Distributing Scarce Drugs for the Medpin Program

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In the 1999 settlement of a lawsuit by the state of California, 19 pharmaceutical firms were required to provide $150 million worth of drugs free of charge to 200 California clinics and hospitals over three years. The Public Health Institute (www.phi.org), an independent, nonprofit organization, was responsible for distributing these drugs in a fair and equitable manner. In 2001, six more firms and $20 million dollars were added to the project. The decision-support system for the drug distribution project (DDP) used management science and operations research concepts to distribute drugs in a timely and fair manner, taking into account various clinic, pharmaceutical, and allocation constraints. Many uninsured patients who would otherwise have had difficult or no access to medication have received their prescribed drugs and sustained their health. Although an accurate count of the patients affected is not available yet, we estimate that 2.6 million, 30-day drug prescriptions were filled as part of DDP between April 2000 and February 2003. Further, many pharmaceutical firms are exploring using the DDP's decision-support system to improve operation of their charitable drug programs.

Key words: health care; pharmaceuticals; decision analysis; systems.

The Drug Distribution Project (DDP) was created in the fall of 1999 to implement the drug-distribution portion of Master Agreement of Settlement and Release of Pharmaceutical Cases I, II, and III in the Superior Court of the State of California, City and County of San Francisco, J.C.C.P. Nos. 2969, 2971, 2972 (“Settlement Agreement”). In this settlement of a lawsuit by the state of California, 19 pharmaceutical firms agreed to provide over $150 million worth of drugs free of charge to a number of California clinics and hospitals over a three-year period. The Medpin (medicine for people in need) program (www.medpin.org), originally called pharmaceuticals and indigent care program, of the Public Health Institute (www.phi.org) in Oakland, California, an independent, nonprofit organization that promotes health for people throughout California and the US, was responsible for distributing these drugs in a fair and equitable manner. The Drug Distribution Project (DDP) was an unprecedented drug-ordering and distribution system combining brand-name drugs from multiple companies, hundreds of diverse safety-net clinics serving indigent Californians, and a specially designed, Internet-based ordering system. From April 1, 2000 to July 8, 2001, the DDP distributed products from 19 pharmaceutical companies pursuant to the original 1999 settlement agreement.

On July 9, 2001, six additional participating companies joined the DDP pursuant to a second settlement agreement expanding the list of products available to clinics through the DDP and an increase of the drug budget amount by $20 million dollars, bringing the total to $171 million dollars. The last DDP order period was February 2003, and final product shipments began the following month. Created to implement major portions of an innovative cy-pres settlement, this project successfully distributed 99 percent of $171 million worth of brand-name medications to indigent patients.

Getting the Participants Together

The DDP was large and difficult to administer. The Medpin program was to serve as the ordering agent, pursuant to §3 of Schedule D-1 of the settlement agreements. Medpin operates under guidance from its advisory board and as part of the nonprofit Public Health Institute.

Before the DDP began, Medpin staff contacted approximately 700 nonprofit community clinics throughout California plus all 61 local health departments in the state. The facilities were approved if they documented to Medpin’s satisfaction that they (1) were one of the types of safety-net providers specified in Section 8 of the settlement agreements and (2) have in-house pharmacy capacity (a drug dispensary or pharmacy) licensed by the California State Board of Pharmacy.
Table 1: Twenty-five companies participated in California's Drug Distribution Project.

<table>
<thead>
<tr>
<th>Company Name</th>
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<tr>
<td>Abbott Laboratories</td>
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<td>American Cyanamid</td>
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<td>American Home Products</td>
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<td>Boehringer Ingelheim</td>
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<td>Bristol Myers Squibb</td>
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<td>Burroughs Wellcome</td>
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<td>Carter Wallace</td>
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<td>Dupont Merck</td>
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<td>Eli Lilly</td>
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<td>Glaxo, Inc.</td>
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<td>Hoechst Marion Roussel</td>
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<td>Hoffmann-LaRoche</td>
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<td>Janssen Pharomeutica</td>
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<tr>
<td>Knoll</td>
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<tr>
<td>Merck &amp; Co. Inc.</td>
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<td>Novartis</td>
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<tr>
<td>Ortho-McNeil</td>
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<td>Pfizer</td>
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<td>Rhone-Poulenc Rorer</td>
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<tr>
<td>Schering</td>
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<tr>
<td>G.D. Searle</td>
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<tr>
<td>SmithKline Beecham</td>
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<tr>
<td>Upjohn</td>
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<td>Werner Lambert</td>
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<td>Zeneca</td>
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The 25 DDP participating companies (“settling defendants” in the settlement agreements) worked with Medpin staff under the operating procedures developed prior to the DDP’s start date (see Table 1). After mergers and acquisitions, they became only 15 companies: Abbott, AstraZeneca, Aventis, Boehringer-Ingelheim, Bristol-Myers Squibb, Church and Dwight, Eli Lilly and Co., GlaxoSmithKline, Johnson and Johnson, Merck, Novartis, Pfizer, Roche, Schering-Plough Schering, and Wyeth. Companies that joined the DDP after February 2000 were informed of DDP operating procedures before they decided to become settling defendants.

