Racial Differences in Switching, Augmentation, and Titration of Lipid-lowering Agents by Medicare/Medicaid Dual-eligible Patients

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Abstract

Research Objective: The goal of this study was to examine prescription fill patterns of lipid-lowering agents among Medicare/Medicaid dual-eligible patients by ethnicity.

Data and Methods: Study data were obtained from the Thomson Medstat MarketScan Medicaid claims database. Medicare/Medicaid beneficiaries who filled prescriptions for lipid-lowering agents during 2003 were included in the study. Logistic regression models estimated the probability that beneficiaries, by ethnicity, switched to a different lipid-lowering medication, augmented therapy with another lipid-lowering agent, or titrated the dosage of the drug upward over the course of the year.

Results: The models revealed that African Americans were less likely to switch lipid-lowering agents (odds ratio [OR], 0.68; 95% confidence interval [CI], 0.60-0.78), augment lipid-lowering agents (OR, 0.53; 95% CI, 0.43-0.66), or titrate upward (OR, 0.75; 95% CI, 0.67-0.84) than whites.

Conclusion: These results suggest that African Americans may be receiving less aggressive treatment than other patients, which in turn may explain why many studies find that African Americans are less likely to reach lipid goals. These treatment disparities merit further study, because they may impact dual-eligible patients moving into Medicare Part D plans.

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Hyperlipidemia is a common disease among the US population. The prevalence of hypercholesterolemia (total cholesterol ≥200 mg/dL) in 2003 was 49.8%.[1] Although the importance of reducing cholesterol to recommended targets is widely recognized, in actual clinical practice only one third to one half of patients achieve recommended cholesterol levels on lipid-lowering therapy.[2]

African Americans have a higher risk for coronary heart disease morbidity and mortality than whites in the United States.[3] Studies have shown that African Americans are less likely than whites to achieve target cholesterol levels once started on lipid-lowering therapy.[4-7] Furthermore, studies have found that even after adjusting for age, sex, income, physician specialty, baseline low-density lipoprotein cholesterol (LDL-C), starting dose, and target LDL-C, African Americans are less likely to reach goal compared with whites.[5,7] Studies have found that part of the reason why African Americans are not achieving National Cholesterol Education Program target LDL-C levels (<100 mg/dL in high-risk patients, with option of <70 mg/dL in very-high-risk patients) is related to incorrect drug regimens, inadequate lipid monitoring, and nonadherence.[8]

One suggestion from this body of research is that African Americans may require more aggressive treatment to achieve goal. There are 3 main options for providers to improve control of LDL-C levels in patients already receiving treatment: increasing the dose of the statin, adding an additional lipid-lowering therapy, or prescribing a more effective agent.[2,9] Switching, augmentation, and dose increase strategies have been found effective at lowering LDL-C across racial groups.[10-13] In general, patients not achieving goal on statin monotherapy will do better with combination therapy as opposed to increasing the dose of the statin. For example, studies have shown that addition of a second drug, such as ezetimibe, to a statin will afford an additional 17% to 24% reduction in LDL-C, whereas a decrease of only about 6% is seen by simply increasing the dose of statin monotherapy.[9]

The type of dyslipidemia and specific needs of therapy are also major factors when considering ways to improve control. For example,

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does the patient have high LDL-C only or combined dyslipidemia, characterized by a low level of high-density lipoprotein cholesterol (HDL-C), elevated apolipoprotein B and triglycerides, and high non–HDL-C? In the latter instance, combining omega-3 fatty acids, niacin, or fenofibrate with a statin may be beneficial, to promote a rise in HDL-C, as well as lowering LDL-C and triglycerides.[9]

The goal of the present study was to examine ethnic and racial differences in treatment patterns of Medicare/Medicaid dual-eligible patients receiving lipid-lowering therapy. By examining treatment patterns we can further understand the factors that may be leading to lower goal attainment by racial minorities. In particular, this study will describe adherence, as well as switching, augmentation, and the upward titration of lipid-lowering agents—3 options that have been described as useful in achieving therapeutic goals. The number of outpatient visits will also be reported. We hypothesize that African Americans will have lower levels of adherence, switching, titration, augmentation, and outpatient visits. The results may inform policies concerning individuals with Medicare/Medicaid dual eligibility who are newly covered under the Medicare Part D insurance benefit.

