Low-Value Services in Value-Based Insurance Design

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Objectives: To identify potentially low-value services for inclusion in value-based insurance design (VBID) programs and to discuss challenges involved in incorporating such information.

Methods: We searched the Tufts Medical Center Cost-Effectiveness Analysis Registry (www.cearegistry.org) to identify examples of low-value services, defined as interventions that make health worse without saving money or those that cost at least $100,000 per quality-adjusted life-year gained. We restricted our attention to papers published since 2000. We supplemented this literature review with a list of services recently rejected by the United Kingdom's National Institute for Health and Clinical Excellence for coverage by the UK's National Health Service.

Results: The list of potentially low-value services includes several drugs to treat cancer, as well as other therapies such as left ventricular assist devices and lung volume reduction surgery. Building negative incentives into VBID programs to discourage use of low-value care will involve a number of challenges, including identification of appropriate candidates; the scope of services to be covered (ie, whether VBID should be expanded beyond drugs to address medical devices, procedures, and diagnostics); and whether VBID programs should target specific subgroups.

Conclusion: Identifying noncontroversial low-value services and designing VBID programs to discourage their use will not be easy. However, to fulfill their promise of improving value and moderating cost growth, VBID programs should target low-value as well as high-value care.

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For author information and disclosures, see end of text.

Value-based insurance design (VBID) has attracted favorable attention since it was proposed almost a decade ago.[1] The topic has been the subject of numerous academic papers and conferences, and admiring articles in the popular press.[2,3] Policymakers have implemented or planned numerous VBID programs.[2-4]

The conceptual appeal of VBID is understandable: tailoring health insurance programs to encourage high-value services and discourage low-value care promises to improve health and reduce costs. However, in practice policymakers have devoted most of their attention to one side of the VBID equation: namely, providing positive incentives to encourage individuals to use high-value care. The flip side—imposing disincentives to the use of substantiated low-value services—has yet to gain traction. Our objective is to explore challenges in identifying low-value services and in incorporating such information into VBID programs.

FOCUS ON HIGH-VALUE SERVICES

Appeal of Value-Based Insurance Design

While tiered formularies have flourished over the past decade,[1,5] existing arrangements have tended to focus on drug price rather than on evidence of a drug's overall value as the criterion for tier placement.[1,6,7] Higher priced drugs are placed on third or fourth tiers with high copayments regardless of whether the drugs provide good value. These "unintelligent" benefit designs create problems. Although they may reduce health costs,[8-12] patients faced with higher copayments are more likely to switch medications or to discontinue medications entirely.[9,13-15] Studies have found that cost sharing can lead to reductions in the use of essential drugs, as well as higher rates of serious adverse events, more frequent visits to the emergency department, and more hospital days.[13,16]

Value-based insurance design combines incentives to encourage individuals to be more cost-conscious about their healthcare choices with information on the effectiveness and cost-effectiveness of healthcare services. For example, drugs with favorable evidence of value or cost-effectiveness would receive preferential formulary status in terms of reduced cost sharing for patients.

Experience With Value-Based Insurance Design to Date

Policymakers have experimented with VBID approaches in recent

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years, but the programs have focused on lowering or waiving copayments for high-value services, rather than raising copayments for low-value care.[17] For example, some employers have waived copayments for certain chronic disease medications. Two well-known examples are programs run by the Pitney Bowes corporation and the city of Asheville, North Carolina.[2] Pitney Bowes, which provides asthma and diabetes medications to its employees for free, has claimed a 19% decrease in costs per asthma patient.[3,18] Company officials have argued that the program has delivered health gains for employees, as well as corporate value in terms of improved absenteeism and presenteeism.[19] The Asheville Project involved waiving copayments for diabetes care for Asheville city employees. The project reportedly improved economic and health outcomes over a 5-year period; while prescription costs rose, overall medical costs declined and glycosylated hemoglobin and lipid levels improved.[20]

