

A Role for Entrepreneurs

An Observation on Lowering Healthcare Costs via Technology Innovation

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Introduction

In many industries, entrepreneurs are asked to undergo a process called “frugal innovation.” This process supports advances in technology that drive down spending and improve results or leave them static. Likewise, in the healthcare system, there is a shift occurring calling for a reduction in spending. Key to this shift will be implementation of innovative devices brought forward by entrepreneurs. Although technology may add to costs in the near-term, most of the empirical analysis shows that the aggregate benefits vastly outweigh expenditures. However, several regulatory and perceptual challenges exist that entrepreneurs will have to overcome.

Background

Innovations in medical technology are cited frequently as one of the drivers of increased healthcare costs. But less empirical attention is paid to the short- and long-term economic benefits of these innovations. Analyses are often biased in the direction of accentuating the costs because they are realized immediately with the outlays showing up on current budgets.¹ But the benefits of a new invention can accrue over many years.

The benefits of medical technology can be difficult to measure in economic terms, such as increases in life span or reductions in morbidity from a disease. Accordingly, technology can also turn procedures that were previously difficult to perform or had to be undertaken in high-cost settings into less-invasive, less-risky, and less-costly endeavors. Innovation has been a transformative force in enabling improvements in health. From 1980 to 2000, new diagnostic and treatment paradigms helped drive a 4% increase in life expectancy in the U.S., a 16% decrease in annual mortality rates, and a 25% decline in disability rates for the elderly.²

Still, many attribute a large share of the age-adjusted growth in per-capita medical spending in recent decades to innovation: the cost of new devices and the procedures they enable. However, the real question is whether the benefits of innovation are increasing faster or slower than the costs.³ The clearest way to solve long-term fiscal challenges with public health programs such as Medicare and Medicaid is to improve healthcare productivity to achieve more medical benefit for each dollar spent on healthcare programs. Consequently, continued advances in medical technology are going to be an important part of this improved productivity.

The role of entrepreneurs, healthcare technology innovations, and their perceived costs of implementation have been contested recently. On the one hand, some researchers argue that innovations in technology (coupled with weak cost-containment strategies) generally increase healthcare costs in the U.S. because they are adopted more readily because of the payment system in place and a lack of regulatory constraints. Others disagree, citing the difficulty for entrepreneurs to make headway with their inventions because powerful institutions (regulators, medical specialists, insurance companies, and hospitals) fight against simpler, cheaper alternatives that threaten their livelihoods. Instead, these researchers believe the healthcare industry needs to open its doors to market forces and *embrace* disruptive technologies and business models that, in the short term, may threaten the status quo but in the long term will improve the quality of health care.

Exemplifying a common argument, Bodenheimer⁴ argues that, by comparison with other countries, greater availability of new technologies in the U.S. is associated with greater per-capita use and higher spending. He submits that new technologies diffuse faster in the U.S. because of easier acceptance by the medical profession largely because of the generous fee-for-service payment system (which does not exist in other countries) and the lack of regulatory constraints. Consequently, this situation makes new technologies prone to over- (unnecessary) use, which, therefore, contributes to greater costs. Associated costs can be contained if some limits are placed on *diffusion* of the technology, particularly through HMOs and through the two mechanisms of

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Medicare expenditure caps and global budgets (in which expenditures for services are predetermined, and the costs for those services may not exceed the budgeted amount).

In a counter-argument, Christensen and colleagues⁵ discuss how the process of innovation (*disruption*) works: It starts with an innovation sneaking in unnoticed while dominant players in the market, intent on improving their products or services beyond most consumers' needs, are not paying attention. In time, the innovations improve to the point where they meet the needs of the majority of users and become adopted.

This natural process of disruption will enable building a new healthcare system characterized by lower costs, higher quality, and greater convenience. The most-powerful disruptions across industries have enabled larger populations of less-skilled people to do something in a more-convenient, less-expensive setting. Examples include the personal computer, the camera, the telephone, and the photocopy machine. The same thing can happen in the healthcare system: Less-expensive professionals in less-expensive settings can be enabled to do progressively more-sophisticated things.

