Original Research

Risk factors of self-reported adverse drug events among Medicare enrollees before and after Medicare Part D

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ABSTRACT[*]

Objectives: Quantify risk factors for self-reported adverse drug events (ADEs) after the implementation of Medicare Part D, quantify self-reported ADEs before and after Medicare Part D and quantify the association between self-reported ADEs and increased use of prescription medication.
Methods: The design was a longitudinal study including an internet survey before Medicare Part D in 2005 (n=1220) and a follow-up survey in 2007 (n=1024), with n=436 responding to both surveys. Harris Interactive® invited individuals in their online panel to participate in this study. Individuals who were 65 or older, English speakers, US residents and enrolled in Medicare were included. Data collected and used in analysis included self-reported ADE, socio-demographics, self-rated health, number of medications, symptoms experienced, concern and necessity beliefs about medicines, number of pharmacies, and whether doses were skipped or stopped to save money.
Results: In 2007, reporting an ADE was related to concern beliefs, symptoms experienced and age. ADEs were experienced by 18% of respondents in 2005 and 20.4% in 2007. The average number of medications increased from 3.82 (SD=2.82) in 2005 to 4.32 (SD=3.20) in 2007 (t= -5.77, p<0.001). Among respondents who answered both surveys (n=436), 18.4% reported an ADE in 2005 while 24.3% reported an ADE in 2007. The increase in self-reported ADE was related to concern beliefs (OR=1.12, 95%CI=1.05, 1.19) and symptoms experienced (OR= 3.27, 95%CI=1.60, 6.69), not number of medications (OR=1.04, 95%CI=0.77, 1.41).
Conclusion: Discussing elderly patients' beliefs about their medicines may affect their medication expectations, symptom interpretation and attributions and future medication attributions.

Keywords: Adverse Effects. Risk Factors. Aged. Medicare Part D. United Stated.

FACTORES DE RIESGO DE EVENTOS ADVERSAS MEDICAMENTOSOS AUTO-REPORTADOS ENTRE ASEGURADOS EN MEDICARE ANTES Y DESPUÉS DE MEDICARE PART D

RESUMEN

Objetivos: Cuantificar los factores de riesgo para eventos adversos medicamentosos (ADE) auto-reportados después de la implantación de Medicare Part D, cuantificar los ADE auto-reportados antes y después de Medicare Part D, y cuantificar la asociación entre ADE auto-reportados y el aumento del uso de medicamentos prescritos.
Métodos: El diseño fue un estudio longitudinal incluyendo un cuestionario por internet antes de Medicare Part D en 2005 (n=1220) y una investigación de seguimiento en 2007 (n=1024), con n=436 que respondieron a los dos cuestionarios. Harris Interactive® invitó a individuos de su panel on-line a participar en este estudio. Se incluyó a individuos que tenían 65 o más 65 años, anglo-parlantes, residentes en USA y beneficiarios de Medicare. Los datos recogidos y utilizados en el análisis incluyeron los ADE auto-reportados, socio-demografía, salud auto-relatada, número de medicamentos, síntomas que sufrían, preocupaciones y creencia de la necesidad de medicinas, número de farmacias, y si se saltaban dosis o abandonaban para ahorrar dinero.
Resultados: En 2007, las ADE comunicadas estaban relacionadas con creencias de problemas, síntomas manifestados y la edad. Los ADE fueron padecidos por un 18% de los respondentes en 2005 y 20,4% en 2007. La media de medicamentos aumentó de 3,82 (SD=2,82) en 2005 a 4,32 (SD=3,20) en 2007 (t= -5.77, p<0.001). Entre los respondentes que contestaron los dos cuestionarios (n=436), el 18,4% comunicó un ADE en 2005 mientras que el 24,3% comunicó un ADE en 2007. El aumento de ADE auto-reportados estaba relacionado con las creencias de problemas (OR=1.12, 95%CI=1.05, 1.19) y los síntomas manifestados (OR= 3.27, 95%CI=1.60, 6.69), pero no con el número de medicamentos (OR=1.04, 95%CI=0.77, 1.41).
Conclusión: Discutir con los ancianos sus creencias sobre medicamentos puede afectar sus expectativas sobre su medicación, interpretación y atribuciones de síntomas, y futuras atribuciones de medicación.

