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Modeling the Development and Dissemination
of an Emerging Medical Technology

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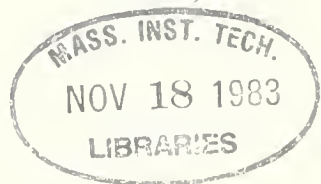
Modeling the Development and Dissemination
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INTRODUCTION

The proliferation of new medical technologies in recent years has produced both excitement and concern among health professionals. The excitement reflects the opportunities to improve the length and quality of life. The concern has been focused primarily on the social costs of technologies whose development, dissemination, and utilization ultimately prove inefficient.

Much attention has centered on a call for policies that would rationalize the diffusion of "emerging technologies," for which only limited effectiveness data are available. The risks and uncertainties which decision-makers face are double-edged and can be described as analogous to Type I ("false positive") and Type II ("false negative") statistical errors. The Type I error would correspond to a situation in which actions taken to facilitate the rapid dissemination of a technology resulted in its overuse. The anticipation of significant benefits to be gained from a new practice may lead to decisions which lack sufficient restraint. A Type I error may not become apparent for several years, if that is the time required to evaluate a technique's true efficacy. The Type II error would correspond to a situation in which actions taken to prevent or slow down the dissemination of a technology effectively deny access to a potentially beneficial practice. Overly cautious or pessimistic attitudes may lead to decisions which inhibit the development of a promising technique so that it, in fact, never does become effective. A Type II error may thus be responsible for the very problem of ineffectiveness a decision-maker may have feared. Both Type I and Type II management errors can be detrimental to society and a major objective of government policy-makers relating to medical technology is to minimize these errors.

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The purpose of this paper is to describe a model of the processes of development and dissemination of an emerging new medical technology. We describe how this approach might be used to assess whether specified alternative policies are likely to facilitate or hinder the development and appropriate use of a new technology. The approach is not a substitute for experience gained from use of the new technology or involvement in its management; rather, the approach builds upon such experience. Our aim is to extend the limits of the current practice of health technology evaluation to allow for changes over time in the technology and its application. In many fields, systematic modeling has permitted analysts to gain insight into future consequences of alternative present actions even when only limited historical data are available as input to the model. We illustrate our approach by examining percutaneous transluminal coronary angioplasty (PTCA), an emerging new technology used in the treatment of coronary heart disease. The results of this analysis are, of course, a function of the particular assumptions that we made regarding medical technologies in general and PTCA in particular. So far as we know, this represents the first application of this approach to medical technology policy analysis.

SIMULATION MODELING AS AN EVALUATIVE TOOL

Simulation models have been used widely in the natural and social sciences, for purposes as diverse as analyzing the economic effects of a proposed tax and optimizing therapy to keep a patient in acid-base balance.^{5,6} A simulation model consists of a sequence of mathematical statements meant to represent the essence of a complex situation or system. Each statement describes a different piece of the system's overall structure and helps to explain how the future flows from the present. A model consists of a possibly large number

of relationships, reflecting the best available information relevant to the problem. Starting with a particular set of assumptions, and with the aid of a computer, the model can produce a relatively detailed picture of future usage of the technology in question, including its changing application and effectiveness. By simulating the model under various sets of assumptions, the analyst may be able to discover underlying conditions responsible for a particular pattern of behavior that has been observed.

In using a simulation framework to analyze the dynamics of new medical technologies, we begin by suggesting that a decision-maker's intuitive understanding of the problem is necessarily limited. An individual's mental model of a complex situation is likely to be incomplete, imprecise, and lacking in objectivity. In such a situation, intuitively appealing policies can turn out to be largely incorrect.⁷ A simulation model, by contrast, is explicit and unambiguous and can be both comprehensive and relatively objective. To be useful a model must reflect a well-informed and logically consistent set of assumptions about the real system.

Simulation models can incorporate both subjective and objective variables, if the analyst is able to clearly formulate the role each variable plays. The analytic formulation of a behavioral relationship may depend on non-numerical, anecdotal information and is therefore subject to much greater uncertainty than the formulation of a quantity that can be measured explicitly. This uncertainty, however, may prove to be a matter of degree rather than a substance; in some cases, it will be possible to clearly specify the direction of a relationship without knowing its magnitude. For instance, it is important to note

that a physician's willingness to adopt a given medical technology (a subjective variable) is often influenced by colleagues, even though it may be difficult to assign precise numerical values to that influence. On the other hand, objective variables, such as the typical patient load of a physician using the technology, can be defined and documented in terms of a much narrower range of numerical values. The structure of the system being modeled--the logic of how its pieces are arranged--is generally much more important in determining its characteristic responses than is the precise set of values associated with those relationships. Physical and social systems are generally resistant to attempts to change their performance and tend to compensate for small perturbations, much as the human body is able to resist disruptive influences with its homeostatic mechanisms. This general insensitivity of complex systems to limited parameter changes argues in favor of an approach to model-building which places more weight on the careful formulation of structure than on the collection of precise numbers.⁸

A good simulation model, however, should prove to be more than a logical and comprehensive set of assumptions concerning the structure of a complex system. It also provides a means for "playing out" the dynamic consequences of these assumptions in a way that the human mind can do neither well nor consistently. A well-formulated simulation model can produce scenarios which are realistic. These scenarios should be explainable in terms that the decision-maker understands, if he or she is already familiar with the model's terminology and assumptions. To say that a model produces realistic outcomes, however, is not to say that they are necessarily the expected ones. It is, of course, encouraging when an analytic tool confirms intuition, but the greatest

value may be realized when the model's projected scenario runs counter to intuition but is convincing in its own right. A model offers not only the potential to reproduce the difficulties encountered in real life but also provides an experimental arena for discovering how they might have arisen. By altering one model relationship or another and observing changes in the simulation results, the analyst can gain a better understanding of the system and its behavior.

