End-Stage Renal Disease (ESRD) Disease Management Demonstration Evaluation Report: Findings from 2006-2008, the First Three Years of a Five-Year Demonstration

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KEY TO SELECTED ACRONYMS AND ABBREVIATIONS

Acronym/Abbreviation	Term
ACEi	Angiotensin Converting Enzyme inhibitor
ACP	Advanced Care Planning
ACO	Accountable Care Organization
AHW	Allied Health Worker
ARB	Angiotensin Receptor Blocker
AV	Arteriovenous
BMI	Body Mass Index
BP	Blood Pressure
CHF	Congestive Heart Failure
CKD	Chronic Kidney Disease
CMS	Centers for Medicare & Medicaid Services
CPM	Clinical Performance Measures
CVD	Cardiovascular Disease
DBP	Diastolic Blood Pressure
DMO	Disease Management Organization
ESRD	End-Stage Renal Disease
FFS	Fee For Service
HbA1c	Hemoglobin A1c
HCC	CMS Hierarchical Condition Categories
HD	Hemodialysis
HWM	Home Weight Monitoring
KDOQI	Kidney Disease Outcomes Quality Initiative
KDQoL	Kidney Disease Quality of Life Survey
LDL	Low Density Lipoprotein
LOS	Length of Stay
LVH	Left Ventricular Hypertrophy
MA Plan	Medicare Advantage Plan
MC	Managed Care
MCS	Mental Component Summary
MedPAC	Medicare Payment Advisory Commission
MRP	Medication Related Problems
NCM	Nurse Care Manager
NKF	National Kidney Foundation
NP	Nurse Practitioner
ONS	Oral Nutritional Supplements
PC	Primary Care
PCP	Primary Care Provider
PCS	Physical Component Summary
PFFS	Private Fee For Service
PPO	Preferred Provider Organization
QoL	Quality of Life
SBP	Systolic Blood Pressure
SF	Short Form

Acronym/Abbreviation	Term
SNP	Special Needs Plan
UF	Ultrafiltration
U.S. DOPPS	United States Dialysis Outcomes and Practice Patterns Study
USRDS	United States Renal Data System
VA	Vascular Access

EXECUTIVE SUMMARY

A. Introduction to the Demonstration and this Evaluation

This report describes the results of the Evaluation of the Medicare End-Stage Renal Disease (ESRD) Disease Management Demonstration. The Centers for Medicare & Medicaid Services (CMS) contracted with Medicare Advantage (MA) Plans that developed Disease Management programs. The Demonstration allowed patients with End-Stage Renal Disease to enroll in MA Plans. The programs in this Demonstration were operationalized by the three Disease Management Organizations (DMOs) (identified in this report as DMO A, B, and C) in order to deliver coordinated care interventions to ESRD beneficiaries enrolled in their plans.

Patients with ESRD require dialysis or transplantation in order to survive as the kidneys are no longer able to perform life-sustaining physiological functions. In 1972 the United States Congress passed the Social Security Amendment [1] that expanded the Medicare program to include treatment coverage for all persons diagnosed with ESRD, regardless of age, making them eligible to receive Medicare coverage for treatment.

Management of ESRD is associated with significant patient morbidity and mortality, as well as significant costs for the Medicare program. In 2007, although there were 387,429 patients with ESRD and Medicare as primary payor (1.2% of the Medicare primary payor population), the ESRD program accounted for a disproportionate 5.8% of the entire Medicare budget [2]. ESRD patients often have multiple comorbidities, which results in increased complexity of their care—from the management of their renal replacement therapies, to their daily decisions about fluid and dietary intake, medication use, and comorbidity management. Clinical care requires transitions across various settings, including dialysis facilities, outpatient clinics, inpatient hospital settings, emergency department (ED) visits, and skilled nursing facilities (SNFs).

The ESRD Disease Management Demonstration sought to evaluate whether DMOs in the setting of MA Plans could improve clinical outcomes and reduce Medicare expenditures. Disease Management is a system of coordinated health care interventions. For patients with ESRD, Disease Management interventions can potentially improve care coordination and enhance implementation of evidence-based care that could translate to better patient adherence, improved quality of care, and subsequent reduction in the need for utilization of costly services.

The Demonstration examined whether Disease Management would 1) be characterized by common strategies across DMOs, as well as consist of components that vary by DMO in specific design, 2) include unique program components that would improve processes of care measures, 3) improve outcomes such as hospitalization, mortality, and transplantation-related measures, 4) improve quality of life and patient satisfaction, 5) be well accepted by providers, and 6) result in a favorable or budget neutral cost profile to the Medicare program.

This Evaluation Report presents results from a comprehensive clinical and financial evaluation of the first three years (2006-2008) of a five year Demonstration of the participating DMOs that designed Disease Management programs for the ESRD population. The Demonstration was scheduled to end in 2008, but there was a delay in finalizing DMO A's conversion into a coordinated care program (Preferred Provider Organization [PPO]) which is required for Special Needs Plans (SNPs). Because of restrictions on contracting managed care staff to work for SNPs, DMO C was not eligible to become a SNP, despite already being a coordinated care plan; DMO A will continue on as a SNP when the Demonstration

concludes at the end of 2010. The key results of these analyses are summarized below, previewing the specific findings reported in subsequent chapters.

B. Comparison Groups

This evaluation utilized various comparison groups. Parts of the evaluation that analyzed the impact of Disease Management on processes of care measures or intermediate markers used either published statistics from the United States Renal Data System (USRDS) or the United States Dialysis Outcomes and Practice Patterns Study (U.S. DOPPS), which is a nationally representative cohort study of practice patterns in the hemodialysis (HD) population. DMO patients were more likely to have patient characteristics that are associated with better health, on average, than the U.S. DOPPS comparison population. For example, DMO patients were younger and more often had the preferred vascular access (arteriovenous fistula).

To evaluate the impact of Disease Management on patient outcomes and cost of care, we compared the DMO population to ESRD patients with traditional Medicare fee-for-service (FFS). Comparisons used statistical adjustment for observed patient characteristics and, in some cases, a subset of the FFS population who were observed to have a similar propensity for enrolling in a DMO as the DMO population – a propensity-score matched comparison group. For the analyses on oral nutritional supplementation (ONS), because serum albumin measurements were necessary, we utilized the ESRD Clinical Performance Measures (CPM) Project as the comparison group. We also used the overall ESRD FFS population as a comparison group in evaluating patient outcomes. Comparison of clinical and demographic characteristics between the DMO and overall FFS population shows similar results as the comparison to the U.S. DOPPS population. Furthermore, DMO patients were found to have similar CMS Hierarchical Condition Categories (HCC) risk scores as compared to the FFS population. Because there are differences between the DMO population and FFS, we accounted for these potential confounding factors by performing statistical adjustments in our analytical models.

C. Key Findings on Common and DMO-Specific Components of Disease Management

The structure of the Disease Management programs varied across the DMOs resulting in unique interventions to improve processes of care including management of comorbidities (e.g., diabetes and cardiovascular disease), improving nutrition (oral nutritional supplement [ONS]), delivery of preventive care (e.g., immunizations); and others (e.g. reducing medication-related errors and facilitating end-of-life planning). Over the course of the Demonstration, all three DMOs modified various components of the program, including type of services delivered, methods of delivery and target patient population. For instance, all DMOs initially provided care coordination spearheaded by an on-site nurse care manager (NCM). Until 2008 DMO C coordinated care by relying on both a telephonic support provided by NCMs at a centralized call center as well as NCMs in the field. After 2008 the expansion of DMO C's health information technology system allowed for a shift to primarily telephonic assessments conducted by NCMs at the call center. These program changes are noted as caveats for interpreting such findings that may be attributed to known changes in program structure, as reported by the DMOs.

D. Key Findings on DMO Interventions and Processes of Care

Disease Management resulted in improvement in several processes of care measures evaluated, but yielded mixed or negative results in others. In several analyses, the impact of specific DMO programs on hospitalization and mortality was also evaluated. These results are summarized in Table ES-1.

Some results on preventive process of care measures are promising in that the Disease Management interventions were associated with improvement in various markers of delivery of care as recommended by evidence-based clinical guidelines when compared to baseline or to comparison groups, namely FFS or a nationally representative sample of U.S. HD patients in the U.S. DOPPS comparison groups.

Table ES-1: Impact of DMO-Specific Interventions

DMO A	DMO B	DMO C
Impact of Pharmacist Involvement on Medication-Related Problems (Chapter 3) • Increase in medication-related problems over time Management of CVD and Cardiovascular Risk Factors (Chapter 4) • Increase in ACEi/ARB use versus baseline among patients with congestive heart failure enrolled for one year, yet a decrease to below baseline at two years • No improvement in blood pressure control among all enrollees Improving Preventive Care Processes (Chapter 5) • More patients received influenza and pneumococcal vaccinations in 2007 and 2008 than in FFS • Significantly more patients with diabetes mellitus received routine HbA1c tests in accordance with established guidelines when compared to FFS and a nationally representative population of HD patients (U.S. DOPPS) comparison populations. • More patients with diabetes mellitus received routine foot and retinal exams by mid-2008 as compared to U.S. DOPPS	Improving Advanced Care Planning (Chapter 6) • Slight increase in adoption of ACP for HD patients versus baseline[a] Improving Diabetes Management (Chapter 7) • Increase in HbA1c tests for patients with diabetes mellitus during period of standing orders • Sharp decrease in HbA1c measurement among patients with diabetes mellitus after standing orders were discontinued • No significant change in achievement of the HbA1c target (HbA1c < 7%) Changing Prescription Patterns of ACEi/ARB Use (Chapter 8) • Increase in ACEi/ARB use versus baseline among patients with persistent hypertension enrolled at least two years	Use of Oral Nutritional Supplement in Patients with Low Serum Albumin (Chapter 9) • Significantly reduced mortality among patients with the clinical indication to receive ONS as compared to the CMS ESRD Clinical Performance Project population. • Increase in serum albumin among patients with the clinical indication to receive ONS. Impact of Home Weight Monitoring on Clinical Outcomes (Chapter 10) • 42% of all patients participated in the HWM program; however, 70% of 2006 enrollees used HWM and only 16% of 2007/2008 enrollees ever used HWM • Short-term effect of reducing IDWG for patients on HWM • No sustained effect of HWM in IDWG after discontinuation • HWM was associated with lower all-cause and cardiovascular mortality and all-cause and cardiovascular hospitalization for 2006 enrollees but this association was not noted for 2007-08 enrollees.

Abbreviations: ACP = Advanced Care Plans; ACEi = Angiotensin Converting Enzyme inhibitor; ARB = Angiotensin Receptor Blocker; BP = Blood Pressure; CHF = Congestive Heart Failure; CVD = Cardiovascular Disease; ESRD = End-Stage Renal Disease; FFS = Fee-for-Service; HbA1c = Hemoglobin A1c; HD = Hemodialysis; HWM = Home Weight Monitoring; IDWG = Interdialytic Weight Gain; LDL = Low Density Lipoprotein; ONS = Oral Nutritional Supplements; U.S. DOPPS = United States Dialysis Outcomes and Practice Patterns Study.
[a] Analysis is limited by inconsistent ACP data, lack of an adequate comparison population, and the small number of patients included in the analyses.

DMOs A and B implemented efforts to improve processes of care measures for diabetes. In DMO A the proportion of patients with diabetes who received foot and retinal exams steadily increased after being initially lower than the U.S. DOPPS comparison group in 2006. By mid-2008, the percentage of patients with both types of exams was slightly higher than the U.S. DOPPS comparison group. Moreover, the percentage of patients receiving quarterly or semiannual hemoglobin A1c (HbA1c) tests was consistently

high for DMO A throughout the Demonstration, ranging from 70% to 80% and exceeding 80% at certain time points between 2006 and 2008. Increases in HbA1c tests were also observed in DMO B as a result of standing orders implemented in the first year of the Demonstration. After the standing orders were implemented the percentage of patients with quarterly HbA1c tests increased from 85% to 95%. However the percentage of patients receiving quarterly HbA1c tests diminished substantially, reaching a nadir of 30% in January 2008 when standing orders were discontinued due to implementation problems, a data system migration, and changes in the medical records systems encountered by DMO B. Moreover, regular quarterly testing was not associated with an improvement in achievement of the HbA1c target (HbA1c < 7%) during the standing orders period or after the standing orders period. DMO A also focused on vaccinations as part of the broader approach to preventive care with 90% of patients receiving influenza vaccinations and 60% of patients receiving pneumococcal vaccinations by the end of 2008; higher than the latest published numbers (2005-2006) for the FFS comparison group.

All three DMOs incorporated cardiovascular disease (CVD) Disease Management as part of their programs. In DMO A, 80% of patients enrolled for one year or more had at least one low density lipoprotein (LDL) measurement in the first year of enrollment, compared to 70% of patients in FFS. Moreover, angiotensin converting enzyme inhibitors (ACEi) or angiotensin-receptor blockers (ARB) use among DMO A patients with congestive heart failure (CHF) enrolled one year increased from 45% of patients at baseline to 58% at one year. However, among patients enrolled at least two years, there was a slight decrease in the rate of ACEi/ARB use (35%) versus baseline (45%), and there was no evidence of improved blood pressure control. In DMO B, prescription of ACEi/ARB medications for hypertensive patients increased for patients enrolled at least two years, from 31% of hypertensive patients at baseline having a prescription to 55% of hypertensive patients having a prescription at two years.

DMO C focused on home weight monitoring (HWM) with an aim to limit interdialytic weight gain (IDWG) based on the rationale that excessive IDWG can accelerate left ventricular remodeling and increase risk for cardiovascular events and death. Analyses demonstrated that HWM was associated with lower IDWG and fewer episodes of clinically relevant excessive IDWG for patients enrolled in the first year of the Demonstration (2006); this association was not seen for patients enrolled during 2007-2008. However, patients who discontinued HWM use showed a marked increase in IDWG, in some cases higher than patients never using HWM. It should be noted there was a marked decline in the number of patients on HWM in 2007 and 2008 compared with 2006 (16% v. 70%, respectively), indicating that increasing use of HWM among enrollees did not occur over the course of the Demonstration, possibly due to technical challenges, patient non-adherence or not accepting the technology, and changes in the inclusion criteria for participation during the evaluation period.

HWM use was also associated with lower one-year mortality and hospitalization (by 45% and 18%, respectively), limited to patients enrolling in 2006. For patients enrolling in 2007-2008, HWM was not associated with reductions in one-year mortality or hospitalization. Taken together, these findings suggest that the results should be interpreted with caution. Patient selection for HWM, low penetration of the program in 2007-2008 compared to 2006, and technical and patient non-adherence/acceptance issues may partially explain the difference in observed associations between HWM use and clinical outcomes over the three-year evaluation period. Therefore, the ability to draw conclusions on the overall association of DMO C's HWM program with the clinical outcomes of interest is limited and the findings should be interpreted with caution.

Because low serum albumin is a recognized predictor of adverse clinical outcomes, DMO C implemented a treatment intervention based on clinical indication, for patients with serum albumin less than 3.8 g/dL. Intention-to-treat analyses demonstrated that there was a significant survival benefit in DMO C's program in that fewer patients with the clinical indication for ONS died at one year follow-up compared to similar patients from the CMS ESRD Clinical Performance Measures Project. The results suggest a

protective benefit of ONS use for 12-month survival, however, no significant association of ONS use with reducing 12-month hospitalization was noted.

DMO B implemented a program to increase adoption of advanced care planning (ACP). The results suggest that Disease Management and a formal ACP program may be somewhat successful in increasing the rate of adoption of formal ACPs among HD patients. Among patients who were enrolled in DMO B for at least 12 months, the number of patients with an ACP increased from 6.6% at baseline to 11.3% after 12 months of enrollment. This analysis is limited by the small sample of DMO B patients (N = 168). Other limitations include the lack of an adequate comparison population, inconsistencies between ACP assessments over time, and the use of multiple ACP assessments during the Demonstration.

Finally, DMO A included a pharmacist on the Disease Management team in order to reduce medication-related problems (MRPs); however, there was an increase in MRPs over time. It is possible this may have been due, at least in part, to a change in the process for review that occurred at the end of 2006. Under the original protocol, the pharmacist was to have direct contact with each patient on a quarterly schedule. At the end of 2006, only patients with medication-related concerns as determined by DMO A's nurse practitioner were evaluated. This could potentially bias the evaluation towards patients with existing MRPs and may, in part, explain the finding of increased MRPs over time. Patient adherence to the medication regimen may also influence the impact of the pharmacist on reducing MRPs. However, it is likely that patient adherence will only have been improved by pharmacist intervention and therefore does not explain our findings.

Several components of Disease Management were added by DMOs as their respective programs evolved. These were not among the original Disease Management interventions designed by DMOs at the beginning of the demonstration in 2006 which were part of the evaluation process for this report. They however reflect developments of their respective Disease Management programs over time.

DMO A instituted a catheter rate reduction program as part of their Disease Management program. The program was designed in conjunction with the ESRD Quality Incentive Payment Demonstration which included a financial incentive to minimize catheter use for enrollees. The catheter reduction program however was implemented after the start of the evaluation period and was not included as one of the selected interventions that were evaluated. DMO B initiated a program which engaged incident ESRD patients in coordinated care upon initiation of HD until the end of their participation in the Disease Management Demonstration at the end of 2008. The program worked with patients throughout their treatment and through transplantation. DMO C implemented a comprehensive and integrated care coordination program that included 14 pathways targeted at improving various aspects of clinical care. Some of these pathways were incorporated in a telemonitoring program that allows for coordinated monitoring by the DMO C nurse care manager. These included blood pressure control, glucose readings for diabetes monitoring, and fluid control (for enrollees with heart failure and CHF). Other clinical pathways developed in the DMO C program included annual enrollee assessments, patient education on advanced directives, depression, smoking cessation, vaccinations, and medication management. Further detail on specific Disease Management components evaluated for the 2006 – 2008 period of the Demonstration are described in the Appendix 1 at the end of this report (Detailed Elements of Disease Management Programs).

E. Key Findings on Patient Outcomes

DMO performance varied markedly on patient outcomes. These findings are presented in Table ES-2.

Patients in the DMOs as compared to the overall FFS population tended to be younger, had longer duration of their ESRD, and were more likely to have diabetes as cause of ESRD. However, the CMS-HCC

risk score was not different between the two populations. After adjusting for all observed differences between the Demonstration and FFS, the evaluation showed a higher percentage of patients survived at one and two years in two of the DMOs (DMO B and C) when compared to the FFS population. Additionally, the percentages of patients hospitalized for all-causes as well as for cardiovascular causes after one or two years of follow-up were significantly lower than FFS in DMO C. Results were mixed for transplantation-related outcomes. The percentage of patients receiving a transplant in the Demonstration was generally lower or similar to FFS. When compared to FFS, DMOs A and C had a higher percentage of patients wait-listed while enrolled in the Demonstration, whereas DMO B had a lower percentage of patients wait-listed while enrolled in the Demonstration. Utilization of services varied somewhat among the DMOs throughout the Demonstration when compared to propensity score matched FFS control groups as shown in Table ES-2.

Table ES-2: Mortality, Hospitalization, and Transplantation Outcomes, DMOs compared to FFS

DMO A	DMO B	DMO C
• No significant survival advantage over FFS at one and two years • No significant difference in all-cause and CV-hospitalizations compared with FFS at one and two years • Hospital admission and readmission rates were not significantly different from FFS • Significantly fewer SNF stays and physician visits than FFS • Significantly higher rates of transplant wait-listing compared to FFS, but no significant difference in transplantation percentages compared to FFS	• Significant survival advantage over FFS at one year and two years • Significantly lower percentage of CV-hospitalizations but not all-cause hospitalization compared with FFS at two years (possibly an artifact of limited data) • Hospital admission rates were not significantly different from FFS; readmission rates exceeded FFS • Significantly fewer physician visits than FFS • No significant difference in ED visits or SNF stays compared to FFS over three-year evaluation period • Transplantation rates were significantly lower than FFS by year 2, and significantly lower rates of transplant wait-listing compared to FFS	• Significant survival advantage over FFS at one year and two years. • Significantly lower percentage of all-cause and CV-hospitalizations compared with FFS at one and two years • No significant difference in hospital admission and readmission rates as compared to FFS over the three-year evaluation period • Significantly fewer SNF stays and physician visits than FFS; no significant difference in ED visits • Transplantation rates were significantly lower than FFS, and no significant difference in transplant wait-listing in the Demonstration compared to FFS

Abbreviations: CV = Cardiovascular; ED = Emergency department; FFS = Fee-for-Service; LOS = Length of stay; SNF = Skilled Nursing Facility
Service utilization analyses were conducted with multiple methodologies; only results consistent across all methodologies are highlighted here.

Although patterns of hospital admissions differed by DMO, overall, hospital admissions were not significantly different for the DMOs compared with FFS. Across all three DMOs, length of stay (LOS) and total hospital days were significantly higher compared to FFS. However, it is likely that the DMOs negotiated flat hospitalization rates with their providers and metrics taking into account hospital days may be less valuable in this evaluation. Utilization was generally significantly lower than the matched FFS control groups throughout the Demonstration for SNF stays and physician visits.

In these current analyses, statistical adjustment and the use of matched control groups were critical, given the observed differences in case-mix, though unobserved differences may persist. It is noteworthy that the observed significant improvement in patient survival for two of the DMOs persisted after adjustment for potential confounders.

F. Key Findings on Patient-Centered Outcomes and Provider Acceptance

The three DMOs performed similarly on patient-centered outcomes and provider acceptance, as shown in Table ES-3.

Table ES-3: Patient-Centered Outcomes and Provider Acceptance

Component	DMO A	DMO B	DMO C
Patient Centered Outcomes	• No change in mental and physical QoL scores at one-year follow-up • Overall patient satisfaction with DMO and NCMs • Initial concerns with cost and billing issues	• Statistically significant but clinically marginal decline in mental and physical QoL scores at one-year follow-up • Overall patient satisfaction with DMO and NCMs • Initial concerns with cost and billing issues	• No change in mental and physical QoL scores at one-year follow-up • Overall patient satisfaction with DMOs • By 2008, a smaller percentage citing NCMs as most helpful service • Initial concerns with cost and billing issues
Provider Acceptance	• Overall satisfaction with DMO impact on comorbidity management and QoL • Satisfaction varied by provider type	• Overall satisfaction with DMO impact on comorbidity management and QoL • Satisfaction varied by provider type	• Overall satisfaction with DMO impact on comorbidity management and QoL • Satisfaction varied by provider type

Abbreviations: NCM = Nurse Care Manager; QoL = Quality of life.

Across all Demonstration patients, the average adjusted mental and physical Quality of Life (QoL) baseline scores were slightly higher (better) than those of the patients in the U.S. DOPPS comparison group. The adjusted analysis for QoL scores showed that mental component summary scores and physical component summary scores did not significantly improve at 12-month follow-up over the course of the Demonstration in DMO A and DMO C between 2006 and 2008, which was similarly observed for the U.S. DOPPS comparison group. Both mental and physical QoL scores for patients enrolled in DMO B showed a statistically, although not clinically meaningful, decline at 12 months. The mixed results suggest that there was no clear impact of Disease Management on improving QoL for patients enrolled in the three DMOs.

In general, the findings suggest a high level of patient satisfaction among patients who remained enrolled throughout the Demonstration. One key finding is that billing and provider issues that were earlier sources of concern for enrollees appeared to improve over the Demonstration. These issues were more quickly resolved when they arose. Also noteworthy is that Nurse Care Managers (NCMs) remained a key aspect of enrollees' experience in, and satisfaction with their DMOs, and was observed across all DMOs in 2006 and 2007. By 2008 for DMO C there was a reduction in the percent of interviewed DMO C patients who cited the NCM as the most helpful service. DMO C relied on the call center NCMs throughout the Demonstration as part of their integrated care program structure, while early on NCMs made periodic on-site visits at DMO C facilities. One potential explanation is that less direct interaction with the NCMs over time may have attributed to a decline in the percent of DMO C

enrollees listing NCMs as the most helpful service. Billing and cost issues and misunderstanding about the DMOs remained the most common reasons for disenrollment throughout the Demonstration. However, several disenrollees from the samples also gave positive feedback and expressed high satisfaction overall with the DMOs despite their decision to leave the DMOs.

Providers interviewed from each DMO reported a perception that the Demonstration had some impact on patient care, specifically in the management of comorbidities, and quality of life. It must be noted these are the perceptions of providers. Data were not available to support whether these perceptions were based on observed clinical outcomes. By the end of the Demonstration, a majority of providers interviewed reported they had overall positive experiences with the DMOs. For example, provider education appeared to smooth out some of the initial implementation problems that enrollees and providers experienced. Providers also seemed to be interested in feedback on how Disease Management is helping their patients. Together these aspects might lead to sustained provider acceptance. Differences in satisfaction were observed among types of providers, with NCMs generally reporting the highest overall satisfaction, followed by Allied Health Workers, then nephrologists.

The results on patient-centered experiences and provider acceptance suggest the potential for Disease Management to improve patient satisfaction with their ESRD care, specifically through a patient's interaction with their NCM who coordinates health care services. Similarly, providers perceived that the Disease Management model of integrated care delivery also improved the quality of care delivered to their patients. It allowed providers to feel they had a greater impact on improving the quality of care and patient quality of life. A central limitation is that these findings are derived from qualitative analyses on the distinct experiences of a very small sample of patients and providers, respectively. Response rates for the quality of life assessment were also low among enrollees. Each round of interviews was also conducted with a different sample of respondents and no inferences can be drawn from one round of interviews to a later round. Selection bias is also a potential in that the final sample represents only respondents who could be contacted, and who agreed to be interviewed. No generalizations can be made to the population of Demonstration enrollees or providers.

G. Key Findings from the Cost Analysis

The Demonstration capitated payments cost Medicare 13.4% more than the *estimated* FFS cost if Demonstration enrollees had remained in FFS, which over the course of these three years translates to approximately $23.5 million. However the higher cost is not surprising and indeed a recent Medicare Payment Advisory Commission (MedPAC) report demonstrated that CMS pays 11% more for Medicare Advantage enrollees than it would have paid on their behalf had they remained in the traditional Medicare FFS setting after adjusting for health risk and demographic factors [3]. Therefore the higher costs cannot be attributed to the Demonstration per se. Moreover, the Affordable Care Act passed by Congress in March 2010 includes provisions that will reduce capitated payments to Medicare Advantage plans over the course of the next several years in order to bring these payments more in line with those in the traditional FFS sector. The Affordable Care Act will keep the 2011 payments at the current 2010 level, and then phase in reductions beginning in 2012 [4].

Overall, the monthly costs for patients in a DMO were higher, at $6,551 per patient per month, compared to the estimated cost if they had remained in FFS at $5,776 per patient per month over 2006-2008. In DMO A, average per patient per month costs were $693 more than the estimated cost for FFS; in DMO B they were $563 higher; and in DMO C, $844 higher than the estimated cost for FFS. For DMOs A and C, the difference in estimated cost from FFS decreased between 2006 and 2008.

Table ES-4: Percent Differences in Costs to the Medicare Program between DMO (capitated payment) and FFS Sector (estimated cost), by DMO and Year

	DMO A	DMO B	DMO C	All DMOs
2006	15.8%	6.5%	15.4%	12.0%
2007	10.9%	14.4%	19.2%	16.7%
2008	12.2%	8.2%	9.2%	10.4%
2006-2008	11.2%	10.9%	14.7%	13.4 %

Abbreviations: FFS = Fee-For-Service
Costs reported as percent higher than FFS costs.

As shown in Table ES-5, both DMO A and DMO B experienced losses relative to FFS based on differences in service utilization while DMO C experienced savings throughout all three years of the Demonstration. In general, savings or losses to the DMOs were driven by the differences in hospital admissions and, to a lesser extent, the differences in SNF stays. As such, it is important keep in mind that the calculations of estimated savings to the DMOs were at least in part based on differences in utilization that were not statistically significant. Including these non-significant differences, particularly hospital admission costs, had a large impact in the calculation of overall estimated savings. It should also be noted that because the costs per service are derived from unique FFS comparison groups selected to match the patient characteristics of each DMO, only differences in costs between DMO and each respective FFS comparison group can be evaluated and costs should not be compared across DMOs. Finally, additional cost analyses will be conducted by CMS based on audited cost data from the DMOs in the future. These analyses will provide more evidence regarding savings or losses and assessment of DMO viability in the long-term.

Table ES-5: Estimated Savings to DMOs due to Differences in Utilization from FFS (using second-stage regression methodology)*

Service	Estimated Savings per Patient per Year											
	DMO A				DMO B				DMO C			
	2006	2007	2008	2006-2008	2006	2007	2008	2006-2008	2006	2007	2008	2006-2008
Hospital Admissions	-$1,311	-$1,945	-$5,040	-$3,098	-$1,486	-$21	-$5,962	-$2,993	$376	-$408	$2,521	$712
SNF Stays	$819	$2,203	$108	$1,057	$1,101	$1,948	-$320	$774	$968	$2,247	$1,354	$1,714
ED Visits	$131	-$14	$109	$66	-$28	$355	$151	$208	-$13	-$20	$59	$7
Physician Visits	$337	$224	$81	$188	$57	$99	$59	$75	$86	$104	$130	$109
Est. Total Savings	-$24	$469	-$4,742	-$1,788	-$355	$2,382	-$6,071	-$1,936	$1,417	$1,922	$4,064	$2,543
Est. Total Savings %	0.0%	0.6%	-5.6%	-2.2%	-0.6%	3.5%	-8.6%	-2.8%	1.8%	2.4%	5.1%	3.2%

Service	Estimated Savings per Patient per Year			
	All DMOs			
	2006	2007	2008	2006-2008
Hospital Admissions	-$209	-$955	-$1,141	-$888
SNF Stays	$837	$1,984	$639	$1,270
ED Visits	$26	$6	$90	$41
Physician Visits	$150	$131	$106	$125
Est. Total Savings	$804	$1,166	-$306	$547
Est. Total Savings %	1.0%	1.5%	-0.4%	0.7%

Abbreviations: ED = Emergency department; FFS = Fee-for-Service; SNF = Skilled nursing facility
*This analysis assumes a flat payment rate for hospitalization and ignores the impact of LOS in the calculation of estimated total savings. Positive dollar amounts represent estimated savings to the DMO; negative amounts, losses. Estimated savings are calculated as the difference between FFS and DMO utilization, multiplied by the FFS cost per unit of utilization. LOS and total hospital days are excluded from this calculation. Finally, estimated total savings are expressed as a percentage of Medicare payment to DMOs.

H. Summary and Conclusion

Overall, the ESRD Disease Management Demonstration appears to have resulted in some positive clinical benefits. Among the positive results found in this evaluation are that two of the three DMOs (DMO B and DMO C) showed higher survival at one and two years compared with FFS. Statistically significant reduction in all-cause and cardiovascular-related hospitalization were noted for DMO C compared with FFS. In addition, a specific process intervention (nutritional supplementation) was also directly associated with lower mortality among enrollees for DMO C. Some process of care measures improved, however results are mixed for other Disease Management process of care measures developed by the DMOs, due in part to problems with or changes in implementation, changes in protocol, and data limitations. Disease Management did not appear to have an impact on improving QoL for DMO enrollees at 12-month follow-up.

Our analyses revealed that across all three DMOs and all three years, capitated payments for DMO enrollees cost Medicare 13.4% more than had they remained in FFS. This is not a surprising result given the expected differential in capitated MA payments compared to FFS, and therefore a differential that cannot be attributed to the DMOs or the Demonstration per se. Given that the cost evaluation also sought to examine whether DMO enrollees experienced lower utilization than they would have had if they remained in traditional FFS, it should be noted that our estimates for costs of utilization with each DMO assumed a similar cost-structure as FFS and were therefore not based on actual DMO costs. CMS will be providing the latter analyses as a separate report.

There are several potential reasons for the DMO-specific differences in the impact of Disease Management on the clinical and cost evaluation findings. First, program design differed by DMO and it is possible that treatment interventions that were incorporated by one DMO in addition to care coordination contributed to the improvement in clinical outcomes. The impact of these interventions – the use of ONS and HWM scales, are described further in Chapters 9 and 10. In addition, the degree of intervention and patient interaction varied across the three DMOs, and it is possible that daily monitoring of patients is necessary to prevent patient hospitalization. Second, programmatic changes observed in the Disease Management components because of operational reasons may have limited their potential impact. These Disease Management program changes are described further throughout this report. Finally, patients with ESRD have had chronic kidney disease for years and attempting to modify ingrained self-care behavior through patient education, screening and preventive maintenance in patients may be difficult. Indeed, this was a point raised in a recent review of several CMS Disease Management demonstrations [6].

There was no observed improvement of QoL, yet other patient centered measures, specifically, patient satisfaction showed generally positive support for the ESRD Disease Management Demonstration, and was reported by patients in all three DMOs. Providers interviewed in 2007 and later a different sample of providers interviewed in the winter of 2009 also expressed general acceptance of the Disease Management program.

There are several strengths of this evaluation. First, we analyzed a comprehensive series of multi-dimensional outcomes including intermediate outcomes, processes of care measures, quality of life, hard clinical endpoints, patient and provider satisfaction, and financial outcomes. Second, we compared the enrollees' outcomes using two different populations: the Medicare FFS ESRD population and the U.S. DOPPS, which is a nationally representative study of HD patients in the United States. Finally, our statistical analyses employed multiple regression models that accounted for the potential effects of confounding variables, including a methodology to identify a FFS comparison group that had a similar propensity for enrolling in a DMO as the DMO population.

The evaluation also includes several limitations. The DMO populations for some analyses were relatively small. For example, fewer than 100 patients were enrolled in DMO B at any time during 2006. This can lead to insufficient statistical power to detect differences that may be relevant to patients, clinicians, and policy makers.

Differences in disenrollment rates across the three DMOs may have had an impact on the observed clinical outcomes. Patients who disenroll may do so because they are sicker or have greater co-morbidity burden thus leading to selection bias among patients who remain in the DMO, something also reported in other studies [7, 8]. Indeed, our analysis comparing patients who disenrolled to those who did not disenroll revealed that disenrollees had significantly higher CMS-HCC risk scores. This difference was partially accounted for in the utilization analyses presented in the chapter on outcomes, and the cost analysis, which used propensity score matching to select the matched control FFS sample.

DMO programs were also evolving over the course of the Demonstration so that the impact of a specific intervention over time may have changed. Moreover, the cost evaluation did not take into account the cost structure of the various DMOs, as the audited data were not available. Therefore the overall impact of the program on each DMO's financial viability cannot be assessed at this time. CMS may examine this issue when the audited data become available.

Program implementation and stabilization appear to be critical for successful Disease Management interventions. The results on clinical outcomes also need to be interpreted in the context of financial analyses of the impact of Disease Management. This may be particularly important in order to observe any longer term impact of Disease Management on outcomes and cost for this complex population with a high disease burden who consume a high proportion of medical services.

Finally, this evaluation is limited to the first three years of the Demonstration. It is possible that further improvements in clinical outcomes, as well as reduction in utilization of clinical services resulting in cost savings may occur with continued implementation of the Disease Management programs.

This ESRD Disease Management Demonstration represented a unique opportunity to identify improvement in clinical outcomes in a population that is ideally suited for Disease Management. The findings merit consideration in the ongoing assessment of the value of Disease Management. Finally, one related approach, among others, that may have benefits for this population is the Accountable Care Organization (ACO). The Affordable Care Act passed by Congress in March 2010 encourages the development of ACOs, which are organizations that provide integrated care, much like Disease Management. Providers that belong to an ACO collectively agree they are all accountable for the care they deliver, namely the quality, cost, and overall care of Medicare beneficiaries [5, 9]. The medical home model is also based on principles of coordinated care delivery. These models would allow for further testing of Disease Management and care coordination concepts for the ESRD population in a FFS setting.

I. References

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CHAPTER 1: INTRODUCTION AND BACKGROUND

This report describes the results of a Medicare Demonstration allowing patients with End-Stage Renal Disease (ESRD) to join three Medicare Advantage (MA) Plans in order to apply Disease Management principles. Disease Management is a system of coordinated health care interventions. This system of care delivery provides support for the physician/practitioner and patient relationship, and emphasizes prevention of acute conditions and complications utilizing evidence-based practice guidelines and patient-education [1]. Disease Management programs in this Demonstration were operationalized by the three Disease Management Organizations (DMOs) in order to deliver coordinated care interventions to ESRD beneficiaries enrolled in their plans.

A. Medicare's End-Stage Renal Disease Program

Patients with ESRD require dialysis or transplantation in order to survive as the body is no longer able to cleanse toxins from the blood, and the kidneys cannot regulate other critical physiological functions, such as blood pressure (BP) and the utilization of nutrients. Dialysis therapy acts as a life-saving treatment to replace the renal function the kidneys no longer perform. Without dialysis or kidney transplantation, persons with complete renal failure will survive for a very short period of time.

In 1972 the United States (U.S.) Congress passed the Social Security Amendment [2] that expanded the Medicare program to include treatment coverage for patients diagnosed with ESRD. The amended legislation made all persons diagnosed with ESRD, regardless of age, eligible to receive Medicare coverage for treatment, specifically dialysis and transplantation.

Both the number of ESRD patients and the cost of providing treatment for ESRD patients have grown in the nearly four decades since 1972. In 2007, although there were 387,429 patients with ESRD and Medicare as primary payor (1.2% of the Medicare primary payor population); the ESRD program accounted for a disproportionate 5.8% of the entire Medicare budget [3]. The total annual costs associated with a patient on hemodialysis (HD), the most common form of treatment for ESRD, increased from $70,190 per year in 2005 to $73,008 per year in 2007 [4].

ESRD is associated with increased morbidity and mortality, particularly in patients with diabetes mellitus (diabetes) and cardiovascular disease (CVD) as comorbidities [5-7]. Complications from ESRD often result in greater utilization of particularly costly health care services, such as visits to the emergency department (ED), hospitalizations, and more frequent outpatient visits to multiple specialists for patients with comorbidities. Patients with ESRD also require many medications for ancillary effects of their ESRD, dialysis treatment, and to treat other comorbidities.

Medicare beneficiaries with ESRD therefore represent a special and costly patient sub-population for Medicare and other payers, and are particularly appropriate for enrollment in a Disease Management program. Originally, Medicare ESRD beneficiaries were prohibited from enrolling in managed care programs such as the earlier Medicare+Choice program and the current Medicare Advantage (MA) program except for ESRD-specific Demonstration projects. This changed in 2006 with the authorization of "Special Needs Plans" (SNPs) representing a further expansion of Medicare's program for patients with ESRD.

B. The Potential of Disease Management

Numerous studies and reports on Disease Management have examined whether this model of care delivery results in better patient outcomes and cost savings for patients with chronic diseases [8-13]. Findings are mixed for the effectiveness of Disease Management to improve clinical outcomes. On the one hand, a number of published studies showed promising results with reduction in hospitalization and mortality. For example, mortality was approximately 19% to 35% lower for ESRD patients enrolled in a Disease Management program, while hospitalization rates were about 45% to 54% lower [14]. In the non-ESRD population, one study of chronic Disease Management reported lower hospitalizations among patients in the treatment group [15]. However, in a recently released study of the Medicare Coordinated Care Demonstration, only one program out of 15 showed improved outcomes in hospitalization, and minimal effects on the quality of care were noted based on the clinical indicators examined [12]. Similarly, a report on the interim findings of the Demonstration for Chronically Ill Medicare Beneficiaries showed limited impact on reducing preventable hospitalizations and mortality [11].

Studies on the financial impact of Disease Management are similarly inconsistent. A 2006 study by The Home Health Care Management and Practice Disease Management program, which studied the costs for treating patients with diabetes, reported gross savings of $14.7 million [10]. A review of studies on Disease Management suggests that some cost-savings can be achieved for programs that manage patients with multiple comorbidities [16]. In addition, a 2009 study on the Indiana Chronic Disease Management Program found evidence that the program appeared to reduce costs to Medicaid [17]. On the other hand, in the Medicare Coordinated Care Demonstration, although three programs yielded lower monthly Medicare expenditures, compared to the control group, these savings were off-set by program and administration fees [12]. The ongoing Medicare Health Support Demonstration also revealed that costs increased with the implementation of Disease Management [18]. These mixed results are reinforced by a 2004 report by the Congressional Budget Office [19] that cautioned against deriving broader conclusions about the effect of Disease Management, because there was an insufficient number of studies jointly evaluating the impact of a Disease Management intervention on costs of providing Disease Management care, in addition to determining whether there are improvements in health outcomes, and processes of care.

The ESRD patient population is particularly well suited for study of Disease Management interventions for several major reasons: 1) the frequent existence of multiple comorbidities in this population requires improved care coordination and specific management plans for diabetes and CVD, 2) the high rates of hospitalization and mortality may potentially be reduced with improved outpatient and preventive care, 3) a number of process of care measures exist, which have been demonstrated to improve clinical outcomes and 4) the cost of care for the ESRD population is disproportionately high [20]. As noted above, ESRD patients comprise just over 1.2% of all Medicare beneficiaries [3]; however the portion of the Medicare budget that goes toward treatment of the ESRD population is about 5.8% [3].

Despite its potential advantages, a Disease Management approach for the ESRD population has not been widely studied. A 2001 study reported low standardized mortality and hospitalization rates in a group of dialysis units that used Disease Management for patients with ESRD; however, the study had no internal or external comparison group [14]. Moreover, there was no examination of the effect of Disease Management on costs.

A more formal evaluation of Disease Management was performed in the Centers for Medicare & Medicaid Services' (CMS) Managed Care (MC) Demonstration, completed in 2002. This Demonstration evaluated the impact of MC on the enrollment experience of patients; clinical outcomes and indicators; and financial impact on CMS and on the MC sites [8]. The results of this earlier Demonstration showed that Medicare patients who enrolled in the MC Plans experienced improved quality of life (QoL) and

overall satisfaction with their MC programs [8, 21]. Indicators for processes of care such as anemia management, dialysis adequacy, and rates of vascular access were also improved. However, after adjusting for patient case-mix and demographic characteristics, no clear impact was observed on hospitalization rates and a significant reduction in mortality was noted only in one participating site [8]. Furthermore, the study found that Medicare paid more for patients in the Demonstration than if they had remained in traditional Fee-For-Service (FFS). Moreover, the Demonstration sites also reported financial losses, or nominal short-term gains, despite the increased capitation payments from Medicare for treatment of Demonstration enrollees [8]. However, given the findings of the MC Demonstration evaluation including some improvement in processes of care measures as well as evidence for the program's operational feasibility, it was thought that Disease Management continued to hold promise in the management of the ESRD population.

C. The ESRD Disease Management Demonstration

Three DMOs serving different geographic areas participated in the Demonstration. Hereafter they are referred to as DMO A, DMO B, and DMO C. The Demonstration initiated enrollment in January 2006. DMO A consisted of one MA Plan in one service area. DMO B consisted of two MA Plans in two service areas and DMO C consisted of four MA Plans in 11 service areas. The benefits offered by DMO B and DMO C are comparable within each of the respective MA Plans offered by DMO B and DMO C. DMO A and C continue to operate at the time of this report, whereas DMO B terminated operations as of December 31, 2008.

DMO A and DMO B established their programs in two sites (two counties in California; and Georgia and Arizona, respectively). DMO C had larger geographic coverage, with Demonstration sites operating in New York, Illinois, Massachusetts, Pennsylvania, Texas, Connecticut, California, Tennessee, and Alabama.

DMOs A and C are primarily operated by dialysis providers that each partnered with health plans in the development and implementation of their respective programs. DMO B was originally working with a dialysis provider that was acquired by another dialysis organization immediately before the Demonstration. Because of this ownership change, the same dialysis provider was part of both DMO A and DMO B. This organizational change impacted on the information flow to DMO B and the dialysis provider. For instance, as a result of this transition, access to diabetes laboratory markers and implementation of diabetes-related standing orders discontinued. For additional information on the impact of this organizational change please refer to the system conversion noted in Chapter 7 on DMO B's diabetes management program.

In 2005 all the DMOs finalized their respective Disease Management programs, and provided feedback to CMS and the Evaluation team in the design of the Disease Management Evaluation. Final negotiations with CMS on payment and risk-sharing arrangements were also completed. Face-to-face meetings between the evaluation contractor, CMS and the DMOs were conducted, along with follow-up teleconferences involving CMS and the DMOs to finalize operational and implementation aspects of the Demonstration. Regular communication by CMS and the contractor was maintained with all the DMOs throughout the Demonstration evaluation study period to discuss operational and scientific matters, such as Disease Management protocols, data transfer protocols, any changes to program structure, enrollment and disenrollment information, and discussion of evaluation methodology and interim findings.

Table 1.1a describes the demographic and clinical characteristics of patients who enrolled in each of the Demonstration DMOs compared with all Medicare fee-for-service patients. Table 1.1b compares each of the Demonstration DMOs to fee-for-service samples in the states where the DMOs operated. The Technical Appendix also presents a comparison of patients in each DMO to patients in the U.S. Dialysis

Outcomes and Practice Patterns Survey (U.S. DOPPS), a nationally representative sample of adult dialysis patients in the U.S. [22].

The CMS Hierarchical Condition Categories (HCC) risk score was used to measure the relative level of comorbidity. We used the CMS-HCC risk score calculated by the ESRD model using conditions from the year prior to enrollment [23, 24]. A small number of patients were new to Medicare the first year of their enrollment in the Demonstration. In these instances a risk score based only on demographic information from the current year was used. A higher score indicates a patient with more chronic conditions who is predicted to use more health care resources.

Table 1.1a: Demographics of Demonstration Enrollees and Medicare Fee-for-Service Patients

	DMO A	DMO B	DMO C	All DMOs	FFS
Patients	722	268	1,374	2,364	477,246
Age: 18 to 44 Years Old	**19%***	**20%***	**18%***	**18%***	13%
45 to 59 Years Old	**39%***	**37%***	**36%***	**37%***	26%
60 to 74 Years Old	**34%***	**37%***	**32%***	**33%***	36%
75 or More Years Old	**8%***	**6%***	**15%***	**12%***	26%
Sex: Female	**39%***	50%	**49%***	46%	46%
Male	**61%***	50%	**51%***	54%	54%
Duration of ESRD: Less than 6 Months	**10%***	**7%***	**7%***	**8%***	48%
6 to 11 Months	**13%***	**7%***	**10%***	**11%***	7%
12 to 35 Months	**30%***	**34%***	**31%***	**31%***	19%
36 to 79 Months	**23%***	**19%***	**21%***	**21%***	11%
80 Months or More	**24%***	**33%***	**32%***	**29%***	16%
Cause of ESRD: Diabetes as Cause of ESRD	**52%***	46%	45%	**47%***	44%
Other Cause of ESRD	**48%***	54%	55%	**53%***	56%
Race: White	**75%***	**33%***	**50%***	**56%***	60%
Black	**18%***	**57%***	**45%***	**38%***	34%
Other Race	**7%***	**9%***	**4%***	**6%***	6%
Ethnicity: Not Hispanic or Latino	**43%***	**76%***	**77%***	**66%***	87%
Hispanic or Latino	**57%***	**24%***	**23%***	**34%***	13%
Modality: HD	**96%***	**100%***	**98%***	**98%***	93%
Peritoneal Dialysis	**4%***	**0%***	**2%***	**2%***	7%
Previous Failed Transplant	**9%***	7%	**10%***	**9%***	6%
CMS-HCC Risk Score	1.05	1.07	1.06	1.06	1.06

Abbreviations: CMS- HCC risk score = Centers for Medicare & Medicaid Services – Hierarchical Condition Categories; ESRD = End Stage Renal Disease; HD = Hemodialysis; n/a = not available; FFS = Fee-for-service traditional Medicare.
CMS-HCC risk score from the ESRD risk adjustment model
Table does not include patients with functioning transplant at enrollment.
*DMO findings differ from FFS ($p < 0.05$).

Table 1.1b: Demographics of Demonstration Enrollees and Medicare Fee-for-Service Patients in the States where the DMOs Operated

	DMO A	FFS A	p-value	DMO B	FFS B	p-value	DMO C	FFS C	p-value
Patients	722	45,693		268	26,029		1,366	139,036	
Age: 18 to 44 Years Old	20%	13%	< 0.01	20%	16%	< 0.01	18%	13%	< 0.01
45 to 59 Years Old	39%	27%		37%	28%		36%	27%	
60 to 74 Years Old	33%	35%		37%	36%		32%	35%	
75 or More Years Old	8%	25%		6%	20%		15%	25%	
Sex: Female	39%	45%	< 0.01	50%	47%	0.38	49%	46%	0.03
Male	61%	55%		50%	53%		51%	54%	
Duration of ESRD:									
Less than 6 Months	11%	46%	< 0.01	7%	45%	< 0.01	7%	47%	< 0.01
6 to 11 Months	13%	6%		8%	6%		10%	7%	
12 to 35 Months	29%	19%		34%	19%		32%	19%	
36 to 79 Months	23%	12%		20%	12%		21%	11%	
80 Months or More	23%	17%		32%	18%		31%	16%	
Cause of ESRD: Diabetes	52%	46%	< 0.01	46%	45%	0.80	45%	47%	0.14
Other Cause	48%	54%		54%	55%		55%	53%	
Race: White	75%	66%	< 0.01	33%	45%	< 0.01	50%	66%	< 0.01
Black	18%	16%		57%	48%		45%	27%	
Other Race	7%	18%		9%	7%		4%	8%	
Ethnicity:									
Not Hispanic or Latino	43%	67%		76%	91%		77%	75%	
Hispanic or Latino	57%	33%	< 0.01	24%	9%	< 0.01	23%	25%	0.24
Modality: HD	96%	93%	< 0.01	100%	93%	< 0.01	98%	93%	< 0.01
Peritoneal Dialysis	4%	7%		0%	7%		2%	7%	
Previous Failed Transplant	9%	6%	< 0.01	7%	5%	0.04	10%	6%	< 0.01
CMS-HCC Risk Score	1.05	1.06	0.12	1.07	1.04	0.01	1.06	1.06	0.63

Abbreviations: CMS-HCC risk score = Centers for Medicare & Medicaid Services – Hierarchical Condition Categories; ESRD = End Stage Renal Disease; HD = Hemodialysis; n/a = not available; FFS = Fee-for-service traditional Medicare.
CMS-HCC risk score from the ESRD risk adjustment model.
Table does not include patients with functioning transplant at enrollment.

The DMOs began enrolling patients January 1, 2006 and continued through the end of the evaluation period on December 31, 2008. Table 1.2a describes overall enrollment and disenrollment in the Demonstration while Tables 1.2b through Table 1.2d describe DMO-specific enrollment and disenrollment. In October 2008, DMO B announced that it was officially terminating its participation in the Disease Management Demonstration, effective December 31, 2008. CMS extended the Demonstration for DMO A and DMO C through December 31, 2010.

It should be noted the high percentage of disenrollment in the DMOs may be associated with health status. Patients who disenroll may do so because they are sicker or have greater co-morbidity burden thus leading to selection bias among patients who remain in the DMO. Indeed, an analysis comparing patients who disenrolled to those who did not disenroll revealed that disenrollees had significantly higher CMS-HCC risk scores, indicating poorer health.