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Palabras clave: Efectos advesos. Factores de riesgo. Ancianos. Medicare Part D. Estados Unidos.

INTRODUCTION

Adverse drug events (ADE), defined as an injury resulting from medical interventions related to the use of a drug, occur frequently in older adults.[1,2] More than 90% of adults age 65 years and older use one medication per week[1] and 10-25% experience an ADE.[1-3] ADEs are responsible for 3.4% to 7.0% of hospital admissions[4] and about 28 percent of these events are preventable.[1-10] The proportion of outpatients with an ADE ranges from 5 to 35 percent, depending upon the particular definition used.[4] Between 14 and 23% of older adults receive a medication they should not be prescribed[8-11] and among 38 million Medicare enrollees, more than 1.9 million ADEs occur each year, 180,000 of which are life-threatening or fatal.[1]

One significant risk factor for having an ADE is the total number of prescribed drugs taken by older adults and the number of inappropriate medications used.[7,12] Patients who take more medications and have more drug allergies are more likely to report medication symptoms, more likely to have had a prior experience of an ADE and thus more likely to be aware of the risk.[3] As well, Green et al, recently showed that the number of prescribing physicians was an independent risk factor for patients self-reporting an ADE.[13]

In addition to medication issues, patient characteristics are associated with an increased risk of experiencing an ADE.[14] A 10-year analysis of medication use showed that increased age, female gender and number of patient co-morbidities were associated with increased risk for all ADEs.[15] Also, persons with more formal education believe ADEs to be significantly less severe[16] while speaking a language other than English is related to patient-reported drug complication which might lead to reporting an ADE.[17]

In an earlier study, we examined several risk factors that were not included in previous studies, including the number of pharmacies and concern and necessity beliefs about medications. We found that number of pharmacies used in the purchase of prescription medicines, number of symptoms experienced in the past month, and concern beliefs in medicines were associated with ADEs.[18] Being female and having a graduate degree also were related to reporting an ADE. There was no statistically significant relationship between number of medicines and self-reported ADEs; rather, it was concern beliefs in medicines. Necessity and concern beliefs about medicines are themes people use in the interpretation of symptoms and causal attributions related to their medicines. Necessity beliefs is related to an individual's perception of the necessity of medication for maintaining health, while concern beliefs in medicine is defined as an individual's concern about the adverse effects of medicines, based on beliefs about the potential for dependence or harmful long-term effects.[19] Concern beliefs in medicines reflect patient's perceptions and experiences of specific medications. They describe patients' anxieties about the harmful effects of their prescribed medication especially, concerns about the potential adverse effects of taking it e.g. becoming too dependent on the medication or believing that regular use would lead to long term adverse effects.[19,20] The concern belief scale which consists of items such as "Having to take my medicine worries me" therefore assesses the negative attitude of individual patients towards medication.[19,20]

The Medicare prescription drug benefit established by the 2003 Medicare Prescription Drug, Improvement and Modernization Act (MMA) was implemented to improve beneficiary access to affordable prescription medicines. However, with an increase in the number of medication used by the elderly, especially in the outpatient setting; there is an increased risk and possibility of receiving an inappropriately prescribed medicine and experiencing an ADE. A small number of studies have shown the impact of Medicare Part D on prescription drug costs and usage.[21] For example, the benefit increased drug utilization via its effect on the out-of-pocket costs of the elderly and cost-related nonadherence.[22-24] Among patients who had no previous drug coverage in 2005, the cost per day of supply for medications fell by 45% after the start of the benefit.[25] It is estimated to have led to modest increases in prescription utilization and modest decreases in out-of-pocket expenditures.[26] Despite the impact of the benefit on patients' drug utilization and expenditures, limited research has examined the effect of these changes on health outcomes. Various studies have called for the examination of the effect of the benefit on health outcomes such as ADEs.[19,24]

