Facilitate High-Value Innovation

The Policy Challenge
In a 2002 commentary in *Health Affairs*, Joseph P. Newhouse observed, “Medical care seems to obtain less value from the resources it uses than other industries do, a phenomenon not limited to the United States.” Many groups, from the Kaiser Family Foundation to the Congressional Budget Office, have noted that the swift adoption and diffusion of expensive new devices, drugs, and procedures is a major factor driving both medical progress and growth of health care spending. What distinguishes innovation in health care from other industries is that adoption of new technologies is largely insulated from concerns about cost.

This series of research briefs presents insights from RAND Health research about the effectiveness of strategies to constrain growth in health care spending. A summary brief synthesizes findings from more-detailed discussions focusing on four broad categories of policy options: (1) foster efficient and accountable providers, (2) engage and empower consumers, (3) promote population health, and (4) facilitate high-value innovation.
Consider the following: Under existing law, the Food and Drug Administration (FDA) decides which drugs, biologics, and medical devices are safe and effective and can be marketed legally in the United States. To make its determination, the agency conducts risk-benefit analyses, but it is not authorized to consider cost or the availability of other, equally effective products on the market. Once a new drug, biologic, or device is approved by the FDA, Medicare generally covers its use. Private insurers are not obliged to follow Medicare’s lead, but most do. The added expense is passed along to consumers and employers through higher premiums and out-of-pocket payments.

In this brief, we discuss four options to promote high-value innovation.

Remove Financial and Regulatory Obstacles to High-Value Innovation

In a recent paper entitled Challenges to Value-Enhancing Innovation in Health Care Delivery, a team of RAND researchers identified barriers to the development, adoption, marketing, and uptake of high-value drugs, devices, and methods of delivering care. After noting various ways that existing policies and market forces discourage developers from pursuing low-cost innovations that produce significant value (see table), the authors called on policymakers to implement measures that would encourage value-enhancing innovations rather than expensive technologies of marginal value that are not worth the added cost.

Enhance the Efficiency of Federally Sponsored Research

Peer Review. Each year, the U.S. government invests more than $34 billion in biomedical research and development through such agencies as the National Institutes of Health (NIH), the Agency for Healthcare Research and Quality, the Biomedical Advanced Research and Development Authority, the Centers for Medicare & Medicaid Innovation, and the U.S. Army Medical Research and Materiel Command. The efficiency with which federal funders assess competing proposals, and the return on investment they achieve from these decisions, has not been independently assessed in a rigorous manner.

Recently, RAND Europe studied the limitations of peer review for the United Kingdom, a nation that employs similar methods to score research proposals as those employed by NIH and other health research agencies. In its report, entitled Evaluating Grant Peer Review in the Health Sciences: A Review of the Literature, RAND Europe highlighted multiple shortcomings with the UK’s approach. A subsequent RAND report described alternatives to the traditional peer-review process, including competitive prizes, portfolio management, and single-person review. RAND Europe also devised techniques to quantify the impact of prior funding decisions. Similar techniques could be developed and applied in the United States to enhance the efficiency and yield of biomedical and translational research funded by federal research agencies.

Randomized Controlled Trials. The “gold standard” for studies of tests and treatments is the randomized controlled trial (RCT). RCTs are costly to perform and can take years to produce meaningful results. Many experts in health care innovation, including a roundtable convened by the Institute of Medicine, argue that once treatment efficacy and safety have been established, relying on RCTs to assess the relative effectiveness of different approaches to health care delivery is neither feasible nor desirable. Much may be learned from such industries as manufacturing and retail trade, which routinely adopt, assess, and refine innovations without resorting to RCTs.

Further Expand Use of Health Information Technology

In 2005, a team of RAND researchers predicted that widespread adoption of health information technology (HIT) could generate annual savings from improved efficiency alone of $77 billion per year. The additional health and safety benefits of HIT could double these savings while reducing illness and prolonging life. RAND and other groups have also published studies that indicate that widespread adoption of HIT should improve the quality of care.

