Characteristics of patients using specialty medications

Taehwan Park[a,b,*], Scott K. Griggs[a,b], Paul D. Chung[c,1]

[a] Pharmacy Administration, St. Louis College of Pharmacy, St. Louis, MO, 63110, USA
[b] Center for Health Outcomes Research and Education, St. Louis College of Pharmacy, St. Louis, MO, 63110, USA
[c] Anesthesiology and Perioperative Care Services, Veterans Affairs Palo Alto Health Care System, Palo Alto, CA, 94304, USA

ARTICLE INFO

ABSTRACT

Background: Specialty medications include innovative drugs and biologic agents requiring special handling and close monitoring. Although specialty medications have been widely used for various chronic conditions, increased use of these medications has contributed a growing share of total health care expenditures.
Objective: The aim of this study was to examine patient characteristics related to specialty medication use.
Methods: Using Medical Expenditure Panel Survey (MEPS) data from 2000 through 2013, this study identified U.S. adults using specialty medications. Andersen's Health Services Utilization model was used to identify potential factors related to specialty medication use. Associations between the variables identified by Andersen's model and specialty medication use were analyzed using logistic multilevel modelling. Sampling weights were considered and standard errors were adjusted to account for the complex survey design.
Results: A fully adjusted model suggested that older adults, individuals with prescription drug insurance, or those using mail order services were more likely to use specialty medications regardless of whether they used traditional medications concurrently. Behaviors of using specialty medications were positively associated with married and active working status and negatively associated with middle or high income and having a usual source of care (visiting a doctor's office, clinic, or health center when sick) when comparing individuals using traditional medications and those using specialty medications. In addition, when comparing individuals using traditional medications with those using both specialty medications and traditional medications, behaviors of using specialty medications were positively associated with female gender, worse health state, and more comorbidities.
Conclusion: This study identified characteristics of patients using specialty medications. Some sociodemographic, economic, and clinical factors were related to specialty medication use among U.S. adults.

1. Introduction

In recent years, specialty pharmaceuticals have attracted increasing attention for their substantial contribution to escalating health care costs. Typically, they are novel medications and biologic agents offering advances in the treatment of complex and life-threatening diseases,[1] but at the same time imposing a substantial economic burden driven in part by high development costs, unique management requirements, and a need for careful and ongoing monitoring.[2] Accordingly, specialty pharmaceuticals are commonly defined by the following characteristics: (1) high cost (generally a monthly price exceeding $600); (2) special handling, administration, preparation, and distribution requirements; and (3) close monitoring requirements (e.g., personalized or frequent dose adjustment requirements).[3]

Recent rapid growth in the use of specialty pharmaceuticals has

contributed an increasing share to total health care costs. In 2015 specialty medications accounted for 33% of total pharmaceutical spending,[4,5] and they are expected to constitute about 50% of pharmaceutical expenditures by 2019.[6] Between 2012 and 2014, growth rates were estimated to be 13% to 24% for specialty medications compared to −1.7% to 1.5% for non-specialty (i.e., traditional) medications. Moreover, there has been an increased focus on research and development of specialty medications over the past decade. Consequently, a large number of specialty medications have received approval in recent years. Although only 26% of new drug approvals were specialty medications from 2005 to 2009, this percent of specialty new drug approvals increased to 54% from 2010 to 2014.[7] Notably, in 2012 and 2013, specialty medications accounted for about 60 percent or more of new drug approvals.[8,9]

Despite the growing popularity of specialty pharmaceuticals, little is

known about the characteristics associated with specialty medication use. Previous studies have focused largely on the increase in costs and utilization of specialty medications,[10–14] clinical and economic outcomes related to a specialty pharmacy program,[15–18] and people's willingness to pay for these medications.[19,20] Recently, Hosseini Jebeli et al. investigated socioeconomic factors affecting demand for specialty medications using a survey instrument.[21] They found that gender, income, education, and job categories significantly influenced user demand for these medications. This study selected four medical conditions (multiple sclerosis, hemophilia, thalassemia, and chronic kidney disease) in which specialty medications are frequently used in Iran. Because this study focused on socioeconomic factors as predictors for demand for specialty medications, it did not include other key variables such as clinical factors (e.g., individuals' health status and comorbidities) that could potentially affect specialty medication use.[21]

The objective of the current study was to identify characteristics associated with specialty medication use by employing a large, nationally representative sample of patients using specialty medications for their chronic conditions in the U.S. Comprehensive theory-based variables were considered as potential factors related to specialty medication use.