The rate of disenrollment across all three DMOs from 2006 through 2008 was 40%, while total disenrollment rates varied across the three DMOs, ranging from 24% to 48%. The annual average rate was 20% for all three DMOs. The overall 2006 to 2008 and annual rates reported here for the ESRD Disease Management Demonstration are higher than what has been reported in the literature for other Demonstrations and for the Medicare HMO and Managed Care sectors. An earlier study by Lied et al, reported annual disenrollments from Medicare Managed Care Plans at 14.5%, based on 1994 and 1995 data [25]. Disenrollees also tended to be in poorer health (disabled) and more recent enrollees compared to those that stayed in the Plans [25, 26]. Moreover, in the final report on the Medicare Preferred Provider Organization (PPO) Demonstration, the overall disenrollment rates for PPO Demonstration plans were reported to range from just over 3% to 46%, with an average overall rate of just over 10% [27]. The average rate in the Medicare FFS sector was lower at 7.4% [27]. This further

suggests that disenrollment rates from the ESRD Disease Management Demonstration were higher compared to what has been presented in other studies reporting disenrollment figures. One potential reason for the higher disenrollment in the ESRD Disease Management Demonstration is that ESRD patients represent a sicker patient population with overall higher disease burden. As noted above, the ESRD Disease Management Demonstration patients in poorer health, as indicated by higher CMS-HCC risk scores, were more likely to disenroll from the Demonstration within 1 year of enrollment (OR = 3.75; 95% CI 2.18, 6.44).

Table 1.2a: Annual Enrollment and Disenrollment, All DMOs, 2006-2008

Year	New Enrollments	Dis-enrollments[a]	Deaths	Enrollment at end of period	Enrolled at any time during period	Cumulative Enrollments	Cumulative Disenrollments
2006	1,077 (100%)	154 (14%)	69 (6%)	854 (79%)	1,077	1,077	154
2007[b]	1,009 (54%)	544 (29%)	165 (9%)	1,154 (62%)	1,863	2,086	698
2008[c]	342 (23%)	266 (18%)	148 (10%)	1,082 (72%)	1,496	2,428	964
Total	2,428 (100%)	964 (40%)	382 (16%)	1,082 (45%)	2,428	2,428	964

Note: Percents are computed using enrollment at any time during period as denominator.
[a] Counts do not include patients who disenroll in December because CMS processes enrollment changes at the start of each month.
[b] A special election was enacted for DMO C in 2007.
[c] DMO B ceased operations at the end of 2008.

Table 1.2b: Annual Enrollment and Disenrollment for DMO A, 2006-2008

Year	New Enrollments	Dis-enrollments[a]	Deaths	Enrollment at end of period	Enrolled at any time during period	Cumulative Enrollments	Cumulative Disenrollments
2006	315 (100%)	43 (14%)	27 (9%)	245 (78%)	315	315	43
2007	277 (47%)	102 (20%)	54 (10%)	366 (70%)	522	592	145
2008	160 (30%)	79 (15%)	55 (10%)	392 (75%)	526	752	224
Total	752 (100%)	224 (30%)	136 (18%)	392 (52%)	752	752	224

Note: Percents are computed using enrollment at any time during period as denominator.
[a] Counts do not include patients who disenroll in December because CMS processes enrollment changes at the start of each month.

Table 1.2c: Annual Enrollment and Disenrollment for DMO B, 2006-2008

Year	New Enrollments	Dis-enrollments[a]	Deaths	Enrollment at end of period	Enrolled at any time during period	Cumulative Enrollments	Cumulative Disenrollments
2006	96 (100%)	8 (8%)	4 (4%)	84 (88%)	96	96	8
2007	128 (60%)	22 (10%)	16 (8%)	174 (82%)	212	224	30
2008[b]	62 (26%)	40 (17%)	19 (8%)	177 (75%)	236	286	70
Total	286 (100%)	70 (24%)	39 (14%)	177 (62%)	286	286	70

Note: Percents are computed using enrollment at any time during period as denominator.
[a] Counts do not include patients who disenroll in December because CMS processes enrollment changes at the start of each month.
[b] DMO B ceased operations at the end of 2008.

Table 1.2d: Annual Enrollment and Disenrollment for DMO C, 2006-2008

Year	New Enrollments	Dis-enrollments[a]	Deaths	Enrollment at end of period	Enrolled at any time during period	Cumulative Enrollments	Cumulative Disenrollments
2006	666 (100%)	103 (15%)	38 (6%)	525 (79%)	666	666	103
2007[b]	604 (53%)	420 (37%)	95 (8%)	614 (54%)	1,129	1,270	523
2008	120 (16%)	147 (20%)	74 (10%)	513 (70%)	734	1,390	670
Total	1,390 (100%)	670 (48%)	207 (15%)	513 (37%)	1,390	1,390	670

Note: Percents are computed using enrollment at any time during period as denominator.
[a] Counts do not include patients who disenroll in December because CMS processes enrollment changes at the start of each month.
[b] A special election was enacted for DMO C in 2007.

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CHAPTER 2: COMPONENTS OF THE DISEASE MANAGEMENT ORGANIZATIONS' PROGRAMS

A. Summary of Disease Management Programs

Table 2.1 summarizes key components designed and implemented by each of the Disease Management Organizations (DMOs). Detailed grids describing elements of each of the DMO's programs are included in Appendix 1 at the end of this report.

Table 2.1: Components of Disease Management Programs, by DMO

Component	DMO A	DMO B	DMO C
DMO Structure	Medicare Advantage Health Maintenance Organization with Point of Service Option	Medicare Advantage Health Maintenance Organization with Point of Service Option	Medicare Advantage Private FFS DMO
Specific Interventions	Pharmacist routine review of medications until 2007 when review only occurred upon NCM referral. BP control, ACEi/ARB use for CHF patients Administering influenza and pneumococcal vaccinations; conducting retinal and podiatric exams for patients with diabetes	Implementation of physician standing orders for HbA1c tests of patients with diabetes. Discontinued in August 2007 due to data system migration. Assessment for ACPs Addressing barriers to ACEi/ARB use for hypertensive patients	Provision of an electronic home weight monitoring system to medically eligible and/or interested patients. Provision of ONS to patients with serum albumin below threshold.
Primary Medical Care	Nephrologist provided overall care with emphasis on a team-based approach, which included nephrologist, PCP, and NCM.	Nephrologist in coordination with NCM or NP for overall care.	Nephrologist provided overall care. Enrollee saw nephrologist, internist, or PCP for other PC services.
Care Coordination	NCM (on-site); coordinated with nephrologist and nephrology NP as needed.	NCM (on-site); also coordinates with nephrologist and NP.	Care coordinated by telephonic NCMs and field NCMs until 2008; after 2008 assessments conducted via call center NCMs and as needed in-person assessments conducted per-diem nurses on-site.
Modality of Patient Contact	In-person; telephonic follow-up (NCM); enrollee self-monitoring.	In-person; telephonic follow-up (NCM and NP).	Both telephonic (Telehealth) and in-person until 2008; by 2008, telephonic with NCMs and in-person with per-diem nurses as needed; for patients with home weight monitors these providers also served as points of contact.
Management for Dialysis- Specific Issues	VA management - used dedicated VA centers and included VA management software, anemia, and mineral metabolism management protocols coordinated between Disease Management team and dialysis unit.	VA management varied by site - use of non-DMO B VA centers. Anemia and mineral metabolism management protocols part of dialysis unit.	VA management - VA centers used if in service area. Protocols for anemia and mineral metabolism management used at dialysis unit.

Component	DMO A	DMO B	DMO C
Comorbidity Management	Diabetes and CVD Disease Management part of overall ESRD Disease Management program. Glucometers provided.	Diabetes and CVD comorbidity management provided. Glucometers provided on patient request.	Diabetes and CVD Disease Management programs provided. Glucometers provided.
In-Hospital Follow-up by Health DMO	Conducted by NCM.	Not by DMO but by dialysis facility.	Provided by Nephrologists.
Hospitalization Discharge Planning	NCM takes part in discharge planning.	Participation of DMO as permitted by dialysis facility.	Initially coordinated by DMO, subsequently coordinated by hospital staff.
Patient Centered Programs	QoL and patient satisfaction surveys; patient education program; Advanced Care Directive Program	QoL and patient satisfaction surveys; patient education program; Advanced Care Directive Program	QoL and patient satisfaction surveys; patient education program; Advanced Care Directive Program
Other DMO Benefits and Services	Prescription drug coverage for patients eligible for Medicare Part D.	Prescription drug coverage for patients eligible for Medicare Part D.	Transportation to VA centers, drug discount program, limited vision and dental benefits.

Abbreviations: ACEi = Angiotensin Converting Enzyme inhibitor; ACP = Advanced Care Plan; ARB = Angiotensin Receptor Blocker; BP = Blood Pressure; CDM = Cardiovascular Disease Management; CHF = Congestive Heart Failure; CVD = Cardiovascular disease; ESRD = End-Stage Renal Disease; FFS = Fee-for-service; HbA1c = Hemoglobin A1c; ONS = Oral Nutritional Supplements; NP = Nurse practitioner; NCM = Nurse care manager; PC = Primary care; PCP = Primary care provider; QoL = Quality of life; VA = Vascular access.

B. Key Similarities in Approaches to Disease Management and Delivery of Care

Consistent with the general strategy of Disease Management with its focus on integrated delivery of care [1, 2], each DMO developed programs that delivered care based on a model of coordinated care delivery, and the management of multiple comorbid conditions. Though each DMO had some variation in actual implementation of Disease Management, all DMOs worked in partnership with the dialysis facilities particularly in dialysis-specific clinical care such as anemia, bone and mineral metabolism and vascular access (VA) management.

All the DMOs offered some form of comorbidity Disease Management. All three DMOs integrated management of both diabetes and cardiovascular disease (CVD) within their larger End-Stage Renal Disease (ESRD) Disease Management programs. For example, DMO B nurse care managers (NCMs) conducted assessments of all patients at enrollment, including assessment for diabetes, heart failure, and coronary artery disease.

Comorbidity management consisted of improving diabetes processes of care (hemoglobin A1c [HbA1c] monitoring and provision of glucometers), and CVD management (increasing the use of angiotensin converting enzyme inhibitors [ACEi] or angiotensin-receptor blockers [ARB] for blood pressure (BP) management, the use of these same drugs for patients with congestive heart failure (CHF), and the use of home weight monitoring [HWM] scales) to monitor weight gain between hemodialysis (HD) sessions whereas preventive care services focused on increasing immunization rates and, for patients with diabetes, foot and eye exams.

Nephrologists were primarily responsible for the overall care of patients, and co-management with Primary Care Providers (PCPs) and other specialists was the general approach of all three DMOs. The DMOs offered additional benefits and services, which often were tailored to specific focal areas of care delivery. All three DMOs offered dietician and social work services that were coordinated at the dialysis facility rather than at the DMO. See Appendix 1 for details on specific features of Disease Management and other benefits and services provided in each DMO.

Care coordination was provided by NCMs across each of the DMOs. Furthermore, the NCM was the front line provider who reviewed all patients' immunization status.

C. Key Differences in Approaches to Disease Management and Delivery of Care

A key difference among the three DMOs is that distinct treatment interventions were included in each Disease Management program. In addition to care coordination and comorbidity management, DMO C instituted an aggressive nutritional supplementation program with the provision of supplements for patients with serum albumin only marginally below what is considered to be "normal". In addition, DMO C provided medically eligible and/or interested patients with home weight monitoring (HWM) scales with a goal of maintaining an appropriate interdialytic fluid weight gain (IDWG), which over time, also served as a communication tool between patients and NCMs.

DMO A and DMO B focused their Disease Management efforts on improving coordination of care. DMO A included a pharmacist on the Disease Management team who reviewed patient medications with the goals of improving medication management and subsequently reducing medication-related problems (MRPs). Reviews initially occurred at routine intervals but were later based upon NCM referral to the pharmacist. DMO A also developed and instituted protocols that were used to improve the management of patients with CVD and diabetes, and to increase pneumococcal and influenza vaccination rates. Finally, a component of DMO A's Disease Management focused on CVD, including 1) the use of ACEi/ARBs for patients with CHF and 2) routine measurement of low-density lipoprotein (LDL) levels.

DMO B developed a Disease Management program for patients with diabetes, with the goal of improving glucose control among these patients. Interventions included the implementation of physician standing orders for the routine screening of hemoglobin A1c (HbA1c), although these were discontinued because of operational factors. DMO B also designed a protocol to enhance the use of ACEi/ARBs among patients with uncontrolled hypertension. Patients' nephrologists were then surveyed in order to identify obstades to prescribing these agents. Finally, DMO B introduced comprehensive health assessments administered by NCMs in order to promote the adoption of Advanced Care Plans (ACPs) among patients.

Another difference was in the modality of contact between NCMs and enrollees. Throughout the Demonstration NCMs oversaw and delivered the education, coordination and interventions derived from the DMO C clinical pathways (see Appendix 1 for the list of all Clinical Pathways). DMO C's clinical pathways relied on Call-Center NCMs throughout the Demonstration, and in the earlier years of the Demonstration (2006 and 2007), DMO C utilized additional field nurses to do in-person periodic assessments with patients. At all points, activities were coordinated via an integrated care electronic and telephonic system by NCMs from DMO C's centralized Call-Center.

By 2008 DMO C transitioned primarily to a telehealth platform in order to establish more frequent assessments (daily monitoring), thus allowing patients to potentially communicate more frequently with nurse care managers. Subsequently DMO C de-emphasized the use of NCMs or other nurses conducting in-person periodic assessments, other than as needed. As the volume of the in-person periodic assessments decreased during 2008, DMO C used contracted per diem rather than employed nurses to perform in-person assessments as needed.

Both the DMO A and DMO B programs utilized NCMs that met with patients in-person and provided telephonic follow-up for specific clinical episodes as needed. In DMO B, both NCMs and nurse practitioners (NPs) were the primary coordinators of care to patients.

The composition of the core Disease Management team was distinct in DMO A in that it formally included a pharmacist as a member of the Disease Management team. Initially, the DMO A pharmacist monitored patient medications through regular review and recommended modifications to both the

nephrologist and the NCM. However, the pharmacist role evolved over time such that pharmacist review only occurred "on indication" rather than on a routine basis.

All DMOs provided additional benefits and services. DMO C provided limited financial benefits to support both vision and dental services as part of Disease Management, in addition to providing a drug discount program. The other two DMOs included Medicare Part D drug benefits.

D. Conclusion

In summary, different types of interventions were designed by each DMO. DMO C implemented two direct interventions to evaluate their respective effect on reducing hospitalization and mortality for certain high risk patients. The first was an electronic scale provided to medically eligible and/or interested enrollees for home monitoring of interdialytic fluid weight gain. Oral nutritional supplements (ONS) were also provided to all their members with sub-optimal nutritional status as defined by a threshold of serum albumin. Initially, DMO A included a pharmacist on the Disease Management team to conduct regular review of patient medications, although this care model changed over time. DMO B used standing orders to increase testing of HbA1c in order to improve glycemic control. Standing orders were discontinued due to a data system migration in 2007. All three DMOs enhanced management of CVD, and DMO A and DMO B enhanced management of diabetes, conditions that are highly prevalent in the ESRD population.

Further details on these DMO-specific programs are provided in subsequent chapters reporting on findings from specific components of each DMO's program.

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CHAPTER 3: DMO A – IMPACT OF PHARMACIST INVOLVEMENT ON MEDICATION-RELATED PROBLEMS

A. Introduction

This chapter evaluates DMO A's inclusion of a pharmacist as part of a multidisciplinary Disease Management team and the pharmacist's effect on decreasing medication-related problems (MRPs). The Institute of Medicine estimated drug errors as the eighth leading cause of death in the U.S. and found at least 1.5 million preventable adverse drug events occur in the U.S. each year, and other studies have found the cost implications of medication errors are high [1-4]. Including pharmacists in the multidisciplinary team can potentially result in the identification and correction of MRPs early enough to prevent the occurrence of adverse health outcomes.

B. Methods

Patients who enrolled in DMO A between January 1, 2006 and December 31, 2008 were included in the analysis. At each review, the pharmacist evaluated a patient's medication list and existing comorbidities in order to identify MRPs derived from Manley et al [5]:

failure to receive drug	a medication is prescribed to treat a medical condition yet the patient has not received the medication due to non-adherence to medication regimen, medication is not accessible (e.g. non-formulary medication), inability to pay for medication (e.g. patient does not have prescription insurance, patient cannot afford medication), etc
drug interaction	patient has a medical problem that is the result of a medication-medication, medication-laboratory, or medication-food interaction
indication without drug	patient has a medical problem that requires a medication yet the prescriber has failed to prescribe a medication
over-dosage	patient has a medical problem treated with too high a dose of the correct medication
lab	patient has not undergone laboratory testing despite indications to monitor medication therapy, to ensure that common comorbid conditions are adequately identified and treated, or to ensure that existing comorbid conditions are adequately treated
wrong drug	patient has a medication indication, but is taking the wrong drug
therapeutic duplication	patient has an inappropriate duplication of therapeutic group or active ingredient
under-dosage	patient has a medical problem that is being treated at a sub-therapeutic dosage
adverse drug reaction	patient has a medical problem that is the result of an adverse response to a drug
drug without indication	patient is taking a medication for no medically valid indication
other	patient has an MRP that could not be classified in any other category, such flagging for potential patient and/or staff education interventions and recommendations due to inappropriate duration

The pharmacist also evaluated the appropriateness of each medication, taking into account the patient's chart, electronic medical records and laboratory measurements. DMO A's protocol initially called for two pharmacists to conduct reviews at enrollment and follow-up reviews quarterly, but by the end of 2006 was revised so that only one pharmacist was allocated to this program, and the pharmacist review of patient records was triggered by referral of the DMO A nurse practitioner (NP) for specific concerns

regarding medication use. With this change in protocol, referral for a medication review occurred because of specific concerns, so not all patients received an initial pharmacist review and not all patients received follow-up reviews.

Table 3.1: Changes in the Pharmacist Medication Review Program

Year	Description	Protocol	Interventions
2006	Direct patient care	Medication review provided within 30 days of enrollment and quarterly	All interventions made to provider directly
2007	Indirect patient care	Medication review upon nurse referral utilizing nurse maintained lists. Nurse member referral occurs within 30 days enrollment, post hospitalization, or upon request	Patient counseling and drug education interventions made to nurse for follow up; other MRP interventions made to provider directly as needed.
2008	Indirect patient care	Medication review upon nurse referral utilizing nurse maintained lists and pharmacy claims data. Nurse member referral occurs within 30 days enrollment, post hospitalization, or upon request	Patient counseling and drug education interventions made to nurse for follow-up; other MRP interventions made to provider directly as needed.

Medication data were collected by DMO A and categorized into 14 groups derived from Manley et al [5] by the Evaluation team: analgesic, anemia management, anti-infective, anti-pruritic, antithrombotic, anti-hypertensive, cholesterol-lowering, other cardiovascular, endocrine, gastrointestinal, psychotropic, vitamins, renal bone disease (calcium/phosphorus control), and miscellaneous/other.

Medications and MRPs were analyzed primarily as the average number of medications per patient or the average number of problems per patient, respectively, because the vast majority of patients had more than one medication and more than one MRP.

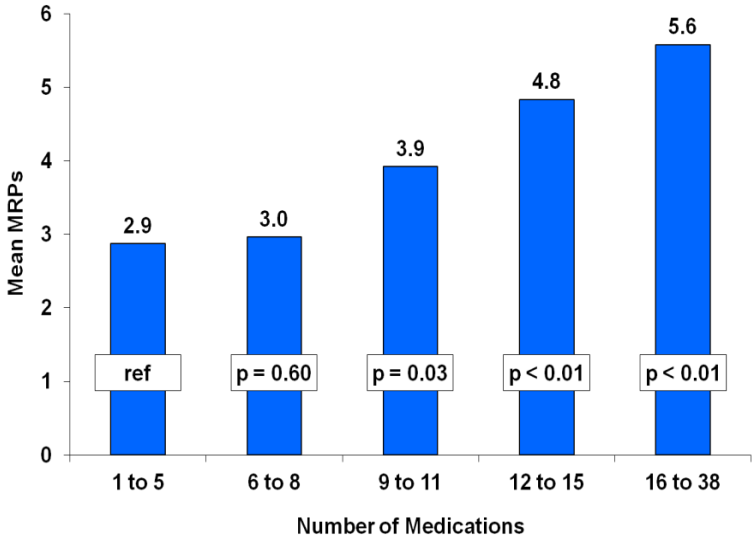
C. Results

1. First Medication Review

The mean time from enrollment to first review was 5.1 months. On average, pharmacists identified 4.0 MRPs for each patient (including patients with only one review). The most common problem was failure to receive drug, followed by drug interaction, indication without drug therapy, and overdosage. Patients were prescribed an average of 11.0 medications; the most commonly prescribed medication types also had the largest number of MRPs: anti-hypertensive agents and medications for renal bone disease (both with 2.0 medications per patient; with a mean of 0.9 and 0.6 MRPs per patient, respectively). Medications to treat anemia stand out as commonly prescribed, at 1.6 medications per patient, but with relatively few MRPs, with only 0.1 per patient. This is likely due to policies surrounding erythropoietin monitoring and administration.

Figure 3.1 shows that the number of MRPs increases linearly with the number of medications prescribed, with the top three quintiles of patients (60%) having significantly more MRPs than the lowest quintile.

Figure 3.1: MRPs at First Review, by Number of Medications, DMO A (N = 512)



2. Follow-up Medication Reviews

Table 3.2 displays the average number of MRPs at first review and at 12 (to 23) months by type of MRP among patients with follow-up medication reviews at 12 (to 23) months. The overall increase is primarily driven by a large increase in failure to receive drug, followed by more modest but still significant increases in therapeutic duplication and adverse drug reaction.

Table 3.2: MRPs at First Review and 12-Month Follow-up, DMO A (N = 231)

	First Review	Follow up	p-value
Total, All Problems	3.7	4.8	< 0.01
Failure to receive drug	0.6	1.6	< 0.01
Drug interaction	0.4	0.5	0.19
Indication, no drug therapy	0.4	0.3	0.03
Overdosage	0.4	0.3	< 0.01
Lab	0.3	0.4	0.15
Improper drug selection	0.3	0.2	0.16
Therapeutic duplication	0.2	0.5	< 0.01
Sub-therapeutic dosage	0.2	0.1	0.03
Adverse drug reaction	0.1	0.4	< 0.01
Drug without indication	0.1	0.1	0.78
Other	0.6	0.4	0.18
Reviewed, No Issue	0.2	0.3	0.31

Abbreviation: MRP = Medication-related problem

In Table 3.3, a patient's first medication review is compared to his or her first follow-up review after a) six months, but not more than 11 months, b) 12 months, but not more than 23 months, and c) 24 months, with no upper limit (other than the 36 month duration of the analysis period). The number of MRPs increased significantly from first review to each of the follow-up time points.

Table 3.3: Mean Change in Medications and MRPs from First Review to Three Follow-up Time Points, DMO A

	First Follow-up Review in		
	6-11 months (median 7 mo)	**12-23 months** (median 14 mo)	**24+ months** (median 25 mo)
Number of Patients with Medication Records	268	219	54
Number of Medications at First Review	11.6	11.7	15.2
Number of Medications at Follow-up Review	11.8	11.7	11.7
Paired p-value	0.52	0.89	< 0.01
Number of Patients with MRP Records	281	231	65
Number of MRPs at First Review	3.9	3.7	4.0
Number of MRPs at Follow-up Review	4.9	4.8	4.9
Paired p-value	< 0.01	< 0.01	0.04

Abbreviation: MRP = Medication-related problem

The overall increase in MRPs is made up of significant increases in MRPs related to three medication categories commonly prescribed in this population: anti-hypertensive agents, renal bone disease medications, and endocrine-related drugs. Two medication categories showed small significant decreases in MRPs: anemia management and vitamins.

Patients with a greater number of medications prescribed at first review and those with a greater increase in number of medications between first review and 12 month follow-up experienced an increase in number of MRPs. Interestingly, patients with more MRPs at first review tended to have less of an increase in MRPs. Patients with a higher number of MRPs initially may be subject to closer monitoring by care providers thus preventing the further increase in MRPs.

D. Discussion

This report presents results for DMO A's MRP analysis by evaluating the impact of incorporating a pharmacist into the multidisciplinary Disease Management team on the occurrence of MRPs. The key findings of this evaluation are:

- a high frequency of MRPs exists in this hemodialysis (HD) population;
- although the inclusion of a pharmacist was associated with a significant reduction in certain types of MRPs, the overall number of MRPs further increased over the course of the Demonstration, perhaps due to the change in DMO A's protocol midway through the study period, and;
- an increase in the number of medications was associated with an increase in MRPs; consistent with prior studies [6-8].

Possible outcomes for the MRP category of "failure to receive drug" included failure to prescribe drug, as well as factors which are outside of the pharmacist's control, such as patient non-adherence or cost-related issues. "Failure to receive drug" was the most common type of MRP observed at baseline and associated with the greatest increase over time. Patient non-adherence and cost-related issues were not captured by this data collection software system, so there is no information as to what extent these issues contributed to "failure to receive a drug". A possible explanation for the increase in the number of MRPs is that the revised pharmacy review protocol by DMO A biased the population of patients with follow-up evaluations towards patients with greater numbers of MRPs. Medication reviews occurred only upon referral by the NP and such referrals were made because of specific concerns regarding medication use. This is a modification from DMO A's earlier protocol in which pharmacists conducted routine regular review of patient medications. Indeed, an earlier interim analysis of DMO A's pharmacist program revealed that the pharmacist involvement was effective in reducing MRPs. In this interim analysis based on 48 DMO A patients with follow-up pharmacist review, mean MRP decreased

from 4.4 to 2.1 and the ratio of MRPs to patient drug exposure was also markedly reduced, from one MRP per 3.2 exposures to one per 6.0.

Another plausible explanation is that patients who were being followed closely by pharmacists had increased disease burden which resulted in greater complexity of clinical and medication management, increasing the possibility of MRPs.

It should be noted that DMO A additionally implemented a program with a goal of improving patient adherence. Evaluation of this aspect of this program was outside the scope of this evaluation.

1. Limitations

The following limitations should be noted in interpreting the results of this specific evaluation: 1) the change in DMO A's pharmacist review protocol only allows patients with medication-related concerns to be evaluated, and thus to be included in the analysis; 2) the change in the data collection software system may have impacted the ability to capture changes in numbers of MRPs, given that MRP categorization differed between the two systems; 3) the change in the data collection software system impacted the ability to capture the final outcomes of the pharmacist's recommendations; and 4) given that the pharmacist evaluating the MRPs is the same pharmacist conducting the intervention, a potential for observation bias exists. The latter would likely lead to a bias towards MRP improvement rather than the MRP deterioration we've observed here. Since these analyses were conducted, DMO A has worked to better integrate the two software systems used to track medication-related data and future analyses may reflect these data system enhancements.

2. Summary

The failure to demonstrate a reduction in MRPs may relate to DMO A's protocol for pharmacist review in that only patients with medication-related concerns as determined by DMO A's NP are evaluated. This potentially biases the evaluation population towards patients with existing MRPs, and our main result could be interpreted as an increase in successful targeting of patients for referral for medication review. Altogether, although the clinical pharmacist plays a potentially important role in management of the complex ESRD patient, the current Demonstration did not demonstrate their benefit in the Disease Management setting.

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CHAPTER 4: DMO A – MANAGEMENT OF CARDIOVASCULAR DISEASE AND RISK FACTORS

A. Introduction

This chapter evaluates the impact of DMO A's Disease Management program on the treatment of cardiovascular disease (CVD) and management of CVD risk factors. The specific aims were to demonstrate 1) improved blood pressure (BP) control, 2) increased use of angiotensin converting enzyme inhibitors/angiotensin receptor blockers (ACEis/ARBs) in patients with congestive heart failure (CHF), and 3) increased measurement of lipid profile.

The aims are derived principally from the National Kidney Foundation's Kidney Disease Outcomes Quality Initiative (NKF KDOQI) Clinical Practice Guidelines for Cardiovascular Disease in Dialysis Patients, Hypertension and Antihypertensive Agents, and Dyslipidemia [1]. Pertinent to these aims, the guidelines state that:

- Aim 1 – Pre- dialysis BP goals should be < 140/90 mm Hg.
- Aim 2 – For the treatment of hypertension, drugs that inhibit the renin-angiotensin system, such as ACEis or ARBs should be preferred because they cause greater regression of left ventricular hypertrophy (LVH), reduce sympathetic nerve activity, reduce pulse wave velocity, may improve endothelial function, and may reduce oxidative stress. Further, CHF is considered a compelling indication for ACEi and/or ARB use.
- Aim 3 – Dyslipidemias should be evaluated upon presentation (when the patient is stable), at two to three months after a change in treatment or other conditions known to cause dyslipidemias, and at least annually thereafter.

B. Methods

DMO data unique to this analysis included:

- Aim 1 – Systolic blood pressure (SBP) measurements, taken just prior to a hemodialysis (HD) session ("pre-dialysis") and reported monthly.
- Aim 2 – Prescribed medications, reported monthly along with start and end dates.
- Aim 3 – Low-density lipoprotein (LDL) levels, reported when measured.

For Aim 1, we examined within-patient change in SBP using 1) unadjusted matched-pair t-tests and 2) an adjusted linear mixed model. We additionally computed the proportions of patients with SBP below 140 mm Hg at baseline and at 6, 12, and 24 months. Comparisons between baseline and the follow-up months used McNemar's test (for matched pairs).

Aim 2 was restricted to patients with CHF, indicated either on the CMS 2728 Medical Evidence Form or in DMO A records. We determined whether patients were prescribed an ACEi or ARB at baseline, 12 months, and 24 months after enrollment (or new CHF diagnosis). Baseline medication data were obtained one month after enrollment (or new CHF diagnosis). Comparisons between baseline and the follow-up months used McNemar's test (for matched pairs).

For Aim 3, the proportions of patients with LDL measured during months 1 to 12 after enrollment and months 13 to 24 after enrollment were calculated. Comparison between these two time periods used McNemar's test (for matched pairs).

Data from the United States Dialysis Outcomes and Practice Patterns Study (U.S. DOPPS) [2, 3] years 2005-2008 were used for comparison for Aims 1 and 2. Data from 2005 from the 2007 United States Renal Data System (USRDS) Annual Data Report [4] were used for comparison for Aim 3. The USRDS comparison group for LDL measurement (Aim 3) included only prevalent ESRD patients with diabetes mellitus (diabetes) as the primary cause of end-stage renal disease (ESRD). However, due to the relatively small number of patients in DMO A, the LDL analysis for DMO A included both patients with and without diabetes. Forty-four percent (N = 269) of DMO A patients did not have diabetes.

C. Results

1. Aim 1 – To Demonstrate Improved Blood Pressure Control

The mean pre-dialysis baseline SBP of DMO A patients was 149 mm Hg (Table 4.1). Thirty-six percent of DMO A patients had SBP < 140 mm Hg at baseline. For these patients, (N = 207), the mean SBP was 127 mm Hg. For DMO A patients with baseline SBP ≥ 140 mm Hg (N = 372), the mean pre-dialysis baseline SBP was 161 mm Hg.

In the adjusted model, the average DMO A patient's SBP was 2.6, 4.1, and 4.0 mm Hg higher at months 6, 12, and 24, respectively, than at baseline ($p < 0.01$ for each). Among DMO A patients with adequate follow-up time, the percentage of patients with pre-dialysis SBP < 140 mm Hg dropped versus baseline at all follow-up points. The percentage with SBP < 140 mm Hg were 6, 10, and 12 percentage points lower at months 6, 12, and 24, respectively, than at baseline ($p < 0.05$ for each). Compared to DMO A participants, U.S. DOPPS patients had the same baseline mean SBP (149 mm Hg) and similar percentages with SBP < 140 mm Hg. However, changes in SBP over time differed between the two groups. In DMO A, mean SBP increased over time and the percentages with SBP < 140 and SBP < 160 mm Hg decreased over time. In contrast, in the U.S. DOPPS sample, mean SBP decreased over time (adjusted change = -3.1 and -4.9 mm Hg after 12 and 24 months respectively, $p < 0.01$ for both), and the percentages with SBP < 140 mm Hg increased.

Table 4.1 (Aim 1): Changes in Systolic Blood Pressure (SBP) and Blood Pressure Control, by Time Enrolled in DMO

DMO A				
	All Patients (N = 579)	**Patients Enrolled for ≥ 6 Months (N = 373)**	**Patients Enrolled for ≥ 12 Months (N = 259)**	**Patients Enrolled for ≥ 24 Months (N = 100)**
Mean SBP (mm Hg) at baseline	149	149	148	145
Mean SBP (mm Hg) at 6, 12, or 24 months	-	153	154	149
Mean within-patient SBP change (mm Hg), unadjusted (p-value)[a]	-	+3.7 (p < 0.01)	+5.5 (p < 0.01)	+3.5 (p = 0.10)
Mean within-patient SBP change (mm Hg), adjusted [b] (p-value)	-	+2.6 (p < 0.01)	+4.1 (p < 0.01)	+4.0 (p < 0.01)
% with SBP < 140 mm Hg at baseline	36	36	38	44
% with SBP < 140 mm Hg at 6, 12, or 24 months	-	30	28	32
Change in % with SBP < 140 mm Hg from baseline to 6, 12, or 24 months, matched pair analysis unadjusted (p-value)	-	-6 (p = 0.03)	-10 (p = 0.01)	-12 (p = 0.04)
U.S. DOPPS				
	All Patients (N = 1349)	**Patients Enrolled for ≥ 4 Months[c] (N = 1083)**	**Patients Enrolled for ≥ 12 Months (N = 813)**	**Patients Enrolled for ≥ 24 Months (N = 436)**
Mean SBP (mm Hg) at baseline	149	149	150	151
Mean SBP (mm Hg) at 6, 12, or 24 months	-	149	146	145
Mean within-patient SBP change (mm Hg), unadjusted (p-value)[a]	-	-0.6 (p = 0.46)	-4.0 (p < 0.01)	-6.3 (p < 0.01)
Mean within-patient SBP change (mm Hg), adjusted[b] (p-value)	-	-1.2 (p < 0.01)	-3.1 (p < 0.01)	-4.9 (p < 0.01)
% with SBP < 140 mm Hg at baseline	37	37	35	32
% with SBP < 140 mm Hg at 6, 12, or 24 months	-	38	43	41
Change in % with SBP < 140 mm Hg from baseline to 6, 12, or 24 months, matched pair analysis unadjusted (p-value)	-	+1 (p = 0.31)	+8 (p < 0.01)	+9 (p < 0.01)

Abbreviations: SBP = Systolic Blood Pressure; U.S. DOPPS = Dialysis Outcomes and Practice Patterns Study

[a] Unadjusted p-value using paired t-test.

[b] Adjusted using a linear mixed model of SBP vs. enrollment time and enrollment time squared, controlling for age, gender, race, Hispanic ethnicity, BMI at enrollment, CMS-HCC risk score, new Medicare enrollee status (patients without a full year of claims history), dialysis dose, serum albumin, calcium, phosphorus, hemoglobin, treatment modality, and diabetes as cause of ESRD. N = 549 patients, 7141 observations.

[c] U.S. DOPPS blood pressure data are collected every 4 months, therefore a 4-month follow-up was used for the U.S. DOPPS.

Note: Reported p-value uses McNemar's test for within-column comparison between baseline and 6, 12, or 24 months.

2. Aim 2 – To Demonstrate Increased Use of ACEi/ARBs in Patients with CHF

Table 4.2 reports ACEi/ARB prescription status at baseline and at 12 and 24 months after enrollment. In DMO A, 41% of CHF patients had an ACEi/ARB prescription at baseline. The percentage with an ACEi/ARB prescription increased to 58% at 12 months ($p < 0.01$ vs. baseline), but decreased to 35% at 24 months ($p = 0.44$ vs. baseline). Among U.S. DOPPS patients with CHF, the percentage with ACEi/ARB prescription was 47% at baseline, 49% at 12 months, and 41% at 24 months.

Table 4.2 (Aim 2): ACEi/ARB Use Among CHF Patients, by Time Enrolled in DMO, Compared to U.S. DOPPS

	DMO A Patients with CHF			U.S. DOPPS Patients		
	All Patients with CHF (N = 273)	Enrolled for ≥ 12 Months (N = 127)	Enrolled for ≥ 24 Months (N = 54)	All Patients (N = 690)	Enrolled for ≥ 12 Months (N = 336)	Enrolled for ≥ 24 Months (N = 166)
% with ACEi/ARB at baseline[a]	41	45	41	47	49	46
% with ACEi/ARB at 12 or 24 months	-	58	35	-	49	41
Change in % with ACEi/ARB from baseline to 12 or 24 months (p-value)[b]	-	+13 (p < 0.01)	-6 (p = 0.44)	-	+0 (p = 0.90)	-5 (p = 0.19)

Abrreviations: ACEi/ARB = Angiotensin Converting Enzyme inhibitor/Angiotensin Receptor Blocker; CHF = Congestive Heart Failure; U.S. DOPPS = Dialysis Outcomes and Practice Patterns Study

[a] CHF patients must have an active ACEi/ARB prescription no later than one month after CHF onset date or enrollment date (whichever comes later) to be counted as having an ACEi/ARB at baseline.

[b] Reported p-value uses McNemar's test for within-column comparison between baseline and 12 or 24 months.

3. Aim 3 – To Demonstrate Increased Measurement of Lipid Profile

Table 4.3 shows that 80% of DMO A patients (both with and without diabetes) had at least one LDL lab during the first 12 months of enrollment. Among those enrolled at least two years, the percentage with LDL measurement decreased from 90% to 80% from the first to second years ($p < 0.01$). By comparison, in 2005, 70% of Medicare FFS patients with diabetes received at least one LDL lab test [4].

Table 4.3 (Aim 3): Measurement of LDL Level, by Time Enrolled in DMO

	Patients Enrolled ≥ 12 Months (N = 309)	Patients Enrolled ≥ 24 Months (N = 157)	USRDS Patients (N = 79,818)[a]
% with ≥ one LDL lab in first 12 months	80	90	70
% with ≥ one LDL lab in second 12months	-	80	-
Change in % with ≥ one LDL lab from first 12 months to second 12 months (p-value)[b]	-	-10 (p < 0.01)	-

Abbreviation: LDL = Low-density Lipoprotein.

[a] USRDS sample includes Medicare patients with diabetes. Only aggregate data were available, so no calculation of within-patient change could be performed.

[b] Reported p-value uses McNemar's test for matched pair comparison between the first 12 and second 12 months of enrollment.

D. Discussion

One of the goals of DMO A's Disease Management program was to improve the management of CVD with the application of Disease Management approaches. Specified CVD management measures included BP control, ACEi/ARB prescription, and lipid profile measurement. Analyses have found 1) no evidence of improved BP control, 2) greater ACEi/ARB prescription to CHF patients at one year after enrollment, but a decline in prescription at two years, and 3) high levels of LDL measurement throughout the enrollment period.

1. Aim 1 – BP Control

There was no evidence of improved BP control over time among DMO A enrollees. As shown in Table 4.1, the adjusted mean SBP rose over time and the fractions with SBP < 140 mm Hg decreased over time. Because some providers may believe that a target pre-dialysis SBP of < 140 mm Hg is too low, we chose to also evaluate a higher target SBP of < 160 mm Hg. Even at this target, we found no evidence of improved BP control during the enrollment period. By contrast, in the U.S. DOPPS sample, adjusted mean SBP decreased over time, and the fractions with SBP < 140 mm Hg and < 160 mm Hg increased.

2. Aim2 – ACEi/ARB Use Among CHF Patients

Among patients enrolled in the program for at least 12 months, the proportion using either an ACEi or ARB at one year increased from baseline. However, among patients enrolled for at least 24 months, use declined at two years to below baseline levels. The proportions using an ACEi or ARB were lower than those in the U.S. DOPPS at baseline and two years.

The notable increase in ACEi/ARB use at one year raises the possibility that the DMO A CVD Disease Management program did successfully increase use of these important medication classes over that time period. If so, the cause of the decline in use at two years is unclear. It is possible that some processes associated with the program were carried out more completely soon after DMO implementation and/or enrollment of each patient. Alternatively, the clinical status of the patients including relative or absolute contraindications may have resulted in a discontinuation of ACEi/ARB. Indeed, the previous chapter's evaluation of the DMO A pharmacist medication review program found a reduction in the number of medications for patients with a follow-up review after 24 months (Chapter 3, Table 3.3). However, the available data do not enable clear distinction between these potential explanations. It should also be noted that since these analyses were conducted, DMO A has worked to better integrate the two software systems used to track medication-related data and future analyses may reflect these data system enhancements.

Although greater than 40% of CHF patients were not prescribed an ACEi/ARB at any time, it is possible that some patients had a contraindication or were intolerant to ACEi/ARB use. As such, the proportion of CHF patients using an ACEi/ARB among eligible patients was likely higher than reported in Table 4.2.

3. Aim 3 – Lipid Profile Measurement

A very high fraction (about 80%) of patients had LDL measured at least once during each year of enrollment (Table 4.3). This fraction is notably higher than what has been reported among Medicare FFS ESRD patients with diabetes [4]. Processes implemented by DMO A appear to successfully facilitate achievement of the clinical practice guidelines recommendation to evaluate dyslipidemia at least annually.

4. Limitations

Some limitations of the current evaluation include: 1) the sample size was relatively small, particularly for evaluation of findings among subgroups such as patients with CHF or enrolled for ≥24 months; 2) the absence of data from patients prior to DMO A enrollment (within-patient controls) limits inference about direct effects of the DMO; and 3) the measures evaluated do not capture the entirety of the process under evaluation, such as processes used to target control of hypertension (e.g., volume management, pharmacotherapy, patient education, and/or combinations of the three).

5. Summary

In summary, the implementation of DMO A's Disease Management program was associated with improvement in the delivery of some, but not all, of the evaluated process of care measures for the management of CVD. Specifically, ACEi/ARB use among CHF patients increased for at least a period of time after enrollment, and LDL cholesterol measurement was exceptionally high throughout the enrollment period. BP control did not improve during the period of DMO A implementation. Additional study is needed to evaluate the impact of Disease Management on modifying cardiovascular outcomes in the ESRD population.

E. References

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2) Young EW, Goodkin DA, Mapes DL, et al. *The Dialysis Outcomes and Practice Patterns Study (DOPPS): An international hemodialysis study.* Kidney Int. 2000; 57(Suppl 74): S74-S81.

3) Pisoni RL, Gillespie BW, Dickinson DM, et al. *The Dialysis Outcomes and Practice Patterns Study (DOPPS): design, data elements, and methodology.* Am J Kidney Dis. 2004; 44:7-15.

4) U.S. Renal Data System, USRDS 2007 Annual Data Report: Atlas of Chronic Kidney Disease and End-Stage Renal Disease in the United States, National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2007. Page 130, Figure 5.24.

CHAPTER 5: DMO A – IMPROVING PREVENTIVE CARE PROCESSES

A. Introduction

This chapter focuses on the impact of DMO A's Disease Management program on preventive care measures. The particular preventive care measures examined were: 1) the administration of pneumococcal and influenza vaccines and 2) the implementation of diabetes mellitus (diabetes) process of care measures — hemoglobin A1C (HbA1c) measurements, foot disease screening, and retinal screening. DMO A's Disease Management program consisted of diabetes management and primary care management by the nephrologist and includes additional oversight and care coordination by primary care nurse practitioners (NPs) (nurses employed by DMO A), the use of standardized diabetes management and immunization protocols, and the provision of both patient and caregiver educational programs.

B. Methods

Patients who enrolled in DMO A between January 1, 2006 and December 31, 2008 were included in the study analysis. Patient demographic and health-related data were available from CMS or DMO A sources. DMO A recorded additional preventive care data for enrollees in order to evaluate the effects of the Disease Management clinical team. This included dates of influenza and pneumococcal vaccinations for all patients, and three preventive care measures for patients with diabetes (calendar months of HbA1c testing, dates of foot examinations, and dates of retinal examinations). The foot examination data included two types: general screening exams by a health service coordinator (a nurse employed by DMO A) and targeted diabetic foot exams. Patients were identified as having diabetes using a composite of the CMS-2728 Medical Evidence Form, which documents the cause of end-stage renal disease (ESRD) and comorbidity at incidence, and the DMO A comorbidity database, which records date of onset of new conditions. Results from these analyses are compared to the fee-for-service (FFS) data from the 2008 United States Renal Data System (USRDS) Annual Data Report [1] and the United States Dialysis Outcomes and Practice Patterns Study (U.S. DOPPS) [2, 3].

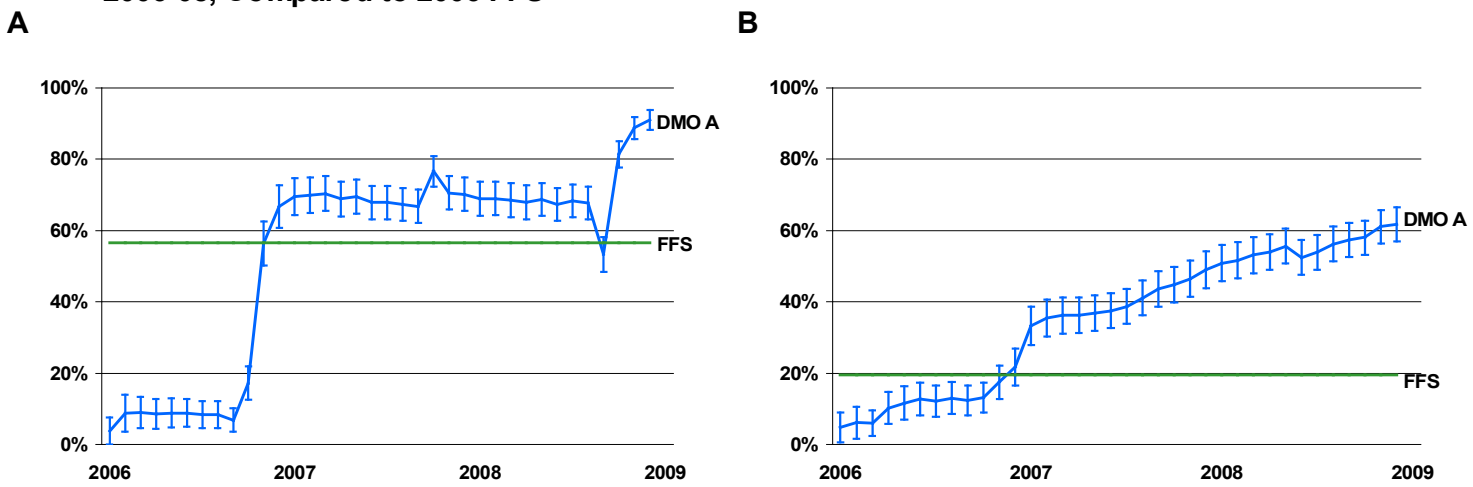
C. Results

Results are displayed for the entire Evaluation period but it is important to note that some of the low rates presented early in the Demonstration are an artifact of initiation of the Disease Management program. For example, few patients would be expected to have an influenza vaccination on record with the DMO before the first flu season during DMO operations.

1. Immunization Practices in the ESRD Population

Figure 5.1 shows the percentage of patients with influenza and pneumococcal vaccinations within recommended intervals by month. Panel A of Figure 5.1 shows the percentage of patients with an influenza vaccination within 12 months. The immunization rate increased sharply in September 2006 and remained higher than the 57% of FFS patients with annual influenza vaccinations in 2006. By the end of the study period, approximately 90% of patients in DMO A had a record of influenza vaccination within the preceding 12 months.

Figure 5.1. Influenza (A) and Pneumococcal (B) Vaccination Rates by Month, DMO A 2006-08, Compared to 2006 FFS



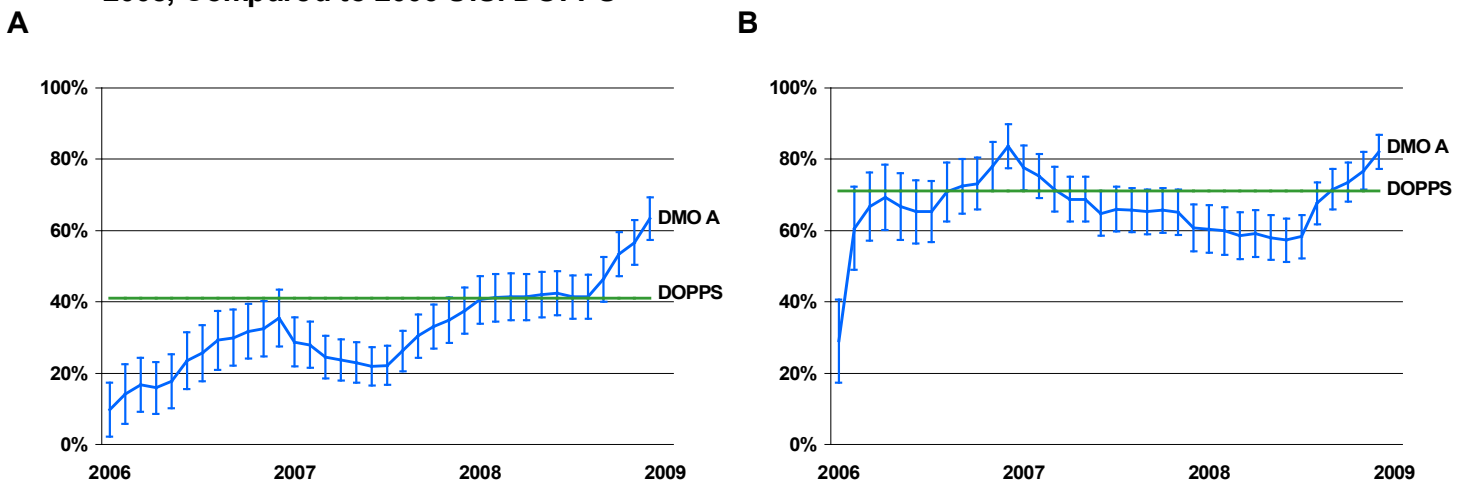
Abbreviations: FFS = fee-for-service.
Note: 2006 data from the United States Renal Data System 2008 Annual Data Report.

Panel B of Figure 5.1 shows the percentage of patients with at least one pneumococcal vaccination since enrolling in DMO A. Clinical guidelines currently recommend a single dose of pneumococcal vaccine to be administered to all dialysis patients with re-vaccination in five years [4]. Throughout the first year of the Demonstration, fewer patients in DMO A had a pneumococcal vaccination on record than the 20% in the FFS population had in the two-year period of 2005 and 2006. By 2007, the percentage of patients with pneumococcal vaccination exceeded that in the FFS comparison group, and by the end of the study period over 60% of patients enrolled in DMO A had documentation of a pneumococcal vaccination.

2. Diabetes Practices in the ESRD Population

Figure 5.2 shows the percentage of patients with diabetes with retinal exams and foot exams within recommended intervals by month compared to the U.S. DOPPS. The U.S. DOPPS comparison is limited because the data are from facility-level self-reporting of practice patterns rather than patient-level data that document actual performance of the various measures. Panel A shows the percentage of patients with a retinal exam within the preceding 12 months. In late 2008, the percentage of patients receiving retinal examinations for DMO A exceeded that reported in the U.S. DOPPS in 2006. Panel B shows the percentage of patients with a foot exam within 12 months. At the start of the Demonstration, a low percentage of patients received a foot examination but this increased quickly so that the percentage of patients receiving foot exams fluctuated between 60%-80%, comparable to the U.S. DOPPS medical director reported facility rate of 71%.