Both arguments have validity. However, further research is needed to determine the long-term value of healthcare innovations and barriers to their implementation. This analysis discusses each argument in depth.

Analysis

New devices make more medical problems accessible to intervention, but there is also ample evidence that such devices have lowered substantially the cost of resulting procedures. Advances that enable procedures to be performed through minimally invasive techniques such as laparoscopy or arterial catheterization have turned extensive surgeries into more-routine and less-costly endeavors.^{6–8} Other devices have enabled procedures previously performed in hospitals to be moved into more-efficient, less-expensive outpatient settings. In fact, inventions that improve productivity, forestall future morbidity, or improve quality of life can provide substantial benefits and ultimately lead to future savings.

However, the potential benefits posed by such devices are being challenged by fiscal problems and the management of Medicare and Medicaid. Notably, spending on medical devices still represents a relatively small portion of overall healthcare expenditures. A recent analysis by the Boston Consulting Group shows that, since 1989, aggregate spending on devices, as a percentage of total healthcare costs, has remained flat at about 5%. In 2009, spending on medical devices totaled \$147.0 billion or 5.9% of total national health expenditures (\$2.5 trillion).

Moreover, government healthcare programs are said to place a strong focus on the cost of new medical technologies and the contribution of these technologies to overall healthcare spending. Part of the reason for this focus is that actuaries often see a device for diagnosing illness or enabling a surgery as not only requiring immediate outlays but also triggering additional healthcare use down the road. However, new technologies can extend the scope of medicine to conditions once regarded as beyond its boundaries.⁹ And the methods for scoring the costs of a new medical technology do not currently take full measure of the dynamic effects of innovation such as the potential for greater productivity, improvement in health, and the opportunity to forestall disease that might have otherwise required additional healthcare expenditures.

New technologies also confront the physician's natural resistance to change. Even when the near-term cost-savings are clear, there is sometimes substantial resistance to adopting new technologies within specialty societies. This is evident in cases where the technology may facilitate a change in the provider group offering the care, leading to turf battles with respect to reimbursement. Societies or groups with more power can quash new technologies by creating financial disincentives to their adoption. Often these same professional societies also exert substantial influence on policy. As a result, they can impede substantially value-based adoption of new technologies.

As a result of all these factors, public healthcare programs increasingly are reluctant to embrace new technologies. Because policymakers are always searching for short-term savings, clamping down on the use of expensive new medical devices is one immediate and obvious answer. But this response creates challenges for innovators not only in getting reimbursement for their products but in getting funding for their development programs in the first place.

Taken together, these factors could preclude further improvements in healthcare productivity as a result of innovation. Programs such as Medicare and Medicaid are determined to adopt policies that give them leverage over reimbursement and coverage of new technologies. But they need to carefully evaluate the role that innovation plays in lowering healthcare costs by changing delivery models and reducing the short- and long-term burden of disease.

Measuring the Value of New Technology

Economists have tried to quantify the value of medical innovation to society. A number of studies have examined the benefits of technology on specific illnesses, such

as heart attacks and depression.^{10–12} Most of these studies have focused on new drugs.

One such analysis by David Cutler and colleagues found that, from 1960 to 2000, average life expectancy increased by 7 years. They attribute half of this gain to improvements in health care. Comparing the value of a year of life (\$50,000–\$200,000) to the study's finding that each year of increased life expectancy costs about \$19,900 in health spending (after adjusting for inflation), the authors concluded that the increased spending, on average, has been worth it.¹³

Fewer studies have looked specifically at the cost-savings from medical devices. Although none of these studies is dispositive, as a group, they generally show that medical innovation has greatly increased value. New inventions frequently yield direct costs in the short run. But, when judged over the long run, they yield improvements in health whose value is far greater than the increase in spending. Some economists estimate that the value of the longer, better lives that have resulted from translating new biomedical knowledge into steps to prevent and slow diseases is worth many trillions of dollars.¹⁴

