

Conference Summary

Bridge the Gap /

Proving the Value of Healthcare Innovation

November 17, 2009 | Washington, DC | Renaissance Mayflower Hotel



Avalere Health's *Bridge the Gap / Proving the Value of Healthcare Innovation* brought together a diverse set of stakeholders to discuss how health reform may impact the future pace of healthcare innovation. Experts in international and domestic health policy, finance and trade, and product development discussed the evolving healthcare environment and prospective barriers to bringing new and innovative solutions to the healthcare industry.

While the conference covered a variety of topics, two primary themes emerged:

- **Innovation is multi-factorial and multi-dimensional.** Innovation can take a variety of forms and what is considered innovative can vary greatly depending on the stakeholder. Innovation can and should be viewed as a broad term impacting every aspect of healthcare, from breakthrough technologies to entirely new systems of care.
- **The impact of health reform on innovation is largely undeterminable.** Elements of health reform (e.g., comparative effectiveness research) may promote innovation, but other elements (e.g., payment reform) may stunt it. Nevertheless, as health reform progresses it is imperative that policymakers take into consideration the value of innovation and understand how to incentivize and pay for it.

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International Perspective on Measuring Innovation

Panelists Kieke Okma, Adjunct Associate Professor at the Wagner School of Public Services and former Senior Policy Advisor to Ministry of Health, Welfare and Sport in the Netherlands, and Kalipso Chalkidou, Director of UK's National Institute of Health and Clinical Excellence (NICE), discussed how innovation is measured and defined outside of the United States.

Okma spoke of the difficulty of defining innovation, as stakeholders value innovation differently. For example, industry may view innovation as the development, expansion, or application of new products, while payers may view innovative products as those providing only a better clinical or cost effective outcome. She reminded the audience that the health reform debate in the United States is similar to international health reform initiatives—both domestic and international policymakers seek to increase quality, expand access, and decrease costs.

Other nations, such as the U.K., have had some success defining the value of innovation, as Chalkidou explained. NICE, for example, uses technology appraisals to determine whether a product's innovativeness is beneficial to society. Chalkidou noted that NICE has yet to identify a standard scientifically-based metric for innovation; however, they use quality-adjusted life years to measure the clinical and cost-effectiveness of individual technologies.

Domestic Policy Roundtable on Healthcare Innovation

Panelists Jean M. Abraham, Assistant Professor at the University of Minnesota's School of Public Health and former Senior Economist of the President's Council on Economic Advisors, Joel Kupersmith, Chief Research and Development Officer at the Veterans Administration (VA), and Barry Straube, Chief Medical Officer and Director of the Office of Clinical Standards and Quality at the Centers for Medicare and Medicaid Services (CMS), discussed current and future U.S. policy initiatives and their potential impact on healthcare innovation.

Abraham detailed the need for innovation to expand beyond drugs and devices to improve productivity and reduce costs, and the need for innovation in healthcare delivery, communication, and measurement tools. Kupersmith noted that the VA has already implemented innovative approaches to healthcare delivery, citing their use of electronic health records and comparative effectiveness research (CER) as examples. Additionally, he posited that as the CER enterprise continues to expand, “accepted” methodologies (e.g., randomized control trials) are likely to change. Straube noted that, particularly in the current economic and budgetary environment, CMS is seeking innovative ways to improve quality and reduce costs, which may ultimately influence the way CMS measures innovation. He also described several areas in need of “innovative attention,” including access to care, end of life care, and alignment of payer incentives to quality performance.

Financing Healthcare Innovation in a Global Economy

In this session, panelists Paul Hadden, Vice President of Cowen Healthcare Royalty Partners, and Stanford McCoy, Assistant U.S. Trade Representative for Intellectual Property and Innovation at the Office of the U.S. Trade Representatives (USTR), discussed the financial challenges healthcare technology companies currently face—and will face if health reform is passed—as they introduce new products to the market.

From a financial perspective, Hadden noted that health reform may have less of an impact on the financing of innovation than the economic recession. Further, Hadden believes that while the dynamics of the market have changed, manufacturers with compelling business plans are likely to continue to have access to financial capital.

McCoy discussed USTR’s work to create a healthy climate for innovation that benefits the U.S. and its trading partners. USTR has worked to ensure innovation is protected, discouraging imbalanced pricing and manufacturing policies, eliminating counterfeit product production, and monitoring falsified testing data in countries around the world.

Avalere Research on CER and Innovation

Panelists Les Paul, Vice President for Clinical and Scientific Affairs at NPC, and Tanisha Carino, Vice President of the Evidence-based Medicine and Health Information Technology Practice at Avalere Health, introduced *Framing the Debate / Untangling the Potential Impact of Comparative Effectiveness Research on Innovation*, an issue brief examining how CER may impact marketplace incentives for bringing new technologies to market. Avalere created a conceptual framework to define how CER generated by a diverse set of actors may be used to inform the healthcare choices of a range of decision-makers in the United States, and how these decisions may in turn affect the decisions of the biopharmaceutical industry to invest in, develop, and commercialize treatment options. Based on the framework, the authors offered a series of research questions aimed at understanding how and what type of CER will lead to changes in the decisions of payers, clinicians, patients, and manufacturers.

Keynote Speaker: The Future of Innovation

Lonnie M. Smith, CEO of Intuitive Surgical, discussed the present and future direction of innovation. Smith noted that the current period of innovation is unlike any other—communication is faster and new technological information doubles every two years. However, Smith hypothesized that the growth in the administrative burden and regulatory environments will shift the “corporate life cycle,” resulting in stagnation and a decline in innovation in countries previously on the forefront. Nations with fewer regulatory barriers, such as India, China, and South Korea, may now be innovating faster than the United States, the European Union, or Japan.

Assessing the Impact of REMS on Innovation

Panelists Penney Cowan, Founder and Executive Director of the American Chronic Pain Association and Joe Grogan, Regulatory Affairs Director at Amgen, discussed the Food and Drug Administration's (FDA) authority to mandate Risk Evaluation and Mitigation Strategies (REMS) programs for both new drug approvals and currently marketed products. Offering both patient and industry perspectives, Cowan and Grogan noted their concern about REMS' impact on both developing and bringing new products into the market, as well as the accessibility of certain FDA approved drugs that have strict onerous REMS requirements connected to their availability. Cowan noted that REMS has increased the cost of bringing a new drug to market, and as a result, companies may begin to abandon commercializing life-saving products early in development.

Thank you again for joining us at the Symposium. Please visit www.avalerehealth.net to see new research and information on upcoming educational events.