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Comparative Effectiveness Research: From Clinical Information To Economic Incentives

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ABSTRACT Comparative effectiveness research has been promoted as a way to control health care costs, but there has been less discussion of the mechanisms through which new evidence actually will influence physician practice, patient preference, and manufacturer investment. Public and private insurers use conditional coverage, consumer cost sharing, provider contracting, and drug payment policies to manage and direct the flow of resources into the health care system. This paper examines how each of these approaches may be adapted to incorporate new evidence from comparative effectiveness research.

Supporters of comparative effectiveness research have promoted it as a means of controlling the cost of health care.^{1,2} However, there has been less discussion of the mechanisms through which new evidence will influence what happens in the health care system.

Simply disseminating some comparative effectiveness findings may change attitudes and behavior, with no need for economic incentives. Many results of comparative effectiveness research studies, however, will be directly counter to established patient preference and provider interest. Economic incentives will be necessary if these results are to lead to change, rather than gathering dust in the clinical research repository.³

Economic incentives can exert both short- and long-term effects on the use, cost, and value of health care. In the short term, incentives—such as higher reimbursements from insurers—can influence which treatments are chosen by and made available to which patients, and hence affect clinical outcomes and producers' revenues.

In the longer term, incentives can influence the direction of research and therefore which drugs, devices, tests, and procedures will be developed for which conditions. For example, high prices and generous payments for cancer drugs

have encouraged pharmaceutical manufacturers to shift their development initiatives toward oncology and away from therapeutic areas where drug prices are lower.

This paper focuses on the role of public and private health insurance plans and the four incentive mechanisms they use to manage their health care costs. The mechanisms are conditional coverage policy; benefit design and consumer cost sharing; provider contracting and payment; and pharmaceutical company contracting and payment.⁴ Over time these four mechanisms could exert a strong influence on how clinical practice and product development respond to new evidence from comparative effectiveness research.

The Evolution Of Incentive Mechanisms

Most treatments that are known to be effective for some groups of patients with some conditions in some settings are also applied in other cases where the evidence of their effectiveness is not as strong.⁵ A typical example is drugs, which go through extensive testing before the Food and Drug Administration (FDA) approves them for specific uses. After that, they are often prescribed for other uses for which no studies

may have been done.⁶

The most important use of comparative effectiveness research may be in clarifying just how effective established therapies really are in these understudied off-label uses.

Although the preponderance of coming comparative effectiveness research is likely to focus on clinical effectiveness, rather than cost-effectiveness, the research will exert an indirect effect on incentive mechanisms that target high-cost services. These mechanisms have been hobbled by the lack of evidence to use in evaluating the claims that high-cost products, procedures, and providers offer higher quality than their cheaper alternatives. Many comparative effectiveness studies already include cost along with clinical comparisons.⁷

Conditional Coverage Policy

All health insurance plans must limit the services for which they offer reimbursement—known as conditional coverage. Otherwise, all of the premium revenues would be expended on any intervention that any patient or physician believes might provide any benefit. All plans incorporate some reference to “medical necessity” and exclude services deemed to be experimental or cosmetic.⁸

There is often no hard-and-fast evidence to help set the criteria for assessing whether an intervention is sufficiently necessary or non-experimental for purposes of insurance coverage. Insurance plans must choose between providing broader coverage and risking reimbursing some low-value treatments, or providing narrower coverage and risking the exclusion of some high-value treatments. If they choose the latter, health plans incur the risk of adverse publicity and litigation.

During the heyday of enthusiasm for their role as managed care organizations in the 1990s, insurers sought to reduce their costs by excluding treatments that lack evidence of effectiveness, that showed evidence of substantial risk, or that imposed a cost that exceeded the benefit they provided. The subsequent adverse publicity, litigation, and regulation radically reduced insurers' interest in such coverage exclusions.⁹

Over time, however, insurers have increased the use of the conditional coverage policy. This means that a drug, device, test, or procedure is covered only if it is used according to criteria set by the insurer.

TWO USES OF CONDITIONAL COVERAGE There are two principal uses for conditional coverage: to limit access to a service that would not be effective in a particular case, and to produce additional data on a service's effectiveness.

In the first case, some therapies are known to be effective under certain circumstances but ineffective or harmful under others. Conditional coverage in this context is typically enforced through prior authorization. Before using the therapy, the physician seeking eventual reimbursement must submit information indicating that the treatment complies with the insurer's guidelines and must obtain the insurer's approval of the treatment.

Prior authorization can be used to limit the range of conditions that may be treated by a product—for example, denying approval for off-label drug prescription—and the type of patient who may receive it, depending on age, diagnosis, or severity of disease. It also can be used to limit other options, such as the type of provider who may administer a product, the frequency with which it may be administered, and the order in which it may be used relative to other interventions.

