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How Disease Burden Influences Medication Patterns for Medicare Beneficiaries: Implications for Policy

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ABSTRACT: This issue brief provides benchmarks, based on empirical analyses of 2002 data, for evaluating the quality of pharmaceutical care under the Medicare Part D prescription drug benefit. The analyses cover all major classes of pharmaceuticals used by beneficiaries with one of eight chronic conditions. Common patterns observed include: 1) a mounting disease burden is associated with increasingly complex medication regimens in every group, and 2) the intensity and persistence of drug use tend to rise with disease burden up to a point, before declining for beneficiaries with the greatest morbidity. The study concludes that neither traditional drug quality indicators nor new quality assurance mechanisms mandated by law are well aligned to capture suboptimal medication use at either end of the spectrum of disease burden in the Medicare population. A holistic approach to medication management is needed to ensure that Part D plans meet beneficiaries and policymakers' expectations for high-quality care.

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OVERVIEW

It is well known that Medicare beneficiaries are heavy users of prescription medications. This fact dominated the policy debate over the voluntary prescription drug

This issue brief is based on *Medication Use by Aged and Disabled Medicare Beneficiaries Across the Spectrum of Morbidity: A Chartbook*, published by the Peter Lamy Center on Drug Therapy and Aging at the University of Maryland Baltimore in 2007. To obtain a copy, please visit the center's Web site at www.pharmacy.umaryland.edu/lamy.

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benefit that became available in January 2006. Much less is known about the quality and effectiveness of medication use by beneficiaries. This is partly due to the federal government's delay in releasing prescription drug data from Part D plans, but the problem will not be solved simply by making Part D prescription claims available to researchers. A more fundamental problem is that there are no systematic, evidence-based guidelines available to evaluate medication regimens of older patients, particularly those with complex morbidity.

Building the evidence base for appropriate drug therapy for Medicare beneficiaries must begin with an empirical, population-level assessment of how medication regimens vary across the continuum of disease burden. To accomplish this objective, the researchers used data from the period prior to the implementation of the new drug benefit to describe the breadth, intensity, and persistence of medication regimens for the Medicare population as a whole and for beneficiaries with eight common chronic conditions: diabetes, depression, dementia, chronic obstructive pulmonary disease (COPD), arthritis, hypertension, ischemic heart disease, and heart failure.

Two features of this study distinguish it from previous research on medication use by Medicare beneficiaries. First, it examines drug utilization patterns for beneficiaries with each of these chronic conditions in the larger context of their overall disease burden. Over their lifetimes, few Medicare beneficiaries suffer from single diseases with well-accepted, evidence-based treatment recommendations. Rather, most ultimately develop multiple conditions, for which treatment guidelines are either lacking or ambiguous in the presence of significant comorbidity. Geriatricians have developed various clinical recommendations and best practice statements for dealing with complex morbidity in older patients. The development of evidence-based guidelines for treating complex morbidity has proven elusive, however, in part due to scant epidemiologic data describing how treatment patterns for particular chronic conditions change with rising morbidity. This study was designed to help build this evidence base.

A second unique feature of the study is that it takes into account the prescription drugs used to treat all of the diseases that beneficiaries suffer—not just those specific to the eight chronic conditions. This analysis examines how beneficiaries' medication regimens evolve with accumulating morbidity, highlighting areas of potential concern regarding underuse, overuse, and inappropriate use of medication therapy for particular segments of the chronically ill population.

METHODOLOGY

The sample for the study (N=8,455) was selected from the 2002 Medicare Current Beneficiary Survey (MCBS). The MCBS collects extensive information on prescription drug utilization and spending from self-reports and reviews of medication containers. The MCBS also provides claims data for Part A (inpatient and outpatient hospital and post-acute services) and Part B (physician and other provider services) for each respondent. Diagnostic indicators from the claims data, together with self-reports of chronic conditions, were used to define the eight disease cohorts. In order to capture the full spectrum of rising disease burden, each cohort was stratified into 10 equal-size deciles, based on cumulative health care spending during the year from all payer sources, including beneficiaries' out-of-pocket expenses.[1] Medication statistics were computed at the individual beneficiary level, aggregated by disease cohort and decile of disease burden, and then weighted to be nationally representative of the community-dwelling Medicare population. Beneficiaries enrolled through the Medicare+Choice program (privately administered plans, now called Medicare Advantage) and those in long-term care facilities were excluded due to lack of critical data elements.

The study focused on four sets of indicators designed to benchmark the quality and effectiveness of beneficiaries' medication use before the advent of Part D drug coverage. The first indicator is the fraction of total health care spending devoted to prescription drugs. This captures changes in the allocation of health resources used to treat beneficiaries with rising disease burden.

The second set of indicators depicts the increasing breadth and complexity of medication utilization with rising disease burden. Two recognized measures of drug regimen complexity were profiled: the number of unique therapeutic categories and the number of unique pharmacologic classes represented in each beneficiary's annual course of drug therapy. The study used the United States Pharmacopoeia (USP) classifications published in December 2004 as guidance for Part D plans in 2006.[2]

The third set of indicators shows how average intensity of medication use evolves with rising disease burden. Two measures were employed here as well. One is the average number of fills per medication-intensive condition diagnosed in Medicare claims. Medication-intensive comorbidity was identified using the Centers for Medicare and Medicaid Services (CMS) Prescription Drug Hierarchical Coexisting Conditions (RxHCC) model used to risk-adjust payments to Medicare Part D plans.[3] The other intensity measure is the average number of prescription fills per pharmacologic class represented in each beneficiary's medication regimen.