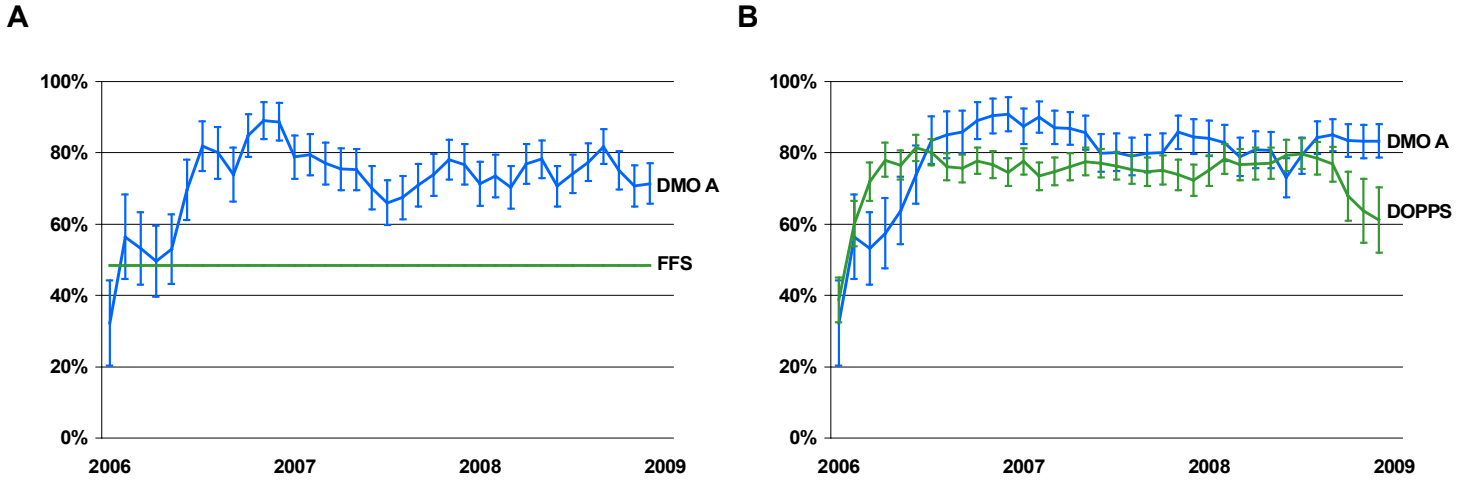
Figure 5.2. Diabetic Retinal Exam (A) and Foot Exam (B) Rates by Month, DMO A 2006-2008, Compared to 2006 U.S. DOPPS



Abbreviations: U.S. DOPPS = United States Dialysis Outcomes and Practice Patterns Survey
Note: Data from 2006.

Figure 5.3 shows the percentage of patients with diabetes in each month with HbA1c tests within the recommended intervals of between three (Panel A) to six months (Panel B) depending on blood glucose control. The percentage of patients with a HbA1c test within three months stabilized near 70%, well above the 48% reported in the FFS population in 2006. After the initial period, the percentage of patients in DMO A with a HbA1c test within six months stayed near 80%, at or above the level reported in the U.S. DOPPS comparison group.

Figure 5.3. Diabetic HbA1c Tests within (A) 3 Months Compared to 2006 FFS, and (B) 6 Months Compared to U.S. DOPPS, DMO A 2006-2008



Abbreviations: FFS = Fee-for-service: U.S. DOPPS = United States Dialysis Outcomes and Practice Patterns Study
Note: FFS data from United States Renal Data System 2008 Annual Data Report.

Two measures of diabetes care showed statistically significant improvement between 2006 and 2008- the percentage of DMO A patients with diabetes receiving annual retinal exams (increasing from 30% in early 2006 to 53% in 2008, $p < 0.01$) and the percentage of patients with diabetes with at least four HbA1c tests during the year, increasing from 23% in 2006 to 36% in 2008 ($p < 0.01$). Similar to the increase in the percent of patients with at least four HbA1c tests, Figure 5.3a shows an increase in the percent of patients receiving an HbA1c test within the last quarter. Fewer patients had four HbA1c tests in a year (not shown) compared to those receiving quarterly testing (Figure 5.3A) because many patients

were enrolled for less than a full calendar year, and also because of differences in achievement between quarters in the same calendar year. The percentage of DMO A patients with diabetes with at least one foot exam during the year declined from 77% in 2006 to 70% in 2008 (p = 0.14), although there was a trend in late 2008 toward percentages seen in 2006.

D. Discussion

This analysis of this aspect of the DMO A Disease Management program demonstrates overall increased rates of diabetes and immunization processes of care measures from baseline, and achievement of clinical guidelines to a generally greater degree than the FFS or the U.S. DOPPS comparison groups.

Fulfillment of these preventive care measures in the ESRD population is important for several reasons. Infections have been reported to contribute to 30%-36% of deaths in patients on dialysis and that many of these are preventable by greater vigilance in administering vaccinations [5]. ESRD patients with diabetes have higher comorbidity and poorer outcomes as compared to patients who do not have diabetes largely due to increased risk of cardiovascular disease (CVD) which may be mitigated to a certain extent by improved glycemic control [6-8]. Prior reports document low rates of implementation of various preventive care measures in the ESRD population [9, 10].

1. Limitations

A limitation of the current evaluation is that the process measures do not capture the entirety of diabetes or immunization management. Other diabetes and immunization processes of care measures are not captured by the study design, including HbA1c level achievement or hepatitis B immunizations.

2. Summary

In summary, the implementation of DMO A's Disease Management program was associated with significant improvement in the delivery of select preventive and diabetes process of care measures.

E. References

1) U.S. Renal Data System, USRDS 2008 Annual Data Report: Atlas of Chronic Kidney Disease and End-Stage Renal Disease in the United States, National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2008.

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CHAPTER 6: DMO B – IMPROVING ADVANCED CARE PLANNING

A. Introduction

This chapter focuses on the impact of DMO B's Disease Management program on enrollees' Advanced Care Planning (ACP). DMO B uses clinical assessments to determine patients' ACP status, and involves the Disease Management team to facilitate the ACP process. The primary aim of our analysis was to evaluate whether the percentage of patients with an ACP increased over the course of DMO B's Disease Management program, 2006 through 2008. Secondarily, we examined clinical and demographic characteristics that were associated with the presence of an ACP.

B. Methods

Patients who enrolled in DMO B between the start of operations on February 1, 2006 and termination of DMO operations on December 31, 2008 were included in the study analysis. Patient ACP information was recorded using four different types of assessments.

- The Standard Comprehensive Assessment was used in 2006 and was administered by NCMs within 30 days of the patient's enrollment into DMO B and semi-annually thereafter. The interview occurred over the course of one to two visits in either the home or in the outpatient clinic using paper-and-pencil data collection forms. This assessment was gradually phased out at the end of 2006 and discontinued in 2007.

- The Community Assessment replaced the Standard Comprehensive Assessment starting in October 2006, and was administered by nurse care managers. This assessment was similar but shorter, and was collected electronically. Follow-up assessments were pre-populated with the responses from prior Community Assessments.

- The Post-Hospitalization Assessment was administered electronically by nurse care managers (NCMs) within one week of discharge from an acute inpatient stay. It took place during one visit in either the home or in the outpatient clinic. Follow-up assessments were pre-populated with responses from prior Post-Hospitalization Assessments.

- The Subjective Objective Assessment and Plan (SOAP) was administered by nurse practitioners (NPs) on varying schedules, but most patients received the assessment three to five times a year. The SOAP was initially paper-and-pencil but converted to electronic format in October 2006. NPs were not required to administer the Advanced Directive sub-assessment as part of the SOAP. Follow-up assessments in the electronic system were pre-populated with responses from prior SOAP Assessments.

Using ACP data collected in these four types of assessments, the Evaluation Team identified patients as having an ACP when they replied affirmatively in at least one assessment to one or more of the following:

- The presence of a Living Will,
- The presence of a Do Not Resuscitate and Comfort Care order,
- The presence of an Advanced Directive, or
- Designation of someone as Power of Attorney.

On the SOAP assessment the presence of a living will or an advanced directive was collected using the same question. Respondents were asked if they had a living will/advanced directive and only a "Yes" or "No" was recorded. The other assessments allowed the patient to identify the specific type of ACP they had in place.

Baseline ACP status was defined using patients' responses to the ACP questions found on the first assessment administered within the first three months of their enrollment. Follow-up ACP status was defined using patients' responses to the ACP questions found on any assessment administered during their enrollment period. Once a patient was recorded as having an ACP, the patient was assumed to have an ACP in place for the remaining duration of their enrollment period. Results from these analyses are compared to facility-level data collected for the 2008 United States Dialysis Outcomes and Practice Patterns Study (U.S. DOPPS) [1, 2].

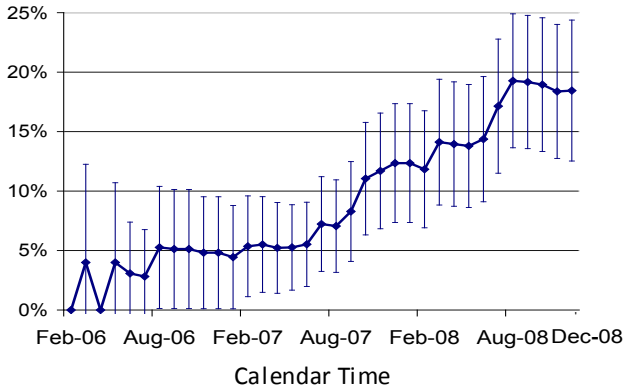
C. Results

At baseline, 8% of the 200 patients with multiple assessments had an ACP. Over the course of the Demonstration, a total of 19.5% of the 200 patients with multiple assessments had an ACP in place. The first ACP assessment occurred, on average, slightly over one month after enrollment (1.2 ± 3.0 months), consistent with the DMO B protocol of conducting an ACP assessment soon after enrollment. After adjusting for multiple confounders, patients who were black, American Indian/Alaska Native, and patients identified as Hispanic/Latino were significantly less likely to have an ACP. Patients who died over the course of the Demonstration were more likely to have an ACP in place as compared to survivors.

Figure 6.1 shows the trend in the percentage of patients with an ACP over the course of the Demonstration. The data points show the percentage of patients with an ACP among patients currently enrolled in each month of the Demonstration. Over the course of the Demonstration there was a gradual increase in the percentage of patients with an ACP such that by August 2008, 19% of patients had an ACP in place. During the last quarter of the Demonstration (October to December 2008), no further increase in the percentage of ACP was noted. In comparison, U.S. DOPPS facility nurses reported an average estimate of 36% of facility patients as having an ACP, although this represents a gross estimation without patient-level verification.

In order to evaluate whether the increase in ACP can be attributed to an increase in ACP adoption by patients over the duration of the Demonstration, we examined the ACP status at baseline versus 12 months later, among patients who were enrolled in DMO B for 12 months or greater (N = 168). Results showed 6.6% of patients enrolled for 12 months or longer had an ACP at baseline. Among patients with adequate follow-up time, the percentage of patients with an ACP increased to 11.3% at month 12 (McNemar's test, $p < 0.01$).

Figure 6.1: Percentage of Patients with an Advanced Care Plan by Month, DMO B, 2006-2008[a]



[a] Data points show the percentage of patients with an ACP among patients currently enrolled each month. Numerator is the number of patients enrolled during the month with an ACP. Denominator is the patients enrolled during the month. Both numerator and denominator include patients who were new enrollees during the month.
Error Bars show 95% Confidence Interval

D. Discussion

The most important finding of this component of DMO B's evaluation is that Disease Management resulted in a significant increase in the percentage of patients with an ACP in place. We observed a steady increase in the percentage of patients with an ACP, over time, specifically among patients enrolled for a 12 month period (Figure 6.1). This suggests DMO B was somewhat effective in implementing the ACP component of their Disease Management program. This finding of 11% with an ACP falls within a national range of 6% to 51% [3].

The positive effects of ACP are illustrated by prior studies. In the Advanced Illness Coordinated Care Program (AICCP), patients in the intervention group were noted to have a greater frequency of putting ACPs in place, and were also more likely to report higher patient satisfaction with care as compared to the control group [4]. Among patients with end-stage renal disease (ESRD) on dialysis, choices to discontinue dialysis and decide where patients end their life can contribute to a shorter duration until death, and being with family rather than in hospital [5]. Given the apparent benefits of ACPs, the increase in the percentage of patients with an ACP in DMO B's Disease Management program demonstrated that DMO B's initiative is noteworthy.

We found that patients who are older and of white race were more likely to have an ACP than younger patients and those of black or American Indian/Alaska Native race or Hispanic ethnicity. It is necessary to recognize that culture and language in particular may influence discussions of dying and the last stages of one's life. It has also been suggested that because patients and families regard these as private family matters, they should primarily take place within the family [3, 6].

We found that patients who died during their enrollment in the Demonstration were more likely to have an ACP in place. This is consistent with prior studies that suggest that a patient's overall health state markedly influences end-of-life planning [7].

1. Limitations

These findings should be taken in the context of data limitations as DMO B underwent a system migration that resulted in the loss of some data. A related limitation is that the assessments that were administered by DMO B had different levels of detail. For example, the SOAP assessment captured ACP type in a general manner, with "living will or advance directive" as the only option, contributing to our findings that a living will is the most common form of ACP.

Similarly, the quality of data collection for the various assessments was inconsistent. It is possible that ACP assessments were under-reported. We also noted inconsistencies in ACP assessments over time. Lack of an adequate comparison population limits the ability to interpret the degree of success of DMO B's ACP program. We utilized the U.S. DOPPS-reported ACP rates as a comparison; however, this was used only as a reference point since patient-level data were not available. Finally, DMO B's announcement in October 2008 of its voluntary termination may have influenced the eventual success of the program in improving ACP rates.

2. Summary

Our analysis of the DMO B ACP initiative suggests that Disease Management and a formal ACP program may be somewhat successful in increasing the rate of adoption of formal ACPs in the hemodialysis population. Because Disease Management emphasizes a more encompassing approach to treating patients who suffer from multiple comorbidities, DMO B's ACP initiative represented a unique opportunity to evaluate the effectiveness of Disease Management on increasing rates of formal advanced care planning.

E. References

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CHAPTER 7: DMO B – IMPROVING DIABETES MANAGEMENT

A. Introduction

This chapter focuses on the impact of DMO B's Disease Management program on the management of diabetes mellitus (diabetes). The aims of this aspect of DMO B's evaluation are to (1) determine whether adherence to hemoglobin A1c (HbA1c) screening guidelines improves with Disease Management, (2) identify factors that are associated with reduced adherence to HbA1c screening guidelines and (3) evaluate whether Disease Management improves glycemic control among end-stage renal disease (ESRD) patients with diabetes mellitus. A related aim is to evaluate the impact of standing orders for HbA1c screening, which was a component of DMO B's Disease Management program between September 2006 and August 2007.

B. Methods

Patients who enrolled in DMO B between the start of operations on February 1, 2006 and the termination of DMO B operations on December 31, 2008 were included in the study analysis. For patients enrolling multiple times in DMO B (N = 15), only the first enrollment was studied.

DMO B implemented standing orders for quarterly HbA1c monitoring in September 2006 for all patients, however, several programmatic issues led to difficulties in implementing these orders. Most notably, after a system conversion in August 2007, DMO B lost the ability to enter and view standing orders for quarterly HbA1c testing. Nurses also lost the ability to access medical record data and could not directly view patients' clinical data. Due to these programmatic issues and the change in medical record systems, DMO B discontinued these standing orders in August 2007.

Patients with diabetes were identified using DMO B's comorbidity file and information from the Centers for Medicare & Medicaid Services (CMS) Medical Evidence Form (Form 2728); HbA1c laboratory testing dates and results were provided by DMO B. Results from these analyses were compared to patient-level data collected from the 2008 United States Dialysis Outcomes and Practice Patterns Study (U.S. DOPPS) [1, 2] and the fee-for-service (FFS) data from the 2008 United States Renal Data System (USRDS) Annual Data Report [3].

C. Results

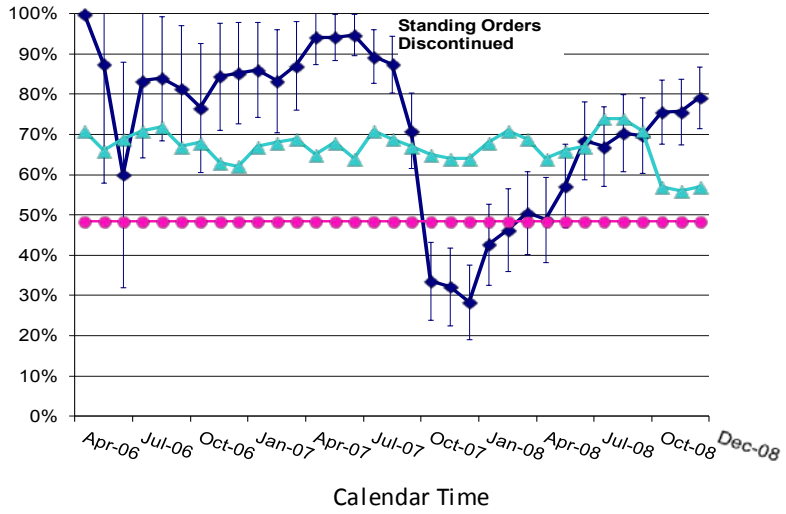
1. Impact of Disease Management on HbA1c Testing

Figure 7.1 presents the percentage of patients with a three-monthly HbA1c test by calendar time with the U.S. DOPPS comparison group noted. Approximately 85% of patients with diabetes received an HbA1c test every three months prior to September 2006, further increasing to 95% after implementation of the standing orders in September 2006. This precipitously dropped in August 2007, when standing orders were discontinued, reaching a nadir in January 2008, where only 30% of diabetic patients received an HbA1c test within the last three months. A gradual increase in the percentage of patients receiving an HbA1c test within the last three months was observed in early 2008. The percentage of U.S. DOPPS patients with a three-month HbA1c test remained fairly steady, fluctuating between 60% and 70%. Before the standing orders were discontinued and towards the end of 2008, the percentage of DMO B patients with a three-month HbA1c was well above the 48% reported in the FFS population in 2006 (USRDS data). The percentage of patients who received a quarterly HbA1c test

throughout the standing orders period was 71.3%. In the post-standing orders period, this percentage dropped to 29.6%. Among the patients enrolled during both periods, the percentage of patients with quarterly HbA1c testing decreased significantly between the standing orders period and the post-standing orders period (72.2% versus 15.6%, respectively; $p < 0.01$).

Figure 7.1: Number of DMO B Patients with Diabetes, and Three-Month HbA1c Testing[a] Among Patients with Diabetes, by Calendar Month

Legend: ♦ = DMO B patients with Quarterly HbA1c Testing; ▲ = U.S. DOPPS patients with Quarterly HbA1c Testing; ● = FFS patients with at least 4 HbA1c Tests in 2006



Abbreviations: FFS = Fee-for-service: U.S. DOPPS = United States Dialysis Outcomes and Practice Patterns Study
Note: FFS data from United States Renal Data System 2008 Annual Data Report.
[a] Quarter HbA1c testing = Quarterly testing defined as a Hemoglobin A1c test received that month or in the prior two months.
Error Bars show 95% Confidence Interval

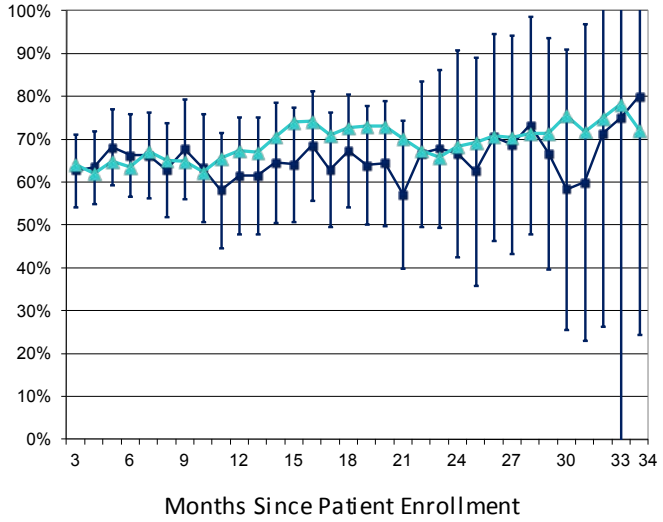
We evaluated the characteristics associated with quarterly testing in both the standing orders period and the post-standing orders period. After adjusting for other demographics, patients with a higher CMS-Hierarchical Condition Categories (HCC) risk score were more likely to receive quarterly HbA1c testing (odds ratio [OR] = 23.31, $p = 0.02$) during the standing orders period. The opposite was found in the post-standing orders period. Patients with a higher CMS-HCC risk score were less likely to receive quarterly HbA1c testing, although this was not statistically significant (OR = 0.13, $p = 0.10$). These results suggest that regular HbA1c testing was more likely to occur when standing orders were in place among patients with a higher burden of comorbidity.

2. Impact of Disease Management on Glycemic Control

As shown in Figure 7.2, between 60%-80% of DMO B patients achieved the target HbA1c < 7%, which is similar to the 60%-80% observed in the U.S. DOPPS. Among patients enrolled in both the standing orders period and post-standing orders period, there was no significant difference in the percentage of patients achieving a median HbA1c < 7%.

After adjusting for other demographic characteristics, there was a trend for an association between quarterly HbA1c testing and achievement of a median HbA1c < 7% but this did not achieve statistical significance (OR = 1.91, $p = 0.18$). The opposite trend was found in the U.S. DOPPS analyses (OR = 0.72, $p = 0.19$).

Figure 7.2: Percentage of Patients with Median[a] HbA1c < 7%, by Enrollment Month[b]
Legend: ■ = DMO B patients Median HbA1c < 7%; ▲ = U.S. DOPPS patients Median HbA1c < 7%



[a] Median HbA1c = Median HbA1c is defined as the median of the HbA1c results in current and prior two months.
[b] The sample sizes ranged from 2 - 124.
Error Bars show 95% Confidence Interval

D. Discussion

This analysis demonstrates the effectiveness of Disease Management, particularly DMO B's implementation of standing orders in the achievement of diabetes processes of care measures. DMO B's implementation of standing orders in September 2006 and subsequent discontinuation in August 2007 serve as a unique and natural experiment that provided an opportunity to observe changes in HbA1c screening rates without standing orders. When standing orders were in place, HbA1c tests were administered every three months to approximately 90% of patients, much higher than percentages observed in the U.S. DOPPS, and well above the 48% reported in the FFS population in 2006 [3]. Our analyses demonstrate that HbA1c screening percentages drastically reduced to 30% (with a statistically significant 56.6% drop) soon after termination of standing orders. We also observed that when standing orders were implemented, patients with higher burden of comorbidity as measured by the CMS-HCC risk score were significantly more likely to have quarterly HbA1c monitoring, whereas after discontinuation of standing orders, this was no longer observed.

Fulfillment of the HbA1c screening measure for ESRD patients with diabetes is important for several reasons; ESRD patients with diabetes have higher comorbidity and poorer outcomes as compared to ESRD patients without diabetes largely due to increased risk of cardiovascular disease (CVD) which may be mitigated to a certain extent by improved glycemic control [4-7]. Good glycemic control may prevent or slow the progression of retinopathy, neuropathy and potentially macrovascular disease, although very few studies have addressed the clinical impact of intensive glycemic control in the ESRD population [8]. The National Kidney Foundation's Kidney Disease Outcomes Quality Initiative (NKF KDOQI) guidelines for managing diabetes in chronic kidney disease (CKD) patients recommend a target HbA1c level below 7%, consistent with the American Diabetes Association (ADA) guidelines [4, 5]. As part of the clinical guidelines, patients with diabetes should receive two to four HbA1c tests per year depending on the level of glycemic control.

Although DMO B's implementation of standing orders improved frequencies of screening of HbA1c levels, we did not observe an impact on achievement of the target HbA1c (HbA1c < 7%). A potential explanation for why the standing orders did not affect the percentage of DMO B patients achieving

HbA1c levels < 7% may be the recognition by care providers that HbA1c measurement in the ESRD population may be less reliable than in the general population. For instance, falsely depressed HbA1c levels may result from reduced red blood cell life span and the use of erythropoietin whereas factors that may lead to falsely elevated HbA1c levels include metabolic acidosis and carbamylation of hemoglobin [4]. Therefore more frequent screening of HbA1c levels may not have affected the actual treatment of DMO B patients.

1. Limitations

A limitation of the current evaluation is that the process measures did not capture the entirety of diabetes management. Other diabetes processes of care measures, such as retinal screening, CVD screening, and podiatry care were not captured by DMO B's diabetes management program. Another limitation is the small sample size in the DMO B population, particularly in conducting the analysis over enrollment time. As shown in Figure 7.2, the error bars for the various estimates become wider over time, demonstrating the very small patient numbers as duration of enrollment increases.

2. Summary

In summary, DMO B's implementation of standing orders was associated with the achievement of HbA1c screening frequencies as recommended by clinical guidelines. The discontinuation of DMO B's standing orders provided an opportunity to evaluate the effectiveness of standing orders since HbA1c measurement frequencies markedly declined in the absence of standing orders. We did not detect an improvement in achievement of HbA1c target levels, either during the standing orders period or the post standing orders period. Although there was no improvement in the achievement of HbA1c target levels over the study period, the impact of standing orders on this process measure is encouraging.

E. References

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CHAPTER 8: DMO B – CHANGING PRESCRIPTION PATTERNS OF ACEI/ARB USE

A. Introduction

This chapter evaluates angiotensin converting enzyme inhibitor/angiotensin receptor blocker (ACEi/ARB) prescription patterns among patients with hypertension enrolled in DMO B. The study's specific aims are 1) to determine ACEi/ARB usage among participating dialysis patients with uncontrolled hypertension, and 2) to describe barriers to the use of ACEi and ARBs as noted by patients' attending nephrologists.

B. Methods

Disease Management Organization (DMO) data unique to this analysis included:

- Aim 1 – Systolic blood pressure (SBP) and diastolic blood pressure (DBP) data, measured just before the start of every hemodialysis (HD) session ("pre-dialysis") and prescription claims data, which were matched to a list of generic and brand-name ACEi and ARB medications.

- Aim 2 – Surveys completed by five attending nephrologists for DMO B patients with hypertension who enrolled in 2006 or 2007 and never received a prescription for an ACEi or ARB medication.

For Aim 1, uncontrolled hypertension (hereinafter referred to as hypertension) was defined as three consecutive pre-dialysis SBP readings greater than 150 mm Hg or three consecutive pre-dialysis DBP readings greater than 90 mm Hg. After the third consecutive occurrence of elevated blood pressure, the patient was classified as having hypertension at all subsequent time points. Since many patients' prescription claims were every three months, we assumed that all claims were for 90-day supplies. For this reason, baseline medication status (yes/no) was defined as whether the patient had a claim for an ACEi or ARB in the first three months after diagnosis of hypertension. Data from the United States Dialysis Outcomes and Practice Patterns Study (U.S. DOPPS) [1, 2] years 2005 to 2008 were used for comparison, and this comparison sample included all study participants, with or without hypertension, as it was not possible to determine hypertension status in this sample.

For Aim 2, the questionnaire, modified from the Roy et al. survey of ACEi/ARB prescription patterns [3] was sent in March 2008 to the attending nephrologist linked to each of DMO B's 14 patients with hypertension who never received a prescription for an ACEi/ARB medication. The surveyed nephrologists were asked to identify any of eight potential reasons a patient was not prescribed an ACEi or ARB medication. Completed surveys were received from nephrologists for 12 of the 14 patients.

C. Results

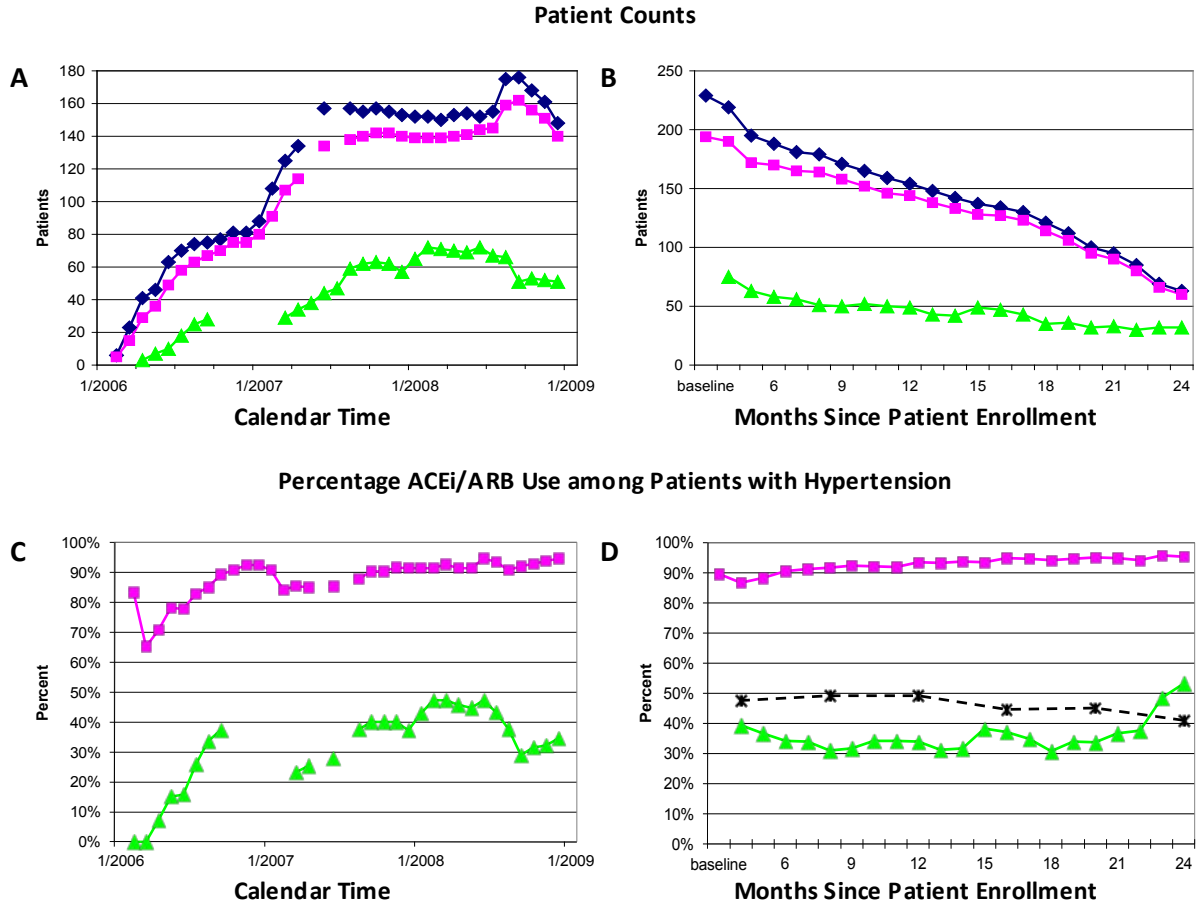
1. Aim 1 – ACEi/ARB Use

Figure 8.1 presents the prevalence of hypertension and shows ACEi/ARB use according to calendar time and enrollment duration. As shown in Figure 8.1 the proportion of patients with hypertension remained high (90% or higher) throughout most of the Demonstration period (Figures 8.1A and 8.1C) and across patient enrollments (Figures 8.1B and 8.1D). ACEi/ARB use varied somewhat over calendar time and enrollment duration (Figure 8.1C and 8.1D). Low use in early 2006 may be due to either a lag in medication claims data during the initial stages of the implementation of DMO B's Disease Management

program, or a true lag in initiation of medications during the start of DMO B's Disease Management program. As shown in Figure 8.1D, percentage ACEi/ARB use was 30% to 40% from onset of hypertension through 22 months of enrollment. ACEi/ARB use rose to 53% at two years of enrollment, though only 63 patients were enrolled in DMO B for at least two years.

Figure 8.1: DMO B Patients with Hypertension[a], and ACEi/ARB Use[b] among Patients with Hypertension, by Time

Legend: ♦ = All DMO B patients; ■ = DMO B patients with hypertension; ▲ = DMO B patients with hypertension and prescribed an ACEi/ARB; × = DOPPS patients prescribed an ACEi/ARB.



Abbreviations: ACEi/ARB = Angiotensin Converting Enzyme inhibitor/Angiotensin Receptor Blocker; DOPPS = Dialysis Outcomes and Practice Patterns Study

Note: 229 patients were eligible for the analyses (restricted to patients having both blood pressure data and at least three months of enrollment). Gaps in figures indicate missing data. ACEi/ARB use rates were not calculated from 09/2006 through 03/2007 due to missing medication data. ACEi/ARB use rates were not calculated for 05/2007 and 07/2007 due to missing blood pressure data.

[a] Hypertension defined as three consecutive systolic blood pressure readings > 150 mm Hg or three consecutive diastolic blood pressure readings > 90 mm Hg.

[b] ACEi/ARB use indicates an ACEi/ARB medication claim within the past three months. Medication tracking begins three months after enrollment month to account for gaps between enrollment and first prescription refill.

Table 8.1 presents within-patient change in ACEi/ARB use during the enrollment period. Among DMO B patients with hypertension at some point during their enrollment (N = 214), 35% had an ACEi/ARB prescription within three months after onset of hypertension (as defined above). Among patients enrolled one year after hypertension onset (N = 140), there was no change in overall ACEi/ARB use, with 36% of patients prescribed an ACEi/ARB at both 0 and 12 months.

However, among those enrolled for at least two years after hypertension onset (N = 41), ACEi/ARB use increased from 31% at onset to 55% at 24 months ($p < 0.01$).

ACEi/ARB use was higher in the U.S. DOPPS population than in DMO B, with the exception of use at 24 months when use was higher in DMO B. Among all U.S. DOPPS patients, 47% had an ACEi/ARB prescription at baseline, compared to 35% in DMO B. Change in ACEi/ARB use in the U.S. DOPPS sample after 12 or 24 months did not achieve statistical significance.

Table 8.1: ACEi/ARB Use among DMO B Patients with Hypertension, by Time Enrolled in DMO, Compared to U.S. DOPPS Patients

	DMO B			U.S. DOPPS		
	All Patients with Hypertension[a] (N = 214)	Patients Enrolled for ≥ 12 Months after diagnosis of Hypertension (N = 140)	Patients Enrolled for ≥ 24 Months after diagnosis of Hypertension (N = 41)	All Patients (N = 690)	Patients Enrolled for ≥ 12 Months (N = 336)	Patients Enrolled for ≥ 24 Months (N = 166)
Percent prescribed ACEi/ARB[b] at baseline[c]	35	36	31	47	49	46
Percent prescribed ACEi/ARB at 12 or 24 months	-	36	55	-	49	41
Change in percent prescribed ACEi/ARB from baseline to 12 or 24 months months (p-value)[d]	-	+0 (p = 1.00)	+24 (p < 0.01)	-	+0 (p = 0.90)	-5 (p = 0.19)

Abbreviations: ACEi/ARB = Angiotensin Converting Enzyme inhibitor/Angiotensin Receptor Blocker; U.S. DOPPS = United States Dialysis Outcomes and Practice Patterns Study

Note: there were 229 DMO B patients eligible for the analyses (restricted to patients having both blood pressure data and at least three months of enrollment).

[a] Hypertension defined as three consecutive systolic blood pressure readings > 150 mm Hg or three consecutive diastolic blood pressure readings > 90 mm Hg.

[b] At any time, DMO B patients were considered as being prescribed an ACEi/ARB if they had an ACEi/ARB pharmacy claim during the previous three months.

[c] For DMO B patients, baseline was defined as the time of diagnosis of hypertension (i.e., at the third consecutive BP reading above 150/90). For U.S. DOPPS, baseline was defined as the date the patient entered the study. Prescription of ACEi/ARB within three months after onset of diagnosis of hypertension.

[d] Reported p-value uses McNemar's test for unadjusted within column comparison between baseline and 12 or 24 months.

2. Aim 2 – Describe Barriers to ACEi/ARB Use

Barriers to the use of ACEi/ARB medications among patients with hypertension not prescribed either medication class were evaluated, as perceived by the attending nephrologist caring for each patient (Table 8.2). Completed surveys were received from the nephrologist for 12 of the 14 identified patients, with at least one survey from each of the five identified nephrologists.

Table 8.2: Results of Nephrologist Survey: Barriers to ACEi/ARB Use (N = 12 patients, Cared for by 5 Nephrologists)[a]

Reason for ACEi/ARB non-use, ranked in order of greatest to least number of patients affected
The patient's compliance to these medications is poor.
Risks associated with these medications outweigh the benefits.
The cost of these medications is prohibitive for the patient.
The patient is already administered a large number of medications.
Dialysis provides sufficient and adequate control of hypertension.
There are concerns about prior adverse reactions.
There is no proven benefit of these medications on mortality in dialysis patients with uncontrolled hypertension.
Due to previous acute myocardial infarction, the patient is on a beta-blocker.

Abbreviations: ACEi/ARB = Angiotensin Converting Enzyme inhibitor/Angiotensin Receptor Blocker

[a] Survey was sent to nephrologists for patients with hypertension, but without an ACEi/ARB prescription (refer to text for full description of survey methods.)

D. Discussion

The aims of these analyses were to determine ACEi/ARB use among participating dialysis patients with uncontrolled hypertension, and to describe any barriers to ACEi/ARB use. These aims are generally consistent with the principles of the National Kidney Foundation Kidney Disease Outcomes Quality Initiative (NKF KDOQI) Clinical Practice Guidelines on Hypertension and Antihypertensive Agents in chronic kidney disease (CKD) [4]. Pertinent KDOQI recommendations include 1) pre-dialysis blood pressure goal should be < 140/90 mm Hg, and 2) drugs that inhibit the renin-angiotensin system, such as ACEis or ARBs, should be preferred for the treatment of hypertension. For this evaluation, hypertension was defined as SBP > 150 or DBP > 90 mm Hg on three successive HD sessions. By these requirements, fewer patients will be diagnosed with hypertension than by the KDOQI criteria. Nevertheless, the observed prevalence of hypertension by study criteria was extremely high (Figure 8.1A and 8.1B). The NKF KDOQI guidelines rated the strength of these recommendations as grade B or C (on an A to C scale), because they were based on "moderately strong" or "weak" evidence and definitive clinical trial data are lacking. Although the evidence is not considered strong, the NKF KDOQI recommends that "clinicians routinely follow" or "consider following" the guidelines. Thus, these are considered by many to be the current standards of care and, as such, are useful medication classes to study as indicators of quality in the DMO B Disease Management program.

During the DMO B enrollment period, ACEi/ARB prescription among patients with hypertension ranged from 30% to 53% (Figure 8.1D). While these prescription rates are quite low, U.S. DOPPS data also indicate that use is low (< 50%) in a nationally representative sample of adult U.S. HD patients. Additionally, it was evident that during the course of DMO B's Disease Management program, a significant increase in ACEi/ARB use was noted among patients with hypertension who were enrolled for at least 24 months (Table 8.1), potentially demonstrating a positive impact of DMO B's Disease Management program.

Addressing barriers to ACEi/ARB prescription, as identified by nephrologists for a sample of DMO B patients (Table 8.2) may serve as a means to raise future rates of ACEi/ARB prescription in similar patients.

In sum, interventions aimed at providers and/or patients to lessen these barriers may increase ACEi/ARB use and could also be used to inform strategy to improve achievement of other quality indicators.

1. Limitations

Two limitations to our findings merit mention. First, the small patient sample size generally limits the extent of the inference we can draw from our analyses. Second, because we have no record of ACEi/ARB use prior to enrollment, these data cannot directly address whether participation in the DMO B Program was, in and of itself, associated with increased ACEi/ARB prescription.

2. Summary

ACEi/ARB prescription rates among patients with hypertension during the DMO B enrollment period ranged from 30% to 53%, and were generally comparable, though initially slightly lower, to rates in a nationally representative sample of U.S. adult HD patients. Over the course of DMO B's program, a significant increase in rate of ACEi/ARB use was noted among patients with hypertension who were enrolled for 24 months or longer. Potentially modifiable barriers to ACEi/ARB use were identified. Additional study is needed to evaluate the impact of interventions to improve medication management and related quality indicators among dialysis patients with hypertension.

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CHAPTER 9: DMO C – USE OF ORAL NUTRITIONAL SUPPLEMENTS IN PATIENTS WITH LOW SERUM ALBUMIN

A. Introduction

DMO C incorporated two interventions in its Disease Management program in addition to care coordination. One such intervention provided early administration of oral nutritional supplements (ONS), which was initiated once serum albumin was found to be below 3.8 g/dL. Because low serum albumin is a recognized predictor for adverse clinical outcomes, DMO C's intervention offered a unique opportunity to evaluate the effectiveness of ONS on increasing serum albumin as well as improving clinical outcomes. The specific aims of this analysis were to evaluate the impact of ONS on 1) serum albumin values, 2) all-cause hospitalization and 3) all-cause mortality.

B. Methods

Patients who enrolled in DMO C between the start of DMO operation on February 1, 2006 through December 31, 2008 were included in the study analysis. In 2006, DMO C's Disease Management program was implemented in Texas, Massachusetts, and Pennsylvania. In 2007, the program was expanded to include Connecticut, Alabama, Tennessee, and California. For patients enrolling multiple times in DMO C (N = 20), only the first enrollment was studied. Patients with a functioning transplant at enrollment were excluded from these analyses.

DMO C placed patients with a mean serum albumin below 3.8 g/dL on ONS. During the inception of the program a three month mean was used to determine ONS eligibility, however eligibility requirements were broadened later in the Demonstration. In August 2006 DMO C began placing patients with a two month mean serum albumin of less than 3.8 g/dL on ONS. Supplements were discontinued as soon as the three month average serum albumin exceeded 3.8 g/dL. Patients were provided 24 cans per month of the standard oral supplement Ensure Plus (Abbott Laboratories), and were advised to consume one can per day at home, with a certain number of days off per week. The days when a patient did not consume a can of ONS were up to the discretion of the patient. In 2007, Glucerna (Abbott Laboratories), a nutritional supplement designed for patients with diabetes mellitus (diabetes), was used for patients with diabetes.

Results from these analyses were compared to patient-level data collected from the 2007 Centers for Medicare & Medicaid Services (CMS) End-Stage Renal Disease (ESRD) Clinical Performance Measures (CPM) Project [1]. In this Project, serum albumin was recorded in October, November, and December of 2006. Hospitalization and mortality data were evaluated for these patients in 2007. In all analyses, serum albumin data were limited to patients with measurements utilizing the bromcresol green (BCG) laboratory method.

We performed an "intention-to-treat" analysis, which is similar to statistical methodologies used in randomized clinical trials where patients are analyzed according to treatment randomization regardless of whether the patient received the treatment or not. In such an analysis we make the conservative assumption that all patients with the appropriate indication received ONS, thereby including non-adherent patients in our treatment group. Thus, in this intention-to-treat analysis, we restricted the study population to DMO C's hemodialysis (HD) patients who had the indication to receive ONS in the first two months of enrollment (n = 417). A two month time frame was selected as the cut-off period since DMO C's indication for ONS use was a two-month mean serum albumin of 3.8g/dL. Although

treatment indication was originally based on a three-month mean, a two-month mean is more inclusive and was therefore used to gain statistical power.

C. Results

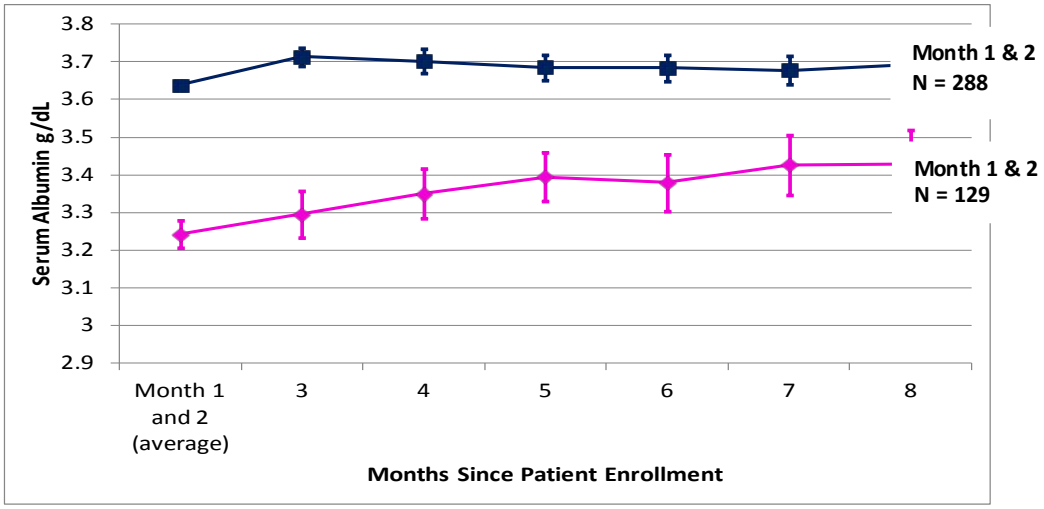
Among the patients included in the analyses (N=1,377), 51.7% received ONS (N = 712) for a mean cumulative duration of 7.7 (± 6.8) months. Patients were on continuous ONS use for a mean of 3.4 (± 4.0) months, and were placed on ONS for a mean of 2.3 (± 1.4) episodes. Patients could refuse the supplements or dieticians could determine that ONS was not appropriate for the patient; as a result 97 patients did not receive ONS despite having persistently low serum albumin. These patients were typically enrolled in the Demonstration for a shorter period of time compared to all others (patients who did not receive ONS despite a serum albumin < 3.8 g/dL were enrolled for an average of 9.0 months versus 13.7 months for all other patients, p < 0.01). Consistent with DMO C's protocol of using serum albumin to initiate ONS, patients on ONS had a significantly lower mean baseline serum albumin as compared to those without ONS use (3.6 g/dL versus 4.0 g/dL, p < 0.01, respectively).

1. Impact of Oral Nutritional Supplements on Serum Albumin

Figure 9.1 shows the relationship between mean serum albumin and the month of enrollment among patients with an initial serum albumin of less than 3.5 g/dL as compared to those with an initial serum albumin greater than or equal to 3.5 g/dL and less than 3.8 g/dL (intention-to-treat analysis). Although both patient groups experienced an increase in mean serum albumin within the first three months of enrollment, the increase in albumin was more robust among patients with a lower initial serum albumin. This suggests that even among patients with significant hypoalbuminemia, ONS use can result in an improvement in serum albumin.

Figure 9.1: Mean Serum Albumin (g/dL) By Month of Enrollment, Among Patients with Indication for ONS

Legend: ■ = DMO C patients with an average serum albumin greater than or equal to 3.5 g/dL and less than 3.8 g/dL within first 2 months of enrollment ♦ = DMO C patients with an average serum albumin less than 3.5 g/dL within the first two months of enrollment.



Abbreviation: ONS = Oral Nutritional Supplements.
Error Bars show standard deviation

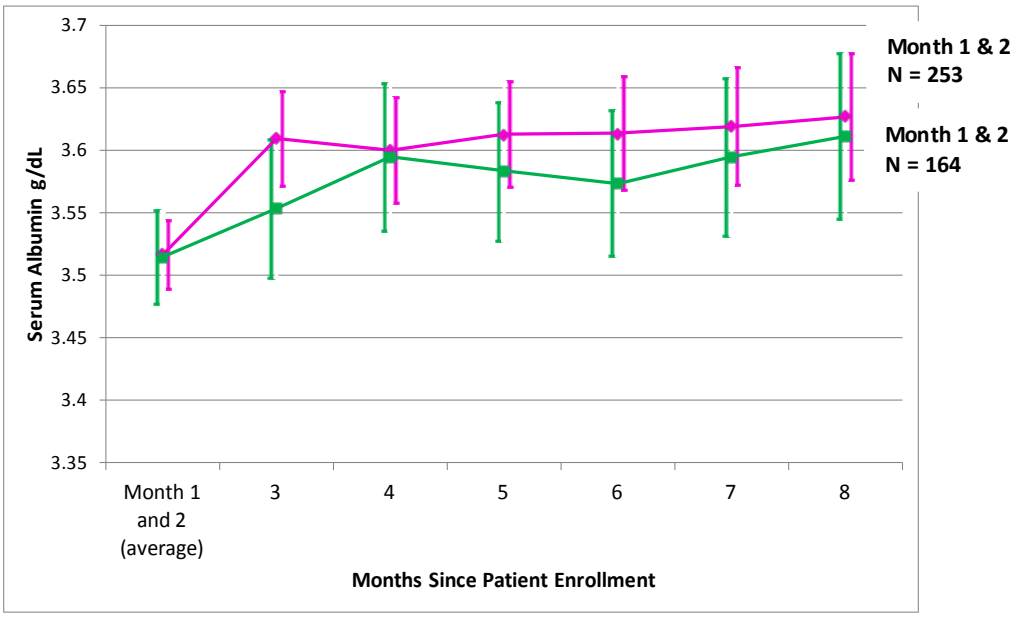
The ability to infer a relationship between the ONS program and increases in serum albumin is also limited by the possibility that any increases in serum albumin may be explained by regression to the

mean. In order to examine this possibility we limited our analysis to patients with an indication to receive ONS, based on the 2 month average serum albumin < 3.8 g/dL, and compared change in serum albumin among patients who received ONS within three months of enrollment to the change in serum albumin among patients who did not receive ONS within three months of enrollment. ONS use was defined within the first three months of enrollment since the third month of enrollment is the cut-off at which a patient within the first 2 months with the appropriate indication should receive ONS. This analysis allows us to compare the changes in serum albumin among patients with initially low serum albumin, based on whether patients received ONS or not and allows us to identify any differences in the trajectory of serum albumin concentrations between the two groups. This methodology results in an evaluation of the overall approach of DMO C to patients with low serum albumin soon after enrollment into the DMO. Because it is possible that any observed increases in serum albumin among patients with ONS is due to regression to the mean, we also examined whether the increase in serum albumin (if any) in the ONS group exceeds that observed among patients who did not receive ONS.

As shown in Figure 9.2 serum albumin did increase among patients with an initially low serum albumin regardless of whether ONS was prescribed or not. However, among patients who received ONS, the slope of increase in serum albumin was steeper. In addition after the fourth month of enrollment, average serum albumin declined in patients without ONS while it continued to increase among patients who received ONS. Altogether these additional analyses demonstrate that although some of the increase in serum albumin may be attributed to regression to the mean, ONS use appears to result in a real increase in serum albumin.

Figure 9.2: Mean Serum Albumin (g/dL) By Month of Enrollment, Among Patients with Indication for ONS, Stratified by ONS Use

Legend: ♦ = DMO C patients with an average serum < 3.8 g/dL within first 2 months of enrollment and who received ONS within 3 months of enrollment ■ = DMO C patients with an average serum albumin < 3.8 g/dL within first 2 months of enrollment and no ONS within 3 months of enrollment



Abbreviation: ONS = Oral Nutritional Supplements.
Error Bars show standard deviation

It should be noted that the analyses captured initiation of ONS based on fulfilling a mean two month average serum albumin within the first two months of enrollment. In addition, patients without ONS may be receiving ONS later in their enrollment period, particularly patients who enrolled in the first six months of the program when a three month average serum albumin was used to determine ONS use.

Therefore some of the patients in no-ONS group may be receiving ONS between 3rd and 4th months of enrollment.

2. Impact of Oral Nutritional Supplements on Hospitalization

We performed an intention-to-treat analysis which restricted the hospitalization and mortality analyses to DMO C patients who had the appropriate indication for ONS use at enrollment. These patients were defined as HD patients with an average serum albumin < 3.8 g/dL within the first 2 months of enrollment. Our comparison population included HD patients in the 2007 CMS ESRD CPM sample with an average serum albumin < 3.8 g/dL in November and December of 2006. Table 9.1 presents the adjusted hospitalization percentages at one year for patients with indication to receive ONS in the DMO C program and in the ESRD CPM sample. The intention-to-treat analysis did not demonstrate a significant association of DMO C's ONS program with reduction in hospitalization at one year.

