Utilization of Pharmaceutical Patient and Prescription Assistance Programs via a Pharmacy Department Patient Assistance Program for Indigent Cancer Patients

Limin Gao MD, MPH, PhD^{}; Jivin Joseph[†]; Marcelle Santoro-Levy MS, RPH[‡];
Alan S. Multz, MD[‡], and Vladimir K. Gotlieb, MD[§]*

ABSTRACT

Background: With the advances in cancer treatments, mortality rates in the United States have been consistently falling but they are accompanied by substantial increases in the cost of cancer care. Patient and prescription assistance programs (PPAPs) are offered by pharmaceutical manufacturers to provide free medications to medically indigent patients. To assist the Cancer Care Center (CCC) at Nassau University Medical Center (NUMC) with drug costs for chemotherapies, the pharmacy department uses a patient assistance program (PAP) to obtain medications from the drug companies at no cost.

Purpose: This study evaluates the impact of the PAP at a public hospital from which indigent cancer patients obtain assistance for chemotherapy.

Methods: We followed all patients requiring assistance with chemotherapy who enrolled in the PAP from January 1, 2011 through December 31, 2012. Medications included both oral and parenteral chemotherapy drugs and antiemetics used in the outpatient clinic setting.

Results: The program served 347 patients in 2011 and 579 patients in 2012. The total number of visits in the clinic over 24 months was 9,405. The total cost savings of the medications was \$1,066,000 in 2011 and \$1,715,538 in 2012.

Conclusions: A pharmacy-based PAP to procure free medications from PPAPs for cancer patients has helped to defray the expense of providing care at NUMC, increased patients' compliance with chemo protocols, and allowed many patients to receive the treatment they otherwise would not be able to afford. The combination of PPAPs and PAP provides a safety net to ensure that indigent cancer patients receive needed prescription medications in the outpatient clinic setting.

Key Words— cancer patients, patient assistance program, patient and prescription assistance program

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Major advances in the early detection of some cancers and better understanding of the pathogenesis of the disease have led to improvements in prevention strategies and therapy. This has resulted in consistently falling cancer death rates in the United States.^{1,2} However, with these

advances has come a substantial increase in the cost of cancer care, which causes a serious financial burden to patients, families, and society at large.³ With more expensive targeted therapies being adopted as standards of care, the average cost of treating the most common cancers has increased.⁴ According to

^{*}Division of Hematology and Oncology, Tufts Medical Center, Boston, Massachusetts; [†]Department of Pharmacy, Nassau University Medical Center, East Meadow, New York; [‡]Mt. Sinai St. Luke's Hospital, New York; [§]Hematology/Oncology, Brookdale University Hospital and Medical Center, One Brookdale Plaza, Brooklyn, New York. Corresponding author: Limin Gao, MD, MPH, PhD, Tufts Medical Center, Division of Hematology/Oncology, 800 Washington Street, #245, Boston, MA 02111; phone: 617-636-5000; fax: 617-636-8538; e-mail: lgao@Tuftsmedicalcenter.org

the report by the US Bureau of Census, the population aged 65 years and older is expected to increase from 40 million in 2009 to 70 million in 2030.⁵ Because cancer incidence is highest in the elderly, the costs of cancer care are expected to escalate even more rapidly in the near future.

It is well documented that the growth in the cost of health care (including cancer care) in the United States exceeds that of the overall growth of economy.^{6,7} Recent studies suggest that an increasing number of Americans will be less able to afford the economic burden of health care in general, and high-quality cancer care in particular,⁸ in part as a result of the expense of new treatments and the growing number of cancer patients as the population ages.⁹ The annual medical cost of cancer care was estimated to be \$124.6 billion in 2010 and is projected to increase to \$157.8 billion by 2020.¹⁰ New advances in medical technology, including advances in imaging, robotics as applied to surgery, and therapeutic radiology, contribute to overall health care spending. Prescription cancer drugs are an important driver of increasing costs in oncology. Antineoplastics are now one of the leading categories of drugs in hospital drug expenditures.¹¹ Cancer patients and the care they receive are profoundly affected by the increasing costs in a number of ways. In the United States, access to innovative medications can be challenging due to heterogeneity and design of health insurance coverage, as many commercial or governmental programs offer different coverage plans. Also, some patients are uninsured.¹²⁻¹⁴ The United States is in the midst of the most significant health insurance expansion and market reforms since Medicare and Medicaid were enacted in 1965. The Patient Protection and Affordable Care Act (ACA) aims to insure millions of people without health care coverage and make medical care and premiums more affordable with coverage. Since the passage of the ACA in March 2010, the number of adult Americans between 19 and 64 years of age who lack health care insurance coverage has fallen substantially, from 37 million adults in 2010 to 29 million by the second half of 2014. However, in 2014 there were still 66 million adults who did not get needed health care because of cost and 64 million adults reported problems paying their medical bills.¹⁵ This not only leads to increased out-of-pocket spending for medications, but it also increases the likelihood of deliberate nonadherence to medications and thus poorer health, increased use

of emergency services, increased hospitalizations, and increased medical bills. For cancer patients, studies showed that the lack of insurance is associated with decreased rates of cancer screening, later stage at diagnosis, and increased cancer mortality. Even for patients with insurance, out-of-pocket expenses associated with cancer treatment may be substantial and lead to delay in treatment, noncompliance, exhaustion of savings, and personal bankruptcy. Indeed, recent studies showed that among individuals who declare bankruptcy for medical reasons, cancer is the highest cost diagnosis.¹⁶

The pharmaceutical manufacturers have responded to the challenge of making high-cost medications available to indigent populations who lack prescription coverage by implementing PPAPs with the primary intent of supplying free medications.¹⁷⁻²⁶ Each pharmaceutical company assistance program has different eligibility and documentation requirements; these generally include documentation of limited income (poverty level), lack of prescription drug coverage, and ineligibility for public assistance, including Medicaid.²⁵ The drugs provided by PPAPs are brand-name medications. No company provides access to generic products.

