Introduction

The Institute of Medicine has defined clinical practice guidelines as "systematically developed statements to assist practitioner and patient decisions about appropriate health care for a specific clinical circumstance" [1]. The marked expansion of interest in this area has arisen as a result of two converging themes in modern health care. The first proposes that one step toward controlling rising medical costs is the elimination of diagnostic tests and therapeutic interventions that do not contribute to a beneficial outcome for the patient [2].

The second maintains that today's physicians do not routinely base their medical practices on solid evidence, since it is virtually impossible for a single individual to process and objectively evaluate the mass of data impacting on medical decision-making [3]. This is especially true when, paradoxically, there may be critical gaps in the data. The confluence of these perceptions has led policy makers and health service researchers to consider clinical practice guidelines as a vehicle for encouraging practices that are sound, consistent, and cost-effective.

Faced with these demands, the oncologic disciplines are being called upon by sundry sources to develop practice guidelines. As all who venture into this field rapidly learn, the complexities of managing the cancer patient place demands on oncology guideline developers that far exceed those confronting experts in other areas. Besides the sheer volume of diagnoses subsumed under the term "oncology," the task is complicated by the heterogeneity of clinical and pathophysiologic variables for each patient, which makes the delineation of comprehensive pathways extremely difficult. For these reasons, guideline activity in oncology has lagged behind that in other disciplines. A recent survey of 831 articles related to guidelines and outcome measures cites only 61 papers related to cancer, of which half address screening issues [4].

Despite these difficulties, the goal of providing instruments to assist in clinical decision-making remains a valid one, since the ultimate objective, the improvement of care for cancer patients, may be furthered by soundly derived guidelines.

Current Guideline Activity

As yet, no single authoritative body has emerged as the ultimate developer of practice guidelines in oncology. However, a wide spectrum of groups, ranging from federal agencies and medical societies to formal and informal groups of oncologists, are currently involved in developing these instruments (Table 1).

Federal Agencies

The federal initiative is being carried forth by the Agency for Health Care Policy and Research (AHCPR) [5]. To date, panels of this organization have developed seven guidelines, only one of which, "The Management of Cancer Pain"[6], is directed at cancer care.

The National Institutes of Health consensus process fosters the development of statements that evaluate broad areas of clinical care and delineate the current state of appropriate practice [7]. Consensus statements are the products of an invited panel of experts who review relevant data and, in a nonstructured process, develop a consensus opinion. Recent consensus statements in the area of oncology have addressed the adjuvant therapy of colorectal carcinoma (1990), early breast cancer (1991), diagnosis and treatment of melanoma (1992), and management of ovarian cancer (1994). The National Cancer Institute, in response to recent debates over mammographic screening in women age 40 to 49 years, has redefined its role in this area, reasoning that its goal should be to support relevant research, and thereby serve as the scientific resource agency in the guideline
Medical Groups and Societies
A second major developer of guidelines has been medical groups and societies [9]. The American Cancer Society has been instrumental in formulating the parameters and indications for a broad range of screening and support activities [10,11]. The ACS has fulfilled a major requirement of sound guideline practice, namely, the commitment to periodic review and revision [12].

Another major group involved in guideline development has been the American College of Physicians, through its Clinical Efficacy Assessment Program (CEAP) [13]. Initiated in 1981, this project has produced over 200 position papers, including several related to cancer topics, such as parenteral nutrition in cancer patients [14].

One of the first major guideline efforts in oncology was undertaken by the Oncology Nursing Society, which published a comprehensive set of pathways for performing nursing assessments of the cancer patient [15]. The Association of Community Cancer Centers recently announced plans to convene working groups to derive management plans for the common cancer sites.

During the past 2 years, three of the major oncology specialty societies, the American Society of Clinical Oncology, the American Society of Hematology, and the Society of Surgical Oncologists, have formed committees to develop guidelines related to oncology practice. The American Society of Clinical Oncology is utilizing expert panels to derive evidence-based guidelines. The first of these documents, on hematopoietic growth factors, was published recently [16]. Future guidelines will focus on the use of tumor markers in breast and colon cancer, and issues related to the role of peripheral stem-cell support of high-dose chemotherapy.

The American Society of Hematology is approaching guideline development from a disease-oriented perspective, and will address specific neoplastic entities in the future. The surgical group is developing a set of guidelines related to the site-specific surgical management of a broad range of tumors.

Another avenue to practice guideline development was recently opened by the Eastern Cooperative Oncology Group, which has promulgated a set of guidelines delineating practice parameters related to bone marrow transplantation [17].