The objectives of this study were to 1) quantify risk factors for self-reported adverse drug events (ADEs) after the implementation of Medicare Part D, 2) quantify self-reported ADEs before and after Medicare Part D and 3) quantify the association between self-reported ADEs and increased use of prescription medication. The number of medications was expected to be higher in the year after Medicare Part D, and the increase in medication utilization was expected to be associated with increased reporting of ADEs.

METHODS

Design

This was a longitudinal study that included self-administered internet surveys before and after implementation of Medicare Part D. Both surveys were administered by Harris Interactive® on behalf of investigators at the University of Iowa College of Pharmacy, and the project was approved by the University of Iowa Institutional Review Board.

Patients/Setting

Harris Interactive maintains a confidential panel of individuals who will participate in telephone and/or online surveys. Harris Interactive invited individuals to participate, and they received credit from Harris Interactive for completing the survey. The inclusion criteria for the baseline and follow-up surveys were being 65 or older, English speakers, U.S. residents and enrolled in Medicare. In the baseline survey, Harris Interactive provided data to University of Iowa researchers from a convenience or non-probability sample of 1220 anonymous respondents. In the follow-up survey, Harris Interactive provided data on a sample of 1024 anonymous respondents. The follow-up survey included 436 individuals who had participated in the baseline survey and these data were linked by Harris Interactive.

Data collection

Two internet-based surveys were administered; the baseline in October 2005 and the follow-up in October of 2007. The survey was about 160 items but it included numerous skip patterns for questions that did not apply to some respondents. Also, respondents could answer part of the survey and return later if necessary for completion.

In 2005, data used in this analysis included socio-demographic data, self-rated health, number of prescription medications used, sum of symptoms experienced, concern beliefs about medicines, necessity beliefs about medicines, number of pharmacies, self-reported ADE and whether subjects skipped doses of their medications to save money or stop taking the medicines due to cost.[18] Similar items were collected in the 2007 survey and were used in this analysis.

The dependent variable, self-reported ADE, was "seeing a doctor about any side effects, unwanted reaction or other problems from medicines you were taking in the past year." Previous studies have used this question in the identification of self-reported ADEs.[1,29] Self-reporting ADEs represents the patients' view of this outcome, and it is important because patient reporting of possible ADEs and symptomatology is the basis for identifying ADEs in the community setting. Such reporting increases the rate at which ADEs have been identified.[3]

For socio-demographic data, the age of the respondent, racial background, gender, highest level of education completed, household income and geographical region/territory where respondents resided was determined. Age was recoded into three different categories. Self-rated health status was examined. Respondents rated their health and a five item response scale anchored with poor and excellent was used.[27,28] To determine the number of medications used, respondents indicated the number of different prescription medicines used in the past month. Then, respondents were asked to indicate the number of medications that they took on a regular basis, among those they had taken in the past month. To examine their concerns and necessity

beliefs about their medications, the 10 items from Horne et al were used.[19] Five items ask about concern beliefs and five items ask about necessity beliefs. The specific concern sub-scale which assesses concern beliefs consists of the items 'I sometimes worry about the long term effects of my medicines', 'Having to take my medicines worries me', 'I sometimes worry about becoming too dependent on my medicines', 'My medicines disrupt my life', and 'My medicines are a mystery to me'. This scale assesses the patients' beliefs about the medication he is prescribed in relation to his concerns about taking them. Concern beliefs in medicine as a construct comprises both the emotional (e.g. having to take my medicines worries me) and cognitive representations (My medicines are a mystery to me) of patients' medication. Similar to the necessity sub-scale, the response options for the concern belief sub-scale is a five point Likert scale (ranging from strongly disagree to strongly agree) where individuals indicate their level of agreement or disagreement with each of the individual statements within each scale.[19,20] Within the concern and necessity beliefs sub-scales, the five items were summed with a range of 5-25. Higher scores on the concern belief scale indicate stronger negative attitudes towards taking medicines. Previous studies using these scales reported reliability estimates ranging from 0.65-0.86 and its construct validity had been established.[19]

