Forecasting The Demand for a New Drug in a New Market: When History Does Not Repeat Itself

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ABSTRACT

The past offers few guidelines for forecasting the future of a drug in a new therapeutic category, but a systems dynamics model that counts patients instead of prescriptions can help predict demand for the product.

INTRODUCTION

Most efforts to forecast the demand for a new prescription drug have taken a historical approach that focused on extrapolating measures of potential physician activity such as new and refill prescriptions. This approach is consistent with the traditional role of physicians as the prime decision-makers in the diagnostic and therapy selection process. Other factors that are considered include market size, market growth, market share, promotion and the competition. It is customary to try to gauge how other drugs in that or a similar market have performed, which is viable when the product and market characteristics are known or comparable (Figure 1).

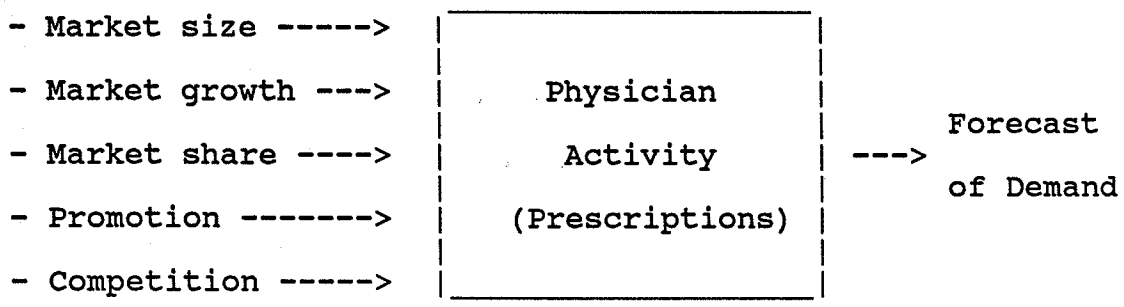


Figure 1

But what happens when there is no historical precedent - when a new drug is launched into a new market?

In such a case the past is no longer a relevant guide to the future; it's time to resort to analytical tools other than trend lines and to assumptions other than "business as usual". To forecast demand under these conditions takes a prospective approach. It is feasible, under certain market conditions, to develop a framework for forecasting future demand of patients.

What are these conditions?

First, it is necessary to have a good estimate of the potential patient population. As with traditional forecasts, which use the number of prescriptions in a therapeutic class, this represents an upper limit on the demand. Second, the number of potential patients who will adopt the new drug each month must be known with some precision. As with forecasts of attainable prescription share, an estimate with wide variability will not be very useful. Third, interaction with and experiences of other patients are assumed to influence the adoption process. This is relevant when patient consent is necessary for treatment - undergoing a major operation - as opposed to cases in which a therapeutic decision is made by the physician alone. Finally, it is critical to know how many patients will have to discontinue the drug - the drop-out rate - in order to forecast the extent of maintenance therapy. Other characteristics of treatment, such as duration of therapy and dosing regimen, are useful data in order to convert patient demand to volume of drug use. A patient-based approach involves the following factors (Figure 2):

