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Supportive Care Treatment Guidelines: Value, Limitations, and Opportunities

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Abstract

Evidence-based guidelines in clinical oncology practice are now prominent, with emphasis on clinical, health outcome and economic perspectives. Given the complexity of cancer management, a multidisciplinary approach is essential. Evidence-based guidelines to address supportive cancer care have merged expert opinion, systematic evaluation of clinical and research data, and meta-analyses of clinical trials. Production of supportive care guidelines by the interdisciplinary team is dependent on sufficient high-quality research studies. Once published, it is essential they be customized at institutional and national levels. Implementation in clinical practice is perhaps the greatest challenge. Optimal management occurs through integration of country-specific issues, including care access, healthcare resources, information technology, and national coordination of healthcare practices. The purpose of this article is to: (1) provide an overview of interdisciplinary cancer management using evidence-based guidelines; (2) delineate the theory and practice of guideline dissemination, utilization and outcome assessment; and (3) recommend future research strategies to maximize guidelines use in clinical practice.

Clinical practice guidelines have become more important in clinical oncology over the past decade.^{1–12} Although the methodology to create the guidelines may range from expert opinion to meta-analysis, overall they are designed to improve clinical outcomes and reduce healthcare resource utilization and costs. Unfortunately, application to actual clinical problems is often a challenge,¹³ for reasons including that multiple toxicities often occur concurrently in the same patient.^{14–16}

In addition to the medical complexity of patients, there are several additional reasons that have led to the current status as well. For example, communication across the health

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professional team is important but not always achieved. Target audiences are not limited to oncology, but also include dental medicine and oral oncology, and nurse oncology. In addition, durable impact on clinical practice is essential. Country- and institution-specific issues associated with incorporation of published guidelines into oncology practice are important, which adds further complexity to the use of guidelines internationally.

Identification of the need for new or revised supportive care guidelines often begins with clinical observation and empiric management. These issues, if of sufficient clinical consequence, can prompt investigators and clinicians to investigate pathobiologic etiology modeling, for which molecularly targeted drugs and/or devices can be developed. Extensive phase I, II, and III clinical studies, if successful, can lead to new drugs or other agents in clinical practice. Data from the studies provide a basis for new or revised guideline.

THE THEORY OF GUIDELINE DISSEMINATION AND UTILIZATION

Evidence-based clinical practice guidelines are not useful without two important processes: dissemination to potential users and application to appropriate patient populations.⁷ The process of adopting guidelines in clinical practice to achieve optimal patient management can be influenced by multiple issues, including care access, healthcare resources, information technology, and national coordination of healthcare practices. These issues vary based on both the country in which the guidelines are being addressed, and the circumstances unique to a given institution within that country.

In addition, individual clinician behavior is also often dependent upon the ability of each clinician to remain current with published guidelines and willingness to adopt them when feasible to do so. Numerous models have been developed for implementation, such as evidence-based practice guidelines.

The *Diffusion of Innovation* model¹⁷ has been the subject of considerable research. It incorporates dissemination of new information as a means by which individual behavior can be changed. In this model, diffusion (ie, dissemination) is defined as a process in which an innovation (ie, guidelines) is shared through communication channels within a specified period of time to individuals who are members of a social system (ie, healthcare professionals).¹⁷ In this process, a new idea or practice is implemented by clinicians through knowledge of the innovation, being persuaded to use it, and finally, making a decision to adopt the practice.

Key elements of the decision to adopt new behaviors include:

- *Relative advantage*—better than previous ideas or practices;
- *Compatibility*—consistent with existing values, past experiences;
- *Complexity*—degree to which it is perceived as difficult to understand and use;
- *Trialability*—degree to which it can be experimented with on a limited basis;
- *Observability*—degree to which results are visible to others.

Communication is the means by which messages regarding the innovation transfer from one individual to another. This can occur through mass media, like journals, radio, or television. Such approaches are rapid and efficient means to reach many people. Communication also can occur through interpersonal (face-to-face) contact among two or more people; this often can be more effective in persuading people to adopt changes. A third means is the interactive method on the Internet, which is increasingly important for disseminating information (eg, guidelines cited on the National Guidelines Clearinghouse website¹⁸). The most important facilitator of innovation is subjective evaluations from similar people who have adopted the innovation. Diffusion is a social process involving interpersonal communication relationships.¹⁷

The time involved in deciding to whether or not to adopt an innovation has three components. First, time is required for the innovation–decision process; an individual passes from first knowledge to adoption or rejection. Second, the relative earliness or lateness with which an individual adopts the innovation warrants consideration. Third, the rate of adoption into a system (eg, number of people who adopt the innovation in a given time period) is an additional factor.

