

@MASTERSERIES, @EYEWIRE

For Cost-Reducing Technologies, Knowing Markets Is to Change Them

Benefiting from an Understanding of Economic and Political Markets Includes Recognition That Engineers Themselves Can Change These Environments

ROBERT P. HUEFNER, NORMAN WAITZMAN, JOSEPH D. ANDRADE, AND STEVEN E. KERN

Sponsored research from a NSF Foundation/Whitaker Foundation initiative on cost-reducing technologies brought together faculty from engineering, medicine, and social sciences to link economic and policy assessments to engineering design. The technology under development is to be an inexpensive. easy-to-use monitor for self-management of metabolic diseases by patients, with specific application to phenylketonuria (PKU). While the technology remains in development, the experience, including discussions with others in the Whitaker and National Science foundations' program, raised interesting issues about economics, policy, and cost-reducing technologies.

The project's initial focus and purpose, of enhancing costconsciousness in healthcare technology, evolved to consider opportunities of the information age and changing expectations of patients' roles in their own healthcare management. Technology development is an iterative experience that, when thus understood, 1) is benefited by economic and policy analysis that is incremental and integrated rather than definitive and independent. 2) has more cost-reducing potential as market incentives change, 3) can be efficiently improved by a stronger base of accessible information, and 4) has potentially important roles for patients in using, facilitating, and shaping future technology.

Two additional thoughts concern presumptions of policy and economic analyses. First, in assessing policies and politics on the basis of the distribution of benefits and costs, avoid presumptions that politics are zero-sum confrontations. Second, in assessing economic markets by the ways healthcare fails to meet presumptions of classical economic theory, consider not just the present market but future changes and supplements.

Learning Through Incremental and Integrated Analysis

While the purpose of this multidisciplinary project concerned the influence of economics and policy upon technology, the work soon surfaced the reversed linkages: the influence of technology upon economics and policy, particularly by the effects of technology that increases the role of patients in selecting and managing their care. Exploring, with clinicians and families, the economics of PKU suggested that inexpensive and easy-to-use monitors could change treatment. Monitoring could be far more frequent (even several times per day rather than once per month), would provide more reliable measures (for example, reducing the temptation to relax compliance with dietary guidelines between tests), and give instant feedback (rather than the days or weeks for present testing) to more clearly relate body chemistry to behavior (eating and exercise). This would increase the family's understanding of the condition and its treatment and the family's ability, approach, and motivation for managing it. It also could change treatments by providing new insights among clinicians and more powerful tools for researchers.

The potential evolution in treatment and family responsibility reinforced an initial presumption that was made in this project that economic and policy assessments should not be made as one-time studies that, while sophisticated and thorough, are expensive in dollars and time and can provide information that is too late to assist technology development. Like the technology development itself, economic and market impact assessments seem most helpful as a succession of increasingly sophisticated and targeted analyses, achieving a progressive precision as technology is developed and integrated into practice. This allows an earlier connection with the technology development, enabling the assessments and the technology development to guide each other as they progress. Besides making sense, this is consistent with studies of innovation [1], [2], which find that innovative technology development is aided by having connections within a project development group between technical, commercial, and regulatory personnel.

Understanding healthcare and other technology markets includes an understanding that the markets sometimes don't just exist—they are altered and sometimes created by the technology. The common direction of development is for a technology to go looking for a use, rather than for a need going looking for a new technology. Innovation tends to be "technology-push" rather than "demand-pull" [3].

For all the above reasons, economic and policy assessments are better used in technology development as ways of thinking rather than as hard decision rules. They often offer incomplete answers to questions such as whether the market will support a developing technology, in our case a blood phenylalanine monitor, whose development had not yet determined whether the technology would develop into a Understanding healthcare and other technology markets includes an understanding that the markets sometimes don't just exist—they are altered and sometimes created by the technology.

stand-alone monitor or as a platform technology that will be applied to and supported by the treatment of a number of conditions. But as ways of thinking, they are important in identifying and understanding other important questions. Thus, in the case of phenylalanine monitors for PKU, questions raised included how benefits would be distributed among patients as well as among suppliers of medical services and technology. Also, how effectively would the market monetize benefits? Such questions lead the assessments and the technology development to explore ways to better design a product or to a broader agenda about how to improve incentives by restructuring the market. Does, or can, the monitor reduce, or increase, the costs of physician support? Is, or could, quality of life be monetized by the market?