Respondents indicated the number of pharmacies where they got their prescription medicines in a typical month. They also indicated whether they had stopped taking their medications due to cost or skipped their doses to save money on a scale of never, 1-2 times, 3-4 times or more than 4 times.

Subjects were asked to indicate health symptoms they experienced in the past month (yes/no) and 'past month' was used to improve recall. A list of ten symptoms to identify ADEs in primary care was included in these surveys.[3] The symptoms reported by respondents included headaches, dizziness or problems with balance, stomach or gastrointestinal problems, muscle aches, incontinence or problems with urinating, rash or itching, problems with sleep, changes in mood, fatigue and sexual problems. Also, a variable "sum of symptoms" was calculated by summing responses to these ten symptoms that ranged from 0-10. The variable was categorized into 0, 1, 2, 3 and 4 or more with those having no symptoms as the comparator in the analysis. There was no opportunity to report other non-listed symptoms in 2005 and this was rectified in the 2007 survey.

Analysis

All analyses were completed by the University of Iowa investigators.

Descriptive analyses of socio-demographic and clinical/behavioral characteristics were completed. For objective one, independent factors associated with self-reporting an ADE were examined using multiple logistic regression analyses and odd ratios (ORs) with 95% confidence intervals. The dependent variable was presence of a self-reported

ADE. Independent variables included socio-demographics, self-rated health, number of medications, sum of symptoms experienced, concern and necessity beliefs in medicines, number of pharmacies, and whether subjects skipped doses of their medications to save money or stopped taking the medicines due to cost. This analysis repeated the 2005 analysis previously reported[18], but number of physicians was added separately.

For objective 2, the prevalence of ADE in 2007 was compared with the prevalence in 2005 for all respondents using chi-square analysis. Also, for a subset of the sample who answered both 2005 and 2007 surveys, associations between self-reported ADE and year and use of prescription medications and year were quantified using chi-square tests and paired sample t-tests, respectively.

Using only respondents who answered both surveys, logistic regression was used to determine if the number of prescription medications, concern beliefs and number of symptoms experienced differed by year and if these differences predicted self-reported ADE in 2007. These variables were included because they were statistically significant predictors in the 2005 and 2007 (reported here) analyses. Age, gender and number of pharmacies were used as control variables in the analysis. Statistical analyses were performed using SPSS software (version 15.0).

RESULTS

Four hundred and thirty six respondents from the baseline survey responded to the follow-up survey. New respondents were added to achieve a sample size of at least 1,000 individuals. Participants were between 65 and 98 years old, and 57.8% were female (Table 1 and 2). Most respondents were white, had some college experience, used more than one prescription medicine on a regular basis and obtained their prescription medicines from one pharmacy, had more than one regular physician and had relatively good health.

In 2007, reporting an ADE was related to concern beliefs in medicines (OR=1.09, 95%CI=1.01:1.17), 4 or more symptoms experienced (OR=2.21, 95%CI=1.23:3.98) and older age (OR=2.58, 95%CI=1.10:6.06) (Table 3). When the number of physicians seen was added, only concern beliefs (OR=1.09, 95%CI=1.01:1.17) and number of symptoms experienced (OR=1.98, 95%CI=1.09:3.62) remained statistically significant.