The social system involved in adoption is a set of interrelated units engaged in joint problem solving to accomplish a common goal.¹⁷ Members can be individuals, informal groups, organizations, or subsystems. In a social system, members cooperate for mutual goals. Since diffusion occurs within a social system, the social structure affects diffusion:

- Effect of group norms and values;
- Roles of opinion leaders and change agents;
- Types of innovation–decisions;
- Consequence of the innovation.

The historical assumption in diffusion has been that if new information (like clinical practice guidelines) is developed and disseminated, then it is a simple matter of time for diffusion into clinical practice. Experience has identified the need for additional proactive steps to maximize application and use of guidelines.¹⁹ Rogers' *Theory of Diffusion of Innovation* provides a framework for proactive process required for adoption. It also may be useful for systematically revising guidelines over time, and developing effective strategies for implementing guidelines that are limited in scope and/or expensive to apply.

Application of these principles inherent is discussed below, with examples of guideline development, dissemination, and utilization.⁸

THEORY IN PRACTICE: MUCOSITIS GUIDELINE DEVELOPMENT AND IMPACT

The Multinational Association of Supportive Care in Cancer (MASCC), in collaboration with the International Society of Oral Oncology (ISOO), is an international multidisciplinary health professional organization that has produced evidence-based supportive oncology care guidelines. Mucositis guideline development emerged from several decades of mucosal

biology advances and increased awareness of the importance of toxicity^{3,20} (Figures 1 and 2).

A number of diverse strategies have been used for dissemination of the mucositis guidelines. These include publication of the guidelines manuscripts in scientific journals, citation of the guidelines in review manuscripts and book chapters, and oral presentations of the guidelines at scientific meetings. A user-friendly summary of the guidelines has been posted at the MASCC website, along with translations of this summary in German and Greek. The guidelines also have been posted at www.guidelines.gov,¹⁸ the previously noted National Guidelines Clearinghouse, which is a central resource for clinical practice guidelines. These online dissemination methods are particularly suited to measurement of impact. For example, the mucositis guidelines were viewed 8,892 times at www.guidelines.gov¹⁸ between August 1, 2009 and July 31, 2010. In addition, the mucositis guidelines were viewed more than 5,000 times at www.mascc.org²¹ over a 1-year period ending June 2010. These statistics permit measurement of dissemination of these guidelines and indicate a significant clinical distribution.

There also have been important lessons learned from related guideline development, including antiemetic approaches (Figure 3). These include (but are not limited to) initial clinical experiences, single drug availability, advances in pathobiologic modeling, development of multiple approved agents, and clinician ability to customize preventive and therapeutic interventions based on individual patient risk. These lessons were integrated into the mucositis process and permitted more rapid expansion of the high-quality scientific and clinical database about mucosal injury.

Strategies to further assess impact of mucositis guidelines are needed (Figure 4). Systematic collection of outcome data is essential, so that the impact on clinical course can be assessed. By comparison, new clinical technologies may cause strategic changes in clinical practice that drive revisions in (or creation of new) guidelines for future use. These dynamics can individually, or in aggregate, result in revision in current guidelines or creation of new guidelines. Development is thus a continuum in which the interplay of research, clinical care, clinical outcomes, and revision or creation is dynamic.

DISSEMINATION OF THE MASCC/ISOO MUCOSITIS GUIDELINES TO ONCOLOGY NURSES: THE NEXT STEP

One of the authors (D.B.M.), as a representative of the MASCC/ISOO Mucositis Study Group, collaborated with the MASCC/ISOO Patient and Professional Education Study Group to adapt the Mucositis Guidelines initially for American oncology nurses.^{7,22,23} This approach represents the importance of capitalizing on a multi-professional health professional group to customize development for a target audience.

The goal was to adapt the Mucositis Guidelines for oncology nurses as one mechanism for disseminating and facilitating their adoption.⁷ This was part of a larger project to improve dissemination and use among healthcare professionals, specifically nursing, medicine, and

dental medicine. A specific outcome was the development of a laminated, pocket-sized card that practitioners could use in daily practice.

