Special Report

The Valium Project: Diagnostic restrictions as a utilization control in a Medicaid drug program

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This study examines the effectiveness of diagnosis restrictions as a drug utilization control in California's Medi-Cal (Medicaid) program. The numbers of Valium prescriptions dispensed, the numbers of Medi-Cal beneficiaries using Valium and the expenditures represented by those prescriptions were measured during application of a diagnosis restriction for a 33-month base period, followed by removal of the diagnosis restriction for a 14-month period.

Introduction

Drug expenditures under Medicaid programs (Title XIX of the Social Security Act) have historically been exposed to a variety of utilization controls. These controls have included maximum dollar expenditures per prescription or per beneficiary per month; limitations on prescription size and scope of drugs available (using drug formularies); restrictions on place-of-service (skilled nursing facilities, hospitals, etc.), and diagnosis.

California has utilized most, if not all, of the above controls except that of a maximum dollar limit per patient per month. Utilization data that is more specific to various aid categories of Medi-Cal (California Medicaid) beneficiaries is needed to target areas where greater attention to utilization or cost controls should be placed. For example, disabled persons constitute only 16.3 percent of the Medi-Cal users yet account for 32.1 percent of the Medi-Cal drug dollars. Identifying such higher cost groups is but the starting point to focus such cost-containment efforts, however. Other California cost-containment strategies have included a proposal that the State limit its purchasing to the lowest-priced pharmacies in the community, and, most recently, the Prudent Purchase of Drugs Program, in which the State acts as a "prudent buyer" of drugs in the Medi-Cal Drug Formulary. (Although California firmly supports the use of the Drug Formulary, questions have been raised in various National studies as to the effectiveness of such listings. The results of most of these studies have been equivocal for numerous reasons, including variations in study populations, differences in reimbursement policies, lack of data comparability, and so forth.)

An emphasis on generic prescribing and dispensing has also been used for cost-containment in California. A 1978 comparison by Medi-Cal staff reviewed the extent to which the top multisource drugs were used Nationally compared with the same drugs under the Medi-Cal program. Marked differences in choice of brand were noted. A far greater number of generic manufacturers were used in the Medi-Cal program than were used in the National surveys.

Capitation, another cost-containment strategy used in California, is an indirect and often unrecognized utilization control. Under a capitation approach, the control takes the form of an economic disincentive for the prescriber (if he or she is the one who receives the capitation payment) to overprescribe. The use of less expensive generic drug products or alternative drug therapy by the prescriber can result in a direct financial gain. Studies both nationally and in California on the methods by which pharmaceutical services are financed or delivered under prepaid health plans confirm this disincentive as being an effective one.

In California, the use of diagnostic restrictions as a utilization control in public medical care programs preceded the Medi-Cal program by 7 years. The basic assumption for the use of such a control was that questionable use of certain drugs could be eliminated by restricting the prescribing to those diagnoses for which there were generally accepted medical indications. Examples of drugs for which such a utilization control was used include nalidixic acid, with a restriction to use in urinary tract infections (UTI) resistant to sulfonamide therapy or when the patient is demonstrated sensitive to sulfonamides; diazepam, restricted to use in cerebral palsy, athetoid states, or spinal cord degeneration; and methylphenidate, restricted to use in minimal brain dysfunction in children between 6 and 16 years of age.

Background

Within the Medi-Cal program, prescribed drugs are available to Medi-Cal beneficiaries through a drug formulary or through prior authorization by State-employed Medi-Cal consultants for products not listed in the formulary. California has found prior authorization to be an effective utilization control. In 1972, a study was commissioned by the Department of Health Services to assess the deterrent value of Treatment Authorization Requests (TARs), used for obtaining prior authorization relative to services covered by the program. The findings of that study indicated that the estimate of the drug utilization dollars saved per TAR dollar spent was $16.45. Of this, less than $1.00 was due to drug denials. The estimate of the reduction in the total monthly value of claims paid was $2.005 million or a reduction of 29 percent.

These savings were achieved with an average increase in administrative costs of about $111,000 or a net savings of $1.894 million per month. The incremental benefit-cost ratio was 18 to 1.

In a later study, it was found that TAR processing prior to or during hospital admission generates program savings of $12.6 million to $18.8 million annually, with a mid-range savings estimate of $16.3 million. TAR-processing for other medical services generates program savings of about $12.7 million annually. Note that these measures are based solely on the value of services denied and do not include an estimate of the effects of deterrence.