There are some obvious examples of the ability of technology to improve outcomes and lower costs. In the 1990s, improvement in the diagnosis and treatment of coronary artery disease led to a dramatic reduction in morbidity and mortality. Other factors, such as new drugs and better rehabilitation, also played a substantial role. But so did new devices that enabled more-accurate diagnosis of heart disease (nuclear imaging); revascularization of arteries (catheterization); and long-term management of damaged hearts (implantable defibrillators). In fact, as a result of these and similar advances, from 1980 to 2000, the overall mortality rate from myocardial infarction fell by almost half, from 345.2 to 186.0 per 100,000 people.¹⁵ In a similar example, in the early 1980s, relatively few seniors had cataracts removed because the procedure often had complications, was difficult to perform, required hospital admission, and yielded imperfect results. However, improvements in technology have enabled millions of seniors with more-modest visual impairment to benefit from less-invasive surgery.

Assessing the total value of these advances tends to be imprecise. To estimate the population-wide benefits of a new technology, economists have applied several approaches.¹⁶ In one method, known as the residual approach, economists estimate the impact of technology on healthcare spending by first estimating the impact of factors they can reasonably account for that drive increased spending. These factors might include changes in income or in the age of a population.¹⁷ The residual costs then are attributed to changes in technology. Still, it should be

noted that the factors included will largely drive the findings.

Harder to measure still are the aggregate benefits of individual technologies, largely because these benefits will be accrued by individual patients over many years. As a result, policymakers increasingly are willing to challenge coverage and pricing of new technologies. For example, the Centers for Medicare & Medicaid Services have expressed a desire to engage in reference pricing for medical devices by asserting “Least Costly Alternative Authority.”^{18–20}

Under this policy, Medicare deems differing approaches to a particular medical problem clinically interchangeable. This means that, if Medicare believes various approaches yield similar outcomes, it only reimburses at an amount equal to the least-costly approach. This puts the onus on innovators to demonstrate to Medicare (much as they are required to demonstrate to the FDA) why their new products are sufficiently differentiated from others and produce better outcomes to merit increased reimbursement. This construct has the effect of creating a second regulatory hurdle to the adoption of new products.

Next Steps

Making the Economic Case

Recent developments are also changing the traditional investment model for new medical technology. Increasingly, to secure reimbursement, entrepreneurs are being required to demonstrate that their inventions can lower direct medical costs. This requirement, in turn, has become an increasingly common criterion by which investors judge—and invest in development of—technologies. Before development is funded, entrepreneurs must demonstrate how their devices will show a “value proposition.”

One prominent article, written by David Cassak in the publication *In Vivo*,²¹ framed the issue in the following manner: “Payors, providers, physicians, and perhaps even patients are now willing to discount the absolute value of innovative technology advances and accept a compromise—equal clinical value in exchange for greater systemwide cost-savings. And product companies will have to follow suit, much like healthcare services companies have taken advantage of opportunities to reduce overall healthcare costs without reducing quality. This phenomenon, in which new technology must focus as much attention, if not more, on lowering costs as on improving outcomes, was referred to by Cassak as “negative innovation.”

This shift in attitude from the traditional model for development and commercialization of medical products

that has placed a priority on constantly improving clinical outcomes is unique to medical devices. Stanford economist Victor Fuchs observes that most healthcare innovations have historically focused largely or entirely on improving outcomes. Very few focus on reducing direct costs. Yet in other industries, in a process called “frugal innovation,” it is common for advances in technology to drive down spending, even as they improve results or leave them static. Fuchs argues that we are going to see more of an emphasis on technology that reduces costs, with or without commensurate improvements in quality-of-life or long-term outcomes.²²

Cassak²¹ argues that the rationale underlying negative innovation is not foreign to physicians and device companies. He submits that one can point to technology advances in many clinical areas such as the migration of physicians from traditional surgeries to minimally invasive procedures. While providing equal or improved outcomes, these new technologies and approaches have reduced overall healthcare costs.

