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Evaluation of Patient Assistance Program Eligibility and Availability for Top 200 Brand Name and Generic Drugs in the United States

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Key Words: Patient assistance programs; eligibility; availability; prescription drugs.

Abstract

One strategy to encourage uninsured and underinsured patients' compliance with medication regimen is to refer them to pharmaceutical industry-sponsored patient assistance programs (PAPs). In order to receive the requested medications, patients should be qualified based on the program eligibility requirements. The purpose of this study was to examine PAP eligibility criteria for the most commonly dispensed prescriptions in the United States. We identified 136 unique chemical entities in the Top 200 drug list and 111 (82%) of these pharmaceutical products were offered by PAPs. Among the available medications, 69 (62%) were brand name; 29 (26%) were generic, and 13 (12%) had both brand name/generic forms. In terms of the availability of types of drugs (brand name vs. generic) provided by PAPs, differences in PAP eligibility requirements were found for citizenship ($p < 0.001$), permanent residency ($p < 0.001$), and prescription drug coverage ($p < 0.001$), but not for income limits ($p = 0.051$). Overall, PAPs could help low-income patients to obtain necessary medications; however, U.S. citizenship/permanent residency and restriction on prescription coverage are more likely to be required for brand name drugs rather than for generics. PAPs also provide some options for the underinsured and those with private insurance or Medicare Part D plan that offers inadequate prescription coverage.

Introduction and Study Objective

The rising cost of prescription drugs has been a major public health concern in the United States. Current trend shows that pharmaceutical expenses consume a major part of total health care expenditure and have a significant effect on the U.S. health care industry.¹ It is estimated that prescription drug spending will continue to grow, and the price of the drugs is likely to increase over time.^{2,3} Such high cost of prescription drugs often creates a barrier to medication access for patients. Both insured and uninsured patients have reported cutting back on doses of their medicine⁴ or

even forgoing filling needed prescriptions.^{1,4,5} The consequences of medication non-use and underuse can lead to increased emergency room visits and other unnecessary health care resource use, which have been estimated to cost the U.S. healthcare system up to \$100 billion per year.^{6,7}

One alternative to alleviate patients' financial burden to acquire needed medications is to seek help from patient assistance programs (PAPs) established by the pharmaceutical industry. The pharmaceutical companies voluntarily participate in PAPs to offer a portion of their pharmaceutical products free or for a nominal fee to patients who meet the pre-determined PAP eligibility requirements. Each PAP created its benefit structure and qualifications that patients should comply with in order to receive their requested medications. Typically, patients can apply for PAPs either directly with the pharmaceutical companies or through informational websites.

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A recent systematic review of the use of PAPs found that PAPs along with additional medication services (e.g., counseling) were associated with improved disease indicators for patients, positive economic outcomes for patients and institutions due to no-cost drug access, and avoidance of losses from uncompensated drug costs.⁸ However, causal inferences about the clinical or cost-effectiveness of PAPs could not be established due to limitations of the included studies' designs.⁸ One study described the PAP application process as complex and labor intensive for health care providers who served in safety net clinics,⁹ though the study concluded that PAPs could still be helpful to fill the gaps in health insurance coverage if PAP eligibility criteria were more consistent.⁹ Additional studies further demonstrated that PAPs could lead to cost savings for both health institutions^{10,11} and low-income patients.^{12,13} All these previous studies suggested that PAP was one of the few options that the uninsured and underinsured could use to access necessary prescription drugs. The objective of this study was to determine if there was a difference between PAP eligibility criteria for commonly prescribed brand name and generic drugs in the U.S. Understanding this relationship may help health care providers and patients utilize these programs more effectively.

Materials and Methods

Data Sources and Study Sample

We used publicly available data to identify the most commonly dispensed medications in the U.S. and PAP eligibility criteria based on the availability of these prescription drugs. All data collection was conducted from September to December 2009.

First, to determine the America's most commonly dispensed prescription drugs, a study sample was drawn from the list of Top 200 dispensed prescription drugs in 2008 from Pharmacy Times,¹⁴ which was published in May 2009. This list provided each medication's name, drug manufacturer, number of prescriptions dispensed, and its rank in the U.S. market. We excluded medications that had the same chemical formulation but were manufactured by different pharmaceutical companies from the study, because manufacturers' rank in the U.S. market was not considered in this evaluation. Therefore, these medications were counted as one to avoid data duplication. We subsequently classified each prescription drug as brand name or generic and determined its clinical indications by searching the Internet Drug Index - RxList,¹⁵ which provided detailed and current pharmaceutical information on prescription drugs such as drug description, chemical and clinical data, indications, and side effects.