Other programs have reduced drug copayments for patients with diabetes, asthma, and high blood pressure.[21,22] The University of Michigan has offered some diabetes medications at low cost or no cost to staff and their families in an attempt to prevent high-cost medical complications.[4] An evaluation of the program is under way.[21] Choudhry et al reported that of 1075 employers surveyed, 23% had VBID programs in some form.[23] Of employers with VBID programs, 52% have offered low-cost medications for chronic disease management. Of this group, more than half report that the programs are successful, with another 39% stating it is too soon to determine.[23]

Meanwhile, other experiments in providing financial incentives in the form of cash or reduced insurance premiums for improving health also have shown promise.[24-26] Researchers have conducted randomized controlled trials to study the impact of offering incentives to encourage smoking cessation and weight loss. Subjects receiving financial incentives were more likely to quit smoking and to lose weight.[24,25] Elsewhere, researchers have estimated through decision-analytic modeling that providing full coverage (ie, no copayments) for certain drugs such as angiotensin-converting enzyme inhibitors for patients with diabetes would save money overall and improve health.[27-29]

A bill recently introduced in the US Senate called for the establishment of a VBID demonstration program in Medicare.[30] However, the bill focuses on reducing participants' copayments for "high-value" and "high-effectiveness" medications for conditions such as asthma, chronic obstructive pulmonary disease, depression, diabetes, and hypertension.

Take-Away Points

To fulfill their promise of improving value and moderating cost growth, value-based insurance design (VBID) programs should target low-value as well as high-value care.

- Labeling any medical technology or service as "low value" is not straightforward.
- VBID programs might be designed around a broad set of services, including medical management instead of surgery; ideally, these programs would tie incentives to specific indications and to subgroups.
- Targeting low-value services presents political challenges because it involves providing disincentives for care that may offer positive if marginal health benefits.

EVIDENCE REQUIREMENTS TO IDENTIFY LOW-VALUE SERVICES

Measures to discourage use of low-value services, on the other hand, have not established a toehold in VBID programs or proposals. Proponents of VBID have found it easier to focus on "winners" (encouraging high-value services) than on "losers." To be sure, many health plans have created a fourth tier for high-cost specialty products, but tier placement is tied to drug costs rather than to explicit evidence of value.

One challenge in defining low-value care pertains to defining the term. As the health economist Henry Aaron has noted, a costly intervention that is always useless or that harms patients would qualify as pure "waste."[31] Researchers often use the term "inappropriate care" to denote care that often or frequently does not offer positive clinical benefits and possibly results in harm, including prostate cancer screening, prostatectomy, carotid artery stenosis screening, and aggressive interventional procedures at the end of life.[32] However, the term "low-value" goes beyond waste and inappropriate care to include interventions that deliver positive but limited benefits relative to their costs. As Aaron notes, "Most of the care that analysts label as waste is not uniformly useless but produces average benefits that are judged to be small relative to cost."[31]

The question is when to characterize a clinical benefit as "small." Most clinical studies express health gains in terms of disease-specific outcomes, which do not provide a good basis for comparing value across conditions. A researcher studying alternative strategies to treat colorectal cancer may express outcomes in terms of tumor response or progression-free survival. But suppose a new treatment costs $20,000 and improves 5-year survival by 1%. Is it a low-value service? How does it compare with a diagnostic test that rules out a serious illness, or a drug that relieves symptoms of depression or migraine?

Researchers have devoted a great deal of attention to developing standard metrics to help define high-value and low-value care. One such metric is cost-effectiveness, expressed in terms of the incremental cost of a service per quality-adjusted life-year (QALY) gained. A service is of low value if its costs

are large for each QALY gained. The use of QALYs to quantify health benefits raises conceptual and measurement challenges.[33] Moreover, even when QALY estimates are available, there is still the question of how large the cost per QALY gained must be to constitute low value. Researchers most often have used a cost-effectiveness threshold of $50,000 or $100,000 per QALY as a benchmark for societal willingness to pay.[34]

Another challenge relates to the level of clinical evidence required to quantify service benefits. Ideally, data come from a randomized controlled trial comparing the service in question with a clinically relevant alternative therapy. Nonrandomized evidence, including data from well-conducted observational studies, also may prove highly useful in certain situations provided that potential biases have been adequately addressed.[35]

In practice, all clinical evidence has limitations, including evidence from randomized controlled trials. A study may compare a new drug with placebo rather than to an active comparator. It may compare a new drug with an older drug, whereas the relevant alternative may be surgery or another management strategy. Two services with equal or similar estimated benefits may be supported by different studies that have unequal sample sizes and hence different levels of precision.