Proposed policies can potentially be tested within the context of the model. If effective, high-leverage policies are difficult to identify within the simplified setting of a simulation model, they likely would have proven even more difficult to identify on the basis of intuition. With computer-aided simulation, the evaluation of alternative policies can potentially be concluded in relatively little time and with little cost.

MODELING THE DEVELOPMENT AND DISSEMINATION OF PTCA

To illustrate our approach, we chose to concentrate on a single technology for which we could construct a relatively comprehensive and internally consistent model. PTCA was an appropriate choice because it has attracted much attention recently among practitioners and policy-makers and is associated with many of the attributes and concerns generally discussed in connection with emerging equipment-embodied technologies. The drawback of focusing our work on a currently emerging technology lies in the need for making certain assumptions whose validity will only become known for certain with the passage of time. Indeed, a later section will describe how varying a small number of critical assumptions can significantly affect our results.

Since 1977, when PTCA was first used to reduce obstruction in human coronary arteries, journals have presented numerous reports of clinical experience.^{9,10,11,12,13} To date, over one thousand such balloon catheterization procedures have been logged by a registry established by the National Heart, Lung, and Blood Institute (NHLBI), and the results are generally promising. The procedure is considered an alternative in some patients to the more costly coronary artery bypass graft (CABG) surgery for the treatment of coronary heart disease. Current criteria limit the selection of patients for PTCA to a relatively small subset of CABG-eligibles, mostly those with single-vessel disease. Established protocols also specify that a CABG surgical team be available in case the attempted procedure needs to be terminated because of acute complications. Experts are cautiously optimistic that further experience with the technique will lead to some broadening of the patient selection criteria.^{14,15,16,17}

Concern has been expressed that PTCA offers the potential for inappropriate usage and there have been proposals for policies to manage it closely. The Food and Drug Administration (FDA) recently granted approval to the manufacturer of the PTCA catheter to market its product in the United States. The Health Care Financing Administration (HCFA) and, presumably, other third-party insurance carriers are considering whether to grant reimbursement "coverage" for the procedure as standard medical practice. Some practitioners and policy-makers have been seeking a mechanism for restricting the authorized use of PTCA until more data on its effectiveness have been accumulated.^{18,19} In contrast to such formal restrictions, the NHLBI registry represents an attempt to monitor and help guide the dissemination of PTCA on a non-regulatory, voluntary basis.¹⁷

Analytic Framework*

Figure 1 depicts the medical community and the government as two distinct centers of influence in the processes of development and dissemination of a new technology such as PTCA. The focus of the model is on the medical community which encompasses physicians, researchers, manufacturers, health administrators, private insurers, and patients. In the model, we view the medical community as having as its highest priority the provision of health services to maximize the well-being of the patients, having only secondary concern with broader social and economic issues.

The influence of the government is depicted, in a simplified way, as external to the model. Government policy-makers must hold a broader view of the activities of the medical community, considering them in the context of larger social and economic policy issues. Even though some of these issues are best thought of as beyond the scope of the model, our analysis does attempt to account for many of them in a simplified and aggregated manner.

Subsystems of the Model

As seen in Figure 1, there are five subsystems within the overall model: Usage, Patient Selection Criteria, Opinion Formation, Evaluation, and Technical Development. Each subsystem has an internal structure or logic of its own, but is also affected by information, indicated by an arrow, that comes from other subsystems. Each subsystem can be viewed as a mechanism which responds to outside influences in an apparently reasonable manner. However, interactions between the subsystems may

*A detailed account of the methods used for this analysis are described in Appendix 1.