To develop this customized nursing guideline, collaborators used the following systematic process: (1) reviewed the Mucositis Guidelines for items of most relevance; (2) reviewed a dental version that had already been drafted by dentists within the Mucositis Study Group; (3) listed general principles to guide development, goals, and use of the tool; (4) divided selected guideline content into sections for oral mucositis and gastrointestinal mucositis; (5) formulated goals (ie, clinical outcomes); (6) developed a brief, directed and focused format; and (7) created a two-sided instrument for various oncology nursing audiences (Table 1). Subsequent steps will be performed as a joint venture of the Mucositis and Patient and Professional Education Study Groups. An overarching, long-term goal is to customize the instrument for testing the tool in international clinical oncology settings.

Utilization of The Diffusion of Innovation model in this work demonstrates the relevance of its concepts and processes to disseminating Mucositis Guidelines to nurse oncologists. The project principles are also applicable to broader guideline use in clinical oncology. In terms of innovation, the tool appears to be advantageous and compatible, is not difficult to understand, appears to be amenable to clinical testing, is relevant to practice, and has potentially observable results. Communication channels will consist of interpersonal communication among oncology nurses through a social process. The period of time allowed will enable nurses to gain knowledge, provide input on content/format/usefulness, and hopefully be more likely to adopt the guidelines. The use of a social system, ie, oncology nurses, will provide project support facilitated through the MASCC/ISOO Study Groups with the ultimate goal of improved mucositis management.

IMPLEMENTATION OF GUIDELINES IN ONCOLOGY

Another example of these conceptual principles is illustrated by clinical oncology practice in France.^{24,25} A specific protocol for guidelines elaboration and diffusion was established in the French "National Cancer Plans" I and II, a global national project initiated in 2002 and extended in 2009. This includes a comprehensive plan for implementation, using both published materials and the requirement that each cancer patient be evaluated in a multidisciplinary meeting that produces a treatment strategy that adheres to local, regional, or national published guidelines.

One of the principal national guideline efforts was the Standards, Options and Recommendations (SOR) project. This was conducted by the French Federation of Regional Cancer Centers (FNCLCC) and is being further developed by the French National Cancer Institute (INCa). This provides an opportune setting for implementation of mucositis guidelines in the European oncology community. The steps associated with implementation are:

- diffusing knowledge regarding mucositis;
- including mucositis guidelines within the Cancer Caregivers Community, with focus on individual survey and management;

- evaluating changes in clinical practice.

Previous experience with cancer guidelines provides orientation to the key objectives and barriers to implementation. In France, MASCC/ISOO Mucositis Guidelines, translated into the French language, are emerging as official recommendations. This is one of the few evidence-based supportive care guidelines published and validated by several multidisciplinary expert groups (Association Francophone pour les Soins Oncologiques de Support [AFSOS], INCa). However, the precise impact in medical practice requires additional evaluation and improvement.

Important issues have emerged from these and other examples of systematic, guideline-based approaches for clinical practice.^{26–29} These include:

- value of an educational outreach model, rather than less proactive approaches like simple diffusion;
- potential substantial cost savings associated with systematic guideline implementation;
- importance of national and international collaboration, given the often similar development approaches by health professional groups.

The literature supports evidence-based guidelines in clinical practice. However, despite the clear advantages, barriers remain. Systematic approaches for reduction in these barriers are needed.

OPPORTUNITIES TO REDUCE BARRIERS ASSOCIATED WITH IMPLEMENTATION

Barriers are primarily related to limits in guideline diffusion throughout the broad cancer community and difficulty transforming guidelines in new practice standards. Access to evidence-based recommendations throughout the world is also important. In addition (and even with access), the fundamental and comprehensive impact on oncology practice remains an important issue.

To this end, reduction in barriers and increased guideline implementation could be achieved by:

- customizing information for physicians, dentists, nurses, and patients;
- information diffusion through scientific meetings, web-based fora, publications in multiple languages (eg, MASCC antiemetic guidelines are available in 11 different languages²¹);
- increased integration of evidence-based supportive care as a key part of cancer treatment, including data relative to impact on patient survival.

