

Patient-assistance programs: Assessment of and use by safety-net clinics

KATHRYN SAENZ DUKE, KRISTIANA RAUBE, AND HELENE LEVENS LIPTON

Prescription drug costs have been the fastest-growing health care expenditure, rising at double-digit rates each year for the past seven years and making drugs increasingly unobtainable for those with limited means.¹ The cost problem is compounded by the growing percentage of people without health insurance, which stood at 17.1% of nonelderly adults in 2001.² The uninsured are nearly three times as likely not to fill a prescription as those with insurance.³ In addition, state budget deficits of 14–18% have resulted in fewer available resources for helping the most vulnerable.⁴ In combination, these factors have created an environment in which many sick people are not getting the drugs they need. Those without needed medications risk higher rates of morbidity and mortality and ultimately may use more expensive forms of health care to combat untreated problems. Recent passage of the Medicare Modernization Act will provide some financial relief to some elderly and disabled Medicare patients, but significant coverage gaps remain, and the needs of millions of others who are not Medicare eligible are not addressed.⁵

Purpose. Safety-net clinics' use and assessment of patient-assistance programs (PAPs) were studied.

Methods. A multistate telephone survey was conducted on the basis of issues identified during 10 case-study interviews of safety-net clinics serving primarily uninsured and publicly insured patients. Interviewed were pharmacists and other staff taking primary responsibility for helping patients apply to PAPs.

Results. Of 339 survey candidates, 215 provided complete interviews (63% response rate). Ninety-three percent of the completed interviews were with clinics in California, Texas, and Florida. Forty percent of the clinics reported that at least 75% of their patients lacked drug insurance coverage. There was a significant positive relationship between a clinic's likelihood of using PAPs and the percent-

age of its patients lacking drug coverage. PAPs consumed 12 hours of pharmacist time per month and 99 hours of other staff time per month. Clinics most frequently cited program requirements changing without notice and unrealistic income-documentation rules as potential barriers to PAP use and indicated that consistent eligibility criteria and standardized application procedures were needed.

Conclusion. A survey of safety-net clinics indicated that PAPs help fill a major gap in health insurance coverage but that consistent eligibility criteria and application procedures are needed.

Index terms: Charity; Data collection; Economics; Health-benefit programs; Industry, pharmaceutical; Pharmacists; Prescriptions; Sociology; Time studies

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To overcome these obstacles, patients and providers are turning to patient-assistance programs (PAPs), charity programs run by drug manufacturers in which eligible patients receive free or low-cost medications.⁶ PAPs are typically designed to serve only patients who have exhausted other options and have no insurance or personal resources to cover the cost of their medications.⁷ Unlike the

Medicare-endorsed discount-card program available through the end of 2005, PAPs have been in operation for several years, are not expected to be terminated in the future, are available to qualified adults of all ages, and are intended only for patients with financial barriers to obtaining their medications. PAPs are voluntarily offered by nearly all large pharmaceutical companies and many smaller com-

KATHRYN SAENZ DUKE, J.D., M.P.H., is Program Director, Medicine for People in Need, Public Health Institute, Oakland, CA. KRISTIANA RAUBE, PH.D., is Adjunct Professor, Haas School of Business, University of California, Berkeley. HELENE LEVENS LIPTON, PH.D., is Professor, Department of Clinical Pharmacy, University of California, San Francisco.

Address correspondence to Ms. Duke at the Public Health Institute, 180 Grand Avenue, Suite 750, Oakland, CA 94607

(kduke@medpin.org).

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panies and typically include some or all of a company's single-source (i.e., brand-name) drugs, although one pharmacy benefit management company recently announced it would offer a PAP for generic drugs.⁸ An estimated 150–200 PAPs are now operating, offering some 850–1000 drugs to eligible patients.^{7,9,10}

