What it Means to Follow a Guideline

As society moves toward requiring greater accountability for medical practice, clinical practice guidelines based on expert evaluation of relevant data have received greater attention as a potential tool for measuring quality. However, because using guidelines in quality measurement is relatively new, little exploration has occurred regarding what it means to actually “follow” a guideline. This is particularly concerning in an environment in which adhering to recommendations or not might have consequences for patient referrals or financial incentives.

Guidelines are designed to assist the clinician in making appropriate decisions about the patients’ care. A good guideline provides a range of appropriate options—but only appropriate options—that a clinician can choose among for individual treatment decisions. During guidelines development, available evidence is considered and used as the foundation for recommendations, with high level evidence preferred. When high level evidence is not available, guidelines developers use lower level evidence, including phase II studies and retrospective analysis. Experts evaluate the evidence available at the time and make recommendations expecting that, over time, new data will drive changes in the guidelines.

Guidelines developers consider key decisions that must be made in providing appropriate care. They cannot, however, address every possible situation that might arise. In developing the NCCN Clinical Practice Guidelines in Oncology™, for example, panel members invoke the “5% rule”: if a situation will probably not be encountered in more than 5% of the patient population under consideration, that situation is not addressed in the guidelines. This strategy limits undue complexity and emphasizes that, even in the most global sense, guidelines are not expected to apply to all patients. Similarly, individual clinical situations may make applying the guidelines inappropriate for some patients.

Differentiating between guidelines and care plans is important. Guidelines tell you what to do but without the detail contained in institution-specific care plans that describe how to implement the guideline in your practice setting. Using guidelines does not preclude adopting institution-specific care plans and may in fact facilitate their development and implementation.

A number of issues will need to be considered as plans are formulated to define an acceptable level of adherence.

Reasons for Non-adherence

An individual patient might not be treated in accordance with the guidelines for a variety of legitimate reasons. Practicing medicine requires applying knowledge and experience in formulating the best treatment plan for the individual. This is particularly true in a discipline such as oncology, which includes complicated biologic processes, multiple treatment modalities, treatment-related toxicities, and a relatively older patient population, frequently with coexisting medical conditions. Decisions regarding guidelines implementation in individual clinical situations are complex. Subtle differences in patient status can
affect which treatment is appropriate and even whether guideline-adherent treatment is relevant for a particular patient. For example:

- Poor performance status can limit the use of guideline-concordant treatment.
- Limited life expectancy can make aggressive treatment that compromises quality of life unattractive.
- Patients may refuse guideline-adherent treatment for a variety of reasons.
- Guideline recommendations may not address a particular patient’s situation.

Given the range of circumstances that can limit guideline adherence, we can reasonably expect that a physician providing high-quality care will not always be guideline adherent. Developing numerators and denominators for measuring quality using guidelines is not straightforward. One strategy is to use a numerator that consists of the number of patients 1) who are treated in accordance with guidelines, 2) who are participating in IRB-approved clinical trials, and 3) who have been informed of but refused treatment. The number of all patients with the condition of interest can be used as the denominator. A concern with this strategy, however, is that guidelines are developed to provide recommendations for treating the normal range of patients. Frequently, specific exclusions for individual patient circumstances are not explicit, making the denominator somewhat arbitrary. In addition, given other legitimate reasons for non-adherence, the numerator may not include all patients receiving high-quality care. Therefore, a physician with adherence rates approaching 100% might actually be practicing lower-quality medicine than one with an 85% adherence rate. Policy makers will need to determine a threshold at which physicians can reasonably be expected to be accountable.

**The Most Practical Level for Measuring Adherence**

Thus, the question remains: what is the most practical level at which to measure guideline adherence? The NCCN Clinical Practice Guidelines in Oncology™ for disease site management are developed to address the clinical decision-making process from diagnosis through survivorship or palliative care. Because of this, each guideline contains hundreds or, at the most granular level, thousands of recommendations. Key decision points include initial workup (including which tests and procedures are required for adequate staging), selecting primary therapy, need for and selecting adjuvant therapy, monitoring patient response while on therapy, surveillance after treatment is completed, and managing advanced disease. In addition, consideration must be given to appropriately managing both disease- and treatment-related symptoms. Each phase of treatment has multiple components and potential areas for quality measurement.

Given the scope of the recommendations, at which level should adherence be measured? Because of the number of individual recommendations contained in a single guideline and the period of months to years over which care occurs, measuring adherence at the whole guideline level is not practical. One option is to look at the key phases in treatment—work-up, primary therapy, adjuvant therapy if appropriate, surveillance, workup for recurrence, and therapy for progressive or recurrent disease—and measure adherence using these landmarks.

Decision makers must develop a pragmatic framework for evaluating care, realizing that key recommendations must be followed, but others may be less crucial. With the granularity of the guidelines recommendations, evaluating adherence to each component of each recommendation may not be realistic. For example, once a clinician has established that a patient has systemic disease, is it necessary to find all sites of metastases? Can additional scans be omitted in this setting? It depends. Sometimes scans can be omitted, if, for example, widespread disease is apparent and local therapy is clearly not indicated. Sometimes they cannot, such as if a patient has potentially resectable liver or lung metastases from colon cancer but extensive metastases elsewhere would render resection futile.

Arguments can be made that each major decision point is crucial in the overall outcome. Improper staging is likely to lead to over- or under-treatment, with consequences for control of disease, survival, treatment-related toxicity, and quality of life. If a newly diagnosed woman with breast cancer does not have the tumor tested for HER2 status, she risks either not receiving potentially life-saving adjuvant therapy with trastuzumab or receiving trastuzumab without evidence that it would benefit her but with the attendant risk of treatment-related cardiac toxicity. Similarly, in colon cancer, if an inadequate number of lymph nodes

© Journal of the National Comprehensive Cancer Network | Volume 4 Number 7 | August 2006
What It Means to Follow a Guideline

are removed and evaluated during colectomy, can adjuvant chemotherapy reasonably be omitted? Can adjuvant therapy ever be guideline adherent if the appropriate diagnostic testing has not been done? Concordance is not simply following individual recommendations one at a time; it involves care over a longitudinal process.

Later in the disease course, initial staging may be less important. Occasionally, patients who have not received an adequate workup must be treated for recurrent or progressive disease. Can treatment at this point be considered adherent? Yes, provided that disease status is appropriately evaluated before treatment is selected for advanced disease. Similar situations can be envisioned at each phase of treatment. Ideally, specific high-impact recommendations would be identified that must be met at each stage of disease and those would be used to measure adherence.

Choosing Recommendations

With respect to treatment selection within the guidelines with several equivalent recommendations for a clinical situation, can the clinician choose any of the recommendations and be concordant? One of the goals of guidelines is to provide a variety of appropriate treatment options. As long as the treatment follows one of the recommendations, it is adherent. However, also important is that recommendations are based on specific evidence and studies; when specific regimens or procedures are provided, adherent treatment is expected to be provided within the parameters of those recommendations.

References