Data and Methods

Data originated from the Thomson Medstat Marketscan Medicaid claims database. The Medicaid database reflects the healthcare service use of individuals covered by Medicaid programs in several geographically dispersed states. The database contains the pooled healthcare experience of approximately 16 million Medicaid enrollees. It includes records of inpatient services, inpatient admissions, outpatient services, and prescription drug claims, as well as information on long-term care and other medical care. Data on eligibility (by month) and service and provider type are also included. In addition to standard demographic variables such as age and sex, the database includes variables of particular value to researchers investigating Medicaid populations, such as federal aid category (income based, disability, Temporary Assistance for Needy Families program) and race. Medicaid data were from 5 large states representing approximately 23% of Medicaid beneficiaries nationwide. None of the states had any access restrictions on lipid-lowering agents during the study time period.

The study sample was constructed at the individual patient level to assess lipid-lowering agent adherence. Beneficiaries were included in the study if they filled a prescription for a lipid-lowering agent during 2003 and enrolled for the full year in both Medicare and Medicaid. The following outcome measures were created:

Switched lipid-lowering agent medication: Switching was defined as presence of claims for 2 or more different lipid-lowering agent medications at different time points in the course of the year.

Augmented lipid-lowering agent medication: Augmenting was defined as presence of a claim for 2 or more different lipid-lowering agent medications at the same time points in the course of the year.

Titrated lipid-lowering agent medication upward: Titrating dosages upward was defined as occurring if 2 consecutive prescriptions for the same medication showed an increase in dosage.

In addition, other variables were included in the study sample to describe the population and treatment patients, and also to serve as controls in the multivariate models.

These variables were:

Demographic variables: Age (<65 years or ≥65 years), sex, and ethnicity (African American, White, Hispanic, Asian, Other, Missing).

Comorbidities: The Chronic Disease Score (CDS) was used to control for comorbidities. The CDS uses patterns of prescription utilization data previously identified by a consensus judgment process as indicative of chronic disease to construct a weighted score that predicts healthcare cost and utilization. The maximum possible score is 35.[14-16] The CDS has been used in numerous studies. For example, it has been shown predictive of variation in mortality from prostate cancer,[17] death and disability in older community-dwelling populations,[18] and unplanned hospital readmission and length of stay.[19]

Medicaid state: A blind Medicaid dummy variable was used to indicate each Medicaid state but does not reveal the state of interest.

Number of healthcare visits: Healthcare utilization was defined by the number of outpatient visits.

***Days on therapy*:** Lipid-lowering agent use was defined by total days on therapy during the study period.

The Medicaid states could not be identified for privacy reasons. However, they are blinded and included in the multivariate models as controls for any variation in size of Medicaid population or potential practice pattern differentials between the states. This was a broad measure at best, but it was anticipated that some of the variation might be accounted for by including the state controls in the regression models.

Two types of analyses were performed in this study. The first analysis described the sample. Descriptive characteristics are presented for the sample stratified by each of the adherence outcomes of interest. The second analysis was a set of logistic regression models specified to estimate the probability of switching, augmenting or titrating a lipid-lowering agent dose upward. The models controlled for age, sex, state of residence, total days on therapy, number of outpatient visits, and health status as proxied by use of the CDS.

Results

The study sample consisted of 239 530 patients, of whom 62.8% were women. Of the total sample, 102 695 white, 44 221 Asian, 32 670 Hispanic, 22 570 African American, 37 374 other ethnicity lipid-lowering agent users who were dually eligible for Medicare and Medicaid. Table 1 shows the demographics of the population stratified by ethnicity and age. All ethnicities within the "Other" categories were merged into 1 group in subsequent analyses. The study sample consisted of a greater proportion of whites relative to the other ethnicities. The majority of the patients were 65 years or older (187 151).