Pharmaceutical products have to pass two levels of review for inclusion in the Medi-Cal program: (1) the State's Medical Therapeutic and Drug Advisory Committee review for therapeutic value and (2) the State's Department of Health Services evaluation of the financial impact of such inclusion. Several therapeutic classes of drugs are either absent or restricted to one or two representatives. These restricted or absent categories include anabolic hormones, laxatives, nonnarcotic analgesics, multivitamins and some single vitamins, nutritional supplements, and minor tranquilizers.

Expenditures for psychotherapeutic drugs tend to remain fairly constant when compared with total pharmaceutical expenditures. Roche Laboratories, a major manufacturer of pharmaceuticals, drawing on previous experiences and statistical analysis of marketing activity, concluded that one of their foremost products, Valium, was not achieving sales levels within the Medi-Cal program as had been expected based on the national model. It was concluded by Roche that the diagnosis restrictions imposed by the Medi-Cal program not only inhibited the sale of Valium but caused greater sales for the entire group of psychotherapeutic drugs in the Medi-Cal program; the sales for this group of drugs were in excess of the national percentage rate of psychotherapeutic drugs to total pharmaceutical sales.

It was Roche's contention that a freer choice in selecting drugs by physicians would bring the Medi-Cal psychotherapeutic pharmaceutical expenditures more in line with the State and National sales indices and, in doing so, would reduce the Department of Health Services' pharmaceutical costs. To induce the Department to test the theory, Roche offered to guarantee the limit of the State's expenditures on psychotherapeutic drugs. On September 13, 1973, the Department entered into a 4-year agreement, effective October 1, 1973, with Roche Laboratories to test the hypothesis.

Prior to implementation of the pilot project, Valium was listed in the Medi-Cal Drug Formulary on a diagnosis-restricted basis for use by patients with cerebral palsy, athetoid states, or spinal cord degeneration. These limited uses were imposed by the Department under the diagnosis-restriction category known as Code 1. In order for a Valium prescription to be reimbursed under the Medi-Cal program, the pharmacist had to indicate on the billing form that the prescription was being filled for treatment of one of the stipulated conditions. If a physician wished to prescribe the product for some other condition, medical justification had to be demonstrated and obtained from a Medi-Cal consultant. Otherwise, the program would not honor the pharmacist's billing.

The pilot project was predicated on the assumption by Roche staff that if physicians and other prescribers were allowed to prescribe Valium for Medi-Cal patients on an unrestricted basis, that is, remove the Code 1 limitation, then the Medi-Cal program would realize savings in the area of pharmaceutical expenditures. It was hypothesized that physicians would substitute Valium for various other, more costly, psychotherapeutic pharmaceuticals and also would reduce the need for additional drugs to offset side effects from the prescription of more potent psychotherapeutics. This substitution would lead to a reduction of the Medi-Cal program expenditures for psychotherapeutic pharmaceuticals. It was also hypothesized that some people were being treated with various nonpsychotherapeutic pharmaceuticals for conditions that were more amenable to treatment with Valium. Allowance of Valium would reduce expenditures for treatment of these persons.

The attraction of the project to the State was a guarantee that Medi-Cal program expenditures for psychotherapeutic drugs would not, as a result of the project, be in excess of budget projections. In fact, Roche guaranteed to not only reimburse the State for excessive costs, but also to provide a saving over the estimated expenditures for psychotherapeutic drugs.

All other program utilization controls for drugs and other services were to remain in effect during the project. Under the contract, expenditures were not to include drug costs incurred by prepaid health plans but were to include certain specified drug expenditures for other pilot projects. In addition, drugs for inpatients in hospitals were excluded from the calculations.

Since Medi-Cal reimburses the pharmacist for the ingredient cost of the prescription plus a professional fee for services (dispensing fee), certain additional guarantees were made by Roche. In order to protect the State against potential increased expenditures represented by an increase in the number of prescriptions, hence, an increased number of professional fees, expenditure limits were also set for the aggregate pharmacists' professional fees associated with prescriptions dispensed for psychotherapeutic drugs. Limits on expenditures for all of the guarantees were subject to modification in subsequent years of the contract. Guarantee limits were also be to modified if the State were to change the pharmacist's professional dispensing fee during the term of the contract.

The project in total covered a 15-month period, October 1973-December 1974. At that point, the State cancelled the contract because of the expenditure levels described in the following section.

