Medical Innovation: The Right Technology, for the Right Patient, at the Right Price

By James C. Robinson

REVIEWS

“How can we afford the tremendous advances in medical care of the last two decades? In this groundbreaking, thoughtful and engaging book, James Robinson, offers trenchant analysis and innovative solutions. Everyone interested in healthcare should read it and think hard about these clear-eyed proposals.”


“One of America’s leading health policy experts, Dr. Robinson is noted for bringing real-world experience to policy debates and scientific rigor to the professional and industry world.”

The Commonwealth Club of California

“Jamie Robinson’s new book, Purchasing Medical Innovation, is required reading for pharmaceutical and biotech executives seeking to better understand purchasing decisions for innovative therapies in the United States today. In it, he clearly describes the important and varied roles of the FDA, Medicare and private insurers, hospitals and physicians, and patients. Better understanding these perspectives through Jamie’s framework and analysis is sure to help any manufacturer’s efforts at articulating the value of its products, meeting the needs of its markets, and securing a business model that will last.”

Scott Howell, SVP, Clinical Services
Cardinal Health Specialty Solutions

“Jamie Robinson’s new book, Purchasing Medical Innovation, is a significant contribution to advancing the debate on balancing innovation and costs. As the U.S. transitions toward value-based care, life sciences and biotech companies need to develop interventions that make a significant difference, while payers need to ensure they are rewarding innovative technology proportionate to its value. Both stakeholders should pay attention to Dr. Robinson’s market-based prescription for getting past the impasse in the interests of patients.”

Leonard Schaeffer, Founder and retired CEO
WellPoint Health Systems

“Dr. Robinson is a highly respected thought leader on topics related to payment for medical technologies and the procedures that utilize them. His expertise shines through in this short and well-written book on innovation and value in medical technology. As physicians, we are frequently faced with important clinical and economic decisions related to drugs, devices, tests, and procedures, and are under increasing pressure to reduce the cost of the care we provide while optimizing patient outcomes.”

Kevin J Bozic, MD, MBA, Chair, Department of Surgery
Professor of Orthopaedic Surgery
Dell Medical School, University of Texas at Austin
Purchasing Medical Innovation

By James C. Robinson

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Nurses know variations of the medication administration mantra: “right patient, right dose, right time.” James C. Robinson, PhD, MPH, slightly alters this mantra for the subtitle of his new tome, Purchasing Medical Innovation: The Right Technology, for the Right Patient, at the Right Price. Robinson is a University of California, Berkeley (USA), healthcare economist who writes extensively on healthcare payer/provider relationships in California and fosters efficient payer/provider relationship-ships in California through the Integrated Healthcare Association (Oakland, CA, USA), a nonprofit group that initiates statewide, value-based payment (VBP) programs.

VBP ideology has been around awhile but warrants a new look post-Affordable Care Act. This is what Robinson strives for in his 30,000-foot perspective of VBP—casting a wider net to include the roles of the U.S. Food and Drug Administration (FDA) and medical device manufacturers, along with government and private payers, hospitals, physicians, and consumers. Robinson dedicates a chapter to each stakeholder, discussing their contributions to the “right” decisions to deliver innovative therapies appropriately and affordably. He offers praise and criticism, with a dose of optimism that even historical adversaries, such as FDA and health device manufacturers, can be motivated to collaborate for the good of all.

Robinson expresses some impatience with FDA out of a desire for innovative, lifesaving interventions such as transcatheter aortic valve replacement and percutaneous mitral valve replacement to reach the U.S. market sooner. First-generation technologies should “be allowed to improve through experience and experimentation” before clinical trial data are finalized, he asserts. Robinson thinks this can be done through FDA’s improved postmarket surveillance efforts. He is also mindful of rushing to market potentially harmful implantable devices, recalling the DePuy (a Johnson & Johnson Company, Warsaw, IN, USA) ASR™ metal-on-metal hip replacement recall after high failure rates emerged from a U.K. joint registry. These devices were expedited to the U.S. market through the less rigorous 510(k) pathway; however, “the ASR was more than just an incremental modification of prostheses that had been used for decades,” and FDA should have “demanded Premarket Approval,” he writes.