The demographic information for the study sample was then analyzed by each of the outcome variables of interest. Table 2 shows the demographic information and the mean CDS by switching, augmentation, and titration upward. Those patients with missing data on the outcome variable(s) were excluded.

The descriptive results show that the majority of women in this study did not switch, augment, or have their lipid-lowering agent titrated upward. The same pattern was seen among patients aged 65 years or older. Regarding the patterns of change among patients stratified by ethnicity, fewer African Americans (9%) switched lipid-lowering agents than Asians, Hispanics, whites, or other ethnicities (14%, 13%, 12%, and 13%, respectively). Also, fewer African Americans (3%) augmented with another lipid-lowering agent compared with Asians, Hispanics, whites, or other ethnicities (6%, 5%, 6%, and 5%, respectively). The percentage of patients who titrated their lipid-lowering agent upward was greater than those who switched or augmented. This may be the result of several factors. It may indicate that clinicians have been more likely to increase the dosage rather than switch or augment to improve effectiveness. However, it may also

Table 1. Sample Size by Ethnicity and Age

	Age <65 y		Age ≥65 y		Overall
Ethnicity Group	**n**	**Percent**	**n**	**Percent**	**N**
White	29 840	12.46	72 855	30.42	102 695
Asian/Pacific Islander	1864	0.78	42 357	17.68	44 221
Hispanic	7347	3.07	25 323	10.57	32 670
African American	7180	3.00	15 390	6.43	22 570
Other: Missing/Unknown	5865	2.45	30 721	12.83	36 586
Other: American Indian/ Alaska Native	253	0.11	335	0.14	588
Other	30	0.01	170	0.07	200
	Total for Age <65 y 52 379		Total for Age ≥65 y 187 151		Sample Total 239 530

show that the physician prescribed the correct agent and rather than switch, the dose was titrated up for improved effectiveness. The average CDS score is about 8, with higher scores among those who switched, augmented, or titrated.

The CDS was reported for each of the outcomes groups of interest. This score also serves as a predictor of healthcare cost and utilization. We therefore reviewed the healthcare utilization measure in this study (outpatient visits) by levels of the CDS. The outpatient visits are reported by the CDS stratified into quartiles within each ethnicity included in this study. Patients with missing data were excluded from this analysis, which reduced the study sample size from 239 530 to 232 229. The results are shown in Table 3. This was not a temporal analysis but was a cross-sectional picture by quartile. The sample n values are shown in the Table to demonstrate that there are different patients in each quartile.

The highest number of outpatient visits were by white patients in the fourth (ie, highest) CDS quartile. This same group also had the highest mean number of visits over the year (42.03). The other ethnicity groups also showed the highest mean number of visits among patients in the fourth CDS quartile. This was not unexpected, because those patients in the fourth quartile would by definition be sicker as indicated by their greater use of certain prescription medications and require a greater amount of care. Among the ethnicity groups, the higher the CDS quartile, the higher the mean number of visits. The highest percentage increase in mean visits from the first to the fourth CDS quartile was among the Hispanic patients (52.54%) and the lowest percentage increase was among the African American patients (44.13%).

A similar analysis to the one above was conducted for the average days on lipid-lowering agent therapy during the study year. The average days per CDS quartile by ethnicity are reported in Table 3. There was not much variation in the mean length of lipid-lowering agent use. The lowest was in the first quartile Hispanic group (214.34 days) and the highest was in the fourth quartile white group (269.38 days). As seen in the previous analysis, the highest level of utilization was in the highest CDS quartile. The average days on a lipid-lowering agent showed an increase from the first quartile relative to the fourth quartile in all ethnicity groups. The greatest percentage difference between the first and fourth quartile was 10.87% days longer on lipid-lowering agent therapy among the Hispanic patients; the lowest was a 4.00% increase among African American patients. Therefore the sicker