Table 1 Socio-demographics characteristics of the 2007 study population (n=1024)*		
Variable	Number (%)	Mean (SD)
Age		72.38 (5.72)
65-74	717 (70.0)	
75-84	266 (26.0)	
≥ 85	41 (4.0)	
Sex		
Male	432 (42.2)	
Female	592 (57.8)	
Racial background		
White	957 (93.5)	
Hispanic	19 (1.9)	
African American	24 (2.3)	
Other	9 (0.9)	
Highest level of education		
≤ High school degree	196 (19.1)	
Some college	365 (35.6)	
College degree	142 (13.9)	
Graduate degree	173 (16.9)	
Other type of degree	148 (14.5)	
Annual household income		
< $15,000	67 (6.5)	
$15,000 to $24,999	129 (12.6)	
$25,000 to $34,999	148 (14.5)	
$35,000 to $49,999	174 (17.0)	
$50,000 to $74,999	183 (17.9)	
$75,000 or more	177 (17.3)	
Geographic region(state of residence) †		
Midwest	283 (27.6)	
North East	217 (21.2)	
South	310 (30.3)	
West	214 (20.9)	

* Values are number (percentage) except otherwise indicated. Numbers that do not sum to 1220 indicate missing data. 2005 demographics are reported elsewhere.[18]
† The North East region includes Connecticut, Maine, Massachusetts, New Hampshire, New Jersey, New York, Pennsylv[ania], Rhode Island, and Vermont. Midwest region includes Iowa, Indiana, Illinois, Kansas, Michigan, Minnesota, Missouri, Nebra[ska], North Dakota, Ohio, South Dakota, and Wisconsin. South region includes Alabama, Arkansas, Delaware, District of Colu[mbia], Florida, Georgia, Kentucky, Louisiana, Maryland, North Carolina, Oklahoma, South Carolina, Tennessee, Texas, Virginia, and [West] Virginia. West region includes Alaska, Arizona, California, Colorado, Hawaii, Idaho, Montana, Nevada, New Mexico, Oregon, [Utah,] Washington, and Wyoming.

Table 2. Clinical and behavioral characteristics of the 2007 study population (n=1024)*		
Variable	Number (%)	Mean (SD)
Clinical characteristics		
Self rated health		
Excellent	68 (6.6)	
Very good	308 (30.1)	
Good	431 (42.1)	
Fair	180 (17.6)	
Poor	37 (3.6)	
Number of medicines used		
0	114 (11.1)	
1-2	216 (21.1)	
3-4	281 (27.4)	
5-6	220 (21.5)	
7-8	95 (9.3)	
8-25	98 (9.6)	
Sum of symptoms experienced		
0	321 (31.3)	
1	130 (12.7)	
2	139 (13.6)	
3	134 (13.1)	
4 or more	175 (17.1)	
Concern beliefs of meds (ranged 5-25, lower score is less concern)		15.19 (3.97)
Necessity beliefs of meds (range 5-25, higher score is more necessity)		13.81 (3.03)
Behavioral characteristics		
Number of pharmacies		
0	98 (9.6)	
1	704 (68.8)	
2	197 (19.2)	
3-10	21 (2.1)	
Stopped medicines because of cost		
Never	942 (92.0)	
>0 times	78 (7.6)	
Skip doses to save money		
Never	918 (89.6)	
>0 times	106 (10.4)	
Number of physicians seen per year		
None	23 (2.6)	
1	244 (27.6)	
2	308 (34.8)	
3	182 (20.5)	
>4	128 (14.4)	
* Values are number (percentage) except otherwise indicated. Numbers that do not sum to 1024 indicate missing data. 2005 demographics are reported elsewhere.[18]		

In 2005, eighteen percent (n=230) of all respondents reported an ADE in the last year while in 2007, 20.4% (n=208) reported an ADE (chi-square= 1.911, p=0.09). Among those who responded to both surveys (n=436), 18.4% (n=80) reported an ADE in 2005 while 24.3% (n=106) reported an ADE in 2007 (chi-square=19.98, p<0.01). There was also an increase in the mean number of prescription medicines used among those responding to both surveys: (3.83; SD=2.82) in 2005 and (4.32; SD=3.20) in 2007 (t= -5.772, p<0.01).