2. Methods

2.1. Data source

Data were obtained from the Medical Expenditure Panel Survey (MEPS), a nationally representative survey sponsored by the Agency for Healthcare Research and Quality and the National Center for Health Statistics. In particular, the MEPS data for the years 2000 through 2013 were employed in this study to include as many individuals as possible who had used specialty medications. The MEPS collects comprehensive data on health care utilization, expenditures, insurance coverage, and sources of payment for the civilian, non-institutionalized U.S. population.[22] Such data are collected using an overlapping panel design in which each panel is interviewed for a series of five rounds over 30 months.

2.2. Study sample

Our study sample was the MEPS respondents aged 18 or older who received at least one medication during the years 2000 through 2013.

2.3. Independent variables

Andersen's Health Services Utilization Model guided the selection of independent variables.[23] According to this multilevel model, people's use of health services is a function of three major components – their predisposition to use health services (predisposing factors), factors which enable or impede use (enabling factors), and their need for care (need factors).[23] As such, these three factors were considered in this study.

Predisposing factors included age, gender, race/ethnicity, marital status, employment status, education, and census region of residence. Age was a continuous variable while race/ethnicity was categorized as white, black, Hispanic, and other. Marital status, employment status, and education were measured by creating binary variables, each of which indicated whether an individual was married, employed, and had college or higher post-graduate education, respectively. Census region of residence was categorized into four regional groups: Northeast, Midwest, South, and West. All the predisposing variables were identified from the MEPS Household Component files.

Enabling factors included family income level, type of insurance coverage, prescription medication insurance status, usual source of health care, and use of mail-order service. Family income level was categorized based on the Federal Poverty Level (FPL) in the Household

Component files as poor/near poor/low income (< 200% FPL), middle income (200% to less than 400% FPL), and high income (≥ 400% FPL). Type of insurance included any private insurance, public insurance, and uninsured, as specified in the Household Component file. To measure prescription medication insurance status, a binary variable was created using 12 expenditure variables in the Prescribed Medicines file which showed the payment sources of prescription medications. This new variable was able to separate respondents *without* prescription medication insurance who paid all prescriptions out-of-pocket from those *with* prescription medication insurance who had payment source(s) other than out-of-pocket payments. To identify a usual source of care, a binary variable was created using the Household Component file. This variable indicated whether respondents visited a doctor's office, clinic, health center, or other place they usually go when sick or needing advice about their health. A binary variable indicating any use of mail-order pharmacy for TMUs, SMUs, and BMUs was also created using the Prescribed Medicines file.

Finally, medical need factors included self-reported health status and comorbidity conditions. Self-reported health states were categorized as poor, fair, good, very good, and excellent based on the general health variable in the Household Component file. Comorbidities were estimated by computing the Charlson Comorbidity Index, as suggested by D'Hoore.[24] Seventeen comorbidity conditions included in the Charlson Index were identified from the Medical Conditions file using the ICD-9 codes.

2.4. Dependent variables

Specialty pharmaceutical users were identified using the medication name variable in the MEPS Prescribed Medicines file. Among our study sample, those who used any specialty pharmaceuticals listed in the Zalesak et al. study[3] were considered as specialty pharmaceutical users. Consequently, adults 18 or older who used only pharmaceuticals other than specialty medications were considered traditional medication users (TMUs). Because numerous individuals used not only specialty medications but also traditional medications concurrently, they were labeled as both medication users (BMUs) separately from those who used specialty medications only (SMUs). To verify that each specialty medication was associated with its designated condition, the conditions were manually matched with their indicated specialty medications using the International Classification of Diseases, Ninth Revision (ICD-9) code in the MEPS Medical Conditions file for a random sample of 100 individuals.

As the study objective was to identify characteristics of patients using specialty medications chronically when traditional medications were also available as a treatment option, specialty pharmaceuticals used for acute disease or supportive care were not included in this current study. Accordingly, traditional pharmaceuticals were not included if they were used for conditions where there were no viable specialty medication substitutes. For the same reason, specialty pharmaceuticals (e.g., orphan drugs) were also not included if there were no viable traditional medication options.

Because the primary outcome of interest was use of specialty medications, a binary variable indicating a SMU was created to identify characteristics of SMUs compared with TMUs (i.e., those who used traditional medication only). Similarly, a binary variable indicating a BMU was generated to compare BMUs with TMUs.

2.5. Statistical analysis

For the selected variables, descriptive statistics were examined by computing means, standard error, and proportions. To identify the characteristics of specialty pharmaceutical users compared with traditional pharmaceutical users, each variable between SMUs and TMUs as well as between BMUs and TMUs was compared using bivariate logistic regression. Multivariate logistic regression in a hierarchical fashion was