Table 2. Sample Demographics Stratified by Outcome Variables

		Switching		Augmenting		Titrated Up	
	n	Switched (%)	Did Not Switch (%)	Augmented (%)	Did Not Augment (%)	Titrated Up (%)	Did Not Titrate Up (%)
Total sample	239 530	12.32	87.68	5.64	94.36	16.23	83.77
Female	150 440	12.04	87.96	5.10	94.90	16.06	83.94
Male	89 090	12.96	87.04	6.93	93.07	17.77	82.21
Age ≥65 y	187 151	12.09	87.91	5.25	94.75	15.65	82.43
Age <65 y	52 379	13.14	86.86	7.04	92.96	18.27	76.45
Ethnicity							
White	102 693	11.79	88.21	6.08	93.93	16.60	83.40
Asian	44 221	13.69	86.31	6.18	93.82	16.26	83.74
Other	37 374	13.24	86.76	5.51	94.49	17.14	82.86
Hispanic	32 675	13.32	86.68	5.33	94.65	16.69	83.28
African American	22 570	9.08	90.92	3.24	96.76	13.15	86.85
Average CDS		8.52	7.91	8.64	7.94	8.42	7.90

CDS indicates Chronic Disease Score.

the patient was, the longer their duration of lipid-lowering agent therapy.

The next set of analyses involved the multivariate models. Each outcome variable (switched, augmented, titrated upward) was fitted to a logistic regression model. Table 4 provides the results of the 3 models. The odds ratios (ORs) and 95% confidence intervals (CIs) are reported in addition to the Wald chi square value (along with its significance level). The reference category for the ethnicity groups is white.

The logistic regressions showed that African Americans were statistically significantly less likely to switch lipid-lowering agents (OR, 0.68; 95% CI, 0.60-0.78), augment lipid-lowering agents (OR, 0.53; 95% CI, 0.43-0.66), or titrate upward (OR, 0.75; 95% CI, 0.67-0.84) than whites. In most of the models, the Hispanic and Asian patients were significantly more likely to augment, switch, or titrate upward. The exception is that Hispanic patients were less likely to augment than whites, but this variable was not significant in the model. The "Other" group did not attain statistical significance. Relative to whites, only the African Americans had a lower probability of a change in lipid-lowering agents. To test for the possibility that this group of patients may be healthier than the others, thus perhaps being the cause of the decrease in lipid-lowering agent change, the CDS data were interacted with African American ethnicity to control for health in this specific patient group. The ORs in all 3 models are greater than 1, indicating a greater likelihood of change than whites, but statistical significance is not achieved. This interaction term therefore serves as a control for health of this ethnicity group, and may mean that the decrease in the probability of lipid-lowering agent change is caused by factors other than health status.

There were a few effects seen in the other independent covariates included in the models. Among all 3 models, women and persons 65 years or older were significantly less likely to have any of the 3 changes in lipid-lowering agent use. The lower probability for older patients may indicate that these patients were already established users and the therapy changes may have taken place closer to therapy initiation. A higher CDS significantly increased the probability that lipid-lower-

Table 3. Average Days on a Lipid-lowering Agent and Number of Outpatient Visits by CDS Quartile and Ethnicity

Ethnicity	CDS Quartile	n	Average Days on a Lipid-lowering Agent	Average Number of Outpatient Visits
White	Q1	34 776	258.34	22.46
White	Q2	19 170	267.68	28.02
White	Q3	17 835	268.78	32.10
White	Q4	25 845	269.38	42.03
Asian	Q1	17 387	250.31	15.77
Asian	Q2	9123	261.08	19.76
Asian	Q3	8389	261.46	22.84
Asian	Q4	9237	260.75	28.72
Other	Q1	13 404	246.84	17.52
Other	Q2	7503	258.81	22.34
Other	Q3	6749	260.18	26.02
Other	Q4	8528	261.96	33.14
Hispanic	Q1	12 332	214.34	13.93
Hispanic	Q2	6799	232.43	19.09
Hispanic	Q3	6065	239.18	21.77
Hispanic	Q4	7320	240.47	29.35
African American	Q1	6804	235.14	19.94
African American	Q2	4646	243.57	24.09
African American	Q3	4304	243.91	27.28
African American	Q4	6013	243.45	35.69
		232 229		

Q1 = CDS <6; Q2 = CDS ≥6 but <8; Q3 = CDS ≥8 but <10; Q4 = CDS ≥10.
CDS indicates Chronic Disease Score; Q, quartile.

