This product is part of the RAND Corporation occasional paper series. RAND occasional papers may include an informed perspective on a timely policy issue, a discussion of new research methodologies, essays, a paper presented at a conference, a conference summary, or a summary of work in progress. All RAND occasional papers undergo rigorous peer review to ensure that they meet high standards for research quality and objectivity.

OCCASIONAL
PAPER

Challenges to Value-Enhancing Innovation in Health Care Delivery

Commonalities and Contrasts with Innovation in Drugs and Devices

Steven Garber, Susan M. Gates,
Margaret E. Blume-Kohout, James R. Burgdorf,
Helen Wu

Sponsored by RAND COMPARE and the Ewing Marion Kauffman Foundation

HEALTH and KAUFFMAN-RAND INSTITUTE
FOR ENTREPRENEURSHIP PUBLIC POLICY

The research described in this report was sponsored by RAND Health's Comprehensive Assessment of Reform Efforts (COMPARE) and the Ewing Marion Kauffman Foundation and was conducted in RAND Health and the Kauffman-RAND Institute for Entrepreneurship Public Policy (KRI). KRI is housed within the RAND Institute for Civil Justice (ICJ). Both RAND Health and RAND ICJ are divisions of the RAND Corporation.

Library of Congress Control Number: 2011938451

ISBN: 978-0-8330-5907-9

Published 2011 by the RAND Corporation
1776 Main Street, P.O. Box 2138, Santa Monica, CA 90407-2138
1200 South Hayes Street, Arlington, VA 22202-5050
4570 Fifth Avenue, Suite 600, Pittsburgh, PA 15213-2665
RAND URL: http://www.rand.org
To order RAND documents or to obtain additional information, contact
Distribution Services: Telephone: (310) 451-7002;
Fax: (310) 451-6915; Email: order@rand.org

Summary

Limiting the growth of health care costs and improving population health are among the most important and difficult challenges facing U.S. policymakers. The role of innovation in advancing these social goals is controversial, with many seeing innovation as a major source of cost growth and many others viewing innovation as necessary for improving the quality of care and health outcomes. We argue that mitigating the tension between promoting health and controlling costs requires more-nuanced perspectives on innovation and its role in the health care system. We focus on innovation that increases U.S. capabilities or know-how related to diagnosing and treating medical conditions—that is, "medical technology" broadly defined to include drugs, devices, and methods of delivering health care—and we consider innovation in health care financing only to the extent that it may affect invention and use of medical technologies.

Particular innovative activities may or may not be worth their social costs. We refer to activities that are worth their social costs as *value-enhancing* or *socially desirable* and activities that are not worth their social costs as *value-reducing* or *socially undesirable*. Barriers to innovation may be socially desirable or undesirable. Our fundamental premise is that policymakers should attempt to identify innovative activities that are worth their social costs and those that are not and use policy to encourage the former and discourage the latter.

Conceptual Perspectives

To help policymakers consider which innovative activities are and which are not likely to be socially desirable, we propose and apply a simple, but powerful, conceptual framework. The framework confronts two major complications for policymakers, namely, that effects of health care and health care innovation (HCI) are realized over many years and that these effects are uncertain at the time that policymakers choose their actions. To address the former, we define outcomes in terms of trajectories over time and use (mathematically) expected values to represent uncertain outcomes.

More specifically, we define the (social) value of health care as the difference between the time-discounted future trajectories of the expected values of (1) population health, measured for each time period as population-level aggregate quality-adjusted life years, and (2) total social costs of resources devoted to health care. Accordingly, we define the social value of HCI in the aggregate or of particular innovative activities as the expected change in the social value of health care attributable to innovation. In other words, the social value of an innovative

activity is the difference between the resulting changes in (mathematically expected and time-discounted) population health and aggregate health care costs.

We apply this framework to consider a variety of policy issues pertaining to innovation in pharmaceuticals, medical devices, and health care delivery—three domains that are typically considered in isolation. Drawing upon and synthesizing wide-ranging literature, we discuss commonalities and contrasts between drugs and devices on the one hand and delivery on the other.

The Importance of Delivery Innovation

We emphasize delivery innovation (DI) for several reasons, including the following. The Institute of Medicine's (IOM's) (2001) *Crossing the Quality Chasm* suggests that DI is lagging behind other kinds of HCI, and that DI may have great potential for increasing quality, reducing costs, or both. Moreover, enhancing social value through commercialization and adoption of DIs has proved to be very challenging—seemingly much more so than for drugs and devices—because of difficulties in effectively implementing promising inventions.

Cross-Cutting Perspectives

Some conceptual perspectives that we develop in this paper pertain broadly to drugs, devices, and delivery, and we begin by discussing them. For example, we propose a system for prioritizing HCIs for policy attention, discuss tensions between promoting social value in the short and long runs, and introduce the "value chasm," which generalizes the IOM's "quality chasm" to include social costs along with the quality of care.

