



IMPLEMENTING THE HEDIS[®] MEDICARE HEALTH OUTCOMES SURVEY

Linking Medicare Health Outcomes Survey Data and Part D Drug Data

Final

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1.0 INTRODUCTION

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) established Medicare Part D, a voluntary prescription drug benefit that was implemented on January 1, 2006. This law improved access to and affordability of prescription drug coverage for Medicare beneficiaries, and Medicare became the main source of drug coverage for dual-eligible beneficiaries. Previously, states' Medicaid programs were responsible for providing payments for beneficiaries covered by both Medicare and Medicaid.¹

Two types of plans provide prescription drug coverage under the Part D program: stand-alone prescription drug plans (PDP) and Medicare Advantage prescription drug plans (MA-PD). MA-PDs provide Medicare beneficiaries with all Medicare benefits, including prescription coverage, while PDPs provide coverage to beneficiaries in traditional fee-for-service (FFS) plans.²

Interest has grown in evaluating how health outcomes and cost have been affected by the implementation of Medicare Part D, and recent release of Medicare Part D data has facilitated investigation into prescription drug effectiveness in disease treatment. Researchers can use this opportunity to link Medicare Part D claims data with other data sources, to evaluate whether Part D has influenced providers' delivery of care, disease management programs (Hoadley, 2006), unnecessary hospitalizations and doctor visits, and to assess vulnerable beneficiaries' experience with the benefit and verify whether it satisfies their health care needs.³

¹ Hoadley, J. 2006. Medicare's New Adventure: The Part D Drug Benefit. http://www.commonwealthfund.org/~media/Files/Publications/Fund%20Report/2006/Mar/Medicare%20New%20Adventure%20The%20Part%20D%20Drug%20Benefit/Hoadley_medicarenewadventure_911%20pdf.pdf (February 9, 2010).

² Kaiser Family Foundation. 2010. <http://www.kff.org/medicare/upload/7615-03.pdf>

³ Neuman, et al. 2007. http://www.commonwealthfund.org/~media/Files/Publications/In%20the%20Literature/2007/Aug/Medicare%20Prescription%20Drug%20Benefit%20Progress%20Report%20%20Findings%20From%20a%202006%20National%20Survey%20of%20Seniors/Neuman_MedicareRxdrugbenefitsurvey_1061_itl%20pdf.pdf

Linking Medicare HOS Data and Part D Drug Data

To date, there has been minimal research on drug safety and effectiveness in the elderly and disabled populations (CMS, 2008)⁴, and whether enrollment in the program is proven beneficial has yet to be determined.⁵ According to the 2004 Medicare Current Beneficiary Survey, Medicare beneficiaries fill an average of 28 prescriptions a year, with the number increasing to 45 for those considered to be in poor health.

Linking the Medicare Health Outcomes Survey (HOS) and Part D data provides a unique opportunity to directly examine associations between drug benefits and use, as well as patient-specific health and functional status. For this year of the HOS contract, the initial analysis focused on assembling a linked HOS and Part D data master file and evaluating key demographic differences between HOS respondents who had a Part D benefit claim and those who did not. The second part of NCQA's analysis examined Part D prescription drug use among MA members in the HOS sample.

⁴ Centers for Medicare & Medicaid Services, U.S. Department of Health and Human Services. 2008. Fact Sheet: Final Medicare Part D Data Regulation (CMS-4119-F). <http://www.cms.hhs.gov/PrescriptionDrugCovGenIn/Downloads/PartDClaimsDataFactSheet.pdf> (February 3, 2010).

⁵ Jacobson, G., and G. Anderson. Ongoing Challenges for Doctors and Patients. Annual Review of Medicine 2010. 61:469–76. Available at: med.annualreviews.org.

2.0 METHODS

The study used data from the 2006–2008 Medicare Cohort 9 HOS, merged with 2006–2007 Medicare Part D Drug Event (PDE) data. Two separate analyses were conducted. The first analysis focused on HOS respondents and sought to determine the “match rate” of a merged HOS and Part D data file and to understand sociodemographic differences between HOS respondents who had a Part D claim and those who did not. The second analysis sought to understand overall Part D drug use among MA plan members—including type, number of drugs and number of refills dispensed—and focused on the entire HOS sample frame. In each analysis, the individual was the unit of analysis.

