

“Starting a Pharmaceutical Program”

Program for Pharmaceutical Care
to Underserved Populations

Field Report

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A report written by organizers of volunteer-based health care programs serving the uninsured.

PHARMACEUTICAL

“Starting a Pharmaceutical Program” Program for Pharmaceutical Care to Underserved Populations

Volunteers in Health Care Note: Please be advised that regulations exist in every state regarding the dispensing of pharmaceuticals. In addition, the U.S. Food & Drug Administration has its own regulations regarding drug samples and in December, 2000 issued new regulations for their handling, management and distribution. Before starting a program, be sure to look into the regulations in your state as well as those of the FDA. For more information on the new FDA regulations specific to drug samples please visit the VIH website at www.volunteersinhealthcare.org or call toll-free at 1-877-844-8442.

Who we are

The Program for Pharmaceutical Care to Underserved Populations (PPCUP) operates under the auspices of the University of Pittsburgh School of Pharmacy. Established in 1995, the program, in collaboration with Health Care for the Homeless Project (HCHP), links volunteer pharmacists and students with three organizations providing primary health care to homeless and low-income individuals in the city. Through the participation of the School of Pharmacy, pharmacists, and pharmacy students, the PPCUP stores medication for its partners; sends pharmacists and pharmacy students to join volunteer medical staff as they provide health care at shelters and drop-in centers; and works with partner organizations to support cost-effective prescribing.

The PPCUP uses volunteer pharmacists and students from the Pittsburgh area to provide pharmacy services at free primary care clinics at shelters and drop-in centers in Pittsburgh. The program serves primarily homeless and low-income people. Pharmacists work with a team of other health care providers including physicians, nurses, and other allied-health professionals in an interdisciplinary model of care. This effort is a collaboration between PPCUP, Health Care for the Homeless Project, Program for Health Care to Underserved Populations (PHCUP, an initiative at the University of Pittsburgh using volunteer physicians, nurses, and health professions students to provide health care to homeless and low-income people), and Operation Safety Net, a tax-exempt program that provides medical care to the unsheltered homeless population.

Although these four groups are distinct entities, resources such as medications and personnel are shared. Each collaborator has a budget set aside for medications, and PPCUP provides volunteer pharmacists to reduce cost and assure safe and effective drug therapy. Strategic planning and problem solving for the program occurs on an informal basis with the PPCUP director soliciting input from volunteer pharmacists and the clinic outreach coordinator.

PPCUP was conceived, developed, and continues to be administered by faculty members from the University of Pittsburgh School of Pharmacy. Approximately 100 pharmacy students participate in PPCUP annually; currently, nine pharmacists provide care in ten half-day clinics per week at seven different locations. In 1999, they dispensed 1,561 prescriptions on-site. Sixteen additional clinics operate without a pharmacist due to the limited number of volunteers available. At these locations, medications are provided through a voucher program paid for by HCHP. Homeless patients obtained 1,459 prescriptions from local pharmacies through the voucher program. A total of 5,366 patients received care at the free clinics.

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The Program for Pharmaceutical Care to Underserved Populations (PPCUP), located in Pittsburgh, PA, operates under the auspices of the University of Pittsburgh School of Pharmacy. Established in 1995, the program links volunteer pharmacists and students with three organizations providing primary health care to homeless and low-income individuals in the city. Through the participation of the School of Pharmacy, pharmacists, and pharmacy students, the PPCUP stores medication for its organizational partners; sends pharmacists and pharmacy students to join volunteer medical staff as they provide health care at shelters and drop-in centers; and works with partner organizations to support cost-effective prescribing.

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The free clinics serve a predominantly African-American population (57%), followed by Caucasian (34%). Sixty-one percent of patients are male, and 47% are between the ages of 25-44 years old. Seventy-five percent have incomes at or below 100% poverty level. Sixty percent have no health insurance, 33% receive Medicaid, and the remaining patients have private insurance, Veterans benefits, or Medicare. We provide medications primarily for acute medical conditions; however, our services continue to expand to address the needs of chronic diseases such as hypertension, diabetes, and asthma.

There are no eligibility requirements for patients participating in our program, although the clinics provide service to adults only. We do not bill for any services, there are no co-payments, annual caps, or limits on the number of prescriptions per patient. However, we encourage all patients (if eligible) to pursue state Medicaid health insurance options in order to increase their continuity of care.