Technology, Costs, and Incentives

The presumption of the NSF/Whitaker initiative, that technologies including devices can be cost saving, was not that technology alone could reduce the growth in healthcare expenditures. At the heart of the motivation behind the initiative was the growing consensus that technology development was a cost-driver in the healthcare system as currently configured, and as the market for healthcare is being revolutionized, the development of cost-saving technologies may lag behind the emerging incentives to adopt such technologies. So the initiative's limited expectation was that cost-saving technologies can make significant differences in the future expenditures for healthcare. But this limited expectation still faced cynicism and perhaps even opposition from some observers of, and participants in, biotechnology who engaged in the discussions held as part of the initiative. The cynicism came because of the role technology has played in the escalation of healthcare expenditures. There may have been another concern, or even opposition, that a focus upon cost savings might jeopardize future high-cost, but ultimately worthwhile, advances.

The disagreements too often built upon failures to clarify terminology of purpose: was the project seeking technologies a) that individually reduce costs of treating (or preventing) an instance of a particular condition, even though the availability of the new technology may increase total healthcare costs by being used to treat conditions that otherwise would be untreated or less effectively treated; b) that individually reduces costs even when considering all uses of this particular technology; or c) that collectively, with all other new technologies, reduces the total cost of healthcare? Some, especially among the skeptics, considered anything short of the third (collective savings) a failure but worried that such an outcome itself would constitute failure because it could be accomplished only by damaging the market for new technologies that, like the preponderant new technologies of the 20th century, provided treatments that increased the costs of healthcare and may or may not have passed a cost-effectiveness test.

Skeptics also presented arguments based upon inadequacies of the market. Cost savings may more likely be found in technologies with early expenditures for future savings, as in the case of preventive treatments. But, skeptics point out, the market undervalues the long-term because of corporate quarterly reports and provider reluctance to make changes in procedures; the market fails to monetize quality of life for patients and their families; benefits may not be recouped by units that incur cost; and market forces, as configured, may be inadequate to support development of treatments for rare conditions (such as PKU), even when they offer promise of reducing costs for the individual patient.

Some technologies escape these market barriers, such as immunizations and fluoridation. They may, as in immunizations, mean government or foundation subsidies of development, moving primary support from the for-profit to the public or not-for-profit sectors. Or they may, as in fluoridation, mean public assumption of operating costs. They also may mean, as they have in both of these cases, public programs of regulation and/or distribution to assure appropriate usage.

In other cases, various circumstances or means allow these barriers to be hurdled. As healthcare costs become concentrated among a few payers (for example, federal and state governments), the full societal benefits of cost-reducing technologies are more fully recognized, increasing the incentives and means to finance and apply such technologies. Improved information also reduces the limits of healthcare markets. Outcome and expenditure data help understand cost implications of new technologies. Prevalence data, of conditions and treatments, help predict the market and determine financing for proposed technologies.

Information Is Efficient Support

Opportunities to connect technology development with economic and policy assessments are enhanced by two aspects of information-age technology. The first is the expansion of data from healthcare payers/providers and of tools of medical informatics. The second is the exploding possibilities of greater patient participation, especially through the Internet.

The first of these includes aggregation and use of clinical and administrative data. It addresses a major limitation of healthcare markets: lack of information, for example, for asA less expensive and more effective means to monitor a disease such as PKU enhances the likelihood that insurers will cover costs of such monitoring.

sessing effectiveness and cost-effectiveness of treatments and technology. Information systems, joining clinical data to assess effectiveness and administrative data to assess cost-effectiveness, promise both problems and benefits. If developed for managing the costs, and not also regularly employed to monitor quality, such quality will be particularly susceptible to compromise. If more carefully developed, they can be cost-reducing and quality-improving technology themselves and, additionally, provide data to target and assess new technology. Developing and providing access to these data are means to stimulate and support technology development. If these are considered as government subsidies, they have potential advantages of 1) neutrality, 2) openness, 3) ease of administration, 4) a narrower range of uncertainty, 5) shorter product development time, and 6) provider and consumer education (for rational treatment and product demand).