Findings

The total Medi-Cal program expenditures for pharmaceutical products during the first 12 months of the project ran $96.4 million (Table 1). During the remaining three months of October-December 1974, there was another $26.9 million in expenditures for pharmaceutical products. These figures are actual figures from the Medi-Cal program's computerized monthly paid claim files. However, the computer files have been aggregated by the date the prescription was filled (month of service) rather than the usual date that the prescription was paid (month of payment) in order to get a truer picture of the expenditures under the project.

Actual payments for Valium (Figure 1) ran $6.9 million for prescriptions filled October 1973-September 1974 and $2.4 million during the last three months of 1974. Payments for Valium were increasing sharply: in the first year of the project, payments were a little over 34 percent of all payments for all psychotherapeutics; during October-December 1974, payments were 41 percent. Figure 2 shows the dramatic change that occurred during the project in the total expenditures for Valium. By contrast, during the 12 months immediately preceeding the project, Valium expenditures ran $2.6 million, slightly over 17 percent of expenditures for all psychotherapeutics.

Table 1

Roche Valium Project: Psychotherapeutic drug expenditures, Actual and estimated months of service: October 1973-December 1974

Item	Medi-Cal expenditures [1]			
	Actual	Estimated	Amount difference	Percent difference
Oct. 1973-Sept. 1974				
Total	$96,396,150	$91,760,580	$4,635,570	---
Psychotherapeutics	20,263,182	17,370,180	2,893,002	---
Valium	6,902,350	3,594,440	3,307,910	92.03
All other	13,360,832	13,775,740	-414,908	-3.01
Nonpsychotherapeutics [2]	76,132,969	74,390,400	1,742,569	2.34
Oct.-Dec. 1974				
Total	26,927,106	24,576,860	2,350,246	---
Psychotherapeutics	5,856,012	4,743,000	1,113,012	---
Valium	2,384,249	1,086,570	1,297,679	119.4
All other	3,471,763	3,656,430	-184,667	-5.01
Nonpsychotherapeutics [2]	21,071,091	19,833,860	1,237,231	6.23

[1]Expenditures are rounded independently and may not add to totals.
[2]Nonpsychotherapeutic drugs differ from the estimate by only 2.34 percent, very close to the difference in psychotherapeutic drugs of -3.01 percent. Since the contract only covered Valium, the difference between the actual and estimated values for other psychotherapeutic and nonpsychotherapeutic drugs would be expected to be very small. Therefore, it could be concluded that the estimating model is accurately estimating within 3 percent of actual expenditures.

During the 12-month contract period ending September 1974, expenditures for Valium were $3.3 million over expenditures that were projected using Code 1. This increase was offset by a slightly less than $415,000 decrease in expenditures for other psychotherapeutics. The net result of the first year of the project was an increase of $2.9 million in Medi-Cal program expenditures for all psychotherapeutics (Table 1). Furthermore, expenditures for Valium during October-December 1974 cost the Medi-Cal program an additional $1.3 million under the project and were slightly offset by a $185,000 reduction of costs for other psychotherapeutics.

All cost figures set forth in Table 1 represent total pharmaceutical costs, that is, drug-ingredient cost and dispensing fee cost, as opposed to those in the agreement that addressed only the drug-ingredient cost. During the project period, Medi-Cal's reimbursement of the pharmacist's dispensing fee was $2.42.

Conclusion

Upon the State's termination of the project, the State presented a bill to Roche for the increased expenditures. Roche filed suit claiming that failure by the State to complete the project was cause for damages in the extent of $10 million. Out-of-court settlement of $1.7 million in favor of the State occurred in April 1980.

It is the State's firm belief that selected diagnostic restrictions are cost-effective and do not adversely impede the provisions of quality medical care. To be effective, such an approach requires an authorization system as well as a means of validation of diagnostic information. The potential cost savings must be sufficient to justify the costs of the authorization and validation efforts.

The estimates or projections found in the table and figures are based on a multiple-regression estimating technique.[1] This technique is the basic procedure used to estimate Medi-Cal program expenditures for the State's official annual budget.

The computerized model used to develop these estimates essentially extrapolates trends from a 3-year data base. In Figure 1, total actual Medi-Cal expenditures are shown by month for the 4-year period January 1971-December 1974; estimates from the model for the same period are also shown. The model for the base period quite closely fits the estimated values for the actual expenditures.

The expenditures shown in Figure 1 are the end result of the estimating procedure. Estimates are made independently for 18 different aid categories of users of three drug types: Valium, other psychotherapeutics, and nonpsychotherapeutics. Units of service (prescriptions) and then expenditures are independently generated for these 18 categories of users. The

[1]Available from the author.

period January-June 1971 was one of program cutbacks implemented December 14, 1970. Severe program restrictions were in effect and the trend for actual users reflects this. In July 1971, after removal of those restrictions, there was a relatively sharp increase in users. From July 1971 until implementation of the Valium project, users increased gradually and consistently.