In addition to the oncology specialty organizations, the subspecialty oncology groups are also generating guidelines specific to their areas. The American Society of Bone Marrow Transplant is developing guidelines for the appropriate resources for performing transplant procedures and for the credentialing of bone marrow facilities. The International Society of Hematotransplant and Graft Enhancement has been working with the Office of Health Technology Assessments to formulate a set of guidelines covering the technical aspects of procuring bone-marrow, peripheral stem-cell, and cord specimens.

Nononcologic specialty societies have also become involved in cancer topics as part of their general guideline activities. Recent examples include the American College of Obstetrics and Gynecology, which developed several technical papers directly dealing with oncologic problems [18]; the American Society of Colorectal Surgeons, which promulgated guidelines for the management of colorectal cancers [19]; and the American Academy of Dermatology, which published guidelines for the management of malignant melanoma [20].

Other Groups
The third, and probably most active, locus of guideline development has been a multiplicity of formal and informal groups operating at the local, regional, and national levels. The aim of these groups has been to delineate the clinical practice pathways for the majority of common tumors. These pathways seek to standardize diagnostic and staging workups, detail appropriate primary and adjuvant therapies, specify types and schedules of follow-up examinations, and outline options for salvage therapy.

The impetus for this grass-roots guideline effort is the desire to decrease variations in oncology care, with the assumption that this will curtail the overutilization of services and thereby decrease costs. Since guidelines must be implemented on the local level, "buy-in" by practicing oncologists may be heightened if they are part of the developmental process.

Given the plethora of ad hoc guideline activities, there is probably a considerable amount of overlap in the areas being covered. Since the composition and authority of the panels differ, the methodology used for deriving guidelines varies widely, ranging from the informal consensus of experts to formal, evidence-based processes [21].

Major health maintenance organizations, such as Kaiser-Permanente, are investing significant resources in developing a guideline program. Insurance companies, too, may have a major impact on guideline generation. Blue Cross and Blue Shield organizations in several states have been either
Principles of Guideline Development

Despite the marked expansion of guideline activity, the science of the development of these practice aids must still be considered embryonic. Given the application of various methodologies in guideline derivation, the multiplicity of objectives being pursued, the frequent lack of documentation of underlying processes, and the diverse composition of guideline panels, the comparison of guidelines, even if focused on similar topics, is exceedingly difficult. At present, certain general principles appear to be germane to the process of guideline development, and therefore should be addressed by oncologists preparing to become involved in this activity.

Types of Guidelines

Guidelines are derived under a profusion of names and titles, eg, standards of care, clinical protocols, practice parameters, and standard paths. For the purposes of oncology, it is useful to group guidelines into three major categories: path guidelines, boundary guidelines, and critical care pathways (Table 2).

Guidelines provide information to practitioners about which tests and therapeutic interventions are appropriate for the management of a clinical condition. They address the issue of what care should be delivered. Critical care pathways focus on how to deliver that care once the clinical decisions have been made, and focus on the sequence and timing of the interventions [22]. Guidelines encompass two basic types of instruments: Path guidelines detail the step-by-step management of a particular tumor type, usually on a stage-specific basis. Clinical algorithms represent a common form of path guideline [23]. A guideline of this type would be the delineation of the medical decisions to be made in managing stage II breast cancer, including the staging workup, primary and adjuvant therapy, and appropriate surveillance schedule. A path guideline may define the optimal level of management or establish the minimal requirements.

Boundary guidelines evaluate modalities and procedures in order to define their range of appropriate applications. Usage outside the established boundaries would be considered inappropriate, and would require justification by the treating oncologist. The ASCO growth factor guideline is an example of a boundary guideline. The majority of initiatives by regional organizations fall into this category.

Selection of Topics

The resources required to generate a guideline, especially in terms of time, cannot be underestimated. Thus, careful thought must be given to the selection of suitable topics. Given the plethora of site-specific path guidelines currently under development, it is likely that multiple examples will be available to those initiating a guideline program. Since there is a commonality of clinical data that support most guidelines, there probably is no need for every organization to start de novo. A more efficient approach would be to utilize rationally derived guidelines as templates, and then submit them to systematic local review. The adaptation of regional or national practice parameters to local specifications allows for the reexamination of data in relationship to local experience, and also permits accommodation to local preferences and unique capabilities [24]. Criteria for selection of a guideline topic include significant variations in care, controversy about appropriate management, high costs, high volume of usage, and availability of adequate scientific evidence to support the guideline process. The use of these criteria should ensure that substantial resources are not wasted in pursuit of trivial or unanswerable topics.

Objectivity of the Developmental Process

The soundness of a guideline rests on the objectivity of the process used to derive it. When assessing this objectivity, two dimensions should be considered: the composition of the panel and the methods employed to arrive at the guideline recommendations. Panels not only should be composed of individuals with documented expertise in the area under discussion but also should include broad representation of all clinical disciplines involved in that area. This may be of concern when subspecialty societies derive guidelines. Insofar as a guideline focuses on technical issues related to that subspecialty, a narrowly constituted panel may be appropriate. If the same panel addresses issues related to the broad, general usage of a modality, however, alternatives espoused by other specialties must be represented. Failure to do so may lead to the perception that the final product is self-serving, rather than objective.