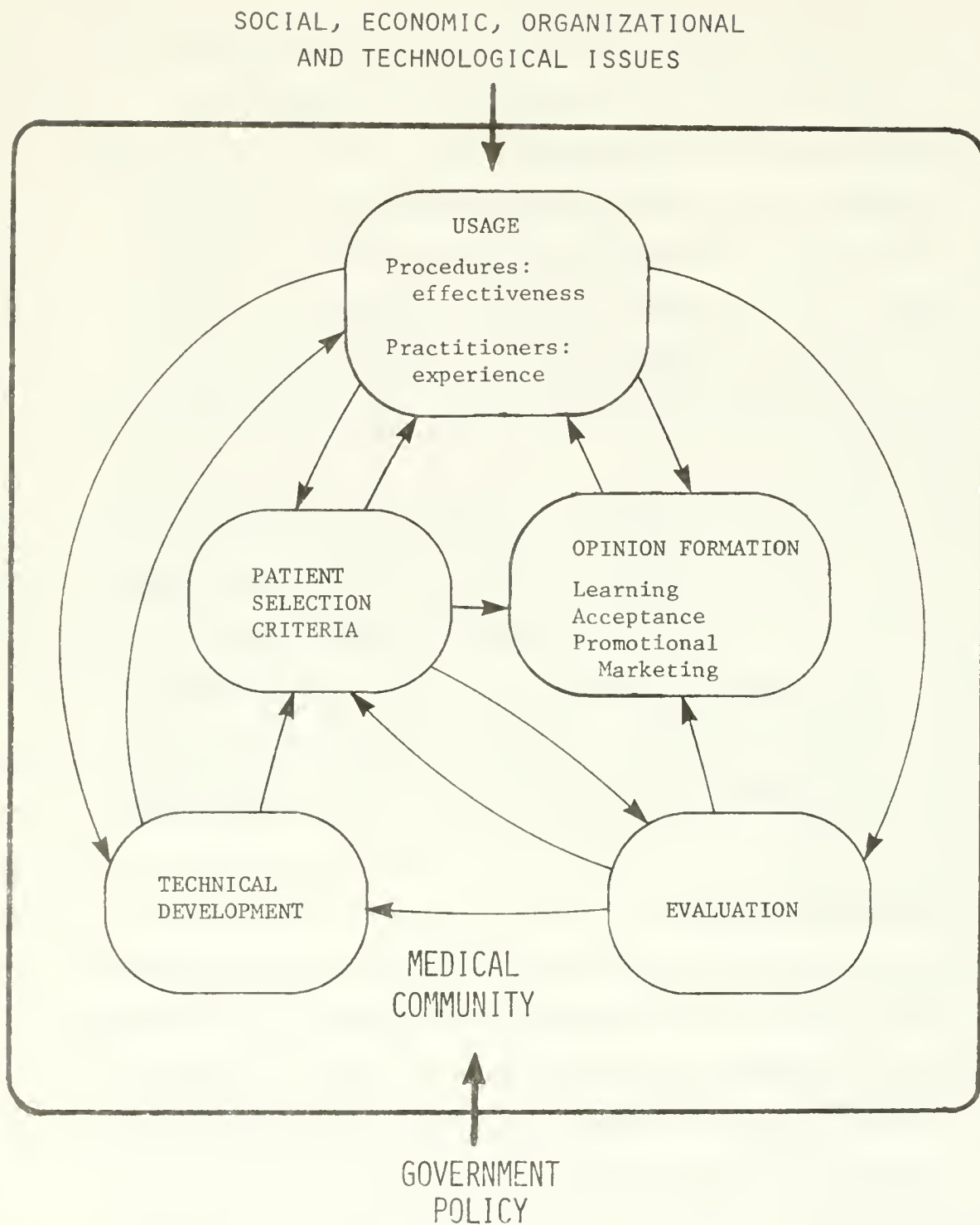


FIGURE 1. OVERVIEW OF FRAMEWORK FOR ANALYZING THE DYNAMICS OF AN EMERGING NEW MEDICAL TECHNOLOGY

produce unexpected or uncontrolled behavior.

The Usage Subsystem produces the most important model outputs: the patterns over time of demand, supply, and effectiveness of the new medical technology. Demand for the new procedure is determined by the number of referring physicians, the criteria or protocols they use for the selection of patients as candidates, and the relative availability of the technique. Supply adjusts to increased demand by increasing the utilization of existing capacity and by training more practitioners. A simplifying assumption of the model is that support personnel, materials, equipment, and facilities remain in proper balance with the number of practitioners; an inadequate supply of the technique would thus be equated with an insufficient number of practitioners.

Effectiveness refers to the extent to which PTCA improves the health status of the recipient; specifically, effectiveness reflects the long-term benefit-to-cost ratio for the procedure. The model allows for differences between actual effectiveness and apparent effectiveness in the short term; a number of drugs and devices which appeared efficacious at first have turned out to have little value or unacceptable long-term consequences.^{20,21,22,23,24} Two factors in the model determine effectiveness: the experience of individual practitioners and the relative breadth of the patient selection criteria in use. As experience is gained in using the technique, proficiency increases according to a "learning curve".²⁵ Greater effectiveness can also be attained by narrowing the criteria to those patients who are most certain to benefit.^{26,27}

The Patient Selection Criteria subsystem reflects those factors which can affect the size of the patient population which practitioners consider eligible for PTCA. Modifications which enhance the technique's safety and efficacy are the major driving force for criteria expansion; some medical innovations, such as CABG and PTCA may require significant improvements to the original technique before they are considered to have widespread applicability.²⁸ The factor which can restrain the expansion or lead to contraction of the selection criteria is the publication of unfavorable or mixed evaluative research results. For example, the PTCA procedure was originally attempted with patients suffering from single- or multiple-vessel coronary occlusions. Evaluations indicating higher risk for multiple-vessel patients, however, have led to an awareness of the technique's present limitations, and, therefore, have suggested greater selectivity in the use of PTCA. However, increased selectivity is not necessarily achieved quickly. Experience with other health practices suggests once a technology becomes well-established, practitioners and hospitals may be reluctant to cut back on its use, even after evidence is available that casts great doubt on its effectiveness.^{29,30}