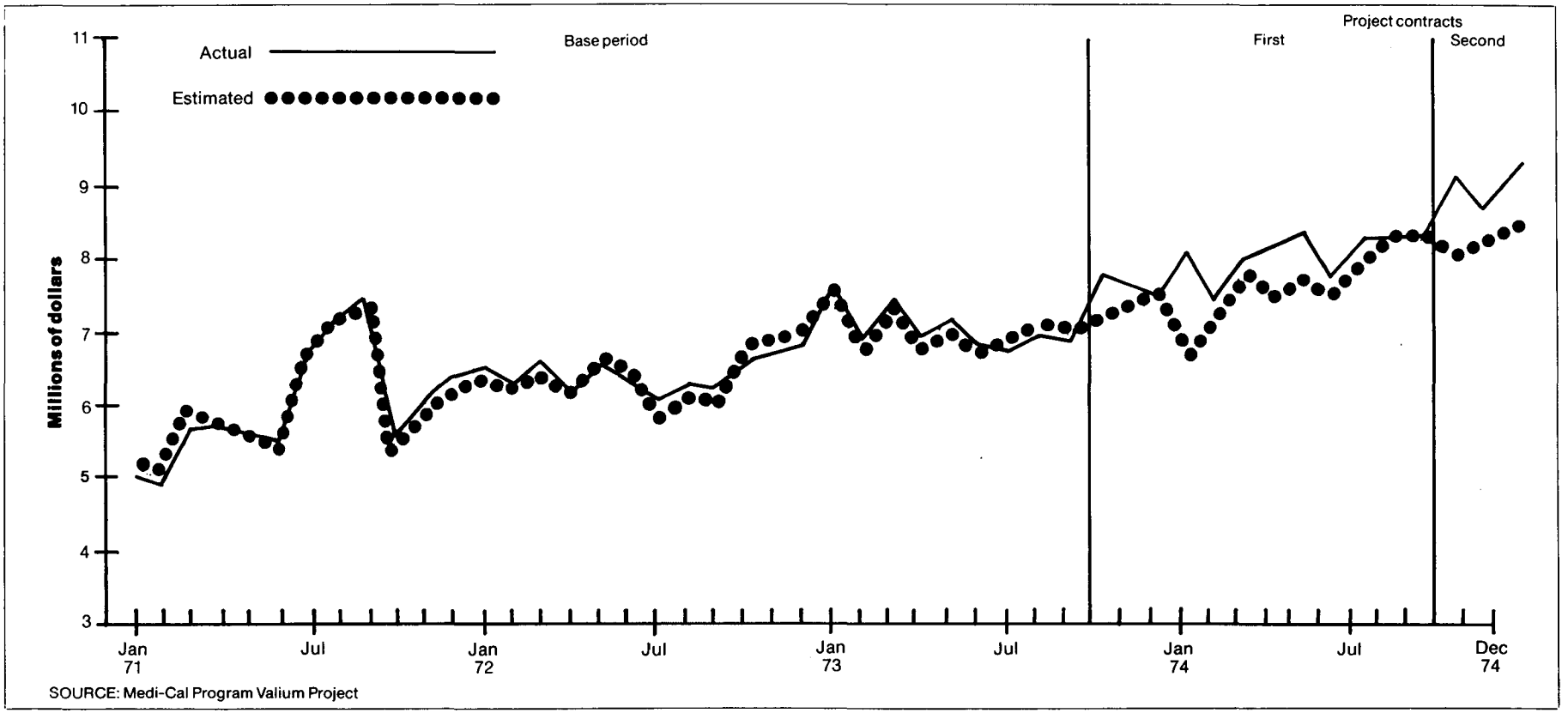
Valium users increased sharply with the advent of the project, from 24,974 in October 1971 to 78,801 by September 1974. By contrast, the expected users from the projected trend line would have been only 34,980 by September 1974, a difference of 43,821 users.

The actual users during the first few months of the project were higher than the estimate. At the beginning of the project, there would still be authorized refills for psychotherapeutics requested by the patients, tending to keep the rate from dropping as fast as might have been anticipated. There would also be a short learning curve as prescribers became accustomed to the new availability of Valium. Substitution of Valium for other drugs would not be expected to occur as rapidly as new prescriptions for Valium for persons not using other psychotherapeutics.