The Pharmaceutical Research and Manufacturers of America (PhRMA) reports that more than 6.2 million patients received free prescription medications through PAPs in 2003, a more than fourfold increase over the 1.5 million patients reported to have been helped by PAPs five years earlier.¹¹ Many PAP-eligible patients receive their health care from safety-net providers, organizations that give patients access to services regardless of their ability to pay and that have a substantial share of uninsured, Medicaid, and other vulnerable patients.¹² Safety-net providers include community clinics, free clinics, and county health-system outpatient clinics. These clinics are especially interested in encouraging and helping their qualified patients to use PAPs.^{13,14} At the same time, some of these clinics have commented on time-consuming enrollment procedures, suspicions that PAPs may lead to an overall rise in health care costs, and concern about the risks associated with reliance on voluntary programs that can be suddenly changed or eliminated.^{15–17}

Although a number of articles describe specific PAPs and how health care providers can access them,^{18–25} we found only one article evaluating the use of PAPs by safety-net clinics caring for vulnerable patients.²⁶ This lone article examined manual versus computerized methods of processing PAP applications and the direct financial benefits of PAP drugs.

Our study was designed to extend the published literature by examining safety-net clinics' use and assessment of PAPs. Specifically, we wanted to know if there is variability across states

regarding safety-net patients' need for and actual use of PAPs, if the probability of a clinic taking steps to help its patients use PAPs differs in California compared with other states, what characteristics make a clinic more or less likely to help its patients use PAPs, what staff resources are used in connection with PAPs, what features of PAPs are perceived as the most important barriers to their use, and what impact PAPs have on patient care and clinic operations.

Methods

Case studies. Ten case studies were conducted between December 2001 and March 2002 to identify critical issues to be explored more widely in a multistate telephone survey. The case-study sites were selected to maximize the diversity of clinic size, clinic type (part of a nonprofit community clinic organization or part of a county health system), clinic location (urban, suburban, or rural), type of care provided (primary or mental health), and clinic staff experience in using PAPs. All clinics considered for the case studies were located in California and were participating in a PAP-like program operating in that state from 1999 to 2003.²⁷

Telephone survey. We used the case-study findings to develop a telephone survey for a larger number of clinics in California and other states. To design and conduct the telephone survey, we worked with a separate survey research group with extensive experience in health-related telephone surveys. An initial questionnaire was developed, reviewed, and revised several times. The questionnaire was then pretested on a small number of participants. The pretest results provided the basis for developing a final version of the questionnaire and interviewer instructions.

To create the sampling frame, we contacted three state community clinic associations with large memberships in Texas, Florida, and Illinois. In addition, information was

obtained from the pharmacy school at Oregon State University regarding several community clinics in Oregon, a state that did not at that time have a statewide community clinic association. For California clinics, we used information compiled by the Medicine for People in Need (Medpin) program, a nonprofit organization that works on pharmaceutical issues with community clinics, free clinics, and county health system outpatient clinics in California. Most of these clinics had been participating in Medpin's Drug Distribution Project.

All three state community clinic associations provided the requested data on their member clinics (clinic name, address, representative name, telephone number, and available data on number of outpatient visits or encounters for a recent year). This information, along with information from Medpin on California and Oregon clinics, was sent to the survey research group for use in its telephone contact database. The state associations and Medpin also sent e-mails to all the clinics identified, explaining the purpose of the survey and encouraging the clinics to participate.

The survey telephone calls began July 22, 2002, and ended September 5, 2002. Every clinic staff person contacted for the survey was informed of the study's purpose and asked if he or she was the best staff person to answer questions about the clinic's participation in PAP-related activities. Sites were selected for initial calls to achieve a maximum number of completed interviews for each of the five states and a total of at least 200 completed interviews. A telephone number was eliminated after only one refusal to participate, and a maximum of 15 calls were made to attempt to reach an appropriate person at a site.

After we began analyzing the survey results, we gathered additional published information on the number and percentage of uninsured people in each state and unpublished information from PhRMA on the

number of prescriptions filled for people in each state through PAPS.

Data analysis. Survey responses were analyzed by using the Statistical Package for the Social Sciences, version 11.5 (SPSS Inc., Chicago, IL). Frequency distributions were examined, and response categories for some questions were collapsed to make the final analysis more robust. The relationships among variables were explored by using either cross-tabulations or comparisons of means. Statistical tests used were the chi-square test and, whenever an interval level of measurement could be assumed, analysis of variance. The a priori level of significance was 0.05. Binomial and multinomial logistic regression was performed to predict the probability of the occurrence of the outcome event as a function of the independent variables. This technique generates the coefficients of a prediction formula (and standard errors for estimates and significance levels) and odds ratios (with their 95% confidence intervals).