The importance of data is a theme that quickly developed during the project. Risk limits investments, of time or money, in technology development. Risk may be reduced by public investments, including investments in information, in loan guarantees, or in direct subsidies (of grants or tax preferences). Of the three, information does the least to distort, and the most to promote, natural market forces. Finally. by increasing understanding of care and outcomes, it offers guidance in designing the technology.

In this project, we found that economic assessments of healthcare technologies are made easier, more complete, and more accurate by the growing collections of patient care and outcome data. These collections include the federal data for Medicare, the states' data for Medicaid, the federal assemblage of Medicaid data for a number of states, the claims of the private carriers, and the procedures and billing records of large providers. Because this project concerned a rare condition whose management is particularly important in infants and children, the Medicaid data and the data of large providers (e.g., Kaiser/ Permanente) offered particular value.

The potential advantage of these data sets, however, was limited by the difficulty of gaining access to them. The expenditures of time and money experienced in seeking access were beyond that affordable without the support of a foundation grant. The problem of gaining access to the data appeared to be problems of economics, not privacy. Particularly frustrating was the inability to access the federal depository of Medicaid data without paying fees of \$50,000 to \$100,000. These fees apparently are intended to help finance the data set itself, rather than the much smaller costs of accessing the data. But if the public interest in technology innovation is sufficient to justify public support, one mechanism should be the relatively inexpensive, neutral, and market-correcting approach of improved access to information: to support technology as the Census supports commerce and industry.

Patients as Primary Players, in Care and in Policy

An interest that developed with the project was how information facilitates patient involvement. Technologies that provide easy, frequent, accurate, and relevant monitoring of chronic conditions can enhance patient involvement in their own healthcare. An inexpensive and simple monitor allows more frequent testing of body chemistry and immediate reading of test results. This means quicker alerts to problems and immediate feedback to encourage appropriate management. The project's experiments with frequent monitoring and rapid feedback suggested that patient involvement can enhance understanding of the condition and increase commitment to treatment protocols, as well as enabling more sensitive treatment of the condition.

The project found it necessary to contrast these purposes with some rhetoric of patient empowerment. The perspective of the project was not upon a power struggle between patient and practitioner. In fact it was the opposite: to facilitate patient/practitioner, and even payer, teamwork in managing chronic conditions. It did open up the thinking of providers, payers, and patients by engaging the perspectives of the patients and their families. It surfaced an originally unanticipated value of the monitor: providing a tool for finer-grain research of the cycles, progression, and treatment of PKU. It also revealed that payers, supplying the data base for the assessments, were not aware of, and showed initial disbelief of, co-morbidities that providers and patients recognized and that their own data proved to be additional costs of poor management of PKU.

It brought better understanding to the technology development by connecting the development with the experiences of patients and families, both directly in the trials and less directly through the Internet connections of families concerned with PKU. It raised, and helped assess, questions of how important is it to the patient that such a monitor not involve the uncomfortable access to draw blood and how important is it to the physicians' trust and acceptance that blood, the traditionally tested body fluid, be used rather than other body fluids not requiring such invasive access.

The growing Internet connections of patients and families open a final possibility of their involvement: the development of an effective political clientele to support the public policies to correct the limits of the market. These might include improving the quality and availability of information, financing of research on the nature and treatment of the condition, or direct services or financial support for those with the condition.

Reflections on Policy Perspectives

The project to engage economics, the "dismal science," and political science, rooted in Machiavellian ruthlessness, needed the nourishment of optimism inherent in engineering. Since improvements in quality of life are inadequately captured by the market, will political "markets" develop subsidies or regulations to encourage technology?