The Opinion Formation subsystem accounts for the physician's decision to recommend PTCA; in our model, patients are assumed to play a passive role in this decision and are therefore not represented explicitly as decision-makers.³¹ Acceptance of the new technology is modeled as requiring two stages: first, gaining awareness or knowledge of the technology and second, gaining the conviction necessary to recommend the procedure to qualified patients. Awareness may be gained from colleague discussions, journal articles, and promotional marketing by manufacturers.^{32,33,34} These three basic sources of awareness also play roles in the process of convincing a physician that the

new technology is effective and worth recommending.^{32,35} Our model allows for the rejection or abandonment of the technology on the basis of discouraging evaluative data.

The Evaluation subsystem provides information that may be used by practitioners of PTCA to adjust their protocols and by non-practitioners to form their opinions about the worth of the technique. The incentive to conduct evaluations is greatest when there is a large difference between the amount of information already available and the amount desired. The desired amount of evaluative information increases as the range of applications of the technology increases. If completed evaluations seem to reach ambiguous or contradictory conclusions, then more information may be needed to clarify matters. However, it may be impossible to undertake the desired evaluations if the appropriate number or types of practitioners or patients are not available. For example, a large randomized clinical study may be unfeasible in the early stages of a new medical technology such as PTCA, simply because there are not yet enough procedures being done under the ideal conditions that may be required for such a study.

Our model recognizes the possibly long delays that may be an intrinsic part of the evaluation process. It can take years to determine the effectiveness of some medical technologies. However, medical pioneers often publish interim reports about new technologies which have demonstrated encouraging short-term benefits on the assumption that more extensive research will corroborate the early evidence. Such reports on work-in-progress may help generate enthusiasm for the technique before it has been thoroughly evaluated.

The Technical Development subsystem portrays the processes of technical modification and development that are responsible for PTCA's evolving

capability. Improvements and adaptations are engineered, produced, and distributed by manufacturers, whose ideas may be largely based on the suggestions of skilled practitioners.³⁶ A primary motivation for continuing to invest time and money in a particular line of development is the perception that the effort stands a reasonable chance of success or that the expected "payoff" makes the investment worthwhile. A similar "return on investment" criterion is used by many firms to evaluate research and development proposals.^{37,38}

Opposite Patterns of PTCA Use Over Time

Research literature offers two opposite usage patterns that could, in theory, be observed for PTCA, depending upon whether or not the technique proves to be successful over time. The "successful" pattern refers to a situation in which use of the technology grows exponentially until a saturation point is approached (Figure 2). An "S-shaped" usage curve has been observed in empirical studies of the growth of a number of ultimately successful equipment-embodied and pharmaceutical technologies.^{32,39,40} If, in the long-term, the practice is "unsuccessful", its usage over time will have risen and fallen to reflect early popularity with the technique and later abandonment following unfavorable experience with it (also Figure 2.)⁴¹

Using our model of the processes of development and dissemination of PTCA and the DYNAMO computer simulation package, we sought to determine the nature of the assumptions that would be required to generate those opposite utilization patterns. Figure 2 displays the different assumptions that we have found critical for producing the two opposite patterns of PTCA use with our model. The baseline PTCA model, in which we assumed that the technology had relatively high potential for development