Next, pharmaceutical industry-sponsored PAPs that offered medications in the Top 200 list were identified by searching RxAssist,¹⁶ a PAP database developed by Volunteers in Health Care (VIH). RxAssist provides company contact information, eligibility requirements, and program applications on its website, and both patients and health care professionals can access this database to search for medications or pharmaceutical companies. For each prescription drug in the Pharmacy Times' Top 200 list, we searched for PAPs that offered brand name and generic drugs and collected the relevant program eligibility criteria: (1) U.S. citizenship; (2) permanent residency; (3) restriction on prescription drug coverage; and (4) income limits. Our data search for PAPs did not include retailer discount programs created by national or regional retail pharmacies because those programs were not classified as PAPs. In addition, search results of the retail programs from RxAssist were not comprehensive. We chose RxAssist as our primary source to collect PAP eligibility criteria based on its capacity to yield more extensive results when searching for all PAPs that supplied either brand name or generic form of a specific medication, or both forms if applicable. We performed a quality check by using other websites (i.e. rxhope.com, pparx.org, and needymed.com) that provided similar PAP databases; however, the results from these websites either did not provide a full range of PAPs with respect to a specific medication, or multiple searches were required to obtain the same results as RxAssist's. If further clarifications were needed, the pharmaceutical companies were contacted directly by phone, or their official PAP websites were searched to verify the eligibility information.

Data Analysis

Chi-square analysis was used to examine the difference between PAP eligibility criteria in relation to the types of medications (brand name or generic) offered by the programs. We then compared and determined whether the availability of brand name or generic drugs was significantly associated with PAP eligibility criteria. All statistical analyses were conducted using STATA software, version SE 11.0 (StataCorp, College Station, Texas, USA). The tests were two-tailed, and p-value < 0.05 was deemed to be statistically significant.

Results

A total of 200 chemical entities were included from the list of Top 200 dispensed prescription drugs. We excluded 64 prescription drugs that contained duplicate chemical formulation. The final sample consisted of 136 unique chemical entities with prescription status in the U.S. Of these, 111 (82%) were offered through PAPs. Sixty-nine (62%) of

these medications were brand name, 29 (26%) were generic, and 13 (12%) were available in both forms.

We found that most of these medications were for the treatments of chronic conditions such as heart-related diseases, asthma, depression, and epilepsy (Table 1). Overall, medications for hypertension were most likely to be offered by PAPs and were available in both brand name and generic forms. PAPs sponsored by pharmaceutical companies only supplied brand name drugs to qualifying patients. Pfizer, GlaxoSmithKline, and Johnson & Johnson provided more pharmaceutical products compared with other drug companies (Table 2). We also found two pharmacy businesses, which were not the originator manufacturers, established their version of PAPs to offer low-cost or free medications to eligible patients (Table 2). One of these pharmacy businesses was operated by Xubex Pharmaceuticals, an online mail-order pharmacy that offered the majority of generic medications and some brand name drugs in the Top 200 list. Patients were typically responsible for some fees in different Xubex's PAPs. For example, patients could pay \$20 for a 90-day supply if he or she was qualified for Xubex Pharmaceutical Services program. The other pharmacy business was Rx Outreach, a subsidiary of a pharmacy benefit management company (i.e. Express Scripts), and it offered generic drugs to low-income patients and required patients to pay a discounted price for medications based on its program's tiered formulary.