Analysis 1: HOS-Part D Data Link and Analysis

Analysis focused on HOS respondents who returned a complete Baseline survey (≥ 80 percent complete) or a partially complete Baseline survey (50 percent–79 percent complete), resulting in an analytic sample of 118,279 individuals. HOS data included key sociodemographic information for MA plan members (age, gender, race, Census region). Age, gender and race were based on Centers for Medicare & Medicaid Services (CMS) data, rather than on self-reported data. PDE data included prescription drug claim information for beneficiaries receiving prescription drug benefits under Part D, through either a stand-alone PDP or MA-PD.⁶ In theory, since MA members may not enroll in stand-alone PDPs (which are meant for fee-for-service beneficiaries, and in fact enrollment in a PDP results in disenrollment from a MA-PD)⁷, PDE data for HOS respondents would only represent drugs dispensed via a MA-PD.

⁶ Centers for Medicare & Medicaid Services, U.S. Department of Health and Human Services. Questions and Answers on Obtaining Prescription Drug Event (PDE) Data.

<https://www.cms.gov/PrescriptionDrugCovGenIn/Downloads/PartDClaimsDataQA.pdf> (June 7, 2010).

⁷ Centers for Medicare & Medicaid Services, U.S. Department of Health and Human Services. Medicare Managed Care Manual, Chapter 2 (Section 30.2.3, p29): Medicare Advantage Enrollment and Disenrollment. <http://www.cms.gov/HealthPlansGenInfo/Downloads/mc86c02.pdf> (June 8, 2010). For a condensed version of the federal rules and regulations, see also Medicare Enrollment Periods, Center for Medicare Advocacy.

A HOS-PDE master file was created by merging the master list of HOS partial and complete baseline respondents data and an unduplicated listing of patient identifiers (IDs) in the Part D data, based on an anonymous patient ID present in both the HOS and PDE data sets. Bivariate and multivariate analyses were used to compare two defined subgroups, based on their HOS-PDE link status: those whose HOS-PDE data were linked through a common patient ID compared with those whose HOS-PDE data were not linked. Associations between HOS-PDE link status and key sociodemographic factors—gender, race (White, Black, Asian, Hispanic, North American Native, Other, Unknown), age group (<65, 65–69, 70–74, 75–79, ≥80 years) and Census region—were examined using χ^2 analysis.

Six logistic regression models examined linked HOS and Part D PDE data as a function of gender (Model 1); race (Model 2); age group (Model 3); Census region (Model 4); gender, race and age group (Model 5); and gender, race, age group and Census region (Model 6). Model 6 was selected as the final model because it included the full set of independent variables of interest. A fixed reference group was used to assess differences: for gender differences, males were the referent group; for age group, individuals 65–69 years were the referent group; for race, White was the referent group; and for Census region, the Northeast was the referent group.

Analysis 2: Part D Prescription Drug Use Among MA Plan Members

To address questions related to prescription drug use among MA plan members, we sought to understand the frequency and type of drugs dispensed for MA plan members overall. Hence, this section of the analysis used the entire HOS Cohort 9 Baseline sample frame (not only HOS respondents), resulting in an analytic sample of 188,515 individuals. We created a HOS-PDE

http://www.medicareadvocacy.org/InfoByTopic/MedicareSummaryAndGeneralInfo/Medicare_EnrollmentPeriods.htm
(June 8, 2010).

master file by merging the HOS data and the PDE file, based on an anonymous patient ID present in both the HOS and PDE data sets.

The PDE data use a National Drug Code (NDC) to identify prescription drugs dispensed under Medicare Part D.⁸ The NDC field is reported in a standard 11-digit format that identifies the firm, product and package codes. (The firm code identifies the firm that manufactures, repacks, relabels or distributes the drug; the product code identifies a specific strength, dosage form and formulation for a particular firm; the package code identifies package sizes and types for a particular firm).⁹ To streamline data manipulation, the last two digits of the NDC—which identify only differences in drug package size—were stripped away, leaving behind the priority codes on drug firm and product (i.e., the first nine digits).