Robinson is less encouraged by government and private payers’ ability to get the “right technology” at the “right price.” In theory, the U.S. Centers for Medicare & Medicaid Services’ (CMS) coverage-with-evidence-development process is a step toward the “right” technologies, but national coverage decisions have historically not followed “a coherent policy framework.” Robinson contends that while CMS’s coverage with limitations efforts “offers the means” for the agency to cover new technologies, the stipulated limitations “have no effective enforcement mechanism.” CMS’s process has been hampered by inconsistent registry data collection, no follow-on studies, and political backlash that trumps evidence and overrides informed decisions, writes Robinson. Getting the “right price” is impeded by a Congressional mandate forbidding CMS to calculate cost-effectiveness into coverage decisions.

Private payers are in no better position, according to Robinson. Consumer entitlement is such that “almost any limitation on reimbursement is an invitation for litigation.” Yet he is also frustrated with medical management programs that withhold coverage for new expensive technology, thereby stifling innovation. “Insurance has little leverage to influence appropriate use of medical technology,” he concludes.

Robinson declares that “value-based purchasing is shifting to physicians,” hospitals, and patients themselves. The medical arms race isn’t over, but the playing field is changing with hospital mergers and health systems acquiring physician practices. More physician-populated technology assessment committees make purchasing decisions on new technologies, moving away from “golf outings [between physicians and medical device manufacturers] to evidence-based discussions” between manufacturers and technology assessment committees.

No two healthcare systems are the same, so Robinson looks at five hospitals in Orange County, California, all of which are part of larger healthcare systems of varying size and culture, to illustrate how different contract models and relationships between hospitals and medical device manufacturers can affect purchasing.

Today’s insured consumer, the least incentivized to get the “right price,” is not off the hook in Robinson’s VBP model. But he criticizes shared-cost attempts such as high-deductible plans that inadvertently discourage patients from preventive screening and medication adherence, coverage caps that stick sick patients with large bills, and health savings accounts that force ill, vulnerable patients to shop for care.

“Financial incentives are more effectively focused on providers than patients,” said Robinson, suggesting that shared-cost models could adopt rewards though medication adherence and disease management programs. For example, a hospital copay could be waived if a patient participates in a presurgical program. Providers benefit by reduced lengths of stay and readmissions. “Consumers cannot expect free access to the best care if they do not do their part,” writes Robinson. “Cost sharing should be targeted at inappropriate tests and therapies, not at those therapies that are important to health and wellbeing.”

Book Review: Value-based Purchasing from Multi-stakeholder Perspectives

Summary: A University of California, Berkeley, economics professor describes a framework of value-based purchasing from various perspectives in the U.S. healthcare system.
Purchasing Medical Innovation, by James Robinson, is a worthwhile account of the forces that promote or constrain medical innovation in the U.S.

It begins with the correct observation that innovation is the source of better, but also very often more expensive health care. This alone is not necessarily problematic as we should be willing to pay for innovation that is sufficiently valuable. What is problematic is that not all innovation that we pay for meets this condition. Health care technology is often used on the wrong patient at the wrong time. These are troubling sources of waste.

From such a beginning, many authors would then consume 150 pages explaining how we might completely revamp the health system so we achieve better and cheaper care, the politics, feasibility, and even desirability of such a thing be damned. To his credit, Robinson does not take this course.

Instead, he explains what shapes the nature and cost of health care innovation in the U.S. with a clear, useful framework. To be supplied and consumed in the system, most technology must pass over four hurdles:

1. The FDA must approve it for market access—a hurdle for safety and efficacy.
2. Insurers must cover it—a hurdle for clinical and cost effectiveness.
3. Physicians and hospitals must offer it—a hurdle for appropriateness and quality.
4. Patients must want it—a hurdle sensitive to preferences and risks.

To be sure, there are other hurdles and factors relevant to each of these, and none is ideal in its specified role. But, Robinson does not argue for removal or dramatic reform of any of these hurdles. Implicitly, he seems to accept them as necessary, if imperfect, means of guiding health care innovation.

Importantly, the behavior of each is shaped by organizational structure and financial incentives, which are malleable. Indeed, today they are changing, in some cases in helpful ways. The overriding message of the book is that the era of “cost-unconsciousness” is ending and one emphasizing “value” is underway.

How can we enhance that value? Each of the four hurdles is covered in at least one chapter (the second and third hurdles received two each) that explains its role and address that question.