We observed differences in numbers of available brand name and generic drugs in relation to PAP eligibility requirements. As shown in Table 3, slightly more than two-thirds (68.3%) of brand name drugs were offered by PAPs that required U.S. citizenship/permanent residency; however, this criterion was not needed for generic drugs. PAPs also had different requirements for patients who had prescription coverage—mainly for privately insured and Medicare Part D beneficiaries. Based on our findings, nearly 82.9% of brand name drugs were offered by PAPs that required applicants to have no prescription coverage, whereas, this requirement did not apply to generic drugs. Patients who had prescription plans might be eligible for Xubex Pharmaceuticals' Co-pay program, which would cover all or a part of patients' co-payment; however, Medicare Part D patients were not qualified for this program. Instead, Part D patients could apply for Xubex Free-Medication program and Xubex Pharmaceutical Services program that only offered generic medications with some fees. Overall, the eligibility information for Medicare Part D beneficiaries varied greatly across PAPs, as many programs did not provide specific details of their policy on Part D coverage, or such information was not available. Some programs stated that Part D patients

could still submit applications and their claims would be evaluated on a case-by-case basis, depending on their financial situation and insurance status. We also found that some pharmaceutical companies established special PAPs (Table 4) to serve only Part D patients for certain medications in the Top 200 list. Apart from meeting the aforementioned PAP eligibility requirements, these Part D applicants needed to submit other supplementary documents to complete the application process (Table 4). In terms of PAP's income limits requirement, patients needed to meet specific income standards set by the programs in order to be qualified for brand name drugs (91.5%) and all generic drugs. The typical range of PAP income-limit requirement was from \$10,890 to \$43,320 for an individual, and from \$14,710 to \$58,280 for a family size of two. Some programs would make exceptions if patients could prove financial or medical hardship.

Our results from chi-square analysis suggested that there were statistically significant differences between brand name and generic drugs offered by PAPs based on eligibility criteria (Table 3). We found that brand name drugs were more available to patients who were U.S. citizens/permanent residents ($p < 0.001$) and those who did not have prescription drug coverage ($p < 0.001$) than generic drugs. When examining income limits requirements, we found that the availability of medications did not differ significantly between brand name and generic drugs ($p = 0.051$).

Discussion

Our findings suggest that the availability of types of medication offered by PAPs is associated with program eligibility criteria. Overall, brand name and generic drugs are available to low-income patients. In order to be qualified to receive brand name medications, most patients must comply with PAP requirements for citizenship/permanent residency, restriction on prescription drug coverage, and income limits. Applicants who applied for generic drugs only needed to meet the income limits requirements. We found that patients who were low-income U.S. citizens/permanent residents without prescription drug coverage were more likely to receive brand name drugs through PAPs than those who did not meet all these criteria. However, the income bracket required by PAPs is very broad, and every program has a specific standard, ranging from 100% to 400% of federal poverty level.^{17,18} As a result, patients in different low-income strata will have unequal access to medications offered by PAPs. Moreover, we found that privately insured and Medicare Part D patients were usually not qualified to apply for PAPs that offered brand name drugs. Additionally, because of varying levels of eligibility requirements among the programs, the application process could become even more complex for Part D patients who may need more than

one drug for their disease management. Given the observed variations of eligibility requirements for Part D patients, we were unable to assess the difference in PAP eligibility criteria for Part D prescription coverage in terms of the availability of medications.

With the current high health costs and economic recession, PAPs can provide safety-net assistance to patients who have no choice but to bear high drug cost, especially for chronically ill Americans who have been reported to have medication non-adherence due to cost pressure.¹⁹ The Department of Health and Human Services has already recognized the significant role of PAPs in providing safety net assistance to indigent patients and the chronically ill.²⁰ We found that 82% of the top 200 commonly dispensed prescription drugs in the U.S. in 2008 were available through PAPs, compared with only 53% of dispensed prescription drugs in 1999.²¹ Although this finding indicates that there is an increasing availability of prescription drugs offered by PAPs, our study suggested that some patients had limited access to the programs due to PAP eligibility requirements, especially for those with prescription drug coverage. PAPs' restriction on prescription drug coverage for brand name drugs may have unintended consequences for the insured who have inadequate drug coverage, in which co-payment, co-insurance, and deductibles can be very high and, subsequently, put some specialty medications out of reach even for patients with purported prescription plan. For Medicare Part D patients, the variations in eligibility requirements make the PAP application process cumbersome, as some patients may not have a steady income and are required to submit multiple applications to determine whether they are qualified for PAPs. The situation could become more difficult when Part D beneficiaries are in doughnut hole (i.e. coverage gap) where they are responsible for uncovered prescription expenses and this creates a greater financial burden for them to obtain needed medications without PAP's help. If PAP eligibility requirements could be better structured, these programs could be more accessible to low-income insured patients to obtain medications when other resources in the health system are exhausted. For example, details regarding the eligibility requirements for Medicare Part D beneficiaries and privately insured patients should be explicitly stated; clearer information disclosure will help patients access PAPs without confusion. In addition, an electronic database with a standardized PAP application could help reduce excessive administration costs and time required to complete complex paperwork for both health institutions and patients.