3. Impact of Oral Nutritional Supplements on Mortality

We conducted an intent-to-treat analysis for one-year mortality similar to the hospitalization analysis. The DMO C population was restricted to patients with an average serum albumin < 3.8 g/dL within the first 2 months of enrollment and the 2007 ESRD CPM sample was restricted to patients with an average serum albumin < 3.8 g/dL in November and December of 2006.

Table 9.1 presents the adjusted mortality percentages at one year for patients with indication to receive ONS in the DMO C program. Among DMO C patients with the indication for ONS use, 16.2% of patients died within one year as opposed to 23.4% among ESRD CPM patients with the appropriate indication. These results suggest that in an intention-to-treat analysis, DMO C's ONS program was associated with significantly reduced mortality at one year.

Table 9.1: Adjusted[a] Hospitalization and Mortality Percentages at One Year, DMO C and the 2007 ESRD CPM Sample[b], Patients with and without ONS, by Achieved Serum Albumin Status

	Hospitalization Percentage (95% CI)	Mortality Percentage (95% CI)
DMO C patients with average serum albumin < 3.8g/dL within two months of enrollment (n=417)	71.8 (66.1, 76.6)	16.2 (11.8, 20.3)
ESRD CPM patients with average serum albumin < 3.8g/dL in Nov/Dec 06 (n=2425)	72.2 (70.0, 74.3)	23.4 (21.2, 25.4)

Abbreviations: CPM = Clinical Performance Measures; ESRD = End-Stage Renal Disease; ONS = Oral Nutritional Supplements
[a]Adjusted to the entire DMO C population. Adjusted for age at enrollment, race, Hispanic ethnicity, years since ESRD onset at enrollment, and diabetes as a comorbidity.
[b] Data from 2006-2008 for DMO C and from Nov-Dec 2006 for ESRD CPM sample.

D. Discussion

The key findings of the evaluation of DMO C's ONS program are that ONS use can result in a significant increase in serum albumin, and even more importantly, reduced the risk of mortality at one year. In the adjusted analysis, the percentage of patients who died was significantly lower among patients who had an indication to receive ONS under DMO C's Disease Management program compared to patients in the ESRD CPM sample with the appropriate indication. DMO C's ONS program did not significantly reduce all-cause hospitalization at one year compared with patients in the ESRD CPM sample with the appropriate indication.

Hemodialysis patients are at a particularly increased risk of malnutrition for several reasons [2]. These include poor energy and protein intake because of numerous factors such as frequent hospitalizations,

anorexia, and delayed gastric emptying; the presence of ongoing inflammation related to multiple comorbidities and type of vascular access; metabolic derangements such as metabolic acidosis; and HD-specific factors such as bio-incompatibility and amino acid losses that may lead to a persistent catabolic state [3]. As indicated in the National Kidney Foundation Kidney Disease Outcomes Quality Initiative (NKF KDOQI) clinical guidelines on the management of nutrition in ESRD, there is an urgent need for studies that evaluate whether nutritional intervention can increase markers of nutrition such as serum albumin and whether this translates to a reduction in morbidity and mortality in HD patients [4].

The improvement in serum albumin and reduced patient mortality at one year in DMO C's ONS program indicate that there may be a benefit associated with the early initiation of ONS with DMO C's protocol, as well as overall Disease Management. Initiating ONS among patients with marginally reduced serum albumin may have resulted in greater responsiveness of patients who are in the early stages of malnutrition. Finally, unmeasured components of DMO C's Disease Management program may have also contributed to the overall benefit to their patient population. Early dietitian intervention and close interaction with nurse care managers (NCMs), among others, may have resulted in intangible patient benefits that could have resulted in improved dietary intake.

1. Limitations

Limitations of the treatment-as-received analysis were addressed with an intention-to-treat analysis in that DMO C's program was evaluated based on treatment indication regardless of whether a patient received ONS or not. This is a more robust statistical methodology as this is not subject to treatment by indication bias as well as patient factors (e.g. adherence) that may modify clinical outcomes. Another limitation of this analysis is that patients who received ONS may also have received other treatment intervention(s) concurrently as part of DMO C's overall Disease Management, thus ONS is likely to have contributed only partially to the improved one-year survival noted.

2. Summary

In summary, DMO C's protocol of early ONS use was associated with a significant improvement in serum albumin, as well as a significant reduction in mortality rates at one year. One-year hospitalization rates were not significantly different from the comparison group in the intention-to-treat analysis. The impact of DMO C's ONS program is a promising component of Disease Management in the ESRD population.

E. References

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2) Toigo G, Aparicio M, Attman P-O, et al. Consensus Report: Expert working group on nutrition in adult patients with renal insufficiency (Part 2 of 2): Clinical Nutrition 2000; 19(4): 281-291.

3) Pupim LB, Ikizler TA. Uremic Malnutrition: New insights into an old problem. Semin Dial. 2003; 16(3): 224-232.

4.) National Kidney Foundation: KDOQI Clinical Practice Guidelines for Nutrition in Chronic Renal Failure. Am J Kidney Dis 2001; 37 (Suppl 2): S66-S70.

CHAPTER 10: DMO C – IMPACT OF HOME WEIGHT MONITORING ON CLINICAL OUTCOMES

A. Introduction

Available evidence indicates that limiting excessive weight gain between hemodialysis (HD) sessions (inter-dialytic weight gain [IDWG]) influences clinical outcomes including hospitalization and mortality [1-4]. This chapter evaluates the impact of the DMO C home weight monitoring (HWM) program on clinical outcomes among HD patients. The program was intended as a means for patients and providers to monitor and limit occurrences of excess IDWG.

1. Relevant Background and Rationale

The rationale for the HWM program is based on a wide body of data that excess IDWG adversely affects clinical outcomes among HD patients, and that control of IDWG may be a useful strategy to improve outcomes [1-4]. Excess IDWG and associated insufficient ultrafiltration (UF) volume during dialysis contribute to poor outcomes because the resultant excess extracellular fluid volume typically exacerbates hypertension, which has well-established detrimental effects on the cardiovascular system. Additionally, excess IDWG necessitates higher UF volume and typically more rapid UF rate in efforts to normalize extracellular fluid volume status. High UF volume and rapid UF rate often lead to interdialytic hypotension, which can compromise dialysis adequacy, contribute to loss of residual kidney function and coronary and/or cerebral ischemia, and have potentially life-threatening consequences [1].

The National Kidney Foundation's Kidney Disease Outcomes Quality Initiative (NKF KDOQI) Clinical Practice Guidelines for Hemodialysis Adequacy (2006 Update) Guideline 5 states that "…to obtain favorable results, an intense, totally committed, and prolonged effort—with a high degree of motivation—is required from caregivers, as well as from the patients themselves."[1]. To this end, the DMO C HWM Program was implemented as a potentially important means to monitor IDWG, optimize target (dry) weight, and control blood pressure (BP). Despite the potential advantages of HWM in dialysis patients, this strategy has not been evaluated previously.

2. Specific Aims

Specific aims for the DMO C HWM program were as follows:

Aim 1: To evaluate whether HWM is associated with lower IDWG
Aim 2: To evaluate whether HWM is associated with reduced need for extra dialysis sessions
Aim 3: To evaluate whether HWM is associated with fewer hospitalizations and longer survival
Aim 4: To evaluate whether HWM is associated with fewer cardiovascular-related hospitalizations and lower cardiovascular-related mortality
Aim 5: To identify demographic and clinical subgroups in which HWM is most effective

B. Methods

1. Data Elements

Data utilized in this chapter included:

- **HWM use:** HWM use was divided into a maximum of three time periods for each patient: (1) time before using HWM, including all enrollment time for patients who never used HWM; (2) time while using HWM (for patients who ever started HWM); and (3) time after using HWM (for patients who stopped using HWM during the enrollment period). All patients had some enrollment time before HWM use. There were 49 patients who stopped and later resumed use of HWM (4% of all patients and 9% of HWM users). Among these patients, the median time spent on HWM was nearly one year while the median time between HWM periods was less than three months. Because the time spent between HWM periods was relatively small, the earliest start date and latest stop date were used to construct one continuous HWM use period.
- **IDWG:** IDWG was calculated as the weight at the start of a HD session minus the post-dialysis weight at the end of the previous dialysis session. Percentage IDWG (% IDWG) was computed as (100 × IDWG / post-dialysis weight from prior session). Clinically important IDWG was defined as IDWG greater than 5.7%. This corresponds to a 4 kg weight gain in a 70 kg patient, and has been previously identified as a relevant cut-point for excess IDWG [2].
- **Hospitalization and mortality:** DMO C provided dates and causes of hospital admission as well as date of hospital discharge. Cardiovascular-related hospitalizations were identified by the presence of a cardiovascular-related diagnosis code. Hospitalization counts were computed as the sum of distinct hospital admissions. Date and cause of death were obtained from the Centers for Medicare & Medicaid Services (CMS) Death Notification Form (Form 2746). We computed time-to-death beginning at enrollment, and ending at time of disenrollment, transplant, or the end of the enrollment period.
- **DMO C health assessment**: DMO C administered a general health assessment at enrollment and at changes in patient clinical status thereafter. Higher scores indicate poorer health (observed scores ranged from a minimum of 0 to a maximum of 101).

2. Indications for HWM Use

DMO C's administration protocol for the HWM program changed over time. Throughout 2006, the HWM scales were made available to all patients, and the program was advertised in the DMO's marketing and welcome materials. However, in 2007, DMO C began more exclusively targeting the HWM program to patients with a history of weight fluctuation and/or certain pre-existing medical conditions, although any patient could request the HWM scale. For patients new to the HWM program, a commitment agreement was instituted to encourage patient utilization of the HWM scales. DMO C also held a special election period in 2007, which resulted in a high attrition rate from the managed care plan. These administrative changes may have resulted in differences in characteristics of the patient sample over time. Therefore, we performed separate analyses for 2006 enrollees and 2007/2008 enrollees, in addition to an overall analysis combining 2006-2008 patients.

3. Analytic Methods

Demographic and clinical characteristics of HWM users and HWM never-users were compared using t-tests and Chi-Square tests for continuous and categorical variables, respectively. Rates of HWM use among DMO C patients were presented graphically using plots of enrollment and HWM use versus calendar time and enrollment time.

For Aims 1 and 5, percentage IDWG according to HWM use/non-use was modeled using separate linear mixed models for HD sessions two days apart and three days apart, controlling for age at enrollment, sex, race (white, black, or other race), ethnicity (Hispanic or non-Hispanic), body mass index (BMI) at end-stage renal disease (ESRD) onset, time since ESRD onset at enrollment, diabetes as cause of ESRD, CMS-Hierarchical Condition Categories (HCC) risk score at enrollment, new Medicare enrollee status (enrolled less than one year) at time of DMO enrollment, mode of vascular access (VA) (arteriovenous [AV] fistula, AV graft, or catheter), and baseline lab values (dialysis dose, serum albumin, albumin-corrected calcium, phosphorus, and hemoglobin). For Aim 1, we also examined the association between HWM use and the odds of clinically important IDWG (> 5.7%) using a logistic regression model with repeated measures by patient, with the same covariates as above. For Aim 5 (sub-group analyses), additional interaction terms for demographic and clinical factors that may affect HWM efficacy were added.

Aim 2 used a logistic regression model predicting the odds of having more than three dialysis sessions in a calendar week according to HWM use/non-use for the entire week. For each patient, all calendar weeks in which the patient was enrolled for the entire week were included. All control variables listed above were included in the analysis.

For Aims 3 and 4, the number of hospitalizations and cardiovascular-related hospitalizations according to HWM use/non-use was modeled using Poisson regression, controlling for the same factors as above, scaled by months enrolled in the Demonstration. Poisson regression is a form of regression analysis used to model count data—in this case the number of hospitalizations. The time to death and time to cardiovascular-related death were modeled using Cox regression, with HWM use as a time-dependent variable and with all control variables listed above. Cox regression is used to model the effect of variables on the time to reach a certain event, such as the patient's death.

4. Comparison Groups

Data from the 2009 United States Renal Data System (USRDS) Annual Data Report [6-8] were used for comparison for Aim 3 and Aim 4. Patients served as their own controls for all Aims, as the effect of using HWM was examined relative to time before/never using HWM and time after using HWM.

C. Results

Table 10.1 shows characteristics of DMO C patients participating in the HWM program by year of enrollment (2006 vs. 2007/2008 enrollees). The percentage of patients participating in the HWM program varied over calendar time. Among patients enrolling in DMO C in 2006, 70% (453 of 647) ever used HWM; however, only 16% (114 of 693) of 2007/2008 enrollees ever used HWM. HWM users who enrolled in 2007/2008, compared with those enrolling in 2006, were younger (54.2 vs. 57.2 years, $p = 0.04$), and scored slightly lower on the DMO C health assessment (23.0 vs. 25.1, $p < 0.01$). Time spent in the HWM program also differed by enrollment year ($p < 0.01$). No other differences (based on $p < 0.05$) were observed in sample composition over calendar time.

Table 10.1: Patient Characteristics by Year of Patient Enrollment and HWM use

	2006 Enrollees Ever on HWM (N = 453)	2007/2008 Enrollees Ever on HWM (N = 114)	2006 Enrollees Never on HWM (N = 194)	2007/2008 Enrollees Never on HWM (N = 579)
	Value	Value (p-value vs. 2006 ever users)	Value (p-value vs. 2006 ever users)	Value (p-value vs. 2007 / 2008 ever users)
Patient Characteristics (mean)				
Age (years)	57.2	54.2 (0.04)	59.6 (0.05)	59.4 (< 0.01)
CMS-HCC risk score	1.05	1.08 (0.84)	1.07 (0.16)	1.04 (0.16)
DMO C Health Assessment Score	25.1	23.0 (< 0.01)	26.0 (0.54)	20.4 (0.10)
Females (%)	236 (52%)	54 (47%) (0.37)	108 (56%) (0.40)	250 (43%) (0.41)
Race (%)				
White	232 (51%)	52 (46%) (0.52)	85 (44%) (0.11)	245 (42%) (0.74)
Black	203 (45%)	56 (49%) (0.52)	104 (54%) (0.11)	307 (53%) (0.74)
Hispanics (%)	101 (22%)	26 (23%) (0.91)	43 (22%) (0.97)	146 (25%) (0.59)
Cause of ESRD (%)				
Diabetes	183 (40%)	54 (47%) (0.09)	85 (44%) (0.80)	280 (48%) (0.61)
Hypertension	132 (29%)	24 (21%) (0.09)	57 (29%) (0.80)	133 (23%) (0.61)
Months Enrolled in DMO C (mean)				
Before / never using HWM	1.3	3.6 (< 0.01)	11.1 (< 0.01)	10.2 (< 0.01)
While using HWM	11.7	7.5 (< 0.01)	n/a	n/a
After ending use of HWM	6.7	3.8 (< 0.01)	n/a	n/a

Abbreviations: CMS-HCC = Centers for Medicare & Medicaid Services Hierarchical Condition Categories; ESRD = End Stage Renal Disease; HWM = home weight monitoring; IDWG = interdialytic weight gain; n/a = not applicable

Figure 10.1 depicts use of HWM among DMO C patients by calendar time and Figure 10.2 depicts HWM use by months since patient enrollment. Over calendar time (Figure 10.1) the number of patients on HWM rose until August 2006 when participation peaked at 359 patients, then dropped to 142 patients at the end of 2007 (despite higher overall DMO C enrollment in 2007) and 92 patients at the end of the study period in December 2008. In contrast to the variation over calendar time, we observed that the HWM program participation according to duration of patient enrollment was fairly steady (Figure 10.2) when evaluated as the proportion of all DMO C patients at any enrollment time. For example, 35% and 32% of all DMO C patients were using HWM at 12 and 24 months, respectively. Figure 10.2 also illustrates the fact that across all enrollment durations, participation in the HWM program was much higher among 2006 enrollees than among patients who enrolled in 2007 or 2008.

Figure 10.1: Counts of DMO C Patients and HWM Users by Calendar Time
Legend: ♦ = All DMO C patients; ■ = DMO C patients currently on HWM.

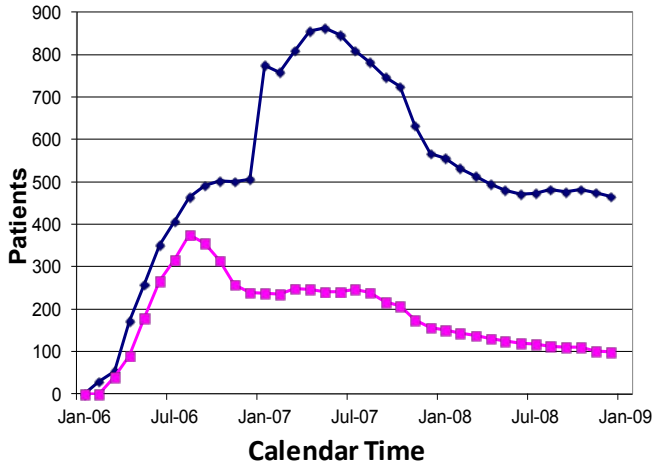
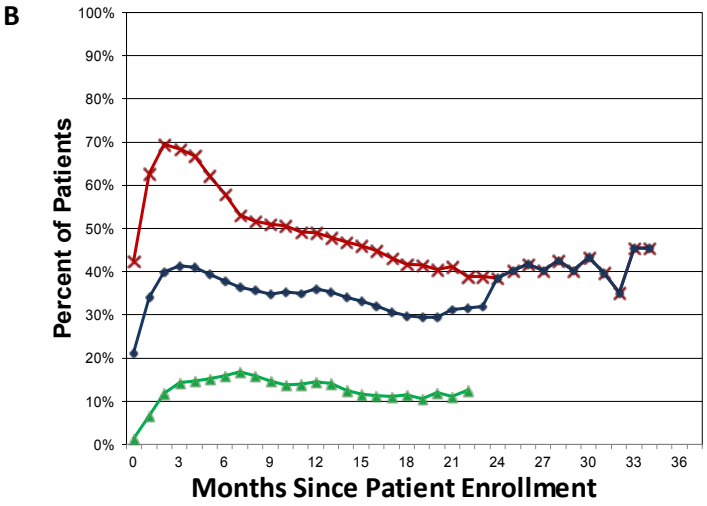


Figure 10.2: Percent of All DMO C Patients on HWM by Time Enrolled in DMO C
Legend: ♦ = All DMO C patients; × = 2006 enrollees; ▲ = 2007/2008 enrollees.



1. Aim 1 – To evaluate whether HWM is associated with lower IDWG

A total of 210,372 of 224,305 HD sessions obtained from the DMO C database were included in the analysis, with 1,328 of the 1,340 enrollees (99%) represented. For sessions two days apart, the mean IDWG was 2.75 kg, while the mean IDWG was 3.76 kg for sessions three days apart. Overall, the mean % IDWG was 1.72% per day, which agrees with values previously reported in the literature [5]. On average, 9% of all dialysis sessions two days apart had clinically important IDWG (> 5.7%), while 31% of all sessions three days apart had clinically important IDWG.

Table 10.2 presents estimated linear models predicting percentage IDWG according to HWM use/non-use and patient characteristics, by two or three days between dialysis sessions and year of patient enrollment. The models indicate that across all enrollees (N = 1340) and for sessions two days apart, HWM use was not significantly associated with less IDWG than sessions before/never using HWM, but this was of marginal statistical significance (reduction in % IDWG = 0.04; p = 0.06). For all enrollees' with sessions three days apart, a significant reduction in IDWG for HWM use was noted (reduction in % IDWG = 0.08%; p = 0.02). For all enrollees, dialysis sessions after ending HWM (not shown in table) were also

associated with less IDWG (reduction in % IDWG = 0.07, p < 0.01, for sessions two days apart, but not for sessions three days apart, reduction in % IDWG = 0.06, p = 0.14).

The effect of the HWM program on IDWG varied by year of patient enrollment (Table 10.2). HWM use in a model limited to 2006 enrollees (N = 647) was associated with a reduction in IDWG of 0.08% for sessions two days apart (p < 0.01) and a reduction of 0.14% for sessions three days apart (p < 0.01). On the other hand, among 2007/2008 enrollees alone (N = 693), HWM use was not associated with a change in IDWG (p = 0.98 for two days between sessions; p = 0.83 for three days between sessions).

Table 10.2: Adjusted Effects of HWM on IDWG, Hospitalization, and Mortality by Year of Patient Enrollment

Association of HWM[a] with	All Enrollees (N = 1340; 567 on HWM)		2006 Enrollees (N = 647; 453 on HWM)		2007/2008 Enrollees (N = 693; 114 on HWM)	
% IDWG	**Estimate[b]**	**p-value**	**Estimate[b]**	**p-value**	**Estimate[b]**	**p-value**
two days between sessions	-0.04	0.06	-0.08	< 0.01	0.00	0.98
three days between sessions	-0.08	0.02	-0.14	< 0.01	0.01	0.83
Clinically Important IDWG	Odds Ratio[c]	p-value	Odds Ratio[c]	p-value	Odds Ratio[c]	p-value
two days between sessions	0.83	0.07	0.72	0.03	0.92	0.64
three days between sessions	0.86	0.08	0.79	0.05	0.83	0.22
Risk of Hospitalization	Relative Risk[d]	p-value	Relative Risk[d]	p-value	Relative Risk[d]	p-value
All Causes	0.82	< 0.01	0.70	< 0.01	0.92	0.59
Cardiovascular	0.80	< 0.01	0.67	< 0.01	0.94	0.68
Risk of Mortality	Hazard Ratio[e]	p-value	Hazard Ratio[e]	p-value	Hazard Ratio[e]	p-value
All Causes	0.55	< 0.01	0.45	< 0.01	1.09	0.85
Cardiovascular	0.65	0.13	0.38	< 0.01	1.09	0.89

Abbreviations: CMS-HCC = Centers for Medicare & Medicaid Services-Hierarchical Condition Categories; HWM = Home weight monitoring. IDWG = Interdialytic weight gain.

[a] The effect of HWM use is estimated relative to time before using / never using HWM, and adjusted for all patient characteristics listed in Table 1. Estimates of the effect of HWM after ending use of HWM were estimated, but not displayed.

[b] Estimates indicate the linear mixed model coefficient for the effect of HWM use on % IDWG.

[c] Odds ratios represent the estimate of the effect of HWM use on the odds of having a clinically important IDWG.

[d] Risk ratios represent the estimate of the effect of HWM use on the risk of each additional hospitalization.

[e] Hazard ratios represent the estimate of the effect of HWM use on the risk of mortality.

We also found that overall, HWM use was not significantly associated with lower odds of clinically important IDWG for dialysis sessions two days apart (OR for IDWG > 5.7% = 0.83 vs. before HWM, 95% CI = 0.67 to 1.01, p = 0.07) and for sessions three days apart, OR = 0.86 (95% CI = 0.72 to 1.02, p = 0.08). After ending use of HWM, the odds of clinically important IDWG did not differ significantly from no HWM use (p = 0.64 for two-day model, p = 0.31 for three-day model). As before, these findings differed by enrollment cohort. Among 2006 enrollees, HWM use was associated with lower odds of clinically important IDWG for sessions both two days apart (OR = 0.72, p = 0.03) and three days apart (OR = 0.79, p = 0.05). There was no significant association between HWM use and clinically important IDWG for 2007/2008 enrollees (OR = 0.92, p = 0.64 for sessions two days apart; OR = 0.83, p = 0.22 for sessions three days apart).

2. Aim 2 – To evaluate whether HWM reduces the need for extra dialysis sessions

Out of 82,395 patient weeks in the study, 1,282 weeks had a fourth, or "extra," dialysis session (1.6%). A total of 367 of 1,340 (27%) DMO C patients had at least one extra dialysis session. Logistic regression was used to model the odds of having an extra dialysis session during all calendar weeks. Across all

patients, there was no significant association between HWM use and the odds of having additional dialysis sessions (OR = 1.00, 95% CI = 0.73 to 1.37, p = 0.99). Similarly, there was no association between HWM use and the odds of having additional dialysis sessions for 2006 enrollees alone (OR = 0.95, 95% CI = 0.66 to 1.35, p = 0.77) or for 2007/2008 enrollees alone (OR = 1.23, 95% CI = 0.60 to 2.51, p = 0.58).

3. Aim 3 – To evaluate whether HWM is associated with fewer hospitalizations and longer survival

Out of 1,340 DMO C patients, 801 were hospitalized a total of 2,893 times during the study (rate = 1.86 per patient year, compared to 1.89 per patient year in the U.S. HD population in 2007) [6]. There were 199 deaths among DMO C enrollees during 18,696 patient months (rate = 128 per patient 1,000 patient years, compared to 195 per 1,000 patient years in the U.S. HD population in 2007) [7].

Table 10.2 presents the adjusted relative risks associated with all-cause hospitalization from Poisson regression models predicting the number of hospital admissions per time at risk. Across all enrollees, HWM use was associated with an 18% lower rate of hospitalization (RR = 0.82, 95% CI = 0.72 to 0.93, p < 0.01). After ending use of HWM, there was no significant difference in the rate of hospitalization relative to time before/never HWM use (RR = 1.04, 95% CI = 0.91 to 1.20, p = 0.57).

The hazard ratios associated with all-cause mortality from adjusted Cox regression models predicting time to death are also shown in Table 10.2. HWM use was associated with 45% lower mortality rates among all enrollees (HR = 0.55, 95% CI = 0.37 to 0.82, p < 0.01). After ending use of HWM, mortality rates were similar to those for before/never HWM use (HR = 0.98, 95% CI = 0.65 to 1.46, p = 0.91).

The effect of the HWM program on hospitalization and mortality also varied by enrollment cohort. Among 2006 enrollees, HWM was associated with greater reductions in hospitalization and mortality compared to the model with all enrollees. On the other hand, among 2007/2008 enrollees alone, HWM use was not significantly associated with reductions in either hospitalization or mortality.

4. Aim 4 – To evaluate whether HWM is associated with fewer cardiovascular-related hospitalizations and reduced cardiovascular-related mortality

Out of 1,340 DMO C patients, 785 were hospitalized for cardiovascular-related events a total of 2,791 times during the study for a rate of 1.80 per patient year. For comparison, there were 0.54 cardiovascular-related hospitalizations per patient year among U.S. HD patients in 2007 [6]. It should be noted, however, that the USRDS identifies cardiovascular-related events using the principle diagnosis code, whereas we utilized all diagnosis codes. This is likely to cause higher numbers of cardiovascular-related events to be observed in the DMO C population. There were 102 cardiovascular-related deaths among DMO C enrollees during the Demonstration for a rate of 65 per 1,000 patient years. For comparison, from 2005 to 2007 the unadjusted cardiovascular-related mortality rate for U.S. HD patients was 100 per 1,000 patient years [8].

Table 10.2 presents the adjusted relative risks associated with cardiovascular-related hospitalizations from Poisson regression models. Use of HWM was associated with a 20% lower rate of cardiovascular-related hospitalizations (HR = 0.80, 95% CI = 0.70 to 0.91, p < 0.01). There was no significant reduction for cardiovascular-related mortality (HR = 0.65, 95% CI = 0.38 to 1.13, p = 0.13).

As in the other analyses, the effect of the HWM program on cardiovascular-related hospitalization and mortality varied by enrollment cohort. Among 2006 enrollees, HWM was associated with reductions in cardiovascular-related hospitalization and mortality while on the other hand, among 2007/2008 enrollees alone, HWM use was not significantly associated with cardiovascular-related hospitalization or mortality.

5. Aim 5 – To identify demographic and clinical subgroups in which HWM is most effective

Linear models predicting % IDWG associated with HWM use and patient characteristics were fitted separately for dialysis sessions two days apart and three days apart as in Aim 1. Additional interaction terms were added for demographic and clinical covariates that may be related to HWM efficacy. For dialysis sessions both two days apart and three days apart, there were significant interactions for black race ($p < 0.01$) and Hispanic ethnicity ($p < 0.01$) when evaluating the entire cohort. Specifically, HWM use was associated with greater decreases in % IDWG in blacks than in non-blacks, and in Hispanics than in non-Hispanics. There were no significant differences in the associations of HWM with % IDWG by sex or diabetes as cause of ESRD. The above findings were consistent when analyses were limited to 2006 enrollees alone and to 2007/2008 enrollees alone, with the exception that Hispanic ethnicity was no longer associated with greater decreases in %IDWG for 2007/2008 enrollees ($p = 0.53$ for sessions two days apart; $p = 0.92$ for sessions three days apart).

The interaction between age and HWM varied by cohort. Among 2006 enrollees, increasing age was associated with reduced HWM benefits on % IDWG for sessions two days apart; ($p = 0.04$; $p = 0.94$ for sessions three days apart). Conversely, among 2007/2008 enrollees, increasing age was associated with greater reductions in % IDWG ($p = 0.01$ for both two and three days between sessions). In the combined model, however, we noted no differences in the effect of HWM by age ($p = 0.31$ for sessions two days apart; $p = 0.38$ for sessions three days apart).

D. Discussion

1. Patient Characteristics and HWM use

There was a notable decrease in HWM users in 2007 which occurred despite an increase in DMO C participants early in the year. This change was likely due to a series of administrative changes in the promotion of HWM that occurred over this time period. This complicates interpretation of study findings because HWM users and/or HWM implementation may have changed systematically over the course of the Demonstration period.

It should be noted that DMO C's changes in HWM program administration occurred in response to challenges experienced throughout the program's implementation. Initially, DMO C intended to give every patient the HWM device. However, issues of patient non-adherence/non-acceptance and technical challenges such as patient difficulties using and hooking up the scale made this impractical. In some cases, patients stopped using the scale and returned it to the DMO. In response, DMO C modified its protocol to provide HWM devices on clinical indication or upon patient request as described above.

Toward the end of 2008, DMO C transitioned to an improved home weight monitoring device, which was intended to enhance care coordination by facilitating interactions between the DMO and the patient, in addition to serving its primary purpose of tracking patient weights. The new device also allowed for the use of a blood pressure cuff and glucometer in addition to the HWM scale. However, few patients were able to utilize it due to the lack of a land line telephone. As of October 2009, DMO C planned to utilize wireless devices for their patients, but data on this program were not available at the time of this report.

2. Aim 1 Findings

HWM use was associated with lower % IDWG for both two-day and three-day interdialytic periods for 2006 enrollees; a similar association was not found for patients who enrolled later in the evaluation period (2007-2008). The differences in impact of HWM on IDWG may be partially explained by changes in DMO C's protocol for providing home weight monitoring scales. At the initiation of the program, all

patients were eligible for HWM, however by 2007 this was modified to providing HWM based on clinical indication. As such, analyses performed for the 2007-2008 cohorts may be subject to treatment by indication bias in that patients receiving HWM may be sicker as compared to those not on HWM. The temporal association of HWM use with lower % IDWG (i.e., within-patient decrease in IDWG during HWM use, vs. before or after HWM use, among patients using HWM at some time in the Demonstration) provides additional evidence that HWM may have an effect on lowering IDWG, and that this effect is short-term, i.e. there is no measurable carry-over effect.

3. Aim 2 Findings

No association was found between HWM use and additional dialysis sessions. This analysis was limited because only 1.6% of patient weeks included an extra recorded session, defined as four or more sessions per week. Often, extra sessions are provided in the hospital because they are required urgently, and these sessions were likely not captured in this dataset.

4. Aim 3 Findings

Overall, patients using HWM had lower risks of mortality and hospitalizations than patients before/never using HWM. This finding was primarily driven by the experience of the 2006 enrollee cohort. Given the known risks associated with excess IDWG and the finding that HWM use was associated with lower clinically relevant IDWG (Aim 1), HWM use may plausibly have had a direct impact on improving clinical outcomes for some patients.

Subgroup analysis by year of enrollment demonstrated that for 2006 enrollees, HWM was associated with lower risks of hospitalization and mortality for 2006 enrollees, but not for 2007/2008 enrollees (Table 10.2). Notably, HWM users in 2007/2008 did not appear to have greater co-existing illness burden than HWM users in 2006, based on distributions of the CMS-HCC risk scores (Table 10.1), and in fact, the DMO C health assessment scores suggest that 2007/2008 enrollees may instead be healthier. Thus, the reasons for the differences in clinical outcomes by HWM use from 2006 to 2007/2008 are not immediately apparent. This limits the ability to draw conclusions about the impact of DMO C's HWM program on mortality and hospitalization.

5. Aim 4 Findings

It is believed that excess IDWG causes adverse clinical outcomes principally because it leads to cardiovascular events such as myocardial ischemia and/or heart failure exacerbations. Similar to the findings for one-year all-cause hospitalization and mortality, these findings indicate that HWM was associated with lower rates of cardiovascular-related hospitalizations but not cardiovascular-related death for the 2006 enrollee cohort only. There was no significant association of DMO C's HWM program with lower rates of cardiovascular-related hospitalizations or mortality for the 2007-2008 enrollee cohort.

6. Aim 5 Findings

Across all patients, HWM use was associated with greater reductions in % IDWG in blacks than in non-blacks and in Hispanics than in non-Hispanics. By cohort, similar interactions were found, however, the effect of HWM did not vary by Hispanic ethnicity among 2007/2008 enrollees. The reason(s) for the observed racial/ethnic disparities is/are uncertain. There were no significant differences in the associations of HWM with % IDWG by sex or diabetes as cause of ESRD; however, increasing age was associated with greater reductions in % IDWG among 2007/2008 enrollees alone and reduced benefit among 2006 enrollees alone. There was no age interaction noted in the model fitted to all enrollees. The reason(s) for the observed differences is/are uncertain.

7. *Limitations*

Because this analysis is observational, differences between patient groups (HWM users vs. never users) may be at least in part due to differences in (i.e., confounded by) patient characteristics, rather than a direct effect of HWM. Additionally, temporal (secular) trends unrelated to HWM may account in part for the observed differences. The observation period prior to beginning HWM was short for many patients. Programmatic changes instituted during the evaluation period, as well as the large reduction in participation in the program during 2007-2008 compared to 2006, technical challenges, and patient non-adherence/acceptance issues may have contributed to the disparate findings noted between the 2006 and 2007-2008 enrollee cohorts. Therefore, the ability to draw conclusions on the overall association of DMO C's HWM program with the clinical outcomes of interest is limited and the findings should be interpreted with caution. Lastly, certain components of processes associated with, or services offered along with the HWM program may have been more effective than others for limiting IDWG. However, this study was not designed to evaluate different aspects of the DMO C HWM program.

8. *Summary*

In summary, the DMO C HWM Program was introduced as part of a multidisciplinary team approach to limit IDWG among HD patients. These analyses demonstrate that HWM may be associated with lower IDWG potentially resulting in fewer episodes of clinically relevant excessive IDWG. HWM may also be associated with lower rates of mortality and hospitalizations as shown by our analyses among patients who were enrolled in 2006, however, there was no significant association of DMO C's HWM program with reduced all-cause and cardiovascular mortality or hospitalization for the 2007-2008 enrollee cohort. Though the finding that HWM may effectively limit IDWG is encouraging, the notable differences in outcomes according to year of patient enrollment suggest that our findings should be interpreted with caution as differences in patient selection, HWM implementation, technical challenges, and patient non-adherence/acceptance may partially explain the disparate findings by enrollment cohort. Additional study of HWM as a potential means to improve clinical outcomes in this high risk population is indicated.

E. References

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8) U.S. Renal Data System, USRDS 2009 Annual Data Report: Atlas of Chronic Kidney Disease and End-Stage Renal Disease in the United States. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2009, Supplemental Data, Table H.a.3

CHAPTER 11: IMPACT ON PATIENT OUTCOMES

A. Introduction

Previous studies of Disease Management programs in populations other than end-stage renal disease (ESRD) suggest their potential for improving processes of care [1]. ESRD is conceptually an ideal target for Disease Management because of the co-existence of complex comorbidities, fragmentation of patient management, the associated high morbidity and mortality, and the high cost of care [2]. Though national trends in mortality rates are encouraging, hospitalization rates have shown little change since 1980 [3]. Furthermore, because kidney transplantation is the treatment of choice for patients with ESRD, identifying whether Disease Management is able to address obstacles in the pathway from dialysis to eventual transplantation is important. This chapter will describe findings for one- and two-year survival, all-cause and cardiovascular hospitalizations, and kidney transplantation outcomes. An evaluation of the program's impact on service utilization rates, including hospital admission rates, readmission rates, length of stay (LOS), total hospital days, skilled nursing facility (SNF) stays, emergency department (ED) visits and outpatient visits is also presented.

B. Methods

1. Populations and Data Sources

Patients who enrolled in the Demonstration at any time from January 1, 2006 through December 31, 2008 and were receiving dialysis at the time of enrollment were included in these analyses. Patients with functioning transplants at enrollment were excluded and analyses were restricted to each patient's first enrollment period. Adult dialysis patients in traditional fee-for-service (FFS) Medicare during the same period served as the comparison group. For Demonstration patients, follow-up time started at DMO enrollment and for FFS patients, this started on January 1, 2006 or the date of the first dialysis claim for patients new to ESRD and/or FFS Medicare. Patient time at risk ended at the first of Demonstration disenrollment, death, three days prior to transplant (so as not to include the hospitalization for transplantation), or December 31, 2008.

Medicare records provided most data including state of residence, date of Demonstration enrollment, date of ESRD onset, date of death, and patient characteristics (including age, sex, race, Hispanic ethnicity, cause of ESRD, and renal replacement modality). The Centers for Medicare & Medicaid Services (CMS) Hierarchical Condition Categories (HCC) risk score was used to measure relative level of comorbidity. We used the CMS-HCC risk score calculated by the ESRD model using conditions from the year prior to enrollment. A few patients were new to Medicare the first year of their enrollment in the Demonstration. In these instances a risk score based only on demographic information from the current year was used [4]. The CMS-HCC risk score is a measure of health status and is based on demographic factors and the number of chronic conditions an individual is receiving treatment for, as indicated by diagnosis codes on FFS claims or reporting by private health plans for patients in Medicare Advantage (MA) Plans [5]. A higher score indicates a patient with more chronic conditions who is predicted to use more health care resources. If a patient is new to Medicare (less than one year enrollment), diagnosis codes are not available so only demographic variables are used to calculate the CMS-HCC risk score.

Hospitalizations and utilization counts were identified from FFS claims or DMO encounter data. Transplant referral data (and reasons for non-referral) were collected by the DMOs; these data are not collected for FFS patients. Data from the federally-funded national registry of wait-listing and

transplantation, collected by the Organ Procurement and Transplantation Network and analyzed by the Scientific Registry of Transplant Recipients, were used to examine wait-listing rates and combined with Medicare data to examine transplantation rates for each program. Patients aged 70 years or older were excluded from the transplantation, wait-listing, and transplant referral analyses.

2. Analytic Time-to-Event Methods for Survival, Hospitalization, and Transplantation

Annual rates of mortality and hospitalization were calculated for each DMO. However, patients who enrolled in the Demonstration DMOs differed on demographic and clinical variables that are known to be related to both survival and hospitalization. To illustrate, if one of the groups had a higher percentage of patients with diabetes, then unadjusted differences in mortality rates may simply be due to the higher prevalence of diabetes in one group. Therefore, it is less informative to simply compare unadjusted mortality or hospitalization rates of the DMOs to a comparison group such as the FFS group. Using statistical methods, it is possible to compare different groups of patients while accounting for characteristics that can influence these outcomes ("confounders"). Specifically, we calculated adjusted survival, hospitalization, and transplantation percentages using stratified Cox proportional hazards models, which is one of the most established methodologies in healthcare outcomes research [6-10]. The multivariate models were adjusted for patient age, sex, race, Hispanic ethnicity, diabetes as cause of ESRD, duration of ESRD, modality, previous failed transplant, state of residence, and CMS-HCC risk score. Only FFS patients in the same geographic areas where the DMOs operated were included in the time-to-event analyses.

3. Analytic Methods for Utilization

We compared utilization of selected services among in-center hemodialysis (HD) patients in each DMO to propensity score matched FFS control groups who were observed to have a similar propensity for enrolling in a DMO. The propensity score model allowed for the creation of a matched sample in which each DMO patient was matched to a FFS patient. Factors evaluated for comparison between the DMO populations and the propensity-score matched FFS samples included age, sex, race, Hispanic ethnicity, geography, Medicaid status, new enrollee status, duration of ESRD, CMS-HCC risk score, cause of ESRD, among others. Please see the Technical Appendix for a comparison of the FFS matched samples and the DMO patient populations as well as for additional details on the propensity score matching methodology. Although months in which a patient transitions between HD and other modalities may still be under the clinical responsibility of the DMO, partial HD months were excluded to ensure that differences in utilization measures were not due to the transition to another renal replacement modality. Thus, follow-up time for all utilization analyses was restricted to months in which patients received HD for the entire month. Months when DMO patients had Medicare as a secondary payer, which were 2.65% of patient-months in the Demonstration, were also excluded from the analysis since comparison FFS data on service utilization (e.g. hospitalization) will likely not capture the entirety of the experience of these patients.

Utilization services that we evaluated included hospital admissions, total hospital days, hospital readmissions within 30 days, LOS, physician visits, ED visits, and SNF stays. ED visits that resulted in an inpatient stay were excluded from the ED visit metric to avoid double counting with the hospitalization metrics. We used nine multiple logistic regression models to select the matched control patients from the FFS population for each DMO and year on baseline demographic and clinical characteristics that impact on a patient's probability of enrolling into a DMO (propensity score method). To account for residual differences remaining after the propensity-score methodology, a second-stage multivariate regression adjustment was performed using a negative binomial regression model. We also examined Poisson regression models (with correction for over-dispersion) and found similar results. As described in further detail in the Technical Appendix, both methods are commonly used for count data such as

service utilization. The negative binomial regression results are shown in this Report because these models generally fit the data better.

C. Results

There were 2,364 dialysis patients in the Demonstration after excluding 14 patients with functioning transplants at enrollment. This included 722 dialysis patients in DMO A, 268 dialysis patients in DMO B, and 1,374 dialysis patients in DMO C. When compared to the 477,246 patients in traditional FFS Medicare, Demonstration patients were younger, had ESRD longer, reported Hispanic or Latino ethnicity more often, were more often receiving HD, and had similar levels of comorbidity according to the CMS-HCC risk score (See Tables 1.1a and 1.1b in Chapter 1). The Demonstration also had more black patients, more patients with diabetes mellitus (diabetes) as cause of ESRD, and more patients with a previous failed transplant when compared to FFS, but these results differed by DMO. DMO A had more males, more white patients, more patients with ESRD caused by diabetes, and more patients with previous failed transplants. DMO B had more black patients. DMO C had more females, more black patients, and more patients with previous failed transplants. These differences in patient characteristics highlight the importance of statistical adjustment for the analyses presented in this chapter.

1. Mortality and Survival

Table 11.1 and Figure 11.1 show survival at one year and at two years. Adjusted analyses demonstrated that a larger percentage of patients in DMO B and DMO C survived to these time points. Although unadjusted analyses demonstrated significantly improved survival among patients in DMO A, this was no longer apparent after statistical adjustment.

Table 11.1: Patients Surviving to One Year and Two Years, by DMO or FFS

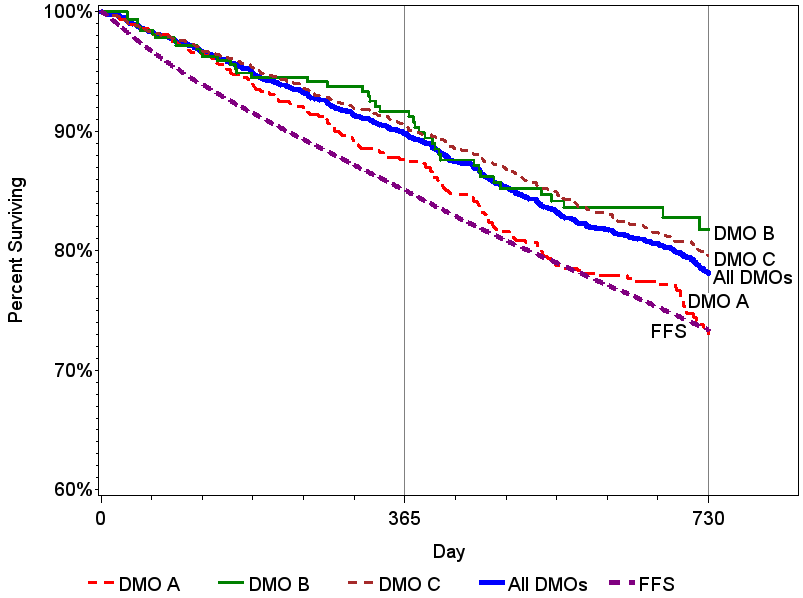
	DMO A	FFS A	DMO B	FFS B	DMO C	FFS C	All DMOs	All FFS
Unadjusted One Year Survival (%)	**87.2***	79.7	**90.8***	79.8	**88.3***	78.7	**88.2***	77.7
Adjusted[a] One Year Survival (%)	88.0	85.8	**91.2***	84.2	**90.7***	85.4	**89.8***	85.0
Unadjusted Two Year Survival (%)	**72.4***	65.7	**80.9***	66.3	**76.0***	64.1	**75.5***	62.7
Adjusted[a] Two Year Survival (%)	73.5	74.6	**80.7***	72.3	**80.1***	73.9	**78.1***	73.3

Abbreviation: FFS = Fee-for-Service

* Numbers shown in **bold** are significantly different from FFS ($p < 0.05$).

[a] Adjusted for patient age, sex, race, Hispanic ethnicity, geography, diabetes as cause of ESRD, duration of ESRD, modality, previous failed transplant, and CMS-HCC risk score.

Figure 11.1: Patients Surviving, Adjusted[a], by DMO or FFS



Abbreviation: FFS = Fee-for-Service

[a] Adjusted for patient age, sex, race, Hispanic ethnicity, geography, diabetes as cause of ESRD, duration of ESRD, modality, previous failed transplant, and CMS-HCC risk score.

2. First Hospitalization: All-Cause and Cardiovascular

Table 11.2 and Figure 11.2 show first hospitalization percentages at one year and at two years. These analyses revealed that a smaller percentage of patients in DMO C were hospitalized for the first time by one year and two years. The gap between the hospitalization percentage between patients in DMO C and FFS increased over the course of the evaluation such that about 15 percent fewer patients in DMO C were hospitalized for the first time by two years as compared to FFS. In contrast, adjusted analyses did not reveal significant differences between hospitalization percentages in DMO A or DMO B as compared to FFS.

Table 11.2: Patients Hospitalized by One and Two Years, All-Cause, by DMO or FFS

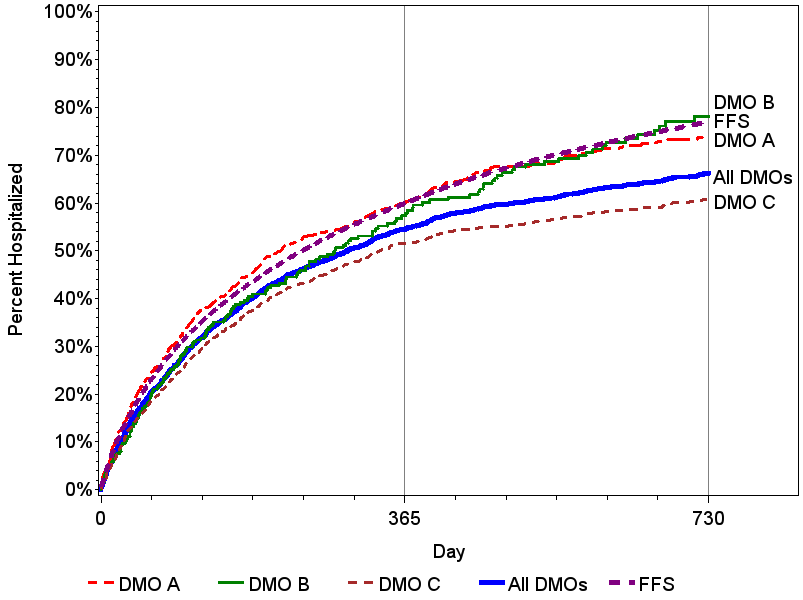
	DMO A	FFS A	DMO B	FFS B	DMO C	FFS C	All DMOs	All FFS
Unadjusted One Year All-Cause Hospitalization (%)	55.0	58.2	**56.1***	63.0	**54.8***	63.9	**55.0***	65.3
Adjusted[a] One Year All-Cause Hospitalization (%)	56.4	55.9	58.2	60.9	**51.1***	59.1	**54.5***	59.9
Unadjusted Two Year All-Cause Hospitalization (%)	**68.8***	73.6	76.1	78.2	**64.2***	79.3	**66.6***	80.7
Adjusted[a] Two Year All-Cause Hospitalization (%)	70.6	72.4	78.9	77.1	**60.5***	76.1	**66.2***	77.0

Abbreviation: FFS = Fee-for-Service

* Numbers shown in **bold** are significantly different from FFS ($p < 0.05$).

[a] Adjusted for patient age, sex, race, Hispanic ethnicity, geography, diabetes as cause of ESRD, duration of ESRD, modality, previous failed transplant, and CMS-HCC risk score.

Figure 11.2: Patients Hospitalized, All-Cause, Adjusted[a], by DMO or FFS



Abbreviation: FFS = Fee-for-Service
[a] Adjusted for patient age, sex, race, Hispanic ethnicity, geography, diabetes as cause of ESRD, duration of ESRD, modality, previous failed transplant, and CMS-HCC risk score.

Table 11.3 shows first cardiovascular hospitalization percentages at one year and at two years. Consistent with the analysis evaluating all-cause hospitalization, a significantly smaller percentage of patients in DMO C were hospitalized for cardiovascular disease (CVD) by each time point. Unadjusted analyses revealed significantly lower two year cardiovascular hospitalization percentages for DMO A, however, these differences were no longer significant after statistical adjustment. With regards to DMO B, evaluation of cardiovascular hospitalization was inconsistent with the findings of all-cause hospitalization in that significantly fewer patients in DMO B were hospitalized for cardiovascular causes. Given that cardiovascular hospitalization is one of the leading causes of hospitalization in ESRD patients, the seemingly large reduction in DMO B may be in part due to data limitation issues in that DMO B reported fewer total diagnosis codes on hospitalization encounter data. Hence, secondary diagnoses of CVD may be captured at a lower rate than in the other DMOs and FFS.

Table 11.3: Patients Hospitalized for Cardiovascular Disease at One Year and Two Years, by DMO or FFS

	DMO A	FFS A	DMO B[a]	FFS B	DMO C	FFS C	All DMOs	All FFS
Unadjusted One Year Cardiovascular Hospitalization (%)	54.1	57.3	**40.2***	62.3	**53.8***	63.1	**52.4***	64.4
Adjusted[b] One Year Cardiovascular Hospitalization (%)	55.5	55.0	**41.6***	60.3	**50.0***	58.2	**51.8***	59.0
Unadjusted Two Year Cardiovascular Hospitalization (%)	**68.1***	72.8	**53.0***	77.6	**63.5***	78.6	**63.6***	80.0
Adjusted[b] Two Year Cardiovascular Hospitalization (%)	69.9	71.5	**55.2***	76.5	**59.7***	75.2	**63.1***	76.2

Abbreviation: FFS = Fee-for-Service
* Numbers shown in **bold** are significantly different from FFS ($p < 0.05$).
[a] Data for DMO B were limited and reduced CV hospitalization may be in part due to these data limitations.
[b] Adjusted for patient age, sex, race, Hispanic ethnicity, geography, diabetes as cause of ESRD, duration of ESRD, modality, previous failed transplant, and CMS-HCC risk score.

