Development and Use of Clinical Practice Guidelines

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Clinical practice guidelines are systematically developed recommendations that target specific areas of clinical practice in which sufficient evidence does not always exist. The purpose of clinical practice guidelines are many: (a) to appraise existing evidence in a specific clinical practice arena; (b) to assist practitioners in clinical decision making; (c) to minimize inappropriate practice; (d) to provide quality indicators for self and practice appraisal; and (e) to standardize and improve care so that it best reflects the evidence that exists (Schiffer et al., 2001). In addition, clinical practice guidelines assist governmental and private insurers with reimbursement decisions. Attributes of good clinical guidelines are included in Table 1 (AGREE Collaboration, 2003; Schiffer et al., 2001).

Development of Clinical Practice Guidelines

WHO DEVELOPS GUIDELINES?

Professional organizations such as the American Society of Clinical Oncology (ASCO; American Society of Clinical Oncologists, 2007), the National Cancer Comprehensive Network (NCCN; National Comprehensive Cancer Network, 2010), and the Oncology Nursing Society (ONS; Oncology Nursing Society, 2010) often initiate the development of guidelines in cancer care. Ideas are usually generated through work groups, organizational strategic planning, and discussion among colleagues. Health-care professionals representative of the targeted population, such as clinical practitioners and research representatives, are invited to participate in guideline development panels. For example, the team that developed the ONS *Putting Evidence into Practice* guidelines included staff nurses, advanced practice nurses with specialty in the given area, and nurse scientists with expertise in research. Patient and public input may also be solicited depending on guideline content (Boivin et al., 2010).

HOW ARE GUIDELINES DEVELOPED?

The methodology used for the search and appraisal of evidence should be transparent and clearly stated. Guideline authors should specify the databases searched, the timeline from which the literature was selected, and the criteria used to determine article inclusion. In addition to the database search, bibliographies of selected articles are often included in the collection process.

Table 1. Attributes of good clinical guidelines

Attribute	Comments
Clarity	Easy to understand and interpret
Validity	Extent to which the guideline is well founded and addresses the defined practice
Reliability	Extent to which the guideline produces consistent results
Reproducibility	Ability of the guideline or practice to be replicated consistently in practice settings
Clinical applicability	The guideline's relevance to practice
Clinical flexibility	The guideline is not restrictive to the degree that it cannot be tailored to individual groups of patients and scenarios
Multidisciplinary process	Development involves individuals with expertise in a variety of related disciplines such as medicine, nursing, and science
Review of evidence	Review should be thorough and well described

Note: Data from Schiffer et al., 2001, and AGREE Collaboration, 2003).

Next, appraisal of evidence should be described. A numeric level of evidence and/or a grading system are often used to represent the guideline panel's decision regarding a particular practice area. For example, level I represents the most scientifically rigorous evidence stemming from meta-analyses or well-designed, randomized controlled studies. Level V would be the lowest level of evidence represented by case studies and clinical anecdotes.

After assigning the literature a level of evidence, panels can grade each recommendation. For example, ASCO assigns a grade of A through D, with A indicating the highest recommendation and D the lowest. ONS uses a descriptive grading system that includes *Recommended for Practice, Effectiveness Not Established, Benefits Balanced With Harms, Not Recommended for Practice, and Expert Opinion.* These descriptors are intended to clearly guide health-care and nursing practice decisions. The NCCN employs a unique strategy that is different from the ONS or ASCO methods. Inclusion in the NCCN Clinical Practice Guidelines in Oncology is determined by the strength of the evidence and the degree of consensus by panel members (NCCN, 2010).

Application of Clinical Practice Guidelines

The best way to illustrate the application of clinical practice guidelines is through clinical examples. The ASCO Platelet Transfusion guidelines (Schiffer et al., 2001) and the ONS Prevention of Bleeding guidelines (Damron et al., 2009) will be used as examples. First, the advanced practitioner should determine when the guideline was developed and the timeline from which the literature was selected. The ASCO guideline was developed in 2001, almost 10 years ago, and has not been updated since; however, the ONS guideline, which concurs with the ASCO guideline, was more recently developed. The advanced practitioner can compare both guidelines but should search for any additional significant studies that have been conducted since the guideline timeline. Next, the practitioner can examine the guidelines to answer practice questions about platelet transfusions and the prevention of bleeding. Finally, the level and grade of evidence should be noted along with considerations that translate the guideline into clinical practice. Table 2 includes practice questions, recommendations from the Platelet Transfusion and Prevention of Bleeding guidelines pertaining to these questions, and translation into practice considerations. Tools are available in the literature for integration of specific clinical practice guidelines system wide. For example, Shiffman and colleagues developed the GuideLine Implementability Appraisal (GLIA), a 31-item tool that helps to identify barriers to the implementation of guidelines in the clinical setting. (Shiffman et al., 2005).

Table 2. Platelet transfusion guidelines: Prevention of bleeding

Clinical scenario	Guideline recommendation	Practice decision
It is day 10 of induction therapy for a patient with acute myelogenous leukemia. The patient's platelet count is 14,000/µL. Is platelet count sufficient or should the patient receive a prophylactic platelet transfusion?	ASCO recommends a threshold of 10,000/µL for prophylactic platelet transfusion in patients with adult leukemia receiving chemotherapy. The evidence is rated as level I with grade A. ONS recommends the same (Recommended for Practice).	In this case, the patient may not need a platelet transfusion, but further clinical assessment is warranted. If the patient has signs of bleeding, high fever, hyperleukocytosis, rapid fall of platelet count, or coagulation abnormalities, the patient may need transfusion.
You are working up a diagnosis in collaboration with the physician. The patient has a platelet count of 22,000/µL. You are asked to obtain a bone marrow biopsy on the patient. Is the platelet count sufficient enough to safely undergo a bone marrow biopsy?	ASCO guidelines recommend a platelet level of 40,000/µL to 50,000/µL to safely undergo surgical or invasive procedures, but the guideline goes on to state that certain minor procedures such as bone marrow biopsy can be performed at lower count levels, even at those less than 20,000/µL. ONS guidelines concur (Recommended for Practice).	Since the patient's platelet count is over 20,000/µL, it is probably not necessary to administer platelets unless the patient has other signs of bleeding. As ONS guidelines state, however, pressure should be applied to the site to prevent bleeding and ecchymosis. If bleeding at the site were to occur, direct pressure should be applied to the site for 10–15 minutes.
A patient with ovarian cancer is undergoing chemotherapy for advanced disease. Treatment has caused significant thrombocytopenia, and her platelets are low at 28,000/µL. She arrives in the emergency room via ambulance, because she fell at home and fractured her left humerus. Is she a candidate for major surgery?	ASCO reports that a platelet count of 40,000/µL to 50,000/µL is sufficient to perform major surgery. Because this is a practice that does not lend itself to clinical trials, evidence is limited and rated at level IV with a grade C recommendation. ONS guidelines concur (Recommended for Practice).	The advanced practitioner will order platelet transfusion(s) to increase the patient's platelets to the 40,000/µL to 50,000/µL level. A posttransfusion level should be drawn to verify that the goal is attained, immediately prior to surgery. Often, other disciplines outside of oncology will have guidelines that may or may not concur.

Summary

In summary, clinical practice guidelines are a template to translate research into practice. Advanced practitioners in oncology have a responsibility to be aware of guidelines that exist, and to understand their clinical utility and limitations, so that they may use guidelines to provide safe, quality care.

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