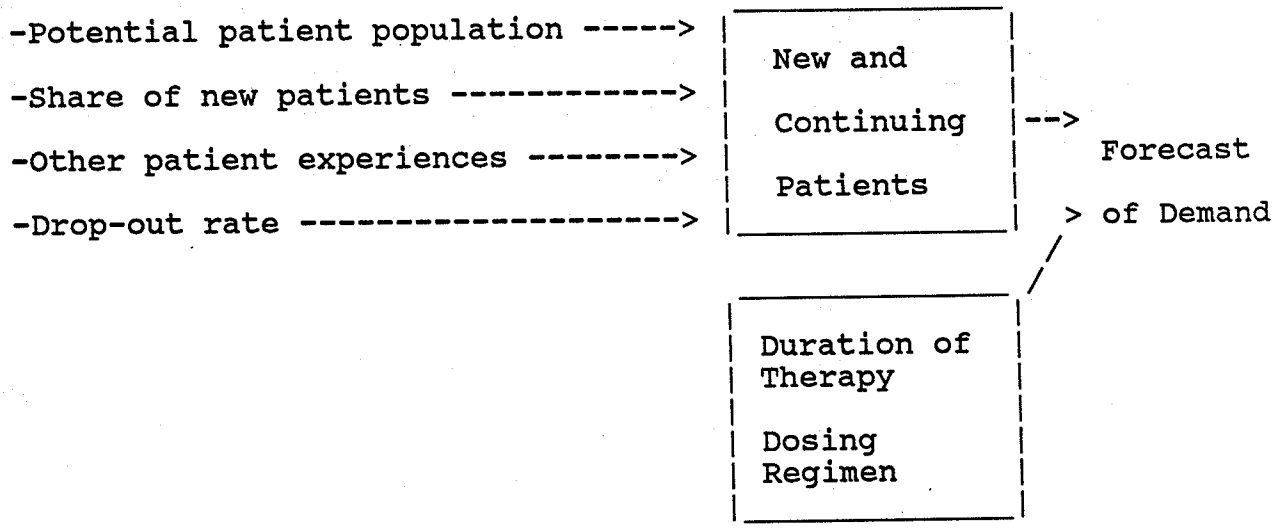


Figure 2

"MODELING THROUGH..."

In a seminal paper on new product growth models 15 years ago, Frank Bass declared (Bass 1969, p.215):

> "Long-range forecasting of new product sales is a guessing game, at best. Some things, however, may be easier to guess than others."

He also raised a philosophical issue about the use of models, on the basis of which many long-range forecasts are now being generated (Bass 1969, p.216):

"Is it easier to guess the sales curve for the new product or to guess the parameters of the model?"

When using a microcomputer, is it more desirable to use a series of numbers on a spreadsheet or to use a series of equations - a model? The answer boils down to deciding whether one has enough confidence in the equations to substitute them as a rationale for long-range forecasting. If one chooses the equations, much fewer parameters need be estimated; and the fewer the re-estimates, the easier it is to understand their consequences when the assumptions change.

The model in this paper is designed to forecast the demand for a new drug for which new patients can be identified as a key determinant of demand. Theories of new product growth are used for modeling the dynamics of changes in demand. We present the case of a drug that will be used for chronic treatment over a number of months or years that requires also explicitly tracking "old" (continuing) patients.

MODELING PATIENTS

The model used here has its roots in the economic literature about the adoption of a new technology (Mansfield 1961, Chow 1967). Economists distinguish between adopters and non-adopters of a new product; they describe and differentiate the rate of adoption of the product by time of trial. Innovators and early adopters try it first; then the early majority, the late majority, and the laggards follow. The population itself is the finite upper limit - or "ceiling" - on the total number of triers.

New drug users and new technology consumers have different ceilings. For consumer durables or industrial products the ceiling is fixed over the life of the product; for new drug users it is a renewable number. Furthermore, because some of the new patients are put on maintenance therapy and others drop out of therapy as time goes on, one must distinguish between the variable rates of new patients and continuing patients. Thus our model is broken down into a two-step process:

model new patients; then model continuing patients

THE NEW PATIENT PROCESS

Twenty years ago Professor Edwin Mansfield of Carnegie Tech published an analytical model to describe the rate of innovation and imitation (Mansfield 1961). Much of the more recent new product growth models draw on his concepts. We used his model to represent the new patient adoption process as continuous over time:

$$\frac{dn}{dt} = b * n(t) * [\bar{n}-n(t)] \qquad (1)$$

where

$\frac{dn}{dt}$ = rate of adoption

$n(t)$ = number of adopters - new patients in month t

$\bar{n}$ = maximum number of adopters in month t

$\bar{n}-n(t)$ = number of non-adopters in month t

b = coefficient of imitation

In words, equation (1) says:

> The rate of change of new patients in month t is proportional to the interaction between adopters and non-adopters.

That is, the rate of adoption is proportional to the mathematical product of the sizes of the two groups. "Interaction" is a surrogate for the "word-of-mouth" effect - users communicating the benefits of a new drug to non-users. When there are only a few users - innovators at first - the rate of adoption is low. As the number of users grows, the rate of adoption increases; when the number of users equals the number of non-users, the rate of adoption is maximal. After most of the population has adopted the drug, its rate of adoption decreases.

