort enrolled in 2010 only (4.3% vs 5.0%, $P < .001$). In the pre-intervention period, the MTM group had a higher percentage of hospitalization compared with the control group (absolute between-group difference of +5.75%) and a higher percentage of ED visits (absolute difference of +9.3%) (Table 1). In the postintervention period, the MTM groups showed an absolute reduction in hospitalization of 4.1% while the control group showed an increase of 2.1% (absolute between-group differences of +0.5%). Similar change was seen with ED visits with an absolute between-group difference of 6.2%, down from 9.3%. In the 2010 cohort, a significantly lower proportion of the MTM group was hospitalized (Table 3: 24.1% vs 24.9%), despite higher percentage of hospitalization in pre-period (27.3% vs 22.1%). We also observed a narrowing in the absolute difference in the percentage of ED visits (3.4% during study vs 7.7% before study). A difference in change of daily median prescription cost was also observed between the 2 study groups, with a median decrease of \$0.39 for the MTM group and a median increase of \$0.10 for the matched group ($P < .001$).

The adjusted outcomes comparing the MTM group with the matched group are presented in Table 4. The adjusted proportional hazard ratio for mortality was significantly lower at 0.86 (confidence interval [CI], 0.84-0.88, $P < .001$) for the entire cohort and at 0.71 (CI, 0.68-0.75, $P < .001$) for the 2010 cohort. The adjusted logistic regression analysis shows a significantly lower odds of hospital admission in the MTM group (odds ratio [OR] = 0.97 [CI = 0.94-0.99, $P = .016$] for the entire cohort and OR = 0.91 [CI 0.87-0.95, $P < .001$] for the 2010 cohort). The OR of ED visits was significantly higher in the MTM group. The change in daily medication costs for the MTM group was not different from the matched group.

DISCUSSION

In this large, retrospective, matched cohort study, we observed a 14% reduction in the risk of mortality, a 3% reduction in the risk of hospitalizations, 17% increased risk for ED visits, and no differences in change in median daily medication costs for MPD beneficiaries within 12 months after receiving MTM services, compared with a matched group of Medicare patients who did not receive MTM services. The same trend, but with a more profound magnitude, was observed in the subgroup enrolled in 2010 when the criteria for MTM services had changed. The improvement in patient outcomes may be due to a combination of services and interventions provided by MTM ambulatory care pharmacists. These interventions included optimizing medication regimens under physician-approved protocol, providing education on medi-