The focus on PKU added challenges of a limited market and little political clout. Further, the project involved a small research operation, while a common (though questioned) presumption of the literature says the complexity of our science-based society favors large organizations to internalize a knowledge base and link R&D to production and marketing [4], [5], [3]. Attempts to marry economics and policy too easily see zero-sum conflicts by providing new benefits with which to oil compromise and cooperation that in turn further enhance benefits. A less expensive and more effective means to monitor a disease such as PKU enhances the likelihood that insurers will cover costs of such monitoring, hence enhancing the prevalence of the monitoring and reducing the costs of poor management of PKU.

One aspect of policy assessments is to understand the policy environment, at present and as it might evolve, in order to better see opportunities and challenges. Incentives supporting cost-saving technologies particularly depend upon the level and nature of pressures to contain costs.

For example, what interests will be particularly concerned with costs of healthcare? Society ultimately pays for healthcare, whether payment is made by patients, employers, or government. But who writes the check makes a difference in terms of what other expenditures compete with healthcare expenditures: retirement benefits compete for federal expenditures; education competes for state expenditures; and personal consumption competes for employer and patient expenditures. Who writes the check also makes a difference in terms of market power and in the interests pursued by this power: government payment can concentrate bargaining power and can represent a particularly broad opportunity for affecting healthcare benefits and costs. But realization of this breadth is challenged by the very complexity of government that may relegate influence to narrow interests or concentrate upon a singular broad interest such as the budget.

This leads to a second aspect of policy analysis: how might the future policy environment be influenced? Will future policy be shaped by broad public discussion or by relatively private negotiations in legislative committees and administrative agencies? Types of politics may be distinguished by how a proposal concentrates or distributes benefits and costs [6]. As an example, subsidizing medical technology to manage PKU concentrates benefits (for those suffering from the condition) and distributes costs (across the general public, as taxpayers), producing a "client" politics highly dependent upon organizing an effective interest group for private negotiations.

Policy changes may be critical, say, to use public subsidies to correct for a market that fails to recognize quality-of-life benefits from better technology for orphan conditions. Engineers and patients interested in the technology usually lack the political capacity to make such changes, especially in the case of orphan conditions. Cost-saving technologies can be valuable in these instances, if they make patient support less expensive and/or provide financial incentives for payers and providers to add their much more substantial political capacities. The connection between product development, practitioners, and families with PKU was important in designing the sensor's properties, in financing the design, as well as thinking prospectively about selling the product.

This is not analysis of zero-sum conflicts, and it is significantly different because the approach is to engineer better healthcare technology solutions. Successful engineering reduces costs relative to benefits, irrespective of whether or not it reduces costs. It offers a broader range of possibilities for managing politics: to whom and how might benefits be differently distributed to adjust incentives for cost-effective healthcare?

Reflections on Economic Perspective

Economic analysis for the PKU monitors considered probable expenses and returns within the present market. But it needed more: to consider how policies affect incentives for the development and use of the monitors, with special attention to managing orphan conditions and to serving populations disadvantaged by chronic conditions.

Much is made of possibilities of market forces to contain healthcare costs, including incentives for cost-reducing innovation [7]. But the absence of conditions for a perfect market also has been cataloged. Markets can encourage efficiency by allowing individuals to choose, on the basis of full costs, goods and service they value from competing producers. But healthcare does not meet many market assumptions. For example, prices do not incorporate full societal costs. Consumers' tastes are not predetermined and are subject to influence through advertising and prevailing culture. Tastes also are not necessarily independent of the distribution of resources. Markets do not capture the satisfaction garnered by healthy individuals who desire that the sick and disabled be treated [8]. These actual, not perfect, markets bias outcomes and produce inefficiencies.

Present markets work poorly for PKU. Being a rare condition, technology is seldom attentive. For the same reason, PKU families have difficulty becoming well informed. For technology to manage chronic conditions that heavily burden patients and families, markets more likely capture cost savings to the payers (private insurance or government) than those generating better quality of life for patients and families. Low prevalence of orphan conditions limits demands for, and economic returns to, technologies. Low prevalence limits understanding of conditions and their consequences, making the development and dissemination of technologies more difficult.