PATTERN

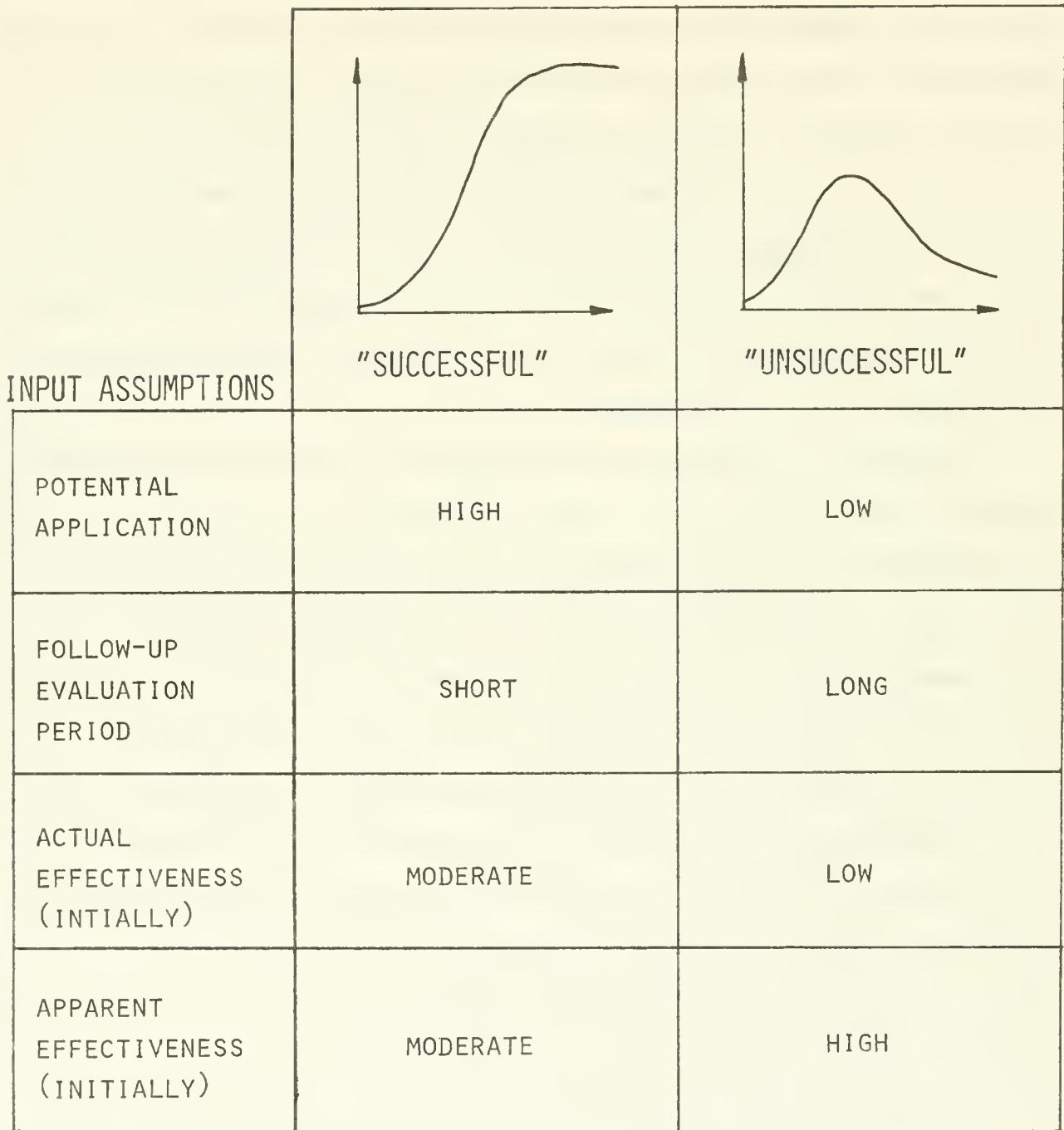


FIGURE 2. USAGE BEHAVIOR PATTERN OVER TIME AS A FUNCTION OF ASSUMPTIONS FOR PTCA

(consistent with current opinion in the cardiovascular community), generated the familiar "S-shaped" usage curve that characterizes successful technologies. Three stages of the curve were observed: (1) an initial period of slow growth marked by uncertainty and intense evaluation; (2) a period of rapid growth marked by physician acceptance, technical development, and broadening of the patient selection criteria; (3) a slowing down of the growth rate following nearly complete acceptance of the procedure and diminishing incentives to find new applications for the practice once its technical limits are approached.

A different set of assumptions was required to generate the unsuccessful long term usage pattern for PTCA. When the technology is assumed to be relatively low in potential application, our model will still predict at least moderate success of the procedure unless three other critical assumptions are made. It is necessary to assume that: (1) the follow-up period for completing evaluations is relatively long; (2) actual effectiveness is initially low due to overly broad patient selection criteria; and (3) initial estimates of effectiveness (apparent effectiveness) are far too optimistic. The observed unsuccessful usage pattern can be interpreted as follows: Initially, there are high hopes and expectations for the technique. Even though the true effectiveness of the technique is rather low, early partial evaluative data are not discouraging and the practice gains popularity. However, as evaluations are completed and appear to be unfavorable, the technology is discredited and largely abandoned.

Projecting the Impact of Alternative Policies on PTCA Use

We now examine the possible impact of alternative policies on the utilization and effectiveness of PTCA, under the assumptions we made, for the successful and unsuccessful patterns of usage.

The same policy may have a particular sort of impact for a successful technology and cause entirely different effects for an unsuccessful practice. If policy-makers understand these differential impacts, it may be possible to reduce the risks of overuse and underuse, the Type I and Type II errors, as the technology is disseminated.

The particular policies under consideration include regulations that would restrict dissemination of the technique until convincing clinical effectiveness data have been accumulated, and a voluntary registry of cases intended to link practice of the procedure more closely with its evaluation. The federal government presently has two clear mechanisms for implementing a regulatory policy: (1) the "Class III" designation applied by the FDA to devices which require favorable safety and efficacy data for marketing approval, and (2) the experimental status designation used by the Health Care Financing Administration for decisions prior to granting reimbursement coverage under Medicare. Though those decisions have largely been made already for PTCA, it is of interest to test their impact using our model. The second type of policy decision we test with our model is whether or not to sponsor a voluntary registry that would collect and evaluate case-specific data from a large number of practitioners of the technique. In the case of PTCA, such a registry has been implemented by the National Heart, Lung, and Blood Institute.