NCQA then examined various sources of drug classification data that enabled classification of drug type based on NDC firm and product numbers. One source of drug classification data was identified as available for public use: a drug classification system used by the Veterans Administration (VA). We retrieved these data from the VA Web site and constructed a 9-digit NDC code. We merged the VA drug classification data and the HOS-PDE master file, based on the modified 9-digit NDC code present in both data sets.

We conducted descriptive analyses to characterize the prescription drugs dispensed in the analytic sample and calculated summary statistics on the frequency of prescription drugs dispensed across the analytic sample. Frequency of prescription drugs dispensed can be presented using three approaches. We present all three in this analysis.

⁸ Centers for Medicare & Medicaid Services, U.S. Department of Health and Human Services. Medicare Part D Prescription Drug Event (PDE) Data Elements.

<https://www.cms.gov/PrescriptionDrugCovGenIn/Downloads/PDEDataElements.pdf> (June 9, 2010).

⁹ National Drug Code Directory, Food and Drug Administration, U.S. Department of Health and Human Services. <http://www.fda.gov/drugs/informationondrugs/ucm142438.htm> (June 11, 2010).

Linking Medicare HOS Data and Part D Drug Data

1. The number of *unique* 9-digit drug numbers for which MA plan members received at least one prescription. This represents a basic count of the number of unique (different) drugs a patient received in the two-year period (2006–2007).
2. The number of times an MA member filled a prescription for each 9-digit drug number.
3. For drugs filled more than one time, the average number of refills per drug (9-digit drug number).

Analysis also examined frequency of drug *class* dispensed under Part D PDE data, based on the VA drug classification system.

3.0 RESULTS

Analysis 1: HOS-Part D Data Link and Analysis

HOS and Part D Match Rate

A total of 118,279 HOS respondents returned a complete or partially complete Baseline survey (Table 1). Of these, 85.3 percent (n=100,873) could be linked to Part D PDE drug claims data from 2006 and 2007 (the linked “HOS-PDE” population). The remaining 14.7 percent (n=17,406) respondents could not be linked to the Part D PDE data (the unlinked “HOS-only” population).

This may be because:

1. The respondent was enrolled in Part D but did not use the benefit in 2006 and 2007, **or**
2. The respondent was in an MA-only plan (not an MA-PD) and thus was not enrolled in Part D.

The following sections present descriptive analysis of the sociodemographic differences between the linked and unlinked HOS and PDE populations, with notable variations.

Distribution by Gender, Age, Race and Region

Overall, women were more likely than men to be enrolled in and use the Part D benefit (87 percent of female HOS respondents vs. 82 percent of male HOS respondents, $p < 0.0001$, Table 1). While representing only 8 percent of the analytic sample, the youngest beneficiaries were most likely to use the Part D benefit, with just over 90 percent of HOS respondents <65 years enrolled in and using Part D (Table 1). Among respondents >65 (age groups 65–69, 70–74, 75–79, ≥ 80 years), the proportions enrolled in and using the Part D benefit were similar and ranged from 84 percent–86 percent in each age group.

White respondents comprised the great majority of respondents, but linked to the PDE file at a lower rate than other racial and ethnic groups. 85 percent of White respondents had a link to the

PDE file, whereas Asian and Hispanic populations exhibited the greatest likelihood of enrollment in and use of the Part D benefit (92 percent and 95 percent, respectively, Table 1). Black and North American Native respondents were also more likely than White respondents to use Part D benefits (88 percent for both).

HOS respondents residing in the Mid-Atlantic (81 percent) and East North Central (75 percent) regions were the least likely to use the Part D drug benefit compared with other Census regions. Respondents in the South Atlantic (94 percent), U.S. Territories (95 percent), and Northeast (91 percent) were most likely to have a PDE record.