The types and extent of market inefficiencies and biases depend upon whether physicians, healthcare plans, or pa-

Recognizing the complexity of economics and policy recognizes that understanding sometimes comes in a burst of insight but more usually, and surely, builds in steps.

tients predominate in purchasing choices. Especially when price does not include all benefits and costs, it makes a difference who does the buying and how the markets influence their tastes. Technology also is affected by the categorization of expenditures, as in capitated coverage that encourages development and use of drugs and disease management technologies when they cost less than the alternative of acutecare procedures.

As a cottage industry, medicine favored procedures understood by, controlled by, and beneficial to physician practitioners. This resulted in a proclivity to value procedures over prevention. Institutionalization of medical care shifted the bias to products and services profitable to large organizations. Both cottage-industry physicians and provider institutions may give less priority to cost-effectiveness than would those paying for the care, and less priority to long-term quality of life than would their patients. The shifts in market structure to prospective payments and capitated care encourage cost management. Future changes in market structure, such as patient concerns about quality and choices of providers, will further adjust priorities.

Predictions are inherently uncertain and rewards limited in markets for cost-saving technologies. This is partly because markets are not perfect, and healthcare markets will not be perfect. Further, because of the unequal distribution of resources and of disease conditions, neither perfect nor imperfect markets will fully nor fairly meet the needs for health care. Finally, these circumstances are exaggerated for orphan conditions. Yet markets have important roles—that may be increased or improved—to allow for greater exercise of choice, to accommodate change, and to stimulate innovation. The Utah project showed the importance of going beyond the question of how the market is likely to accept proposed products and assess related policy questions about the importance of future market changes or supplements.

Since improvements in quality of life are inadequately captured by the market, will political "markets" develop subsidies or regulations to encourage technology? Will a growing understanding of PKU by families increase their power and initiative to pressure for public programs supporting technology development? Will family understanding of co-morbidities be shared with insurers, increasing insurers' interest in better treatment of the condition?

Challenging Markets

The environment for technology reflects two markets: economic and political. In both cases, money is only part of what shapes and is transacted in these markets. These complex markets, going beyond money, challenge simplistic predictions and easy rules of management. Individual preferences shape the economic environment; these are unstable preferences, influenced by cultures, promotions, events, and politics. Policy is at least as complicated; cultures and events, as well as leadership, influence and change politics, the politics that adjust public, and private, policies. Technology shapes both the economic and political markets. Persons developing technologies can benefit from an understanding of these two environments, especially an understanding that includes recognition that they can themselves change these environments.

Recognizing the complexity of economics and policy recognizes that understanding sometimes comes in a burst of insight but more usually, and surely, builds in steps. The speed by which these steps are taken, as well as their direction, are different when the incremental efforts is integrated with technology development. It then is less likely to set boundaries, of limits and requirements described by outside advisors, and more likely to open up thinking and possibilities. Integration also increases the chances that the lack of stability in these markets offers opportunities as well as complications, as with the PKU importance of piggybacking the development and marketing of monitors upon similar technology for other conditions.

Robert P. Huefner, professor of political science, held the Governor Scott M. Matheson Professor of Political Science and directed the University of Utah's Governor Scott M. Matheson Center for Health Care Studies. His publications address public finance and budgeting, policy and administrative roles of elected leadership, and health policy. Before joining the University of Utah faculty, he worked in city, county, state, and federal governments, being on the personal staffs of Utah Governors Clyde and Rampton and (as a White House Fellow) of U.S. Treasury Secretary Henry Fowler. He was a member of the Commission on the Operation of the U.S. Senate and other local, state, and national committees concerned with planning, budgeting, finance, administrative organization, and health. His education includes a University of Utah civil engineering degree, an M.I.T. master's degree in city planning, and a Harvard Business School doctorate in finance.

Norman J. Waitzman is an associate professor in economics at the University of Utah. In the area of health services research, his main focus has been on cost-of-illness methodology and its application to healthcare policy; in the area of the production of health, his research has focused on socioeconomic disparities of health.