How we got started

In 1994, a new faculty member with interest and experience in working with underserved populations, met with Pittsburgh providers who were already offering medical care in free clinics. The faculty member's previous involvement with the Minnesota Health Care for the Homeless Program led her to suspect that pharmaceutical access may have been a problem among the Pittsburgh underserved population as well. Her discussions with local providers confirmed her suspicion. The following factors led to the decision to develop the pharmaceutical access program:

1. Recognition of an unmet need: Homeless people lack access to appropriate drug therapy that significantly compromises their health.
2. Assessment of our capabilities: We had the available expertise, interest, level of commitment, financial resources, and personnel to address this problem.
3. Receptivity of other providers: We met with and surveyed health care providers from three medical programs that served homeless patients in free clinics at that time and found them receptive to our possible involvement.
4. Support of School of Pharmacy: The Dean and Department Chair offered full support for the project because they saw potential benefits for the community and for the School. The benefits to the School are two fold. First, the program allows the School of Pharmacy to fulfill its commitment to serving the community. Second, it offers a valuable learning experience and the opportunity to foster the value of community service among our students.

The most important questions to address:

What are the needs of the community that we wish to serve? (We were very careful to create a service that fits the unique needs of the community.) Do we have the resources and support to make a commitment to the community for the long-term?

Program design

Medications that are dispensed on-site include both samples and medications purchased in bulk. In addition, for medications not available on-site, there are arrangements with local retail pharmacies to accept medication vouchers that are paid monthly by Health Care for the Homeless Project. HCHP provides vouchers for patients in clinics served by all three medical programs. This arrangement is part of our commitment to working collaboratively. We also use the pharmaceutical manufacturer's patient assistance programs where appropriate. The clinic outreach coordinator completes approximately 12 manufacturer applications per month.

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The decision to dispense medications on-site was based upon:

1. A desire to eliminate barriers to access
2. Our philosophy that medication should be dispensed as part of a comprehensive pharmacy service program and should include:
 - An assessment of the appropriateness of the prescribed therapy, e.g., correct drug dose, no drug interaction, etc.
 - A determination of the cost-effectiveness of the therapy—do we have an equally effective but cheaper alternative
 - Patient education and drug therapy monitoring to enhance outcomes
3. A commitment to decreasing cost to collaborating programs that operate with a limited drug budget:
 - By purchasing medicines in bulk, using sample medications, and taking advantage of pharmacist volunteers to dispense medicines on-site, we reduce the need to use vouchers that, on average, cost about five times more per prescription. These cost-savings allow our collaborating programs to serve more patients.

The basic design of the operation has not changed since its inception. Medications are dispensed under the physician-dispensing model, with pharmacists functioning as physician extenders. This decision to use a physician-dispensing model is based upon practical limitations, as it would be impossible to get pharmacy licenses for each location. The drug inventory belongs to the medical directors of the three medical programs with whom pharmacists collaborate, while the School of Pharmacy donates space for storing medications. PPCUP provides pharmacist expertise, including advising the medical programs on drug purchasing and formulary management, helping to manage inventory, assisting physicians with cost-effective prescribing, and counseling patients on appropriate medication use to maximize the likelihood of positive therapy outcomes. Pharmacists also transport drugs to the clinics.

Procuring medications

Drug samples

Physicians meet with pharmaceutical representatives and accept donations of samples that are useful to the program. A physician may call certain pharmaceutical representatives for specific sample medications that are needed. Pharmaceutical representatives bring donated medicines directly to the physicians' offices. Physicians will bring the samples to the clinic or notify the clinic outreach coordinator to transport the medications from the office or clinic to the central location. Local physicians who are familiar with our program will also drop off bags of samples from their offices and inquire what medications are needed. These samples are transported to the central location, sorted, and added to the inventory. The clinic outreach coordinator, under the direction of the program director, is the primary person responsible for the inventory. Work-study students and student volunteers also help sort medications. We do not repackage for dispensing. An important lesson is to refuse sample medicines that are not appropriate for your client population and buy bulk bottles of appropriate medicines that are unavailable as samples.

Retail or other pharmacies

HCHP has arrangements with a number of local pharmacies to accept prescription vouchers and shares the vouchers with collaborating programs. Retail pharmacies fill prescriptions for medications not available at the clinic. The nurse will fill out a voucher for the patient to bring with the prescription to a retail pharmacy, and

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HCHP is billed monthly. There is no formal written agreement with the pharmacies and no negotiated discounts.