Table 1. Demographic Characteristics of Nonlinked HOS Respondents vs. HOS Respondents Linked With Part D PDE Data by Gender, Age, Race and Region (N=118,279)

	HOS and Part D PDE Link Status				Difference (P-Value)
	Nonlinked (HOS Only) N	%	Linked (HOS-PDE) N	%	
Total Individuals	17,406	14.70	10,0873	85.30	
Gender					<0.0001
Male	8,877	18.20	39,948	81.80	
Female	8,529	12.30	60,925	87.70	
Age					<0.0001
<65	705	7.93	8,187	92.07	
65-69	3,476	13.83	21,654	86.17	
70-74	4,396	15.13	24,653	84.87	
75-79	3,963	15.66	21,343	84.34	
≥80	4,866	16.27	25,036	83.73	
Race					<0.0001
White	15,607	15.40	85,563	84.57	
Black	1,308	12.03	9,565	87.97	
North American Native	27	12.39	191	87.61	
Asian	141	8.15	1,590	91.85	
Hispanic	106	4.83	2,089	95.17	
Other	198	9.95	1,792	90.05	
Unknown	19	18.63	83	81.37	

	HOS and Part D PDE Link (Linked) Status				Difference (P-Value)
	Nonlinked (HOS Only) N	%	Linked (HOS-PDE) N	%	
Census Region*					<0.0001
Northeast	536	8.56	5,728	91.44	
Mid-Atlantic	4,472	19.29	18,712	80.71	
East North Central	5,362	25.20	15,914	74.80	
West North Central	1,625	13.86	10,097	86.14	
South Atlantic	955	6.50	13,728	93.05	
East South Central	682	11.15	5,436	88.85	
West South Central	580	10.09	5,170	89.91	
Mountain	1,218	10.35	10,553	89.65	
Pacific	1,854	12.25	13,283	87.75	
U.S. Territories	122	5.14	2,252	94.86	

*Census Region is the region where an individual resides, from 10 regions.

- | | |
|---|--|
| 1. Northeast (CT, MA, ME, NH, RI, VT) | 6. E. South Central (AL, KY, MS, TN) |
| 2. Mid-Atlantic (NJ, NY, PA) | 7. W. South Central (AR, LA, OK, TX) |
| 3. E. North Central (IL, IN, MI, OH, WI) | 8. Mountain (AZ, CO, ID, MT, NM, NV, UT, WY) |
| 4. W. North Central (IA, KS, MN, MO, NE, ND, SD) | 9. Pacific (AK, CA, HI, WA, OR) |
| 5. S. Atlantic (DE, DC, FL, GA, MD, NC, SC, VA, WV) | 10. U.S. Territories (PR, VI) |

Logistic Regressions

In general, patterns exhibited in the bivariate analyses remained unchanged in the multivariate regression analyses, adjusting for all sociodemographic factors. For example, all else being equal, females were significantly more likely than males to use the Part D benefit (odds ratio [OR]=1.65, confidence interval [CI] 1.60–1.71, p<0.0001). Compared with HOS respondents 65–74 years, respondents <65 years were more likely to use Part D (OR=1.79, 95% CI= 1.64–1.95, p<0.0001), while respondents from all other age groups (70–74 years, 75–79 years, ≥80 years) were less likely to use it.

Adjusted regression results for race patterns were also virtually unchanged from unadjusted bivariate results. Non-White respondents were about twice as likely as Whites to use the Part D drug benefit (from an OR of 1.29 for Blacks [95% CI, 1.22–1.38] to an OR of 2.61 for Hispanics

[95% CI 2.14–3.19], all $p < 0.0001$). North American Native respondents were the exception, with results that were not statistically significant.

The effect of Census region was similar after adjustment. Consistent with bivariate results, respondents residing in the South Atlantic and U.S. Territories were significantly more likely than those in the Northeast to use Part D (for South Atlantic, OR=1.25, 95% CI=1.12–1.40, $p < 0.0001$; for U.S. Territories, OR=1.31, 95% CI=1.06–1.60, $p < 0.01$). Respondents in all other Census regions were less likely than those in the Northeast to use Part D benefits.