The final set of indicators drilled down to the prevalence and persistence of specific drugs used to treat particular medical problems. This set included four measures. First is the annual prevalence of every therapeutic drug category used by at least 5 percent of the beneficiaries in each disease cohort (typically 20 to 25 drug groups). Next is the mean number of prescription fills per user of drugs in each category (this measure captures the persistence of use over the year). Additional measures gauged the utilization of drugs recommended by consensus guidelines for the treatment of the eight chronic diseases. Here, too, drug use is characterized by any use (prevalence) and number of annual prescription fills among users (persistence of use). The full report contains an extensive set of appendix tables that characterizes each study cohort by sociodemographic factors, health status measures, and selected health system utilization variables.

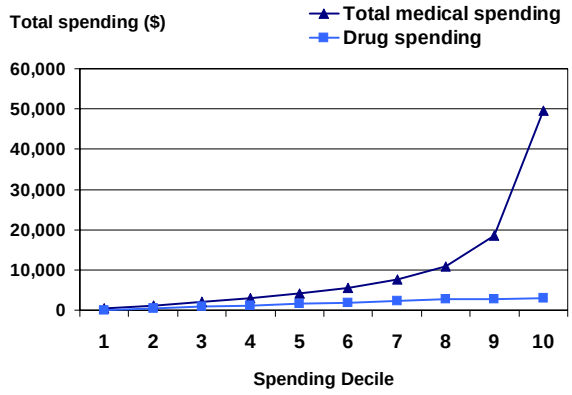
FINDINGS

This issue brief highlights a small sample of the findings presented in the overall study.[4]

The Medicare Population

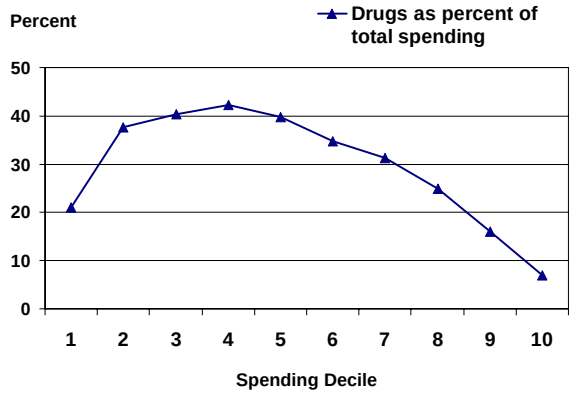
Prescription drugs represent a significant component of the medical care received by Medicare beneficiaries, accounting for 20 percent to 31 percent of total spending for the average individual across the eight conditions studied. Beneficiaries with diabetes and hypertension had the highest average shares of spending devoted to prescription drugs (31% each), while beneficiaries with heart failure and COPD had the lowest shares (20% and 21%, respectively). Figure 1 plots drug spending and total medical expenditures for community-dwelling beneficiaries as a function of rising disease burden. On average, Medicare beneficiaries spent $1,700 on prescription drugs in 2002. Spending rose at a nearly constant rate from $103 in decile 1 to decile 7 before flattening out in the top three deciles, finally reaching $2,924 in decile 10. Total medical spending exhibits a very different growth pattern. The average beneficiary consumed $10,210 in all medical services in 2002, ranging from $363 in the lowest decile to $49,519 in the highest. The sharply rising expenditure rates from the sixth through the tenth deciles are primarily a result of hospitalization. About one of five beneficiaries was hospitalized that year and 90 percent of this group fell in the top three spending deciles.

Figure 1. Relationship of Drug Spending to Total Medical Spending for Community-Dwelling Medicare Beneficiaries, 2002



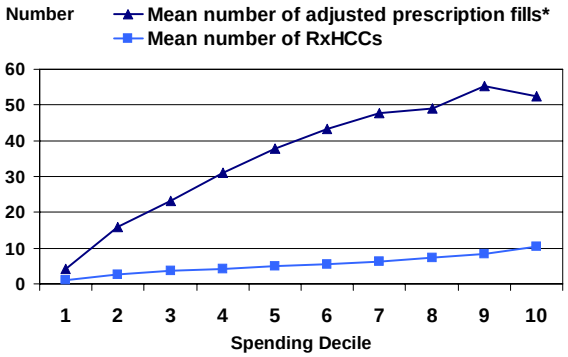
These differential trends mean that the proportion of medical spending devoted to prescription drugs doubled, from 21 percent in the first decile to a peak of 42 percent in decile 4, and then fell back sharply to just 7 percent in decile 10 (Figure 2). The declining drug share in the top (e.g., higher cost) half of the distribution is not surprising, because drugs are cheap compared with hospitalization. However, the rising proportion of spending devoted to prescription drugs in the bottom half of the distribution is worth noting. While there is no inherently "right" fraction of health care that should be devoted to prescription drugs, to the extent that drugs substitute for more expensive services, the middle of the curve seen in Figure 1 may reflect the most efficient allocation of services across the spectrum of morbidity.