Another area that must be addressed at the beginning of the guideline process is the determination of possible conflicts of interest of panel members. The definitions for conflict of interest and
procedures for declaration must be made explicit, so that the users of the guideline can evaluate whether any biases exist. The process used to arrive at guideline recommendations should be as objective as possible. Woolf [25] has described four basic methods for guideline development (Table 3): 1) Informal consensus, consisting of expert individuals or groups deriving guidelines based on their best judgment; 2) Formal consensus, exemplified by the NIH Consensus Panels, which bring together a group of experts to review all pertinent data, but have no explicit rules for evaluating the data; 3) Evidence-based reviews, as used by the ASCO growth factor panel, which employ a formal system for rating the quality of the evidence and the strength of recommendations so that the user can directly assess the underlying reasoning and scientific justification (many groups have used a form of the Canadian Prevention Task Force's method of assessing the strength of evidence [26]); and 4) Explicit processes, which attempt to derive recommendations based on quantifiable analyses of the outcomes of various interventions, thereby selecting the most effective and economically sound alternatives [27]. Unfortunately, the data and expertise for performing these types of analyses do not exist for the majority of guideline topics.

**Provisions for Review and Revision**

One of the givens in oncology is that the field is constantly progressing, and that new approaches must be incorporated into standard management plans on an ongoing basis. If guidelines are to be relevant to oncologic care, therefore, formal provisions for review and revision must be written into the guideline process. The schedule and mechanism for review should be spelled out when the guideline is written to ensure that this critical element is not left to chance.

**Guideline Implementation**

As expounded by the Institute of Medicine definition, the purpose of guidelines is to aid clinical decision-making. It therefore follows that the most sound evidence-based guidelines will have no impact if they are not utilized by clinicians [28]. It has been pointed out that there may actually be a paradox, however, in that guideline acceptance may be fostered by local development, but local generation may involve a narrower perspective leading to less rigorously derived recommendations [29].

Follow-up studies of the impact of oncology guidelines have been unable to demonstrate significant changes in physician behavior as a result of these documents. In a recent analysis of the impact of the NIH Consensus statement recommending the use of radical prostatectomy or radiation therapy, the investigators could not document any sharp increase in the use of these modalities following publication of the statement [30]. Of perhaps even greater import, an analysis of the impact of disease-specific, locally derived guidelines by NCI-sponsored Community Hospital Oncology Program participants failed to demonstrate significant diffusion of the guideline recommendations to clinical practice [31]. Since this community-based guideline process was implemented over a decade ago, it is likely that the new forces impinging on the health-care system may make these findings irrelevant to today's clinical environment. At the same time, they still show that the science of guideline implementation is still in its infancy, and the factors facilitating acceptance are still to be defined.

Methods of influencing physician behavior fall into several categories: education, feedback, use of respected leaders, administrative mechanisms, and institution of incentives or punitive actions [32]. Education as the sole means of implementation, although leading to knowledge about the guideline, does not necessarily result in changes in practice [28]. Feedback on a physician's practice patterns vis-à-vis his or her colleagues can be instrumental in modifying practice.

The increasing use of computer systems to provide real-time feedback will undoubtedly facilitate compliance in the future [33]. In the long run, however, the reorientation of health-care systems toward a managed care environment will probably result in the implementation of more administrative mechanisms for ensuring compliance with guideline directives. Ultimately, the credentialing of physicians based on their adherence to standard pathways, with its resultant rewards and punishments, may become the dominant factor in the implementation process.

**Validation**

The discussion of the development and implementation of guidelines highlights the newness of the field. The use of guidelines must still be considered experimental, since very few studies have shown
that guidelines accomplish their objectives [34]. The demonstration that oncology guidelines reduce variations in care, and that this improved consistency leads to more beneficial outcomes at reduced cost, will entail the mounting of broadly based effectiveness trials, often outside the traditional clinical trial mechanism. The use of administrative databases and the measurement of cancer costs will require new methods of data management and analysis. These demands should lead to the recruitment of an increasing cadre of health services researchers with oncology expertise to the field.

**Summary**

The development of oncology guidelines is currently being carried out by a large number of organizations. As these activities proceed, the quality of efforts will improve and the sophistication of the guideline developmental process will increase. How to ensure that these guidelines will be used will require the systematic evaluation of different implementation strategies. Although the hope is that the use of guidelines will lead to better oncology care for fewer dollars, the value of guidelines still must be considered unproven. Certainly, however, this area deserves intense study.

**References:**


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