3. Utilization of Services

Tables 11.4 and 11.5 show utilization of select services (hospitalizations, physician visits, ED visits, and SNF stays) in the Demonstration and in propensity-score matched samples of FFS patients, respectively. Analyses on the matched sample were limited to in-center HD patients with Medicare as primary payer that could be matched to patients in FFS who had a similar propensity for enrolling in a DMO. Hence, this analysis included 242, 408, and 415 patients in 2006, 2007, and 2008 respectively in DMO A; 78,

170, and 191 patients in 2006, 2007, and 2008 respectively in DMO B; and 529, 959, and 612 patients in 2006, 2007, and 2008 respectively in DMO C. The same numbers of FFS patients were included in the control groups for each DMO and year.

Table 11.4: Utilization of Select Services in the Demonstration, by DMO

	DMO A				DMO B				DMO C				All DMOs			
	2006	2007	2008	All	2006	2007	2008	All	2006	2007	2008	All	2006	2007	2008	All
Hospital Admissions[a]	1.57	1.78	1.80	1.74	2.03	1.46	2.12	1.85	1.92	1.82	1.77	1.82	1.81	1.77	1.84	1.80
Total Hospital Days	10.80	13.17	13.42	12.80	16.12	10.77	17.76	14.76	12.87	13.02	13.83	13.26	12.51	12.79	14.34	13.32
Readmissions[b]	0.45	0.70	0.69	0.64	0.87	0.42	0.94	0.72	0.66	0.65	0.61	0.64	0.61	0.64	0.69	0.65
LOS	6.90	7.41	7.47	7.34	7.93	7.37	8.37	7.99	6.72	7.15	7.80	7.27	6.90	7.24	7.80	7.39
Physician Visits	5.20	6.70	8.82	7.27	5.95	6.56	8.72	7.48	8.17	8.75	8.11	8.43	6.97	7.95	8.44	7.96
ED Visits	0.73	1.12	1.14	1.05	2.19	1.56	1.39	1.57	1.42	1.37	1.68	1.48	1.27	1.33	1.46	1.36
SNF Stays	0.33	0.30	0.36	0.33	0.19	0.16	0.42	0.29	0.18	0.29	0.32	0.28	0.23	0.28	0.35	0.30

Abbreviations: ED = Emergency department; LOS = Length of stay; SNF = Skilled nursing facility
Note: Numbers are average per patient per year. No formal significance testing was performed. ALL = 2006-2008
[a] Includes readmissions within 30 days of discharge.
[b] Readmissions within 30 days of discharge.

Table 11.5: Utilization of Select Services Among Matched FFS Controls, by DMO

	FFS Controls for DMO A				FFS Controls for DMO B				FFS Controls for DMO C				FFS Controls for All DMOs			
	2006	2007	2008	All	2006	2007	2008	All	2006	2007	2008	All	2006	2007	2008	All
Hospital Admissions[a]	1.45	1.61	1.77	1.64	1.73	1.52	1.82	1.68	2.05	1.87	2.02	1.96	1.85	1.76	1.90	1.83
Total Hospital Days	9.36	9.96	10.81	10.15	9.27	9.19	10.17	9.62	11.86	10.77	12.33	11.50	10.93	10.38	11.46	10.87
Readmissions[b]	0.43	0.59	0.61	0.57	0.45	0.43	0.62	0.52	0.73	0.67	0.75	0.71	0.62	0.62	0.68	0.64
LOS	6.46	6.19	6.10	6.21	5.35	6.04	5.60	5.71	5.79	5.77	6.11	5.87	5.89	5.90	6.03	5.94
Physician Visits	10.13	10.64	10.42	10.44	7.29	8.40	9.64	8.72	9.79	10.64	11.16	10.57	9.65	10.38	10.67	10.30
ED Visits	0.96	1.21	1.43	1.24	2.01	1.74	1.83	1.83	1.48	1.30	1.73	1.47	1.38	1.32	1.64	1.44
SNF Stays	0.55	0.48	0.46	0.49	0.17	0.33	0.39	0.33	0.43	0.67	0.63	0.60	0.44	0.58	0.54	0.53

Abbreviations: ED = Emergency department; FFS = Fee-for-Service; LOS = Length of stay; SNF = Skilled nursing facility
Note: Numbers are average per patient per year. No formal significance testing was performed. ALL = 2006-2008
[a] Includes readmissions within 30 days of discharge
[b] Readmissions within 30 days of discharge.

Table 11.6a shows the difference between the Demonstration and control groups, with a negative difference representing less utilization in the Demonstration and a positive difference representing more utilization in the Demonstration. Table 11.6b presents the results of applying a second-stage regression adjustment using negative binomial regression. In a separate analysis of the excluded patients who have Medicare as a secondary payer, we generally found comparable utilization of services including hospital admission rates. However, we excluded these patients as their utilization data may not be complete.

The propensity score adjustment results (Table 11.6a) and the second-stage multiple regression results (Table 11.6b) were similar for most findings. Focusing on these results, although patterns of hospital admissions differed by DMO, overall, hospital admissions were not significantly different for the DMOs compared with FFS in both analyses. Hospital readmission rates were higher for the DMOs than the FFS comparison groups in some cases and in the pooled analysis of all DMOs and all years after second-stage multivariate regression modeling adjustment. Across all three DMOs and all years, LOS and total hospital days were significantly higher compared to FFS. However, it is likely that the DMOs negotiated flat hospitalization rates with their providers and metrics taking into account hospital days may be less valuable in this evaluation. Utilization was generally significantly lower than the matched FFS control groups throughout the Demonstration for SNF stays and physician visits in both analyses. ED visits were not significantly different for the DMOs compared with FFS after second-stage multivariate regression modeling adjustment. The second stage multivariate regression modeling adjustment is additionally

limited by the ability of statistical models to fit the data; as discussed in the Technical Appendix, model fit was generally adequate however goodness-of-fit was lowest for physician visits and SNF stays.

Table 11.6a: Utilization Differences between DMOs and Matched FFS as a Percent of Matched FFS, by DMO, using Propensity-Score Matched Comparison as Adjustment

	DMO A				DMO B				DMO C				All DMOs			
	2006	2007	2008	All	2006	2007	2008	All	2006	2007	2008	All	2006	2007	2008	All
Hospital Admissions[a]	+8%	+10%	+1%	+6%	+17%	-4%	+17%	+10%	-6%	-2%	**-12%**	**-7%**	-2%	+0%	-3%	-1%
Total Hospital Days	**+15%**	**+32%**	**+24%**	**+26%**	**+74%**	**+17%**	**+75%**	**+54%**	**+8%**	**+21%**	**+12%**	**+15%**	**+15%**	**+23%**	**+25%**	**+23%**
Readmissions[b]	+3%	+18%	+12%	+14%	**+91%**	-4%	**+51%**	**+40%**	-9%	-3%	-19%	-10%	-2%	+2%	+1%	+1%
LOS	+7%	**+20%**	**+23%**	**+18%**	**+48%**	**+22%**	**+49%**	**+40%**	**+16%**	**+24%**	**+28%**	**+24%**	**+17%**	**+23%**	**+29%**	**+24%**
Physician Visits	**-49%**	**-37%**	**-15%**	**-30%**	**-18%**	**-22%**	-10%	**-14%**	**-17%**	**-18%**	**-27%**	**-20%**	**-28%**	**-23%**	**-21%**	**-23%**
ED Visits	-24%	-7%	**-20%**	**-15%**	+9%	-11%	**-24%**	**-14%**	-4%	+5%	-3%	+1%	-8%	+0%	**-11%**	-6%
SNF Stays	**-41%**	**-36%**	-22%	**-32%**	+12%	-51%	+7%	-13%	**-57%**	**-57%**	**-49%**	**-53%**	**-47%**	**-52%**	**-34%**	**-44%**

Abbreviations: ED = Emergency department; FFS = Fee-for-Service; LOS = Length of stay; SNF = Skilled nursing facility
Positive number mean higher utilization in the Demonstration; negative numbers mean lower utilization in the Demonstration (relative to the matched FFS control group). **Bold** indicates significant difference from FFS ($p < 0.05$). ALL = 2006-2008
[a] Includes readmissions within 30 days of discharge
[b] Defined as readmissions within 30 days of discharge.

Table 11.6b: Adjusted Utilization Differences between DMOs and Matched FFS as a Percent of Matched FFS, by DMO, with Second-Stage Regression Adjustment

	DMO A				DMO B				DMO C				All DMOs			
	2006	2007	2008	All	2006	2007	2008	All	2006	2007	2008	All	2006	2007	2008	All
Hospital Admissions[a]	+5%	+6%	+17%	+9%	+7%	+0%	+24%	+12%	-2%	+2%	-8%	-3%	+1%	+4%	+4%	+3%
Total Hospital Days	-13%	+20%	+29%	+16%	+42%	+29%	**+60%**	**+47%**	+14%	+16%	+12%	**+15%**	+12%	**+20%**	**+27%**	**+20%**
Readmissions[b]	+23%	+15%	+37%	+21%	**+119%**	+16%	+65%	**+57%**	**+37%**	+6%	-11%	+6%	**+41%**	+11%	+13%	**+16%**
LOS	+3%	+7%	+4%	**+6%**	+11%	**+15%**	**+13%**	**+14%**	**+11%**	**+9%**	**+12%**	**+11%**	**+8%**	**+10%**	**+11%**	**+10%**
Physician Visits	**-51%**	**-31%**	-11%	**-29%**	-14%	**-20%**	-10%	**-15%**	**-15%**	**-16%**	**-19%**	**-18%**	**-26%**	**-20%**	**-16%**	**-20%**
ED Visits	-20%	+2%	-10%	-8%	+3%	-17%	-14%	-12%	+2%	+2%	-4%	-1%	-3%	-1%	-7%	-4%
SNF Stays	-36%	**-48%**	-3%	**-34%**	-43%	**-70%**	+20%	-28%	**-49%**	**-59%**	**-43%**	**-53%**	**-42%**	**-55%**	-24%	**-45%**

Abbreviations: ED = Emergency department; FFS = Fee-for-Service; LOS = Length of stay; SNF = Skilled nursing facility
Positive numbers mean higher utilization in the Demonstration; negative numbers mean lower utilization in the Demonstration (relative to the matched FFS control group). **Bold** indicates significant difference from FFS ($p < 0.05$). ALL = 2006-2008
[a] Includes readmissions within 30 days of discharge.
[b] Defined as readmissions within 30 days of discharge.

4. Transplantation, Wait-listing, and Referral

Transplant-related analyses were limited to patients under 70 years of age. There were 1,879 such patients in the Demonstration (611 in DMO A, 227 in DMO B, and 1,041 in DMO C) and 295,633 in the FFS group.

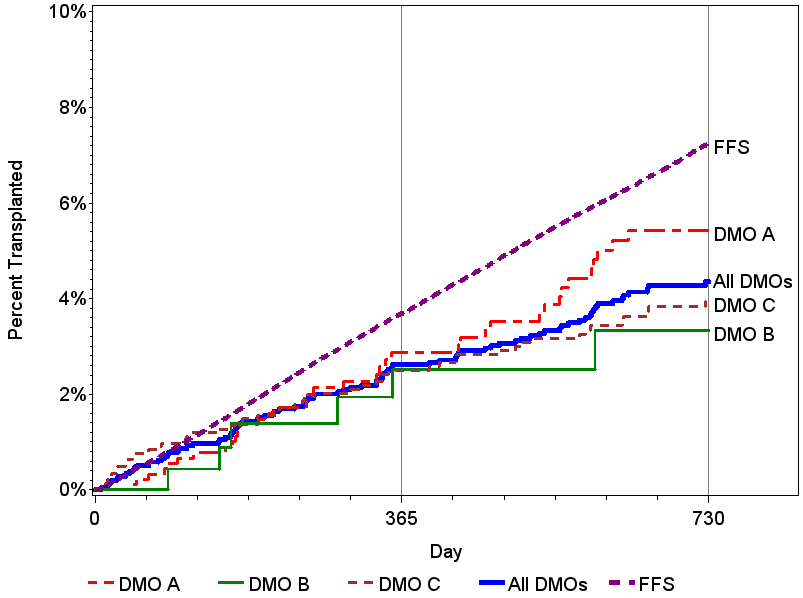
Table 11.7 shows transplantation percentages at one year and at two years. Across all DMOs the percent of patients transplanted was lower at all time points evaluated as compared to the geographically-matched FFS comparison populations, however, the difference at one year was only significant for DMO C and the difference at two years was only significant in DMO B and DMO C. Figure 11.3 shows the adjusted transplantation percentages over time.

Table 11.7: Patients Transplanted at One Year and Two Years, by DMO or FFS

	DMO A	FFS A	DMO B	FFS B	DMO C	FFS C	All DMOs	All FFS
Unadjusted One Year Transplantation (%)	4.3	4.8	2.5	3.4	3.5	4.6	**3.6***	4.8
Adjusted[a] One Year Transplantation (%)	3.0	3.7	1.7	2.5	**2.5***	3.7	**2.6***	3.7
Unadjusted Two Year Transplantation (%)	8.2	9.8	**3.2***	6.4	**5.5***	9.2	**6.0***	9.6
Adjusted[a] Two Year Transplantation (%)	5.6	7.3	**2.2***	4.6	**3.9***	7.4	**4.4***	7.3

Abbreviation: FFS = Fee-for-Service
* Numbers shown in **bold** are significantly different from FFS ($p < 0.05$).
[a] Adjusted for patient age, sex, race, Hispanic ethnicity, geography, diabetes as cause of ESRD, duration of ESRD, modality, previous failed transplant, and CMS-HCC risk score.

Figure 11.3: Patients Transplanted, Adjusted[a], by DMO or FFS



Abbreviation: FFS = Fee-for-Service

[a] Adjusted for patient age, sex, race, Hispanic ethnicity, geography, diabetes as cause of ESRD, duration of ESRD, modality, previous failed transplant, and CMS-HCC risk score.

Table 11.8 presents the percentage of patients wait-listed for transplantation among all eligible patients and among the patients not already wait-listed at enrollment for each DMO and for the FFS population. DMO A had significantly higher percentages of patients wait-listed at any point compared with FFS, with approximately 11 percentage points more patients being wait-listed in DMO A during the Demonstration. DMO C had a significantly higher percentage of patients wait-listed when the periods before or during the Demonstration were combined, however, this percentage wait-listed was no longer significant in DMO C when limited to the Demonstration period. Finally, DMO B had significantly lower percentages of patients wait-listed when compared to FFS at any point.

Table 11.8: Patients Wait-Listed, by DMO or FFS

	DMO A	DMO B	DMO C	All DMOs	FFS
Wait-Listed at Any Point (%)	**54.7***	**22.9***	**43.6***	**44.7***	30.1
Wait-Listed in Demonstration[a] (%)	**26.1***	**5.9***	16.7	**17.9***	14.7

Abbreviation: FFS = Fee-for-Service

* Numbers shown in **bold** are significantly different from FFS ($p < 0.05$).

[a] Among patients not already wait-listed at enrollment into the Demonstration. Wait-listing data for all patients were collected by the Organ Procurement and Transplantation Network and obtained through the Scientific Registry of Transplant Recipients.

Transplant referral data were collected by the DMOs; these data are not collected in the FFS population. Table 11.9 shows the percentage of patients referred for transplantation by DMO among patients not already transplanted. Across all DMOs, a majority of patients who were not already transplanted were either not referred for transplant or had unknown referral status. DMO A had the highest percentage of patients referred for transplant evaluation, consistent with its highest percentage of patients being placed on the transplant waiting list.

Table 11.9: Patients Referred for Transplant, by DMO

	DMO A	DMO B	DMO C	All DMOs
Referred Before Demonstration (%)	0	0	11	6
Referred in Demonstration (%)	39	15	24	28
Not Referred in Demonstration (%)	61	12	66	57
Unknown Status[a] (%)	0	73	0	9
Total Patients in Transplant Analyses (n)	611	227	1,041	1,879

Abbreviation: FFS = Fee-for-Service
Note: No formal significance testing was performed.
[a] DMO B was unable to provide transplant referral data for most patients.

Table 11.10 shows the reasons why patients were not referred, by DMO. The most common specified reason across all DMOs was patient refusal, followed by medical contraindication. Relatively few patients were noncompliant. A majority of patients in DMO A and DMO C had some other reason or an unknown reason for not being referred. These categories were rare in DMO B, but this may be an artifact of the large percentage of patients with unknown referral status in DMO B (Table 11.9).

Table 11.10: Reasons Patients Not Referred for Transplant, by DMO

	DMO A	DMO B	DMO C	All DMOs
Patient Refusal (%)	20	70	21	22
Medical Contraindication (%)	17	26	13	15
Noncompliance (%)	0	0	3	2
Other (%)	11	4	32	24
Unknown Reason (%)	52	0	30	37
Total Patients not Referred (n)	371	27	682	1,080

Abbreviation: FFS = Fee-for-Service
Note: No formal significance testing was performed.

We examined predictors of transplant referral in DMO A, DMO C, and in the Demonstration overall. There were not enough patients in DMO B with known transplant status for this analysis, but these patients were included in the model evaluating the total Demonstration population. In general, patients who were younger were more likely to be referred for transplant. For DMO A, only younger patient age was predictive of increased likelihood of referral for transplantation. Additionally, patients with the following characteristics in DMO C were more likely to be referred for transplantation: shorter duration of ESRD, diabetes as cause of ESRD, other race (than white or black), Hispanic or Latino ethnicity, and less comorbidity as measured by the CMS-HCC risk score.

D. Discussion

For the pooled DMO data, findings of the ESRD Disease Management Demonstration showed significantly improved one- and two-year survival among DMO patients over the course of the evaluation. Improvements in first all-cause hospitalization and first cardiovascular hospitalization were also observed in analyses that combined all DMO data. However, DMO performance varied markedly and survival and hospitalization findings observed with Disease Management differed by DMO. Hospitalization admissions did not differ significantly from FFS over the three-year evaluation period. Utilization of other services including SNF stays and physician visits were significantly lower across all participating DMO programs when compared to FFS.

1. Patient Mortality

An important finding of this evaluation is the significant reduction in mortality in at least two of the three DMOs when compared to the FFS population. The average survival difference was significantly greater for DMO B and DMO C at both one and two year time points, and persisted after adjustment for potential confounding factors such as patient age, sex, race, Hispanic ethnicity, geography, diabetes as cause of ESRD, duration of ESRD, modality, previous failed transplant, and CMS-HCC risk score. 8.4%

and 6.2% more patients were surviving in DMO B and DMO C, respectively, by two years when compared with FFS.

The overall improvement in patient survival in two of the three DMOs may partly be explained by the actual Disease Management interventions. Other analyses for this project compared types of DMO program design and interventions and found several of these components of the three DMOs translated to improvement in certain processes of care. For instance, DMO B's program of implementing HbA1c standing orders for patients with diabetes mellitus was associated with improvement in HbA1c measurement rates, and DMO C's oral nutritional supplementation (ONS) program resulted in a significant increase in serum albumin, and more importantly a reduction in the risk of mortality.

With regards to DMO A, unadjusted analyses demonstrated significantly increased survival, however, this was no longer observed after statistical adjustment. As presented in earlier sections of this report, improvement in processes of care measures resulted from DMO A's interventions, however, these interventions focusing on care coordination may have been insufficient to result in a reduction in mortality.

It should be noted that differential disenrollment rates across the three DMOs may have impacted the observed clinical outcomes. In particular DMO C had relatively high disenrollment during 2007. It is conceivable that patients who disenrolled had a higher mortality rate, and this is supported by an analysis which showed that patients with higher CMS-HCC risk scores were significantly more likely to disenroll after less than a year in the Demonstration (OR = 3.75; 95% CI 2.18, 6.44). As such, disenrollment of sicker patients from the DMOs may have left healthier patients in the Demonstration, potentially contributing to the improved survival percentages observed among DMO enrollees. It is equally important to account for the special election period enacted by DMO C in 2007 which may have inflated disenrollment rates.

2. Patient Morbidity

In addition to the positive impact of the Demonstration on patient survival, improvement was seen in time to first hospitalization for one DMO as evaluated by percentage of patients hospitalized, with DMO C demonstrating reduced one- and two-year hospitalization percentages as compared to FFS after adjusting for potential confounding factors. Cardiovascular-specific hospitalization was similarly reduced for DMO C throughout the evaluation. DMO A demonstrated reduced all-cause and cardiovascular hospitalization on unadjusted analyses, however, this reduction was no longer observed with statistical adjustment. With regards to DMO B, no significant reduction in all-cause hospitalization was observed. The analysis on cardiovascular hospitalization percentages for DMO B has limitations as data on cardiovascular diagnoses were limited.

Overall, hospitalization rates remain high in the DMO population, and as shown by the United States Renal Data System (USRDS), there has been no reduction in ESRD hospitalization rates since 1993 [11]. The prior ESRD Managed Care Demonstration [12] did not reveal any significant reduction in hospitalization rates in patients enrolled in the Managed Care plans. The analysis of service utilization in this Demonstration found no evidence of a robust, systematic reduction in hospitalization rates. Some trends appear encouraging, as for example the apparent non-statistically significant reduction in hospitalization rates for DMO C, however, either there were not adequate sample sizes or consistency across adjustment methodologies to confidently conclude these were more than random variations.

A possible explanation for finding variations in hospital admissions and readmissions across DMOs and years may be related to the differences in structure and implementation of Disease Management. DMO C, which demonstrated reduction in service utilization as compared to FFS, incorporated two treatment interventions in addition to care coordination. First, it provided ONS to patients with

marginal reductions in serum albumin. Reduced serum albumin is associated with chronic inflammation and malnutrition and as presented in Chapter 9 of this report, DMO C's program of early nutritional supplementation was associated with improved survival. Possible explanations for the lack of clear improvement in clinical outcomes may relate to several factors. First, programmatic changes observed in Disease Management components because of operational reasons may have limited their potential impact. In DMO A, involvement of a pharmacist in the clinical team translated to a significant reduction in medication-related errors on interim analysis. However, modification of this program removed the routine pharmacist evaluation of patient medications. Similar examples were also observed in DMO B where standing orders for HbA1c measurements were attempted and then stopped due to technical reasons, and in DMO C where the protocol for distributing home weight monitoring (HWM) scales changed mid-way through the evaluation period. Although these programmatic changes reflect single components of each DMO's Disease Management program, they may have potentially impacted other components of enrollees' clinical care and outcomes. A second potential explanation is that Disease Management which focuses on care coordination, modification of self-care behavior and prevention may be insufficient to effect change on clinical outcomes. Particularly among patients with ESRD where patients typically have long-standing disease, modification of behavior may be challenging. Finally, differences in degree of interaction between patients and members of the health care team may influence the effectiveness of Disease Management. Although all three DMOs utilized various methodologies for maintaining close contact with the enrollees, DMO C's HWM scale functioned also as a communication device, which may have resulted in near daily interaction by the nurse coordinators with certain patients. However, a specific analysis evaluating the impact of HWM on communication and care coordination was outside of the scope of this evaluation.

3. Utilization of Services other than Hospitalization

Although there were no significant differences in ED visits for DMO patients compared with FFS over the three-year evaluation period, generally, a significant trend for fewer physician visits and SNF stays was noted for all DMOs compared with their FFS comparison groups. This is a promising finding and demonstrates the ability of care coordination at the dialysis facility to replace the need for utilization of additional services elsewhere. In particular, regular interaction during dialysis sessions may reduce the need for outpatient physician visits.

4. Transplant-Related Outcomes

We evaluated three transplant-related outcomes: transplantation, transplant wait-listing and referral for transplantation. Our analyses reveal that transplantation rates were not improved by the Disease Management program; however, transplant wait-listing rates were significantly higher for DMO A and DMO C compared with FFS. Transplant wait-listing was particularly high for DMO A, both at any point and over the course of the Demonstration when compared to FFS. DMO A appeared to be more successful in emphasizing transplantation as a treatment option for ESRD given the relatively higher referral rates for transplant evaluation, as well as the greater success in placement on the transplant waitlist. DMO C appeared to focus less on transplantation, as shown by the low rate of referral for transplant evaluation and the very high percentage of patients with unknown transplant referral status. Altogether, these findings suggest that the majority of HD patients have not benefited from the possibility of a renal transplant, despite the fact that among those without a medical contraindication, transplantation offers improved survival and better QoL compared with chronic dialysis [13, 14]. Furthermore, the high frequency of patient refusal as a reason for non-referral for evaluation suggests the need to strengthen patient education efforts on the benefits of kidney transplantation. Finally, the high percentage of missing data accounting for reasons for non-referral suggests that this information is not routinely collected in dialysis facilities. Identifying reasons for non-referral of a patient for transplant evaluation is important in determining and addressing obstacles to kidney transplantation.

Interestingly, we noted a significantly higher likelihood of wait-listing for transplantation among patients of Hispanic ethnicity in DMO C but not in DMO A. Reasons for this observation are unclear, however, it is interesting to note that recent literature suggests that patient and graft survival rates are better among patients of Hispanic ethnicity [13] – previously described as part of the "Hispanic paradox" in that patients of Hispanic ethnicity may have better health outcomes despite having more clinical risk factors as compared to non-Hispanics [14]. It is plausible that social and cultural factors among Hispanics may lead to increased focus on health and well-being of sick relatives leading to improved clinical outcomes [13]. Family culture may promote increased attention to transplantation as a treatment option for ESRD.

5. Strengths and Limitations

There are several strengths of this evaluation. First, we analyzed several components of patient outcomes including survival, hospitalization and transplantation-related outcomes. Second, we compared the enrollees' outcomes using two different populations: the propensity-score matched FFS comparison group, as well as the overall FFS population. Finally, our statistical analyses employed multiple regression models that accounted for the potential effects of confounding variables, including the propensity-score methodology, which allowed us to identify a FFS comparison group who were observed to have a similar propensity for enrolling in a DMO as the DMO population and second-stage multivariate regression modeling that took into account residual differences between the DMO and the propensity score matched comparison groups.

Several limitations need to be pointed out in our analyses. The DMO populations for some analyses were relatively small. For example, fewer than 100 patients were enrolled in DMO B at any time during 2006. This can lead to insufficient statistical power to detect differences that may be relevant to patients, clinicians, and policy makers. There was no random assignment of patients to DMO treatment, so statistical adjustment was used to compare DMO populations to the more general FFS populations. Statistical adjustment allows for a more fair comparison, but relies upon measuring all variables that may differ between the populations and be causally associated with the outcomes of interest. While these analyses adjust for a wide set of demographic and clinical variables, unmeasured variables due to the lack of available data always represent a potential limitation in observational studies.

There are also limitations specific to the utilization analyses. First, the propensity score matching methodology used in the utilization analyses for this study attempts to measure what the utilization of DMO enrollees would have been if they had instead been treated under a FFS system. This was accomplished in part by defining a comparison group of patients treated in a FFS setting who were observed to have a similar propensity for enrolling in a DMO as the DMO enrollees. A potential limitation of this type of approach is that despite the level of balance that was achieved between DMO and FFS groups based on measured characteristics, the matching process may not balance DMO and FFS groups based on unmeasured confounders. We attempted to address this limitation by performing multivariate second-stage regression as described above.

A second limitation of using the propensity score matching and second-stage regression analysis is the reduced statistical power to identify statistically significant effects of the Demonstration due to limiting the FFS sample to the number of patients in the Demonstration. These analyses used a one-to-one match which is the most common implementation of the propensity score method [15]; while it is possible that increasing the number of FFS patients included in the analyses by using a many-to-one match would increase statistical power, it is unclear how many matches would be required. Furthermore, many-to-one matching may require additional exclusions from the Demonstration sample for patients who cannot be matched to multiple FFS patients. One-to-one matching identified several statistically significant differences. Simulations to reduce the size of confidence intervals around estimates of FFS utilization rates revealed limited benefits of more complex matching strategies: for

example, increasing the matching ratio so that the confidence interval for DMO A's 2006 hospitalization rate is cut by half would still not provide the statistical power to label the observed 8% difference as "significant." The second-stage regression model may also be associated with lower statistical power given the limited sample size and the number of variables used for adjustment; hence, these results are shown in addition to the basic propensity score adjustment.

As such, we compared the time to first hospitalization in the DMOs to the overall FFS population as another comparison group, statistically adjusted for differences between the DMO and FFS populations, which allowed us to ensure longer follow-up and sufficient power to determine statistically significant differences in our findings. In order to address potential differences between the DMO and FFS populations, we performed statistical modeling techniques to adjust for potential confounding factors including age, sex, race, Hispanic ethnicity, geography, diabetes as cause of ESRD, duration of ESRD, and other clinical and demographic factors.

A third limitation of the propensity score method used for the utilization analysis is that longitudinal effects of the program on utilization and cost were not taken into account. By design, the primary purpose of the utilization analyses was to evaluate a counterfactual which is what these same patients would have cost Medicare and the DMOs if they were in FFS. In doing so, we removed the longitudinal effects of Disease Management and compared DMO and FFS patients within each year. This methodology allows us to more accurately estimate what the utilization of Demonstration patients might be had they remained in FFS in each year of the analysis. A comparison between the changes in utilization across the years in the DMOs to changes in utilization across the years in the FFS matched samples was not the intention of the analyses. Finally, as noted earlier, differential disenrollment rates in the DMOs may have influenced the results of our analyses in that patients who disenrolled may have different outcomes than those who stayed in the Demonstration. This would be of particular concern in the service utilization analyses, where DMO enrollment was more dynamic than the comparison FFS groups. Sensitivity analyses stratified by enrollment times revealed no substantive differences from the results reported here.

6. Summary

This ESRD Disease Management Demonstration provides promising evidence that Disease Management may improve survival and hospitalization in a select patient population. This evaluation differs from prior Disease Management demonstrations because of three key aspects. First, DMO A and DMO C were developed in partnership with the dialysis organizations ensuring close coordination in care delivered between the health plan and the dialysis clinical care teams. On the other hand, DMO B was originally working with a dialysis provider that was acquired by another dialysis provider immediately before the Demonstration. This organizational change impacted the information flow in DMO B between the health plan and the dialysis provider, which may have led to some differences observed here. DMO B had the least communication between the dialysis facilities and the health plan and experienced the most difficultly in implementing some of the interventions as planned (e.g. standing orders for diabetes management). Second, in DMO C, Disease Management incorporated treatment interventions that went beyond care coordination and improved self-management. These interventions may have translated to improved clinical outcomes in DMO C. Third, the ESRD population presents unique challenges and opportunities for Disease Management. The complexity of ESRD care with management by multiple providers and the presence of numerous comorbidities often lead to fragmented care delivery. On the other hand, the frequent contact with ESRD patients receiving thrice weekly HD may facilitate improvement in processes of care delivery, which may translate to improved clinical outcomes.

In summary, evaluation of the ESRD Disease Management Demonstration suggested improved patient survival and potentially reduced utilization of certain high-cost services. DMO performance varied, with

two of the three DMOs (DMOs B and C) demonstrating a benefit of Disease Management with improved one- and two-year survival. Longer time to hospitalization, reduced physician visits and SNF stays were observed in DMO C, which incorporated treatment interventions as part of its Disease Management program. On the other hand, hospitalization utilization appeared to be greater in DMOs A and B. Our findings suggest that differences in DMO program intervention may explain variations in the impact of Disease Management on clinical outcomes. In particular, emphasis on care coordination and modification of patient behavior as part of Disease Management may be insufficient and treatment interventions may be necessary to impact clinical outcomes significantly. The evaluation also suggested an impact of Disease Management on reducing utilization of other services, including SNF stays and physician visits across all DMOs as compared to FFS. In this current analysis, statistical adjustment and the use of matched control groups were critical given the observed differences in case-mix, though unobserved differences may persist. It is noteworthy that our observed significant improvement in patient survival, among other results, persisted after adjustment for potential confounders for two of the DMOs.

The percentage of patients receiving a transplant in the Demonstration was generally lower or similar to FFS. When compared to FFS, DMO A consistently had a larger percentage of patients wait-listed, DMO B consistently had a smaller percentage of patients wait-listed, and DMO C had mixed results. These outcomes, however, have some aspects which are outside of the direct control of the DMOs. Rates of referral for transplant evaluation, which is under the direct control of the DMO, could potentially be improved by further Disease Management efforts, including reducing rates of patient refusal for transplant evaluation (which may be considered a marker for improved patient education) and reducing racial disparities in transplant referral rates.

This ESRD Disease Management Demonstration represented a unique opportunity to identify improvement in clinical outcomes in a population that is ideally suited for Disease Management. We observed promising survival benefits in this notably fragile and complex patient population. Furthermore, reductions in physician visits and SNF stays were observed for DMO patients compared with FFS over the three-year evaluation period.

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CHAPTER 12: IMPACT ON QUALITY OF LIFE

A. Introduction

This chapter presents the results of the quality of life (QoL) evaluation for the Evaluation of End-Stage Renal Disease (ESRD) Disease Management Demonstration, from 2006 through 2008. QoL is severely compromised for patients with ESRD due to treatment, associated chronic conditions and financial burdens of managing their kidney disease. Research strongly suggests that QoL status can predict outcomes for hospitalization, morbidity, and mortality in ESRD patients on dialysis [1-4].

The current ESRD Disease Management Evaluation aimed to determine whether integrated health care from the Disease Management programs in the three DMOs resulted in demonstrable improvements in QoL for ESRD patients.

B. Methods

Each of the DMOs supplied methodological information about how QoL surveys were administered. Both DMO A and DMO C relied on a combination of methods from 2006 to 2008. These were in-center self-and/or nurse-assisted survey administration to patients; telephonic administration by a nurse or care coordinator (for DMO A this was done for Spanish-speaking patients only); and mailed surveys to patients that required self-administration. DMO B mailed surveys to patients and used this same method throughout the Demonstration.

The QoL survey instruments also varied by DMO. DMO A and DMO B QoL survey data were collected using the QualityMetric Short Form (SF)-12v2 instrument. DMO C initially assessed QoL using the QualityMetric SF-36 survey instrument at dialysis facilities, but later began supplementing these data with data collected using the QualityMetric SF-12v1 survey instrument by mail or telephone. The United States Dialysis Outcomes and Practice Patterns Study (U.S. DOPPS) comparison patients completed the Kidney Disease Quality of Life (KDQoL) survey, which includes the SF-36 in addition to dialysis-specific questions.

The two primary measures derived from the survey instruments are the Mental Component Summary (MCS) and the Physical Component Summary (PCS). These two summary scores are composite scales based on four domains of mental health and four domains of physical health. All QoL scores were computed using methods published by QualityMetric [5]. A change of five percentage points (on a scale of 0-100) or more in sub-scales or composite scores was considered a clinically meaningful change, based on accepted norms in the literature [6]. All QoL surveys completed during a patient's first enrollment period were evaluated and all surveys with missing data were excluded. Baseline surveys were defined as the first survey completed after enrollment and the twelve month follow-up was defined as the first survey completed at least twelve months after the baseline survey. Patients who died during the Demonstration period were included in analyses if the patient had appropriate QoL survey data. Due to small sample sizes for peritoneal dialysis and transplant groups, only patients who remained on hemodialysis (HD) through their entire enrollment were analyzed.

Unadjusted change in patient QoL over time was assessed with matched-pair t-tests performed for MCS, PCS, and the eight QoL subscales. Adjusted change in MCS and PCS was also assessed with repeated measures linear mixed models controlling for baseline demographic and clinical variables. For statistical models using DMO C data, we included an indicator of whether the QoL survey was an SF-36 administered at the dialysis facility or an SF-12v1 conducted while the patient was at home to control

for potential differences in response due to mode of survey administration, as have been found previously [7].

C. Results

1. Response Rates and Patient Characteristics

Survey response rates and follow-up rates differed widely across the three DMOs and the U.S. DOPPS comparison group. During the analysis period, 17% of DMO A, 87% of DMO B, 64%, of DMO C and 74% of U.S. DOPPS patients completed at least one survey. Among these respective groups of patients, 27%, 59%, 49%, and 36% completed a follow-up survey. Significant differences in response rates by race and ethnicity were found in each DMO and in the comparison population. In the pooled DMO data, black patients were more likely to have two or more completed QoL surveys than white patients and patients of other races, while the opposite was found in the U.S. DOPPS. Hispanic patients in the pooled DMO data were less likely to have at least one completed QoL survey, but there were no differences in response rates between Hispanics and non-Hispanics in the U.S. DOPPS.

Respondents also differed across some clinical variables. Notably, patients who had completed one or more QoL surveys tended to have values indicating better health. Survey respondents in the pooled Demonstration data tended to be younger ($p < 0.01$), had higher BMI ($p < 0.01$), had higher serum albumin ($p < 0.01$) and had a lower Centers for Medicare & Medicaid Services (CMS) Hierarchical Condition Categories (HCC) risk score ($p < 0.01$). These significant differences between Demonstration respondents and non-respondents in age and CMS-HCC risk score were primarily driven by differences in DMOs B and C ($p < 0.01$ for both age and CMS-HCC risk score), while the body mass index (BMI) difference was primarily driven by a difference in DMO A ($p < 0.01$). These differences in DMO-specific findings demonstrate the limitations of pooled analyses.

2. Baseline QoL

After adjustment, there were no significant differences in baseline PCS between the DMOs and U.S. DOPPS (Table 12.1). Baseline MCS scores were significantly higher, but the difference was not clinically meaningful in DMO B and DMO C compared with the U.S. DOPPS comparison group. DMO A adjusted baseline MCS scores did not significantly differ from U.S. DOPPS.

Table 12.1: Baseline QoL Summary Scores, Unadjusted and Adjusted, Compared with U.S. DOPPS

DMO	Number of Patients[a]	MCS[c]				PCS[d]			
		Unadjusted	p-value	Adjusted[b]	p-value	Unadjusted	p-value	Adjusted[b]	p-value
DMO A	104	42.6	< 0.01	41.6	0.10	32.4	0.34	31.0	0.13
DMO B	224	50.1	< 0.01	48.8	< 0.01	38.2	< 0.01	34.9	0.41
DMO C	832	50.4	< 0.01	47.8	< 0.01	37.7	< 0.01	34.9	0.16
All DMOs	1160	49.6	< 0.01	47.9	< 0.01	37.3	< 0.01	34.9	0.12
U.S. DOPPS	1101	45.9	Referent	45.6	Referent	33.4	Referent	33.9	Referent

Abbreviation: U.S. DOPPS = United Stated Dialysis Outcomes and Practice Patterns Study

[a] Adjusted means are restricted to patients with no missing covariate data. The adjusted means are calculated for 93 patients in DMO A, 188 patients in DMO B, 739 patients in DMO C, 1020 patients in all DMOs, and 720 patients in U.S. DOPPS.

[b] Adjusted to the average U.S. DOPPS patient, using DMO-specific linear models controlling for age, gender, race, Hispanic ethnicity, BMI, months on dialysis at enrollment, dialysis dose, serum albumin, corrected calcium, serum phosphorus, hemoglobin, vascular access mode, and QoL administration mode (for models with DMO C data).

[c] MCS = Mental Component Summary

[d] PCS = Physical Component Summary

3. Unadjusted Time Trends in QoL

Table 12.2 presents unadjusted matched-pair t-test analyses of patient QoL scores between baseline and a 12-month follow-up. Clinically meaningful changes were noted only for some components of MCS for DMO A respondents. These unadjusted data suggest no significant or clinically meaningful changes in summary MCS and PCS scales of QoL for DMO B and DMO C and in pooled Demonstration results, consistent with findings for the U.S. DOPPS comparison group. On DMO-level analysis, different patterns in QoL scores are apparent, as illustrated by the clinically meaningful improvement in role-emotional and vitality scores and the clinically meaningful decline in social functioning scores for DMO A. However, these analyses were not adjusted for variables that may influence change in QoL over time. Moreover, although there appeared to be clinically meaningful changes in the respective role emotional and vitality scores (improvement) and social functioning (diminishment) these changes were not statistically significant, most likely due to small sample size. For DMO B and DMO C and the pooled DMO data, other components of mental and physical QoL changed slightly, but were neither clinically meaningful nor obtained statistical significance.

Table 12.2: Mental and Physical QoL Summary Scores, by DMO, Compared with U.S. DOPPS, 2006-2008, Baseline and 12-Month Follow-Up, unadjusted

	DMO A[a]			DMO B (N = 70)			DMO C (N = 116)		
	Baseline	12-month Follow-up	p-value	Baseline	12-month Follow-up	p-value	Baseline	12-month Follow-up	p-value
Mental (MCS)				52.8	50.2	0.02	49.6	48.9	0.52
Mental Health				53.7	50.4	< 0.01	48.9	48.9	0.97
Role-Emotional				44.7	42.1	0.03	44.4	41.2	0.01
Social Functioning				51.7	51.1	0.56	43.7	43.4	0.85
Vitality				48.6	45.4	< 0.01	45.6	46.3	0.46
Physical (PCS)				41.5	40.3	0.13	37.2	36.5	0.42
Physical Functioning				40.3	37.6	< 0.01	34.9	33.2	0.06
Role-Physical				43.0	40.7	0.01	40.5	39.0	0.28
Bodily Pain				50.3	49.4	0.45	45.0	44.9	0.88
General Health				41.4	40.8	0.69	38.9	38.7	0.81

	All DMOs (N = 192)			U.S. DOPPS (N = 331)		
	Baseline	12-month Follow-up	p-value	Baseline	12-month Follow-up	p-value
Mental (MCS)	50.6	49.3	0.10	47.6	47.0	0.49
Mental Health	50.5	49.3	0.14	67.4	66.9	0.51
Role-Emotional	44.1	41.4	< 0.01	63.6	61.6	0.44
Social Functioning	46.7	46.1	0.47	62.7	58.8	0.06
Vitality	46.3	45.8	0.45	38.1	37.3	0.65
Physical (PCS)	38.5	37.6	0.12	34.1	33.3	0.08
Physical Functioning	36.6	34.6	< 0.01	33.5	30.8	0.09
Role-Physical	41.1	39.4	0.05	40.3	38.6	0.25
Bodily Pain	46.7	46.2	0.54	61.9	57.6	0.02
General Health	39.5	39.1	0.57	41.6	42.9	0.58

Abbreviations: MCS = Mental Component Summary; PCS = Physical Component Summary; U.S. DOPPS = United States Dialysis Outcomes and Practice Patterns Study

[a]Data suppressed, N < 11

4. Adjusted and Unadjusted Changes in QoL at 12 months

Average unadjusted and adjusted 12-month changes in QoL scores as analyzed by linear mixed models (Table 12.3) were consistent with results presented above. Adjusted MCS and PCS scores did not change

significantly over the course of the Demonstration for DMO A and DMO C, similar to the U.S. DOPPS comparison population. In DMO B, statistically significant declines in both MCS and PCS scores were noted after adjustment, but the declines were not clinically meaningful.

Table 12.3: Estimated 12-Month Change in QoL by DMO, Compared with U.S. DOPPS, 2006-2008

	DMO A		DMO B		DMO C		All DMOs		U.S. DOPPS	
	Change	p-value	Change	p-value	Change	p-value	Change	p-value	Change	p-value
MCS (unadjusted)	-	-	-2.60	0.02	-0.70	0.52	-1.30	0.10	-0.60	0.62
MCS (adjusted)	0.79	0.69	-1.47	< 0.01	0.46	0.29	-0.02	0.96	0.28	0.51
PCS (unadjusted)	-	-	-1.20	0.13	-0.70	0.42	-0.90	0.12	-0.80	0.04
PCS (adjusted)	-0.15	0.93	-1.09	< 0.01	-0.07	0.85	-0.29	0.33	0.01	0.99

Abbreviations: MCS = Mental Component Summary; PCS = Physical Component Summary; U.S. DOPPS = United States Dialysis Outcomes and Practice Patterns Study

Note: unadjusted change was estimated with matched-pair t-tests; adjusted change was estimated using DMO-specific linear mixed models (LMM) controlling for age, gender, race, Hispanic ethnicity, BMI, months on dialysis at enrollment, dialysis dose, serum albumin, corrected calcium, serum phosphorus, hemoglobin, vascular access mode, and QoL survey administration mode (for models with DMO C data).

DMO A: Unadjusted data suppressed, N < 11; N = 93 patients, 126 surveys in LMM
DMO B: N = 70 patients, 140 surveys in t-test; N = 188 patients, 394 surveys in LMM
DMO C: N = 116 patients, 232 surveys in t-test; 739 patients, 1455 surveys in LMM
All Demo DMOs: N= 192 patients, 384 surveys in t-test; 1,020 patients, 1,975 surveys in LMM
U.S. DOPPS: N = 467 patients, 934 surveys in t-test; N = 720 patients, 878 surveys in LMM

D. Discussion

Across all Demonstration patients, the average adjusted mental and physical QoL baseline scores were slightly higher than those of the patients in the U.S. DOPPS comparison group. Over the course of the Demonstration adjusted analyses demonstrated no clinically meaningful decline in QoL in DMOs A and C, consistent with the U.S. DOPPS comparison group. In DMO B, statistically significant but not clinically meaningful dedines were noted in the MCS and PCS scores.

Altogether, these suggest that there was no clear impact of Disease Management on improving QoL for patients enrolled in the three DMOs. In interpreting these findings it is important to note the overall 52% response rate in the Demonstration differed widely among the three DMOs (17% for DMO A; 87% for DMO B and 64% for DMO C) and compared to the U.S. DOPPS (74%), therefore limiting the ability to make systematic comparisons in QoL scores between patient populations at the DMO-level or to the U.S. DOPPS comparison group.

The absence of a significant decline in the MCS scores reported here are consistent with other findings that show general stability of these scores over time [8-10]. Results reported in the literature are more mixed on whether PCS improves, diminishes, or remains about the same over time [8-11 ,14, 15].

A potential explanation for why changes in MCS and PCS scores in DMOs A and C were no different than the observed changes in the U.S. DOPPS comparison group is that survey respondents were significantly healthier compared with non-respondents. Healthier patients are known to perceive better QoL [12]. In short, Disease Management may have a greater effect for patients in poorer health than for healthier patients, on improving QoL. However, DMO B demonstrated significant declines over time in adjusted MCS and PCS scores. This decline is noteworthy given that DMO B respondents to the QoL survey were healthier than DMO B non-respondents.

In the context of the prior ESRD Managed Care (MC) Demonstration which ran from February 1998 until September 2001, enrolled patients tended to have higher MCS scores at their one-year follow-up, but no significant change in PCS scores [13]. A potential reason for the difference in MCS outcomes between the current Demonstration and the prior ESRD MC Demonstration is that the survey

administration methodology in the latter used trained staff to administer surveys that were not part of the patients' dialysis team. As a result, 85% of enrollees responded to the survey compared to the overall 52% response rate in the current Disease Management Demonstration. Another potential explanation for differences in findings is that analyses in the previous MC Demonstration were unadjusted. Key potential confounding factors including patient race, Hispanic ethnicity, clinical variables such as use of arteriovenous (AV) fistula, BMI, CMS-HCC risk score or comorbidity, among others, that may explain the difference in QoL scores over time were, however, were accounted for in the adjusted analyses for the current Demonstration.

1. Limitations

An important limitation of this study is the very low response rate for one of the DMOs. Relatedly, respondents were markedly different, and healthier than non-respondents which limits the generalizability of these findings. Second, the analyses did not adjust for other potential confounders, particularly socio-economic variables that measure employment, education, and income. These have been found to be predictive of MCS and PCS in other analyses [12]. Finally, as Unruh et al [7] found in the HEMO study, modality of survey administration may produce a selection bias in the type of patients who complete surveys and have QoL scores. In the current analyses, method of survey administration was modified at least once in two of the three DMOs throughout the course of the Demonstration. In order to mitigate the impact of these potential influences, the analyses adjusted for varying survey methods, specifically for DMO C, where systematic differences in QoL scores were noted depending on whether patients took the survey at home or at the dialysis facility.

2. Summary

The findings demonstrate that despite implementation of Disease Management programs, QoL scores did not significantly improve at 12-month follow-up over the course of the Demonstration in DMOs A and C. QoL scores for patients enrolled in DMO B showed a statistically, although not clinically meaningful, decline at 12 months. These findings should be interpreted in the context of prior studies of QoL among dialysis patients showing no consistent trends in changes for physical QoL over time, while scores for mental QoL are more stable [8, 9, 10, 11, 14, 15].

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CHAPTER 13: IMPACT ON PATIENT SATISFACTION

A. Introduction

This chapter presents findings from the Patient Satisfaction component of the Evaluation. Patient satisfaction has implications for the operational feasibility of the DMOs. The evaluation assessed satisfaction among beneficiaries in the participating DMOs, and also assessed beneficiaries' reasons for disenrollment from the DMOs.

B. Methods

1. Data Collection

Three rounds of patient satisfaction interviews were conducted with enrollees from the three DMOs. For the first round, focus groups were conducted with 49 enrollees from the three DMOs in the early fall of 2006. For the second round, telephone interviews with 30 enrollees who were included in the 2006 focus groups were conducted approximately one year later, in early fall of 2007. The third round of interviews was conducted in fall of 2008 with 27 enrollees who had not previously been interviewed in 2006 and 2007.

In order to assess beneficiaries' experiences regarding disenrollment from the DMOs, two rounds of interviews were conducted with patients who voluntarily disenrolled from the DMOs participating in the Demonstration. The first round of disenrollment interviews was conducted with 20 disenrollees in early spring of 2008, and the second round of interviews was conducted with 12 new disenrollees in the spring of 2009.

On October 1, 2008, DMO B formally announced it was terminating its participation in the Centers for Medicare & Medicaid Services (CMS) End-Stage Renal Disease (ESRD) Disease Management Demonstration on December 31, 2008. Following DMO B's announcement, CMS and the Evaluation team decided to initiate the second round of interviews for DMO B earlier than originally scheduled in order to recruit disenrollees who disenrolled prior to the October 1, 2008 notification to DMO beneficiaries about the impending program termination. Several attempts were made to recruit DMO B disenrollees, but these were unsuccessful. The disenrollment evaluation for DMO B was discontinued and therefore the experiences of DMO B disenrollees are not included in the results for the second round of the disenrollment interviews reported in this chapter.

A semi-structured interview approach was used to assess both patients' satisfaction with the DMOs, and reasons for disenrolling from the DMOs. The advantage of semi-structured interviews is that their conversational nature allows for unanticipated, though often important and relevant topics to emerge, while critical questions are addressed. DMO protocols across DMOs covered the same themes regarding satisfaction and reasons for disenrollment, but questions were tailored to the features of each DMO. All telephone interview protocols took an average of 30 minutes to complete. In order to assess the cultural competency of the DMOs, interviews for the third round of interviews with enrollees and the second round of interviews with disenrollees also included a sample of Spanish-speaking respondents. These interviews were conducted by a Spanish-speaking interviewer and used the same DMO protocols, translated into Spanish.

2. Analysis

Due to the qualitative nature of these analyses, as well as small sample sizes, tests for statistical significance are not reported. Data were collected through the use of audio-recording and note-taking. The notes were compiled into one database and were then analyzed and coded for central concepts and themes. Questions were meant to elicit qualitative responses, and included what enrollees felt were the most helpful services of the DMOs, and also the reasons for disenrolling from the DMOs. In addition, the Patient Satisfaction protocol asked respondents to rank their overall satisfaction with the DMO, using a numerical scale of 1 to 5.