Figure 2. Prescription Drug Spending as a Percent of Total Medical Spending for Community-Dwelling Medicare Beneficiaries, 2002



The next two figures show how prescription drug use and the conditions for which they are prescribed vary with increasing disease burden. The upper line in Figure 3 plots the number of annual adjusted prescription fills. This measure takes into account the fact that some prescriptions contain more than a single medication (e.g., codeine plus acetaminophen). For such combination products, each pharmacological class represented in the prescription is counted as a separate fill.[5] The relationship between the number of adjusted prescription fills and spending decile is nearly linear from decile 1 (4.3 fills) to decile 9 (55.3 fills), before falling back slightly in decile 10 (52.4 fills). The lower line presents counts of medication-intensive conditions based on the RxHCC metric, and rises slowly from 1.1 condition per beneficiary in decile 1 to 10.5 conditions per beneficiary in decile 10.

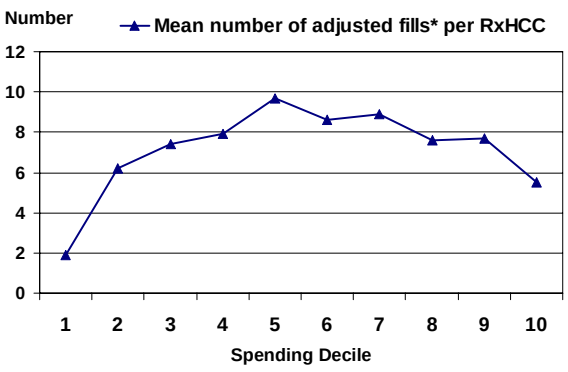
Figure 3. Relationship of Drug Use to Medication-Intensive Conditions (RxHCCs) for Community-Dwelling Medicare Beneficiaries, 2002



* Adjusted to account for combination products containing drugs in two or more pharmacologic classes.

Differential rates of increase in these two indicators—number of adjusted fills and counts of medication-intensive conditions—generate the "inverted U" pattern observed in Figure 4. The ratios range from 1.9 fills per condition in decile 1 to a peak of 9.7 in decile 5 and then back to 5.5 fills per condition in decile 10. A similar pattern was observed for each of the eight disease cohorts, with intensity peaking in the middle of the range, between 25 percent and 58 percent above levels observed at either extreme. This is a basic finding of this study: while higher levels of intensity of drug therapy do not necessarily imply better treatment, the fact that intensity levels are systematically lower

Figure 4. Intensity of Prescription Drug Use per Medication-Intensive Condition (RxHCC) for Community-Dwelling Medicare Beneficiaries, 2002

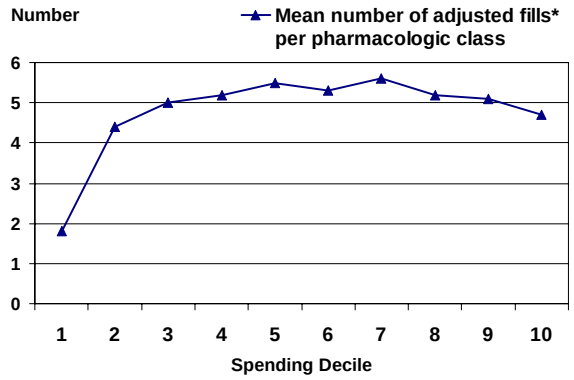


* Adjusted to account for combination products containing drugs in two or more pharmacologic classes.

for beneficiaries with both low and high disease burdens may signal that chronic medications are being underutilized and/or misutilized by these individuals. Further, the broadly similar patterns in Figures 2 and 4 suggest that intensity of drug use is an important factor underlying the rising and then falling drug share of spending observed.

Figure 5 shows another way of measuring intensity of drug use among community-dwelling beneficiaries. The denominator of this measure—adjusted prescription fills—is the same as in the previous figure. The numerator is the number of USP pharmacologic classes represented in each beneficiary's drug regimen. Pharmacologic classes represent the unique properties of the drug that make them medically effective. The ratio of adjusted fills to pharmacologic classes produces an "inverted U" pattern, as seen in Figures 2 and 4. However, the curve in Figure 5 is flatter at the top, indicating a broad plateau in the mean number of prescriptions filled per drug class before the rate begins to decline after the seventh decile of medical spending. The interpretation of this pattern is similar to that for Figure 4. High intensity of drug use is not desirable per se, except to the extent that it is driven by medications for chronic conditions that generally should be administered throughout the year in order to be optimally effective.

Figure 5. Intensity of Prescription Drug Use per Pharmacologic Class for Community-Dwelling Medicare Beneficiaries, 2002



* Adjusted to account for combination products containing drugs in two or more pharmacologic classes.

Medicare Beneficiaries with Diabetes

This section summarizes findings relating to treatment of diabetes in the Medicare population. The sample for this analysis comprised 1,956 community-dwelling beneficiaries with the disease in 2002. The focus is on six drugs and drug classes widely recommended by diabetes treatment guidelines as a means to help prevent or delay complications of the disease. The guidelines recommend regular use of antidiabetic drugs (primarily oral hypoglycemics but also insulin in severe cases), ACE-inhibitors (or ARBs for people who are intolerant of ACE-inhibitors), and statins or other lipid lowering agents for those with LDL cholesterol >100 mg/dL. Adults with diabetes are also recommended to have an annual influenza vaccination and a pneumococcal vaccination every five years. In reviewing these findings, it is important to recognize that not every older adult with diabetes is a candidate for each medication.