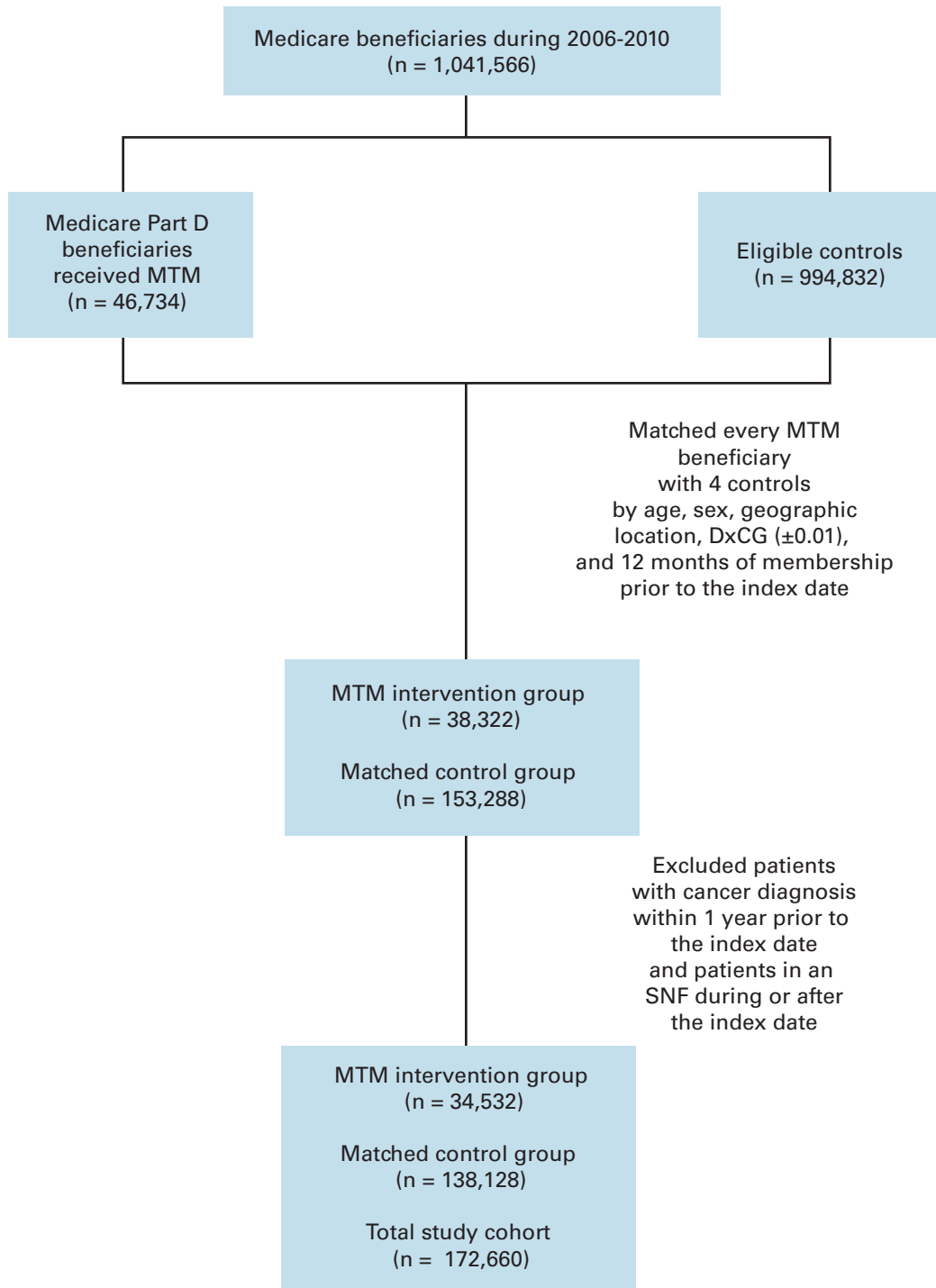
cation use to enhance patient understanding and appropriate use which may lead to increased adherence, ordering necessary laboratory testing, and coordination of care. Optimizing drug therapy by the pharmacist usually consisted of simplifying treatment regimens, titrating existing medication regimens to achieve therapeutic goals or reduce the likelihood of adverse reactions, initiating new medications when gaps in therapy were identified, discontinuing duplicate or unnecessary therapies, including drugs on the Beer's List recommended to be avoided in the elderly; and switching drug therapy to avoid drug-drug interactions. These interventions may help achieve targeted clinical goals that benefit the patient's health status.^{3,4,6,7} Lastly, participating MPD beneficiaries and plans providing MTM services can benefit economically by managing prescription drug costs through appropriate drug use, use of generics, and elimination of unnecessary medications.^{6,8} These measures may reduce total drug spending and delay the time for MPD beneficiaries to reach the coverage gap (donut hole) and incur out-of-pocket costs. Although we did not observe a significant decrease in change of daily medication costs in this study, we were able to find improvement in other outcomes without an increase in medication costs. We do not have data on the number or type of interventions outlined above during 2006 to 2009 as they were not recorded in an analyzable format. In 2010, there were a total of 51,732 interventions recorded by the MTM program. The impacts of specific types of interventions warrant future study.

The results of this study support findings reported in the available literature. In a study by Welsh et al,¹⁰ a reduction in mortality risk was observed in patients enrolled in an MTM program (OR 0.5; 95% CI, 0.3-0.9). The results of our study did not show as great a decrease in mortality for the entire study population or the 2010 subgroup. This may be due to differences in study design between the 2 studies. Our study design included matching, with the intention of obtaining groups with similar cost burden using DxCG scores. Conversely, the study by Welsh et al compared patients who agreed to enroll in the MTM program with those who declined participation.

A mixed impact of the MTM programs on hospital admissions and ED visits was observed in the literature. Some studies have shown no difference or a reduction in hospital admissions, while others have shown an increase associated with MTM programs.^{8,10,14,22} Explanations for the reduction in proportion of patients being hospitalized include improved medication management, while the increase in hospitalizations may be due, in part, to a reduction in mortality. Our study demonstrated that there was a reduction in hospital admission but an increased rate of ED visits in

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■ **Figure.** Flow of Study Population for Individuals Who Completed 2 Health Assessment Questionnaires (T1 and T2) at Least 6 Months Apart Between 2008 and 2010



DxCG score indicates diagnostic-cost-group score; MTM, medication therapy management; SNF, skilled nursing facility.