In the past, a local chain pharmacy that had relationships with the School of Pharmacy also donated over-the-counter drugs in sufficient amounts to supply the clinics for the whole year. We asked the Dean of the School of Pharmacy for names of people in the chain pharmacy whom we should contact and made telephone calls to these individuals. We followed up with a letter specifically stating the medications, doses, and quantities we were requesting. We encountered no barrier to having our request met. The process took about one month to make the contact by phone and correspond by mail. We had to wait further for the order to be filled. However, this chain pharmacy has since been bought out by another chain. The new chain pharmacy and numerous other pharmacies that we contacted expressed no interest in donating over-the-counter medicines. A lesson to share with other organizations is that it is difficult to get donations directly from chain pharmacies unless you have some personal contact with key individuals in these companies.

Donations from hospitals/other health care institutions

We have an arrangement with the outpatient clinic pharmacy of a major hospital located near the School of Pharmacy. The supervisor of this outpatient pharmacy shares extra sample medications and makes requests to pharmaceutical representatives for medications that we need. Our interactions with this outpatient clinic pharmacy are informal and infrequent. The supervisor will call us if they have samples they wish to donate and we will call them if we have need of samples. We have had a good working relationship and have not encountered any barrier to establishing and maintaining our relationship. A lesson to share is that institutions and clinics may be potential resources for sample medications. If you let others know about your program and how they can help, you may find that an informal network develops that can be of benefit to all involved.

Donations from drug companies

Currently, we have informal arrangements with two drug companies through PHCUP physician volunteers. Pfizer works with the volunteer medical residents to provide samples and Merck provides samples directly to PHCUP. We have written to pharmaceutical companies to request donations and have had no success; it is easier to get donations from pharmaceutical representatives.

Bulk purchasing

Health Care for the Homeless Project participates in the federal government's 340B pricing program. This program requires pharmaceutical manufacturers who want to participate in Medicaid programs to provide discounts on covered outpatient drugs purchased by certain government-supported facilities, including homeless shelters. HCHP is the only one of the three collaborating programs that purchases drugs through the 340B program, but medications purchased through 340B are dispensed to homeless patients served by HCHP, PHCUP, or Operation Safety Net. (As PHCUP and Operation Safety Net are subcontractors of HCHP, their patients qualify for 340B drugs.) We purchase the most commonly used drugs that we cannot get as samples through 340B.

HCHP also operates community health centers, one of which has an on-site pharmacy. After researching the issue, the community health center pharmacist informed us that it would be possible for her to order the medications for our program through her pharmacy at a reduced cost. (This is possible because the medications are purchased for a homeless clinic, a "covered entity" under 340B.) We also buy smaller quantities of medicines through the outpatient clinic and local pharmacies described earlier. These purchases occur when we need a medication quickly and can't wait for the next shipment of medications from the 340B purchase. We did not encounter any barrier in making the arrangement for 340B purchasing. However, it took several

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months to investigate the possibility of this arrangement, since there are specific requirements for 340B purchasing. We needed to clarify our eligibility and devise a mechanism for ordering, purchasing, and picking up the medicines from this community health center. A lesson to share with other organizations is that for eligible organizations, 340B purchasing can drastically cut the cost of your medication purchases. It is worthwhile to pursue the possibility of buying under this arrangement. *(To see if your organization qualifies to participate in this program, visit the Office of Pharmacy Affairs website at www.hrsa.gov/odpp.)*

Recommendations/observations

Important lessons we can share with other programs:

- Forming good relationships with the pharmacists is important. Once pharmacists knew about our services, they became a valuable resource and advocated for our patients in the community.
- Programs should explore the possibilities of getting discount prices for prescriptions filled at retail pharmacies. Dealing with corporate offices of large chain stores can be complicated. The monthly billing comes from the corporate office, so be prepared to deal with bureaucratic complications. Keep very careful records of your interactions and have copies of all paper transactions.
- Vouchers can be overused and costs can add up quickly. Closely monitor voucher use.

Program operations

Staffing

The PPCUP has three staff. The director is a faculty member employed by the School of Pharmacy, which donates 30 hours of her time per week. She oversees general operations, serves on advisory boards of collaborating community agencies, works with collaborators to maintain an updated formulary, provides patient care at some of the clinic sites, organizes pharmacy student rotations at the clinics, oversees pharmacy student curriculums related to underserved care, and secures funding for program operations. The School donates an additional 25 hours of another faculty member's time to assist with writing grants and managing program data. A third staff member, the clinic outreach coordinator, is shared between this program and the Program for Health Care to Underserved Populations.