Table 2. Logistic Regression Model Predicting HOS and Part D PDE Data Link, N=118,279

Independent Variable	Odds Ratio	95% Wald Confidence Limits	
Gender (referent: Male)			
Female	1.653**	1.599	1.708
Age (referent: 65-69 years)			
<65 years	1.793**	1.644	1.954
70-74 years	0.917**	0.873	0.963
75-79 years	0.874**	0.831	0.919
≥80 years	0.825**	0.786	0.866
Race (referent: White)			
Black	1.293**	1.215	1.376
Asian	1.943**	1.628	2.318
Hispanic	2.609**	2.137	3.185
North American Native	0.955	0.634	1.437
Other	1.488**	1.279	1.731
Unknown	0.665	0.399	1.107
Census Region (referent: Northeast)			
Mid-Atlantic	0.359**	0.326	0.394
East North Central	0.268**	0.244	0.295
West North Central	0.573**	0.516	0.635
Southern Atlantic	1.251**	1.120	1.398
East South Central	0.671**	0.595	0.756
West South Central	0.772**	0.682	0.874
Mountain	0.780**	0.701	0.868
Pacific	0.618**	0.558	0.685
U.S. Territories	1.305*	1.063	1.063

* $P \leq 0.01$; ** $P \leq 0.0001$

Analysis 2: Part D Prescription Drug Use among MA Plan Members

Frequency of Drugs Dispensed

A total of 188,515 MA plan members were in the HOS Cohort 9 Baseline sampling frame. Table 3 summarizes the frequency of Part D drug use for this analytic sample. On average, MA plan members had prescriptions for about 15 different prescription drugs (based on 9-digit NDC numbers) during 2006 and 2007 (minimum=1 drug dispensed, maximum=177 drugs dispensed). Each drug was filled an average of 4.3 times during this period. Among drugs that were filled more than once, the average number of refills per drug was 5.7.

Table 3. Part D Drug Use Among MA Plan Members, Cohort 9 Medicare HOS Baseline Sample Frame (n=188,515; n=160,167 With a Part D Prescription Drug Event)

Descriptor	Number of <i>Unique</i> (Different) Drugs Dispensed^a	Number of Times Prescription Was Dispensed^b	Number of Refills Dispensed^c
Mean	14.8	4.3	5.7
Minimum	1	1	1
Maximum	177	132	131

^a=Number of unique (different) prescription drugs dispensed per person (for NDC numbers that appear only once, a simple basic count of these numbers).

^b=Number of times a prescription was filled per drug per person.

^c=Number of refills dispensed per drug per person (for drugs filled more than once).

Class of Drugs Dispensed in Part D PDE Data

A total of 10,309,177 drug event records were in the Part D PDE data set, representing 3,421 unique 9-digit NDC numbers. Out of these records, only 58.8 percent (n=6,059,539) contained NDC numbers that were classifiable with the VA drug classification system. Because of this high proportion of missing drug class data, Table 4—which describes the frequencies of classifiable drugs—must be interpreted with caution.

Table 4 lists the most common classes of drugs used by people in the HOS sample frame. More than half of all drugs were for cardiovascular conditions, followed by medications for the central nervous system, which include medications for most mental disorders.

Table 4. Most Common Classes of Drugs Used by Patients in the HOS Sample Frame (n=6,059,539 Classifiable Part D Drug Records)

VA Drug Class	N	%
Cardiovascular Medications	2,561,213	53.9
Central Nervous System Medications	848,933	17.9
Hormones/Synthetics/Modifiers	407,775	8.6
Gastrointestinal Medications	232,099	4.9
Antimicrobials	202,321	4.3
Blood Products/Modifiers/Volume Expanders	176,791	3.7
Dermatological Agents	88,041	1.9
Genitourinary Medications	65,143	1.4
Autonomic Medications	49,644	1.0
Antihistamines	46,479	1.0

4.0 CONCLUSIONS

The results of these analyses suggest that enrollment in and use of the Part D benefit were associated with being female, non-White, <65 years of age and living in the South Atlantic or U.S. Territory Census regions. On average, members were taking 15 drugs per person in 2006 and 2007, with an average of nearly 6 refills per drug among those filled more than once. Only 58.8 percent of drug event records from the Part D PDE data could be classified using the VA drug classification system. Of these, members of the HOS sample frame were most likely to use a drug for a cardiovascular condition or a disorder of the central nervous system, including mental health conditions.