Another challenge relates to the target population. Ideally, clinical studies should include patient groups representative of the target population. In practice, many studies exclude patients with "complicating" conditions that might interfere with analysis of the results, or the studies end after a limited period of time.[36] Moreover, interventions typically affect individual patients differently. The resulting averages conceal information that may be important to patients and providers.[31] A service that may be of low value to one subgroup of patients may be of high value to another.

Yet another issue relates to the strength of cost-effectiveness evidence. A large and growing cost-effectiveness literature attempts to synthesize the best information to evaluate health intervention incremental costs and clinical benefits.[37] This literature can provide a useful guide to defining high-value and low-value services, though it is hampered by well-known limitations including variations across studies in methods used to measure costs and health effects.[37,38] In addition, some of the analyses do not compare interventions with the most relevant comparators.

EXISTING DATA ON LOW-VALUE SERVICES

To provide some guidance about existing information on potentially low-value services, we searched the Tufts Medical Center Cost-Effectiveness Analysis (CEA) Registry (www.cearegistry.org), a comprehensive database of some 1700 cost-effectiveness analyses through 2007 in the medical and public health literature that report incremental costs per QALY gained.[37] The CEA Registry details the service or technology evaluated, the comparator, the assumed eligible population, and the reported cost-effectiveness ratio. For purposes of this study, we defined low-value services to be those that make health worse (without saving money) or those that cost at least $100,000 per QALY gained.[34,39] We restricted our attention to papers published since 2000, as these studies more likely pertain to contemporary medical practice.

Table 1 provides an illustrative list of potential low-value services from the CEA Registry. The list includes several drugs to treat cancer, as well as other therapies such as left ventricular assist devices and lung volume reduction surgery.

We supplemented this literature review with a list of services rejected by the United Kingdom's National Institute for Health and Clinical Excellence (NICE) for coverage by the UK's National Health Service. Based on a series of detailed reports (available at www.nice.org.uk), NICE rejected certain services with net costs that are too high relative to their net benefits. As **Table 2** indicates, NICE recently rejected coverage for a number of technologies, including cancer drugs and drug-eluting stents for coronary artery disease (these stents are generally covered in the United States).

KEY CHALLENGES IN IDENTIFYING LOW-VALUE SERVICES

Identifying Appropriate Services and Subgroups

Building negative incentives into VBID programs to discourage use of low-value care will involve a number of challenges, the first of which is the identification of appropriate candidates. One could begin by investigating services addressing conditions responsible for high levels of healthcare spending. Services to be designated as low value could then be identified by examining the cost-effectiveness literature or by convening panels of experts to comb through the available evidence.

Another strategy would involve identifying those services for which spending varies substantially across geographic regions without an accompanying difference in healthcare outcomes. Research on large and unexplained regional variations in US health spending and the fact that this variation is not correlated with health outcomes suggests an abundance of potential low-value targets.[40-46] However, research to date has not done as good a job of identifying specific low-value services,[31,40,41] though some guidance is available. Fischer et al reported, for example, that physicians in high-spending regions are much more likely to recommend discretionary

