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SPECIAL ISSUE: BRIDGING THE GAP BETWEEN RESEARCH AND HEALTH POLICY-INSIGHTS FROM ROBERT WOOD JOHNSON FOUNDATION CLINICAL SCHOLARS PROGRAM

Value-Based Insurance Design: More Health at Any Price

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When everyone is required to pay the same out-of-pocket amount for health care services regardless of clinical indication, there is evidence of underuse of high-value services and overuse of interventions of no or marginal clinical benefit. Unlike most current health plan designs, value-based insurance design (V-BID) acknowledges heterogeneity of clinical interventions and patient characteristics. It encourages the use of services with strong evidence of clinical benefit and likewise discourages the use of low-value services. Implementing this concept into the national policy debate required a strategy that included conceptual framework development, program implementation, rigorous evaluation, media outreach, and an advocacy plan. Upon completion of this strategy involving several colleagues from multiple disciplines, Congress included language specifically authorizing V-BID in the Patient Protection and Affordable Care Act. A wide-ranging approach, planned as early as possible, can lead to the successful translation of health services research to policy.

Key Words. Health care organizations and systems, clinical practice patterns/guidelines/resource use/evidence-based practice, health care financing/insurance/premiums, health policy/politics/law/regulation, incentives in health care

Restoring Health to the Health Care Reform Debate

Cost sharing plays a critical role in defining the health care benefit. To balance the demands for access to medical interventions with pressures to constrain costs, levels of cost sharing must be set in a manner that achieves appropriate clinical and financial outcomes. In most public and private plans, however, the level of patient cost sharing is the same for every doctor visit, diagnostic test, or prescription drug within a specific pharmacy tier, regardless of clinical indication. While health care services are heterogeneous in the clinical benefit produced, setting the same coinsurance rate for all cancer screenings independent of the evidence base, and charging the same copayment for prescription

drugs for the treatment of diabetes and onychomycosis seemed inefficient and can lead to underutilization of essential medical services. To mitigate the negative health impact of this archaic "one size fits all" benefit design, we proposed an alternative "clinically sensitive" approach that adjusts patients' out-of-pocket costs based on an assessment of clinical benefit. This concept came to be known as value-based insurance design (or V-BID, originally referred to as the "Benefit-Based Copay") (Fendrick et al. 2001; Fendrick and Chernew 2006; Chernew, Rosen, and Fendrick 2007).

Given the abundant evidence that U.S. adults receive only about one half of recommended care (McGlynn et al. 2003) and use services of marginal or no benefit (Hoffman and Pearson 2009), applying clinical nuance to set patients' out-of-pocket costs made sense from clinical and financial perspectives. On this basis, a research hypothesis emerged that the alignment of patients' financial incentives with evidence-based care would encourage the use of high-value services and ultimately produce more health at any level of health expenditure. Soon after, a parallel agenda to translate research into policy was developed. Achieving this policy objective required a strategy that included the following: conceptual framework development; program implementation; rigorous evaluation; media outreach; and an advocacy plan that would move the idea from academia to the attention of key health policy stakeholders, including consumer advocates, health plans, professional societies, employers, labor leaders, and policy makers.

Conceptual Foundation Development

In 2001, the conceptual framework for V-BID—with mathematical derivation and clinical applications—was published in the *American Journal of Managed Care* (Fendrick et al. 2001). That paper made clear that blunt cost-sharing mechanisms implemented to constrain costs raised concerns regarding missed opportunities to enhance clinical outcomes and the possibility of higher long-term medical expenditures. Acknowledging the critical role of cost in defining the health care benefit, it was argued that cost-sharing levels must be set in a manner that achieves appropriate clinical and financial outcomes. Since cost

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containment efforts should not produce preventable reductions in quality of care, a novel design was introduced, in which patient contributions are based on the potential for clinical benefit, taking into consideration the patient's clinical condition. Implementation of such a system would provide a financial incentive for individuals to make treatment decisions based on the value of their services, not exclusively their price, and potentially mitigate the decreased use of essential services due to high levels of patient cost sharing.

Research Supporting Increases in Cost Sharing Reduces Use of High-Value Services

Services with strong evidence of clinical benefit—usually primary prevention interventions and services that treat chronic diseases—are relatively easy to identify, because many are integrated into quality improvement programs such as pay for performance, disease management, and health plan accreditation. While underuse of these services was well established (McGlynn et al. 2003), it was necessary to demonstrate that patients use these services less when it costs them more. Review of the published evidence concluded that charging patients more reduced the utilization of high-value services (e.g., cancer screenings (Trivedi, Rakowski, and Ayanian 2008), drugs for chronic diseases (Huskamp et al. 2003; Gibson, Ozminkowski, and Goetzel 2005; Hsu, Price, and Huang 2006; Goldman, Joyce, and Zheng 2007; Zeber, Grazier, and Valenstein 2007), physician visits (Trivedi, Moloo, and Mor 2010), reduced quality metrics as measured by HEDIS (Chernew and Gibson 2008), and worsened health care disparities (Chernew et al. 2008a).