Among respondents who completed both surveys, reporting a self-reported ADE was related to a change in the concern beliefs in medicines (OR=1.12, 95%CI=1.05:1.19) and number of symptoms experienced in 2007 (OR=3.27, 95%CI=1.60:6.69). The mean of change in concern beliefs in medicines was 3.37 (SD=4.33) showing an increase over two years, from 11.62 (SD=3.81) in 2005 to 15.11 (SD=3.77) in 2007. A change in the number of prescription medications used was not

significantly related to reporting an ADE (OR=1.04, 95%CI=0.77:1.41) (Table 4).

DISCUSSION

Over 1000 older adults currently enrolled in Medicare in 2005 and after the start of the benefit in 2007 were asked about ADEs. Self-reported ADEs increased after Medicare Part D was implemented, and the increase was associated with increased concern beliefs in medicines. Though the number of medicines used by respondents to both surveys increased, there was no association with self-reported ADEs.

Analyses in 2005 showed that ADE was related to being female, number of pharmacies used, number of symptoms experienced, concern beliefs with medicines and having a graduate degree.[18] Similar significant variables were expected in the 2007 data. However, in the full model, only concern beliefs and number of symptoms experienced were significant. When the number of physicians seen

regularly was added, concern beliefs and number of symptoms still remained statistically significant. Having stronger concern beliefs about medicines was significantly related to self-reporting an ADE in 2005, 2007 and over time.[18] Patients with stronger concern beliefs in medicines may have self-selected to complete this survey because of its topic. This circumstance in the design does not however preclude a conclusion that concern belief in medicines is an important factor in self-reported ADEs. Respondents with stronger concern beliefs seem to be dependent on their medicines and worry about their long term effect, as indicated by the items of the scale. They may therefore be more sensitive to symptoms and pay particular attention to unwanted reactions that occur, possibly making them more likely to report an ADE.

Patients' beliefs about their medicines can be influenced by their past experiences with the medicines, adverse effects from using them, and the patient-provider communication in clinical consultations.[20] Patients who have experienced a previous ADE in the past may therefore have more concerns, be more watchful for symptoms and more likely report any reactions to medicines. Also, poor provider communications about the effects, benefits and risks of prescribed medicines may shape the beliefs of the patient about their medicines and cause concerns about them. It is therefore important for self-reported assessments of ADEs by patients to be confirmed with follow-up by healthcare professionals in order to verify the causal attribution. As well, patients' beliefs about their medicines need to be assessed in clinic consultations as this may affect the interpretations of their therapy and their attribution about their medicines.

Since concern beliefs in medicines showed consistent relationships to ADEs even after Medicare Part D; these beliefs therefore appear to be an important mechanism involved in the interpretation of patients about their adverse events which may/may not be related to the start of the benefit. Due to increased access to medicines, Medicare Part D has provided opportunities for varying medication use experience which may inherently shape concerns about medicines and beliefs about their long term effects.

Among respondents who answered both surveys, there was an increase in the number of prescription medications used from 2005 to 2007. This may have occurred due to improved access to prescription drug insurance from Medicare Part D. Previous research showed that Medicare enrollees with chronic conditions such as asthma, high cholesterol, diabetes and hypertension had significant increases in the number of prescriptions on average filled per month with the start of the Part D benefit. Also, there were improvements in access to medicines in each month for these patients.[25] The increase in the number of medications used may also have occurred due to the aging of the respondents across the years.

Contrary to expectation, there was no statistically significant relationship between number of medicines and self-reported ADEs in the 2005 or 2007 analyses or in the model including subjects who completed both surveys. Previous studies have shown a relationship between ADEs and number of medications, although there are conflicting results.[7,10-13,30-32] Conflicting results may arise because of different ways of assessing ADEs such as using chart reviews or self-report, and the type of patients in the study, whether in-patients or outpatients, older age group or across all ages. The present finding was not consistent with previous literature using similar measures and similar population.[1] This may occur because a vital socio-psychological variable such as concern beliefs in medicines was included. This variable might be more important than the number of medicines used by patients because the interpretation of symptoms and their attribution to medications may be based upon motivation to tolerate or not tolerate adverse effects, past experience with the symptoms and previous reporting about the symptom to physicians or other health professionals. Concern belief is a concept that reflects knowledge and experience from past and present medication use.