Of course, it is possible that these less-invasive approaches have increased use by making patients who would have been medically excluded from more-invasive approaches now eligible. Specifically, these approaches might have persuaded patients who previously opted to forgo surgery, with its increased morbidity and longer recovery time, to undergo the procedure. Therefore, the proposition that less-cumbersome and less-risky procedures will lower direct spending is hard to defend. In many cases, the exact opposite is true.

These market developments create concerns for entrepreneurs and their ability to develop technologies that can satisfy these apparent demands. Part of the concern relates to the regulatory process, which is ill equipped to enable these opportunities. There is no regulatory scheme that permits manufacturers to pursue new products merely on the basis of the ability of a product to lower healthcare delivery costs. Nor are there clear and efficient pathways to enable sponsors to make economic claims. In many respects, the regulatory process works at odds with policy goals aimed to inspire notions of “value.”

The FDA was instructed, in the 1997 Food and Drug Administration Modernization Act (FDAMA), to issue guidance on how manufacturers should make economic claims about their products. But the FDA still has not delivered such guidance.²³ The FDA also holds a conservative view on comparative claims among products, generally requiring superiority studies. Although there are arguments that the FDA should not use the cost-effectiveness of treatments as a criterion in weighing clearances and approvals, there should still be discussion on finding a way for sponsors to pursue those claims on

their own. Such studies can play a valuable role toward competition in the marketplace.

In recent years, the FDA, by increasing its regulatory requirements, also has increased substantially the cost of bringing new technologies to market.^{24,25} This aspect of the process is born of internal issues relating to the agency’s growing aversion to risk and challenges in managing its review processes. But it also reflects the pressure the FDA is under to impose new requirements on the review and approval of medical devices.

Some consumer advocates and politicians see regulation as a way to slow the introduction of new technologies that could lower healthcare costs. But exactly the opposite is true. Increased regulation raises the cost of investment and development, which ultimately translates into higher prices for the resulting technology. Regulatory barriers also reduce competition by limiting the number of new products. On the other hand, when multiple forms of angioplasty catheters or implantable hips and knees were introduced, they increased competition, forced new entrants to innovate, and lowered technology costs, making procedures more affordable and accessible.

All these developments are in conflict with the way many technologies develop in the postmarket. Technology evolves through practical applications that allow practitioners to optimize its use. This is especially true when it comes to medical devices. Demands that new devices demonstrate up-front savings could forestall the sort of real-world deployment that eventually finds the most-productive use for a new product.

Conclusion

Although technology may add to costs in the near term, most of the empirical analysis shows that aggregate benefits vastly outweigh expenditures. Regulatory constructs that determine coverage policies based on a static measure of a technology’s benefits at the time of its introduction can underestimate dramatically the economic value of the innovation. Such approaches can fail to capture downstream development that takes place through the practical application of a new tool in real-world medical settings. Yet, new product developers increasingly are being asked to make this case a priori, even though empirical tools to demonstrate it are not available.

Of course, in an environment of tight budgets, asking a payer to assume the burden of financing this practical, postmarket development work—in the absence of proof that the net benefits will outweigh costs—is an increasingly unlikely proposition. But public programs such as Medicare are not ordinary payers. The decisions that Medicare makes often set a ceiling on what will be reimbursed by private payers. The program’s outsized influ-

ence on the marketplace makes it a key determinant of what kinds of technologies will win adoption and, increasingly and more importantly, which ventures get financed in the first place.

As Medicare clamps down on its support for innovation, these opportunities are being forgone. Data show that even though overall healthcare expenditures over recent years have increased, the percentage of costs attributable to technology has remained flat. In view of these findings, innovation in technology offers perhaps the best chance to tackle rising healthcare costs while maintaining high-quality care.