Adoption of V-BID

The acceptance that higher levels of cost sharing hindered use of high-value services enabled the implementation of V-BID demonstration projects that allowed the opportunity to prove the hypothesis that removing financial barriers would enhance their use. As the peer-reviewed evidence accumulated and drew attention from the popular press (Hensley 2004; Freudenheim 2007; Fuhrmans 2007), public and private entities, including employers, health plans, and pharmacy benefit managers, began to implement V-BID programs. The positive press reporting about early adopters was spontaneous, but media outreach later evolved into an important component of implementation and

legislative outreach. Reports focusing on V-BID's approach to aligning incentives helped translate academic language into policy-ready material. Pitney Bowes is the most celebrated V-BID early adopter; its program providing copay relief for drugs to treat asthma and diabetes demonstrated that V-BID is feasible, acceptable to employees, and produces clinical and economic returns (Mahoney 2008). Other VBID pioneers, including Aetna Insurance; the City of Asheville, North Carolina; Marriott International; the State of Maine; WellPoint Inc; United HealthCare; and the University of Michigan have been well chronicled (Fuhrmans 2007). V-BID is used by a diverse and growing number of entities; two 2008 surveys reported that 12–30 percent of employers use some form of V-BID strategy (Choudhry, Rosenthal, and Milstein 2010).

Research Supporting Decreases in Cost Sharing Increases Use of High-Value Services

Measuring the effects of V-BID programs is inexact, but efforts have shed light on the impact of different cost-sharing arrangements on health care utilization. Most early data, although compelling, were self-reported and anecdotal, derived from the popular press, or based on pre–post experiences without control groups. More rigorous computer simulations conclude that copay reductions for diabetes and hyperlipidemia treatments would save lives and money when compared to the status quo (Rosen et al. 2005; Goldman, Joyce, and Karaca-Mandic 2006).

There is a dearth of data from well-designed prospective evaluations of V-BID programs. In a study of one large employer's V-BID initiative, Chernew et al. (2008b) used an appropriate control group to assess the effects of reducing copayments for five chronic medication classes in the context of a disease management program. This study found increased adherence in four of the five classes and a decrease in nonadherence by 7–14 percent. An accompanying financial analysis concluded that from the societal perspective, the V-BID program led to reduced use of nondrug health care services offsetting the costs associated with additional drugs used due to lower cost sharing (Chernew et al. 2010).

Choudhry and colleagues reported that Pitney Bowes' program that eliminated copayments for statins increased adherence by 2.8 percent. Adherence rose by 4 percent when copayments were reduced for clopidogrel (Choudhry et al. 2010). A study by Maciejewski and colleagues examining Blue Cross Blue Shield of North Carolina's broad efforts to eliminate or reduce

copayments for medications produced similar results; adherence for enrollees with diabetes, hypertension, hyperlipidemia, and congestive heart failure increased between 1.5 and 3.8 percent when patients paid less than employees who were not offered the V-BID option (Maciejewski et al. 2010). A study by Gibson et al. assessed the impact of a V-BID program for two groups of diabetic patients, those who participated in a disease management program and those who opted out of it. The 3-year evaluation reported a similar modest effect on medication adherence and that the V-BID program reduced diabetes-specific spending and did not increase aggregate health care expenditures (Gibson, Mahoney, and Ranghell 2011).

From the available evidence, it appears—but is not definitively proven—that patients respond to both increases and decreases in out-of-pocket costs when it comes to the use of essential medical services. Yet it is abundantly clear that cost is one of many factors that contribute to nonadherence to potentially life-saving interventions. Debate continues, however, over the extent to which these increases in utilization will impact clinical outcomes and whether the estimated savings/return on investment (ROI) will be realized.

From Research to Inclusion of V-BID in National Health Reform

Formal advocacy efforts began in late 2006. The initial goal was to present the potential merits of V-BID and educate stakeholders about how this concept could relate to ongoing health care policy deliberations. Our team met with staff for Members of Congress, including then-Senator Hillary Clinton, House Energy and Commerce Committee Chairman John Dingell, Senator Edward Kennedy, and then-Senator Barack Obama, who drafted the first bill on V-BID, which was never formally introduced due to other political priorities. Presentation materials included peer-reviewed publications, media reports, and case studies of implementation, but the most effective piece was a one-page summary that concisely described our clinical and policy goals.