Issues Specific to Drugs and Devices

We also discuss some issues that are largely specific to drugs and devices. For example, we emphasize that the social value of drug and device innovation depends on how much and how the drugs and devices are used, thereby highlighting the potential influence of DI on the social value of drug and device innovation. We also review literature pertaining to social tradeoffs related to patentability.

Varieties of Delivery Innovation

There are a wide variety of DIs, and there appears to be no widely accepted taxonomy. This lack of a taxonomy may impede understanding of the challenges to DI, which may differ across categories of such innovations. In this paper, we take some steps toward developing such a taxonomy. We highlight and discuss several categories of DIs that are not nearly as widely adopted as they may become. These DIs include those intended to improve the quality of care management for patients with chronic diseases, such as the Chronic Care Model and disease

management programs; innovations in health information technology; and new settings for delivering care, such as retail health clinics and specialty hospitals.

Market- and Policy-Based Obstacles to Value-Enhancing Innovation

Furthermore, we discuss factors that appear to impede the potential of innovation to enhance the value of health care. Many of these obstacles to value-enhancing HCI fall into seven categories that pertain to drugs and devices as well as delivery. As detailed in Table S.1, these categories fall into two major groups, namely, market imperfections (imperfect information, externalities, and lack of effective competition) and policy choices (payment, regulations, tort liability, and budget pressures). Table S.1 provides selected examples of obstacles falling into the seven categories for drugs and devices (the second column) and delivery (the third column). Additionally, we highlight two obstacles to improving the social value of DI that are largely specific to DI, namely, (1) the need for coordination across distinct public and private policymakers and (2) resistance to innovation from powerful stakeholders who believe their interests are threatened.

The Value Chasm in Theory and in Practice

Increasing the degree to which innovation in health care delivery promotes social value is critical to improving the overall performance of the U.S. health care system. As for the quality chasm, the value chasm pertains to gaps between what is possible in theory and what is achieved in practice. Difficulties in implementing DIs suggest, however, that the value actually realized from DI will often fall short of what is possible in principle. Policymakers who do not consider likely implementation difficulties will be unrealistically optimistic about the expected social value of many DIs.

Challenges for Policymakers in Enhancing Value Through Delivery Innovation

Intentionally and otherwise, federal, state, and private policymakers affect the levels and directions of innovative activities related to health care delivery by promoting or hindering innovative activities of different kinds. In the final chapter of the paper, we use insights from our analysis of selected DIs to consider the market and policy challenges to value-enhancing DI in greater depth.

Policymakers actively seeking to enhance the social value of DI confront several formidable challenges. Perhaps the most daunting challenges are (1) identifying DI activities to be encouraged or discouraged; (2) designing effective, feasible policy responses; and (3) garnering the required support to put such policies into effect.

Improving the social value of DI will require sustained efforts by both policymakers and policy researchers. Researchers can help policymakers identify DI activities that are and those that are not likely to be socially desirable, suggest promising policy actions, and predict how different public policies are likely to affect the mix of innovative activities.

As public policymakers confront such daunting challenges, private actors may also play major roles in shaping the future of DI. The role of private entrepreneurs in promoting DI, which has not been extensively studied, may also be crucial in shaping the future contours of U.S. health care.

Table S.1
Selected Obstacles to Value-Enhancing Health Care Innovation and Selected Examples

Obstacles	Drugs and Devices	Delivery
Market Imperfections		
Imperfect information	Lack of cost-effectiveness information for key subpopulations Inadequate incentives to produce or disseminate cost-effectiveness information Assessments substantially lag technological changes	Exceptional difficulty of assessing many DIs Major variation in implementation of many DIs
Externalities	Imitation undermines incentives to invent	Uncertain property rights for methods of service Network effects of health information technologies
Lack of effective competition	Limited price competition among manufacturers Quality competition among providers often ineffective	Quality and price competition among providers often ineffective Little competition on convenience or price transparency
Policy Choices		
Payment	Tension between marginal and average costs Payment rates that do not cover costs of cost-effective products and associated services	Fee-for-service payments fail to reward cost-effective activities and offer more revenue for bad outcomes High-margin activities tend to encourage competition that may not be value enhancing
Regulations	Costs of some Food and Drug Administration regulations may discourage cost-effective development and use	Awareness and compliance with Medicare and Medicaid rules require substantial resources Scope of practice laws can impede cost-effective staffing Certificate of need regulations can impede value-enhancing facilities-based competition
Tort liability	Product liability distorts mix of drug development High transaction costs of disputing	Use of innovative methods can increase medical malpractice exposure Costs of "defensive medicine" far exceed social benefits High transaction costs of disputing
Budget pressures	Short-sighted decisionmaking can preclude cost-effective investments	Short-sighted decisionmaking can preclude cost-effective investments