Sometimes prior authorization is used to deny coverage for the use of a drug when results from a diagnostic test or a biological characteristic of a patient suggests that the drug would not be effective.

In the second case, conditional coverage is used to motivate physicians and patients to participate in activities that generate additional evidence about a treatment's net benefits, such as further clinical trials or data registries. Medicare has developed a policy called “coverage with evidence development,” which offers reimbursements for selected products and procedures if the patient's data are entered into a registry or monitored as part of a clinical trial.^{10,11}

PROSPECTS FOR CONDITIONAL COVERAGE POLICY Prior authorization is the most obvious incentive mechanism to encourage providers to take account of the complex scientific distinctions likely to emerge from comparative effectiveness research. The disadvantage of prior authorization is that it is an insurer-driven, top-down approach that adds to the delivery system's administrative costs, the length of time needed before a treatment, and patients' and providers' uncertainties. As a result, it blocks some patients' access to effective treatment.

In addition, it is easily portrayed as interference with physicians' decisions and patients' preferences. Many private insurers renounced the effort to administratively limit patients' referrals to specialists as part of an effort to rebrand themselves as consumer-driven health organizations.¹² It is not likely that they would reverse course at this point.

Some “coverage with evidence development” initiatives have faced strong opposition from patient advocacy groups as well as from manu-

facturers.¹³ The outcry during the health reform debate over so-called death panels highlights how ready the public is to believe the worst about perceived governmental interference with individual choices.¹⁴

Prior authorization and coverage with evidence development have traditionally been interpreted as mechanisms to reduce the use of ineffective services. In an environment of ever-higher health care costs and insurance premiums, however, conditional coverage may become a way to promote the use of effective services.

Insurers are more likely to cover a new therapy whose effectiveness has not yet been proved if they can limit that coverage to cases where the available evidence suggests some net benefit. Similarly, if a controversial new therapy is embedded in a conditional coverage program that generates more evidence about it, insurers are more likely to cover it.

Benefit Design And Consumer Cost Sharing

During the era of managed care, the conventional wisdom was that incentives should be targeted at physicians rather than at patients. As a result, consumer cost sharing was reduced. However, when the managed care backlash restricted health plans' ability to enforce these "supply side" incentives, "demand side" incentives for patients became more appealing.^{15,16} Consumer cost sharing is not as strict a mechanism as coverage denial because the patient can choose to have the treatment and still receive partial insurance coverage.

The trend toward higher cost sharing has been framed as a way of empowering consumers to make their own choices with their own money. It is a core component of so-called consumer-directed health plans.¹⁷

The most prominent uses of increased cost sharing have been in the raising of deductibles for preferred provider organization (PPO) coverage (sometimes called high-deductible health plans) and the addition of a fourth tier to drug formularies—or preferred drug lists—under which patients using high-cost specialty drugs incur a percentage coinsurance cost rather than a more modest fixed copayment.¹⁸

The increase in consumer cost sharing raises concerns that patients might not be willing to pay for effective services, even when those services' use is called for. To reduce that risk, there is a new trend toward "value-based insurance design."¹⁹ Insurance coverage with such a design reduces cost sharing for services that evidence indicates would have a large clinical effect and

increases cost sharing for services that lack evidence of effectiveness.²⁰

As a practical matter, it is difficult to increase cost sharing for individual services that have been found to be ineffective, since every service has its provider and patient advocates. Value-based insurance design principles are thus commonly used to reduce cost sharing selectively for the most effective drugs, tests, and procedures rather than to increase cost sharing on low-value interventions.

The most effective incentive mechanism developed by insurers over the past decade has been the tiered formulary, with drugs assigned to particular tiers based on their cost. Cost-based formularies and the consumer cost-sharing differentials associated with them have produced a major shift in market share from brand-name drugs to generic products. They also have led to substantial price rebates for brand-name products as their manufacturers compete for favorable formulary placement.^{21,22}

As mentioned above, many health plans have added a fourth tier to their formularies, imposing sizable coinsurance charges for biologics and other high-cost specialty drugs.²³ As new comparative effectiveness research identifies the indications or settings where a specialty drug is particularly effective, use of the drug in those settings could be shifted to a lower tier with reduced cost sharing.²⁴

There are many impediments to the implementation of value-based insurance design based on comparative effectiveness research. It is inherently hard to distinguish, much less communicate to patients, differences in drug value according to the severity of disease or other clinical indications. To get around the inability of most consumers to understand complex science, cost sharing can be used to encourage patients' participation in care management and shared decision-making programs that include patient education, monitoring for drug effects and toxicity, and regular review of drug regimens.