Medpin selected over 200 clinics to receive DDP drugs and dispense them to their uninsured patients. They included free clinics, community clinics, freestanding county clinics, and outpatient clinics of county hospitals located in rural, suburban, and urban areas throughout California. They serve patients of diverse cultural and linguistic backgrounds. They had 125 drugs in more than 20 drug categories to distribute, ranging from routine antibiotic drugs, such as Amoxicillin, to complex drugs, such as Artane (for the nervous system) and Epivir (for HIV), see Table 2.

Operation of the Drug Distribution Project

Medpin’s first task after determining eligible clinics was to determine how much budget to allocate to each clinic. It used a system of DDP credit limits based on transparent, evidence-based methods to apportion the DDP’s total product balance equitably and efficiently. The clinics knew in advance the maximum amount of free product they could request each year. Medpin computed the maximums annually and assigned them to the clinics based on the most recent, publicly available records of the amount of care each clinic provided. As a result, Los Angeles County Medical Center, a large clinic, had a DDP credit limit more than 100 times the size of the limit for Mt. Shasta Medical Clinic or Casa de Salud, a small community clinic. Medpin determined these limits following the state of California’s established rules for determining the drug budgets for clinics based on such characteristics as location, population served, and financial condition. In the settlement, participating clinics had indicated different preferred frequencies and time periods for accepting DDP drug orders. To move toward a consolidated and cost-effective system, the DDP specified dates for DDP order periods, typically three to four months apart.

Developing the ordering and distribution system was beyond the technical capabilities of the Public Health Institute, so Medpin contracted with Kentucky-based Choice Systems Inc. to create a custom-designed, Internet-based Web site to handle and track DDP orders. This system also helped Medpin to cut back on order requests in an equitable and systematic manner, so that no product totals exceeded the appropriate dollar amount for that drug company nor, when applicable, for that particular product or class of products.

The order-entry system developed by Choice Systems provided clinics with the ability to enter their orders using the Internet through a Web browser using their user names and passwords. Clinics could prepare, modify, and submit orders during each ordering period (every quarter). Further, the system automatically checked that clinics met minimum-order constraints (imposed by the pharmaceutical firms) and did not exceed their drug budgets. At the end of an ordering period, the order-processing system accumulated the orders and computed the allocations based on our approach. It also provided reports on the dollar value of the drugs remaining at the end of each order period so that clinics would know how likely they were to obtain particular products in the next order period. Even with Medpin’s use of DDP credit limits and visual cues to steer order requests toward the products most or least available through the DDP, there were significant differences between the amounts of the order requests Medpin received from clinics and the amounts of the product orders Medpin transmitted to the drug companies. For example, $128 million worth of available products was requested through the DDP during its final program year. Out of this total, Medpin was able to order products whose total value was no more than $72 million, due to each company’s limits on total product balance or other ordering restrictions imposed by different companies.

Although Choice Systems had the software skills for developing the order system, it could not allocate drugs or drug types in short supply. Medpin needed a robust decision-support system to allocate drugs in a fair manner to the clinics.
Drug Allocation Problem

As part of the settlement, each drug company negotiated restrictions in terms of the total wholesale value of drug categories and individual drugs it could provide in a given period. The clinics had restrictions on minimum-order amounts per period, in dollars as well as drugs. Medpin assigned each participating clinic a maximum total dollar value of drugs that it could receive during each of the program’s three years of operation. Because the companies were to provide the drugs free of charge, clinics were expected to order primarily the most critical drugs and to order up to their maximum dollar-value allocations. This posed a problem in allocation: because the companies set an overall dollar-value cap on the amount of each drug they made available for distribution, Medpin expected that orders for certain critical drugs would exceed the quantities available. Further, given the large number of clinics and the dollar value associated with the settlement, it was important that Medpin use an approach that not only maximized the number of clinics that participated (and patients that benefited) but also distributed drugs in an easy, timely, and fair manner. The Medpin decision-support system was created to accomplish these goals.