■ **Table 1.** Demographics of Study Population

	MTM Group	Matched Group	
N	34,532	138,128	1:4 match
Age (SD)	74.8 (7.9)	74.8 (7.9)	
Gender (Female)	19,843 (57.5%)	79,372 (57.5%)	
Median DxCG score (IQR)	1.5 (0.8-2.5)	1.5 (0.8-2.5)	
Geographic Location			
% North	18,431 (53.4%)	73,724 (53.4%)	
% South	16,101 (46.6%)	64,404 (46.6%)	
Enrollment Year			
2006	6592 (19.1%)	26,368(19.1%)	
2007	4987 (14.4%)	19,948 (14.4%)	
2008	4294 (12.4%)	17,176 (12.4%)	
2009	5257 (15.2%)	21,028 (15.2%)	
2010	13,402 (38.8%)	53,608 (38.8%)	
			P
Median Charlson Comorbidity Index (CCI) (IQR)	4.0 (2.0-6.0)	2.0 (1.0-4.0)	<.001
Preperiod Utilization			
Inpatient hospitalization (%)	9,406 (27.2%)	29,696 (21.5%)	<.001
Mean inpatient hospitalization (SD)	0.44 (0.92)	0.31 (0.74)	<.001
ED visit (%)	17,253 (50.0%)	56,278 (40.7%)	<.001
Mean ED visit (SD)	1.15 (1.87)	0.80 (1.66)	<.001
Median pre-intervention period daily medication costs (IQR)	\$11.56 (\$8.89-\$15.26)	\$2.52 (\$1.11-\$5.04)	<.001

DxCG score indicates prospective diagnostic-cost-group score; ED, emergency department; IQR, inter-quartile range; SD, standard deviation.

■ **Table 2.** Unadjusted Observed Outcomes by Study Group for Patients Enrolled During 2006-2010

	MTM Group	Matched Group	P
N	34,532	138,128	
Death within 1 year (%)	1958 (5.7%)	7777 (5.6%)	.774
Inpatient hospitalization (%)	8322 (24.1%)	32,555 (23.6%)	.038
Mean inpatient hospitalization (SD)	0.39 (0.92)	0.35 (0.80)	<.001
ED visit (%)	16,897 (48.9%)	58,961 (42.7%)	<.001
Mean ED visit (SD)	1.13 (1.89)	0.89 (1.71)	<.001
Median change in daily medication costs (IQR)	-\$0.39 (-\$3.30 to \$2.56)	\$0.10 (-\$0.62 to \$1.23)	<.001

ED indicates emergency department; IQR, inter-quartile range; MTM, medication therapy management; SD, standard deviation.

a sicker MTM study population compared with a control group.

Similarly, studies have shown the impact of MTM on medication costs can vary due to a multitude of reasons.^{6-8,10} Reductions in medication costs include discontinuation of duplicate medications and those to be avoided in the elderly,

and medications with an inappropriate indication. Increased medication costs may be due to the addition of medications identified as gaps in therapy, titrating of medications, and increased adherence.

This study, as far as we know, is the largest in size with 172,660 participants and a long follow-up time of 12 months

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■ Table 3. Unadjusted Observed Outcomes by Study Group for Patients Enrolled During Year 2010

	MTM Group	Matched Group	P
N	13,402	53,608	
Death within 1 year (%)	570 (4.3%)	2695 (5.0%)	<.001
Inpatient hospitalization (%)	3229 (24.1%)	13,367 (24.9%)	.044
Mean inpatient hospitalization (SD)	0.38 (0.85)	0.37 (0.78)	.083
ED visit (%)	6356 (47.4%)	23,068 (43.0%)	<.001
Mean ED visit (SD)	1.09 (1.96)	0.91 (1.83)	<.001
Median change in daily medication costs (IQR)	\$0.15 (–\$2.30 to \$3.53)	\$0.15 (–\$0.56 to \$1.60)	<.001