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References

- Gottlieb S. Devices prolong life—but at a big expense. *USA Today* 2002, Apr 4.
- The value of investment in health care, MEDTAP International, 2004. www.aha.org/aha/content/2004/PowerPoint/ValuePresentation.ppt.
- McClellan MB. Technology and innovation: their effects on cost growth of health care. Statement before the Joint Economic Committee, U.S. Congress. July 9, 2003. www.fda.gov/NewsEvents/Testimony/ucm161029.htm.
- Bodenheimer T. High and rising health care costs. *Ann Intern Med* 2005;142(11):932–7.
- Christensen CM, Bohmer R, Kenagy J. Will disruptive innovations cure health care? *Harv Bus Rev* 2000;78(5):102–12, 199. www.johnkenagy.com/documents/Disruptive%20Innovation.pdf.
- Jönsson B, Zethraeus N. Costs and benefits of laparoscopic surgery—a review of the literature. *Eur J Surg* 2000;(585):48–56.
- Murray A, Lourenco T, de Verteuil R, et al. Clinical effectiveness and cost-effectiveness of laparoscopic surgery for colorectal cancer: systematic reviews and economic evaluation. *Health Technol Assess* 2006;19(45):1–141, iii–iv.
- McCormack K, Wake B, Perez J, et al. Laparoscopic surgery for inguinal hernia repair: systematic review of effectiveness and economic evaluation. *Health Technol Assess* 2005;9(14):1–203, iii–iv.
- Rettig RA. Medical innovation duels cost containment. *Health Aff (Millwood)* 1994 Summer;13(3):7–27.
- Lichtenberg, Frank R. Are the benefits of newer drugs worth their cost? Evidence from the 1996 MEPS. *Health Aff (Millwood)* 2001;20(5):214–51.
- Kleinke JD. The price of progress: prescription drugs in the health care market. *Health Aff (Millwood)* 2001;20(5):43–60.
- Lichtenberg FR. The effect of new drugs on mortality from rare diseases and HIV. NBER Working Paper W8677, December 2001.
- Cutler DM, Rosen AB, Vijan S. The value of medical spending in the U.S., 1960–2000. *N Engl J Med* 2006;355(9):920–7.
- Cutler DM, McClellan M. Is technological change in medicine worth it? *Health Aff (Millwood)* 2001;20(5):11–29.
- AdvaMed. The value of investment in health care: better care, better lives. 2004:14–21. www.advamed.org/newsroom/medtap/medtapreport.pdf.
- How changes in medical technology affect health care costs. March 2007. www.kff.org/insurance/snapshot/chcm030807oth.cfm.
- Newhouse JP. Medical care costs: how much welfare loss? *J Econ Perspect* 1992 Summer;6(3):3–21.
- Ray N. Clarifying Medicare's authority to apply least costly alternative policies. October 7, 2010. www.medpac.gov/transcripts/LCA%20v1_public.pdf.
- Hays v. Sebelius, No. 08-5508. blogs.findlaw.com/dc_circuit/2009/12/hays-v-sebelius-no-08-5508.html.
- Elimination of Least Costly Alternative (LCA). NHIC Corp, A Medicare part B contractor. www.medicarenhic.com/cpt_agree.shtml.
- Cassak D. Negative innovation: helping reduce health care technology costs. *In Vivo* 2010, Jun.
- Fuchs V. Presentation at the Stanford Center for Cardiovascular Technology Annual Symposium. September 2010, Palo Alto CA.
- FDA. Regulatory information: Food and Drug Administration Modernization Act (FDAMA) of 1997. www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticAct/FDCA/SignificantAmendmentsToTheFDCA/FDAMA/default.htm.
- California Health Care Institute and Boston Consulting Group. Competitiveness and regulation: the FDA and the future of America's biomedical industry. February 2011.
- Makower J, Meer A, Denend L. FDA impact on U.S. medical device technology innovation. November 2010.