In allocating drugs, Medpin took into account efficiency, effectiveness, and equity measures necessary in a nonprofit environment. We measured efficiency by the extent to which all resources available were in fact distributed. We minimized the total dollar...
value of the drug budget left over every period. We measured effectiveness by the extent to which clinics received drugs that met their needs. To maximize effectiveness, we used a priority-weight matrix that determined the importance of drug $k$ for clinic $i$, taking into account clinic type (we gave mental-health clinics higher priority for mental-health drugs) and size. We measured equity by the extent to which allocations were fair, respecting varying characteristics of clinics, such as financial resources, geographical remoteness, and medical specialization. To achieve equity, we allocated drugs so that each clinic got a fraction of the requested amount proportional to that amount weighted by its priority for any drug in short supply.

Given the above measures, we formulated the problem with two objectives (appendix): to minimize the leftover budget in each period (the equivalent of maximizing the dollar value of the drug allocation) and to minimize the difference between the ratio of the allocations and the weighted orders from the clinics, thereby addressing the effectiveness and equity measures. Further, in making the allocations, we needed to take into account the following constraints on participating clinics and pharmaceutical firms.

Clinic constraints ensured that the clinics did not exceed their respective budgets.

Pharmaceutical firm constraints ensured that, in any given period, the dollar values of total disbursement, category-level disbursement, and drug-level disbursement did not exceed the limits set in the settlement agreement.

Allocation constraints ensured that the dollar value of a drug Medpin delivered to a clinic was less than or equal to the amount requested and that it met the minimum order quantity for each drug and clinic.

The allocation problem has multiple objectives, is nonlinear, and has integer variables. The size of the problem (up to 250 possible clinics, 25 pharmaceutical firms, 125 drugs, and 20 drug categories) makes it difficult to achieve optimal allocation in a reasonable time. Because Medpin would use the optimization model with a subjective priority-weight matrix regularly, we developed a fast heuristic solution to the problem. The heuristic first allocates the maximum possible amount of each drug to each clinic and then, in case of scarcity, allocates the drug in proportion to the requested amount weighted by the clinic’s priority. Finally, a second-pass heuristic converts the dollar allocation to package-level allocation to the different clinics. Swaminathan (2003) explains this problem formulation and the solution method in detail.

**Execution Details**

Although in principle, the drug-distribution system looked fairly straightforward to implement, we had to work out several details. Clinics could use the Internet to prepare, modify, and submit orders during each ordering period. While placing their orders, the clinics saw a running total of their orders and the remaining budget, and the system accepted only orders that were within the budget and greater than or equal to the minimum-order quantity. They could sort drugs by category and by pharmaceutical firm. To centralize and standardize Medpin operations as much as possible, we presented a single list of drugs available for the upcoming order period to all clinics. This list was based on the specific products enumerated in the original settlement agreements and was revised before each order period. It included no controlled substances. We continually revised the list to remove products deleted because they had been bought by another company or discontinued. The system displayed drug names in strike-out type once their annual or total dollar limit had been reached. We used visual cues to indicate a product’s limited availability (often for mental-health drugs) or extensive availability (because the product was generally not popular). Medpin gave extra attention to products voluntarily added to the drug list at Medpin’s request, subsequent to the settlement agreement, by using visual cues in the drug list or by sending e-mail messages periodically to participating clinics as they prepared for the next order-request period. Medpin often had to teach clinic employees how to submit orders using the Internet and to explain that they might not get exactly what they ordered because of scarcity.

At the end of each ordering period, the order-processing system compiled the orders and computed the allocations based on the heuristic, using the priority-weight matrix Medpin provided. With over 200 clinics and 125 drugs, the full matrix would contain 25,000 values. To simplify determination of priority weights, we assigned a priority weight for each clinic consisting of a base value (determined by the size of the clinic) and a drug-specific value (to be added to the base value) for certain crucial drug categories, such as mental health and HIV. For the remaining drugs, we used the clinic’s base value as the priority weight. Medpin managers could then input different base values and drug-specific weights to the allocation heuristics to obtain reasonable and realistic allocations.

Because of the DDP’s uniqueness and its limited time frame, we faced special challenges in computing each participating company’s remaining DDP balance or budget. In addition to the glitches expected in any new information system, the following issues sometimes arose in the computation of DDP product balances and the processing of DDP orders:

1. Companies track and supply product-shipping
information differently and with differing degrees of centralization and automation, leading to multiple data and information formats. (2) Back orders made accounting for a company's "expanded" and "remaining" product balances confusing. (3) Differences between amount of product ordered and amount shipped made reconciling Medpin and company figures difficult. (4) DDP program-year dates did not coincide with many drug companies' time frames for tracking products. (5) Some companies did not use a single wholesale acquisition cost price throughout a DDP program year. (6) Some companies' figures on their DDP product balances may have reflected individual product shipments, debits, or credits mistakenly sent or attributed to Medpin staff or to the wrong clinic. (7) Medpin could not always confirm reconciled figures for all companies' remaining product balances in time to use those figures in calculating order limits for the following DDP program year.