■ Table 4. Adjusted Outcomes for MTM Group Compared With Matched Group

	Adjusted Outcomes	P
Death ^a HR (95% CI)	0.86 (0.84-0.88)	<.001
Inpatient hospitalization ^b OR (95% CI)	0.97 (0.94-0.99)	.016
ED visit ^c OR (95% CI)	1.17 (1.14-1.20)	<.001
Change in daily medication costs ^d (SD)	\$0.50 (\$106.22)	.052
For 2010 cohort only		
Death ^a HR (95% CI)	0.71 (0.68-0.75)	<.001
Inpatient hospitalization ^b OR (95% CI)	0.91 (0.87-0.95)	<.001
ED visit ^c OR (95% CI)	1.09 (1.04-1.13)	<.001
Change in daily medication costs ^d (SD)	\$0.14 (\$91.82)	.693
<small>CI indicates confidence interval; ED, emergency department; HR, hazard ratio; OR, odds ratio. ^aAdjusted for age, sex and Charlson Comorbidity Index using Cox proportional hazard model. ^bAdjusted for age, sex, Charlson Comorbidity Index, and having inpatient hospitalization during pre-period using multiple logistic regression. ^cAdjusted for age, sex, Charlson Comorbidity Index, and having emergency room visits during pre-period using multiple logistic regression. ^dAdjusted for age, sex, Charlson Comorbidity Index, and daily medication costs during prior pre-period using multiple ordinary least squares model.</small>		

to evaluate MTM services. The validity of our results was strengthened, as the size of the study population allowed us to detect very small differences in outcomes. Our study matched MTM to control patients by age, gender, location, and DxCG score. The ability to match at a 1:4 ratio also increased the power and provided greater precision in estimates and tests. We decided to use DxCG as a matching criterion because all but 1 of our outcomes was related to resource utilization. Matching non-MTM-eligible patients may avoid some of the selection bias. Several previous MTM studies analyzed populations of patients who opted in versus those who opted out of MTM participation. Patients who opted in for MTM services may have been more engaged in their healthcare, favoring results for patients enrolled in MTM. The matching in our study was not perfect, as sub-

jects in MTM services had a higher disease burden at baseline, with greater hospitalization, ED visits, and medication costs. This may be due to the fact that eligibility for MTM required meeting a threshold annual medication cost and having multiple chronic conditions. The control group in our study were Medicare members, without 2 of the chronic conditions as stated in KP MTM criteria; or having a lower-than-threshold annual Part D medication cost. After matching for age, gender, and DxCG, we found that our control group did not have the same disease burden in terms of prior hospitalization and ED visit rate and medications used, when compared with MTM study group. We used CCI and specific prior utilization to adjust the outcomes and conducted a difference in differences comparison in order to account for these baseline differences. It is impossible to conduct a

cohort study that avoids all selection bias because MTM eligible patients have a higher disease burden by definition when compared to all non-eligible Medicare enrollees. The current study matched with a control group with less disease burden, based on baseline utilization. Hence, the primary outcome of mortality would be expected to be lower in the control group. Yet, we observed a favorable mortality rate in our MTM intervention group.

Given that KP is an integrated care system and the current study was limited to patients in California, there might be limited generalizability of the results.

The retrospective nature of this study inherently requires a level of caution when interpreting the results. Our study did not examine into what specific components or processes from the MTM program were associated with the outcomes. For example, pharmacist-led discontinuation of skeletal muscle relaxants, a class of medications to be avoided in the elderly, may have been a significant factor in the reduction in inpatient hospitalization. We also did not evaluate any surrogate markers, such as blood pressure, lipid levels, or glycated hemoglobin. Since the 2 groups were not matched on disease burden and not everyone would have these surrogate markers measured during the time period, we decided to look at outcomes that we could observe for the entire cohort. We also did not estimate the return on investment for the MTM services provided at KP California, as other studies had investigated this matter extensively.^{6-8,23,24}

This study is the largest to date, helping to supplement and strengthen available literature. Studies such as ours are essential to ensure that MTM services continue to provide a positive impact on health outcomes. The KP California Medicare MTM program provides targeted services that, when combined with other healthcare services, are likely to improve patient outcomes. Although the direct effect of specific interventions was not investigated, it can be noted that there is a reduction in mortality and inpatient hospitalizations when usual care is supplemented with a pharmacist-led MTM program.

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MMS, EWJ, JC); statistical analysis (RLH, BDY); provision of study materials or patients (EWJ); administrative, technical, or logistic support (RLH).

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