The FDA chapter was the first thing I’ve read about the agency’s process that I could follow. Perhaps I’ve been reading the wrong things, but most accounts of the FDA I’ve seen either assume I know how it works or only explain a small part of what it does, then move quickly to how it fails. Robinson is more thorough and balanced, specifying the purpose and value of the FDA’s activities, but also indicating where it might make some useful changes to avoid both over- and under-regulating.
The insurance chapters address how Medicare and commercial market insurers make coverage and payment decisions. I suspect most health policy wonks will find much (though perhaps not all) of the material in these chapters familiar: Medicare’s national and regional coverage decision processes, the roles of comparative and cost effectiveness, medical/utilization management, selective- and value-based design and contracting, the variety of reimbursement and payment mechanisms (fee for service, per case, per diem, per episode, capitation, and the like).

My favorite chapters of the book were on hospital purchasing. Robinson doesn’t specify which hurdle plays the most significant role and is most rapidly changing, but my sense is that this is it. Whereas hospitals once competed with one another by offering all of the latest and greatest technology (at high expense) to attract physicians and their referrals, the new paradigm is for hospitals to at least attempt to manage technology purchasing to drive down costs. The basic approaches include technology assessment committees and volume purchasing that forces suppliers to compete more vigorously on price and quality. How do hospitals perform at these?

It’s a big struggle, mostly because it’s difficult to convince a large number of physicians, potentially across disparate facilities in a system, to come to (or accept) consensus on technology. The chapter that looks directly at how Orange County, CA health systems (including Kaiser) do this and the extent to which they succeed is fascinating. I’ve never read a health economist write in such specificity about how hospitals are run. (If I’d read these chapters on hospitals without knowing the author, I’d have guessed he was a physician or hospital administrator, not a health economist. I’d love for doctors who work in hospitals or hospital managers to read chapters 4 and 5 and let me know how accurately it reflects their experiences.)

The book then turns back to more familiar territory: how different varieties of cost sharing and patient engagement affect patient demand and behavior. Robinson concludes with ways in which the FDA, insurers, providers, and consumers can collaborate today to motivate development and use of more valuable technology tomorrow.

For the FDA, this implies lower barriers to initial market access, more extensive postmarket surveillance, and a willingness to retract authorization for products found to be unsafe or ineffective. For insurers, it implies rapid coverage and generous pricing for breakthrough products, thereby allowing evidence to accumulate and products to improve with experience, coupled with price discounting for follow-on therapies and medical management for inappropriate uses. For physicians and hospitals, it implies methods of payment that reward improved product assessment, procurement, and use. For consumers, it implies a structure of cost sharing that encourages adherence to evidence-based care and discourages demand for overpriced services.

I’m grateful and honored Robinson sent me a copy of his book. Though I didn’t have to pay for it, I would have. It’s an innovation worth the price.

@afraht http://theincidentaleconomist.com/wordpress/purchasing-medical-innovation/
James C. Robinson's "Purchasing Medical Innovation"

James C. Robinson is Leonard D. Schaeffer Professor of Health Economics and Director of the Berkeley Center for Health Technology at the University of California, Berkeley. His articles appear in a broad range of scholarly, medical, and journalistic publications, including Health Affairs, JAMA, and the Wall Street Journal.

He applied the "Page 99 Test" to his new book, Purchasing Medical Innovation: The Right Technology, for the Right Patient, at the Right Price, and reported the following:

From page 99:

But after years of acquiring each new technology, regardless of cost, hospitals no longer contract with every vendor, turn a blind eye to questionable marketing practices, and pay any price demanded. Hospitals are evolving from passive payers into active purchasers of medical technology.

Purchasing Medical Innovation addresses the dual imperatives of controlling costs and promoting innovation in the health care system. The book highlights the increase in health care expenditures caused by the introduction and utilization of new medical technology, including drugs and devices. At the same time, it underscores the importance of not undermining innovation through blunt increases in regulation, cuts in payment, or reductions in coverage for patients. The book argues that all four major players on the technology assessment and purchasing side of the U.S. health care system—the FDA, insurers, providers, and consumers—must alter the way they evaluate and adopt innovation.