Conclusions
The Medpin drug-distribution system went into effect in 2000. It provided three years of direct benefits of approximately $57 million worth of medications annually to California's indigent patients. Medpin produced several benefits: Many uninsured patients who would otherwise have had little or no access to medication obtained their prescribed drugs. Based on the use of drugs supplied by Dupont, Bristol Myers Squibb, Warner, and Pfizer, who offer a cross-section of drugs available in the Medpin program, and extrapolating those values to include all the pharmaceutical firms, we estimate that the Medpin program distributed 2.6 million 30-day supplies over the three-year period. Medpin and other safety-net provider groups have asked the DDP participant companies to follow up on their litigation-related DDP participation with separate, voluntary commitments to ongoing levels of drug assistance for California indigents similar to those companies' efforts during the DDP's 2000–2003 time period. Further, many pharmaceutical firms are exploring the use of Medpin's decision-support system for more efficient and equitable operation of the charitable drug programs they now operate. Although the Medpin program's general training and education benefits continue at some level, the end of the direct drug benefits came at a difficult time. California faced a severe state-budget crisis already putting unprecedented strains—due to reduced reimbursement plus increased numbers of uninsured patients—on this state's outpatient, safety-net clinics at exactly the same time that the Medpin drugs were no longer available to help them. The future of pharmaceutical care for indigent California patients holds many uncertainties; Medpin will continue to try to reduce barriers for patients in need of medication they cannot afford.

Appendix
The Model
Indices/Sets
i: index that represents the different clinics (i = 1, ..., I).
j: index that represents the pharmaceutical firms (j = 1, ..., J).
k: index that represents the different drugs (k = 1, ..., K).
S: set of scarce drugs.
Dj: set of drugs manufactured by pharmaceutical firm j.
Cij: set of drugs manufactured by firm j that are classified under drug category l.

Data
Mk: total number of packages in which drug k is sold.
qkm: size of one package of drug k (by quantity contained) in package size m (m = 1, ..., Mk).
cpk: negotiated price of one package of drug k in package size m.
Bj: total budget allowed for clinic i.
dij: maximum disbursement of drugs in the period by firm j (in dollars).
dkj: maximum disbursement of drug k in the period by firm j (in dollars).
dcj: maximum disbursement of all drugs in the category l in the period by firm j (in dollars).
ek: minimum order for drug k from any clinic in a period (in dollars).
Omk: dollar value of drug k requested by clinic i.
OPkm: number of packages of size m of drug k ordered by clinic i.
πik: priority weight of drug k for clinic i.

Decision Variables
Rik: dollar value of drug k received by clinic i.
Yik: 0–1 variable that represents whether clinic i obtained any allocation of drug k.

Objectives
O1: \( \min \sum_{j=1}^{J} \left( d_{ij} - \sum_{k \in D_j} R_{ik} \right) \).

O2: \( \min \sum_{j \in S} \sum_{k \in \delta_{ijk} > 0} \sum_{n \in \delta_{ijk} > 0} (R_{nk} \pi_{nk} \Omega_{nk} - R_{nk} \pi_{nk} \Omega_{nk})^2. \)

Constraints
Clinic Constraints
\( \sum_{j=1}^{J} \sum_{k \in D_j} O_{ik} \leq B \forall i. \) (1)
Pharmaceutical-Firm Constraints

\[
\sum_{i=1}^{l} \sum_{k \in D_j} R_{ik} \leq d_l \quad \forall j, \tag{2}
\]

\[
\sum_{i=1}^{l} \sum_{k \in C_p} R_{ik} \leq d_{c_l} \quad \forall j, l, \tag{3}
\]

\[
\sum_{i=1}^{l} R_{ik} \leq d_{d_l} \quad \forall j, k \in D_j, \tag{4}
\]

Allocation Constraints

\[
O_{ik}, Y_{ik} - R_{ik} \geq 0 \quad \forall i, k, \tag{5}
\]

\[
R_{ik} - Y_{ik} \cdot c_k \geq 0 \quad \forall i, k, \tag{6}
\]

\[
R_{ik} \in \mathbb{R}^+, \quad Y_{ik} \in [0, 1]. \tag{7}
\]

Reference