Table 1. Selected Services With Relatively Unfavorable Cost-Effectiveness

Service	Compared With:	Cost-Effectiveness (2007 US Dollars)
Lung volume reduction surgery	Continued medical treatment	$100,000-$300,000 per QALY[40]
Cetuximab for the treatment of metastatic colorectal cancer after failure of chemotherapy	Active/best supportive care	$110,000-$410,000 per QALY[41,42]
Anastrozole in women with estrogen-receptor positive breast cancer	Tamoxifen	$270,000 per QALY[43]
Transmyocardial revascularization for patients with severe angina refractory to standard medical therapy	Continued medical therapy	$440,000 per QALY[44]
Left ventricular assist devices	Optimal medical care	$500,000-$1.4 million per QALY[45]
Pemetrexed to treat non–small-cell lung cancer	Docetaxel Erlotinib and docetaxel	$870,000 per QALY[46] Increases cost and results in worse health outcomes[47]
Positron emission tomography in Alzheimer's disease	Standard examination	Increases cost and results in worse health outcomes[48]

QALY indicates quality-adjusted life-year.

Table 2. Technologies Rejected by NICE on Grounds of Poor Cost-Effectiveness

Technology	Cost-Effectiveness Ratio	Date of NICE Decision
Gemcitabine for metastatic breast cancer[a]	£38,699-£58,876	2007
Cinacalcet for secondary hyperparathyroidism in ESRD[b]	£39,000-£92,000	2007
Pemetrexed for non–small-cell lung cancer	£458,000-£1.8 million	2007
Pegaptanib for age-related macular degeneration	£163,603 per QALY	2008
Drug-eluting stents for coronary artery disease[c]	£183,000-£562,000	2008
Bevacizumab for first-line treatment of metastatic breast cancer[d]	Lacking evidence of cost-effectiveness	2008
Cetuximab for metastatic colorectal cancer after failure of oxaliplatin[d]	Lacking evidence of cost-effectiveness	2008

ESRD indicates end-stage renal disease; NICE, United Kingdom's National Institute for Health and Clinical Excellence; QALY, quality-adjusted life-year.
[a]Not recommended unless docetaxel monotherapy or docetaxel plus capecitabine also are appropriate.
[b]Not "generally" recommended except when patient has "very high levels of parathyroid hormone in their blood that cannot be lowered by other treatments" or patient cannot have "an operation to remove the parathyroid glands (a parathyroidectomy) because of the risks involved."
[c]Recommended only when the target artery has less than a 3-mm caliber or when the lesion is longer than 15 mm.
[d]Not recommended because manufacturer could not substantiate cost-effectiveness.

services such as referral to a subspecialist for typical gastroesophageal reflux or stable angina.[40] Variation in the level and growth of health spending appears to be driven by the use of technologies with widely varying benefits for different populations such as specialist consultations and diagnostic imaging.[47]

A key question pertains to the scope of services to be covered by VBID programs. To date, VBID programs have focused much of their attention on drugs. Whether VBID can be expanded to address medical devices, procedures, and diagnostics is an important area for inquiry. Conceivably, VBID programs might be designed around a broad set of services, including medical management over surgery (eg, stents vs coronary artery bypass graft surgery, noninvasive vs invasive strategies for low back pain).

Invariably, clinical choices are complex and labeling any medical technology or service as "low value" is not straightforward. As many observers have noted, identifying inefficient areas of medicine is surprisingly difficult. Even those interventions deemed excessively costly usually help some patients and may be high value in selected subgroups.[31] Almost every clinical service can be defined to be high or low value if used in appropriate or inappropriate patient groups. Ideally, VBID programs would tie incentives not to broad patient populations but to specific indications and to narrowly defined subgroups, though that would likely raise other challenges and concerns about equity.

Implementation Issues

Linking incentives to narrow clinical indications will likely require upgrades to existing infrastructure. For example, current information systems typically do not capture the level of clinical detail required to link payment to specific indications or patient subgroups. The data collected in administrative and claims files must capture the clinical detail needed to identify services as low or high value. The advent of electronic health records affords an opportunity to capture and use such information in future VBID programs.