Page 99 of the book focuses on the third of these four players: the changing role of hospitals as purchasers of medical innovation. Hospitals have historically competed with one another to attract physicians and patients by adding new technologies. While competition in other industries is typically a force for efficiency increases and cost containment, it has led to cost increases in health care. Locked in a “medical arms race,” many hospitals adopted new technology without regard to its cost-effectiveness.

The nature of hospital purchasing is changing, however. Financial incentives such as shared savings in Medicare and capitated payments from private insurers are encouraging hospitals to deliver high-quality care while containing their supply costs. Hospitals are moving away from passive adoption of new technology and playing an active role in evaluating and purchasing innovation.

Hospitals are important as purchasers and users of technology, but they are only one player. Systemic change is needed to curb costs and promote innovation in the long term. Regulators must ensure safety and efficacy while not creating insuperable barriers to market access. Insurers must weigh evidence from comparative clinical and cost-effectiveness research to make coverage decisions that improve the value of the services prescribed by physicians and adopted by patients. Physicians must not simply respond to the fee-for-service payment incentive to do more to make more. And consumers must become more engaged in medical decision-making.

--Marshal Zeringue

Learn more about Purchasing Medical Innovation at the the University of California Press website.

Posted by Marshal Zeringue at 11:05 AM

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March 22, 2015

The demand for medical care services in the U.S. has long been the envy of other industries. Americans are generally not accustomed to going without, typically despise most non-market forms of rationing, and don’t like government telling them what they can and can’t have. Beneath this culture of consumption lies several layers of public and private insurance, the main effect of which is a decoupling of prices and consumption, at least from the consumer perspective. The net result has been, as we all know, growth in medical care spending consistently outpacing growth in just about everything else.

After several attempts at reform, stretching from the 1970s until the recent passage of the Affordable Care Act to whatever will be in store for us should the Republicans control the federal government after the next presidential election, it has become clear that the attributes of the U.S. health care industry that have challenged managers, divided politicians and puzzled consumers are, in the end, the characteristics of the industry. We can talk about changing everything, but that’s not really a feasible option. As the Nobel Laureate (and my former dissertation committee member) Oliver Williamson constantly opined, there’s no point in comparing anything to a hypothetical ideal; we are better off focusing on options that are in the set of feasible alternatives. We need to get more comfortable and smart about working with what we have.

This is why the new book by James Robinson, a professor of health economics at the University of California Berkeley, Purchasing Medical Innovation: The Right Technology, for the Right Patient, at the Right Price, is so welcome as we enter a more realistic and practical phase of U.S. health care evolution. In the spirit of full disclosure, Robinson was my dissertation chairman while I pursued my PhD at U.C. Berkeley. But this does not bias me in favor of the book; on the contrary, it provides me with a rare opportunity to retaliate for the all the red ink with which Robinson drenched my chapter drafts back in the day. This urge to retaliate is moderated at least somewhat by another disclosure—Dr. Robinson is also a Director here at Avalon Health Economics. I think the net result is a fair and balanced review.

I’ll begin with some basics. The book is concise, at around 150 pages (excluding chapter notes, indices, etc.), and is written for an audience with some “entry level” knowledge of the U.S. health care industry. The style of writing strikes a pleasant balance between the need for technical detail and the desire for a more engaging, narrative approach. There are some data presented when necessary, and some citations for the ambitious reader to track down on their own, but these are not critical to the main points.

As the title implies, the focus of the book is on the purchasing of medical innovation in the U.S. The term “purchasing” is complicated in our health system, because there are many different types and forms of purchasers. Perhaps more importantly, the purchase of medical innovation is inextricably tied to issues regarding: (1) regulatory approval, (2) coverage and payment, (3) prescription and adoption by providers, and (4) engagement and adherence by consumers. Indeed, the main theme of the book, which is divided into an introduction followed by six content chapters, is the passage of medical
innovation (drugs, devices, and diagnostics) across these four hurdles. Along the way, rather than waiting until the end, Robinson provides insights into how these hurdles can be improved with the overall objective, again as the title implies, of seeking the health industry nirvana of “the right technology, for the right patient, at the right price.”