THE ULTIMATE ACHIEVEMENT: IMPROVED CLINICAL HEALTH OUTCOME AND ECONOMIC EFFICIENCY VIA GUIDELINE USE

Collective modeling has set the stage for the new frontier in supportive care guidelines. This is envisioned as integration of molecular pathobiology linked to targeted interventions, comprehensive clinical data systems to facilitate guideline use, and longitudinal outcome assessments. Key research directions include:

(1) Enhancing the use of guidelines in clinical oncology practice

There is a need for new research about how to maximize impact of supportive care guidelines. Despite some paradigm shift advances, important gaps remain relative to optimal guideline impact in clinical oncology. Key questions exist that provide new research directions in the field (Figure 5). The following areas represent fertile areas for guideline study:

- Systematic measurement of compliance, reasons for noncompliance and timely revisions;
- Determination of clinical and economic impact of comprehensive use versus more limited or no use;
- Analysis of practical impact developed via (a) expert opinion, (b) systematic reviews, and (c) meta-analysis;
- Study of behavior modifications that enhance use among health professionals;
- Determination of optimal approaches to maximize patient and caregiver compliance with guideline-based recommendations;
- Intervention studies to reduce adoption barriers and increase utilization.

(2) Outcome assessments based on guideline use

The full process of guideline development, dissemination, and utilization can have paradigm-shift effects on clinical, healthcare, and economic outcomes. In current clinical oncology practice, choice of supportive care interventions often depends on the clinical expertise and experience of the oncology team. High-quality guidelines are not uniformly available for many clinically significant symptoms. In addition, comprehensive study of cancer outcomes is typically complex; thus, there are limited data.

Fortunately, the current state of science is now sufficiently mature to foster new research and clinical directions relative to outcome assessment by:

- capitalizing on molecular modeling for symptom development^{30,31} in response to targeted therapeutic interventions;
- using clinical decision-making computational models³²;
- studying outcome assessments, including inpatients with advanced cancers.^{33,34}

Short- and long-term outcomes of guideline implementation have been limited in scope. Important new research opportunities are now at hand and warrant pursuit.

SUMMARY

The potential impact of guidelines in clinical oncology practice is based on several key elements. These include the strength of the evidence that grounds the guidelines and degree of success in disseminating and using the information in relevant patient populations. In addition, guideline use is typically directly dependent on a unique administrative and financial context to each country and the institutions within that country.

Production of supportive care oncology guidelines by more than one health professional organization provides an important opportunity for comparison of the strengths and limitations of each group's documents. It is essential to capitalize on this to develop a cohesive national and international approach to supportive cancer care, with emphasis on evidence-based clinical practice.

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Figure 1.
Evolution of the study of mucositis.

Figure 2.
Assessing the impact of guidelines in clinical practice.

Figure 3.
Lessons learned from the anti-emetic world.

Figure 4.
Guidelines: how can we complete the cycle?

Figure 5.
Key research questions relative to guideline utilization and associated clinical outcomes in national and international practice settings.

Table 1**Nursing Mucositis Management Tool ***

PRINCIPLES: Interdisciplinary approach including dentist (for oral mucositis); dentist (for oral mucositis); Patient/family education; Outcome evaluation using quality improvement process

ORAL MUCOSITIS—Goals: Good oral hygiene; Clean moist mouth; Reduced discomfort and pain

Do:

1. Use a validated oral assessment tool
2. Use a validated pain assessment tool
3. Implement a systematic oral care “protocol” consisting of:
 - Regular rinsing with bland agents (normal saline, sterile water, salt, and soda)
 - Brushing with soft toothbrush
 - Flossing
 - Water-based moisturizers for oral mucosa and lips
 - Use oral cryotherapy 30 minutes in patients on bolus 5-fluorouracil or high-dose melphalan
 - Collaborate with physicians to give palifermin in high-dose autologous stem cell patients
4. Use topical anesthetics and analgesics including Patient-controlled analgesia if indicated

Do Not:

1. Use sucralate, chlorhexidine, combination mouthwashes, petroleum-based products, or acyclovir

GASTROINTESTINAL MUCOSITIS—Goals: Relief of diarrhea; Adequate hydration; Reduced discomfort and pain

Do:

1. Assess GI discomfort using a validated pain tool
2. Assess diarrhea using common clinical methods
3. Assess hydration status; consider lactose intolerance and infectious processes
4. Provide comfort measures based on nature and severity of symptoms
5. Facilitate adequate hydration
6. Collaborate with physicians to use sulfasalazine, amifostine, sucralate enema, ranitidine, omeprazole, loperamide, or octreotide in appropriate patients

Do Not:

1. Use oral sucralate, 5-amino salicylic acid/mesalazine/olsalazine, or systemic glutamine

*Source: Multinational Association for Supportive Care in Cancer/International Society of Oral Oncology: Keefe et al., Updated clinical practice guidelines for the prevention and treatment of mucositis, Cancer. 2007;109:820–31.