Guidelines and Value-Based Decision Making:
An Evolving Role for Payers

Janet L. McCauley

Payers use evidence-based guidelines to promote effective health diagnoses and treatments for their members and to ensure that members are not subject to harmful or wasteful care. Payer guidelines inform coverage, but the content of these guidelines relies on the same evidentiary base as clinical treatment guidelines. Recent strategies to foster value through benefit design and alternative reimbursement methodologies illustrate emerging applications for evidence-based guidelines. The current focus on cost effectiveness within health technology assessment, comparative effectiveness research in collaboration with payers, and transparency around payer evidence assessment could better align payers' interests in evidence-based care with those of other stakeholders. The move to value in health care will depend upon credible clinical evidence to enable informed decision making.

Successful development, dissemination, and adoption of clinical guidelines is a key focus of evidence-based practice. Years ago, Grimshaw and Russell adopted a definition of clinical guidelines that still applies today: "systematically developed statements to assist practitioner decisions about appropriate health care for specific clinical circumstances" [1]. Although the extent to which physicians adhere to practice guidelines has been debated over time, acceptance of clinical guidelines continues to grow.

Public and private payer guidelines are integral to coverage and payment decisions, which constitute separate and distinct functions from direct clinical decision making and provision of care. Despite this key difference in utility, payer guidelines are remarkably similar to practice guidelines in their link to clinical evidence. This commentary will explore why evidence-based guidelines are adopted by health plans, their evolving uses, and how payers may be involved in the growth of evidence-based information.

Basics of Coverage

Appropriate health care may be achieved in 2 ways: by promoting recommended care, and by avoiding ineffective, harmful, or unproven care. These objectives are shared across all health care stakeholders. The pitfalls of delayed adoption of best practices have been widely discussed [2]. Conversely, negative consequences have resulted from premature adoption of unproven treatments [3, 4]. Thus, the challenge to practitioners, health plans, and health systems is to identify which services and treatments belong in each category and to facilitate either utilization (for treatments proven effective) or abandonment (for those proven ineffective or harmful); they also must determine when an unproven service or treatment moves into one of the "proven" categories.

Health plans indirectly impact care delivery through reimbursement and coverage. The first step to determining coverage is not the application of guidelines, but the determination about whether a service is a covered benefit. Lists and descriptions of covered benefits constitute the contractual basis between a purchaser and the health plan—or, in the case of public coverage, the statutory basis. In the United States, the purchaser for commercial health insurance is typically an individual or an employer group; in the public sphere, the purchasers are combinations of government entities, taxpayers, and, more recently, individuals. Commercial health plan benefits include coverage for basic categories of services such as office visits, durable medical equipment, surgery, and skilled nursing care, but coverage excludes other categories, such as cosmetic procedures, unproven services, and nonmedical services. Within specific categorical exclusions, benefit contracts may also exclude specific services.

Once a service is determined to be a covered benefit, it must meet basic requirements of being clinically appropriate and in accordance with standard medical practice. The original Medicare legislation, Title XVIII of the Social Security Act, addressed payment only for items and services that are "reasonable and necessary for the diagnosis or treatment of illness or injury" [5]. Today the basis for private and public coverage remains essentially the same, requiring that the covered service meet specified standards of clinical necessity.

Additional coverage caveats apply to new technology. By fulfilling the regulatory requirements set by the Food and

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Address correspondence to Dr. Janet McCauley, PO Box 2291, Durham, NC 27702-2291 (Janet.McCauley@bcbsnc.com).

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Drug Administration, a drug or device has demonstrated its safety and efficacy. Efficacy may mean that an item or treatment works in a controlled setting and for a specific population or set of clinical conditions, but not necessarily that it results in improved outcomes in a broader clinical setting outside of clinical trials. Until the service satisfies additional standards of effectiveness—based on sufficient information and conclusive scientific evidence—its true effectiveness is unknown, so it remains in the "unproven" category. An efficacious item or service may also be considered unproven if it has not been shown to be as beneficial as an established alternative. By excluding items and services that are "unproven," and by including those that are "reasonable and necessary" as a contractual basis for coverage, health plans set standards of effectiveness, clinical utility, and efficacy. Accordingly, they also have an obligation to collect evidence regarding primary and comparative effectiveness and to translate that evidence into usable guidelines.

How Guidelines Are Developed and Used by Health Plans

Most health plans are not directly involved in the generation of new scientific evidence or its initial synthesis. Instead, health plans collect clinical evidence using the same tools and resources as practitioners and other health care stakeholders: clearinghouses such as the Agency for Healthcare Research and Quality's National Guideline Clearinghouse and the Cochrane Database of Systemic Reviews, evidence evaluation programs such as the US Preventive Services Task Force (USPSTF) and the Technology Evaluation Center at the Blue Cross and Blue Shield Association, various specialty society clinical publications and practice guidelines, and professional consensus at both a national and local levels. New guideline development is an iterative process. At Blue Cross and Blue Shield of North Carolina, all commercial medical policies are reviewed at least annually, and this process includes external vetting by specialty matched consultant advisory panels. If significant new evidence arises between scheduled reviews, an off-cycle review may occur.

The best researched and vetted guidelines will unfortunately have no impact unless they are adopted. Implementation of guidelines by health plans takes many forms. One mechanism is to determine on a case-by-case basis whether an individual's circumstances satisfy the specific evidence-based criteria of the medical policy. An advantage of this mechanism is specific linkage of the service to an individual member at a certain point in time, yielding a precise method of determining eligibility for coverage. Further, by tying the decision to reimbursement, there is assurance that the member may actually receive the desired service. Disadvantages of this mechanism include the time and resources required for clinical review; the need to communicate detailed information about the member's individual circumstances; and the need for the member, provider, and health plan to have a mutual understanding about evidence standards within the medical policy. For the latter reasons, case-by-case determinations are usually reserved for areas involving the newest technology, highest potential for abuse, or greatest risk for complications and downstream negative clinical impact.