As discussed previously, our model describes actions taken within the medical community; government policy decisions have been assumed to originate from outside this community. It is therefore necessary to translate each policy alternative into a direct effect on decisions made within the medical community, as represented in the model. Figure 3 describes how this was accomplished for each of the policies under

| | | POLICY | |
|-----------------------------------|--|---------------|------------|
| | | NO REGULATION | REGULATION |
| INPUT VARIABLES | | | |
| START-UP PERIOD FOR PRACTITIONERS | | NORMAL | LONG |

| | | POLICY | |
|---|--|-------------|----------|
| | | NO REGISTRY | REGISTRY |
| INPUT VARIABLES | | | |
| AVAILABILITY OF PROCEDURES FOR EVALUATION | | NORMAL | HIGH |

FIGURE 3. ALTERNATIVE POLICIES FOR EMERGING MEDICAL TECHNOLOGIES

consideration.

In the model, restrictions on early dissemination are translated into a longer start-up period for practitioners until the practice is considered legitimate by government regulators. Legitimacy depends on both the quantity and the content of evaluative data. In the model, a registry of cases is translated into a larger sample of the procedures becoming available for evaluation. This means that any given level of usage will receive more thorough scrutiny than it would have in the absence of a registry.

RESULTS*

We used our simulation model to test the impact of four different hypothetical policies under the assumption of a successful long-term use pattern for PTCA. The effects of the same four policies were also evaluated assuming that the technology proved to be ultimately unsuccessful. The four policies we tested were: (1) Regulations which impose restrictions on early use of PTCA; (2) A voluntary registry of clinical experience with PTCA; (3) A combination of regulation and registry; and (4) No intervention by government either in the form of regulation or registry. Our results suggest that if PTCA proves to be successful in the long-term none of these policies would prevent the technology from achieving nearly its full potential use, though alternative policies were responsible for delays of different durations. If PTCA were ultimately unsuccessful, our model predicts that regulatory restrictions on dissemination would have the desired effect of discouraging inappropriate use; the impact of the registry is, however, more difficult to interpret.

Figure 4 shows the impact of these alternative policies on PTCA under the assumptions of a successful technology. Each of the four curves

*The results are presented in greater detail in Appendix 2.