Table 1 shows prevalence rates by spending decile for the six recommended agents. Except for pneumococcal vaccinations, prevalence rates are lowest at the bottom of the scale; that is, Medicare beneficiaries who have the least severe disease burden are also the least likely to get recommended preventive measures. That does not imply, however, that those with high disease burden are necessarily more likely to receive these treatments. In fact, the prevalence of oral hypoglycemic use is the same in deciles 1 and 10 (47%), much below the peak of 65 percent in deciles 6 and 7. Annual flu vaccinations, use of ACE-inhibitors or ARBs, and use of statins or other lipid lowering drugs also reach peak prevalence rates below decile 10. Only insulin use is highest in decile 10, and that reflects severity of diabetes rather than the health risks associated with other comorbidities.

Table 2 shows mean annual prescription fills by Medicare beneficiaries with diabetes who used oral hypoglycemic agents, ACE-inhibitors or ARBs, dyslipidemics, and insulin in 2002. Two features of these findings are worth noting. First, given that a typical prescription fill is for a 30-day supply, oral hypoglycemic agents are the only preventive treatment in which average utilization rates approach continuous therapy across the year.[6] Persistence in use is much lower for the other medications. The second point is that persistence rates for all four medication classes are lower at the extremes of the range of disease burden compared with the middle,

and the differentials are large. For example, in percentage terms, users of oral hypoglycemic agents in decile 10 had 33 percent fewer annual fills compared with users in the peak decile (6). They had 23 percent fewer RAASI fills from peak levels, 26 percent fewer fills for dyslipidemic agents, and 33 percent fewer insulin fills. Equally large differentials are observed between the middle and low ends of the disease spectrum.

With the exception of insulin, these are medications recommended for most if not all diabetes patients. Therefore, the treatment patterns observed in Tables 1 and 2 suggest that Medicare beneficiaries with this disease are much less likely to receive optimal medication therapy if they happen to be at either extreme of the disease burden spectrum.

Medicare Beneficiaries with Ischemic Heart Disease

This section focuses on beneficiaries with ischemic heart disease, also known as coronary artery disease (N=2,184). Treatment goals for this condition are to reduce the probability of cardiac events by modifying the course of the disease and to relieve symptoms associated with angina. Recommended medications include beta-blockers, antiplatelet agents, ACE-inhibitors or ARBs, and statins or other lipid lowering agents. Nitrates and beta-blockers are recommended to control angina pain.

Overall, 85 percent of the cohort with ischemic heart disease filled prescriptions for one or more of the drug classes shown in Table 3. However, only in the case of cholesterol lowering agents and ACE-inhibitors/ARBs does the annual prevalence exceed half of the cohort (52% in each case). On average, 49 percent used beta-blockers, 14 percent used antiplatelet agents, and 27 percent used nitrates. The prevalence of beta-blockers, lipid lowering agents, ACE-inhibitors/ARBs, and nitrates rises with disease burden, reaching peak levels between deciles 4 and 9. Prevalence of antiplatelet agents is highest in decile 10 (at nearly 30%).

Table 4 shows the average number of annual prescription fills among users of these drugs. The utilization rates exhibit the same pattern seen in Table 2, with the mean number of fills rising with disease burden to a peak and then gradually falling thereafter. Utilization rates for antiplatelet agents peak in decile 4 (6.7 fills) and then decline by half to 3.5 fills per year in decile 9. Peak fill rates for lipid lowering agents and nitrates occur in decile 5 (at 7.5 and 6.8 fills, respectively), and ACE-inhibitor/ARB use peaks in decile 6 (6.8 fills). In each case utilization rates declining by between 20 percent and 30 percent by decile 10. Beta-blocker utilization rates rise from 5.7 fills to a peak of 6.8 fills per year over a wide swath of the spending distribution (deciles 2 to 7) before falling back to 4.9 fills per annum in decile 10. As in the case of diabetes, these utilization patterns suggest that Medicare beneficiaries with ischemic heart disease are much less likely to receive optimal medication therapy if they happen to be at either extreme of the disease burden spectrum.

Medicare Beneficiaries with Other Chronic Diseases

The full report contains additional charts characterizing drug use for beneficiaries with other chronic diseases including arthritis, COPD, depression, dementia, heart failure, and hypertension. Similar patterns are found to those exhibited here; namely, drug regimen complexity increases with overall disease burden, but the intensity and persistence of use generally exhibit the "inverted U" patterns seen in Figures 2, 4, and 5.

DISCUSSION

These recurrent utilization patterns have important implications for the quality and effectiveness of medication use by Medicare beneficiaries. For beneficiaries with the lowest disease burden, rising morbidity is initially accompanied by increases in every benchmark measure—drug spending relative to other health services, breadth of drug regimen, intensity of use per medication-intensive condition and per drug class, and persistence of use for specific agents. One plausible explanation for these patterns is a version the "surveillance hypothesis," which posits that persons with multiple diseases have more frequent physician contacts, thereby increasing the likelihood of receiving necessary and appropriate care.[7] This interpretation is

bolstered by the fact that, in every disease studied, prevalence and persistence rates for recommended therapies initially increase with additional health care spending. This might be considered a good thing except that it implies that beneficiaries who do not have these additional health system contacts may be systematically undertreated. Indeed, it is possible that failure to receive recommended therapies when disease burden is low is a root cause of the burden ultimately rising.