C. Results

1. Most Helpful Services of DMOs

After discussing the services that the DMOs offered, respondents were asked to name the services they found the most helpful.

In the first round of interviews, with the 2006 focus groups, 18 out of 49 respondents (37%) cited the nurse care manager (NCM) as the most helpful service offered by the DMOs. The second round of interviews in 2007 found that 11 out of 30 respondents (37%) cited the NCM as the most helpful service. For the third round of interviews in 2008, 12 out of 27 respondents (44%) cited the NCM as the most helpful service. Participants discussed specific actions of the NCM, such as setting up doctor's appointments, providing emotional support, and providing health education. DMO A and DMO B respondents ranked NCMs among the most helpful services, suggesting that the NCM is an increasingly comprehensive aspect of the care coordination component for DMOs A and B. By 2008 for DMO C patients who were interviewed, there was a marked reduction in the percent of DMO C patients that cited the NCM as the most helpful service (2006 – 47%, 2007 – 50% and 2008 – 22%). DMO C relied on the call center NCMs throughout the Demonstration as part of their integrated care program structure, while early on NCMs made periodic on-site visits at DMO C facilities. The findings for DMO C may be attributed in part to a shift in most assessments conducted telephonically by the Call-Center NCMs. One potential explanation is that less in-person interaction with the NCMs beginning by 2008 may have attributed to a decline in the percent of DMO C enrollees listing NCMs as the most helpful service.

Help with medications and medical supplies were cited as the next most helpful services across all three DMOs, with 35% of respondents citing medications as helpful in 2006, and 30% and 19% citing this service in 2007 and 2008, respectively. Respondents in DMO C in particular reported that they found the medical supplies as most helpful, including the interactive fluid weight monitoring scale. In third round interviews for DMO A, respondents reported NCMs as the most helpful service, but in the first round focus groups, over a majority of respondents reported medications as the service most helpful service provided by DMO A, with about a third citing the NCM services as useful. DMO B respondents also ranked NCMs and medications among the most helpful services provided by the DMO.

In the first and second rounds of interviews, respondents also cited specialists and dialysis center staff as helpful. For the third round of interviews, respondents cited lower copayments as another helpful aspect of the DMOs.

2. Overall Satisfaction with DMOs

In order to assess overall experience and satisfaction with the DMOs, respondents were asked to rate their overall level of satisfaction with the DMOs on a scale from 1 to 5, where 1 = not satisfied at all, 2 = barely satisfied, 3 = somewhat satisfied, 4 = satisfied, and 5 = very satisfied. Table 13.1 describes respondents' overall satisfaction with the DMOs.

Table 13.1: Overall Satisfaction with the DMOs as Rated by Disease Management Demonstration Enrollees, by DMO, 2006, 2007, and 2008

Overall Satisfaction*		*DMO A*	*DMO B*	*DMO C*	*All DMOs*
First Round	2006	4.4	4.6	4.8	4.6
Second Round	2007	4.3	4.9	4.6	4.6
Third Round	2008	4.7	4.6	4.4	4.5

(Rating scale: 1 = not at all satisfied, 2 = barely satisfied, 3 = somewhat satisfied, 4 = satisfied, 5 = very satisfied)
*Mean scores for level of satisfaction on a scale of 1 to 5

The average ratings from respondents indicated that, in general, they were satisfied with the services provided by the DMOs throughout the course of Demonstration (first round = 4.6, second round = 4.6, third round = 4.5). However, overall satisfaction with DMO A increased over the three year study period, whereas overall satisfaction with DMO C decreased. No individual respondent gave a score lower than three to any DMO. In addition, all but one respondent said they would enroll again in their DMO, and would recommend the DMO to a friend.

Across all three DMOs, most respondents said their level of satisfaction had improved during their enrollment in the DMO. Reasons for increased level of satisfaction among respondents included greater acceptance of DMO coverage among providers, an improved understanding of the DMO structure and services, and better access to a greater number of services. A reduction in the costs of medications was also cited as a reason for increased satisfaction. Reasons for decreases in satisfaction included discontinuation of home visits during enrollment and unresolved billing issues over copayments.

For the third round interviews in 2008, respondents were asked whether their individual level of overall satisfaction changed over the time that they had been enrolled in their DMO. Most respondents said their satisfaction had not changed over time because they were satisfied with the DMOs throughout their enrollment. Across all three DMOs, 30% of respondents said that their overall satisfaction changed, with all but one respondent reporting an increased level of satisfaction over time. These results suggest broad satisfaction with the DMOs.

3. Reasons for Disenrolling from the DMOs

Rates of disenrollment varied across all three DMOs. In DMO A disenrollment was 14% in 2006, 20% in 2007, and 15% in 2008. In DMO B disenrollment was 8% in 2006, 10% in 2007, and 17% in 2008. A second round of disenrollment interviews was not conducted for DMO B due to their termination from the Demonstration, announced October 1, 2008 and effective December 31, 2008. In DMO C disenrollment was 15% in 2006, 37% in 2007, and 20% in 2008. The large number of DMO C disenrollees in 2007 was the result of a special election period which was enacted for DMO C in 2007.

The reason for disenrollment was categorized by patient perception of the problem(s) they encountered. During the interviews, respondents were also asked about other potential reasons for disenrollment, including provider issues, problems with scheduling appointments with specialists or other doctors, dissatisfaction with services, availability of services, quality of services, and the costs associated with the DMOs. Based on their experiences, respondents discussed whether any of the aforementioned factors contributed to their decision to disenroll.

The main themes included misunderstandings about the DMO, issues related to costs/billing, problems with providers, and dissatisfaction with DMO services. For each DMO, the "other" category outlines any additional reasons for disenrollment that were mentioned by respondents.

Respondents across all three DMOs cited misunderstandings about the DMOs as the most common reason for disenrolling, with 19 out of 20 respondents (95%) citing this reason in the 2007 first round interviews and all respondents (100%) citing this in the 2009 second round interviews. The second most

common reason for leaving the DMO was issues with cost/billing, with 90% of respondents citing this reason in the first round and 75% citing this reason in the second round. General dissatisfaction with the DMOs' services was cited as an additional reason for disenrolling from the DMOs. Provider issues were the least common reason for disenrollment, with no respondents citing this reason in the first round and only a small percent (8%) citing this reason in the second round. "Other" reasons for disenrollment, e.g. benefits perceived as not different than Medicare, provider recommended disenrollment, negative interaction with DMO staff, were cited by a slightly larger percent of this small sample, 25% in the first round, and 17% of respondents in the second round. During the second round disenrollment interviews, after describing the reasons that they disenrolled, a majority of respondents commented on the helpfulness of the DMO's special services and DMO staff, and expressed that they regretted having to leave the DMO. The percent citing misunderstandings about billings was highest in each DMO in round one, but remained the top reason only for disenrollees in DMO C in the round two interviews.

D. Discussion

1. Most Helpful Services of the DMOs

For DMOs A and B, findings indicated that respondents cited their NCM as the most helpful aspect of the DMOs. Respondents mentioned different aspects of their nurse care manager's services that they valued most, ranging from emotional support to a broader education about health benefits and health needs. For DMO C, over time, a smaller percentage of respondents cited the NCM as the most helpful service. This may be due, in part, to DMO C's de-emphasizing a combination of periodic visits on-site by NCMs, and in turn centralizing all assessments with the call center NCMs beginning in December 2007. However, the expansion of DMO C's telehealth program potentially allowed for more frequent patient assessments.

Medication-related support and services were the next items most commonly listed as helpful. At least one respondent from each of the three DMOs mentioned that the most valuable aspect of the DMO was that it lowered the costs of medication. Other aspects included helping with the delivery of medications to respondents' homes; and helping respondents to manage their medications (i.e., take the right medications at the right time).

A few respondents cited other aspects of their DMO's program as the most helpful. These included access to transportation, lower copayments, medical supplies, health education, and emotional support.

2. Overall Satisfaction with the DMOs

Respondents across all three DMOs gave high ratings of overall patient satisfaction in each of the three rounds, with 96% of respondents in the third round of interviews saying that they would enroll again if given the choice and would recommend the DMO to a friend.

When looking for changes within DMOs in average satisfaction, the ability to draw conclusions in this area is limited. The average satisfaction was over four (on a five-point scale) for all three DMOs in all three rounds of interviews. Additionally, an effort was made to include Spanish speakers in the third round of disenrollee interviews (as a percent of the overall enrollee population for each DMO), which slightly lowered the average satisfaction levels in 2008 as these individuals appeared to be less satisfied with the DMOs than other respondents. In general, although there may be some variation within DMOs, satisfaction appeared similar across all of the DMOs.

Interviews with Spanish-speaking respondents suggested that they were satisfied with the DMO (mean rating = 3.8), but their satisfaction was lower than the satisfaction of English speakers (mean rating =

4.7). Nearly all Spanish-speaking respondents reported receiving DMO materials in Spanish, but none reported having a NCM who could speak more than a little Spanish. Forty-percent of Spanish-speaking respondents cited the limited ability to communicate with DMO staff in Spanish as a direct reason for experiencing a lower level of satisfaction with the DMO. Because a very limited sample of Spanish-speakers was interviewed, it is difficult to determine whether the inability to communicate with a NCM had a widespread impact on the satisfaction of Spanish-speaking respondents. However, within the small sample, satisfaction was clearly lower among this group.

Billing and provider issues had generally become less of a problem over time for respondents in the Demonstration. During the second round interviews, several respondents encountered delayed or limited access to providers primarily due to the fact that providers were not familiar with the DMOs or believed that they were HMOs. Findings from the third round suggest that issues related to billing and access to providers decreased. Although a small number of these problems remained, challenges were resolved quickly by the DMOs' NCMs.

It is important to note that these satisfaction findings represent only respondents who have remained enrolled in their DMOs. As found in the interviews with disenrollees, individuals who had voluntarily disenrolled were generally less satisfied with the DMOs than those who remained enrolled, something that is supported by research studies reporting the existence of an inverse relationship between patient satisfaction and disenrollment [1-3].

3. Reasons for Disenrolling from the DMOs

As shown in Table 13.3, the most common reasons for disenrollment from the DMOs were confusion and misunderstandings about the DMOs and cost/billing issues. Often, the two issues were related: several disenrollees reported receiving unexpected bills for services that they believed were covered by the DMO, or they left the DMO because their preferred provider, specialist, or hospital did not recognize or would not accept the DMO insurance. Other cost and billing issues that arose included medication-related costs. Based on discussions with disenrollees, many of these provider access and cost/billing issues stemmed from a misunderstanding about the DMOs.

Many respondents reported that they did not fully understand how their benefits would change after enrolling in the DMO. It appears that respondents were not given enough information about the DMO during the enrollment process, or potentially did not understand the information communicated to them by the DMO's staff. For example, one reason cited had to do with a misunderstanding that DMO coverage would be a supplement to Medicare. Other respondents expected that ambulance transportation would be covered by their DMO.

A small percent of Spanish-speaking respondents was interviewed in the second round of the disenrollment interviews. Based on responses it appeared that the language barrier may also have exacerbated such misunderstandings. These results, along with the results from the interviews with respondents who remained enrolled, do not explain the extent to which communication challenges affected patients' satisfaction with care due to Spanish being their primary language. However the literature suggests that language, communication, and culture have implications for patients' perception of their care and their overall satisfaction [4, 5]. It is impossible to draw conclusions from these findings, but it points to another area that the DMOs may want to monitor to ensure that beneficiaries have the appropriate information when they enroll in a DMO.

In other cases, confusion or misunderstandings may have been the result of the health care provider's lack of knowledge about the DMOs. For example, numerous respondents were told that their provider, specialist, or hospital would not accept the DMO coverage. Some physicians told respondents that they should re-enroll in traditional Medicare. Based on the interviews, it is possible that these

misunderstandings stemmed from a lack of provider education about the DMOs (i.e., the provider or provider's staff did not know enough about the DMOs, the process for billing and getting reimbursed, how the DMOs differed from traditional Medicare) – rather than a lack of patient education. Additional provider education may also be desirable.

Finally, because of DMO B's termination in the Demonstration, the second round of disenrollment interviews included only two of the three DMOs, reducing the overall number of study participants and is a limitation of this study.

4. Limitations

There are some limitations to these analyses. First, surveys were conducted with a small sample of respondents that may not be representative of all enrollees in the Demonstration. Relatedly this limits the extent to which generalizations can be made based on the responses collected from a small, possibly unrepresentative sample. Finally, DMO B disenrollees were not included in the second round of interviews as DMO B had ceased operations in 2008.

5. Summary

In general, the findings suggest a high level of patient satisfaction throughout the Demonstration among enrollees who remained enrolled in all three DMOs. Billing and provider issues that were causing problems for some beneficiaries appear to have improved and were quickly resolved when they arose. NCMs remained a key aspect of beneficiaries' experience in, and satisfaction primarily with DMOs A and B. For DMO C it remains unclear whether the gradual evolution of conducting most assessments telephonically by the Call-Center NCMs, therefore resulting in reduced in-person interaction with NCMs, may have resulted in a reduction in the percentage of patients citing the NCM as the most helpful service.

The most common reasons for disenrollment across the DMOs remained consistent throughout the Demonstration: confusion and misunderstandings about the DMOs, and cost/billing issues. These findings are also consistent with those of Mobley et al in their study of voluntary disenrollment from MA plans, 2000-2005 [6]. Prior research also suggests that disenrollees tend to be in poorer health [6-9], and indeed, our analysis comparing patients who disenrolled from the DMOs to those who did not disenroll revealed that disenrollees had significantly higher CMS-Hierarchical Condition Categories (HCC) grouper scores.

However, other research, such as by Schlesinger et al found that sicker enrollees were less likely to disenroll versus healthier patients [10]. Poor health status may limit their ability to make an informed decision to leave a health plan and act on that decision. Therefore these qualitative results need to be taken in context in that other factors, such as health status, may also influence voluntary disenrollment. It should be noted, however, that disenrollees from this study also provided positive feedback and high satisfaction with the DMOs despite their decision to leave the DMOs.

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CHAPTER 14: IMPACT ON PROVIDER SATISFACTION

A. Introduction

This chapter presents findings from the provider satisfaction component of the Evaluation and explores provider acceptance of Disease Management. Such acceptance speaks to the feasibility of broader implementation of Disease Management services and may influence health outcomes. The Evaluation assessed provider satisfaction among health care providers who serve Medicare beneficiaries enrolled in the participating DMOs.

B. Methods

1. Data Collection

For each DMO, three types of providers were interviewed: nephrologists, nurse care managers (NCMs), and allied health workers (AHWs - i.e., nurses, social workers, dieticians and other providers serving DMO beneficiaries). Each DMO sent the Evaluation team a list of participating providers. The lists were not independently verified. The strategy for selecting providers to be interviewed was the same for DMOs A and B in the 2007 and 2009 rounds of interviews. Recruitment letters were sent to the full census of providers due to the small population of each provider type. DMO C had a larger population of nephrologists and AHWs. These providers were selected for interviews from stratified random samples of each provider type. Due to the small number of DMO C NCMs, all were selected for recruitment. The same data collection methodology for each DMO C provider type was used in both the 2007 and 2009 rounds of interviews. First round data were collected in the fall of 2007 from a final sample of 40 providers and second round data were collected from a final sample of 33 providers in the winter of 2009.

All interviews were conducted via telephone, and each provider was screened for their eligibility during the initial portion of the interview and before proceeding with the remaining interview questions. NCMs were eligible to participate if they directly worked for the DMO and served beneficiaries in one of the eligible DMO service areas. AHWs and nephrologists were eligible for an interview if they served beneficiaries who were enrolled in the DMO and worked in one of the eligible DMO service areas. Providers were not eliminated based on the amount of time they were involved in the Demonstration.

A semi-structured interview approach was used to assess providers' satisfaction with the DMOs. The advantage of semi-structured interviews is that their conversational nature allows for unanticipated, though often important and relevant, topics to emerge, while critical questions are addressed. DMO protocols across DMOs covered the same themes, but questions were tailored to the features of each DMO and to the different roles of each provider type. All protocols took an average of 30 minutes to complete.

2. Analysis

Due to the qualitative nature of these analyses, as well as small sample sizes, tests for statistical significance are not reported. Data were collected through the use of audio-recording and note taking. The notes were compiled in a database, and were analyzed and coded for central concepts and themes. Questions were meant to elicit qualitative responses, but each protocol included four semi-quantitative questions asking respondents for a discrete rating. Questions asked about the implementation of the

Disease Management program, management of comorbid conditions, quality of life (QoL), health outcomes, and overall satisfaction.

C. Results

1. Perceived Impact of the DMOs on the Management of Comorbid Conditions

Providers were asked to discuss their impressions of the impact of the DMOs on the management of comorbid conditions for enrollees. Providers were also asked to rate the impact of the DMO on the management of comorbid conditions on a scale of 1 to 5, where 1 = no improvement and 5 = much improvement.

Findings for the first and second round interviews showed consistent average ratings from NCM respondents across all DMOs (first round = 3.9; second round = 4.0). Findings from DMO A NCMs were consistent (first round = 3.9; second round = 4.1), while average ratings increased slightly for DMO C NCMs (first round = 3.6; second round = 4.0). However DMO B NCM respondents were not included in second round interviews due to an inability to recruit a sufficient sample size. All of these respondents said that at least a moderate improvement in the management of comorbid conditions occurred after patients enrolled in the DMO. For AHW respondents, overall mean ratings increased from 2007 to 2009 (first round = 2.7; second round = 3.5), as did the mean rating for nephrologists (first round = 2.4; second round = 3.5).

DMO A and DMO C overall showed the largest increase in average ratings from the first to the second round (DMO A first round = 3.6, second round = 4.2; DMO C first round = 2.5, second round = 3.5), while DMO B ratings across all providers essentially remained the same from round one (3.0 and 3.1, respectively), with providers overall still expressing moderate improvement in management of the patient's comorbid conditions. Ratings from DMO A nephrologist respondents dramatically increased in the second round, by 2.3 points on the 5-point scale (first round = 1.7, second round = 4.0). AHW and nephrologist respondents in DMO C similarly gave higher ratings of the DMO for improving management of comorbid conditions. For example, DMO C AHW respondents had an overall low mean rating of 1.8 in the first round, but in round two, DMO C AHW respondents' average rating increased to 3.3. We observed a similar increase for DMO C nephrologist respondents (first round = 2.5, second round = 3.2). DMO B AHW and nephrologist respondents also gave higher ratings in round two, but DMO B nephrologist respondents were more positive in and expressed a perception of moderate improvement compared to AHW respondents who as a group felt there was low improvement.

Across all three DMOs, average ratings for all providers increased (first round = 3.0; second round = 3.6). Specifically, NCM respondents cited education, prevention and early detection services, and care coordination as reasons that the management of comorbid conditions improved (second round = 4.0). Both AHW and nephrologist respondents often acknowledged the NCM as an important contributing factor in the improvement of the management of comorbid conditions. AHW respondents who gave the DMOs positive marks on this measure often reported that the NCM served as additional support for enrollees' needs that are not always addressed by dialysis staff. In addition, a small percent of AHW respondents in 2009 reported that they had seen evidence for improvement in the management of comorbid conditions because of reduced hospitalizations and patients' access to dietary supplements improving protein intake numbers. Those who were less positive saw the NCM's role as redundant with services the dialysis facility was already providing.

Overall, the increase in scores for each provider type suggests that program stabilization may reflect how implementation of Disease Management positively impacted management of comorbid conditions.

2. Perceived Impact of the DMOs on Enrollees' Health Outcomes

Across all three DMOs, providers were asked whether participation in the DMO had improved enrollees' health outcomes. Providers were also asked to provide examples of why they thought that the DMO had improved health outcomes, and were also asked to rate the impact of the Demonstration on health outcomes on a scale of 1 to 5, where 1 = significantly worse and 5 = significantly better.

The average rating from respondents for the improvement in health outcomes in 2009 was slightly higher (second round = 4.2) compared to the average provider rating in 2007 (first round = 3.6). Some respondents said that their perceptions were based on clinical outcomes that they observed for their patients (e.g., lab data), while others discussed specific aspects of the program (e.g., medication management) that they believed impacted enrollees' health outcomes. Across all DMOs and provider types in the 2009 second round interviews, 76% (25/33) of respondents indicated that they observed an improvement in outcomes for their patients. Specifically, 33% (11/33) of respondents in 2009 reported they had seen evidence (e.g., lab data, medical reports etc.) that the DMO caused an improvement in enrollees' health outcomes. About 60% of NCM respondents most frequently cited evidence, followed by 35% of AHW, and nephrologist respondents (10%). Not surprisingly, respondents who reported they had seen evidence rated the improvement in health outcomes as higher than other respondents in their respective DMO; none of these respondents, for example, rated the improvement in health outcomes lower than a four.

In DMO A, the mean rating of nephrologist respondents increased, from 3.0 (no effect on health outcomes) in round one to 4.0 (better health outcomes) in round two. Similar increases in ratings were observed for nephrologist respondents in DMO B and C with these providers saying they perceived better health outcomes. AHW respondents in the second round also appeared to be more positive in how the DMOs were improving health outcomes for patients. For example, in DMO C the average rating increased from 2.9 (virtually no effect on health outcomes) in the first round to 4.0 (better health outcomes) in the second round. DMO B AHW respondents also reported higher ratings in the second round (overall, better health outcomes), while NCM respondents in DMO C gave the DMOs higher ratings in the second round. The average rating for DMO C NCM respondents was almost 1 point higher in 2009 (first round = 3.9, second round = 4.7).

3. Perceived Impact of the DMOs on Enrollees' QoL

Across all three DMOs, respondents were asked whether they believed that the DMO improved QoL for enrollees. Respondents were also asked to explain how and/or provide an example of how beneficiaries' QoL improved, and also to rate the impact of the Demonstration on QoL on a scale of 1 to 5, where 1 = significantly worse and 5 = significantly better.

The average rating from respondents across all DMOs, regarding the impact of the DMOs on enrollees' QoL increased from 2007 to 2009 (first round = 3.5; second round = 4.1). Across all DMOs and provider types, 82% (27/33) of respondents in 2009 discussed specific aspects of the program (e.g., emotional support for patients, care coordination, medication management) that they believed impacted enrollees' QoL. Approximately 6% of respondents felt that the DMO either indirectly or directly improved enrollees' QoL basing their perceptions on clinical outcomes they observed for their patients (i.e. reduced hospitalizations). In most cases, average ratings across all provider types were higher in the second round of interviews. Within each DMO the average rating of nephrologist and AHW respondents, increased by as much as over 1 point (on the 5 point scale), from round one to round two. For example, the average rating for DMO A nephrologist respondents increased from 3.1 to 4.2 and for DMO C nephrologist respondents, from 3.0 to 4.0 by round two. Average ratings increased from 2.7 to 4.1 for AHW respondents in DMO C. However, ratings by DMO C NCM respondents increased only from 4.1 to 4.3, round one and round two, respectively. Providers often mentioned an aspect of care (i.e.

emotional support for patients) they believed made enrollees' lives easier as justification for why they perceived QoL to have improved. Other reasons given for a positive impression of improvements in QoL included citing improvements in enrollees' attitude, and perceptions that patients were able to lead more active lives.

4. Overall Satisfaction with DMOs

In order to assess overall experience and satisfaction with the DMO, respondents were asked: (1) to rate their overall level of satisfaction with the DMOs on a scale of 1 to 5, where 1 = not at all satisfied and 5 = very satisfied; (2) whether their overall experience with the DMO has been positive or negative; and (3) whether their level of overall satisfaction changed over time.

The average rating from respondents in 2009 across all three DMOs indicated that they were generally satisfied with their respective DMOs (second round = 4.3), in comparison to the mean rating for the interviews in 2007 (first round = 3.3). In 2009, 88% (29/33) of respondents described their experience with their respective DMO as positive. A small percentage of respondents had mixed reviews, however, fewer actually described their experience as somewhat negative.

Across all three DMOs, almost half of the respondents in 2009 noted an improvement in program implementation over time, and cited that as a reason for increased satisfaction with the DMO. However, for fourteen of the respondents, overall satisfaction did not change during the duration of the Demonstration. Most respondents reported that they had been consistently satisfied with the DMO. Only 9% of respondents said their overall satisfaction with their respective DMO decreased.

As a group and within DMOs NCMs generally reported higher satisfaction in round one when compared to other provider types. In contrast, two provider groups, DMO nephrologists and AHW respondents respectively, were markedly more satisfied in round two than in round one (nephrologists, round one = 2.9, round two = 4.1; AHWs, round one = 2.7, round two = 4.3). Their average ratings within DMOs increased noticeably in the second round, in some cases by as much as 1.8 points as shown for AHW respondents in DMO C (round one = 2.2, round two = 4.0). DMO A nephrologist respondents in round one overall reported they were barely satisfied (rating = 2.6), but this improved in the second round (rating = 4.3) suggesting as a group they experienced higher satisfaction with the DMO. This may be in part attributed to DMO A adding a Provider Relations Specialist that worked directly with nephrologists to help them better navigate the DMO A billing system and better understand specific DMO benefits offered to enrollees. DMO C nephrologist respondents also reported higher satisfaction in the second round interviews going from barely satisfied in the first round (rating = 2.5) to satisfied in the second round (rating = 4.3). NCM respondents overall reported similar satisfaction in both rounds (round one = 4.3, round two = 4.4). These findings suggest an improvement in overall provider satisfaction from 2007 to 2009.

5. Perceived Issues with DMO Implementation

One of the primary goals of interviewing providers at a second point in time was to assess whether problematic issues surrounding program implementation had been reduced or resolved altogether. In particular, this evaluation examined whether reported problems concerning access to providers and billing diminished from 2007 to 2009.

NCMs play a central role in the DMO and constitute the provider type most closely involved with implementation of the DMO's Disease Management approach. Because each DMO had different implementation changes and strategies in 2009 compared to 2007, each DMO's set of NCM respondents had separate reactions to their DMO's implementation. As such, a broad summary of NCMs' satisfaction with implementation across all three DMOs is not included in this report. For AHW respondents, in 2009

only 28% of respondents reported problems surrounding implementation. This is an area of noticeable improvement in comparison to 2007, when a majority (62%) of AHW respondents reported problems with implementation.

Nephrologist respondents' views on DMO implementation often depended on the respondent's degree of understanding of the DMO. In comparison to DMO NCMs and AHWs, nephrologists are less involved with the implementation aspects of the DMOs. Across all three DMOs, nephrologist respondents were aware that their patients had a NCM and were receiving additional benefits. The degree to which the nephrologist respondent understood the specific benefits and services the DMO provided for its enrollees varied by respondent, but not by DMO. In 2009, nephrologist respondents mentioned few to no problems surrounding implementation. The few problems that were mentioned, however, did not have an effect on this provider type's overall satisfaction. These findings suggest an improvement from 2007, when more nephrologist respondents offered more complaints and in some cases, expressed frustration and dissatisfaction with their respective DMO.

D. Discussion

1. Perceived Impact of the DMOs on Management of Enrollees' Comorbid Conditions, on Enrollees' Health Outcomes, and on Enrollees' Quality of Life

In 2009, provider respondents reported that they believed the DMOs had positively influenced the management of comorbid conditions, and enrollees' QoL and health outcomes, results that are similar to those of several successful programs that focused on care coordination and which showed similar positive impacts on health outcomes [1,2]. Although this study examined perceptions regarding improvements in comorbid conditions, QoL, and health outcomes in separate sections, it is worth noting that respondents perceived them as highly interrelated. Some respondents asserted the belief that an improvement in the management of comorbid conditions and an emphasis on prevention invariably leads to better QoL, which they felt in turn increased patient adherence (i.e., medication adherence, dialysis attendance, etc.). The result they perceived was an improvement in health outcomes which also reinforced improved QoL. An improvement in health outcomes and QoL may also encourage a patient to better manage their comorbid conditions.

2. Overall Satisfaction with the DMOs

For the second round of interviews in 2009, the vast majority, 88% (29/33) of providers interviewed said they had a positive experience with the DMOs. Differences in provider satisfaction among the DMOs were minimal, as were differences in satisfaction among different provider types. In the second round of interviews, each provider type within each DMO had a mean satisfaction score of at least four out of five. In some cases, this represents a notable improvement in provider satisfaction from first round findings. Because of these individual DMO improvements, provider satisfaction taken together across all the DMOs has improved.

It appears that NCM/Call Center NCM respondents are generally satisfied with their experience working for these DMOs, and believe they are making a difference in patient care. In general, these providers were already satisfied with the DMOs in the 2007 provider interviews. Reviews were more mixed among other providers in 2007, but AHW and nephrologist respondents in 2009 gave similarly positive reviews of the DMOs. Whereas a few nephrologists were dissatisfied with their respective DMOs in 2007, we found no evidence of nephrologist respondents being dissatisfied in 2009.

3. Limitations

There are several limitations to these analyses. First, surveys were conducted with a small unrepresentative sample of providers. This limits the extent to which generalizations can be made based on provider responses. Next, the second round of interviews with providers was conducted with a different set of respondents from the first round in 2007. This is regarded as a limitation in that trends or changes cannot be inferred from the 2007 round which involved a different set of respondents from different DMO service areas. Third, due to recruitment ineligibility, no DMO B NCMs were included in the second round of interviews. Finally, the point ranking system utilized in the various provider assessments are relative changes in preference or perception and therefore qualitative rather than actual quantitative measurements of differences.

4. Summary

Provider acceptance is one element of the feasibility of broader implementation of Disease Management services. The findings of these provider satisfaction interviews imply two key lessons learned for any such endeavor. First, careful logistical planning involving the multiple payers responsible for beneficiaries with ESRD (Medicare, Medicaid, employers, and other supplemental insurance) will be required to minimize billing issues. Provider education also seemed to help smooth out some of the initial implementation problems that enrollees and providers were experiencing. Second, providers are interested in feedback on how Disease Management is helping their patients. If DMOs communicate data back to providers and if those data show positive outcomes for enrollees, providers are more likely to accept the program.

Finally, findings from these provider satisfaction interviews indicate that it can take a significant amount of time for programs to reach a steady-state level that might best reflect what implementation would look like on a broader scale.

E. References

1) Peikes D, Chen A, Schore J, Brown R. Effects of care coordination on hospitalization, quality of care, and health care expenditures among Medicare beneficiaries: 15 randomized trials. JAMA. 2009; 301: 603-18.

2) Sands, JJ. Disease management improves ESRD outcomes. Int J Artif Organs. 2006; 29: 154-9.

CHAPTER 15: COST ANALYSIS

A. Introduction

The three DMOs participating in the End-Stage Renal Disease (ESRD) Disease Management Demonstration operate as Medicare Advantage (MA) Plans and receive capitated payments based on the Centers for Medicare & Medicaid Services Hierarchical Condition Categories (CMS-HCC) risk-adjusted ESRD payment model for delivering all Medicare covered services and any additional benefits that are offered in their benefit package.

This chapter evaluates two research questions. First, did CMS pay more or less for DMO enrollees than it would have paid if those beneficiaries had remained in the traditional fee-for-service (FFS) setting? Second, did the DMO enrollees have lower utilization than they would have had if they had remained in the traditional FFS setting, and what are the estimated savings or costs from any differences in utilization?

The first question involved a comparison of capitated payments from CMS to the DMOs (per patient per month) to the estimated costs CMS would have incurred had the DMO enrollees remained in the traditional FFS sector. To address the second question, the savings or costs accruing to the DMO were estimated from utilization of specific services compared to FFS as the product of the differential utilization and the average FFS cost for these services.

B. Methods

Patients who enrolled in a DMO at any time from January 1, 2006 through December 31, 2008 were considered for inclusion in these analyses. Patients in traditional Medicare FFS in the states in which the Demonstration operated with Medicare as their primary payer were considered for the comparison groups. We excluded patient-months in whom DMO patients had Medicare as a secondary payer (2.65% patient months). Follow-up time was restricted to months in which patients received hemodialysis (HD) for the entire month, consistent with methodology used for the analyses evaluating clinical outcomes (Chapter 11).

1. Costs to Medicare

The first analysis addressed the following research question:

> *Did CMS pay more or less for DMO enrollees than it would have paid if those beneficiaries had remained in the traditional FFS setting?*

This question involved a comparison of capitated payments from CMS to the DMOs to the estimated costs CMS would have incurred in the traditional ESRD FFS sector. The capitated payment is by design, an overpayment, and quantification of how much excess Medicare paid versus the estimated costs of these patients had they remained in FFS is a relevant question. Propensity score matching was used to identify a comparison FFS population to minimize the impact of selection bias that may have influenced results of the evaluation [2] and second-stage multivariate regression modeling was used to adjust for any remaining differences in observed factors. This second-stage multivariate regression model adjusted for the same demographic and clinical variables used in the propensity score model and these adjustments are presented in Table TA 3a-c in the Technical Appendix. See the Technical Appendix for a more detailed explanation of the propensity score matching methodology.

Capitated payments by Medicare for each DMO enrollee were obtained from the Monthly Membership Report (MMR) data provided by CMS. During the analysis period all three DMOs participated in a related quality incentive payment (QIP) project, which involved a five percent withhold in payment that can be earned back by the DMOs based on achievement of clinical targets. This five percent withhold was already deducted from the capitated payment data used in this report, so the actual capitation payments may be higher than what are presented in the analyses, the extent to which depends on the degree to which each DMO met the QIP targets.

The estimated costs to Medicare for each DMO enrollee, had they remained in FFS, were based on Medicare claims data from the FFS comparison group. We used linear regression on the FFS comparison group to calculate the effects of demographic, coverage, utilization, and clinical variables on costs (obtained from Medicare FFS claims data). We applied the results of this regression to the DMO patients to estimate the costs to Medicare had they remained in FFS instead of enrolling in the Demonstration. Applying the point estimates of the linear regression derived from the FFS population to the DMO patients allowed us to account for any residual variation that remained after the use of the propensity score matching. Finally, we compared the capitated payments by Medicare to the DMOs to the estimated costs to Medicare had these patients remained in FFS.

2. Estimated Savings to DMOs from Utilization Differences

The second analysis addressed the following research question:

> *Did the DMO enrollees have lower utilization than they would have had if they had remained in the traditional FFS setting? What were the estimated savings or costs that accrued to the DMOs due to differences in utilization?*

We compared utilization of selected services among in-center HD patients in each DMO to a set of propensity score matched FFS control groups who were observed to have a similar propensity for enrolling in a DMO. Please see the Technical Appendix for a comparison of the FFS matched samples and the DMO patient populations as well as additional details on the propensity score matching methodology. Although months in which a patient transitions between HD and other modalities may still be under the clinical responsibility of the DMO, partial HD months were excluded to ensure that differences in utilization measures were not due to the transition to another renal replacement modality. Thus, follow-up time for all utilization analyses was restricted to months in which patients received HD for the entire month. Months when DMO patients had Medicare as a secondary payer, which were 2.65% of patient-months in the Demonstration, were also excluded from the analysis since comparison FFS data on service utilization (e.g. hospitalization) will likely not capture the entirety of the experience of these patients.

Utilization services that we evaluated included hospital admissions, total hospital days, hospital readmissions within 30 days, length of stay (LOS), physician visits, emergency department (ED) visits, and SNF stays. ED visits that resulted in an inpatient stay were excluded from the ED visit metric to avoid double counting with the hospitalization metrics. We used nine multiple logistic regression models to select the matched control patients from the FFS population for each DMO and year on baseline demographic and clinical characteristics that impact on a patient's probability of enrolling into a DMO (propensity score method). To account for residual differences remaining after the propensity-score methodology, a second-stage multivariate regression adjustment was performed using a negative binomial regression model. We also examined Poisson regression models (with correction for over-dispersion) and found similar results. As described in further detail in the Technical Appendix, both methods are commonly used for count data such as service utilization. The negative binomial regression results are shown because these models generally fit the data better.

Since the goal of this aspect of the cost evaluation was to compare the costs incurred by patients in the DMOs assuming the same cost structure as fee-for-service, the estimated savings or costs to the DMOs for each metric were estimated by multiplying the difference in service utilization (i.e., FFS rate minus the DMO rate) by the average cost of the service observed in each DMO's FFS comparison group. Because the costs per service are derived from unique FFS comparison groups selected to match the patient characteristics of each DMO each year, the FFS cost estimates for each service differ by DMO and year. Table TA-2 in the Technical Appendix presents the average FFS cost service in the Medicare FFS claims data for each of the unique comparison groups.

Because average cost per unit of service and the patient populations in each DMO varied across years, aggregated costs/savings for the three year period were calculated as the average of the estimated costs/savings in 2006, 2007, and 2008, weighted by the number of patients enrolled in each year.

This analysis assumed that DMOs paid the cost of hospitalization as a flat rate, in which additional hospital days or reduced hospital days did not change the costs to the DMOs. For this analysis, we used the average cost per hospitalization and ignored the impact of LOS. Thus, estimated savings from utilization of services were the sum of the estimated savings associated with admission rates, SNF stays, ED visits and physician visits, but ignores costs associated with LOS and total hospital days. Utilization rate differences for each of the aforementioned services were included in the calculation of estimated savings or costs regardless of statistical significance.

To validate the reliability of the propensity-score matched FFS samples, we selected a total of five samples and assessed utilization differences for all five samples. The results were similar regardless of which sample was used for the analysis; the first sample drawn is shown in this report (results from the other four samples are not shown). For additional details on the improvement in comparability between the DMOs and respective FFS propensity score matched comparison populations, please see the Technical Appendix.

C. Results

There were few differences in patient characteristics between the DMOs and propensity-score matched FFS groups (Please see Table TA-3 in the Technical Appendix). One exception was that more DMO patients were new enrollees (17.8% vs. 9.9%, DMO and FFS, respectively, $p < 0.01$). (See the Technical Appendix for more detail, which includes a pre-post matching comparison of differences in propensity score distribution and standardized differences for demographic and clinical variables.) Differences across DMOs were also observed, emphasizing the importance of analyzing the DMOs as individual programs rather than pooling these into one aggregate population.

1. Costs to Medicare

Table 15.1 compares the difference in cost to the Medicare program between the Demonstration and FFS. The DMO mean cost per month is the average monthly capitated payment in each DMO by year. The FFS mean cost is the estimated cost of care had the DMO enrollees remained in traditional FFS. Overall, across all three DMOs and all three years of the evaluation period, the monthly capitated payment for patients in the Demonstration was higher, at $6,551 per patient per month, when compared to the estimated cost if they had remained in FFS at $5,776 per patient per month, representing a mean difference of $774 per patient per month. This difference represented a 13.4% higher cost of the Demonstration to Medicare overall. The total mean capitated payments per month across all three years was higher in each DMO than the estimated FFS cost, at 11.2% in DMO A, 10.9% in DMO B and 14.7% in DMO C. These figures are consistent with a prior MedPAC report which suggests that payment for MA plans exceed FFS by 11% on average [1]. The greater difference between DMO C,

a private-fee-for-service (PFFS) plan and FFS is similarly consistent with prior MedPAC analysis demonstrating up to 19% excess payments to PFFS MA Plans as compared to traditional FFS [1]. For DMO C, the percent difference in capitated payments from the FFS estimated costs decreased between 2006 and 2008. No similar pattern was observed in DMOs A and B. As a group, the DMOs were 12.0 % more costly than FFS in 2006; however, this increased to 16.7% in 2007 then decreased to 10.4% by 2008.

Table 15.1: Costs to the Medicare Program, Difference between Capitated Payments to the DMOs and Estimated FFS Costs, by DMO and Year

	DMO Enrollees		Mean Cost per Month		Difference (DMO-FFS)				P-value
					Mean	% of FFS	95% CI		
	N	Months	DMO[a]	FFS			Lower	Upper	
All DMOs									
Total	3,604	30,476	$6,551	$5,776	$774	13.4%	$714	$835	< 0.01
2006	849	5,572	$6,388	$5,704	$685	12.0%	$548	$821	< 0.01
2007	1,538	13,472	$6,521	$5,587	$934	16.7%	$843	$1,025	< 0.01
2008	1,217	11,432	$6,665	$6,036	$630	10.4%	$529	$730	< 0.01
DMO A									
Total	1,065	9,114	$6,872	$6,179	$693	11.2%	$562	$824	< 0.01
2006	242	1,836	$6,678	$5,769	$909	15.8%	$642	$1,176	< 0.01
2007	408	3,505	$6,788	$6,119	$669	10.9%	$459	$879	< 0.01
2008	415	3,773	$7,044	$6,279	$765	12.2%	$548	$983	< 0.01
DMO B									
Total	439	4,048	$5,739	$5,176	$563	10.9%	$413	$714	< 0.01
2006	78	552	$5,304	$4,982	$322	6.5%	-$20	$664	0.07
2007	170	1,607	$5,694	$4,978	$716	14.4%	$502	$930	< 0.01
2008	191	1,889	$5,905	$5,458	$448	8.2%	$194	$701	< 0.01
DMO C									
Total	2,100	17,314	$6,571	$5,728	$844	14.7%	$768	$919	< 0.01
2006	529	3,184	$6,409	$5,555	$854	15.4%	$690	$1,018	< 0.01
2007	960	8,360	$6,568	$5,510	$1,058	19.2%	$953	$1,163	< 0.01
2008	611	5,770	$6,666	$6,105	$561	9.2%	$417	$705	< 0.01

Abbreviation: FFS = Fee-for-Service

This table compares the capitated costs of DMO enrollees to their cost were they in the FFS sector. Cost is prior to any adjudication due to risk sharing.

[a] Due to the DMOs participation in a quality incentive payment (QIP) project, the costs in the Demonstration setting (capitated payments to DMOs) are only 95% of the standard Medicare Advantage payment rates for ESRD patients.

2. Estimated Savings to DMOs from Utilization Differences

Table 15.2 shows overall differences in utilization of select services across all DMOs as a percentage of utilization in the FFS control group. Table 15.2a presents differences in utilization measures based on propensity-score matching only and Table 15.2b presents utilization differences after second-stage regression analyses. Please see the Technical Appendix for more detailed description of these analyses.

Although patterns of hospital admissions differed by DMO, pooled DMO data indicate that hospital admissions were not significantly different for the DMOs compared with FFS. Across all three DMOs, LOS and total hospital days were generally significantly higher compared to FFS. However, it is likely that the DMOs negotiated flat hospitalization rates with their providers and metrics taking into account hospital days may be less valuable in this evaluation. Utilization was generally significantly lower than the matched FFS control groups throughout the Demonstration for SNF stays and physician visits. For the pooled DMO analysis over the three-year evaluation period, readmission rates were significantly higher, with different patterns noted by DMO. No comparisons of ED visits between the DMOs and FFS were significantly different after second-stage adjustment.

Table 15.2a: Propensity-Score Matched Utilization Measures, Difference between DMO and FFS, as a Percentage of FFS, by Year

	DMO A				DMO B				DMO C				All DMOs			
	2006	**2007**	**2008**	**All**	**2006**	**2007**	**2008**	**All**	**2006**	**2007**	**2008**	**All**	**2006**	**2007**	**2008**	**All**
Hospital Admissions[a]	+8%	+10%	+1%	+6%	+17%	-4%	+17%	+10%	-6%	-2%	**-12%**	**-7%**	-2%	+0%	-3%	-1%
Total Hospital Days	**+15%**	**+32%**	**+24%**	**+26%**	**+74%**	**+17%**	**+75%**	**+54%**	**+8%**	**+21%**	**+12%**	**+15%**	**+15%**	**+23%**	**+25%**	**+23%**
Readmission[b]	+3%	+18%	+12%	+14%	**+91%**	-4%	**+51%**	**+40%**	-9%	-3%	-19%	-10%	-2%	+2%	+1%	+1%
LOS	+7%	**+20%**	**+23%**	**+18%**	**+48%**	**+22%**	**+49%**	**+40%**	**+16%**	**+24%**	**+28%**	**+24%**	**+17%**	**+23%**	**+29%**	**+24%**
Physician Visits	**-49%**	**-37%**	**-15%**	**-30%**	**-18%**	**-22%**	-10%	**-14%**	**-17%**	**-18%**	**-27%**	**-20%**	**-28%**	**-23%**	**-21%**	**-23%**
ED Visits	-24%	-7%	**-20%**	**-15%**	+9%	-11%	**-24%**	**-14%**	-4%	+5%	-3%	+1%	-8%	+0%	**-11%**	-6%
SNF Stays	**-41%**	**-36%**	-22%	**-32%**	+12%	-51%	+7%	-13%	**-57%**	**-57%**	**-49%**	**-53%**	**-47%**	**-52%**	**-34%**	**-44%**

Abbreviations: ED = Emergency department; FFS = Fee-for-Service; LOS = Length of stay; SNF = Skilled nursing facility

Note: Table 15.2a provides analysis also presented in Table 11.6a of this report

Positive number mean higher utilization in the Demonstration; negative numbers mean lower utilization in the Demonstration (relative to the matched FFS control group). **Bold** text indicates significant difference from FFS ($p < 0.05$). ALL = 2006-2008.

[a] Defined as readmissions within 30 days of discharge.

[b] Includes readmissions within 30 days of discharge.

Table 15.2b: Second-Stage Adjusted Utilization Measures, Difference between DMO and FFS, as a Percentage of FFS, by Year

	DMO A				DMO B				DMO C				All DMOs			
	2006	**2007**	**2008**	**All**	**2006**	**2007**	**2008**	**All**	**2006**	**2007**	**2008**	**All**	**2006**	**2007**	**2008**	**All**
Hospital Admissions[a]	+5%	+6%	+17%	+9%	+7%	+0%	+24%	+12%	-2%	+2%	-8%	-3%	+1%	+4%	+4%	+3%
Total Hospital Days	-13%	+20%	+29%	+16%	+42%	+29%	**+60%**	**+47%**	+14%	+16%	+12%	**+15%**	+12%	**+20%**	**+27%**	**+20%**
Readmissions[b]	+23%	+15%	+37%	+21%	**+119%**	+16%	+65%	**+57%**	**+37%**	+6%	-11%	+6%	**+41%**	+11%	+13%	**+16%**
LOS	+3%	+7%	+4%	**+6%**	+11%	**+15%**	**+13%**	**+14%**	**+11%**	**+9%**	**+12%**	**+11%**	**+8%**	**+10%**	**+11%**	**+10%**
Physician Visits	**-51%**	**-31%**	-11%	**-29%**	-14%	**-20%**	-10%	**-15%**	**-15%**	**-16%**	**-19%**	**-18%**	**-26%**	**-20%**	**-16%**	**-20%**
ED Visits	-20%	+2%	-10%	-8%	+3%	-17%	-14%	-12%	+2%	+2%	-4%	-1%	-3%	-1%	-7%	-4%
SNF Stays	-36%	**-48%**	-3%	**-34%**	-43%	**-70%**	+20%	-28%	**-49%**	**-59%**	**-43%**	**-53%**	**-42%**	**-55%**	-24%	**-45%**

Abbreviations: ED = Emergency department; FFS = Fee-for-Service; LOS = Length of stay; SNF = Skilled nursing facility

Note: Table 15.2b provides analysis also presented in Table 11.6b of this report

Positive number mean higher utilization in the Demonstration; negative numbers mean lower utilization in the Demonstration (relative to the matched FFS control group). **Bold** text indicates significant difference from FFS ($p < 0.05$). ALL = 2006-2008.

[a] Defined as readmissions within 30 days of discharge.

[b] Includes readmissions within 30 days of discharge.

Table 15.3a presents the estimated savings/costs accruing to DMOs from the observed utilization differentials in the use of propensity-score matched adjustments as shown in Table 15.2a. Table 15.3b presents the estimated savings/costs accruing to DMOs from the estimated utilization differentials using the second-stage adjusted utilization rates as shown in Table 15.2b. As described in the methods section, costs associated with LOS and total hospital days were ignored in this analysis, and services included were limited to hospital admissions, SNF stays, ED visits, and physician visits. It should be noted that the estimates presented included utilization differentials that were not statistically significant.

Cost analyses using the propensity score methodology (Table 15.3a) and the second stage regression (Table 15.3b) generally yielded similar conclusions. Overall, both DMO A and DMO B experienced losses relative to FFS based on differences in service utilization while DMO C experienced savings throughout all three years of the Demonstration. In general savings or losses to the DMOs were driven by the differences in hospital admissions and, to a lesser extent, the differences in SNF stays. As such, it is important keep in mind that the calculation of estimated savings to the DMOs were at least in part based on differences in utilization that were not statistically significant. Including these non-significant differences, particularly hospital admission costs, had a large impact in the calculation of overall estimated savings/costs.

Table 15.3a: Estimated Savings to DMOs due to Differences in Utilization from FFS*

Service	Estimated Savings per Patient per Year											
	DMO A				DMO B				DMO C			
	2006	2007	2008	2006-2008	2006	2007	2008	2006-2008	2006	2007	2008	2006-2008
Hospital Admissions	-$1,951	-$2,624	-$391	-$1,564	-$3,097	$769	-$3,655	-$1,822	$1,411	$490	$3,238	$1,575
SNF Stays	$956	$944	$506	$765	-$73	$723	-$102	$229	$983	$1,295	$1,231	$1,217
ED Visits	$146	$50	$211	$136	-$90	$136	$269	$167	$33	-$43	$35	-$3
Physician Visits	$336	$280	$119	$224	$77	$104	$56	$78	$96	$118	$192	$139
Est. Total Savings	-$513	-$1,349	$445	-$438	-$3,183	$1,732	-$3,432	-$1,348	$2,523	$1,860	$4,695	$2,927
Est. Total Savings %	-0.6%	-1.7%	0.5%	-0.5%	-5.0%	2.5%	-4.8%	-2.0%	3.3%	2.4%	5.9%	3.7%

Service	Estimated Savings per Patient per Year			
	All DMOs			
	2006	2007	2008	2006-2008
Hospital Admissions	$491	-$94	$884	$380
SNF Stays	$844	$1,180	$783	$970
ED Visits	$66	-$2	$128	$59
Physician Visits	$165	$156	$147	$155
Est. Total Savings	$1,567	$1,240	$1,943	$1,563
Est. Total Savings %	2.0%	1.6%	2.4%	2.0%

Abbreviations: ED = Emergency department; FFS = Fee-for-Service; SNF = Skilled nursing facility

*This analysis assumes a flat payment rate for hospitalization and ignores the impact of LOS in the calculation of estimated total savings. Positive dollar amounts represent estimated savings to the DMO; negative amounts, losses. Estimated savings are calculated as the difference between FFS and DMO utilization, multiplied by the FFS cost per unit of utilization. LOS and total hospital days are excluded from this calculation. Finally, estimated total savings are expressed as a percentage of Medicare payment to DMOs.