Political Challenges

Targeting low-value services presents political challenges because it involves discouraging care that may offer positive if marginal health benefits. In contrast, providing incentives for high-value services creates winners, and thus encounters little resistance. Moreover, as our review of the Tufts CEA Registry and NICE decisions reveals, services identified as low value can target diseases such as cancer that are highly sensitive and backed by strong patient advocate groups. Furthermore, services that are low value by conventional standards often are strongly supported by product manufacturers and medical professional societies.

Identifying noncontroversial low-value services and designing VBID programs to discourage their use will not be easy, especially for a public already cynical about managed care. It also creates operational challenges and the potential for "gaming" (eg, physicians may exercise discretion over how they code patients in order to influence coverage).

Including low-value services in VBID programs also could raise questions about fairness. For example, tailoring VBID to limit services based on clinical or demographic characteristics would mean that certain patients would make higher copayments based on the severity of their condition. Some will argue that cost sharing is unreasonable for very expensive technologies (eg, specialty drugs) that cost tens of thousands of dollars. Beyond that there are issues regarding how to measure value—highlighted recently by activities undertaken by NICE, which has recognized that dimensions of patient experience and characteristics of therapies (eg, end-of-life care) may not be well captured by cost per QALY ratios.[48]

We do not presume that addressing these issues will be easy or straightforward. Still, we believe that advancing VBID to include low-value services is worthwhile. Despite challenges, it only makes sense to try to identify and provide disincentives for care that offers little marginal gain for the resources consumed. Some may argue that in developing VBID programs it is preferable to focus on the magnitude of clinical benefits without explicitly considering cost-effectiveness. Others might contend that expensive services low in value would be naturally rejected by intelligent providers. We believe, however, that being explicit about costs and benefits through careful analysis is critical. Previous analysis has highlighted the fact that such analysis can shed light, sometimes in counterintuitive ways, on opportunities for improving health efficiently. For example, researchers have found that although high-technology treatments for existing conditions can be expensive, such measures may, in certain circumstances, also represent an efficient use of resources.[49] Similarly, although certain preventive services offer good value or even save money, many others do not.[50] The alternative is to avoid formal discussions about value and to make decisions about benefit design without adequate information.

ROLE OF FEDERALLY SUPPORTED COMPARATIVE-EFFECTIVENESS RESEARCH

Recent efforts to substantially expand the federal government's role in comparative-effectiveness research could help bolster the evidence base for VBID programs. As a vehicle for understanding the clinical effectiveness of medical care, comparative-effectiveness research promises to help identify types of care that provide little or no health gain. Comparative-effectiveness research also can help to stimulate work on methods and metrics for comparing treatment options, including the use of metrics other than QALYs. In addition, federal support can fund studies that shed light on the impacts of different levels of copayment for various services. The American Recovery and Reinvestment Act of 2009 also established a Federal Coordinating Council for Comparative Effectiveness Research, which can help coordinate comparative-effectiveness research across relevant federal departments and agencies to advise on priorities and infrastructure needs.

Possibly, federal support for comparative-effectiveness research can help target cost-effectiveness research. Although the number of cost-effectiveness analyses published each year has been growing steadily,[37] the publication rate is small relative to the rate at which clinical studies are conducted. Moreover, the existing cost-effectiveness literature seems to showcase "favorable" cost-effectiveness ratios.[51,52] Federal support also could help ensure that the cost-effectiveness analyses cover a broad range of interventions and are conducted using appropriate comparators.

CONCLUSIONS

Limiting attention to the promotion of high-value services in VBID programs is the health policy equivalent of one hand

clapping. It deals with the easy part of the problem and does nothing to dissuade the use of costly care of marginal benefit.

Prevailing wisdom has long held that, unlike people in other countries, Americans cannot openly acknowledge resource limits and will not explicitly ration healthcare. The current economic climate and a new administration intent on expanding access and controlling healthcare spending open new possibilities, however. Using incentive-based systems tied to evidence of value offers a flexible approach, consistent with American values, that is more likely than alternatives to receive political acceptance. However, to fulfill their promise of improving value and moderating cost growth, VBID programs should target low-value as well as high-value care.

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