Nassau University Medical Center (NUMC) is a large academic medical center that cares for a high percentage of uninsured patients (25% of the patient population) and is considered a safety net provider. The rising cost of health care and the high volume of indigent patients have financially burdened the hospital. For the pharmacy department, this has resulted in a lack of reimbursement for pharmaceuticals administered to indigent patients at the oncology clinic. To assist Cancer Care Center (CCC) at NUMC with drug cost for medications and to maintain quality care for cancer patients, a PAP was implemented to procure oncology drugs from pharmaceutical manufacturers. PAPs have been described in various institutional settings. None of the published articles have focused specifically on cancer chemotherapy medications in the outpatient clinic setting. This study describes efforts at NUMC during 2011 and 2012 to reduce patients' out-of-pocket expenses for prescription cancer drugs by incorporating PAP into the CCC's pharmaceutical services.

METHODS

This is a cross-sectional study in which data were collected and analyzed from January 1, 2011

through December 31, 2012. The pharmacy coordinator evaluated patients on a case-by-case basis for PAP enrollment. Individuals who were potentially eligible for PAP were identified by health care providers and office personnel when patients stated that they had difficulty obtaining medications or noted financial concerns. The patients were referred to the PAP for assistance at the same clinic visit; a dedicated full-time pharmacy coordinator whose office was next to the oncology clinic was assigned to this task. The pharmacy coordinator evaluated the referred patients for eligibility for PPAPs based on the individual manufacturer's prespecified qualifications, gathered signatures and required documentation, submitted the application form, and assisted in obtaining subsequent refills when needed. Some PPAPs require that original applications be resubmitted at the time of each refill; others use less complex refill forms that do not require patient or provider signatures; some allow refill renewals by telephone. For patients to continue to use the program, they must keep regular follow-up appointments with their oncologists; this improves access to medications and ensures routine appointments and adherence to treatment regimens.

RESULTS

From January 1, 2011 to December 31, 2012, a total of 926 patients were enrolled in the PAP, with 347 in year 2011 and 579 in year 2012, respectively. Medications obtained from PPAPs include parenteral and oral formulations. For the fiscal year of 2011, with a modest personnel investment, there was a cost savings of \$1,066,000 for 341 patients, with a 98% acceptance rate for patients' applications (347 patients filled out the application forms). For the fiscal year of 2012, among 579 patients who applied to the PPAPs, 573 applications were approved (99% acceptance rate), with a cost savings to patients of \$1,715,538 (Table 1). There were more cost savings in parenteral than oral medications (Figure 1). The average monthly savings in the previous 2 years is \$115,897. There were 12 patients (1.3%) who were

declined by the PPAPs because they did not meet the manufacturers' criteria.

DISCUSSION

This study evaluated the impact of the PAP at a public hospital from which indigent cancer patients request assistance when they have difficulties accessing therapies prescribed by their oncologists. The main finding of the evaluation demonstrated that despite the complex access issues faced by the patients in obtaining prescription medications, the percentage of patients actually receiving medications from PAP during the study period was nearly 100% (98% and 99% for 2011 and 2012, respectively), suggesting that the PAP was successful in overcoming the access challenges faced by the patients seeking support. We have confidence that the assistance provided by the program offers a durable solution for their access problems.

The cost of health care will continue to rise as extraordinary medical progress is made and new medications are developed. Even though the ACA has subsidized insurance options, there were 16% (29 million) uninsured working-age adults by the second half of 2014.¹⁵ Health care providers should investigate all opportunities for providing medications to patients with access challenges. PAPs are one way that health care institutions can make a difference in helping offset the expenses of cancer treatment. The success of the PAP at the CCC at NUMC can be attributed to the skills and efficiency of the pharmacy department in identifying patients needing assistance and contacting the pharmaceutical manufacturers offering the appropriate PPAPs. The coordinator tracks the patients daily on the ambulatory oncology clinic list, confirms insurance status, and works with the patients while they wait for their appointments at every clinic visit. The pharmacy department absorbs fiscal responsibility for the full-time position, and the salary is offset by the cost avoidance of drugs administered to the indigent population at the oncology clinic, which are provided for free by the pharmaceutical companies. This represents considerable savings

Table 1. Number of patients enrolled in the patient assistance program and savings from 2011 to 2012

Time period	No. of patients processed	No. of patients enrolled	% enrolled	Total savings
2011	347	341	98%	\$1,066,000
2012	579	573	99%	\$1,715,600
Total	926	914	98.7%	\$2,781,600

Figure 1. Savings for 2011 and 2012 via the patient assistance program.

for the patients and, ultimately, for the institution as the hospital would underwrite the cost if the PAP was not in place.

Approximately 60% of cancer care in the United States is given in community-based settings.^{27,28} Recent studies show that the average out-of-pocket spending by patients with cancer is \$1,730 to \$4,727 per year depending on insurance status.²⁹ Funding cut backs have led to staff reductions in many of these cancer centers. The PAPs aid indigent patients and reduce bad debt resulting from uncompensated medication assistance at institutions serving large indigent populations. Although PPAPs have been in existence for many years, they have gained increased attention in the current environment of escalating drug costs, especially for those cancer patients.

CONCLUSION

Within the context of a changing health care system, it is challenging to achieve the goals of supporting cancer care provision and improving both patient outcomes and care experiences. PAPs provide a valuable solution to ensure that indigent cancer patients receive needed prescription medications. We conclude that coordinated resources should be developed in every treatment center to facilitate appropriate, timely, and sustainable care for cancer patients.

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