What makes this the right approach to such a compelling and important topic is its emphasis on the interconnectedness of the four hurdles, rather than a linear process that yields a static result. The process is dynamic, and each hurdle is connected with the others in ways that differ across technologies, evolve differently over time, and interrelate differently under various circumstances. While the reader cannot help but feel a sense of helplessness as we go deeper into each chapter, Robinson’s depiction of these hurdles as important industry attributes rather than issues for policy makers to fix gives the reader a vague sense of hope that cooler heads might very well prevail. If we develop a more complete understanding and a fuller appreciation for the structural details, organizational features, and behavioral incentives associated with each of the four hurdles, there is a substantially improved chance that progress can be made toward the primary objective of the right technology, for the right patient, at the right price.

While the themes and main points of the book are applicable to each of the three D’s—drugs, devices, and diagnostics—Robinson has conducted some shoe-leather research in one particularly interesting area—the organizational capabilities of hospitals in the purchase of medical devices. He devotes a whole chapter to reporting on research he and his research team conducted in five different acute care hospitals in Orange County, California. Robinson compares the hospitals in several dimensions, including efforts at assessing new devices, physician contract compliance, device supply chain management, physician incentive alignment (and conflicts of interest), relations with device manufacturers, of contract duration. The chapter offers a deeper dive into issues that are generally underreported in the academic and health management literature.

What are the implications of this research to the medical technology industry? That question is the focus of the final chapter, which brings together most of the main points from the preceding chapters. And it is here where Robinson again draws emphasis on the interconnectedness of the hurdles. The medical industry, he advises, should be more willing to work with the Food and Drug Administration (FDA), while acknowledging the difficulties. The industry needs to get better at providing meaningful data, and the FDA needs to develop its adaptive capabilities. Data can play a similarly helpful role in the industry’s relationship with insurers; establishing an evidence base for coverage policy is in the interest of both parties. As for hospitals, as is the case for many hospital management challenges, the key seems to continue to be physician alignment. “The health care system has suffered from a deficit of effective purchasing,” Robinson concludes, “but this deficit is being overcome. Purchasing is becoming more sophisticated, cost-conscious, and value-based. The bar for innovation is rising.”

-John E. Schneider, PhD
In new book, Robinson looks at medical technology innovation from a purchaser perspective

March 17, 2015

Innovation in medical technology has a tremendous power to supply new drugs, devices, and diagnostics that improve health, reduce risks, and extend life. But innovation in medical technology has also led to unsustainable increases in health care costs in the United States.

In *Purchasing Medical Innovation: The Right Technology, for the Right Patient, at the Right Price*, James C. Robinson analyzes the contemporary revolution in the purchasing of health care technology. Robinson is Leonard D. Schaeffer Professor of Health Economics and director of the Berkeley Center for Health Technology (BCHT) at the UC Berkeley School of Public Health.

“The United States has long had a proactive and sophisticated ‘supply side’ of the market for biomedical innovation—the research-based life sciences and bioengineering industry,” says Robinson. “But it has suffered from a reactive and less sophisticated ‘demand side’ to that market, in the form of insurers, hospitals, physicians, and consumers who have lacked the capabilities and often the incentives to compare price with performance when considering new treatments. This imbalance now is changing.”

*Purchasing Medical Innovation* provides an in-depth look at each of these purchasers and their changing roles:

- The FDA is more thoroughly assessing product performance under real-world conditions as well as in research settings, accelerating the path to market for breakthroughs while imposing use controls on risky products.
- Insurers are improving their criteria for coverage and designing payment methods that reward efficiency in the selection of new treatments.
- Hospitals are aligning adoption of complex supplies and equipment more closely with physicians’ preferences.
- Consumers are becoming more engaged and financially accountable for their health care choices.

Robinson believes the country is moving from an era when research and development could focus on performance improvement regardless of cost to an era of finding improvements in performance that customers value and are willing to pay for. His book highlights opportunities for buyers, sellers, and users to help improve the value of medical technology and get better outcomes at lower cost.

“*Purchasing Medical Innovation* examines an important segment of the health care delivery system—medical equipment and devices—in which new research is sorely needed,” Leif Wellington Haase, Senior Fellow of the New America Foundation and past director of the California Task Force on Affordable Care, wrote in a review. “The book does an excellent job of showing how trends toward increased clinical integration, provider payment reform, and new insurance benefit designs will affect this segment of the industry.”

Robinson’s book builds on years of research conducted at BCHT. It was published by University of California Press in March 2015 and is also available on Amazon.

By Linda Anderberg  http://sph.berkeley.edu/robinson-book-medical-technology-innovation