Results

Survey response. Of 387 clinic names submitted as survey candidates, 339 were called and resulted in 215 completed interviews (63% response rate). Ninety-three percent of the completed interviews were with clinics in California, Texas, and Florida, states whose rates of people without health insurance exceed the national average.²⁸

Patients potentially eligible for PAPS. A major proportion of patients in the study clinics were uninsured and therefore likely to be eligible for PAPS. For each of the four states with more than 10 responses, 54–93% of the clinics served a population for which at least half of members lacked drug insurance (Table 1). Forty percent of the clinics reported that at least 75% of their patients lacked drug insurance (Table 2).

Reasons for not using PAPS. There was a significant positive relationship between a clinic’s likelihood of using PAPS and the percentage of its patients lacking drug coverage (Table 2). A small percentage of clinics not using PAPS were unaware of these programs (17%), while 67% of nonuser clinics reported that PAPS were too time-consuming and complex.

California clinics. California clinics were significantly less likely to participate in PAPS than the clinics in the other states (Table 2). California also was the state with the fewest PAP prescriptions per nonelderly uninsured patient (Table 1). Although we did not investigate the possible explanations for this difference among states, California clinics’ low PAP participation rate may reflect the fact that only those clinics had access to a PAP project called the Drug Distribution Project, which provided indigent patients with an additional source of drugs offered at no cost.

The Drug Distribution Project was operated during 1999–2003 by

an independent nonprofit organization selected to implement a litigation settlement involving 25 major drug companies. These companies had agreed to ship some of their brand-name drugs at no charge to eligible safety-net clinics throughout California. Each of the 235 participating clinics could request drug shipments up to a “credit limit” based on its past level of indigent care provision. The clinics requested products through an online system that combined information for products available from all the participating companies. Product shipments went directly to clinics’ pharmacies or dispensaries, allowing clinic staff to fill prescriptions for eligible patients at no charge. Every company’s product obligation was based on its market share at the time of the lawsuit, for a total product value of \$170 million. Results of a survey of participating clinics indicated that, for more than two thirds, the project provided free drugs whose total value exceeded that of all drugs received through company-controlled PAPS during that same period.²⁷ This finding suggested that California clinics may have been less likely to apply to drug company PAPS because they preferred to use the Drug Distribution Project to help their uninsured patients.

Resources used for PAPS. Clinics reported investing substantial staff resources in managing PAP applications. An average total of 111 hours by

Table 1.
Characteristics of Clinics Surveyed (n = 215)

Characteristic	California	Texas	Florida	Illinois	Oregon
No. clinics interviewed ^a	137	44	20	12	2
% clinics with >50% uninsured patients ^a	54, 60 ^b	93	95	67	0
% nonelderly uninsured residents in clinic’s state	21	26	20	15	14
No. PAP ^c prescriptions per nonelderly uninsured resident in clinic’s state ^d	0.028	0.098	0.083	0.060	0.086

^aAuthors’ analysis of telephone survey results. Data not available for seven clinics.

^bFigures provided separately for California county clinics and community clinics, respectively. Only California had an existing compilation of contact information for county clinics, which resulted in 37 completed interviews.

^cPAP = patient-assistance program.

^dBased on “Sources of Health Insurance and Characteristics of the Uninsured: Analysis of the March 2002 Current Population Survey,” EBRI Issue Brief no. 252, 2002 Dec, and personal communication with Andrew Nannis, Pharmaceutical Research and Manufacturers of America, regarding the total number of PAP prescriptions filled in that state in 2001.

Table 2.
Use of Patient-Assistance Programs (PAPs) by Location and Patient Insurance Status

Characteristic	% Clinics		
	All Clinics (n = 214 ^a)	Clinics Using PAPs (n = 166)	Clinics Not Using PAPs (n = 48) ^b
Location			
California	64	58	83
Other state	36	42	17
Uninsured patients (%) ^c			
>75	40	44	22
50–75	29	30	24
25–49	19	18	24
<25	12	7	29

^aOne respondent from California did not answer the question regarding PAP use and was excluded from all data in the table.