By February, the switch had occurred, so that the number of users of other psychotherapeutics was less than the projected number. The number of prescriptions tended to follow similar trends. From February on, the actual expenditures for other psychotherapeutics were consistently less than the estimated amounts.

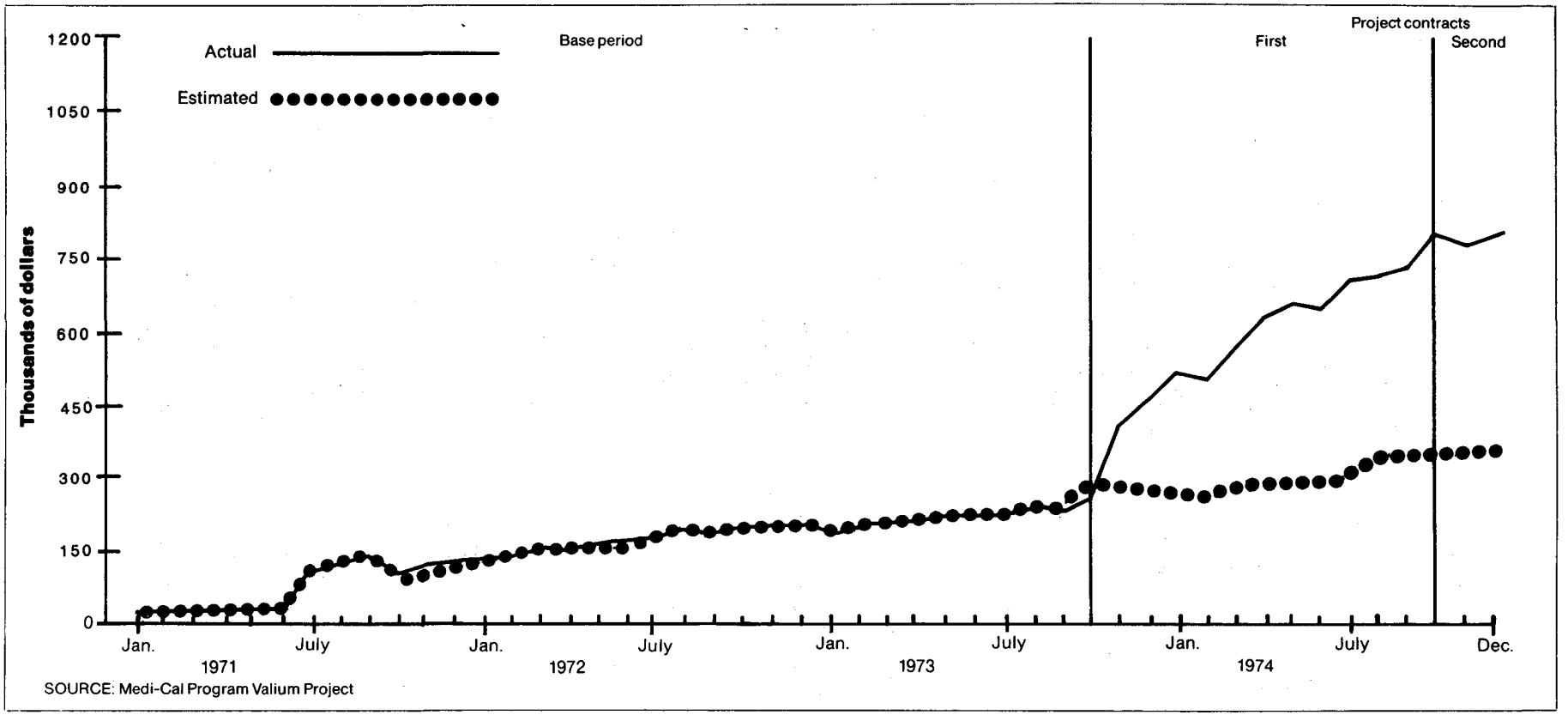
Overall, estimated expenditures for nonpsychotherapeutic drugs were only 2.34 percent lower than actual expenditures. Since the Valium project would not be expected to have an impact on nonpsychotherapeutic drug use in any predictable manner, this nominal difference for the category tends to validate the model's estimations.

Figure 1
Total expenditures for pharmaceuticals, actual and estimated: January 1971-December 1974



SOURCE: Medi-Cal Program Valium Project

Figure 2
Total expenditures for Valium, actual and estimated: January 1971-December 1974



SOURCE: Medi-Cal Program Valium Project