Table 15.3b: Estimated Savings to DMOs due to Differences in Second-Stage Adjusted Utilization from FFS*

Service	Estimated Savings per Patient per Year											
	DMO A				DMO B				DMO C			
	2006	2007	2008	2006-2008	2006	2007	2008	2006-2008	2006	2007	2008	2006-2008
Hospital Admissions	-$1,311	-$1,945	-$5,040	-$3,098	-$1,486	-$21	-$5,962	-$2,993	$376	-$408	$2,521	$712
SNF Stays	$819	$2,203	$108	$1,057	$1,101	$1,948	-$320	$774	$968	$2,247	$1,354	$1,714
ED Visits	$131	-$14	$109	$66	-$28	$355	$151	$208	-$13	-$20	$59	$7
Physician Visits	$337	$224	$81	$188	$57	$99	$59	$75	$86	$104	$130	$109
Est. Total Savings	-$24	$469	-$4,742	-$1,788	-$355	$2,382	-$6,071	-$1,936	$1,417	$1,922	$4,064	$2,543
Est. Total Savings %	0.0%	0.6%	-5.6%	-2.2%	-0.6%	3.5%	-8.6%	-2.8%	1.8%	2.4%	5.1%	3.2%

Service	Estimated Savings per Patient per Year			
	All DMOs			
	2006	2007	2008	2006-2008
Hospital Admissions	-$209	-$955	-$1,141	-$888
SNF Stays	$837	$1,984	$639	$1,270
ED Visits	$26	$6	$90	$41
Physician Visits	$150	$131	$106	$125
Est. Total Savings	$804	$1,166	-$306	$547
Est. Total Savings %	1.0%	1.5%	-0.4%	0.7%

Abbreviations: ED = Emergency department; FFS = Fee-for-Service; SNF = Skilled nursing facility

*This analysis assumes a flat payment rate for hospitalization and ignores the impact of LOS in the calculation of estimated total savings. Positive dollar amounts represent estimated savings to the DMO; negative amounts, losses. Estimated savings are calculated as the difference between FFS and DMO utilization, multiplied by the FFS cost per unit of utilization. LOS and total hospital days are excluded from this calculation. Finally, estimated total savings are expressed as a percentage of Medicare payment to DMOs.

A. Discussion

Our analyses revealed that across all three DMOs and all three years, capitated payments for DMO enrollees cost Medicare 13.4% more than had they remained in FFS. Such differences were observed for each DMO for each year. These findings are not surprising given that prior reports from the Medicare Payment Advisory Commission (MedPAC) demonstrate that the CMS negotiated rate is approximately 11% more for MA enrollees as compared to beneficiaries with a similar health risk profile in traditional Medicare FFS [1]. As such, our findings are consistent with reported payment differences among non-ESRD MA Plans.

1. Costs to Medicare

Due to the clinical severity of ESRD, recipient costs in both the DMO and FFS settings are much higher than the mean cost for all Medicare beneficiaries — averaging more than $5,000 per patient per month. The overall additional Medicare cost of the Demonstration of 13.4 percentage points therefore translated to an additional monthly cost of $774 per patient per month. Given the approximately 30,476 patient-months in the Demonstration, total additional cost was estimated at approximately $23.5 million. That the Medicare capitated payments for DMO enrollees exceeds spending on FFS beneficiaries of similar propensity for DMO enrollment based on demographic and risk profiles in the traditional fee-for-service program is not surprising. Studies of the broader Medicare capitation program (currently named Medicare Advantage) have found similar results. A Medicare Payment Advisory Commission (MedPAC) report estimated that CMS pays 11% more for Medicare Advantage enrollees than it would have paid on their behalf had they remained in the traditional Medicare FFS setting after adjusting for health risk and demographic factors [1]. The MedPAC report estimates that private-fee-for-service plans (PFFS) are paid even more relative to traditional FFS at 19% [1]. As such, the 14.7% excess observed for DMO C, a PFFS plan, is comparably less than previously reported. Given that the capitation payment methodology used for this Demonstration was identical to that used for the broader Medicare Advantage program; it seems consistent that the Demonstration also yielded net costs rather than achieving Medicare savings.

2. Estimated Savings to DMOs from Utilization Differences

Our estimates of savings and losses were derived from differences in service utilization. As such, our cost estimates are subject to the same strengths and limitations of the utilization analyses presented in Chapter 11 (Patient outcomes). Results of the utilization analyses and cost analyses revealed that hospitalization metrics differed by DMO. Overall, both DMO A and DMO B experienced losses relative to FFS based on differences in service utilization while DMO C experienced savings throughout all three years of the Demonstration, with the magnitude of savings appearing to increase over time. These findings should be interpreted with caution since estimates of cost- savings or losses to the DMOs were driven by differences that in most cases were not statistically significant in hospital admissions and, to a lesser extent, the difference in SNF stays. In addition, it should be noted that costs should not be compared across DMOs. The costs per service are derived from unique FFS comparison groups selected to match the patient characteristics of each DMO, and therefore only differences in costs between DMO and each respective FFS comparison group can be evaluated.

Additional cost analyses will be conducted by CMS based on audited cost data from the DMOs in the future. These analyses will provide more evidence regarding savings or losses and assessment of DMO viability in the long-term.

As discussed in Chapter 11, a potential explanation for the reduced hospital admission rates over time and what appears to be increased estimated savings associated with hospitalization for DMO C may in part be due to its use of treatment interventions in addition to care coordination, prevention, and

improvement of self-care behavior. DMO C's program appeared to be more aggressive and individual interventions (e.g. use of oral nutritional supplementation) were found to contribute to improved patient survival. Other potential explanations for the limited financial impact in DMOs A and B include the following: 1) operational changes in DMO A and DMO B's programs may have limited their potential impact; 2) the structure of the DMO interventions with an emphasis on improving processes of care measures and care coordination may not translate to reduction in hospitalization-related costs; and 3) differences in program design and their impact on degree of interaction between patients and members of the Disease Management team may have resulted in variations in reduction in hospitalization rates among the DMOs.

3. Limitations

Several limitations need to be pointed out in our analyses. The DMO populations for some analyses were relatively small. For example, fewer than 100 patients were enrolled in DMO B at any time during 2006. This can lead to insufficient statistical power to detect differences that may be relevant to patients, clinicians, and policy makers. There was no random assignment of patients to DMO treatment, so statistical adjustment was used to compare DMO populations to the more general FFS populations. Statistical adjustment allows for a more fair comparison, but relies upon measuring of all variables that may differ between the populations and be causally associated with the outcomes of interest. While these analyses adjust for a wide set of demographic and clinical variables, unmeasured variables due to the lack of available data always represent a potential limitation in observational studies.

The propensity score matching methodology used in this study attempts to measure what the costs and utilization of DMO enrollees would have been if they had instead been treated in the FFS setting. This was accomplished in part by defining a comparison group of patients treated in a FFS setting who were observed to have a similar propensity for enrolling in a DMO as the DMO enrollees. A potential limitation of this type of approach is that despite the level of balance that was achieved between DMO and FFS groups based on measured characteristics, the matching process may not balance DMO and FFS groups based on unmeasured confounders. For example, this could occur if there are unmeasured differences between DMO and FFS groups which are correlated with the measured predictors and outcomes of interest. As with other studies that use a similar methodology in the absence of experimental data, the comparisons between DMO and FFS groups in this study could be biased if such unmeasured differences between the groups are also associated with the outcomes (e.g., costs and service utilization). In the current context, we attempted to minimize this risk by calculating propensity scores that reflect a relatively broad set of patient factors related to demographics, insurance, ESRD treatment, prior utilization, other clinical indicators, and geographic region. Furthermore, we performed a second-stage multivariate regression to adjust for residual differences between the DMO and propensity-score matched comparison populations.

Another limitation of using the propensity score matching and second-stage regression analysis is the reduced statistical power to identify statistically significant effects of the Demonstration due to limiting the FFS sample to the number of patients in the Demonstration. These analyses used a one-to-one match which is the most common implementation of the propensity score method [10]; while it is possible increasing the number of FFS patients included in the analyses by using a many-to-one match would increase statistical power, it is unclear how many matches would be required. Furthermore, many-to-one matching may require additional exclusions from the Demonstration sample for patients who cannot be matched to multiple FFS patients. One-to-one matching identified several statistically significant differences. Simulations to reduce the size of confidence intervals around estimates of FFS utilization rates revealed limited benefits of more complex matching strategies.

Estimates of savings to the DMOs developed from the utilization analyses were not based on actual costs as reported by the DMOs. Instead, we estimated costs of DMO enrollees by applying the cost per

unit observed in the FFS group. By design, this methodology was utilized since the goal of this analysis was to compare the costs incurred by DMO patients assuming the same cost structure as FFS. Actual costs of services to DMOs are likely to be different as these are based on negotiations between the DMOs and the various providers.

DMOs also have non-medical costs and must be profitable to remain financially viable. This cost evaluation did not take into account the cost structure of the various DMOs, as the audited data were not available. Therefore the overall impact of the program on each DMO's financial viability cannot be assessed at this time. CMS will examine this issue when the audited data become available.

Finally the calculation of savings to the DMOs due to differences in utilization included utilization differentials that in most cases were not statistically significant.

4. Summary

In the ESRD Disease Management Demonstration, these analyses indicate that CMS paid more under the Medicare Advantage program than it would have paid on behalf of the same beneficiaries in the FFS setting. The finding that Medicare's payments under the Demonstration were above the costs that would have occurred in the FFS setting is consistent with previous studies of broader Medicare managed care programs [7, 8] and the earlier ESRD Managed Care Demonstration [9]. The analyses conducted herein showed variations in the impact of Disease Management on hospitalization metrics. In one DMO (DMO C), an apparent reduction in hospitalization rates over time, and reduction in utilization of other services translated to cost savings. Across all DMOs, a significant reduction in physician visits, and SNF stays was observed. Overall, estimated medical cost savings for the services considered in this analysis occurred relative to the FFS setting in one DMO.

Possible explanations for these findings include: 1) variations in DMO design may have resulted in differences in cost impact of Disease Management, with DMO C's treatment interventions translating to greater benefit; and 2) coordination of care as the primary intervention of Disease Management may be insufficient in reducing hospitalization utilization and costs in this population with a high level of patient morbidity.

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CHAPTER 16: SUMMARY AND CONCLUSION

Management of end-stage renal disease (ESRD) is associated with significant patient morbidity and mortality, resulting in significant costs to the Medicare program. In 2007 there were 387,429 patients with ESRD and Medicare as primary payor (1.2% of the Medicare primary payor population); the ESRD program accounted for a disproportionate 5.8% of the entire Medicare budget [1]. ESRD patients often have multiple comorbidities, which results in increased complexity of their care that includes the management of their renal replacement therapies, daily decisions about fluid and dietary intake, medication use, and overall comorbidity management. Clinical care occurs across various settings, including dialysis facilities, outpatient clinics, inpatient hospital settings, emergency department (ED) visits, and skilled nursing facilities (SNFs).

The ESRD Disease Management Demonstration sought to evaluate whether Disease Management Organizations (DMOs) in the setting of Medicare Advantage (MA) Plans could improve clinical outcomes and reduce Medicare expenditures. Disease Management interventions aim to improve care coordination and enhance implementation of evidence-based care, in turn translating to better patient adherence, improved quality of care, and subsequent reduction in the utilization of costly services. This final report presents results from a comprehensive clinical and financial evaluation of the first three years of a five year Demonstration of the participating DMOs that designed Disease Management programs for the ESRD population.

Key Findings of this Demonstration Evaluation are as follows:

Patient Selection:

- Clinical and demographic differences were noted in the comparison between the Demonstration population and the comparison groups.
- Comparisons of clinical and demographic characteristics between the DMO and FFS populations in the states where the DMOs operated show that DMO patients tend to be younger, included a greater percent of Hispanic or Latino enrollees (DMO A and B), had longer duration of ESRD, and were more likely to have a previously failed transplant.
- In DMO A and DMO C the DMO and FFS populations had similar levels of comorbidity as measured by the CMS Hierarchical Condition Categories (HCC) risk score. Patients in DMO B had significantly higher CMS-HCC risk scores compared to FFS patients in the same states.
- These potential confounding factors were taken into account by performing statistical adjustments in our analytical models.
- Within the Demonstration population, differences existed between enrollees and voluntary disenrollees, with the latter tending to be in poorer health as measured by the CMS-HCC risk score.
- For some analyses, we compared the DMO population with a propensity-score matched comparison group.

Improvement in several processes of care measures:

- For example, in DMO A the proportion of patients with diabetes mellitus (diabetes) who received foot and retinal exams steadily increased after being initially lower than the United States Dialysis Outcomes and Practice Patterns Study (U.S. DOPPS) comparison group in 2006.
- The percentage of patients receiving quarterly or semiannual HbA1c tests were consistently high for DMO A throughout the Demonstration.

- In DMO A, at least 80% of patients enrolled for one year or more had at least one low density lipoprotein (LDL) measurement in the first year of enrollment, compared to 70% of patients in FFS.

Improvement in preventive care measures and diabetes management revealed mixed findings:

Diabetes Management

- DMO A and DMO B instituted initiatives that focused on improving processes of care measures for the management of diabetes mellitus, a highly prevalent comorbidity in the ESRD population.
    - In DMO A, Disease Management was associated with improving diabetes-related processes of care measures from baseline, and greater than that observed for the FFS or U.S. DOPPS comparison populations.
    - In DMO B, an initial improvement in diabetes management was noted, but this declined after operational processes resulted in discontinuation of certain components of the diabetes intervention.

Vaccination:

- Disease Management in DMO A was also associated with increased influenza and pneumococcal immunization rates when compared to baseline and the two comparison populations.

Small Improvement in Advanced Care Planning (ACP):

- DMO B focused on increasing adoption of ACP. Results showed a small increase in the percentage of patients with an ACP by follow-up.

Improvement in some measures for the management of cardiovascular disease (CVD) comorbidity (medication and fluid weight monitoring):

- DMO A and DMO B focused on increasing patient use of two classes of medications that have been shown to improve clinical outcomes in patients with CVD or hypertension at baseline [2].
    - DMO A demonstrated increased use of these drugs (angiotensin converting enzyme inhibitors [ACEi] or angiotensin receptor blockers [ARBs]) for patients with congestive heart failure (CHF) at one year. By two years, use had declined to below baseline for DMO A.
    - There was no evidence of improved blood pressure control among DMO A enrollees.
    - Among patients with uncontrolled hypertension in DMO B, there was no change in ACEi/ARB use at 12 months, but use after two years increased from baseline.
- DMO C's Disease Management program provided patients with a home weight monitoring (HWM) scale, whether by indication or by patient preference. There were patient non-adherence/acceptance issues, implementation and technical challenges, as well as programmatic changes during the evaluation period, limiting the ability to draw any conclusions on the effect of this program.
    - HWM was associated with lower one-year hospitalization and mortality, primarily driven by the experience of 2006 enrollees. This association with improved clinical outcomes was not noted for patients enrolled later in the evaluation period (2007-2008).

Improvement in nutritional markers and associated clinical outcomes:

- Early initiation of oral nutritional supplements (ONS) was associated with improvement in serum albumin and reduced patient mortality in DMO C's ONS program.
- No association was observed for early initiation of ONS with a reduction in one-year hospitalization

No decrease in medication-related problems (MRPs):

- DMO A involved a pharmacist in the Disease Management health care team.
- Findings demonstrated that a high frequency of MRPs was noted in this population.
    - Initially pharmacist involvement was associated with a decrease in certain types of MRPs.
- Overall the number of MRPs increased over the course of the Demonstration, potentially related to changes in the DMO's medication review protocol mid-way thorough the Demonstration period, i.e., no longer including all patients in the program, but initiated by nurse referral.

An overall high level of satisfaction with care, but no clear benefits to quality of life (QoL):

- A high level of patient satisfaction was reported by a sample of enrollees interviewed on their respective experiences with the Disease Management Demonstration.
    - Levels of satisfaction were high for those who remained enrolled in the DMOs throughout the Demonstration.
- Results from the analysis of QoL suggested no clear impact of Disease Management on improving QoL at 12-months among patients enrolled in the three DMOs.

Improvement in patient survival:

- Analysis combining all DMOs demonstrated significant reduction in mortality when compared to FFS at both one and two year time points.
- Variations in impact of Disease Management on patient survival by DMO were observed.
    - DMOs B and C demonstrated significantly increased survival at one and two years.
    - DMO A was not found to have significantly improved patient survival after statistical adjustment at one or two years.

Metrics of patient morbidity and service utilization:

- All-cause and cardiovascular-specific first hospitalization percentages
    - Overall, first all-cause hospitalization percentages and cardiovascular-specific hospitalization percentages were lower in the DMOs when compared to FFS.
        - This was largely driven by DMO C, which demonstrated significantly reduced first all-cause and cardiovascular hospitalization percentages throughout the Demonstration.
        - In contrast, DMOs A and B did not demonstrate significantly reduced first all-cause hospitalization rates after statistical adjustment.
        - With regards to first cardiovascular hospitalization, DMO A did not demonstrate a significant reduction as compared to FFS, whereas DMO B's analysis was subject to data limitations for this outcome.
- Service utilization findings consistent across methodologies
    - Hospital admission rates
        - There was no significant reduction in hospital admission rates for the DMOs compared with FFS over the three-year evaluation period

- Other hospitalization metrics
  - Across all DMOs, readmission rates were either not different from FFS or significantly higher than FFS
  - Length of stay (LOS) and total hospital days were higher in all DMOs compared with FFS
  - There was no difference in ED visits between DMOs and FFS.
- Over the three-year period, when compared to propensity-score matched FFS patients, the Demonstration patients had significantly fewer physician visits and SNF stays.

A higher cost of the Demonstration to Medicare as compared to FFS:

- Overall, from 2006-2008, findings indicate that DMO enrollees cost Medicare 13.4% more than had they remained in FFS.
  - Such differences were observed for each DMO for each year.
  - These findings are consistent with prior estimates of risk-adjusted payment rates by Medicare to MA plans

Variations in net cost of care were observed by DMO

- Both DMO A and DMO B experienced losses relative to FFS based on differences in service utilization while DMO C experienced savings throughout all three years of the Demonstration.

- Savings or losses to the DMOs were driven by the differences in hospital admissions and, to a lesser extent, the differences in SNF stays. As such, it is important keep in mind that the calculation of estimated savings to the DMOs were at least in part based on utilization differences in utilization that were not statistically significant.

Despite its potential advantages for improving processes of care and health outcomes, a Disease Management approach for the ESRD population has not been widely examined. A 2001 study reported low standardized mortality and hospitalization in a group of dialysis units that used Disease Management for patients with ESRD [3]. However, the 2001 study had no internal or external comparison group and there was no examination of the effect of Disease Management on costs. The current evaluation findings therefore merit particular consideration in that external comparisons were made to the FFS or U.S. DOPPS populations, and the evaluation included an analysis of Medicare cost impact and costs of service utilization. This Evaluation of the ESRD Demonstration therefore represents a further step to providing evidence on the effectiveness of Disease Management specifically for the ESRD population.

Overall, the ESRD Disease Management Demonstration was associated with some clinical benefits, including improvement for some process of care measures, reduced mortality, and a significant reduction in physician visits and SNF stays. There was no significant reduction in hospital admission rates for the DMOs compared with FFS during this evaluation period; readmission rates were either not significantly different or were significantly higher for the DMOs compared with FFS. QoL was not improved by disease management strategies in this demonstration. Findings suggest a high level of patient satisfaction with the DMOs over the evaluation period. With regards to impact of DMO on costs, Medicare capitation payments exceeded estimated costs for enrollees had they remained in FFS. This is consistent with previously reported negotiated payment rates for MA Plans, and is outside of the DMOs' control.

There are several potential reasons for our findings in which DMO C's program appeared to be associated with some improvement in utilization and cost of care, whereas DMOs A and B have not clearly shown similar degrees of improvement. The most important reason may relate to differences in

the design and structure of the DMO programs. These differences varied by 1) type of intervention and 2) extent of interaction of and differences in efficiencies in program operations. With regards to type of intervention, DMO C provided treatments with actual therapeutic and clinical benefits in addition to enhancing care coordination in order to reduce hospitalization and mortality. On the other hand, DMOs A and B focused primarily on improving process of care measures through care coordination and improving preventive care services. It is possible that in this vulnerable patient population, care coordination is insufficient in impacting clinical outcomes. Differences in the extent of interaction between DMO enrollees and members of the clinical team may have also contributed to the findings. All three DMOs combined telephonic and face-to-face meetings with care coordinators, and indeed DMO C modified its care coordination to occur primarily telephonically later on in the demonstration. DMO C also provided HWM scales which facilitated more regular, and potentially daily, interaction between the nurse care manager (NCM) and the patient. However, the percentage of patients utilizing this technology was very small during the last two years of the evaluation period (16%), due to implementation and technical challenges, patient non-adherence/acceptance issues, as well as programmatic changes. Efficiencies in program delivery may also have varied by DMO. Given that DMO C had the largest number of enrollees among participating programs, there may be efficiencies of scale in both operational and cost components as compared to the smaller DMOs.

Operational modifications in program implementation during the Demonstration may have limited their potential impact. This is illustrated not only by DMO C's programmatic changes in implementation of both the ONS and the HWM programs, but also by DMO A's modification of its pharmacist evaluation of patient medications. On interim analysis, routine pharmacist evaluation resulted in significant reductions in medication related problems; however, the program was modified so that patients were evaluated only on indication. This may have minimized the measurable impact of this component of DMO A's Disease Management program. An even more marked structural change occurred in DMO B. Midway through the evaluation, changes in data and clinical systems occurred such that DMO B lost its ability to modify clinician behavior, such as removal of standing orders for Hemoglobin A1c (HbA1c) measurement, which is a marker of diabetes control, and discontinuation of a program designed to monitor level of blood glucose control among patients with diabetes mellitus. Similarly, for DMO C's HWM program, technical and implementation challenges, patient acceptance of the technology and non-adherence issues, and programmatic changes during the evaluation period may have impacted the effectiveness of this program and contributed to the lack of association of HWM with a reduction in one-year hospitalization and mortality for enrollees later in the evaluation period (2007-2008), thus limiting the ability to draw any conclusions on the effect of this program on improving clinical outcomes.

Although these programmatic changes reflect only partial components of the different Disease Management programs, there may be other unmeasured effects on other components of enrollees' clinical care and outcomes.

Finally, many patients with ESRD have had chronic kidney disease for years. Attempting to modify ingrained self-care behavior through patient education, screening and preventive maintenance in patients may be difficult [5].

This Evaluation has several strengths. First, analysis was performed for a comprehensive series of multi-dimensional outcomes including intermediate outcomes, processes of care measures, QoL, hard clinical endpoints, patient and provider satisfaction, and financial outcomes. Second, we compared the enrollees' outcomes using two different populations: the Medicare FFS ESRD population and the U.S. DOPPS, which is a nationally representative study of HD patients in the U.S. Access to the U.S. DOPPS data allowed us to compare intermediate markers of care which are data elements that are not collected in Medicare data sources (e.g. serum albumin, IDWG, among others). The unique design of each participating DMO also allowed us to identify if certain interventions were associated with improving patient outcomes. Finally, our statistical analyses employed multiple regression models that

accounted for the potential effects of confounding variables, and a methodology that allowed identification of a FFS comparison group who were observed to have a similar propensity for enrolling in a DMO as the DMO population with respect to demographic and clinical characteristics.

Several potential limitations must also be taken into account in interpreting these findings. The DMO populations for some analyses were relatively small. For example, fewer than 100 patients were enrolled in DMO B at any time during 2006. This can lead to insufficient statistical power to detect differences that may be relevant to patients, clinicians, and policy makers. There was no random assignment of patients to DMO treatment, so statistical adjustment was used to compare DMO populations to the more general FFS populations. Statistical adjustment allows for a more fair comparison, but relies upon measuring all variables that may differ between the populations and be causally associated with the outcomes of interest. While these analyses adjust for a wide set of demographic and clinical variables, unmeasured variables due to the lack of available data always represent a potential limitation in observational studies.

Differential disenrollment rates across the three DMOs may have had an impact on the observed clinical outcomes. Relatedly, the high percentage of disenrollment in the DMOs is also a limitation of our analyses. Patients who disenroll may do so because they are sicker or have greater co-morbidity burden thus leading to selection bias among patients who remain in the DMO. Indeed, our analysis comparing DMO patients who disenrolled to those who did not disenroll revealed that disenrollees had significantly higher CMS-HCC risk scores.

DMO programs were also evolving over the course of the Demonstration so that the impact of a specific intervention over time may have changed as programs stabilized or through changes in intervention protocols.

The propensity score methodology used in Chapters 11 (Outcomes) and 15 (Cost Analysis), though resulting in an improvement in comparability between the DMO and the FFS comparison populations, may still be associated with unmeasured confounding as this evaluation was not designed as a randomized clinical trial. More detailed discussion of the limitations of the propensity score method may be found in Chapters 11 and 15.

Additionally, the cost evaluation did not take into account the cost structure of the various DMOs, and therefore the overall impact of the program on each DMO's financial viability cannot be assessed. The evaluation was also limited by the identification of appropriate comparison groups, such as concurrent patients not enrolled in the DMO but receiving dialysis in the same facility as enrollees. Finally, patient-centered and provider acceptance analyses were based on qualitative data, derived from small samples. This limits broader generalizations of these results.

The cost analyses were also limited by the use of estimates developed from the utilization analyses rather than on actual costs as reported by the DMOs. Costs of DMO enrollees were estimated by applying the cost per unit observed in the FFS group. By design, this methodology was utilized since the goal of this analysis was to compare the costs incurred by DMO patients assuming the same cost structure as FFS. Because the costs per service are derived from unique FFS comparison groups selected to match the patient characteristics of each DMO, only differences in costs between DMO and each respective FFS comparison group can be evaluated and costs should not be compared across DMOs. In addition, actual costs of services to DMOs are likely to be different as these are based on negotiations between the DMOs and the various providers. Additional cost analyses will be conducted by CMS based on audited cost data from the DMOs in the future. These analyses will provide more evidence regarding savings or losses and assessment of DMO viability in the long-term.

This ESRD Disease Management Demonstration represented a unique opportunity to identify improvement in clinical outcomes in a population that is ideally suited for Disease Management. We observed significant survival benefit in this notably fragile and complex patient population. Additionally, at least one DMO demonstrated improved metrics in evaluating hospitalization outcomes, including improved time to first all-cause and cardiovascular hospitalization, and hospital admission rate over time. In addition, utilization of other costly services including SNF stays and outpatient physician visits were consistently reduced in the DMOs as compared to FFS. These findings translated to cost savings which was considerable in at least one participating DMO. Although there was no clear impact of Disease Management on improving QoL, patients and providers expressed satisfaction with their experiences with the Disease Management Demonstration. We believe our findings merit consideration in the ongoing assessment of the value of Disease Management. Finally, one related approach, among others, that may have benefits for this population is the Accountable Care Organization (ACO). The Affordable Care Act passed by Congress in March 2010 encourages the development of ACOs, which are organizations that provide integrated care, much like disease management. Providers that belong to an ACO collectively agree they are all accountable for the care they deliver, namely the quality, cost, and overall care of Medicare beneficiaries [6, 7]. The medical home model is also based on principles of coordinated care delivery. These models would allow for further testing of Disease Management and care coordination concepts for the ESRD population in a FFS setting.

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APPENDIX 1: DETAILED ELEMENTS OF DISEASE MANAGEMENT PROGRAMS

DMO A

For each row in the table below, there are fields with DMO A's 2006 baseline and 2008 follow-up responses about the Disease Management components offered at their Demonstration plans.

Component	2006 Response	2008 Response*
Primary Care Provider	Nephrologist	Nephrologist, NCM, PCP
Patient Immunization Status Review	Not asked in 2006.	Nephrologist, NCM, PCP
Comorbidity Disease Management Programs Offered	Diabetes Management provided by nephrologist; CVD Disease Management provided by a cardiologist as appropriate Hypertension and Metabolic Syndrome	Diabetes Management provided by a nephrologist and endocrinologist; CVD Disease Management provided by a cardiologist as appropriate
Programs/Services Offered	Patient Education and Caregiver Education programs; dietician and social work services coordinated with the dialysis center.	Patient Education and Caregiver Education programs; dietician and social work services coordinated with the dialysis center.
Pharmacist on the Disease Management Team?	Yes	Pharmacist routine review of medications until 2007 when review only occurred upon NCM referral.
Non-Electronic Home Monitoring System Used?	No	Patient self-monitoring. Telephonic follow-up by the nurse based on review of the patient self-monitoring.
Detailed Self-Care Program Offered?	No	Beginning October 2007, motivational interviewing provided to patients. Nursing staff trained in behavioral/motivational technique designed to encourage patient empowerment and "patient activation".
Depression Screening	Beck Depression Inventory II, conducted annually	Beck Depression Inventory II, conducted on initial assessment, annually, and as indicated.
Vascular Access Plan	Integrated, comprehensive program at dialysis facility and VA Center conducted regularly; Clinical Exam and ultrasound at some facilities	Action plan at dialysis unit, use of Lifeline centers, VA centers, and VA management software; conducted regularly; Clinical Exam and Hemodynamic Surveillance
Nutritional Supplements Provided	Not provided	Not provided
Anemia Protocol	Coordinated program between dialysis center and Disease Management program	Part of Disease Management program
Mineral Metabolism Protocol	Coordinated program between dialysis center and Disease Management program	Part of Disease Management program

Component	2006 Response	2008 Response*
Benefits offered as Part of Disease Management	None	None
Patient Satisfaction Survey Used?	Yes	Yes
QoL Survey Administration	SF-12	SF-12. Administered either in facility or at home. Until July 2008, administered at baseline, 6 months, 1 year, and annually thereafter. Beginning July 2008, administered at 6 months, at 1 year, and annually thereafter.
In-Hospital Follow-Up	Provided by NCM	Before January 2007, focused on preventive care. After January 2007, focus shifted to high risk (high acuity) patients, e.g. patients recently released from the hospital or are post-transplant. NCMs also make home visits and provide telephonic follow-up.
Hospital Discharge Planning	Provided by NCM	Provided by NCM
Advanced Care Directive Program	Facilitated by NCM, Nephrologist	Facilitated by NCM, Nephrologist
Team-Based Bedside Rounds Conducted?	No	No
Team-Based Sit-Down Rounds Conducted?	Weekly and as needed	Weekly and as needed

Abbreviations: CVD = Cardiovascular disease; NCM = Nurse care manager; PCP = Primary care provider; QoL = Quality of Life; SF = Short form; VA = Vascular access.

*DMO A instituted a catheter rate reduction program later incorporated as part of their Disease Management program. The program was designed in conjunction with the ESRD Quality Incentive Payment Demonstration which included a vascular access target to incentivize reducing catheter use for enrollees.

DMO B

For each row in the table below, there are fields with DMO B's 2006 and 2008 responses about the Disease Management components offered at their Demonstration plans.

Component	2006 Response	2008 Response
Primary Care Provider	Nephrologist, in coordination with NCM or NP.	Nephrologist, in coordination with NCM or NP.
Patient Immunization Status Review	Not asked in 2006.	PCP has primary responsibility, nephrologists and NCMs review as appropriate.
Comorbidity Disease Management Programs Offered	NCM and NP focus on comorbidity management based on individual assessment including individual assessment and plan of care related to Diabetes, Heart Failure, and Coronary Artery Disease.	NCM and NP focus on comorbidity management based on individual assessment including individual assessment and plan of care related to Diabetes, Heart Failure, and Coronary Artery Disease. Glucometers offered at patient request.
Programs/Services Offered	Patient Education and Caregiver Education programs, coordinated by NCM and NP with patient/patient family, dialysis team, social worker and other providers. Dietician, social work services and drug discount, exercise programs also provided.	Patient Education and Caregiver Education programs, coordinated by NCM and NP with patient/patient family, dialysis team, social worker and other providers. Dietician, social work services, and drug discount program provided. Exercise program removed due to zero participation.
Pharmacist on the Disease Management Team?	Yes, part of Part D Pharmacy Management program.	Yes, part of Part D Pharmacy Management program. None separate from Part D.
Electronic/Non-Electronic Home Monitoring Systems Used	Telephonic Management.	No formal Telephonic Monitoring System - telephonic outreach used by CM or NP to communicate with members.
Detailed Self-Care Programs Offered	Assessment of enrollee's self management needs as part of comprehensive assessment and plan of care.	Enrollee self-care encouraged and promoted continuously.
Depression Screening	PHQ-9, conducted bi-annually and based on individual need.	SF-12, Community Assessment, PHQ-12, conducted bi-annually and based on individual need.
Vascular Access Plan	Collaboration between nephrologists and VA centers to promote use of Fistulas. Reuse of dialyzers managed by dialysis center.	Collaboration between nephrologists and VA centers to promote use of Fistulas. Reuse of dialyzers managed by dialysis center. Varies with geographic proximity of centers. Rates and coverage through the plan benefit package.
Nutritional Supplements Provided	Oral nutritional and parenteral nutritional supplements prescribed by physician. Cutoff is based on physician order.	Oral nutritional supplements - dialysis patients received nutritional consultation by facility dietician, who reviews lab data, i.e. albumin levels, and documents monthly. Cutoff is albumin less than 4 g/dL. Parenteral nutritional supplements prescribed by physician - cutoff based on physician order.
Anemia Protocol	Yes	Yes
Mineral Metabolism Protocol	Managed by physician.	Managed by physician.

Component	2006 Response	2008 Response
Benefits Offered as Part of Disease Management	None.	Transportation.
Patient Satisfaction Survey Used?	Yes	Yes
QoL Survey Administration	SF-12, on enrollment and annually.	SF-12, on enrollment and annually. NCM assists in administering survey and ensuring it is completed.
In-Hospital Follow-Up	None, provided by dialysis facility.	None, provided by dialysis facility.
Hospital Discharge Planning	As permitted by facility.	As permitted by facility.
Advanced Care Directive Program	Part of Comprehensive Assessment, facilitated by NCM.	Part of Comprehensive Assessment, facilitated by NCM.
Team-Based Bedside Rounds Conducted?	Yes, at dialysis facility, as permitted by nephrologist's schedule.	Yes, at dialysis facility, as permitted by nephrologist's schedule.
Team-Based Sit-Down Rounds Conducted?	Not conducted.	Not conducted.

Abbreviations: CM = Care Manager; NCM = Nurse care manager; NP = Nurse Practitioner; PCP = Primary care provider; PHQ = Patient Health Questionnaire; QoL = Quality of Life; SF = Short form; VA = Vascular Access

DMO C

For each row in the table below, there are fields with DMO C's 2006 and 2008 responses about the Disease Management components offered at their Demonstration plans.

Component	2006 Response	2008 Response*
Primary Care Provider	Nephrologist, internist, or PCP	Nephrologist provided overall care. Enrollee saw nephrologist, internist, or PCP for other PC services.
Patient Immunization Status Review	Nephrologist, NCM, and PCP.	Nephrologist, NCM, and PCP. NCM shares outcomes with care providers and members.
Comorbidity Disease Management Programs Offered	Diabetes Disease Management provided by managing physician – nephrologist, endocrinologist, or PCP.	Diabetes Disease Management provided by managing physician – nephrologist, endocrinologist, or PCP. Glucometers and test strips provided as needed. CVD Disease Management provided by a cardiologist; Access management, vaccinations, CHF programs also provided by NCMs.
Programs/Services Offered	Patient Education Programs offered by dialysis center and care coordination team. Dietitian, social work services, and drug discount program are also offered.	Patient Education Programs offered by dialysis center and care coordination team. Dietitian services and drug discount program are also offered.
Pharmacist on the Disease Management Team	Yes	No. However, pharmacy benefit manager added later.
Electronic /Non-Electronic Home Monitoring Systems Used	Electronic scale provided and other data to monitor weight gains of the patients at home.	Electronic scale provided and other data to monitor weight gains of the patients at home. New system in 2008, with enhanced patient monitoring – blood pressure cuffs, glucometers, and routine measures of blood pressure.
Detailed Self-Care Programs Offered	None	Yes
Depression Screening	Conducted at initial intake and quarterly risk assessment.	SF-36, conducted at initial intake and quarterly risk assessment.
Vascular Access Plan	VA centers are used if in the area of the health plan. Transportation for access procedures is provided. No regular program of access monitoring used in all areas, local surveillance may be provided. Dialyzers are not reused.	VA centers are used if in the area of the health plan. Transportation for access procedures is provided. No regular program of access monitoring used in all areas, local surveillance may be provided. Dialyzers are not reused.
Nutritional Supplements Provided	Oral nutritional supplements provided to patients with albumin less than 3.8 g/dL.	Oral nutritional supplements provided to patients with albumin less than 3.8 g/dL. Rolling average for 2 months less than 3.8 g/dLqualifies for supplements.
Anemia Protocol	Provided by dialysis centers.	Provided by dialysis centers.
Mineral Metabolism Protocol	Provided by dialysis centers.	Provided by dialysis centers.
Benefits Offered as Part of Disease Management	Transportation services offered.	Transportation, dental, vision, and hearing services offered.
Patient Satisfaction Survey Used?	Yes	Yes

Component	2006 Response	2008 Response*
QoL Survey Administration	Not asked in 2006.	Yes, SF-36, completed at enrollment and annually. Dialysis facility nurses assist patients with completing surveys.
In-Hospital Follow-Up	Nephrologist provides in-hospital services.	Nephrologist provides in-hospital services.
Hospital Discharge Planning	Coordinated by Disease Management program.	Not provided.
Advanced Care Directive Program	Coordinated by the dialysis center social worker and the care management team.	Coordinated by the dialysis center social worker and the care management team.
Team-Based Bedside Rounds Conducted?	No. Monthly CQI meetings are held in each facility with the dialysis center team and the CM for the particular patient.	No. Monthly CQI meetings are held in each facility with the dialysis center team and the CM for the particular patient.
Team-Based Sit-Down Rounds Conducted?	No	No

Abbreviations: CHF = Coronary heart failure; CM = Care Manager; CQI = Continuous quality improvement; CVD = Cardiovascular disease; NCM = Nurse care manager; PCP = Primary care provider; QoL = Quality of Life; SF = Short form; VA = Vascular Access.

*Additional components of DMO C's program included their clinical pathways in the following focus areas:

Annual Assessment / Education
(Depression, Advanced Directives, Smoking Cessation, Pneumovax, Medications)
Blood Pressure Control
Catheter Reduction / Access Placement
Diabetes – General
Diabetes – Glucose Readings
Flu Vaccination
Heart Failure / CHF / Fluid Control
Hospital / ER - Event Assessment
Infection Prevention / Treatment
Malfunctioning Access Triage
Nutritional Supplements
Renal Replacement Options
Sore / Open Wound
Transplant Preparation

APPENDIX 2: TECHNICAL APPENDIX

A. Demonstration Patients

The Centers for Medicare & Medicaid Services (CMS) Member Beneficiary Database (MBD) was used to determine which patients were enrolled in the Demonstration. The MBD also included date of birth, date of death, sex, race, Hispanic ethnicity, and transplant information. Vascular access (VA), modality, and baseline lab data were submitted by the DMOs. Date of end-stage renal disease (ESRD) onset and cause of ESRD were collected from the Medical Evidence Form (CMS 2728). Cause of death was determined using data collected from the Death Notification Form (CMS 2746).

Patient age and time since onset of ESRD were calculated as of the patient's enrollment into the program. Patient body mass index (BMI) was calculated using the height and weight collected at the onset of ESRD using the CMS 2728.

The capitated payments from CMS to the DMOs for each enrollee were obtained from the CMS Monthly Membership Reports (MMR). MMR data from January 2006 through May 2009 were used in order to incorporate any adjustment records for the 2006-2008 analytic period that were reported in the 2009 MMR data.

B. Traditional Fee-for-Service Medicare Comparison Groups

1. ESRD Medicare Population

Comparisons to patients in traditional Fee-for-Service (FFS) Medicare were made throughout this evaluation. The data for these comparisons were obtained from the ESRD database maintained at the University of Michigan Kidney Epidemiology and Cost Center (UM-KECC). In general, patients were eligible for these comparison groups at the latest of January 1, 2006 or the patient's first outpatient dialysis claim with Medicare as the primary payor.

Date of birth, date of death, race, sex, Hispanic ethnicity, date of ESRD onset and cause of ESRD were extracted from the patient summary file which includes data from the Medical Evidence Form (CMS 2728), transplant events from the Organ Procurement and Transplantation Network, the Standard Information Management System (SIMS), REBUS/PMMIS, the Enrollment Database (EDB), the Social Security Death Master File, the Death Notification Form (CMS 2746), and Medicare Claims Data.

Patient age and time since onset of ESRD were calculated at the start of eligibility. Patient body mass index (BMI) was calculated using the height and weight at onset of ESRD collected on the CMS 2728.

Information on treatment modality and transplants was extracted from the treatment history summary file. Each record on this file indicates a period of a patient's dialysis treatment modality and location. Any change in modality or location generates a new record. Several data sources were used to create this file, including the CMS 2728, the SIMS database, transplant events from the Organ Procurement and Transplantation Network, and Medicare claims.

2. General ESRD Population

Statistics from the United States Renal Data System (USRDS) Annual Report were used in the DMO-specific analyses as benchmarks for the U.S. FFS population.

C. The United States Dialysis Outcomes and Practice Patterns Study Comparison Group

The United States Dialysis Outcomes and Practice Patterns Study (U.S. DOPPS) is a prospective observational study involving a sample of hemodialysis (HD) patients randomly selected from nationally representative dialysis facilities in the U.S. Facilities were stratified for random selection based on standardized measures of mortality and hospitalization outcomes.

Table TA-1: Demographics of Demonstration Enrollees and U.S. DOPPS Patients

	DMO A	DMO B	DMO C	All DMOs	National U.S. DOPPS[a]
Patients with at least one enrollment (N)	727	271	1,380	2,378	1,751
Patient Characteristics (mean)					
Months enrolled	15.4*	16.9	14.5*	15.1*	18.3
Age at enrollment	56.2*	56.3*	58.1*	57.3*	63.8
Months since onset of ESRD at enrollment	45.8*	54.6*	56.7*	53.2*	41.5
BMI at onset of ESRD	27.9	29.1*	29.1*	28.7*	27.7
CMS-HCC risk score at enrollment	1.05	1.07	1.06	1.06	n/a
Kt/V at enrollment	1.57	1.58	1.68*	1.63*	1.56
Serum albumin at enrollment	3.88*	3.89*	3.84*	3.86*	3.75
Calcium at enrollment[b]	9.27	9.08*	9.07*	9.13*	9.24
Phosphorus at enrollment	5.77*	5.70*	5.62*	5.67*	5.44
Hemoglobin at enrollment	12.44*	12.12*	11.97	12.13*	11.94
Year of Enrollment (percent)					
2005	n/a	n/a	n/a	n/a	41
2006	41	34	48	44	36
2007	37	44	43	42	18
2008	22	22	9	14	5
Sex (percent)					
Female	39*	50	49	46	46
Male	61*	50	51	54	54
Race (percent)					
White	75*	34*	50*	56	55
Black or African American	18*	57*	46*	38*	34
Asian	3	0*	1*	2	3
American Indian or Alaska Native	0*	8*	0*	1*	3
Native Hawaiian or Other Pacific Islander	2*	0	1	1	1
Other/Multiple Race	1*	0*	1*	1*	4
Unknown	1*	0	0	0	0
Hispanic (percent)					
Yes	57*	24*	23*	34*	9
No	39*	72*	71*	62*	86
Unknown	4	4	5	5	5
Cause of ESRD (percent)					
Diabetes	52*	46	45	47*	36
Hypertension	23*	32	26*	26*	32
Glomerulonephritis	9	7	11	10	8
Cystic Kidney	2	1	2	2	3
Other Cause	8*	11*	10*	9*	16
Unknown	6	3*	6	6	6
ESRD less than 6 months at enrollment (percent)					
Yes	11*	7*	7*	8*	16
New Medicare Enrollee[c] (percent)					
Yes	34	27	22	26	n/a
Modality During Enrollment (percent)					
All HD	96	100*	98*	98*	95
Any Peritoneal dialysis	4	0*	2*	2*	5
Vascular Access at Enrollment (percent)					
AV Fistula	41	52*	46*	45*	42
AV Graft	24	21*	36*	30*	26
Catheter	24*	17*	16*	19*	28
Unknown	12*	10*	2*	6	4

Abbreviations: AV = Arteriovenous; BMI = Body Mass Index; CMS-HCC = Centers for Medicare & Medicaid Services – Hierarchical Condition Categories; ESRD = End Stage Renal Disease; HD = Hemodialysis; n/a = not available; U.S. DOPPS = United States Dialysis Outcomes and Practice Patterns Study.
Note: CMS-HCC risk score data and New Medicare Enrollee designation unavailable for the U.S. DOPPS dataset.
[*] DMO differs from U.S. DOPPS ($p < 0.05$). For continuous variables, t-tests were performed. For categorical variables, significance tests were performed for each level using a two-by-two Chi-Square test of the category versus all others. Significance tests were not performed for CMS-HCC risk score, enrollment year, and new Medicare enrollee status because these variables are not available for DOPPS.
[a] The U.S. DOPPS sample is limited to patients with Medicare as their primary insurer.
[b] Corrected calcium is calculated by using this formula: corrected calcium (mg/dL)= total calcium mg/dL + (0.8*(4-serum albumin g/dL)).
[c] New Medicare Enrollee is defined by the CMS-HCC risk score dataset. New Medicare Enrollees are those without a full year of claims history.

D. CMS-HCC Risk Score from the ESRD Model

In both Demonstration and FFS populations, the CMS-Hierarchical Condition Categories (HCC) risk scores were used as a measure of health status. The CMS-HCC risk score is based on demographic factors and the number of chronic conditions for which an individual is receiving treatment, as indicated by diagnosis codes on FFS claims or reporting by private health plans for patients in Medicare Advantage. A higher score indicates a patient with more chronic conditions who is predicted to use more health care resources. If a patient is new to Medicare (less than one year enrollment), diagnosis codes were not available so only demographic variables were used to calculate the CMS- HCC risk score.

The CMS-HCC risk scores were calculated using the 2005 CMS-HCC ESRD model which was calibrated using dialysis patient data. We used the "model output" data from 2005 through 2007 to calculate the risk scores that would be in use for 2006 through 2008. Most analyses used the CMS-HCC risk score calculated by the ESRD model using conditions from the year prior to enrollment. A few patients were new to Medicare the first year of their enrollment in the Demonstration. In these instances a risk score based only on demographic information from the current year was used. The cost analyses used the CMS-HCC risk score in effect for the year analyzed.

E. Demonstration Utilization Data

Utilization in the Demonstration was determined using institutional and professional claims data submitted by the DMOs. Line items with paid amounts less than or equal to $0 and unpaid claims were treated as corrections to matching claims or removed as appropriate. Claims data were subjected to a series of edits and validation checks to insure completeness and usability.

Inpatient hospitalizations were extracted from the institutional claims using the presence of a diagnosis-related group code or a place of service code of 22. Hospitalizations where the admission and discharge dates were contiguous or overlapped were combined, retaining the earliest admission date and the latest discharge date. If any of the claims included diagnosis codes for cardiovascular disease (CVD), the record was flagged as a cardiovascular hospitalization.

Line items from the institutional claims file that were determined not to be related to an inpatient hospitalization were used to define outpatient emergency department (ED) visits and skilled nursing facility (SNF) stays. Outpatient ED visits were identified using revenue center code values of 0450-0459 or 0981. Line items with a bill type of 200-229 were identified as SNF stays. SNF stays where the service and service thru dates were contiguous or overlapped were combined, retaining the earliest service date and the latest service thru date.

Physician visits were extracted from the professional claims file. Observations included in the analysis were individual line items determined using the following Berenson-Eggers Type of Service (BETOS) codes: M1A, M1B, M4A, M4B, M5A, M5B, M5C, M5D. Line items with the BETOS code M6 were also included if they did not contain the procedure codes 99251, 99252, 99253, 99254, 99255, 99261, 99262, or 99263. Line items with dates of service during an inpatient hospital stay were excluded. When two

line items had the same date and provider identifier, these were considered duplicates and collapsed as one event. If claims did not have a provider identifier, only line items with the same date and claim number were considered duplicates and collapsed.

F. Traditional Fee-for-Service Medicare Utilization Data

Utilization in the ESRD FFS population was determined using the CMS Standard Analytic Files (SAFs).

Inpatient hospitalizations were determined using the inpatient SAF. Hospitalizations where the admission and discharge dates were contiguous or overlapped were combined, retaining the earliest admission date and the latest discharge date. If any of the claims included diagnosis codes for cardiovascular disease, the record was flagged as a cardiovascular hospitalization. Total cost for an inpatient hospital stay was determined using total Medicare payment associated with the claim.

Outpatient ED visits were determined using the outpatient SAF and were identified using revenue center codes values of 0450-0459, or 0981. Total cost for an outpatient ED visit was determined using total Medicare payment associated with the claim that had the ED line item.

SNF visits were determined using the SNF SAF. SNF visits where the dates were contiguous or overlapped were combined, retaining the earliest claim from date and the latest claim thru date. Total cost for a SNF stay was determined using total Medicare payment associated with the SNF claim.

Physician claims were extracted from the Carrier SAF. Observations included in the analysis were determined using the following Berenson-Eggers Type of Service (BETOS) Codes: M1A, M1B, M4A, M4B, M5A, M5B, M5C, M5D. Line items with the BETOS Code M6 were also included if they did not contain the procedure codes 99251, 99252, 99253, 99254, 99255, 99261, 99262, or 99263. Line items with dates of service during an inpatient hospital stay were excluded. When two line items had the same date and provider identifier, these were considered duplicates and collapsed as one event. If claims did not have a provider identifier, only line items with the same date and claim number were considered duplicates and collapsed. Total cost for a physician visit was determined using the Medicare payments reported on the line items with the BETOS and procedure codes listed above. Medicare payments for line items on the claim without these codes were not included in the calculation of total cost.

Table TA-2 shows the average cost per service in FFS. These costs were computed separately for each DMO and each year using the propensity-score matched FFS comparison groups, and were used in Chapter 15 to determine estimated costs/savings in the DMOs due to differences in utilization. The average cost for each service in each year was calculated as the sum of the total cost of the service divided by the number of services. However, because the costs per service are derived from unique FFS comparison groups selected to match the patient characteristics of each DMO, there are systematic differences in the average costs applied to the DMOs. These differences in cost are the result of differences in patient population, and only allow us to compare savings between each DMO and its respective FFS comparison group, not among DMOs.

An average cost per service was not calculated for 2006-2008 since the average cost per unit of service and the patient populations in each DMO varied between years, limiting the interpretability of applying an average 2006-2008 cost to the 2006-2008 utilization differences. Instead, for each DMO, 2006-2008 costs/savings were calculated as the average of the estimated savings in 2006, 2007, and 2008, weighted by the number of patient months in each year.

Table TA-2: Average Cost of Selected Services in FFS

		FFS Controls for DMO A			FFS Controls for DMO B			FFS Controls for DMO C		
Service	**Measure**	**2006**	**2007**	**2008**	**2006**	**2007**	**2008**	**2006**	**2007**	**2008**
Hospital Stays	Cost per stay	16851.85	15632.42	15849.14	10295.31	12848.98	11976.43	10592.2	10812.76	13128.69
Readmissions	Cost per readmission	18850.56	17781.91	17346.17	12802.85	14176.19	13894.71	12363.6	12241.84	13325.41
Total Hospital Days	Cost per day	2609.24	2501.44	2600.07	1925.74	2026.38	2072.02	1787.11	1883.53	2144.08
LOS	Cost per day	2609.24	2501.44	2600.07	1925.74	2026.38	2072.02	1787.11	1883.53	2144.08
SNF Stays	Cost per stay	4221.21	5436.46	4859.9	3421.53	4252.9	3830.43	3957.8	3423.05	4004.94
Outpatient ED Visits	Cost per visit	647.28	606.54	737.97	524.06	732.28	606.51	561.45	611.68	674.61
Physician Visits	Cost per visit	68.069	71.03	74.37	57.45	56.56	60.05	59.21	62.50	62.75

		FFS Controls for All DMOs		
Service	**Measure**	**2006**	**2007**	**2008**
Hospital Stays	Cost per stay	11920.45	12179.71	13832.62
Readmissions	Cost per readmission	13644.09	13792.56	14653.93
Total Hospital Days	Cost per day	1993.01	2054.90	2282.59
LOS	Cost per day	1993.01	2054.90	2282.59
SNF Stays	Cost per stay	4029.29	3918.42	4240.31
Outpatient ED Visits	Cost per visit	572.73	628.59	681.76
Physician Visits	Cost per visit	61.66	64.26	66.29

Abbreviations: ED = Emergency department; FFS = Fee-for-service; LOS = Length of Stay; SNF = Skilled nursing facility

G. Results of the Propensity Score Methodology

1. Description of Propensity Score Methodology

In the Outcomes utilization and cost analyses, propensity score matching was used to reduce the selection bias that may cause DMO enrollees to be different from the FFS comparison population. Using a propensity score methodology attempts to balance observable characteristics that may affect the decision to enroll in a DMO. By using the propensity score matched population, we compare DMO patients to FFS patients who are more likely to have a similar propensity to enroll in a DMO as the DMO patients.