A reversal of these patterns is observed at the other end of the disease spectrum, where increasing morbidity is associated with declining intensity and persistence in medication use. It would seem that physician surveillance (if indeed that is the cause of improved compliance with recommended therapies) has its limits. Similar patterns have been reported in prior studies, leading to the notion that competing demands for physician time may seriously compromise quality of care among patients with multiple morbidity.[8] This conclusion is based on the assumption that failure to receive recommended therapies at recommended doses is a sign of poor quality. By that criterion, the medication patterns observed at the upper end of the disease spectrum would receive very low grades. Not only do many of the sickest beneficiaries fail to receive medications called for in disease treatment guidelines, the persistence of use among those who do is generally far below optimal levels.

A contrasting viewpoint, held by many geriatricians, is expressed well by Durso: "Attempting to manage all relevant illnesses or syndromes with equal vigor according to relevant clinical care guidelines may be impractical, harmful, and negatively impact the patient's quality of life. For some particularly frail individuals, fastidious management of multiple conditions may be unduly burdensome, costly, or lead to unwanted disease-drug or drug-drug interactions"[9] Yet, the medication patterns observed in this study also fail the geriatrician's credo, since too many chronic medications are being taken at such apparently suboptimal levels to do much good (and may well be doing harm). A better strategy would be to winnow out less-effective medications entirely and stress better adherence with those that are truly critical to patient health and well-being.

Arguably the most appropriate utilization patterns observed in the study occur in the middle of the spectrum of disease burden. Medication intensity measured both at the pharmacological class level and by RxHCC reach peak levels for beneficiaries with moderate disease burden. Persistence of medication use for agents recommended by disease guidelines also peaks in the middle of the spectrum for beneficiaries with diabetes, COPD, ischemic heart disease, heart failure, and hypertension. Moreover, the peak persistence levels observed for these medications are generally high enough to achieve therapeutic effectiveness over the course of a year. Discovering the factors associated with desirable patterns of use should thus be a priority for future research.

It is important to stress that these findings reflect information provided by Medicare beneficiaries. Any direct inferences to physician prescribing patterns are unwarranted. Although access to prescription drugs requires the active participation of physicians, that does not guarantee the prescriptions will be filled or refilled according to directions. It is estimated that 20 percent or more of all prescriptions are never filled and an even higher percentage are not refilled in a timely fashion.[10] The most common reasons patients give for failing to fill prescriptions are cost, fear of adverse reactions, lack of perceived need, forgetfulness, and difficulty getting to pharmacies. These reasons may contribute to the suboptimal utilization patterns observed in this study. This is clearly another priority area for future research.

It is also important to note that the survey and claims data used in this empirical analysis are subject to error. A technical appendix to the report considers various sources of error and potential biases in the presentations, including underreporting of drug events, a "disappearing denominator" problem when deaths and hospitalizations cluster in the top spending deciles, and the possibility that the ubiquitous "inverted U" pattern is an artifact of a changing mix in days supply or drug switching regimens over the spectrum of morbidity. None of these factors was shown to materially affect the conclusions of the study.

POLICY IMPLICATIONS

The study findings are based on observational data and do not control for factors other than disease burden. Nonetheless, the recurrent pattern of apparent suboptimal medication utilization among Medicare beneficiaries at both ends of the disease spectrum is strong enough to demand the attention of policymakers. Of particular concern is the fact that available clinical tools designed to improve the quality of medication therapy are not well aligned to address these problems.

Current drug utilization evaluation protocols, including drug use review and consensus guidelines for pharmaceutical care of specific diseases, typically provide little or no guidance on whether recommended therapies should vary depending on the patient's overall disease burden.[11] Standard drug use review programs employed by pharmacy benefit managers and pharmacy providers focus on potentially preventable adverse events from individual drugs or specific drug combinations, rather than possible adverse health consequences of polypharmacy or inadequate compliance with therapy guidelines. Medication quality assurance programs including ACOVE, SCRIPT, and the new Pharmacy Quality Alliance (PQA) are beginning to address noncompliance with guidelines.[12] For example, PQA's preliminary guidelines use time between refills to flag suboptimal drug adherence for statins and other selected cardiovascular medications. Neither the PQA nor earlier efforts, however, address the larger issue of how best to treat a single disease in the context of the whole patient. This is a two-sided problem. For patients with high disease burden, aggressive attempts to follow disease-specific guidelines for each and every condition are unlikely to succeed and, even if they do, the higher drug load from polypharmacy may produce poorer overall outcomes. The problem of noncompliance is very different at the other end of the spectrum. Patients with low disease burden who fail to receive recommended therapies or who are nonadherent users are difficult to reach with current drug use evaluation tools for the simple reason that they have few contacts with the medical system.

The Medication Therapy Management (MTM) programs mandated for Part D prescription drug plans represents a revolutionary departure from the traditional disease–drug approach to medication quality improvement. MTM programs are required to evaluate the entire drug regimen of Medicare beneficiaries who meet annual thresholds for drug spending, polypharmacy, and multiple morbidity. The focus on the whole patient is a positive step, as is the federal rule that permits (but does not require) pharmacists to conduct the reviews.