The equation has the properties of a logistic function, which has the shape of a symmetrical S-shaped curve - a common type of curve in the new product growth models where no prior knowledge exists about the rate of adoption (Figure 3).

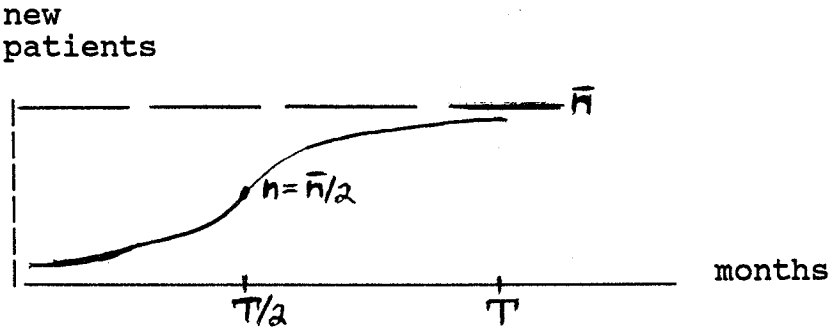


Figure 3

If after T months, the maximum number of new patients, $\bar{n}$, is approximately reached and an initial number of new patients, n_0,

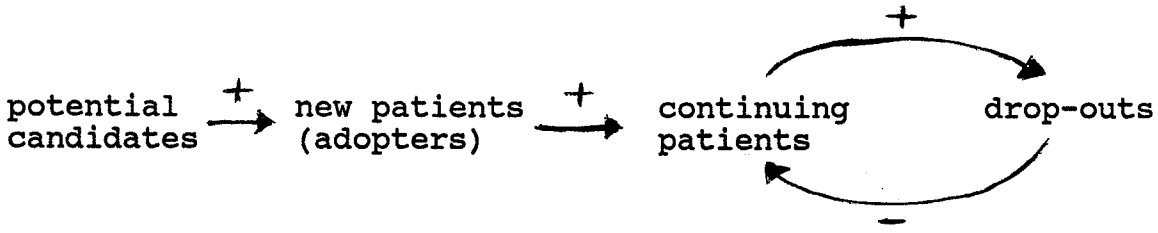
is specified, then the coefficient of imitation, b, can be calculated:

$$b = \frac{\ln [(\bar{n}-n_o)/n_o]}{\bar{n}T/2} \qquad (2)$$

This coefficient denotes the rate at which interaction - "word-of-mouth" effect - between users and non-users occurs.

CONTINUING PATIENTS

To distinguish continuing patients from new patients, one might think of each group as coming from a different pool. The following diagram (Figure 4) shows the patient pools and their "causal" impacts on one another. When potential candidates for therapy first use a drug, they are new patients. As they return for more therapy during subsequent months, they become continuing patients. Some of the latter drop out either because the remedy was succesful or because they don't respond to therapy.



+ = positive influence
- = negative influence

Figure 4

The positive and negative signs illustrate the impact of patient flow from one pool to the next. For instance, the greater the number of new patients, the greater the number of continuing patients. And an increase in the number of drop-outs will reduce the number of continuing patients. Thus, the change in the number of continuing patients is merely the difference between new and drop-out patient rates.

SYSTEMS DYNAMICS CONCEPTS

To incorporate the relationships between new and continuing patients and patient drop-outs, the new patient equation (1) is restated as follows:

$$\frac{dn}{dt} = \lim_{\Delta t \to o} \frac{[n(t+\Delta t) - n(t)]}{\Delta t} = b * n(t) * [\bar{n}-n(t)]$$

when $\Delta t = 1$

$$\frac{[n(t+1) - n(t)]}{\Delta t} = b * n(t) * [\bar{n}-n(t)]$$

or

$$n(t+1) = n(t) + \Delta t * \{ b * n(t) * [\bar{n}-n(t)] \} \qquad (3)$$

where Δt = "change in" t (1 month)

This latter equation represents a simple feedback statement in the field of systems dynamics. Professor Jay Forrester and his group at M.I.T. in the late 1950s and early 1960s developed systems dynamics and the DYNAMO computer language that solves time-dependent problems of this kind. A foundation book, The Limits To Growth, which applies systems dynamics to estimating the global limits of natural and human resources, was published in 1972.