Besides the pharmaceutical industry-sponsored PAPs, discounted generic prescription drug program initiated by some major pharmacy chains and retailers (e.g. Walgreen,

CVS, Wal-Mart) in recent years may serve as an alternative to help uninsured and underinsured patients acquire cost-saving generic medications^{22,23}. For instance, these pharmacy chains typically offer 30- or 90-day supply of select generic drugs for \$4 or \$15, respectively; generic antibiotics are also provided to the customers with prescription plans at no additional costs^{22,23}. It is important to note that, while these retail pharmacy-supported programs can have some significant impacts on improving patients' access to prescription drugs and medication adherence, more studies are needed to assess the quality and safety of these pharmaceutical products, according to a recent study²².

The future of PAPs remains uncertain, as the Patient Protection and Affordable Care Act (PPACA) requires "qualified health plans" to include prescriptions in essential health benefits.^{24,25} If a drug plan becomes mandatory, then the use of PAPs will depend on the levels of new prescriptions coverage, which may differ.^{26,27} In 2011, Part D patients in the doughnut hole started receiving 50% discount on brand name drugs from manufacturers and 7% discount on generic medications plus a \$250 check from the federal government in accordance with PPACA.²⁸ However, these subsidies and one-time check do not completely eliminate the doughnut hole, and there is a concern about manufacturers raising the price of brand name drugs to mitigate their loss.²⁹ Until more details are clarified, there might still be a financial challenge for some patients to pay for their prescription drugs, and health care providers will have to play a role in assisting patients to understand their options for cost-effective medications. To better understand the role of PAPs, future research should assess how PAPs can benefit patients following the health insurance market reform, and whether PAPs are cost-effective when universal prescription coverage is mandated according to PPACA. More research should examine how PAPs could assist Medicare Part D patients after the new income-related premium policy was implemented in 2011, which had an estimated annual growth rate of 7%,³⁰ and before the doughnut hole is fully eliminated in 2020.³⁰

Limitations

Our assessment of the differences in PAP eligibility requirements and availability of types of prescription drugs has limitations. First, we evaluated PAP eligibility requirements for Medicare Part D beneficiaries, but there were numerous variations in criteria across several programs, and most information was not readily available. As a result, we cannot determine whether having Medicare Part D coverage was associated with the types of prescription drugs offered by PAPs. Second, we only used RxAssist database to identify PAPs that offered the most commonly dispensed medications in the U.S. Thus, our results have limited ability

to predict the relationship between PAP eligibility requirements and availability of prescription drugs if data from other informational websites (e.g. rxhope.com, pparx.org, and needymed.com) are used. However, the quality check we performed on other websites showed that RxAssist provided the most comprehensive data to achieve the objectives of this study.

Conclusion

Our study demonstrated that the availability of brand name and generic drugs provided by PAP is associated with PAP eligibility criteria. Patients without citizenship/permanent residency, with prescription drug coverage, or at certain lower-income levels are likely to have limited access to these programs. PAP procedure should be standardized and simplified to improve medication access for those who need assistance. Future studies are needed to understand the extended role of PAPs in the current environment of health care reform.

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Table 1: Indications for the Most Commonly Dispensed Prescription Drugs in 2008 Provided by Patient Assistance Programs

Indication	Number of Drugs Available	Brand Availability	Generic Availability
Allergy	4	3	1
Anemia	1	0	1
Anxiety/Panic Disorder	4	0	4
Asthma	6	5	1
Attention Deficit Hyperactivity Disorder (ADHD)	1	1	0
Bacterial Infection	6	5	1
Benign Prostatic Hyperplasia	1	1	0
Cholesterol	7	6	1
Chronic Obstructive Pulmonary Disease (COPD)	1	1	0
Dementia	2	2	0
Depression	7	6	1
Diabetes	4	3	1
Edema	1	0	1
Epilepsy	7	4	3
Erectile Dysfunction	2	2	0
Fungal Infection	2	1	1
Gastrointestinal Disorder/Symptom	6	5	1
Genital Herpes /Herpes Zoster	1	1	0
Heart Diseases	8	4	4
Hypertension/ Blood Pressure	19	9	10
Hyperurcemia	1	0	1
Hypokalemia	2	0	2
Inflammation (autoimmune disease)	1	0	1
Insomnia	3	2	1
Menopause	1	1	0
Migraine	1	1	0
Muscle Spasm/ condition	4	2	2
Osteoporosis	3	3	0
Pain Management	6	5	1
Rheumatoid Arthritis	3	1	2
Schizophrenia	4	4	0
Smoking Cessation	1	1	0
Stroke/Embolism	1	1	0
Thyroid Hormone Treatment	2	1	1
Urinary Incontinence	1	1	0
Total	124	82	42