Table 4. Logistic Regression Models: Probability of Switching, Augmenting, or Titrating Upward a Lipid-lowering Agent

	Switched		Augmented		Titrated Up	
	OR	95% CI	OR	95% CI	OR	95% CI
Female	0.956	0.931, 0.981	0.780	0.753, 0.809	0.923	0.902, 0.945
Age ≥65 y	0.847	0.821, 0.874	0.686	0.658, 0.716	0.775	0.754, 0.796
Ethnicity						
African American	0.682	0.598, 0.778	0.534	0.432, 0.659	0.748	0.670, 0.836
Hispanic	1.116	1.074, 1.160	0.947	0.895, 1.002	1.110	1.072, 1.149
Asian	1.230	1.187, 1.274	1.105	1.052, 1.161	1.086	1.052, 1.121
Other	1.028	0.990, 1.068	0.968	0.919, 1.021	1.020	0.986, 1.054
CDS	1.052	1.048, 1.056	1.054	1.049, 1.060	1.038	1.035, 1.042
CDS interacted with African American	1.008	0.995, 1.022	1.010	0.988, 1.032	1.006	0.995, 1.018
State						
1	1.189	1.087, 1.300	1.100	0.982, 1.233	0.930	0.866, 0.998
2	1.066	0.966, 1.176	0.903	0.794, 1.027	0.994	0.919, 1.075
3	0.891	0.766, 1.036	0.881	0.726, 1.069	0.976	0.868, 1.097
4	1.263	1.082, 1.473	1.074	0.867, 1.329	1.086	0.954, 1.236
Total days on lipid-lowering agent therapy	0.999	0.999, 0.999	1.004	1.004, 1.004	1.003	1.003, 1.003
Number of outpatient visits	1.001	1.000, 1.001	1.000	0.999, 1.000	1.000	1.000, 1.001
Wald chi square value	1477.45*		2600.53*		3055.99*	

*P <.0001.
Note: The reference category for the ethnicity groups is white.
OR indicates odds ratio; CI, confidence interval; CDS, Chronic Disease Score.

ing agent use was changed. Sicker patients appeared to have a more difficult time reaching a satisfactory dose. However, the number of outpatient visits, which may serve as a proxy for health, did not achieve significance. The total days on lipid-lowering agent therapy, although significant, did not show a very high probability of an increase or decrease in the outcome variables. In addition, the CIs were extremely tight, so there is very little variation.

Study Limitations

This study has several limitations that should be noted. First, the data are left censored; thus it is not known where the individual patient is in terms of course of therapy. New-start patients may be more prone to changes than patients who have been on therapy for a longer period of time. A second limitation is the cross-sectional nature of the data. Patient information was reported by CDS quartile. However, additional research would be of interest to analyze changes in lipid-lowering agent therapy as patients progress from one quartile to the next. Third, the data are based on outpatient claims and do not include laboratory data that would indicate cholesterol levels. With the presence of cholesterol test results, one could tell whether the different treatment and prescribing patterns were associated with the likelihood of reaching goal and whether they explained the differential in goal attainment by ethnicity. Fourth, the data are based on filled prescriptions. It is possible that more prescriptions were provided by providers than were filled. It is also possible that patients filled prescriptions but did not take the medication. Finally, we do not have information on the potency of the drugs prescribed.