On the other hand, there are several negative aspects of the MTM program that will limit its effectiveness in addressing the medication problems identified in this study. First, except possibly in managed care plans, MTM providers do not have access to medical claims or prescriber records, which means that reviewers must infer disease from drug use. This is problematic in that some drug classes are used to treat various conditions (e.g., antihypertensives, anti-inflammatory agents, and autonomic agents), as well as the obvious fact that untreated conditions will be missed. The second problem is that stand-alone prescription drug plans have a financial incentive to minimize drug costs rather than optimize drug therapy from the standpoint of either patient well-being or total health care costs. Third, there are no specific federal regulations regarding how MTM reviews are conducted which, when combined with the aforementioned financial incentives, may lead drug plans to skimp on the reviews. Fourth, the criteria for patient eligibility for MTM services are based on drug costs, not total health care costs. Although drug costs may be an appropriate flag for certain types of problems, total costs are a better way to capture the spectrum of problematic medication use. Indeed, it is possible that high drug spenders are among the most compliant drug users. Finally, because of the focus on high drug spending, MTM reviews fail to identify problems of noncompliance with proven preventive therapies among low spenders. Addressing this problem may produce greater long-term returns than policy tools focused exclusively on high-cost cases.

In addition to the MTM program, the Medicare Modernization Act introduced several initiatives focused on improving treatment for beneficiaries with multiple high-cost chronic diseases in the fee-for-service and

managed care sectors. Medicare Health Support (formerly the Chronic Care Improvement Program) is a demonstration program designed to test whether capitated care management services can pay for themselves in reduced Medicare costs for fee-for-service beneficiaries with diabetes and heart failure. The MMA also authorized Special Needs Plans (SNPs), which are Medicare Advantage plans with enrollments that focus on dual eligibles (those eligible for both Medicare and Medicaid), institutionalized beneficiaries, or beneficiaries with selected chronic conditions. Both Medicare Health Support organizations and SNPs have financial incentives to reduce traditional Medicare service costs, and one of the ways that can be accomplished is through good medication management. But it is also possible to reduce costs through myriad other mechanisms that might actually compromise quality of medication use.

The most recent CMS quality improvement effort is the Physician Quality Reporting Initiative (PQRI), authorized by the Tax Relief and Health Care Act of 2006.[13] Under PQRI, eligible practitioners are able to earn payment bonuses for successfully reporting compliance with specified quality measures. As of this writing, there are 134 quality indicators, of which 45 deal with medication therapy.[14] These draw heavily on existing evidence-based guidelines, none of which consider the overall disease burden of the patient. The PQRI program has the potential to significantly change practice patterns because of its direct link to reimbursement. Whether the bonuses are sufficiently high to realize this potential is yet to be determined. Moreover, the PQRI program is no panacea for some of the most significant problems associated with medication management of Medicare beneficiaries. As it stands, physicians will receive extra payment if they follow PQRI prescribing standards, whether patients fill the prescriptions or not. The payments will have little effect on suboptimal prescribing for beneficiaries who seldom connect with the medical system. And there is the possibility of real harm if the quality measures are blindly followed without taking into account the wishes of patients or the competing demands imposed by significant comorbidity.

In conclusion, while current drug quality assurance programs and demonstration initiatives may improve prescribing and medication adherence for some Medicare beneficiaries, the selective targeting of these mechanisms means that the majority of beneficiaries with suboptimal medication utilization will either be missed altogether or will receive interventions that target only part of the problem, and not necessarily the most important part. It is hoped that the study findings will convince policymakers to take a more holistic approach to medication management in the Medicare program.

Table 1. Prevalence of Drugs Used to Treat and Help Prevent or Delay Complications of Diabetes for Medicare Beneficiaries with Diabetes, by Decile of Annual Medical Spending in 2002[a]

		Prevalence of Medication Use by Spending Decile (%)									
Drug or Drug Class	**All**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**
Oral hypoglycemic agents	58.2	47.1	55.2	63.3	63.1	57.7	64.8	64.8	57.4	60.1	47.4
Insulin	6.8	1.3*	2.3*	4.7*	4.1*	5.6*	5.8	5.1	11.1	13.8	14.3
Renin-angiotensin-aldosterone system inhibitors	58.9	38.2	49.0	59.2	61.6	63.4	57.6	66.0	62.8	71.0	59.2
Dyslipidemics	44.6	22.3	35.1	42.3	51.1	47.5	47.0	45.5	54.2	52.4	47.0
Flu shot (past year)	70.0	53.9	74.5	65.4	68.2	75.5	73.3	71.0	72.3	78.7	65.9
Pneumococcal vaccination (past 5 years)	29.5	48.5	27.0	32.1	27.2	31.4	30.9	27.7	20.6	21.7	28.8

[a] All values weighted to be nationally representative of the population sample frame (beneficiaries having both Medicare Part A and B coverage, community-dwelling, in the fee-for-service sector, and completing all survey rounds).

Note: Values marked with an asterisk have relative standard errors greater than 0.3 and should not be considered statistically stable.

Source: Medicare Current Beneficiary Survey, 2002.