After the 2008 presidential election, health care emerged as a legislative priority. Both parties began an intensive search for promising ideas for containing health care costs and improving quality of care. As a result of a series of meetings with Senate staff, the V-BID concept gathered momentum as one of the few initiatives that simultaneously addressed quality improvement and cost containment. On advice of Congressional staff, an effort to build a coalition of stakeholders, including labor unions, patient advocacy groups, and

payers, was undertaken, as their support was deemed essential before receiving acceptance from policy makers. This coalition-building effort led to additional meetings with organizations such as the Department of Veterans Affairs (which led a draft Senate bill for a V-BID pilot in the VAMC that was never introduced) and the Congressional Budget Office (whose health staff provided key insights on how any V-BID legislation might be "scored"). Once a broad coalition was assembled and no hurdles were identified by key government health care agencies, Senator Kay Bailey Hutchison (R-TX) and Senator Debbie Stabenow (D-MI) introduced S. 1040, the Seniors' Medication Copayment Reduction Act, in May 2009. The bill directed the Secretary of Health and Human Services to establish a demonstration program to test V-BID methodologies for Medicare beneficiaries with certain chronic conditions. The bill defined V-BID as "a methodology for identifying specific medications or classes of medications for which, because of their high value and effectiveness when prescribed for particular clinical conditions, copayments or coinsurance should be reduced or eliminated." Although the bill remained in committee, this would prove to be an important step for V-BID in the national health care reform debate.

Later in 2009, the publication of two white papers enhanced the positioning of V-BID on Capitol Hill. The first was the 2009 Medicare Payment Advisory Committee Report to Congress (Dr. Chernew was a MedPAC commissioner) that included a recommendation to set cost sharing based on clinical benefit (http://www.medpac.gov/documents/Jun10_EntireReport.pdf; accessed August 11, 2010); and a Brookings Institution bipartisan report entitled "Bending the Curve" (Dr. Chernew was a co-author), which noted the utility of V-BID as a cost control mechanism (Brookings Institution, Engelberg Center for Health Care Reform 2010).

While the goal of the Hill meetings remained purely educational, V-BID principles were included in every draft of national health reform legislation. H.R. 3200, the July, 2009 version of the House bill that was considered by the House Committees on Energy and Commerce, Education and Labor, and Ways and Means, stated, "To the extent allowed by the benefit standards applied to all Exchange-participating health benefit plans, the public insurance option may modify cost-sharing and payment rates to encourage the use of services that promote health and value." This language was retained when the three different versions passed out of these committees were combined into H.R. 3962, the so-called tri-committee bill, in October of 2009.

On the Senate side, the Finance Committee approved a version of the legislation in October, S. 1796. The Committee noted in its report,

"A value-based design is defined as a methodology that would reduce or eliminate cost-sharing for the clinically beneficial screenings, lifestyle interventions, medications, immunizations, diagnostic tests and other procedures and treatments to reflect their high value and effectiveness." (Staffers later informed that inclusion of V-BID helped break a deadlock in the negotiations over copayments in the health exchanges between the Committee's Chairman, Senator Max Baucus, and the Ranking Member, Senator Charles Grassley.) In late December, Majority Leader Harry Reid introduced a version of health reform as an amendment to H.R. 3590. This bill, the Patient Protection and Affordable Care Act (PPACA), passed and was signed into law in March 2010, contained the final version of the VBID language in Section 2713(c): "The Secretary may develop guidelines to permit a group health plan and a health insurance issuer offering group or individual health insurance coverage to utilize value-based insurance designs."

TRANSLATION OF RESEARCH TO POLICY

In July 2010, the Department of Health and Human Services, along with the Internal Revenue Service and the Department of Labor, issued an interim final rule (IFR) implementing the portion of PPACA that eliminates copayments for certain preventive services. With these regulations, the Departments created the first definition of V-BID in federal law, "Value-based insurance designs include the provision of information and incentives for consumers that promote access to and use of higher value providers, treatments, and services." The IFR also stated, "The Departments recognize the important role that value-based insurance design can play in promoting the use of appropriate preventive services." These regulations went into effect for private plans in September 2010 and provide an opportunity to conduct rigorous evaluations of the clinical and economic implications of waiving cost sharing for high value preventive services. In March 2011, V-BID was explicitly mentioned in the HHS National Quality Strategy, in which consumer incentives and benefit design were one of the policies and Infrastructure needed to support priorities (http://www.healthcare.gov/law/resources/reports/quality03212011a.html; accessed September 28, 2011).

The ultimate test of health reform will be whether it expands coverage in a way that improves health and addresses rising costs. V-BID addresses both of these critical health reform goals, and it has clear synergies with major health care reform initiatives, such as comparative effectiveness research,

payment reform, and information technology (Chernew and Fendrick 2007; Fendrick and Chernew 2007; Fendrick, Smith, and Chernew 2010). These attributes, coupled with a well-conceived, multistakeholder advocacy strategy, led to the successful translation of health services research to policy.

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