To promote evidence-based care, health plans also apply guidelines to populations of members rather than individuals. An example is value-based benefit designs, in which incentives are provided to members for pursuing and adhering to a pathway of proven effective care. Available evidence supports the fact that patients respond to both increases and decreases in out-of-pocket costs, and it even more clearly shows that cost contributes to lack of adherence to life-saving treatments [6]. One very recent and visible use of member incentives is demonstrated by the Patient Protection and Affordable Care Act of 2010 (ACA), where member copayments and coinsurance are waived for preventive services supported by the highest standards of evidence. The preventive services eligible for 100% coverage include those graded A or B by the USPSTF, as well as recommended vaccinations and women's health services. Evidence of the impact of these measures is now beginning to emerge: A recent evaluation by Lipton and Decker estimates an increased probability of initiation and completion of human papillomavirus vaccination of 7.7% and 5.8%, respectively, since the 2010 implementation of the ACA requirements [7].

Guidelines are increasingly used by payers to create high-performance provider networks through incentives for practice patterns associated with desirable outcomes. This concept is the basis for value-based reimbursement. For example, Medicare integrates cost data with measures on recommended treatments for common conditions, such as pneumonia or asthma care, to assess the relative value of hospital care. These comparative assessments are publically available to Medicare beneficiaries [8]. Reverse incentives have also been implemented. In 2013, a South Carolina collaborative including payers and providers instituted nonpayment for elective deliveries at less than 39 weeks gestation, resulting in a statewide 50% reduction in non–medically indicated induction of labor [9].

Creating Value Out of Evidence: The Move to Cost Effectiveness

In the purest sense, a service or item may be effective in relieving the clinical condition of concern but may come at a cost that is unacceptable to various stakeholders, such as the individual, health system, payer, or society. Determinations of cost effectiveness, therefore, must weigh the incremental clinical benefits of various treatment options against the incremental consequences of cost.

Cost effectiveness plays a more formal role in national coverage decisions in European countries than it does in the United States. For example, in the United Kingdom, the National Institute for Health and Care Excellence employs complex modeling to inform coverage recommendations for new technology; this modeling includes comparative clini-

cal effectiveness, quality-adjusted life-years, an incremental cost-effectiveness ratio, and other measures [10]. In many European countries, a negative recommendation is binding and prohibits public coverage of the item in question.

In the United States, the role of cost effectiveness in formal technology assessment is less apparent, and it remains controversial. The Centers for Medicare & Medicaid Services (CMS) does not specifically consider cost effectiveness in its coverage determinations, in part because it does not have clear statutory authority to do so; instead, CMS focuses on a service's medical benefit. Efforts to include more direct cost comparisons have been countered with concerns about rationing or arguments that the technology assessment process amounts to a budgeting exercise [11].

In private coverage, benefit plans often allow for cost consideration when 2 services or treatments result in equivalent outcomes, in which case the least costly alternative will be covered. But these relatively straightforward cost comparisons, which are made subsequent to evaluation of clinical impact, stop short of the integrated approach of the European models, where coverage is dependent upon standards of cost effectiveness beyond basic efficacy and comparative effectiveness. It remains to be determined if cost effectiveness will be broadly accepted in the United States as a basis for coverage, or if it will continue to serve primarily as an incentive for value-based choices.

Future Directions: Payer Roles in Comparative Effectiveness

Contemporary strategies to improve health and reduce costs will require a more concerted effort among payers and other stakeholders to identify and address the gaps in clinical evidence that contribute to variation in care, waste, and unnecessary expense. Migration to value in health care depends upon expanding this body of high-quality evidence. Several recent developments provide potential collaborative frameworks that may advance our ability to generate evidence and to translate that evidence into actionable information.

Patient-Centered Outcomes Research Institute (PCORI)

Established through the ACA, PCORI is a private, nonprofit organization whose goal is to oversee the end-to-end process of relevant comparative effectiveness research—from funding and conducting trials through implementation of results—in a way that is meaningful to patients and health care decision makers [12]. One new focus is the pragmatic clinical study, which is conducted in real-world health settings. Payer data on utilization and outcomes in these settings may contribute to research conclusions with greater practical utility.

Payer Involvement in Facilitating Research

CMS's Coverage with Evidence Development (CED) bridges Medicare coverage with evidence generation [13]. Initiated in 2005, select national coverage determinations allow coverage contingent upon participation in designated clinical trials or other prospective data collection. CED may contribute to the feasibility of pragmatic trials by expanding availability of service delivery outside of controlled research settings.

Greater Transparency Concerning Evidence Gaps

Lack of reliable information about safe and effective treatments contributes to poor decision making among consumers and policy makers. Payer initiatives to identify evidence gaps for services addressed within their medical policies should better inform understanding of coverage decisions and guide future research initiatives.

Conclusion

Payers have used evidence-based guidelines for years as a basis for coverage determinations. Today that role has expanded. The current need to improve value and enable better health care decisions will increase the demand for better evidence-based guidance. Payers and other health care stakeholders will be challenged to be transparent, creative, and diligent in how to accelerate the generation of valid evidence, to condense that evidence into usable information, and to apply the information once it is available. This transition to evidence-based decision making can help redirect care delivery to the value of services received. NCMJ

Janet L. McCauley, MD, MHA senior medical director, Medical and Reimbursement Policy, Blue Cross and Blue Shield of North Carolina; assistant consulting professor, School of Medicine, Duke University, Durham, North Carolina.

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