Provider Contracting And Payment Methods

The managed care era was defined by the development of contractual networks and payment incentives that sought to channel patients to efficient providers and to pressure providers to limit costs.²⁵ The backlash against managed care had its most important effects on network design strategies because insurers had emphasized changing providers' behavior through contracting and payment methods rather than changing patients' behavior through consumer cost sharing.

The backlash induced insurers to include more physicians and hospitals in their networks and to revert from capitation to fee-for-service payment.²⁶ Now, faced with rapidly rising prices and use of services, health plans are tiptoeing back toward network designs that seek to promote efficiency and moderate costs.²⁷

PROVIDER NETWORK CONTRACTING The clinical and cost-effectiveness of some treatments depends on where and how they are delivered, because physicians differ markedly in their practice patterns, use of resources, and patient outcomes.²⁸ Some comparative effectiveness research will produce evidence that links a treatment's results with characteristics of particular providers or provider types, including the number of cases seen by a surgeon or hospital, the specialty of the physician, and the ability of particular provider organizations consistently to deliver higher quality or lower cost than their peers.

Instead of seeking to develop narrow networks for all services, most health plans today prefer to offer broad networks for most services.²⁹ For commonly used but expensive services such as outpatient radiology and advanced imaging, however, many health plans have developed networks within networks, using cost-sharing incentives to channel enrollees to providers and facilities that charge lower prices or use fewer resources.^{30,31}

The "center of excellence" concept uses a similar approach. The idea is that services where high patient volume is associated with significantly better outcomes or lower costs should be concentrated in a limited number of hospitals, rather than reimbursed at all facilities. The concept has been used with patients needing organ transplants and could be applied whenever comparative effectiveness research identifies particularly effective or ineffective clinical settings, such as for cancer care, orthopedic joint replacement, and spine surgery.

Comparative effectiveness results can also be embedded in network design under the principles of coverage with evidence development, following the example of Medicare's conditional coverage policy for carotid arterial stents, a therapeutic alternative to surgical endarterectomy—or removal of fatty or cholesterol plaques and calcified deposits from the internal wall of an artery—for prevention of strokes. Based on evidence that effectiveness varied greatly across the hospitals where the stents were inserted, in 2005 Medicare limited coverage to hospitals that achieved specified quality performance benchmarks such as procedure volume, certification, emergency management capabilities, and maintenance of a device registry.³²

PROVIDER PAYMENT MECHANISMS Many health plans are experimenting with payment incentives to change providers' behavior. Some have tied pay-for-performance bonuses to efficiency as well as quality;³³ a few are expanding capitation payment for physician and hospital services;³⁴ and some are considering the bundling of payments for all treatments associated with an episode of care.^{35,36}

These payment experiments also seek to make it easier for patients to compare procedure prices and quality. For example, bundling payments for episodes of care allows health plans to publicize comparative cost and quality differences and to design coinsurance around the entire course of care. Comparative effectiveness research can further this process if studies compare performance across entire treatment strategies, and not merely across individual drugs or other components.

In contrast to traditional managed care contracting, where providers were expected to accept lower payment rates in exchange for being included in a network, value-based network designs could pay higher rates to providers with documented quality advantages. Pay-for-performance programs are experimenting with augmented payments for the most efficient providers and delivery systems, defined in terms of risk-adjusted hospitalization rates and total cost of care per patient.

These providers could be held to new standards of performance, including making prices transparent, reporting data about quality, adopting novel payment methods such as bundling, participating in shared decision-making initiatives that promote informed patient choice, and agreeing to cover hospital readmissions without additional charge.

Pharmaceutical Company Contracting And Payment Methods

Insurers' efforts to manage pharmaceuticals are similar to their efforts to manage physician services, combining coverage policy, network contracting, and incentive-oriented payment methods. Conditional coverage is evident in limits on the indications, conditions, or severity levels for which a drug will be reimbursed, and in step therapy, which requires that an enrollee begin with a lower-cost product and move to the more costly alternative only if the first product proves ineffective.

Some insurers are also willing to reduce access barriers to specialty drugs if their use is conditioned on a companion genomic test, as with Herceptin for treatment of breast cancer,³⁷ or the presence of a biological characteristic that

suggests that the patient will benefit from the drug, as with Velcade for treatment of multiple myeloma.³⁸ In each of these cases, the insurers rely on the results of diagnostic and laboratory tests to ascertain whether the drug is appropriate for a particular patient, and will reimburse the cost of the drug only if its use is deemed appropriate.