In general, there are plausible explanations for these findings from what we understand of the population. For example, women may be more likely than men to use the Part D benefit because women are more likely than men to consume some types of health care.¹⁰ Also, Medicare beneficiaries under 65 are by definition disabled and thus more likely to have greater

¹⁰ AS Suominen-Taipale, T Martelin, S Koskinen et al. Gender differences in health care use among the elderly population in areas of Norway and Finland. A cross-sectional analysis based on the HUNT study and the FINRISK Senior Survey. *BMC Health Services Research* 2006, 6:110. Available at: <http://www.biomedcentral.com/1472-6963/6/110>.

health care needs – including prescription drug needs – than beneficiaries ≥ 65 years, who are Medicare-eligible through age, not disability.

Limitations

This analysis has several limitations. First, because each firm assigns its own product and package code, identical drug products and package size might receive different NDC numbers, leading to potential conflict in drug product identification and over-counting the number of drugs a patient is taking. Second, since the data do not allow distinguishing between different MA “benefit packages” or products (e.g., MA-only vs. MA-PD) under the same plan contract (H#),¹¹ it is impossible to tell if some HOS respondents could not be linked to Part D data because they were not enrolled in Part D, or if they were enrolled but simply did not use the benefit. Third, because a large proportion of Part D PDE records could not be classified using the VA drug classification system, the ability to conduct further analysis on the classes (the types) of drugs used was severely limited.

Despite these limitations, this is one of the first studies to attempt linking Medicare health outcomes data with Medicare Part D drug claims data, while also attempting to classify drug classes (type of drug) present in the Part D data. One of the most important steps for effective research with these data will be to classify the drugs used by HOS respondents. In some ways, the challenges are inherent to the task. For example, drugs often have multiple therapeutic classes, so it is hard to determine the “right” drug class for a given instance of utilization. Also, providers often use drugs off-label, so that they are being used for purposes other than those intended and specifically authorized by FDA. The NDC numbering system complicates analysis because the same drug (active ingredient) can be represented by multiple numbers based on the manufacturer, packaging and whether it is available in generic form. Furthermore, known

¹¹The MA plan benefit package number was not included in the dataset until 2009.

issues with the assignment of NDC numbers (e.g., reusing numbers over time) further complicate the process of maintaining a stable list.

The greatest challenge, however, results from the FDA's decision to stop maintaining its drug classification system for NDC numbers. Researchers now must choose from a multiplicity of classification systems devised for a variety of purposes. Some attempt to classify all or most drugs (e.g., the VA drug classification system), others focus on a subset of therapeutic classes or problems (e.g., the Beers list of inappropriate medications for geriatric populations). The multiplicity of systems creates two problems: first, is to find the right classification for a given research purpose; and, second is to find one that is not cost prohibitive to use, as many systems are proprietary.

This preliminary investigation of the VA system highlighted the challenges of simply matching the drugs used by people in the HOS to a drug class. Further effort and consultation with experts in using the VA system might resolve some of the unmatched cases, but additional effort may be necessary to identify alternative systems, including proprietary systems.

The linked HOS and Part D data set presents significant opportunities to enhance the utility of the HOS survey itself. The primary benefit is to examine the link between use of Part D-financed services and health status. This would permit research into whether Part D has improved the health of seniors in Medicare Advantage plans. While there are methodological challenges in the interpretation of such results (e.g., does self-selection account for improvement, or does availability of non-Part D benefits diminish the effect of Part D on health?), various tools exist to address those problems.

A secondary benefit is that the HOS data, plus additional information about HOS participants (e.g., benefit package, which is available in subsequent HOS datasets), provides important information to enhance understanding of patterns in the utilization and cost of the Part D

program. The Part D data set alone would permit investigation into the use of any and how many drugs a senior used and exploration of issues of polypharmacy (e.g., unsafe combinations), timing (e.g., gaps in use of drugs that require on-going use to be effective), and cost. The merged HOS-PDE file allows for examination of the role of various patient attributes including demographic, SES, and health status on these issues.

Future research should address the data limitations described, allowing exploration of additional research questions regarding outcomes and prescription drug use in the Medicare plan population.