Other members of the program team participate as volunteers, including pharmacists from the School of Pharmacy, local hospitals, and community pharmacies. Volunteer pharmacists work with physicians at the clinics to identify and solve drug-related problems, provide drug information, make recommendations for cost-effective therapy, dispense medications, provide patient education regarding appropriate drug use and possible side effects, monitor therapeutic outcomes, and serve as on-site preceptors for pharmacy students on clinical rotations at the clinic sites.

Representatives from our program approach new resident pharmacists within the University to educate them about the program and encourage them to volunteer. Once per year, information about the program and volunteer opportunities is sent out to all registered pharmacists in the University and to some local chain pharmacies. Furthermore, an alumnus who volunteers with the program recruits pharmacists from the alumni pool.

Formulary

At the start of the program, pharmacists surveyed physicians and nurses to determine the medications needed. They also reviewed past prescription vouchers. From this data, and taking into consideration samples currently available, we constructed a list of medications to treat the most common diseases. The use of generic drugs is important because it is a critical component of a cost-effective pharmacy access program. As the program

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expanded, pharmacists continued to solicit input from providers and review current clinic statistics that include diagnoses. The formulary is periodically updated to reflect current patient needs.

The formulary serves primarily as a guide. The purpose is more to assure that the basic medications that are most commonly prescribed are available. We do not have strict rules about prescribing only from the formulary. Pharmacists work with physicians at the clinic to help select the most appropriate medication for each patient. This interdisciplinary teamwork is more effective in enhancing cost-effective prescribing than the strict use of a formulary.

Medications dispensed to patients on-site are labeled with information legally required to be on a prescription label. The labels are handwritten on triplicate forms. One copy is placed on the medication vial, one copy is placed within the patient's chart with notes from the physician and pharmacist, and one copy is retained as the dispensing record. The dispensing records are brought back to the central location and the information entered into the computer. The program tracks physician samples and drugs bought in bulk by keeping records with the following information: patient names, physician names, date, clinic site, medication name, dose, dosage form, directions for use, quantity, manufacturers, and lot numbers. We don't use a computer program for daily dispensing activities or inventory. However, we hired a computer programmer to develop a computer program to store dispensing records that allows us to track medications dispensed. We don't have a formal inventory management system. We order medications as the inventory gets low.

Pharmaceutical budget

The approximate value of prescriptions we provided in 1999 was \$47,000. This value is the sum of donated medications at average wholesale price, bulk-purchased medications, and medications provided through the voucher program. The voucher program accounts for 64% of the total cost, donated medications accounts for 26%, and medications purchased in bulk accounts for 10%.

The medication budget is roughly \$34,000 annually. The bulk of this budget (\$32,000) is available through the Health Care for the Homeless Project. The remainder of the funding is supplied through the other two collaborating programs. Their funding comes from members of the community and foundations. Thus, this source of funding reflects yearly donation fluctuations. Monthly medication needs are estimated using several methods. We begin by assessing the most frequently ordered and requested medications by clinic providers. On a routine basis, we assess the most common disease states encountered and subsequent medication prescribed at each clinic site. And finally, we refer to our current formulary for guidance as to what medications should normally be available to dispense in each drug class. All of these sources allow us to formulate a general monthly medication order and, thus, average monthly costs. These figures are only an average and can commonly fluctuate depending on our flow of donated medications and patient utilization of services.

Our program's general policy/procedures for controlling costs is to accurately establish the patient's insurance status at each encounter. We instruct and encourage all of our volunteer providers to be aware of each patient's status in order to make the most cost-effective decision regarding dispensing of medication. If a patient has adequate medication coverage under their insurance plan, the physician will write a prescription for the patient rather than dispensing from the medications on hand or issuing a voucher. In addition, we try to order and encourage prescribing of generic drugs versus brand names wherever generics can be substituted. Critical to maintaining a cost-effective pharmacy access program is the collaboration between physicians and pharmacists to assure that patients receive appropriate drug therapy.

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Lessons learned

- Collaboration is essential to developing and maintaining a successful program.
- Utilize existing contacts to introduce you to potential volunteers and contributors of resources to the program.
- Volunteers are the essential ingredients to the program.
- Volunteer pharmacists on-site at the clinic are key to assuring that patients receive appropriate therapy at the lowest cost. They also enhance patient outcomes through patient education, monitoring drug therapy for safety and effectiveness, and dispensing medications at reduced cost.
- Schools of Pharmacy are rich resources for community agencies. A partnership with a School of Pharmacy offers benefits for both the community and the School.
- Maximize the use of available medication samples and any reduced-cost agreements. In particular, take advantage of the 340B pricing if you are a "covered entity."

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