Discussion

Lipid-lowering agent use in the United States is substantial. Among the top twenty-five most frequently prescribed drugs for the elderly in the sec-

ond half of 2005, lipid-lowering agents are numbers 2, 4, 18, 19, 21, and 24.[20]

This study finds that among the Medicare/Medicaid dual-eligible patients, there exist differential prescription fill patterns in lipid-lowering agents by ethnicity. Descriptively, we observed lower rates of switching, augmentation, and titrating upward (in African Americans/nonwhites). The multivariate results also showed that lipid-lowering agent utilization for African Americans was evidenced by fewer switches, less augmentation, and less upward titration compared with other ethnicities. The effect size found in the multivariate analysis is relatively large, indicating that African Americans are about 40% less likely to switch statins, 47% less likely to augment statins, and 25% less likely to titrate upward, even after controlling for multiple factors including age, number of office visits, adherence, and severity of illness. All patients were Medicare/Medicaid dual eligibles, so there was no influence of drug coverage on these results. These results suggest that African Americans may be receiving less aggressive treatment than other patients, which in turn may explain why many studies find that African Americans are less likely to reach lipid-lowering goals.[4-7]

The ability of African Americans to reach lipid goals may also be compromised by their lower number of office visits. The study showed there was a lower percentage increase in the number of outpatient visits between the first and fourth quartile of the CDS among African Americans relative to other groups. This finding is consistent with other studies that have shown less access to physicians, less time spent with the physician, and a lack of continuity of care over time among African American patients relative to other ethnicities.[21-23] Yet other studies have shown higher levels of satisfaction of overall care among African Americans relative to white patients.[24,25] Future research is needed to further understand why visit and prescription patterns differ for African Americans and how these patterns may be addressed to improve African Americans' responsiveness to lipid-lowering therapy.

In addition to the differences by ethnicity/race, the study demonstrated that women were less likely to switch, augment, and titrate up than men. The difference between women and men was not as large as that for ethnicity/race. The largest effect was evinced for the likelihood of augmenting. These results also merit further research.

Despite the limitations mentioned, this study has implications for Medicare Part D. The movement of the dual-eligible Medicare/Medicaid patients into Medicare Part D was momentous. According to the Centers for Medicare & Medicaid Services, as of April 2006, there were 30 million enrollees in Part D, who filled over 93 million prescriptions in March 2006 alone.[26] A key change for Medicaid beneficiaries who are now receiving their drug benefits through Medicare Part D is that Medicare Part D will introduce heterogeneity in terms of formulary restrictions and administrative controls.[27,28] For 6 classes of drugs (antidepressants, antipsychotics, anticonvulsants, anticancer agents, immunosuppressants, and HIV/AIDS agents), Medicare Part D plans are required to cover substantially all medications in the class. Lipid-lowering agents are not among those drugs covered. Thus, lipid-lowering agents may be subject to restrictive and changing formularies as well as administrative controls on prescribing such as fail-first policies and dose restrictions. These policies may complicate the ability of physicians to switch, augment, and titrate the therapy of patients who are not attaining goal. However, further research is needed to understand how the formulary and administrative aspects of Medicare Part D might influence optimal prescribing patterns.

Conclusion

The importance of treating hyperlipidemia is widely recognized. A body of research has shown that African Americans are at high risk for coronary heart disease and yet, when compared with other groups taking lipid-lowering therapy, are less likely to reach goal. Results of our study suggest that utilization patterns for lipid-lowering agents in African Americans differ from those in other reported ethnic groups, and support the recommendation by others that further research is indicated to ascertain why this disparity occurs. We found utilization patterns suggesting that less aggressive medication management in African Americans may represent one reason they are less likely to attain target lipid levels. However, this remains speculative; it should be considered a focus of exploration in future studies designed to accurately measure this specific outcome.

The issue of medication management is particularly important for Medicaid patients who are dual eligible. These patients tend to be poor and to suffer from serious chronic conditions. With the movement of their prescription drug benefit from Medicaid to Medicare Part D, care should be taken to ensure health plans' medication management policies do not exacerbate health disparities. Furthermore, Part D plans should consider addressing policies that may complicate lipid management efforts.

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