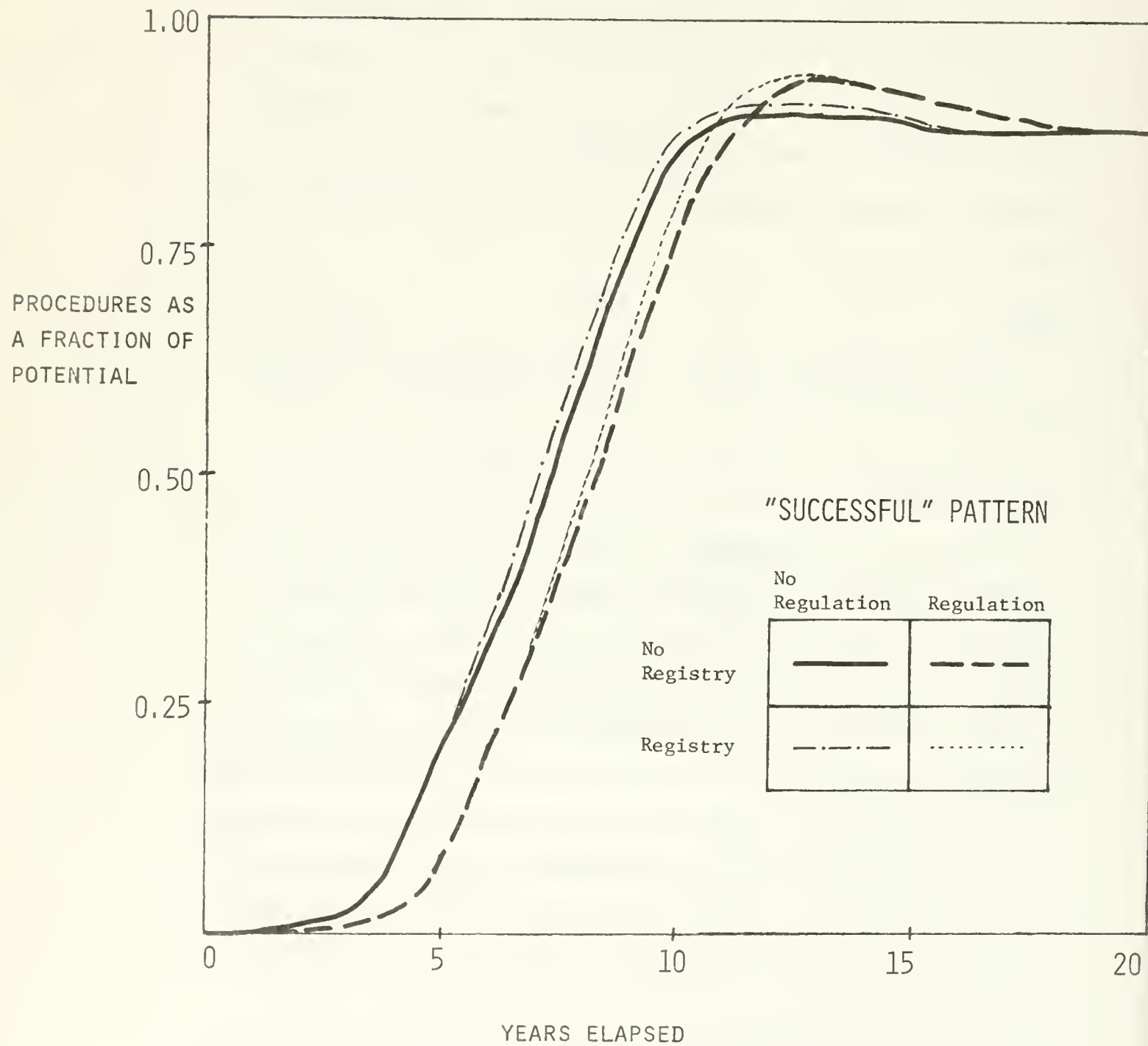


FIGURE 4. POLICY IMPACTS FOR "SUCCESSFUL" USAGE PATTERN

represents twenty years of usage starting with the first clinical application at year 0. The number of procedures performed per year is expressed in relative terms, as a fraction of the technology's potential for effective usage. What stands out most clearly in Figure 4 is the similarity of the four curves. All are "S-shaped" and all converge to the same high level of usage by the end of the period projected by simulation. Regulation does create some lag in usage as might be expected, but does not prevent successful development and dissemination of the technology and the same high level use seen without regulation. The registry seems to have the opposite short-term effect, encouraging slightly earlier use of the technique by channeling more information to the medical community.

Figure 5 shows the results from simulating each of the four policies on the use of PTCA under the assumptions needed to produce an unsuccessful "rise-and-fall" long-term pattern. The duration of this pattern turns out to be about ten years, which is shorter than the duration of changes seen when the technology proves successful. The vertical scale in Figure 5 represents only one-quarter as many procedures per year as in Figure 4, reflecting a potential for effective usage which is that much lower.

The policy of regulation appears to be beneficial under the unsuccessful pattern. Without regulation, the technique gains popularity in the first few years of application, despite little conclusive evidence supporting its effectiveness. This outcome is a reflection of our assumption that the medical community is, at first, relatively confident about the technology. The restrictions on dissemination impose caution on the medical community, so that growth is much slower than in the non-regulated situations. As unfavorable evaluative data accumulates, growth is curtailed and then reverses.