The core concept of systems dynamics is that a system at a certain level at a given time period moves to a new level in the next time period at a certain rate of change:

level (time + 1) = level (time) + rate of change

If the rate of change from one level to another is dependent on the current level of the system, then there is a feedback phenomenon. That is, past performance affects current performance.

In equation (3), the new patient model, the rate of change in the use of a drug by new patients is dependent on the current levels of adoption n(t) and non-adoption $[\bar{n}-n(t)]$. Similarly, the rate of change of drop-outs is dependent on the current level of continuing patients and affects the future level of continuing patients. Thus, both time-dependent relationships fall into a classic feedback system readily solvable using DYNAMO.

CALCULATIONS

The equations and parameters to solve this problem can be described in two steps. The first step, using DYNAMO notation (Roberts et al 1983, Chapter 14), is as follows:

$$NEWPAT.K = NEWPAT.J + (DT)\ (RATE.JK) \qquad (4a)$$

$$RATE.KL = B * NEWPAT.K * (NPMAX - NEWPAT.K) \qquad (4b)$$

where

NEWPAT = number of new patients (adopters)

RATE = rate of new patients

NPMAX = maximum number of new patients ($\bar{n}$)
(market "ceiling" of new patients in a month)

B = coefficient of imitation
(calculated using equation (2))

DT = change in months (=1)

The first equation (4a) provides the number of new patients in month K based on the number of new patients in the previous month J and the rate of new patents between months J and K. The change in the rate of new patients (4b), from one month K to the next month L, is based on equation (1).

In the second step one calculates the number of continuing patients in month K by adding the new patients and subtracting the drop-outs:

$$CONPAT.K = CONPAT.J + (DT)\ (NPRATE.JK-DORATE.JK) \qquad (5a)$$

$$NPRATE.KL = NEWPAT.K \qquad (5b)$$

$$DORATE.KL = constant * CONPAT.K \qquad (5c)$$

where

CONPAT = number of continuing patients

NPRATE = number of new patients (from equation (4a))

DORATE = number of drop-outs

constant = rate of drop-outs per month

DT = change in months (=1)

Suppose, for example, that the initial number of new patients is 100 and the market "ceiling" (NPMAX) is 1000 patients. What are the numbers of new and continuing patients if the drop-out rate is assumed to be 1 percent per month? If it is 10 percent per month?

The number of new and continuing patients can be calculated (Table 1) over a 12-month period using equations (4a-4b) and (5a-5c).

Month	New Patients	Continuing Patients 1% Drop-out	Continuing Patients 10% Drop-out
1	133	100	100
2	175	232	223
3	228	405	376
4	293	629	566
5	368	915	802
6	454	1274	1090
7	544	1715	1435
8	635	2242	1836
9	720	2855	2287
10	794	3547	2779
11	854	4385	3295
12	900	5116	3819

Table 1

Note that with a 1 percent drop-out rate the number of continuing patients increases to more than 5 times the number of new patients after 12 months; an increase in the monthly drop-out rate from 1 percent to 10 percent can reduce the number of continuing patients by one-third.

These equations were applied to the forecast of a Sandoz product - using an IBM PC with Micro-DYNAMO from Pugh-Roberts Associates,Inc. in Cambridge, Massachusetts. A spreadsheet, used before this model was developed, required more than three hours to run a 60-month forecast. With this model we reduced the computational effort to less than 1 minute! In addition, it was possible to calculate the impact on other related variables: the number of bottles and sales revenue.

In summary, in situations in which market conditions permit forecasting of product demand using patient estimates, we have found that the concepts and tools of systems dynamics can be very useful in developing a patient-based, new drug growth model. With this model one can quickly analyze the consequences for a forecast of changes in marketing and therapy variables and policies.

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