By Paul Wallace, MD

Addressing the Challenge of New Medical Technologies: One Permanente Clinician's View—Part II

Introduction

In Part 1 of this essay, published in the Winter 2001 issue of *The Permanente Journal,* the challenge of objectively assessing technologies in a credible and durable manner was confronted. A role for evidence-based medicine in developing assessments was proposed and was supported as a robust, reliable foundation of care.

The present (final) portion of this essay considers two additional aspects of incorporating new technology into clinical practice:

- the evolving need and process for creating a decision shared by both member and clinician; and
- some real and practical constraints imposed by the insurance contract between member and health plan.

This commentary is intended to help guide clinicians as they confront use of new technology for managing patient care within their practice. The content represents this Permanente physician's personal opinions and perspective and is not a policy statement of the Interregional New Technologies Committee, the Care Management Institute, the Permanente Federation, any other body within Kaiser Permanente (KP), or the Technology Evaluation Center of the Blue Cross and Blue Shield Association.

Integrating Evidence into Shared Decisions

A comprehensive consideration of the process and nuances of supporting members and clinicians in achieving fully informed, shared decisions about use of an intervention (ie, new technology) is beyond the scope of this essay—especially given the rapidly changing roles, responsibilities, and expectations of clinicians and members when confronted with evidence about clinical interventions. Nonetheless, several key observations apply.

In their role as diagnosticians, clinicians confront and solve clinical problems and identify potential interventions (including new technologies). This diagnostic role has been a critical one ever since the emergence of the profession—and will continue to be so. Patients will continue to look to their clinicians to diagnose and identify options for treatment.[1]

Clinicians and patients increasingly share in arriving at clinical decisions—a situation that contrasts with the historical paternal clinician role in selecting and implementing treatment decisions. Patients now—and increasingly—value, seek, and share a role with their clinicians in deciding among potential clinical interventions.[2] Decisions made by patients will be influenced by explicit inclusion of evidence about clinical effectiveness as well as risks of possible interventions. Further, how evidence is presented (ie, in relative terms and in absolute terms) can also be predicted to influence patient decisions. This observation has important implications for how decisions are framed by the treating clinician and understood by the patient.

Extended use of lipid-lowering therapy illustrates how inclusion of evidence influences the process of making medical decisions. In men with known coronary artery disease, lipid-lowering therapy has helped avoid future cardiovascular events as shown by three findings:

- 34% relative reduction in risk of future events;
- 1.4% absolute reduction in risk of future events;
- 71 persons must be treated for one person to benefit from avoiding an event.[3]

All are honest and true statements about the therapy in question, yet when information is shared with members in these differing contexts, members vary in their decisions to undertake therapy with a lipid-lowering drug. Lipid-lowering therapy is chosen by 88% of patients when information is stated to them in terms of relative risk reduction; by 42% when information is described to them in terms of absolute risk reduction; and by 31% of patients when information is presented as the number of persons who must be treated so that one person will benefit.[3] Clinicians therefore have a responsibility to be aware that how they present recommendations will substantially influence patient actions, even when decisions are both accurately informed and shared. Organizations that actively support and advocate for a given therapy will tend to obtain patient acceptance for this therapy by presenting information in terms of relative risk reduction; patients will tend to accept the same therapy differently (and usually less) when information is presented in terms of absolute risk reduction or the number of patients that must be treated for one patient to derive benefit.

This commentary is intended to help guide clinicians as they confront use of new technology for managing patient care within their practice.

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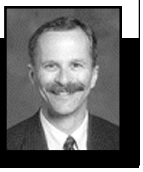

Further, I believe, members will become increasingly more adept at recognizing the context in which information is presented to them. That said, I also believe that as consumers of health care, patients currently have an incomplete understanding of the nuances of how health information is presented to them. This gap in consumer awareness arguably contributes to the success of pharmaceutical direct-to-consumer advertising, a medium that heavily leverages data presented as relative risk reduction—even when absolute benefit may be minimal or when many persons would need to be treated before one person would benefit. Clinicians should also recognize that they too are influenced by the way information is presented to them, even in their customary reference sources such as the peer-reviewed literature.

For the clinicians and members, mutual understanding and trust of clinical observations are the keys to making shared medical decisions.

Roles of Clinicians and Health Plan Members

In making shared decisions, clinicians and health plan members contribute complementary expertise.[4] Clinicians' expertise includes fulfilling the role of scientist and observer by critically and rigorously identifying and assigning importance to clinical observations. Clinicians also identify the diagnosis and treatment options; obtain valid information regarding benefits, harms, and uncertainties of treatment; integrate research information with clinical circumstances; and communicate with patients. Patients' expertise includes judgment relevant to their own particular circumstances; awareness of how they value various outcomes when information is presented to them; and knowing how they feel about various interventions.

For the clinicians and members, mutual understanding and trust of clinical observations are the keys to making shared medical decisions. We should anticipate and expect that the clinician recommendations will be actively tested by the member for consistency with their personal values and preferences.

To many observers, pursuit and validation of a credible, durable and shared standard for gauging and communicating the impact of interventions is a work in progress. However, I contend that the explicitly analyzed content of rigorous, evidence-based technology assessments seems better poised to address and satisfy clinicians' and members' expectations of clarity, consistency, and full disclosure than less systematic, more empirical approaches.