Table 2. Number of Prescription Fills for Drugs Used to Treat and Help Prevent or Delay Complications of Diabetes for Medicare Beneficiaries with Diabetes, by Decile of Annual Medical Spending in 2002[a]

Drug or Drug Class	All	Mean Annual Prescription Fills for Medication Users by Spending Decile[b]									
		1	2	3	4	5	6	7	8	9	10
Oral hypoglycemic agents	9.1	6.7	7.9	10.3	9.6	9.5	10.3	10.0	8.9	9.4	6.9
Insulin	5.7	5.7	3.1	5.7	4.8*	4.5	7.6	9.2	4.9	5.0*	6.2
Renin-angiotensin-aldosterone system inhibitors	5.8	5.1	5.0	6.4	5.4	7.0	6.5	5.7	5.3	5.5	5.4
Dyslipidemics	6.1	4.3	5.0	6.2	5.5	6.8	6.9	6.5	6.7	6.1	5.1

[a] All values weighted to be nationally representative of the population sample frame (beneficiaries having both Medicare Part A and B coverage, community-dwelling, in the fee-for-service sector, and completing all survey rounds).

[b] Restricted to users of each medication.

Note: Values marked with an asterisk have relative standard errors greater than 0.3 and should not be considered statistically stable.

Source: Medicare Current Beneficiary Survey, 2002.

Table 3. Prevalence of Drugs Used to Treat Ischemic Heart Disease for Medicare Beneficiaries with Ischemic Heart Disease, by Decile of Annual Medical Spending in 2002[a]

Drug or Drug Class	All	Prevalence of Medication Use by Spending Decile (%)									
		1	2	3	4	5	6	7	8	9	10
Beta blockers	48.8	39.9	45.8	43.9	46.4	49.1	49.3	55.8	54.0	52.3	51.7
Antiplatelet agents	14.2	2.5*	8.6	2.6*	8.9	11.3	13.7	17.2	25.6	22.2	29.6
Cholesterol lowering agents	52.0	37.9	57.2	53.3	58.6	56.9	51.0	53.9	56.3	45.1	49.0
Statins	49.0	34.9	54.6	52.2	53.9	53.1	48.2	50.2	52.1	42.3	48.0
Other lipid lowering agents	6.9	4.2*	6.1	7.0	7.2	9.3	6.7	9.5	9.9	4.2*	4.8
ACE-inhibitors	39.1	25.1	34.6	42.1	33.5	41.0	39.2	45.3	47.4	41.0	40.9
ARBs	15.7	9.4	12.4	14.8	15.4	15.9	17.1	16.2	18.9	19.1	18.1
Nitrates	27.4	20.2	27.4	20.7	22.0	32.3	30.2	33.8	31.6	24.2	31.5
Any drug used to treat ischemic heart disease	84.9	74.1	85.5	83.7	84.4	88.6	89.0	87.9	87.5	82.4	85.9

[a] All values weighted to be nationally representative of the population sample frame (beneficiaries having both Medicare Part A and B coverage, community-dwelling, in the fee-for-service sector, and completing all survey rounds).

Note: Values marked with an asterisk have relative standard errors greater than 0.3 and should not be considered statistically stable.

Source: Medicare Current Beneficiary Survey, 2002.

Table 4. Number of Prescription Fills for Drugs Used to Treat Ischemic Heart Disease for Medicare Beneficiaries with Ischemic Heart Disease, by Decile of Annual Medical Spending in 2002[a]

Drug or Drug Class	All	Prevalence of Medication Use by Spending Decile (%)									
		1	2	3	4	5	6	7	8	9	10
Beta blockers	6.1	5.7	6.2	6.5	6.6	6.7	6.8	6.6	5.8	5.5	4.9
Antiplatelet agents	4.7	5.8*	6.3	4.9	6.7	5.7	4.7	5.0	4.0	3.5	4.3
Cholesterol lowering agents	6.1	5.0	5.7	6.3	5.9	7.5	6.0	6.8	6.2	5.0	5.5
Statins	5.7	4.6	5.2	5.8	5.8	7.1	5.9	6.3	5.7	4.8	5.3
Other lipid lowering agents	5.0	6.9	6.2	4.6	4.8	5.3	3.3	5.5	5.1	4.7	3.6
ACE-inhibitors	6.0	6.0	6.2	6.3	6.6	7.2	6.7	5.8	5.7	5.1	4.7
ARBs	5.5	5.3	3.9	6.4	6.5	5.9	5.5	6.5	4.9	5.2	5.1
Nitrates	5.9	5.9	6.1	5.7	5.8	6.8	6.4	6.0	6.2	5.1	5.1
Any drug used to treat ischemic heart disease	21.2	15.5	19.7	21.6	21.6	25.4	21.6	24.3	23.2	18.8	19.3

[a] All values weighted to be nationally representative of the population sample frame (beneficiaries having both Medicare Part A and B coverage, community-dwelling, in the fee-for-service sector, and completing all survey rounds).

Note: Values marked with an asterisk have relative standard errors greater than 0.3 and should not be considered statistically stable.

Source: Medicare Current Beneficiary Survey, 2002.

Notes

[1] The dementia and depression cohorts were divided into spending quintiles rather than deciles because of small sample sizes.

[2] USP, *Medicare Prescription Drug Benefit Model Guidelines*, 2004. http://www.usp.org/healthcareInfo/mmg/initialGuidelines.html, accessed Dec. 5, 2006.