Patients who reported more symptoms were more likely to report an ADE. Patients with fewer symptoms were probably able to deal with them, while those with more symptoms would rather seek the help of health providers. Patients' interpretation of symptoms determines the causal attribution of the symptom to a medicine. It is possible that patients with more symptoms labeled the unwanted reaction as an ADE because of the increased number of medicines available due to Medicare Part D. Using more medicines may inherently change how symptoms are interpreted.

The number of prescribing physicians has been shown to be a risk factor for self-reported ADEs[13], but this was not observed in our study. It is possible that concern beliefs may have accounted for the effect of this factor. Patients with stronger concern beliefs are likely to see more physicians and have more opportunities to report their ADEs. These patients may therefore have more physicians because of their concerns about their health and medicines. On the other hand, seeing more physicians regularly may increase concerns of patients about their medications and make them report ADEs.

Older age was statistically associated with a higher risk for reporting an ADE. The importance of age in predicting ADEs has been found in existent literature.[5,13] Increased number of co-morbidities and regularly scheduled medications associated with advanced age may explain the effect of age.

Table 3 Logistic regression (odds ratio and 95% confidence interval) analysis of risk factors for a self-reported adverse drug event in 2007[a] (n=699)[b]

Socio-demographic characteristics	
Age	
65-74	1.0
75-84	1.40 (0.90-2.17)
≥ 85	2.58 (1.10-6.06)*
Gender	
Male	1.0
Female	1.23 (0.81-1.85)
Racial background	
White	1.0
Black/ African American	0.77 (0.24-2.53)
Hispanic	1.62 (0.43-6.18)
Other	2.12 (0.42-10.73)
Highest level of education	
≤ High school degree	1.0
Some college	1.44 (0.80-2.59)
College degree	0.90 (0.40-2.03)
Graduate degree	1.49 (0.73-3.03)
Other type of degree	1.74 (0.84-3.60)
Annual household Income	
<$15,000	1.0
$15,000 to $24,999	0.86 (0.36-2.08)
$25,000 to $34,999	1.21 (0.50-2.94)
$35,000 to $49,000	1.51 (0.65-3.52)
$50,000 to $74,999	1.33 (0.56-3.18)
>$75,000	1.85 (0.76-4.49)
Geographic region (state of residence) †	
Mid west	1.0
North East	1.01 (0.57-1.79)
South	1.34 (0.81-2.23)
West	1.22 (0.69-2.15)
Clinical characteristics	
Self rated health	
Excellent	1.0
Very good	1.55 (0.42-5.70)
Good	2.01 (0.55-7.29)
Fair	2.94 (0.76-11.44)
Poor	2.74 (0.53-14.03)
Number of medicines used	1.0
1-2	1.90 (1.04-3.49)
3-4	1.88 (0.98-3.58)
5-6	1.23 (0.52-2.88)
7-8	1.37 (0.59-3.17)
>8	
Sum of symptoms experienced	
0	1.0
1	2.18 (1.18-4.03)*
2	1.28 (0.68-2.38)
3	1.41 (0.76-2.62)
4 or more	2.21 (1.23-3.98)*
Concern beliefs of medicines	1.09 (1.01-1.17)*
Necessity beliefs of medicines	0.98 (0.89-1.07)
Behavioral characteristics	
Number of pharmacies	
1	1.0
2	0.94 (0.59-1.50)
>3	0.83 (0.24-2.90)
Stopped meds due to cost	
Never	1.0
1 or more times	2.00 (0.90-4.43)
Skipped doses to save money	
Never	1.0
1 or more times	0.74 (0.36-1.54)
Number of physicians seen regularly c	
0	1.0
1	0.42 (0.10-1.70)
2	0.66(0.16-2.63)
3	1.02 (0.25-4.21)
>4	0.85 (0.20-3.69)