Unfortunately, after billions of dollars in federal incentives, including money disbursed through the Health Information Technology for Economic and Clinical Health (HITECH) Act, and billions more in private investment, HIT has not yet produced the promised benefits. In a 2012 essay entitled “Unraveling the IT Productivity Paradox—Lessons for Health Care,” four RAND researchers examined the history of information technology (IT) adoption in other industries to look for the reason why. They noted that when other industries adopted
### Selected Obstacles to Value-Enhancing Health Care:
**Innovation and Selected Examples for Medical Technology**

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<th>Market Imperfections</th>
<th>Drugs and Devices</th>
<th>Delivery</th>
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<tr>
<td><strong>Imperfect information</strong></td>
<td>Lack of cost-effectiveness information for key subpopulations</td>
<td>Exceptional difficulty of assessing many delivery innovations</td>
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<td>Inadequate incentives to produce or disseminate cost-effectiveness information</td>
<td>Major variation in how many delivery innovations are implemented</td>
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<td>Completion of technology assessments (e.g., by government, private companies, and payers) substantially lags technological changes.</td>
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<td><strong>Some actors directly affect the well-being of other actors (externalities or spillovers).</strong></td>
<td>Imitation undermines incentives to invent.</td>
<td>Uncertain property rights for novel methods of providing health care services</td>
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<td>Many HIT or EMR systems do not allow users to easily exchange information with other HIT systems because they are not interoperable.</td>
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<td><strong>Lack of effective competition</strong></td>
<td>Limited price competition among manufacturers</td>
<td>Quality and price competition among providers often ineffective</td>
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<td>Quality competition among providers often ineffective</td>
<td>Little competition on convenience or price transparency</td>
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<th>Policy Choices</th>
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<td><strong>Payment</strong></td>
<td>Tension between the production cost per unit of product (average cost) and the cost of producing the next unit (marginal cost)</td>
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<td>Payment rates that do not cover costs of products and associated services that deliver good value</td>
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<td>Fee-for-service payment fails to reward cost-effective activities that prevent subsequent services, such as emergency department visits or hospital readmissions.</td>
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<td>High-margin activities tend to encourage competition that may not be value-enhancing.</td>
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<td><strong>Regulations</strong></td>
<td>Costs of complying with some FDA regulations may discourage cost-effective development and use.</td>
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<td>Awareness and compliance with Medicare and Medicaid rules require substantial resources.</td>
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<td>Scope-of-practice laws can impede cost-effective staffing.</td>
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<td>State regulations that restrict building/entry of new facilities can impede value-enhancing competition.</td>
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<td><strong>Tort liability</strong></td>
<td>Product liability distorts mix of drug development.</td>
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<td>Use of innovative methods can increase medical malpractice exposure.</td>
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<td>Costs of “defensive medicine” far exceed social benefits.</td>
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<td>High transaction costs of disputing</td>
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<td><strong>Budget pressures</strong></td>
<td>Payer focus on the near term can discourage value-enhancing investments by innovators.</td>
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<td>Payer focus on the near term can preclude adoption, utilization, and investments that would enhance value.</td>
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SOURCE: Garber S et al., 2011.6
NOTES: HIT = health information technology, EMR = electronic medical record.
Insights for the Second Obama Administration and 113th Congress

IT in the 1970s and 1980s, a similar lag in productivity occurred. Although the computing power of the U.S. economy increased more than a hundredfold during this interval, productivity growth initially fell to less than half of what it had been in the preceding 25 years. This “productivity paradox,” as it was termed at the time, persisted until businesses reengineered their practices to take full advantage of IT’s capabilities and refined their IT systems so they were easier for employees and customers to use. Once this happened, productivity soared.

The same sequence of events is likely to play out in health care. Today, lack of interoperability and technical problems with compatibility impede HIT adoption. Many health care providers say that because existing HIT systems are difficult to use, they slow them down. When HIT adoption grows more widespread, more interoperable, and easier to use, its benefits should become more apparent.

HIT is revolutionizing consumers’ role in health care as well. The Internet, handheld wireless devices, and social media are rapidly expanding opportunities for personal health management, home health care, and even self-triage in emergencies. Consumers are also becoming more active users of their electronic health records. If health care providers do not support these trends, consumers are likely to bypass them to seek guidance elsewhere.

HIT is doing more than augmenting existing models of care; it is spawning innovation. HIT-enabled clinical decision support, standardized pathways to manage common problems, and the ready storage and retrieval of health data have already sparked new approaches to the delivery of health care. A case in point is the recent proliferation of retail clinics, which are typically staffed by nurse practitioners. Located in pharmacies, grocery stores, and “big box” stores, retail clinics offer treatment for simple acute conditions, such as bronchitis, as well as some preventive care services. The clinics emphasize convenience, with extended weekend and evening hours, a menu of services with prices, no need for an appointment, and short or nonexistent wait times.