[3] Medication-intensive conditions are defined as disease clusters that significantly predict spending on prescription drugs in the RxHCC model. CMS, *Part D Payment and Risk Adjustment.* http://www.cms.hhs.gov/DrugCoverageClaimsData/02_RxClaims_PaymentRiskAdjustment.asp, accessed Dec. 4, 2006.

[4] B. Stuart, L. Simoni-Wastila, I. Zuckerman et al., *Medication Use by Aged and Disabled Medicare Beneficiaries Across the Spectrum of Morbidity: A Chartbook* (Baltimore: Peter Lamy Center on Drug Therapy and Aging, University of Maryland Baltimore, 2007). The *Chartbook* is available at: www.pharmacy.umaryland.edu/lamy.

[5] Combination drug use was common within the Medicare population in 2002. The number of unadjusted prescription fills for the community-dwelling population was 28.9 compared with 36.5 adjusted fills.

[6] The MCBS does not provide data on the number of days' supply for drug fills, so it is possible that some of the differences in fill counts may mask differences in prescription size. A sensitivity analysis using pill counts found no evidence of systematic bias in prescription size by spending decile. See Appendix A in the *Chartbook.*

[7] S. T. Fleming, H. G. Pursley, B. Newman et al., "Comorbidity as a Predictor of Stage of Illness for Patients with Breast Cancer," *Medical Care,* Feb. 2005 43(2):132–40.

[8] See C. R. Jaén, K. C. Strange, and P. A. Nutting, "Competing Demands of Primary Care: A Model for the Delivery of Clinical Preventive Services," *Journal of Family Practice,* Feb. 1994 38(2):166–71; D. T. Ko, M. Mandani, and D. A. Alter, "Lipid-Lowering Therapy with Statins in High-Risk Elderly Patients," *Journal of the American Medical Association,* Apr. 21, 2004 291(15):1864–70; and D. A. Redelmeier, S. H. Tan, and G. L. Booth, "The Treatment of Unrelated Disorders in Patients with Chronic Medical Diseases," *New England Journal of Medicine,* May 21, 1998 338(21):1516–20.

[9] S. C. Durso, "Using Clinical Guidelines Designed for Older Adults with Diabetes Mellitus and Complex Health Status," *Journal of the American Medical Association,* Apr. 26, 2006 295(16):1935–40.

[10] D. M. Kirking, J. A. Lee, J. J. Ellis et al., "Patient-Reported Underuse of Prescription Medications: A Comparison of Nine Surveys," *Medical Care Research and Review,* Aug. 2006 63(4):427–46; and Boston Consulting Group, *The Hidden Epidemic: Finding a Cure for Unfilled Prescriptions and Missed Doses,* BCG: Boston, 2004. http://doctor.medscape.com/viewarticle/472790, accessed Feb. 23, 2007.

[11] This may be changing. For example, the American Diabetes Association standards of diabetes care in specific populations recommend that aggressive glycemic control may not be appropriate for frail older persons. See ADA guidelines in *Diabetes Care,* Jan. 2006 29(Suppl. 1):S26–S29; and A. F. Brown, C. M. Mangione, D. Saliba et al., "Guidelines for Improving the Care of the Older Person with Diabetes Mellitus," *Journal of the American Geriatrics Society,* May 2003 51(5 Suppl.):S265–S280.

[12] ACOVE (Assessing Care of Vulnerable Elders) is a collaborative project between RAND and Pfizer, designed to identify evidence-based indicators for quality of care for elderly individuals that encompass various domains. including medication use. Together with the American College of Physicians Task Force on Aging, the ACOVE group developed 43 medication quality measures covering prescribing indications, avoidance of inappropriate medications, patient education, and medication monitoring. None of the 43 indicators considers patient disease burden. See T. Higashi, P. G. Shekelle, D. H. Solomon et al., "The Quality of Pharmacologic Care for Vulnerable Older Patients," *Annals of Internal Medicine,* May 4, 2004 140(9):714–22. SCRIPT (Study of Clinically Relevant Indicators of Pharmacologic Therapy) is a collaboration of various health care trade organizations and governmental agencies representing the Coalition for Quality in Medication Use. The purpose of SCRIPT is to develop operational quality measures for medication use in outpatient settings focusing on six disease states: coronary artery disease/post-MI, atrial fibrillation, heart failure, dyslipidemia, hypertension, and diabetes. A unique aspect of SCRIPT is that the medication measures are evaluated longitudinally to capture outcome indicators. However, like ACOVE, there is no explicit consideration for patient disease burden. See www.ahqa.org/pub/uploads/Kogut.ppt, accessed Feb. 16, 2007. PQA (Pharmacy Quality Alliance) is a membership organization representing over 60 public and private organizations with a stake in measuring performance of pharmacy services. As of this writing PQA has approved performance measures that include medication quality indicators for selected cardiovascular drugs, diabetes, and respiratory disorders, plus indicators for exposure to inappropriate medications and drug–drug interactions. The PQA medication quality indicators are all well-established standards and break no new ground. None of the PQA measures to date takes patients' disease burden into consideration.

[13] http://www.cms.hhs.gov/PhysicianFocusedQualInits/, accessed Feb. 23, 2007.

[14] http://www.cms.hhs.gov/pqri/, accessed Jan. 25, 2008.

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