^bAll values differ significantly from corresponding values for clinics using PAPs ($p < 0.001$).

^cSeven clinics answered “don’t know” or “not sure” regarding the percentage of uninsured patients and were excluded from the data for uninsured patients.

of clinic staff time per month was reported as being spent on PAP-related activities. Although PAP applications for various companies appeared to focus on physicians and patients, other health care professionals were substantially involved as well. Pharmacists were reported to spend an average of 12 hours per month, compared with physicians’ 20 hours. Others, such as pharmacy technicians, medical assistants, administrative staff, and other support staff, were reported to spend a mean total of 79 hours per month on PAP activities. Although these are significant investments of time, large standard deviations in the response distributions (29, 68, and 142 hours for pharmacists, physicians, and other clinic staff, respectively) indicate wide variation in clinics’ willingness to redirect or add staff resources toward helping patients with PAPs.

In addition to using their own staff, some clinics (9%) paid a fee for assistance from companies that provided outside help to clinics trying to use PAPs. Many more clinics telephoned individual drug companies (75%), used informal information sources such as colleagues (63%), or used one of several no-cost online information sources (48%) to help them initiate and manage PAPs.

Potential barriers to PAP use.

When asked about potential barriers to PAP use, clinics most frequently cited program requirements changing without notice, followed closely by unrealistic income-documentation requirements for indigent patients (such as requiring copies of tax returns) (Table 3). These reports from clinics using PAPs resonated with the responses from clinics not using PAPs, two thirds of which stated that PAPs were too time-consuming and complex.

Some of these perspectives on barriers to PAP use reappeared in responses to a different survey question. When clinic staff were asked about potential improvements to PAPs, two suggestions characterized as very important were the development of standardized PAP application and reapplication processes across PAP programs (84%) and development of standardized eligibility criteria (83%).

Assessment of PAPs’ impact.

Clinics were asked how strongly their use of PAPs could be related to various potential effects, such as expanded access to new and expensive medications (reported by 63% of clinic staff to be strongly related) and improved medication compliance for patients (56%). Balanced against these positive impacts were reports from

74% of clinics that diversion of their staff from patient care to PAP-related paperwork was either strongly or somewhat related to their use of PAPs.

Ease of use of PAPs across companies. Clinics were asked to name up to three specific companies whose PAP programs they used most often and which companies they used least often because they were “too difficult.” Clinics said they used PAPs from the following companies most often: Pfizer (91 clinics), Bristol-Myers Squibb (80), Merck (60), GlaxoSmithKline (22), AstraZeneca (21), Wyeth-Ayerst (19), Parke-Davis (18), Eli Lilly (15), and GlaxoWellcome (15). Clinics said they used PAPs from the following companies least often because of their difficulty: GlaxoWellcome (15), Novartis (12), and Schering-Plough (10).

Bulk shipments of PAP drugs.

Several clinics reported arranging for bulk or “replenishment” shipments of PAP drugs or vouchers for those drugs. The clinic then dispensed the drugs to patients whose eligibility had been established by clinic staff on the basis of drug company criteria. The company periodically received consolidated information on the patients whose prescriptions were filled from the bulk PAP drug supply. More than 61% of clinics characterized greater use of bulk programs as a very important potential PAP improvement (Table 4). Safety-net clinics that served the largest numbers of uninsured patients were especially interested in bulk-shipment arrangements.