Joseph Andrade received a B.S. degree in materials science from San Jose State University in 1965 and a Ph.D. in Metal-

lurgy and Materials Science from the University of Denver in 1969. He joined the University of Utah in 1969 and is a professor in the Colleges of Engineering and Pharmacy at the University of Utah in Salt Lake City. During his 30-year academic career, he has served as chairman of the Department of Bioengineering and dean of the College of Engineering (1983-1987). He directs the 4M Lab (Lab for the Modeling, Measurement, and Management of the Metabolome). He is internationally recognized for his research on biomaterials and bio-compatibility. Technical honors include the Ebert Prize of the Academy of Pharmaceutical Sciences, the Clemson Award of the Society for Biomaterials, the Outstanding Surface Scientist Award of the Surfaces in Biomaterials Foundation, and a number of local awards, including the Governor's Medal for Science and Technology and the University of Utah's Distinguished Research award. He has published over 100 peer-reviewed technical papers, edited five books, holds five patents with another pending, and graduated 23 doctoral students and 21 masters students. He also serves as director and chair of the Utah Science Center, a new, modern, interactive science and technology center with a strong bioengineering and energy flavor that is scheduled to open in 2004.

Steven E. Kern is an assistant professor of pharmaceutics and anesthesiology and research assistant professor of bioengineering at the University of Utah, Salt Lake City, Utah, USA. He conducts research in drug pharmacokinetics and pharm-

acodynamics and in novel drug delivery methods. He received a doctorate in bioengineering from the University of Utah in 1995 and has been a member of the faculty since 1996. He also holds a master's in bioengineering from Pennsylvania State University and a bachelor's degree in mechanical engineering from Cornell University. He has worked in the private sector as an engineer developing medical devices and continues to consult to the medical device industry.

Address for Correspondence: Robert P. Huefner, DBA, Political Science Department, University of Utah, 260 South Central Campus Drive, Room 252, Salt Lake City, UT 84112-9152 USA. Phone: +1 801 582 6043. FAX: +1 801 585 6492. E-mail: robert.huefner@poli-sci.utah.edu.

References

[1] G. Dosi, "Sources, procedures, and microeconomic effects of innovation," J. Econom. Lit., vol. 26, pp. 1120-1171, 1988.

[2] F.M Scherer, New Perspectives on Economic Growth and Technological Innovation. Washington, DC: Brookings Institution, 1999.

[3] W.M. Cohen and R.C. Levin, "Empirical studies of innovation and market structure," in Handbook of Industrial Organization, R. Schmalensee and R.D. Willig, Eds. New York: North-Holland, pp. 1059-1107, 1989.

[4] J.A. Schumpeter, Capitalism, Socialism and Democracy. New York: Harper & Row, 1942, chapter VIII.

[5] G. Dosi, "Sources, procedures, and microeconomic effects of innovation," J. Econom. Lit., vol. 26, pp.1131-1132, 1988.

[6] J.Q. Wilson, The Politics of Regulation. New York: Basic, 1980.

[7] J.C. Robinson, The Corporate Practice of Medicine: Competition and Innovation in Health Care. Berkeley, CA: Univ. of California Press, 1999.

[8] T. Rice, The Economics of Health Reconsidered. Chicago: Health Administration Press, 1998.

he Journal **'assio** Assistive technology is changing the world. Be part of its evolution.

Every issue of this groundbreaking journal profiles the future of physical and engineering science in biology and medicine. From acoustic dynamics and nerve stimulation to electromyography, neuromuscular signal analysis and human performance measurement, you'll read about the theory and practical clinical applications of the science that changes lives.

Subscribe Today! Join IEEE: www.ieee.org Submit papers: www.embs.org

Technically Sponsored by: • Rehabilitation Engineering And Assistive Technology Society of North America

International Functional Electrical Stimulation Society







IEEE Transactions on Neural Systems and Rehabilitation Engineering

IEEE Pub ID 018-163 • ISSN: 1534-4320 Annual Rate: \$275 IEEE Member Rate: \$25 **RESNA and IFESS Member Rate: \$40** Email: subscription-service@ieee.org