The Relation Between Medical Decisions and Health Coverage

The scope of benefits that a health plan such as Kaiser Foundation Health Plan includes in a member's health care coverage is articulated in the contractual agreement between that member and the health plan. The scope of coverage in an individual member's contract is often the direct result of choices made by an employer (ideally, on the member's behalf) in negotiating the contract. State and other regulations can also define certain aspects of coverage, as can legislated mandates. Services may be explicitly included or excluded in the contract. For example, purchase of pharmaceutical products may be explicitly excluded, covered within limits (with or without restrictions to formularies, co-pays, or both), or entirely included. Similarly, specific services (such as durable medical equipment) may be excluded from the benefit package. Specific exclusions may apply to clinical services (eg, organ transplantation in some circumstances; or other specialized interventions, such as plastic or bariatric surgical procedures) if that decision is reached in the contract negotiation process.

The relation between the clinician-member decision about an intervention and the actual insurance coverage for the intervention in question hinges on two factors: 1) whether, in the opinion of the member and the member's treating clinician, the intervention can improve the health of that member and is appropriate for the specific member's clinical problem, and 2) whether the intervention is included as a benefit for the member under the contractual relationship with the health plan. For the intervention to be delivered as a covered service, both conditions must be met.

Consequently, a service that the treating clinician judges as medically appropriate and that is not excluded by the terms of the insurance contract will be covered by the Health Plan, whereas a service the treating clinician does not believe to be medically appropriate for the specific member will generally not be covered. In addition, a service may be judged medically appropriate but may not be included in the contracted coverage. In this circumstance, members may choose to purchase the service at their own expense. The most common examples of this circumstance consist in medications not eligible for the pharmacy benefit and in durable medical equipment. Another example is when a service such as transplantation of a specific organ has been specifically excluded by the member's negotiated contract.

The Relation Between Medical Decisions and the "Investigational and Experimental" Designation

Much public strife about insurance coverage for new technologies has arisen as a result of variation in the way health plans interpret and apply the definition of "investigational and experimental" therapy. In addition, understanding and use of this definition as an exclusionary criterion for insurance coverage has also varied among clinicians and health plans. Not surprisingly, this variation has resulted in perceived and real questions of equity and fairness.

Requiring a minimum standard of evidence for establishing an intervention as no longer "investigational and experimental," and thus covered as a benefit, has been challenged because much of the core medical care routinely delivered fails to meet the evidence standard proposed for investigational and experimental therapy. Moreover, emerging interventions that have not yet established clear effectiveness to justify general acceptance as being established for any and all members may still be considered by some clinicians to be reasonable options for selected members, especially those who face life-threatening and disabling conditions.

"Investigational and experimental" criteria have therefore not been either delineated or applied consistently—nor, in my opinion, have these criteria by themselves, in the absence of a clinician's judgment of appropriateness for the care of an individual patient, had sufficient credibility to exclusively and consistently guide decisions made by practicing clinicians, by health plan members, by courts of law, or by society at large.

A Credible and Durable Approach to Making Medical Decisions

Although no single approach will address all situations—especially in this era of medical-legal wrangling and maneuvering and of government mandates—a general approach to potential use of new medical technology should include six elements:

- The clinician's explicit, comprehensive review of the evidence, often supported by available technology assessments as well as by consultation with peers, clinical experts, and technology experts.
- A clinician's decision about both the evidence supporting use of an intervention and its applicability for the member in question. In certain circumstances (eg, organ transplantation), consultation among the clinician's peers may be prudent before appropriateness of the option can be fully determined.
- For interventions that may be appropriate options, clinicians and members must understand and discuss both what is known and what is not known about the intervention's risks and benefits. How evidence is presented to members ultimately influences their decisions.
- If the intervention remains an appropriate option for the member, member and clinician may share the decision about undertaking the option. Exclusions or restrictions to benefit coverage should be investigated to fully inform the member's participation in the decision making process.
- For any health plan member who wishes to pursue an intervention not supported by the clinician, the insurance contract (and, in some circumstances, legislative statutes) articulates a process by which members may voice concerns and formally appeal any decisions made.
- If the intervention is medically appropriate for a member but is excluded contractually (ie, the intervention is not a covered benefit), the member retains the option of directly purchasing the service. When a benefit is in dispute or is otherwise questioned, the health plan contract (and in some circumstances, legislative statutes) may articulate the process by which members may express any concerns and formally appeal any decisions. (Questions about health plan coverage for Kaiser Foundation Health Plan members should be referred to the local Kaiser Foundation Health Plan Member Services Department.)

Summary

In considering use of a new medical technology, four factors must be addressed and recognized:

- evidence to support use of the intervention;
- a given intervention's applicability and appropriateness for improving a person's health outcome;
- evolving need and process for creating a decision shared by members and clinicians; and
- the insurance contract between the health plan and its members.

Much public strife about insurance coverage for new technologies has arisen as a result of variation in the way health plans interpret and apply the definition of "investigational and experimental" therapy.

A rigorous, consistent approach involving the clinician, the member, and the Health Plan as key stakeholders for assessing and using new medical technology can form a credible and durable foundation for improving the relationships between clinicians and members and for selecting medically appropriate interventions that secure desired health outcomes. ❖

References

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The Spirit Of Dialogue

… dialogue is the essential human capacity for our times.
Thought creates the world and then denies it.
Changing our world means changing our thinking,
and to do this we must change the way we think.
Dialogue is a way of thinking together that allows
us to participate in the unfolding of meaning.

Daniel Martin, Director of International Communities for the Renewal of the Earth