Discussion

This study increases our understanding of the operations and impact of PAPs from the perspective of safety-net clinics trying to help their indigent patients. Clinic staff reported widespread appreciation for PAPs’ ability to help some patients obtain needed medications. At the same time, clinics reported that these benefits came with additional costs, such as a cumulative monthly aver-

Table 3.
Potential Barriers to Patient Assistance Programs (n = 165)

Potential Barrier	% Clinics		
	Very Important	Somewhat Important	Not Important
Requirements change without notice	71	19	10
Income documentation requirements unrealistic for indigent patients	66	24	10
Limited to U.S. citizens or legal residents	57	21	23
Clinic must conduct additional financial screening of patients	55	33	12
Frequent reapplication required	54	33	13
Applications differ among companies	54	28	19
Lengthy or complicated telephone preauthorization	52	32	16
Difficult to obtain application form	49	25	26
Different applications required for different drugs from same company	48	25	26
Limits on number of drugs provided	46	31	23
Amount or type of physician involvement unrealistic	38	33	29

Table 4.
Potential Improvements for Patient Assistance Programs (n = 166)

Potential Improvement	% Clinics		
	Very Important	Somewhat Important	Not Important (or Do Not Know) ^a
Develop standardized application and reapplication processes	83	14	2
Develop standardized eligibility criteria	83	16	1
Increase awareness of programs and how to use them	63	27	10
Allow greater use of bulk drug shipments	61	21	18
Add assistance programs for generic drugs	51	35	14

^aFigures combined for response categories that were originally separate. "Do not know" responses were 0-1% for all questions, except 11% for the question about bulk shipments.

age of more than 100 hours of clinic staff time spent dealing with PAPs.

Clinics with the largest proportion of patients lacking drug insurance coverage were the clinics most likely to be actively helping those patients access medications through PAPs. Nevertheless, a considerable number of clinics chose not to participate in PAPs, stating that they were too complex and time-consuming. Even clinics that did participate noted substantial potential barriers to PAP participation.

Investigators should further explore PAPs' short-term and long-term benefits and costs for uninsured

patients and for the safety-net providers caring for these patients. These explorations could look at specific programs that use PAPs to improve patient health, and they could compare overall drug spending and staff resources used by safety-net clinics whose patients are accessing brand-name drugs through PAPs with those used by clinics with other strategies for drug cost management.

One focus of further study might be building on our baseline information to assess any changes in PAP use and impact across several states. Also needed is a study of drug companies' specific goals in operating PAPs and

their satisfaction with the methods and costs of pursuing those goals. Because PAPs are intended to be charitable activities outside the sphere of competitive, market-based considerations, drug companies should welcome such investigations.

Another potential area of study is drug companies' and PAP users' responses to the Medicare Modernization Act. How much unmet need for medication access remains after the transitional assistance ends and once the coverage benefits take effect? Have PAPs been revised to fit into the new context of expanded federal funding for outpatient drugs?

More attention should be directed to the questions raised by this study regarding intercompany variations in reported PAP use. It is important to fully understand why the efforts by some drug companies to help uninsured patients are more favorably perceived than other companies' efforts.

Leaders from the major drug companies and the health care provider community should actively pursue the potential improvements listed as very important in Table 4. Pharmaceutical industry leaders and elected officials should work proactively with safety-net clinic organizations and independent nonprofit organizations to periodically assess PAPs' success in meeting stated goals.²⁹ The drug industry should commit time and financial resources sufficient to support regular meetings between people with authority over companies' PAP activities and people representing large numbers of physicians and clinics caring for uninsured or underinsured patients. Discussion topics could include potential barriers to PAP use and potential improvements.

The experiences of California's special PAP project may encourage drug companies to use an independent organization that can pool their charitable medication activities and make them more efficient for all parties involved. Such an organization

could also increase the transparency and predictability of PAP expenditures by using publicly available criteria and data to set PAP product ceilings for drug companies and safety-net providers. This would offer drug companies the certainty of a limit on their charitable expenditures and offer clinics a longer time frame and less uncertainty when planning their medication-related patient care.

The 10 provider organizations in the case studies were chosen to represent diverse organizational characteristics but were all located in a single state (California). The telephone survey included only five states, and these were chosen in part because of the cooperation of active statewide community clinic associations, whose existence may make clinics in those states unrepresentative of community clinics nationwide. In addition, a more in-depth understanding of the financial and clinical implications of PAP participation would have strengthened the study's findings. Despite its limitations, this study provides valuable baseline information.

Conclusion

A survey of safety-net clinics indicated that PAPs help fill a major gap in health insurance coverage but that more consistent eligibility criteria and application procedures are needed.

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