Table 2: Types of Top 200 Dispensed Prescription Drugs in 2008 Provided by Pharmaceutical Industry-Sponsored Patient Assistance Programs

Pharmaceutical Manufactures				
	Number of Drugs	Brand-Name Drugs Available	Generic Drugs Available	Prescriber Signature
Abbott	4	4	0	Physician
AstraZeneca Pharmaceuticals	4	4	0	Physician
Boehringer Ingelheim Cares Foundation	3	3	0	Physician
Bristol-Myers Squibb	4	4	0	Physician
Daiichi Sankyo	2	2	0	Physician
Eisai	1	1	0	Physician
Eli Lilly	4	4	0	Physician
Endo Pharmaceutical	1	1	0	Physician
Forest Pharmaceutical	4	4	0	Physician
GlaxoSmithKline	11	11	0	Any Health Care Prescriber
Johnson & Johnson	7	7	0	Physician
King Pharmaceutical	1	1	0	Physician
Mallinckrodt	1	1	0	Not Required
Merck	4	4	0	Physician/Physician Assistant
Merck/Schering-Plough	2	2	0	Physician
Novartis Pharmaceuticals	1	1	0	Physician
OcuSoft Inc.	1	1	0	Physician
Pfizer	12	12	0	Physician
Procter & Gamble Pharmaceuticals	1	1	0	Physician
Purdue Pharma	1	1	0	Physician
Roche Pharmaceutical	1	1	0	Physician
Sanofi-Aventis	2	2	0	Physician
Schering Corporation	4	4	0	Physician
Takeda Pharmaceuticals America	2	2	0	Physician
Teva Pharmaceutical	1	1	0	Physician
Wyeth Pharmaceutical	3	3	0	Physician
Pharmacy Business				
	Number of Drugs	Brand-Name Drugs Available	Generic Drugs Available	Prescriber Signature
XUBEX Pharmaceutical	51	13	38	Not Required
Rx Outreach	34	0	34	N/A

Table 3: Availability of Brand-Name versus Generic Prescription Drugs by Patient Assistance Programs Eligibility Requirements

Availability of Top 200 Dispensed Prescriptions in 2008			
Eligibility Criteria Required by Patient Assistance Programs (PAP)	Brand Name	Generic	Pearson's (χ^2); p
US Citizenship	68.3%	0%	52.3; < 0.001
US Permanent Residency	68.3%	0%	52.3; < 0.001
Prescription Coverage not Allowed	82.9%	0%	77.12; < 0.001
Income Limits	91.5%	100%	3.80; = 0.051

Table 4: Selected Patient Assistance Programs for Medicare Part D Patients

Pharmaceutical Companies	Patient Assistance Programs	Additional Requirements	Prescriber Signature
Astrazeneca Pharmaceuticals	AZ prescription savings program for people with Medicare Part D	<ul style="list-style-type: none"> Financial information Prescription Year-to-date prescription spend history 	Physicians
Boehringer Ingelheim	Boehringer Ingelheim Cares Foundation, Inc. (PAP for Medicare Beneficiaries)	<ul style="list-style-type: none"> Financial low-income subsidy denial for those with income less 135% of FPL 	Physicians
Eli Lilly	Lilly Medicare Answers Program	<ul style="list-style-type: none"> Financial low-income subsidy denial 	Not required
GlaxoSmithKline	GSK Access	<ul style="list-style-type: none"> Financial information Prescription Copy of patients' Medicare Part D card Low Income Subsidy Notice of Denial (if applicable) Documentation for all sources of income from each member of the applicant's household may be required 	Not required