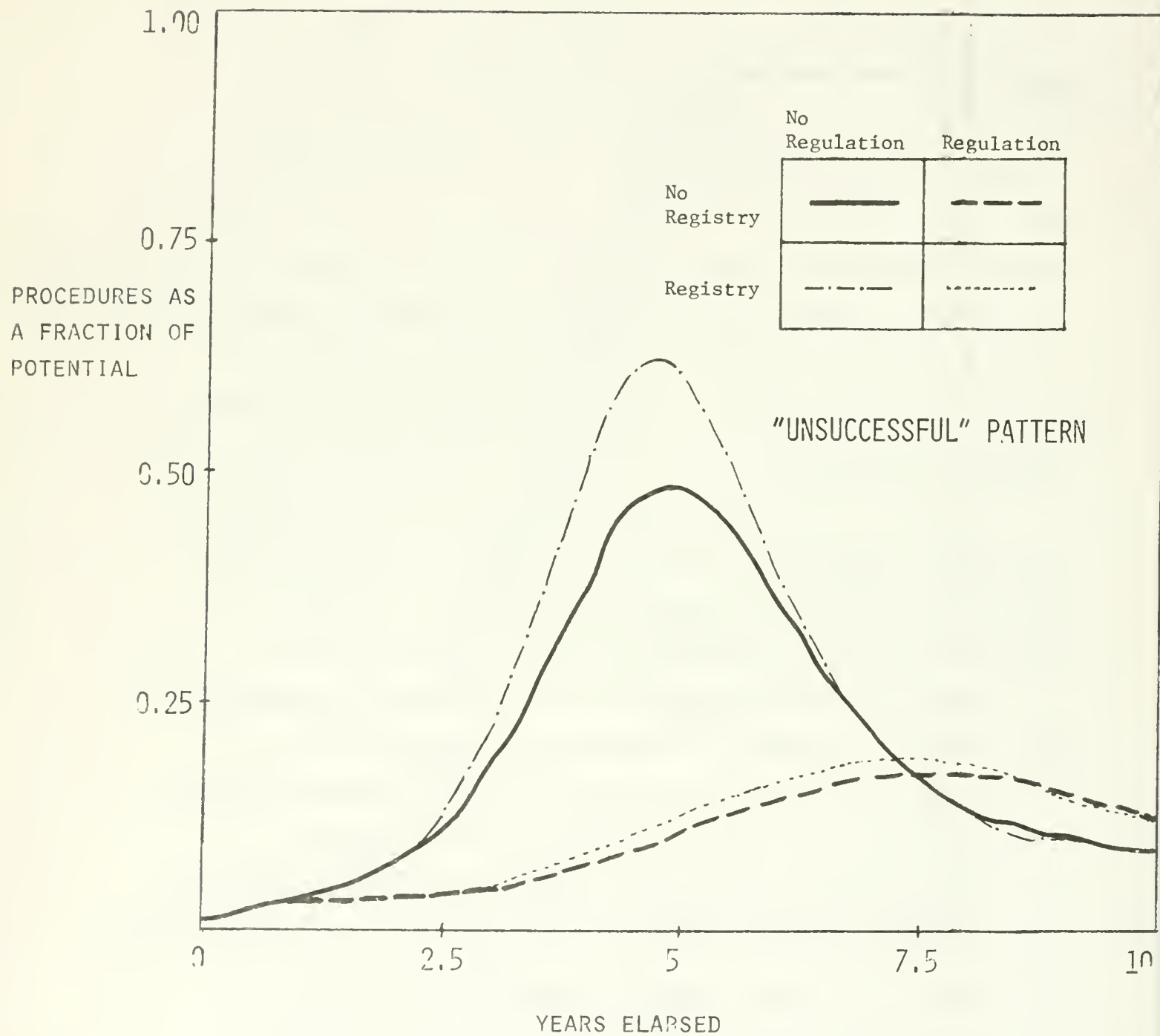


FIGURE 5. POLICY IMPACTS FOR "UNSUCCESSFUL" USAGE PATTERN

The impact of the registry on the unsuccessful growth pattern for PTCA of use appears to be ambiguous. On the one hand, the registry encourages early growth of PTCA by increasing awareness and knowledge of the practice during a period when evaluation results are not yet complete. On the other hand, the registry also leads to the earlier collection of evaluative data that suggest more selectivity and narrowing of criteria for patient referral. In the absence of regulatory restrictions, the first effect appears to dominate: more procedures are performed with the registry than without it and with lower effectiveness. When the registry is used in concert with regulatory restrictions, however, the early burst of usage is prevented and overall effectiveness actually increases due to better patient selection.

LESSONS LEARNED FROM THE SIMULATIONS

Our objective was to model the processes of development and dissemination of an emerging medical technology in order to better understand how alternative policies might affect the realization of its long-term potential use. Short of drawing any definitive conclusions about the impact of certain policies on the future of PTCA or any other emerging technology, a number of important lessons were learned from this simulation. Our confidence in the model is based, in part, on the ability to generate with plausible assumptions both the previously reported "S-shaped" utilization curve for successful technologies and a rise-and-fall pattern for unsuccessful technologies.

Generally speaking, the policy of regulation appeared to have the desired effects of hindering the adoption of an unsuccessful technology while not preventing the full development and dissemination of a successful technology. In both cases, the policy was responsible for a delay in the growth of the practice we studied. One might be tempted to argue that these results supported a policy of regulations restricting early dissemination. The risks of

costly overutilization and underutilization, resulting from the Type I or Type II errors, appear to be low. But this conclusion depends upon such factors as the benefits and costs associated with use of the technology and its various outcomes and the cost of implementing the regulatory policy itself.

The impact of the registry policy is more difficult to judge than the policy of regulation. Its impact on the usage of an unsuccessful technology is neither clearly beneficial nor detrimental and may depend on whether or not a regulatory policy is also implemented. In the case of a successful technology, the registry does appear to offer some benefits. Further analysis is also needed to determine how the benefits compare to the costs.

SYSTEMATIC ANALYSIS AND MEDICAL TECHNOLOGY POLICY

There has been considerable current interest in systematic methods which can be used to assess efficacy or to evaluate the social impact of medical practices in terms of costs, risks, and benefits. Policy-makers are attracted to these methods because they offer a capability to logically and systematically address the pros and cons of a decision. ^{42,43,44,45} Though the specifics of the various methods of analysis do differ, they are similar to the extent that their output is sensitive to the particular set of assumptions made. The PTCA model demonstrates how a few critical assumptions can spell the difference between a successful and an unsuccessful one.

Technology evaluation has frequently suffered from simplifying assumptions that depict the future as different from the present only in a very limited sense. For example, a study of the costs and benefits of a new medical technology might assume that the technique is rapidly disseminated and typically will not allow for later generations of that technology with possibly improving impact on health and changes in the

patient selection criteria. These assumptions may not be realistic for a technology that is still undergoing development and requires time to gain acceptance.^{3,46} Policy-makers who rely on technology evaluations that make relatively static assumptions about an inherently dynamic situation may be unable to fully appreciate real differences between alternative policy options in terms of their likely future consequences.

In an era of scarce resources and increasing costs, health care decision-makers would like to identify those policies which would have the most favorable effect on the costly errors of overutilization and underutilization and hence achieve maximum long-run benefits to society. Assessing the future impact of emerging new technologies is an important task but is also, by its very nature, an uncertain one. Uncertainty about the future use of a new technology can be reduced, to some extent, by seeking expert opinion, but even experts have only limited powers of projection, especially when the state of knowledge is changing rapidly. In the face of this situation, we believe that comparative policy analysis, as commonly performed, could benefit from application of a tool such as simulation-modeling to systematically consider the dynamic interplay of a large number of determinants and influences.

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