The propensity score methodology was designed in two stages. The first stage of this analysis involved running a set of multivariate logistic regression models (separate for each DMO and year), in which the DMO enrollment decision was a function of demographic, coverage, utilization, and clinical variables, and state of residence (variables included in the propensity score model are listed in Table TA-3). The variables were defined at a baseline of January for each year of the Demonstration so as not to be influenced by any prior enrollment decisions. By way of contrast, if one used data as of mid-year, those values might be influenced by the enrollment decisions made earlier in the year, introducing a bias due to endogeneity. Using the coefficient estimates from this logistic regression, we predicted the probability of DMO enrollment for every patient (both patients actually in the DMO and those who remained in FFS). This probability is a patient's propensity score.

The next step was to create (from the FFS pool) a set of control groups that were representative of the Demonstration treatment groups in each DMO and each year. This involved a matching methodology that yielded a FFS control group with almost identical distributions of propensity scores. For each DMO enrollee's score, the algorithm attempted to find a FFS patient with a similar score. This was only possible over the range that the two groups overlapped, called the "common support region". For each

DMO in each year, the lowest score of the DMO population defined the lower bound of the common support region, and the highest score of the FFS comparison population defined its upper bound. For instance, if the propensity score range for a DMO was [0.3, 0.7] and FFS was [0.2, .05], the common support region would have a range of [0.3, 0.5]. The few DMO patients who had scores outside the range of the common support region had to be excluded from the remainder of the analysis. For each of the three years of the Demonstration, every patient who was included in the analysis was matched to a FFS patient with a similar propensity score (within 0.001 percent). We performed the propensity score matching of the FFS comparison population four additional times, and in each match cycle, distribution of propensity scores for the FFS matched groups was nearly identical to the original match, demonstrating stability of the propensity score matching process. A small number of Demonstration patients had propensity scores that were not represented among the FFS population; these patients were considered outside the "common support region".

The propensity matched samples were first used in the service utilization analyses in the Outcomes chapter (Chapter 11). The propensity matched samples were also used in the first part of the Cost Analysis chapter (Chapter 15) to estimate differences between capitated payments to the DMOs compared to costs of the same patients had they remained in FFS. The results from the service utilization analyses in the Outcomes chapter (Chapter 11) were subsequently used in the cost analyses of estimated savings to the DMOs in the second part of the Cost Analysis chapter (Chapter 15). Each analysis that used the propensity matched sample subsequently employed second stage multivariate regression modeling to adjust for any residual differences that persisted after propensity score matching. This second stage regression used the same explanatory variables as the propensity score method to explain remaining variation in observed FFS costs in the FFS samples. For the utilization and cost analyses, negative binomial regression was used to model counts of services. We also examined Poisson regression models (with correction for over-dispersion) and found similar results. Both methods are commonly used for count data such as service utilization. The negative binomial regression results are shown because these models generally fit the data better according to visual inspection of residual plots and examination of model deviance statistics. All models displayed adequate fit; however, models for some services fit better than others. In particular, models for physician visits and SNF stays appeared to fit least well.

For the first part of the cost analysis (comparing capitated payments to DMOs with FFS costs from Medicare claims), a standard linear regression equation built on the FFS control group was then applied to the DMO patients to estimate what these patients would have cost had they remained in FFS.

2. Effect of Propensity Score on Balance

Tables TA-3a through TA-3c compare the DMO and the FFS Matched Samples among the variables used in the propensity score model. The results show that after propensity score matching, patients in the FFS matched sample look similar to patients enrolled in the DMOs, however there are a few exceptions. Across all three years, there were more new enrollees in DMO A and DMO C compared to the FFS matched sample. In addition, DMO A patients in 2008 and DMO C patients in 2007 had lower CMS-HCC Risk Scores compared to their FFS matched samples.

Table TA-3a: Comparison of Patient Demographics in DMO A and FFS Matched Sample

	2006			2007			2008		
	DMO A (N=242)	**FFS (N=242)**	**p-value**	**DMO A (N=408)**	**FFS (N=407)**	**p-value**	**DMO A (N=415)**	**FFS (N=416)**	**p-value**
Age 50 + (%)	69	72	0.55	73	71	0.57	74	78	0.25
Female (%)	43	45	0.65	39	39	0.97	35	37	0.68
Hispanic (%)	57	57	0.85	62	66	0.25	60	63	0.34
Race (%)			0.93			0.44			0.73
Black	19	19		16	13		17	16	
White	74	74		77	80		77	77	
Other Race	7	6		7	7		6	7	
Medicaid Enrollee (%)	91	91	0.75	92	93	0.69	93	96	0.12
New Enrollee (%)	25	11	**< 0.01**	25	15	**< 0.01**	20	12	**< 0.01**
ESRD 4 + Years (%)	44	45	0.78	44	49	0.19	47	48	0.75
Failed Transplant (%)	8	10	0.42	7	6	0.78	7	9	0.53
Last six months of life (%)	4	5	0.52	6	5	0.76	6	8	0.28
Patient in SNF in January	3.31	5.37	0.26	2.45	2.95	0.66	1.93	3.61	0.14
Patient received Home Health Care in January	4.55	5.37	0.68	3.19	3.19	0.99	3.37	4.81	0.30
Number of Inpatient Hospitalizations in January	0.12	0.14	0.50	0.13	0.15	0.72	0.16	0.24	**0.04**
Number of ED visits in January	0.07	0.07	0.87	0.08	0.11	0.21	0.12	0.15	0.41
CMS-HCC Risk Score	1.07	1.06	0.62	1.06	1.09	0.12	1.05	1.09	**0.01**
Cause of Renal Failure (%)			0.88			0.89			0.11
Diabetes	51	52		51	48		51	45	
Cystic Kidney	1	0		1	1		2	1	
Glomerulonephritis	11	12		9	10		10	9	
Hypertension	24	23		25	26		24	26	
Other Cause	13	13		14	15		14	19	

Abbreviations: CMS-HCC risk score = Centers for Medicare and Medicaid Services-Hierarchical Condition Categories; ED = Emergency department; ESRD = End-stage renal disease; FFS – Fee-for-Service; SNF = Skilled nursing facility

Numbers shown in **bold** are significantly different from FFS ($p < 0.05$).

Table TA-3b: Comparison of Patient Demographics in DMO B and FFS Matched Sample

	2006			2007			2008		
	DMO B (N=78)	FFS (N=78)	p-value	DMO B (N=170)	FFS (N=170)	p-value	DMO B (N=191)	FFS (N=191)	p-value
Age 50 + (%)	60	56	0.63	73	68	0.29	69	72	0.58
Female (%)	42	36	0.41	46	52	0.28	51	54	0.54
Hispanic (%)	1	1	1.00	16	15	0.88	22	25	0.47
Race (%)			0.65			0.87			0.80
Black	96	97		69	68		59	57	
White	4	3		21	21		29	32	
Other Race	0	0		10	12		12	11	
Medicaid Enrollee (%)	82	78	0.55	76	78	0.80	81	81	0.90
New Enrollee (%)	19	17	0.68	22	18	0.42	16	13	0.31
ESRD 4 + Years (%)	58	69	0.13	49	52	0.59	49	56	0.22
Failed Transplant (%)	9	13	0.44	8	4	0.17	4	2	0.20
Last six months of life	3	3	1.00	4	2	0.36	6	6	0.83
Patient in SNF in January	0.00	0.00		0.59	0.00	0.32	3.66	4.71	0.61
Patient received Home Health Care in January	2.56	5.13	0.41	1.18	0.59	0.56	0.52	0.00	0.32
Number of Inpatient Hospitalizations in January	0.18	0.23	0.55	0.14	0.14	0.90	0.13	0.19	0.14
Number of ED visits in January	0.21	0.22	0.88	0.20	0.17	0.72	0.14	0.16	0.66
CMS-HCC Risk Score	1.06	1.04	0.71	1.03	1.03	0.96	1.05	1.07	0.28
Cause of Renal Failure (%)			0.95			0.94			1.00
Diabetes	27	28		41	41		47	48	
Cystic Kidney	0	0		0	0		1	1	
Glomerulonephritis	12	14		10	11		6	6	
Hypertension	49	46		38	36		35	35	
Other Cause	13	12		11	12		10	10	

Abbreviations: CMS-HCC risk score = Centers for Medicare and Medicaid Services-Hierarchical Condition Categories; ED = Emergency department; ESRD = End-stage renal disease; FFS – Fee-for-Service; SNF = Skilled nursing facility

Table TA-3c: Comparison of Patient Demographics in DMO C and FFS Matched Sample

	2006			2007			2008		
	DMO C (N=529)	FFS (N=529)	p-value	DMO C (N=960)	FFS (N=960)	p-value	DMO C (N=611)	FFS (N=612)	p-value
Age 50 + (%)	69	74	0.12	73	76	0.17	72	72	0.76
Female (%)	53	53	0.90	47	50	0.17	47	47	0.84
Hispanic (%)	24	20	0.21	23	20	0.09	27	28	0.69
Race (%)			0.85			0.70			0.93
Black	47	49		44	46		49	50	
White	50	48		51	49		46	45	
Other Race	3	3		5	4		4	5	
Medicaid Enrollee (%)	50	47	0.36	58	56	0.38	66	65	0.79
New Enrollee (%)	21	14	**< 0.01**	17	10	**< 0.01**	8	5	**0.03**
ESRD 4 + Years (%)	53	57	0.17	45	47	0.27	54	58	0.16
Failed Transplant (%)	12	12	0.70	9	10	0.39	10	10	0.77
Last six months of life	1	1	0.74	5	5	0.83	7	9	0.39
Patient in SNF in January	1.89	1.70	0.82	2.40	3.13	0.33	2.95	4.75	0.10
Patient received Home Health Care in January	16.82	19.28	0.30	6.04	6.67	0.57	5.73	7.87	0.14
Number of Inpatient Hospitalizations in January	0.14	0.20	**0.03**	0.15	0.20	**0.03**	0.14	0.16	0.28
Number of ED visits in January	0.15	0.14	0.74	0.11	0.08	0.06	0.13	0.19	0.06
CMS-HCC Risk Score	1.06	1.08	0.19	1.07	1.10	**0.01**	1.07	1.09	0.18
Cause of Renal Failure (%)			0.26			0.68			0.43
Diabetes	41	42		43	41		44	42	
Cystic Kidney	2	2		2	3		2	2	
Glomerulonephritis	11	15		12	13		11	9	
Hypertension	29	27		27	26		26	25	
Other Cause	17	14		16	17		17	21	

Abbreviations: CMS-HCC risk score = Centers for Medicare and Medicaid Services-Hierarchical Condition Categories; ED = Emergency department; ESRD = End-stage renal disease; FFS – Fee-for-Service; SNF = Skilled nursing facility
Numbers shown in **bold** are significantly different from FFS ($p < 0.05$).

Another method to assess the propensity score's effectiveness in achieving balance is to examine the standardized differences between the treatment and control groups before and after matching. Figures TA-1 through TA-3 present the absolute standardized differences between the DMO and FFS populations over the covariates used in the propensity score model for each DMO.

As the figures depict, in every DMO year from 2006-2008, across the variables used in the propensity score match, we observed an overall reduction in bias as measured by the standardized differences between the DMO and matched FFS samples. In nearly every case, the absolute standardized differences were reduced to around or below 10% post-matching. Standardized differences above a 10% threshold are sometimes considered to indicate meaningful imbalance [1]. By this metric, propensity score matching improved the overall balance between the DMO and FFS populations although there were a few variables where the standardized differences were greater after matching. For example, in general, the standardized differences for New Enrollee were greater after matching across all three DMOS. It should be noted, however, that given a large number of variables it is unlikely to achieve balance on every variable, particularly if the variable is not strongly related to the propensity of enrollment in the Demonstration given all other factors in the model. This may be true for new enrollee status, as this variable is only significant in three of the nine logistic regression models for the nine DMO/year combinations

Figure TA-1: Absolute Standardized Differences for Variables Used in the Propensity Score Model, Before and After Matching (DMO A)

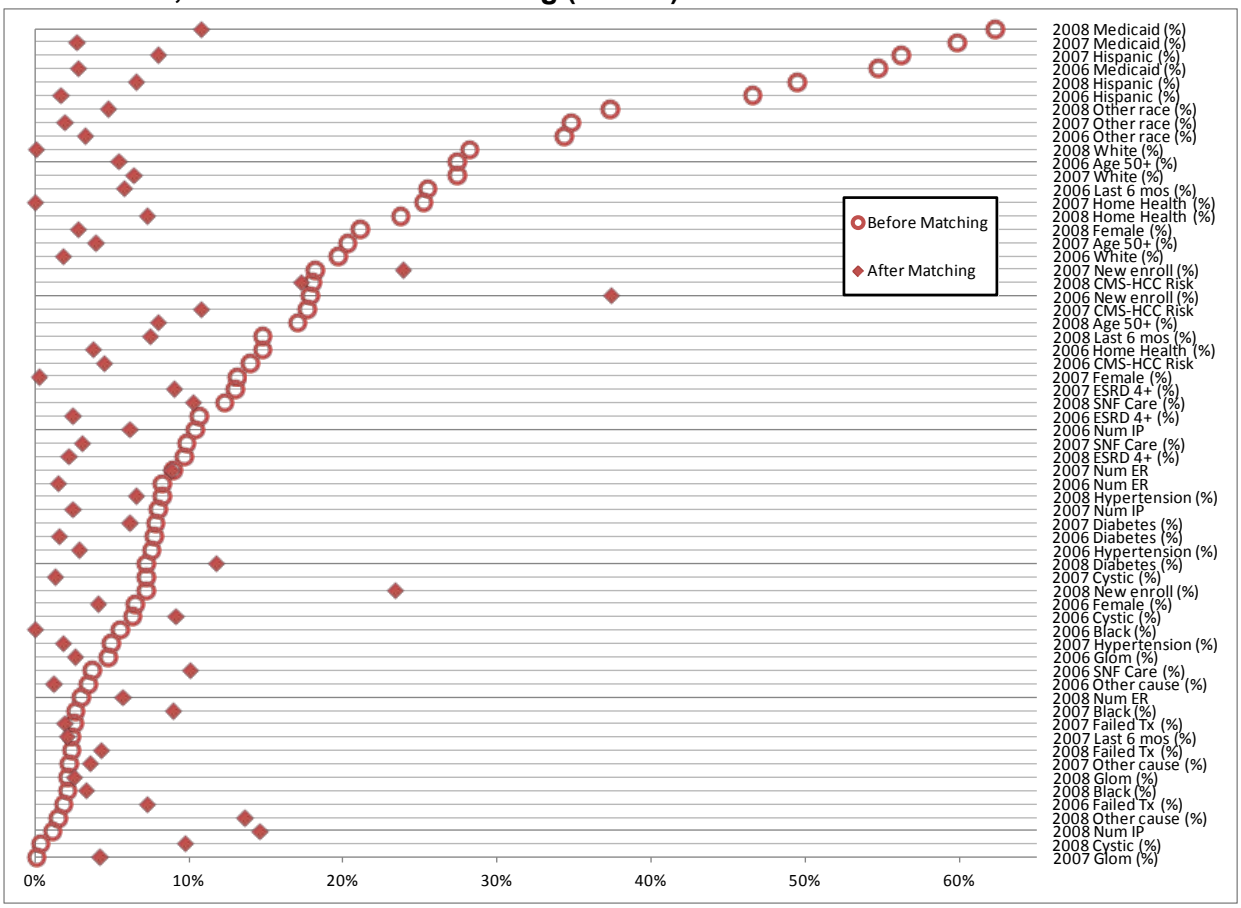


Figure TA-2: Absolute Standardized Differences for Variables Used in the Propensity Score Model, Before and After Matching (DMO B)

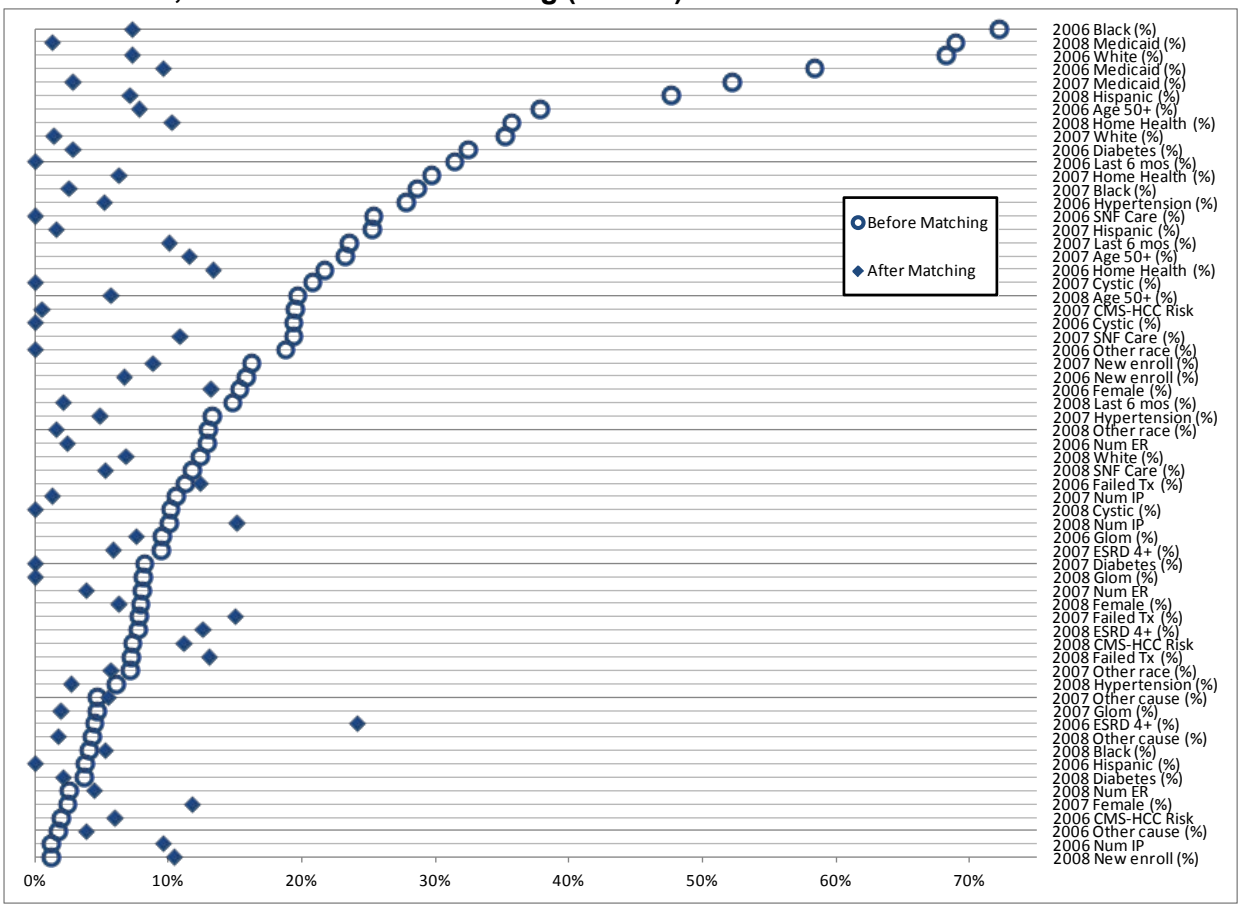
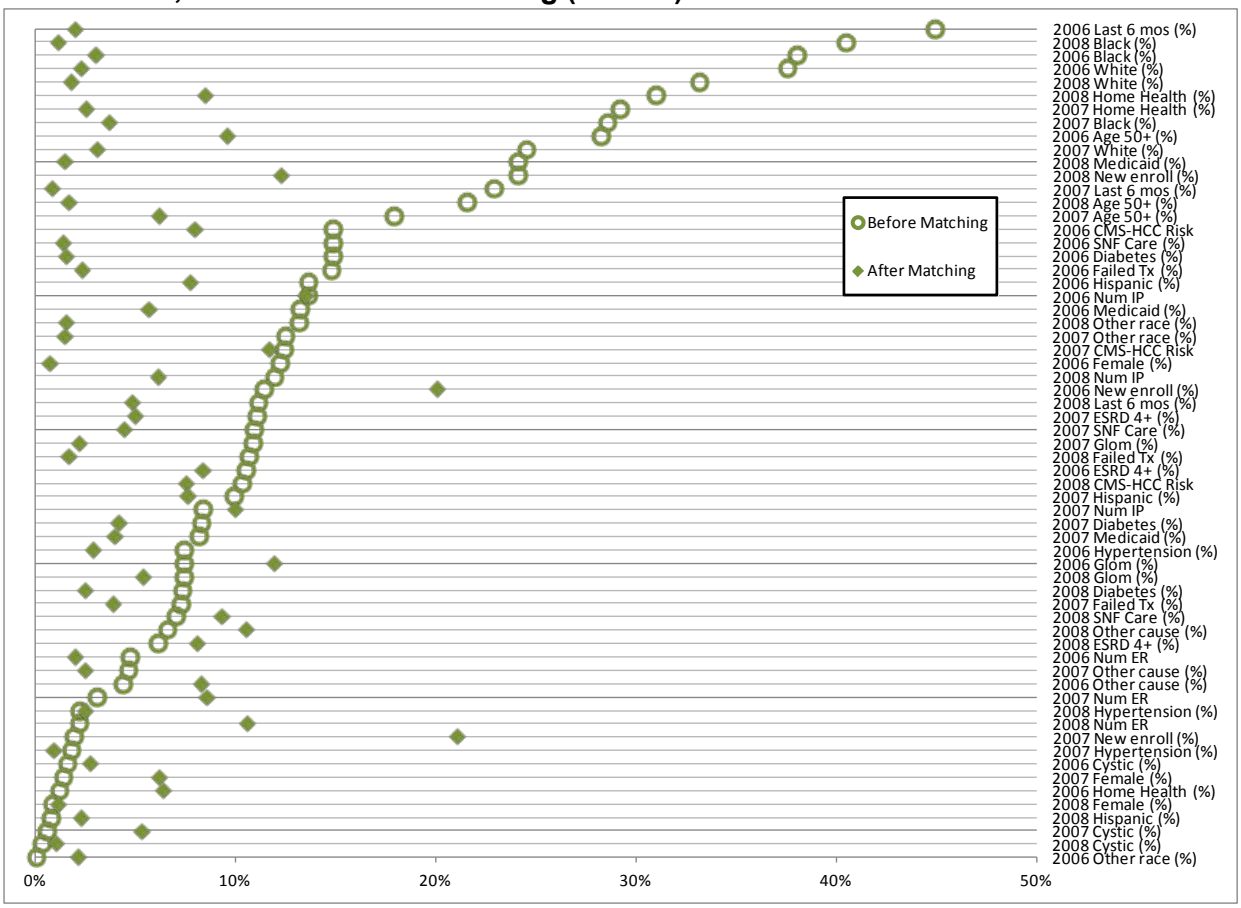


Figure TA-3: Absolute Standardized Differences for Variables Used in the Propensity Score Model, Before and After Matching (DMO C)



3. Patients Excluded from the Propensity Score Matched Samples

Table TA-4 reports the number and percentage of Demonstration enrollees excluded from the matched sample. DMO patients were excluded from the propensity score matched samples for two reasons 1) patients did not meet the criteria for inclusion in the propensity score model and 2) patients could not be matched to comparable FFS patients because they had propensity scores outside of the common support regions. The number of patients who could not be matched to a comparable FFS patient was extremely small, ranging between 0.4%-1% in DMO A, 1%-6% in DMO B, and 1%-2% in DMO C. Therefore, most of the patients excluded from the matched samples did not meet the criteria for inclusion in the propensity score model.

Inclusion in the propensity score model was determined based on the clinical and demographic characteristics of patients, whether the patients were Medicare Primary payor, and whether appropriate baseline data were available. Baseline was determined as January for each year of the Demonstration so as not to be influenced by any prior enrollment decisions. By way of contrast, if one used data as of mid-year, those values might be influenced by the enrollment decisions made earlier in the year, introducing a bias due to endogeneity.

Most of the exclusions were DMO patients who did not receive in-unit HD exclusively for at least one month during the analysis year (5.4%) or DMO patients who were Medicare Secondary payor the entire analysis year (2.4%). In addition, DMO patients were also excluded due to their Medicare coverage, or clinical and demographic characteristics, at baseline. For example 93 patients did not have Medicare pay for their dialysis until after the January baseline month. There were 102 patients who were excluded because they were not ESRD in the January baseline month, and 41 patients excluded because

they did not receive in-unit HD at baseline. In addition there were 27 patients who resided in a non-DMO state in January of the analysis year before moving to a DMO state and enrolling in the program later in the analysis year. These patients were also excluded.

Table TA-4: Reasons for Exclusion of ESRD Patients from Study Population

	Total		DMO A			DMO B			DMO C		
	N	%	2006	2007	2008	2006	2007	2008	2006	2007	2008
All ESRD Demonstration Patients	4,332	N/A	315	510	517	96	204	229	663	1,103	695
ESRD Demonstration Patients in Propensity Score Matched Sample	3604	N/A	242	408	415	78	170	191	529	960	611
Reasons for Exclusion											
Medicare Secondary Payor During Analysis Year	104	2.4%	4	18	2	0	3	0	12	61	4
Could Not Be Linked to Further Medicare ESRD Data	17	0.4%	2	1	1	0	0	0	1	0	0
Not In-Center HD Patient During Analysis Year	233	5.4%	24	44	63	0	2	9	10	37	44
States Added to a DMO Late in the Year	7	0.2%	0	0	0	0	0	0	0	0	7
Failure to Meet Baseline Criteria[a]											
Medicare Secondary Payor During Baseline Month	22	0.5%	1	1	0	0	0	0	0	14	6
New to ESRD after the Baseline Month	102	2.4%	16	11	10	4	4	5	43	3	6
First Medicare Coverage of Dialysis after Baseline Month	93	2.1%	13	12	13	3	9	8	27	4	4
Not In-Center HD During Baseline Month	41	0.9%	6	6	5	2	2	0	9	6	5
Not In DMO State During Baseline Month	27	0.6%	4	2	2	5	2	1	9	0	2
No Medicare Payment in Baseline Month	25	0.6%	1	3	1	0	10	2	6	2	0
Located outside Common Support Region[b]	57	1.3%	1	2	4	2	2	12	12	16	6

Abbreviations: ESRD = End-stage renal disease; HD = Hemodialysis

[a] Data for January was used to predict any DMO enrollment during the year.

[b] The last line represents the matched sample used to predict cost.

Tables TA-5a – TA-5c compare the demographics of patients included in the DMO matched samples and patients excluded from the matched samples. Overall, the significant differences between the two groups reflects the criteria for inclusion, for example, in all three DMOs the matched samples had a significantly larger number of HD patients compared to patients excluded from the matched sample.

Similarly the DMO matched samples had a larger proportion of patients who were new to Medicare or ESRD as indicated by New Enrollee status (DMO A in 2006 and 2008, DMO C in 2007 and 2008). Finally, across all three DMOs and all three years, the patients excluded from the propensity score matched samples had a larger proportion of patients without Medicaid. This difference was partly driven by the decision to exclude patients with Medicare as the secondary payor (MSP). Since MSP patients have private insurance and are not dual eligible, the exclusion of MSP patients from the propensity score analysis lead to systematic difference in the proportion of Medicaid patients in the included and excluded groups.

Table TA-5a: Comparison of Patient Demographics in DMO A Matched Sample and DMO A Patients not in the Matched Sample

	2006			2007			2008		
	DMO A In Matched Sample (N=242)	DMO A Not in Matched Sample (N=73)	p-value	DMO A In Matched Sample (N=408)	DMO A Not in Matched Sample (N=102)	p-value	DMO A In Matched Sample (N=415)	DMO A Not in Matched Sample (N=102)	p-value
Age 50 + (%)	69	64	0.42	73	70	0.52	74	62	**0.01**
Female (%)	43	37	0.40	39	35	0.47	35	36	0.84
Hispanic (%)	57	55	0.69	62	52	0.06	60	47	**0.02**
Race (%)			0.91			0.62			0.95
Black	19	18		16	13		17	17	
White	74	74		77	81		77	76	
Other Race	7	8		7	6		6	7	
Medicaid Enrollee (%)	91	56	**< 0.01**	92	70	**< 0.01**	93	68	**< 0.01**
New Enrollee (%)	25	44	**< 0.01**	25	31	0.19	20	31	**0.01**
ESRD 4 + Years (%)	44	25	**< 0.01**	44	35	0.10	47	38	0.12
Failed Transplant (%)	8	10	0.64	7	13	0.04	7	8	0.90
In-Unit HD	100	37	**< 0.01**	100	42	**< 0.01**	100	24	**< 0.01**
Last six months of life	4	0	0.08	6	4	0.49	6	3	0.22
Patient in SNF in January	3	0	0.18	2	0	0.14	2	0	0.18
Patient received Home Health Care in January	5	0	0.11	3	1	0.29	3	3	0.97
Number of Inpatient Hospitalizations in January	0.12	0.09	0.60	0.13	0.13	1.0	0.16	0.23	0.26
Number of ED visits in January	0.07	0.15	0.28	0.08	0.10	0.57	0.57	0.18	0.68
CMS-HCC Risk Score	1.07	0.99	**0.01**	1.06	0.98	**< 0.01**	1.05	0.98	**< 0.01**
Cause of Renal Failure (%)			0.17			**< 0.01**			0.46
Diabetes	51	40		51	52		51	46	
Cystic Kidney	1	4		1	6		2	5	
Glomerulonephritis	11	15		9	13		10	9	
Hypertension	24	22		25	13		24	23	
Other Cause	13	19		14	17		14	18	

Abbreviations: CMS-HCC risk score = Centers for Medicare and Medicaid Services-Hierarchical Condition Categories; ED = Emergency department; ESRD = End-stage renal disease; FFS – Fee-for-Service; HD = Hemodialysis; SNF = Skilled nursing facility
Numbers shown in **bold** are significantly different from FFS ($p < 0.05$).

Table TA-5b: Comparison of Patient Demographics in DMO B Matched Sample and DMO B Patients not in the Matched Sample

	2006			2007			2008		
	DMO B In Matched Sample (N=78)	DMO B Not in Matched Sample (N=18)	p-value	DMO B In Matched Sample (N=170)	DMO B Not in Matched Sample (N=34)	p-value	DMO B In Matched Sample (N=191)	DMO B Not in Matched Sample (N=38)	p-value
Age 50 + (%)	60	39	0.10	68	59	0.32	69	76	0.37
Female (%)	42	67	0.06	46	53	0.49	51	45	0.50
Hispanic (%)	1	0	0.63	16	47	**< 0.01**	22	45	**< 0.01**
Race (%)			0.40			**< 0.01**			**< 0.01**
Black	96	100		69	29		59	29	
White	4	0		21	62		29	66	
Other Race	0	0		10	9		12	5	
Medicaid Enrollee (%)	82	61	**0.05**	76	68	0.28	81	63	**0.01**
New Enrollee (%)	19	22	0.77	22	24	0.82	16	26	0.14
ESRD 4 + Years (%)	58	33	0.06	49	41	0.38	49	42	0.42
Failed Transplant (%)	9	11	0.78	8	6	0.72	4	11	0.07
In-Unit HD	100	67	**< 0.01**	100	76	**< 0.01**	100	63	**< 0.01**
Last six months of life	3	0	0.49	4	0	0.23	6	3	0.37
Patient in SNF in January	0	0	na	1	0	0.67	4	13	**0.03**
Patient received Home Health Care in January	3	0	0.54	1	0	0.55	1	0	0.68
Number of Inpatient Hospitalizations in January	0.18	0.07	0.25	0.14	0.23	0.41	0.13	0.19	0.42
Number of ED visits in January	0.21	0.14	0.60	0.20	0.13	0.48	0.14	0.16	0.85
CMS-HCC Risk Score	1.06	1.04	0.77	1.03	1.01	0.60	1.05	1.04	0.85
Cause of Renal Failure (%)			0.35			**0.04**			0.88
Diabetes	27	17		41	47		47	53	
Cystic Kidney	0	0		0	3		1	3	
Glomerulonephritis	12	6		10	9		6	5	
Hypertension	49	72		38	21		35	29	
Other Cause	13	6		11	21		10	11	

Abbreviations: CMS-HCC risk score = Centers for Medicare and Medicaid Services-Hierarchical Condition Categories; ED = Emergency department; ESRD = End-stage renal disease; FFS – Fee-for-Service; HD = Hemodialysis; SNF = Skilled nursing facility
Numbers shown in **bold** are significantly different from FFS ($p < 0.05$).

Table TA-5c: Comparison of Patient Demographics in DMO C Matched Sample and DMO C Patients not in the Matched Sample

	2006			2007			2008		
	DMO C In Matched Sample (N=529)	DMO C Not in Matched Sample (N=134)	p-value	DMO C In Matched Sample (N=960)	DMO C Not in Matched Sample (N=960)	p-value	DMO C In Matched Sample (N=611)	DMO C Not in Matched Sample (N=84)	p-value
Age 50 + (%)	69	66	0.54	73	68	0.18	72	54	**< 0.01**
Female (%)	53	55	0.63	47	50	0.48	47	49	0.73
Hispanic (%)	24	17	0.11	23	15	**0.02**	27	31	0.47
Race (%)			0.17			0.20			0.43
Black	47	54		44	52		49	44	
White	50	41		51	43		46	49	
Other Race	3	5		5	4		4	7	
Medicaid Enrollee (%)	50	36	**< 0.01**	58	43	**< 0.01**	66	62	0.46
New Enrollee (%)	21	30	**0.03**	17	21	0.27	8	20	**< 0.01**
ESRD 4 + Years (%)	53	26	**< 0.01**	45	48	0.41	54	57	0.59
Failed Transplant (%)	12	10	0.55	9	16	**< 0.01**	10	20	**< 0.01**
In-Unit HD	100	55	**< 0.01**	100	68	**< 0.01**	100	35	**< 0.01**
Last six months of life	1	1	0.83	5	6	0.72	7	1	**0.03**
Patient in SNF in January	2	0	0.19	2	1	0.20	3	0	0.12
Patient received Home Health Care in January	17	14	0.57	6	4	0.24	6	4	0.46
Number of Inpatient Hospitalizations in January	0.14	0.17	0.55	0.15	0.15	1.0	0.14	0.15	0.73
Number of ED visits in January	0.15	0.04	**< 0.01**	0.11	0.11	0.96	0.13	0.05	**0.01**
CMS-HCC Risk Score	1.06	1.01	**0.01**	1.07	1.03	0.10	1.07	1.01	**0.02**
Cause of Renal Failure (%)			0.98						**0.03**
Diabetes	41	40		43	50	0.31	44	42	
Cystic Kidney	2	1		2	2		2	5	
Glomerulonephritis	11	10		12	13		11	19	
Hypertension	29	30		27	18		26	14	
Other Cause	17	19		16	17		17	20	

Abbreviations: CMS-HCC risk score = Centers for Medicare and Medicaid Services-Hierarchical Condition Categories; ED = Emergency department; ESRD = End-stage renal disease; FFS – Fee-for-Service; HD = Hemodialysis; SNF = Skilled nursing facility
Numbers shown in **bold** are significantly different from FFS ($p < 0.05$).

H. References

1) Austin, Peter C. *Balance diagnostics for comparing the distribution of baseline covariates between treatment groups in propensity-score matched samples*. Statist Med. 2009; 28:3083-3107.

APPENDIX 3: METHODOLOGICAL RESEARCH DISCUSSION

In any research project, there are often multiple approaches to addressing the questions. In the spirit of encouraging rigorous scientific debate, Arbor Research Collaborative for Health (Arbor Research) and the Centers for Medicare & Medicaid Services (CMS) invited the Disease Management Organizations (DMOs) to offer their insights on the evaluation approach taken in this project. To further the dialogue, Arbor Research/CMS carefully considered the important points raised by the DMOs, expanding analyses and textual descriptions throughout the Evaluation Report.

Additionally, each DMO was invited to submit specific comments on the methodology employed which would be included in the Appendix. One DMO chose to offer comments on specific methodological issues, which are presented in the following section. This is followed by a discussion provided by Arbor Research, which addresses the specific methodological issues raised by the DMO. CMS does not endorse one approach over others, recognizing that there are many ways to address the research questions.

DMO A Comment on ESRD Demonstration Interim Report

DMO A would like to thank CMS and the Arbor Research Collaborative for Health for their work on this interim report regarding the initial three of five years of data on the disease management demonstration for beneficiaries with ESRD. We appreciate the opportunity to review and comment on its findings.

DMO A and CMS began this collaboration to jointly explore the promise of patient-centered, integrated care for the ESRD population, emphasizing preventive services and greater coordination of care. We are grateful for this opportunity and have eagerly anticipated interim results that would demonstrate the potential benefits of this approach.

Reviewing the report, we are pleased to find that it confirms that the demonstration has significantly improved both the processes and outcomes of care for beneficiaries with ESRD. We are excited by the numerous positive findings within the report, including:

- Large and statistically significant reductions in utilization of physician visits, emergency room visits, and skilled nursing facilities
- Improvements in preventive care, including immunizations, diabetic retinal exams, and diabetic HbA1c testing

We are particularly pleased that patients in all three DMOs showed statistically significant and comparable improvement in mortality when compared to their Fee For Service counterparts, before the application of statistical techniques to control for potential confounding.

However, as the report acknowledges, the statistical techniques used to control for confounding failed when applied to DMO A, which unfortunately limits the ability to draw inferences from the results. In fact, as we reviewed findings throughout the report, and particularly in the important sections concerning utilization and cost results, we found significant issues that limit its overall utility. It is important to point these out so that subsequent evaluations can improve on the methods used here and deliver greater accuracy in their findings.

Our three major concerns with the analyses contained within this report are that they:

1. Did not appropriately control for incident patients, limiting the ability to compare results to the matched control group
2. Did not appropriately control for baseline healthcare resource utilization
3. Modeled DMO costs and compared them to actual FFS costs

As there are two remaining years of data to be gathered and reviewed, we have focused our comments on how best to carry forward the analysis in a way that addresses the above concerns. We outline below several technical enhancements which could lead to even more accurate and conclusive findings in the final report.

1. Comparability of the matched control group

While the demonstration results were positive, we believe, and the evaluators have acknowledged, that the propensity score match (the process of creating a comparator group) was not successful for DMO A. This limits the ability to draw conclusions from the utilization and cost analysis that compared patients in DMO A to these control patients.

Specifically, the match process to select control patients failed with respect to incident (new-to-dialysis) patients. In 2006, DMO A had 25% of its sample classified as New Enrollees, vs. 11% in its FFS Matched Group; the comparison was 25% vs. 15% in 2007, and 20% vs. 12% in 2008 [Table TA-3a, p. 141]. This difference was statistically significant for all three years [Table TA-3a, p. 141]. In the U.S., incident patients are sicker and more costly than prevalent patients. According to the United States Renal Data System, the average Medicare dialysis patient costs $5,882 per month. However, the average cost in the first month cost is significantly higher, at $14,761. Indeed, the USRDS reports that patients are hospitalized 40% more frequently during the first six months of dialysis than they are during the subsequent six month period.

It is critical that any analysis of healthcare utilization or cost control for these differences in the first 6 months of dialysis. Unfortunately, the propensity score match utilized in the interim evaluation did not adequately control for this. While a Secondary Stage Regression Adjusted model was used in an attempt to correct these imbalances, it is unlikely that the regression model compensated for the large amount of remaining confounding resulting from the poorly constructed identification model used in the propensity score matching. The greater number of incident patients in DMO A relative to its FFS control group confounds the results and obfuscates any mortality, cost, utilization or other benefit associated with the intervention. This critical limitation of the propensity score match, which has been

acknowledged by the evaluators, need to be addressed in future evaluation efforts in order to understand the true impact of the disease management demonstration.

2. Control for baseline healthcare resource utilization

The best predictor of future healthcare resource utilization is past utilization. While the evaluation did include a measure of healthcare resource use as a variable in the propensity match, it limited it to one month, specifically January of each year. Unfortunately, one month's utilization is not sufficiently representative or predictive of a patient's annual utilization profile. For example, for DMO A, 45% of its 2006 members had a hospital admission in 2006, but only 5% had an admission in January 2006. This inadequate control of utilization is clearly seen when looking at 2008 FFS A hospital admissions. The baseline FFS A January 2008 utilization used for the propensity score match is equivalent to 2.88 admissions per member per year (calculated by multiplying 0.24 January inpatient utilizations from Table TA-3a on p. 141 by 12 months). However, the actual 2008 FFS result used for utilization comparisons shows a 39% lower utilization of 1.77 admissions per member per year (Table 11.5, p. 78) instead. The month-to-month variation makes it difficult to draw any conclusions from a one-month observation, and likely introduces significant error into the match. A three to six month sample of healthcare resource use would provide significantly better statistical control.

3. Comparison of modeled DMO costs to actual FFS costs

This evaluation attempted to understand cost savings achieved by the DMOs through a comparison of the estimated FFS cost of the DMO sample with the actual cost of the matched FFS sample. The DMO costs were estimated by applying a regression model, derived from actual FFS utilization and cost data, to the DMO utilization measured in the Chapter 11 analysis of patient outcomes. There is inherent potential for error in using such a model rather than using actual costs, and evidence of such error is included in the report. As an example, the cost factors developed from the propensity score matched FFS A group are significantly out of line with DMO A's own claims data. In Appendix Table TA-2, FFS A's 2006 cost per hospital admission is $16,852, compared to DMO A's actual claims-derived cost of $11,753. Interestingly, DMO A's cost per admission is much closer to FFS B ($10,295) and FFS C ($10,592) than it is to the FFS A result. This disparity between modeled costs and actual costs fundamentally alters the interpretation of the results–from finding cost savings to finding incremental cost.

The evaluators recognized the issues associated with modeled cost, and CMS will be conducting an additional study using actual demonstration costs. The results of this analysis will be a more definitive valuation of the programs' impact on beneficiary cost.

In conclusion, we are excited about the meaningful directionally positive results from the collective ESRD demonstration, despite the methodological limitations detailed above. Of the two remaining demonstration participants, both have seen improved utilization and cost results in the last two years, and a final evaluation at the end of the program will allow the renal community to maximize its learning from this important experiment. We look forward to continuing to work with CMS to see this project

through to its conclusion. In addition, we are working with an independent evaluator to reanalyze the current data and to conduct a final evaluation of the entire five-year demonstration, using the robust analytical approaches we believe are essential to producing the most accurate and appropriate conclusions on the clinical and financial outcomes of this project. We look forward to sharing this new work with CMS and the renal care community.

Arbor Research Response to DMO A Comments

DMO A, one of the participants in this Demonstration, has brought forth important issues related to the completed analyses. Some of the issues brought forth by DMO A arise as a consequence of the observational nature of a Demonstration, some of the issues relate to specific choices made in the evaluation of this Demonstration, and some of the issues relate to the fact that this Evaluation Report covers the first three years of the five-year Demonstration period. Additional analysis of the experience during the last two years of the Demonstration period might provide insights not observed during the first three years. The Arbor Research perspective on these issues is summarized in this document.

Background: CMS selected Arbor Research to perform this independent evaluation; which in part built on our earlier work on the Managed Care (MC) Demonstration for the ESRD population. Arbor Research worked with CMS and each DMO to establish the goals, timelines, and analytical methodology of this evaluation. We also sought input from the Demonstration's multiple stakeholders throughout the Evaluation. Because of the complexity of each DMO's program, we engaged each organization to propose additional research questions to examine the impact of Disease Management components unique to each DMO.

This evaluation was not designed to be a randomized clinical trial. Therefore, the analytical methodology used several patient groups to serve as comparisons to the selected Disease Management interventions. These comparison groups were identified in order to be similar to the Demonstration groups, subject to availability of data. Data on non-DMO patients receiving ESRD care in the same dialysis facilities were not available through the DMOs. For the key analyses of mortality, morbidity, cost and service utilization, the Evaluation used concurrent fee-for-service (FFS) comparison groups. Some analyses utilized geographic-matched comparison populations, and others used a propensity-score matched comparison population. For analyses evaluating the impact of Disease Management on processes of care, we accessed the United States Dialysis Outcomes Practice Patterns Study (U.S. DOPPS) population, which includes a nationally representative study of hemodialysis (HD) patients. The U.S. DOPPS provided data on specific clinical practices not currently available for the CMS FFS population. Altogether, these methods for comparing the intervention group to a comparison population allowed for the evaluation of multiple endpoints including processes of care, clinical outcomes, service utilization, patient-centered measures, and financial outcomes. Finally, we utilized analytical tools that took into account clinical and demographic factors that would be expected to impact findings for the respective endpoints evaluated. The Evaluation Report notes both strengths and potential limitations for interpreting the findings, such as differential disenrollment rates, and limitations of the propensity score methodology. It is important to recognize that results from any non-

randomized study, such as this one, can be influenced by potential differences between comparison groups, and it is appropriate to consider those possibilities, as DMO A has done. However, it is also necessary to draw the most accurate conclusions possible from the existing data recognizing the potential uncertainties in those conclusions.

DMO A has made suggestions of alternative analytical approaches that could have been used for the Evaluation. Many different specific methodologies could have been used in this demonstration evaluation, as in the general analysis of research questions. Prior to seeing the results of the analysis, Arbor Research worked with the participating DMOs to identify methods that were deemed appropriate to the goals of the project. Indeed, many of the methods utilized for the evaluation were shared with the DMOs as interim reports during Year 2 of the Demonstration. As described below, multiple methods were used to test several of the research questions. In these instances, the different methods yielded consistent results, suggesting that the results are relatively robust to the method used to carry out the analysis. In response to DMO A's comments, the following points may be important to consider:

Regarding comparability of the matched control groups and controlling for new dialysis patients in the propensity score models: With regards to DMO A's comments on the "failure" to achieve comparable groups, the propensity score methodology is a well-established approach to minimizing selection bias in observational studies and is one of several methodologies that we employed in our evaluation. As described in the report, the propensity score method attempts to identify a comparator that has the same "propensity" for enrolling in the DMO as actual enrollees. Various clinical and demographic factors were taken into account in the propensity score method. However, the actual matching process is based on the overall "propensity score" rather than on individual clinical and demographic factors. Because of the relatively large number of covariates used in the propensity score regression model and relatively low DMO enrollment, perfect balance is likely not an achievable goal. We clarify that propensity score matching did not "fail" as demonstrated by the improvement of standardized differences post-matching on nearly all variables (see details provided in the Technical Appendix). Our examination of the improvement in comparability of propensity score matched populations shows reduced bias overall and is consistent with published literature evaluating success of the propensity score matching process [1]. Looking across all three years, all three plans, and all covariates matched on shows that the model greatly reduced differences between the DMO and FFS comparison group. Furthermore, a lack of balance may arise because a specific variable is not strongly predictive of DMO enrollment. Indeed, the "new enrollee" variable was only statistically significant in one of DMO A's three annual propensity score regression models. In summary, while there is some evidence for residual differences in the groups, there does not appear to be evidence for a large amount of remaining confounding. Nonetheless, we have included supporting analyses and substantial text on these issues in the report.

Residual differences between the DMO and the propensity-score matched FFS population were taken into account by second-stage multiple regression models which yielded the utilization analyses presented in the report. These models provide for direct statistical adjustment for characteristics that continued to differ after the propensity score methodology. While these models are inherently limited

by application after the propensity score methodology, there is no reason to believe these models failed to statistically adjust for observed residual differences.

All DMOs had a significantly lower percentage of patients in the first six months of dialysis compared to the FFS comparison groups (Table 1.1a). We agree a separate examination of the subgroup of patients new to ESRD would be of value in the future. Such analyses may require a specific Demonstration design and/or evaluation for new ESRD patients in order to enroll a patient sample that has sufficient power to answer this specific question.

Regarding controlling for baseline healthcare resource utilization: One important control used in the analysis was to adjust for baseline levels. It is valuable to have adequate data for such adjustment. At the onset of this evaluation we discussed with each DMO the availability of pre-intervention data; however, the Demonstration teams decided this was not possible. Measuring baseline utilization over a longer time period has the potential to improve the accuracy of the propensity score models for some patients. However, use of a longer baseline period would not be expected to reduce bias in the results but would primarily increase precision in the estimates. In this case, using a longer baseline period might improve the accuracy of the baseline adjustment for those patients included in the analysis, but at the expense of possibly excluding more patients from the analysis. One month was selected to minimize the exclusion of patients new to ESRD and/or Medicare. Although it may be possible to collect more pre-Demonstration utilization from Medicare FFS data, using these data would require restricting the sample to prevalent ESRD patients who were Medicare primary payer the entire year prior to their enrollment. This would fail to analyze many patients new to ESRD and would reduce overall statistical power. Furthermore, there are concerns about the endogeneity of measuring baseline utilization after an implicit decision is made by patients not to enroll in the Demonstration. For example, it may not be appropriate to adjust for 2006 FFS utilization as "baseline" for a 2007 DMO enrollee because this enrollee may have made a decision not to enroll in 2006, and hence the 2006 utilization would have transpired after an enrollment decision (in this example a decision not to enroll in 2006) has been made.

Regarding comparison of modeled DMO costs to actual FFS costs: One of the goals of the Evaluation is to estimate the savings experienced by the DMOs due to differences in utilization. To fairly estimate savings in the Demonstration compared to the FFS setting, it is necessary to quantify utilization in each DMO and FFS based on a consistent cost structure. As such, we used the average FFS costs in the geographic region of each DMO. Using actual DMO medical costs from claims may create an invalid comparison since the cost structures in the DMOs may differ from FFS.

As stated in multiple sections of the report, an analysis using actual cost data will be conducted by CMS and is outside the scope of this report. In regard to the differences in average utilization costs across the three FFS comparison groups, we checked DMO A's FFS group and did not find evidence that the cost differences were driven by outliers. Rather, the entire distribution of costs per admission was shifted perhaps consistent with higher Medicare reimbursements observed in DMO A's specific geographic service areas.

In summary, we agree that the issues raised by DMO A are important to consider. Although it is possible that results from future studies might lead to different conclusions than were reached in our analyses of existing data at the 3-year time-point, the use of multiple methods that yielded consistent results suggests conclusions robust to any particular method. In addition it is important to recognize the uncertainties resulting from any non-randomized study. Like DMO A, we recognize the critical implications of this demonstration given the continued high morbidity and mortality observed in the ESRD population and the potential impact of integrated and coordinated care. We believe that advances in understanding are most reliable when based on replicated and iterative studies of important issues. All providers of care should be encouraged to seek opportunities to improve the outcomes of their patients, as DMO A has done in this demonstration, and to critically review the available data and evidence about evaluations of those efforts.

References

1) Austin, Peter C. *Balance diagnostics for comparing the distribution of baseline covariates between treatment groups in propensity-score matched samples.* Statist Med. 2009; 28:3083-3107.