Benefit design principles and consumer cost sharing are at the core of formulary policy, in which the insurer creates tiers of preferred and nonpreferred drugs to extract lower prices from manufacturers. Network contracting principles are to be found in drug distribution, where insurers contract with chains of retail pharmacies and, in the case of high-cost biopharmaceuticals, with specialty pharmacy distributors—entities that deliver high-cost biotechnology drugs to physicians' offices—to obtain drugs and biologicals.

To reduce the high prices of certain drugs, especially specialty drugs for cancer, autoimmune diseases, and other complex conditions, some insurers and pharmaceutical firms have begun to experiment with payment and pricing policies that link reimbursement to appropriateness and outcome.

Manufacturers seek to set prices for new drugs based on the perceived price-sensitivity of health plans, physicians, and patients.³⁹ These prices are “value-based” in the sense that they reflect how much purchasers and consumers are willing to pay for one drug instead of other drugs and alternative therapeutic regimens. Basing pricing on value is an important way to focus research on conditions and therapies that offer the greatest potential benefit.

The principles of value-based pricing imply that products' prices should vary according to the way a particular product is used—for example, the price might be lower for off-label use. In the short term, tying price to value is very difficult. Manufacturers and distributors have little influence over how or for whom a drug is used.

However, it is important to try this kind of price adjustment. Uniform reimbursement for an intervention without regard to its effectiveness underpays manufacturers for the evidence-based, high-value uses of their products and overpays them for the unproven, low-value uses. Uniform reimbursement gives incentives to manufacturers to market their products for uses that are not supported by evidence and undermines their incentives to pursue follow-up effectiveness studies.

Experiments in value-based pricing are occurring in Europe for specialty drugs.⁴⁰ Some pharmaceutical firms have proposed performance-based models, with higher prices for uses where

evidence of effectiveness is strong, and lower prices in other cases.⁴¹

In time, new comparative effectiveness evidence on a treatment's differing values may be reflected in the varying prices charged for that treatment.

Implementation Challenges

If comparative effectiveness results are to influence the choices of physicians and patients, the results must be accompanied by economic incentives. Conversely, if economic incentives are to promote high-value clinical interventions and discourage low-value ones, they need to embody comparative effectiveness results.

However, the conjoining of evidence and incentives is plagued by administrative complexities, difficulties in communicating with patients, and the public's skepticism about limiting access, even to unproven therapies.

It is administratively difficult to adjust economic incentive mechanisms to the different outcomes a drug, device, or other therapy may have when used on different conditions, on patients whose disease is more or less severe, or in different clinical settings. Prior authorization burdens physicians with the need to document the reason why they chose a particular therapy for a particular patient. It also requires the development of guidelines and the employment of medical directors to review cases, and it can lead to contention about reimbursement between the physician and the insurer.

It is very difficult to charge different copayments for the same drug or service depending on the patient's condition. Physician payments and pharmaceutical prices are negotiated on a periodic basis and cannot easily be adjusted based on whether the service or product in question is being used in an evidence-based fashion.

Difficulties in communicating with patients about coverage and copayments abound even when the price of a therapy is constant. Efforts by employers to reduce drug copayments for patients with diabetes, for instance, have encountered resistance from other enrollees who demand equally low copayments for the same drug, even if they have less need for it or if there is less evidence that the drug would benefit them.

The adjustment of incentives to information increases the need for authoritative entities to vouch for the validity of the data. FDA drug labeling, pharmaceutical compendiums, clinical guidelines developed by specialty societies, and health plans' medical management guidelines have been used to differentiate high- from low-value treatments, but objectivity and scientific validity are hard to prove. Many patients and

providers are skeptical about the contemporary shift from experience-based to evidence-based medicine.⁴²

Applying evidence to incentives requires moving quickly and strongly enough to influence the practice of medicine without creating administrative complexities or stimulating a patient backlash. This can best be accomplished through the targeting of particular incentives to particular clinical contexts.

Conditional coverage policy, consumer benefit design, provider contracting and payment, and pharmaceutical payment policies differ in terms of which types of evidence and levels of uncertainty they are most appropriate for, and in terms of their short- and long-term potential. What is needed is a thoughtful alignment between types of clinical uncertainty and comparative effectiveness evidence, on the one hand, and the types of economic incentives to promote and improve evidence-based care, on the other hand.

A Thoughtful Alignment

The most difficult and important context for aligning evidence and incentives will be where a therapy is effective for some clinical indications and patient populations, but not for others (Exhibit 1). The culture of health care, combined with fee-for-service payment and comprehensive

insurance coverage, often leads to the use of therapies beyond the range of their documented effectiveness—sometimes even into the range of their documented ineffectiveness.⁴³

For all its administrative burdens and complexity, conditional coverage policy is the best short-term incentive mechanism to use in managing care outside evidence-based indications, since it at least includes the clinical expertise of the insurers' medical management programs. Cost sharing, in contrast, relies on the limited expertise of the patient in deciding which treatments are worth purchasing.