a. Those excluded from the analysis included respondents who took no prescription medicines (n=114), respondents who had pharmacy (n=98) and respondents who had missing data on all other variables (n=113).
b. Pseudo-R2 statistics = 0.156; χ2 = 9.60, df =8, p>0.1 (Hosmer and Lemeshow test)
c. Results from a separate logistic regression with similar independent variables
*. p<0.05

Table 4. Logistic regression analysis of risk factors for a self-reported adverse drug event before and after Medicare Part D (n=436) [a]	
Variable	*Odds ratio (95% Confidence Interval)*
	Model 1 [b]
Age	
65-74	1
75-84	1.1.00 (0.60:1.68)
≥ 85	1.1.18 (0.37:3.77)
Gender	
Male	1.
Female	0.0.67 (0.40:1.13)
Change in number of medications used	1.1.04 (0.77:1.41)
Change in concern beliefs about medicines	1.1.12 (1.05:1.19)*
Sum of symptoms experienced in 2007	
0	1
1	1 1.61 (0.72:3.59)
2	1 1.95 (0.88:4.33)
3	2 2.34 (1.10:5.03)*
4 or more	3 3.27 (1.60:6.69)*
Number of pharmacies in 2007	
1	1
2	0 0.91 (0.49:1.67)
>3	0 0.75 (0.14:4.09)
a. Responded to both baseline and follow-up surveys in 2005 and 2007. b. Pseudo-R2 statistics = 0.115; χ 2 =6.38, df =8, p>0.1 (Hosmer and Lemeshow test) *. p<0.05	

In summary, the rates of self-reported ADE increased after Medicare Part D and there was a bivariate association between ADE and year. However, increases in medication use from 2005 to 2007 were not statistically related to the increased report of ADE. Concern beliefs and number of symptoms experienced predicted self-reported ADE among the respondents who answered both surveys and did not differ by year. These risk factors may be the driving force for self-reported ADE.

This study had some limitations. First, the measurement of ADEs was self-report and therefore may be over-estimated. Also, the subjects used in this study were online users and a convenience sample. Thus, these results are not generalizable to the whole US population 65 and older.

These findings have implications for the Medicare Part D Medication Therapy Management (MTM) programs for specified enrollees, and such programs may include face-to-face or telephonic communication with patients. This communication provides pharmacists or other MTM providers with an avenue to discuss concerns about medications with older adults and possibly decrease ADEs. In this study, ADEs increased after Medicare Part D, and these ADEs were linked to symptoms experienced due to prescription utilization and the concerns about using their medications.. An MTM session provides pharmacists and other providers with an opportunity to address patients' beliefs in medicine, increase patient awareness of the correct way to take their medications through patient education and possibly decrease ADEs. Pharmacists in institutional and clinic settings have shown that MTM services can reduce ADEs.[33-36] Medicare Part D provides an opportunity for similar clinical pharmacy services to be delivered in community pharmacies.

CONCLUSIONS

These findings suggest that Medicare Part D led to an increase in self-reported adverse drug events among older adults. The creation of Medicare Part D has improved drug coverage and lessened the financial burden of many beneficiaries with chronic illnesses, yet, it is important to consider if the extent of increased access and increased utilization has only improved the health and safety of elderly patients and beneficiaries. Further research is needed to more fully understand the intended effects such as utilization and costs along with its unintended consequences such as ADEs. This is vital to ensure medication safety for older adults.

CONFLICT OF INTEREST

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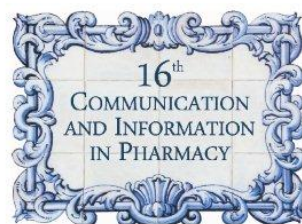
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