In a series of studies, RAND developed a comprehensive profile of retail clinics. Most are located in major metropolitan areas, within easy reach of one-third of the U.S. urban population. They typically serve younger adult patients who do not have a regular health care provider. About 90 percent of clinic visits are for treatment of ten simple acute conditions or preventive care, such as a flu shot.

By focusing on a narrow spectrum of services, retail clinics deliver care of equivalent quality to traditional providers at significantly lower cost (Figure 1). RAND researchers estimate that within their current capabilities, retail clinics could handle approximately one in five visits to primary care physicians and one in ten visits to emergency departments.

Given the rapidly expanding capabilities of tablet computers and handheld wireless devices, it is possible that HIT

Figure 1. Retail Clinics Provide Comparable Quality at Lower Costs Without Discouraging Preventive Care

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<th>Retail clinics provide comparable quality...</th>
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<td>Retail clinics</td>
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<td>Emergency departments</td>
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SOURCE: Mehrotra A et al., 2010.22
NOTE: Conditions studied were otitis media (inflammation of the middle ear), pharyngitis (sore throat), and urinary tract infection.
will spawn even more transformative innovations in the years ahead. Today, in communities big and small across the United States, more than 200,000 emergency medical technicians and paramedics provide around-the-clock emergency care under the license of their supervising medical directors. In the years to come, a similar approach, utilizing “community paramedics” or perhaps even “primary care technicians” supported by wireless technology, could dramatically expand the efficiency and reach of primary care physicians.

Use States’ Experiences to Assess Innovative Health Policies

In the United States, health care is largely regulated at the state level. And because the states’ health laws, economies, and circumstances vary, federal health policy can exert different effects from state to state. The Affordable Care Act (ACA) is a case in point. Because the law expands coverage and imposes additional costs on state governments, officials need reliable projections of its likely impact in their state. To demonstrate the usefulness of modeling for state-level decisionmaking, RAND used COMPARE, its microsimulation model, to predict how implementation of the ACA would affect state spending rates of and coverage in five states—California, Connecticut, Illinois, Montana, and Texas.

Regardless of federal actions, state governments retain considerable latitude over how they choose to pursue health reform within their borders. Oregon and Vermont, for example, have chosen very different paths than Texas and Alabama. Sharp differences in approach to everything from insurance regulation to scope-of-practice laws provide opportunities to assess the impact of different policies before they are considered for nationwide implementation. Massachusetts played this role in the recent past. Other states may play a similar role in the future.

One issue among many that is amenable to state-level experimentation is medical liability reform. Recently, the RAND Institute for Civil Justice analyzed data for nearly 41,000 physicians covered by a large nationwide liability insurer. It estimated that by age 65, 99 percent of physicians in high-risk specialties, such as neurosurgery and thoracic surgery, have been sued at least once. Fully three-quarters of physicians in “low-risk” specialties, such as pediatrics and dermatology, have been sued at least once by age 65 (Figure 2).
Critics of medical malpractice (MM) law assert that it drives up costs by encouraging providers to practice “defensive medicine”—ordering extra tests and treatments to avoid possible liability later if something was not done. In a policy memo submitted to Congress in 2011, two senior RAND researchers summarized existing knowledge about the effects of various policy options to limit MM liability on health care costs and quality of care.30 They found that MM reform tends to reduce health care costs to some degree, but its impact on patient care is mixed. Some studies found that the threat of lawsuits promoted safer care. Others found no effect.

One idea that might break the current stalemate over MM reform and decrease defensive medicine is the concept of a legal “safe harbor” for physicians who treat patients based on the best available medical evidence.31, 32, 33 The simplest version of a safe harbor would permit best practice guidelines to be entered as evidence for establishing the standard of care in an MM trial. Stronger safe harbors, particularly if coupled with payment reform,34 might provide a powerful incentive for providers to reduce “defensive medicine.” This cannot be proven without real-world evidence compiled in willing states.

Conclusion

American ingenuity made the United States a global economic power. But the ingenuity that made American manufacturing, agriculture, communications, and other sectors of our economy among the most efficient in the world has not has not achieved the same results in health care. Although the United States holds more Nobel Prizes in medicine and economics than any other country, our health care system is less efficient, in terms of health per dollar spent, than those of other high-income countries. This brief, and the other four in this series, have explored policy options to foster a functional health care marketplace, and, hopefully, generate lasting benefits for our nation and the world.

Notes


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