Value-based insurance design principles can reduce cost sharing for the uses that are most based on evidence, but they require the often-unsophisticated patient to differentiate between appropriate and inappropriate indications. Pay-for-performance bonuses can reward selective high-value processes, but they require providers to accept lower reimbursements for uses that are only weakly supported by evidence. The most promising long-term mechanism is to pay more for drugs, devices, and procedures when they are used within evidence-based guidelines, and less otherwise.

Some comparative effectiveness evidence will highlight the importance of provider rather than product characteristics in determining effectiveness (Exhibit 1). Conditional coverage may limit the use of some services to centers of excellence,

EXHIBIT 1

Alignment Opportunities For Evidence And Incentives

	Area of intervention			
	Conditional coverage policy	Consumer cost sharing	Provider contracting and payment	Drug pricing
Comparative effectiveness evidence indicates that treatment's effectiveness varies by:				
Clinical indication	Prior authorization	Lower cost sharing for high-value uses	Pay-for-performance	Value-based pricing
Disease severity	Step therapy	Same as above	Same as above	Same as above
Provider setting and characteristics	Coverage limited to centers of excellence	Lower cost sharing for use by preferred provider	Tiered networks, bundled payments, pay-for-performance	None
Patient education and compliance	None	Lower cost sharing if patient is in care management or shared decision-making program	Pay-for-performance bonus if patient is in care management or shared decision-making program	Value-based pricing
Comparative effectiveness evidence remains unclear; additional data needed	Coverage with evidence development	No copayment if patient participates in coverage with evidence development	Physician payment incentives for data collection and reporting	Price based on biomarker evidence of effectiveness

SOURCE Author's analysis.

but the main incentive here will be in provider contracting and payment methods, supported by consumer cost-sharing designs that charge patients less if they choose physicians and hospitals with the desired characteristics or with documented quality and efficiency.

Other comparative effectiveness studies will probably find that patient education and therapy adherence promote effectiveness. Here the incentive burden falls on benefit design to create incentives for patients to participate in programs of care management and shared decision making. Provider payment and, over the longer term, pharmaceutical payment policies could support these programs by paying more for care when the patient participates and adheres to evidence-based guidelines, and less otherwise.

Finally, insurer-incentive mechanisms can be used to promote not only the incorporation of new comparative effectiveness evidence into practice but also the development of that evidence (Exhibit 1).

Coverage with evidence development is the strongest incentive for this purpose, but it often

faces opposition from providers and patients seeking unlimited access to unproven treatments. The acceptance of coverage with evidence development, and the willingness of physicians and patients to participate in that development despite the administrative burdens involved, will depend on insurers' reducing consumer cost sharing and increasing provider payments for participants.

Conclusion

Better evidence from comparative effectiveness research is necessary but not sufficient to improve the performance of the US health care system. The contemporary policy debate focuses on clinical evidence without paying adequate attention to economic incentives, while the contemporary insurance market develops economic incentives without linking them to clinical evidence. After having tried every other alternative, perhaps the health care system is finally ready to do the right thing and align incentives and evidence. ■

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NOTES

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Jamie Robinson writes in this issue about translating the results of comparative effectiveness research into the design of health insurance products and other economic incentives to influence health care practice. According to Robinson, "the policy debate over comparative effectiveness research is full of good intentions but weak on hard-headed thinking as to how comparative effectiveness research results actually will influence the

practice of medicine, particularly with respect to helping moderate the growth in costs."

An economist, Robinson is the Kaiser Permanente Professor of Health Economics and director of the Berkeley Center for Health Technology at the University of California, Berkeley. He launched the center to focus on how insurance and payment determine patterns of care and cost. Robinson is also the senior director for medical technology at the Integrated Healthcare Association, where he leads a project on value-based purchasing for medical devices in orthopedics and cardiology.

Robinson was editor-in-chief of *Health Affairs* during 2007-8. He now serves as a contributing editor of the journal. He has also written

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Robinson received his master of public health degree in health planning and policy from Berkeley's School of Public Health in 1981, followed by a doctorate in economics from Berkeley's Department of Economics in 1984. He was also a health policy postdoctoral fellow at the Institute for Health Policy Studies, University of California, San Francisco.

Robinson's research and professional activities have centered on the role of insurance coverage and payment methods in influencing the use, appropriateness, and cost of health care.