

**Ensuring Quality Cancer Care:**

*Clinical Practice Guidelines, Critical Pathways, and Care Maps*

A draft proposal submitted to the National Cancer Policy board  
August 31, 1998

Thomas J. Smith, MD, FACP  
Associate Professor of Medicine and Health Administration  
Division of Hematology/Oncology  
And

Bruce E. Hillner, MD, FACP  
Professor of Medicine  
Division of General Internal Medicine

From the Massey Cancer Center and the Department of Internal Medicine  
Medical College of Virginia at Virginia Commonwealth University

*Disclaimer and agreement to confidentiality: In several areas within the text, we refer to studies in press or that have been supplied as “personal communications” on the basis of confidentiality. When so stated, we ask that this information be held in strict confidence.*

Supported in part by a Faculty Scholar Award, *Project on Death in America*, Open Society, New York (TJS); a grant from the Office of Cancer Communications, National Cancer Institute (RFP CO 94388-63) (TJS); a Faculty Research Award from the American Cancer Society (BEH); a grant from the National Cancer Policy Board; and a grant from the Virginia Commonwealth University Department of Internal Medicine Center for Outcomes Research.

Running Title: *Clinical Practice Guidelines*

Word Count: 16,564

Address correspondence to TJ Smith, Virginia Commonwealth University, Massey Cancer Center, 401 College Street, MCV Box 980037, Richmond, Virginia 23298-0037; Telephone (804) 828-0450; FAX (804) 828-8453; E-mail **Error! Bookmark not defined.**

## Table of Contents

Section	Content	Page
	Executive Summary	3
	Introduction	4
	The charge	4
	The need for guidelines	4-6
I.	The background on guidelines	6
	Our perspective as clinicians and health service researchers	6
	The ethics of guidelines	6-7
	The legal aspects of guidelines	7
	A practical model to evaluate the likelihood of guideline success	7
	What guidelines are available and who is making them?	7-8
	What is the quality of published guidelines?	9-10
	Guidelines, evidence, and differing philosophies	10-11
	Barriers to physician compliance	11-12
	Using guidelines to monitor practice	12
	The audience for guidelines and their evaluations	12
II.	Review of the Published Data	12
	<i>United States</i>	
	U.S. 1987: Community Hospital Oncology Program	13-15
	U.S. 1995: Outcomes management for gynecologic oncology	15-16
	U.S. 1994: Management of prostatectomy	16
	U.S. 1997: Model practice management	16-17
	U.S. 1996: Endoscopic sinus surgery	17
	U.S. 1995-6: High dose chemotherapy	17
	U.S. 1994-present: American Society of Clinical Oncology Programs	17-21
	U.S. 1994: Lung, breast, colorectal cancer management	21-22
	U.S. 1996: Cancer pain relief in Utah	22-23
	U.S. 1996: American Urologic Association Programs	23
	<i>Relevant Experience in the World</i>	
	British Columbia, 1991: Early stage breast cancer	24-25
	Ontario, 1995: Paclitaxel for refractory breast cancer	25
	Italy, 1987: Italian National Research Council Evaluation of breast, colorectal and ovarian cancer guidelines	25-28
	France, 1995: Breast and colorectal cancer	28-29
	France, 1996: breast and colorectal cancer	29-30
	Problems anticipated in U.S. medicine based on the available data: <i>evidence-based medicine meets demand-based medicine</i>	30-31
	Summary	32
III.	Interviews with leaders in the field	33-35
IV.	Recommendations	36
	Appendices	37-38
	References	39-44

## **Executive Summary**

There have a modest number of successful clinical practice guideline/critical pathway efforts in the United States, Canada, and France. Improvements have been demonstrated in compliance to evidence-based guidelines or evidence-based medicine, and in short term length of stay, complication rates, and financial outcomes. There has been one instance of improvement in disease-free and overall survival of breast cancer patients, but causality cannot be inferred. The published data suggest that patient complications can be reduced with standardized care, and that satisfaction can be maintained.

The components of the successful clinical practice guidelines can be summarized as follows:

- **Development:** the guideline is based on evidence, and formulated by key physicians in the group.
- **Dissemination:** all affected physicians and health care professionals are given the guideline to review, and are expected to critique.
- **Implementation:** successful guidelines have given direct feedback on performance to physicians, or general feedback on system performance
- **Accountability:** all physicians must be accountable. This accountability can be voluntary peer-pressure to conform to evidence-based medicine, and does not require financial reward or penalty. There must be some willingness to change, based on perceived or real opportunity or threat.

Conversely, those programs that have not succeeded have relied on voluntary change in practice behavior with no incentives to change, or have had no accountability. Simply making information available at meetings, by mailings, or by publication has not lead to significant or timely change in prescribing patterns or practice changes. Alternately, compliance with established guidelines such as clinical staging can be accomplished by administrative directive, such as threat of loss of privileges or deselection, without the guideline process.

For care to improve with clinical practice guidelines, health care providers must be willing to change their practice, must be provided feedback on their performance, must be given information about their performance on specified outcomes, and/or be held accountable for their performance.

Further research is needed on the performance of guidelines outside of organizations demonstrably committed to improvement, ways to improve guideline compliance for health care providers who are not committed to change, methods to improve accountability, and methods to improve incentive programs. Further research is also needed to determine how U.S. consumers will adapt to limits on cancer care that may have some benefit but at a high cost, and how the fee-for-service and capitation incentive system interacts with clinical practice guidelines.

**Introduction**

*The charge*

The National Cancer Policy Board, as part of a project on quality of care, sought information on the formulation and use of clinical practice guidelines. The Board wished to address the following questions:

- What is the state of guideline or standard protocol development for cancer care?
- What is currently available, who has developed them, and how have they been developed? Do they conform to "guidelines for developing guidelines" prepared by the Institute of Medicine (IOM) and other organizations?
- What evidence is there that they are being used?
- Where they are being used, are they having a measurable effect on cancer care quality?
- When guidelines with different recommendations have been issued, what has been the basis of these differences and how have practitioners and patients responded?

*The need for guidelines*

The development of clinical practice guidelines has been driven by concerns about the rapid escalation of cancer care costs and the quality of cancer care. The international concerns<sup>1-3</sup> about practice variations, quality of care, and subsequent patient outcomes appear to be well founded, with documented variations in fields ranging from breast conservation instead of mastectomy, to coordinated care, to surgical mortality, to chemotherapy results for testicular cancer. (See accompanying review by Hillner and Smith.)

The economic concerns are real<sup>4</sup>, since direct medical costs for cancer have risen from \$35 billion in 1990<sup>5</sup> to one estimate of \$50 billion in 1996.<sup>6</sup> There are only limited ways to control costs, listed in Table 1.

Table 1: Options to control health care costs (modified from Smith<sup>7</sup>, 1997)

Options	Consequences
1. Decrease the benefits available to beneficiaries.	Set a standard list of services, similar to Oregon Medicaid.
2. Decrease the number of beneficiaries.	Increase the age limit, or do a financial "means test".
3. Increase beneficiary payments	Increase co-payments or deductibles
4. Dramatically increase efficiency of health care providers, by management of the care process with clinical practice guidelines, incentives, etc.	Unclear how big the savings can be. Positive industry reports <sup>8</sup> , but no published experience on routine treatment of metastatic disease, or in end of life care.
5. Decrease payments to providers	Ongoing, in both fee for service or managed care.

These attempts at cost control, regardless of whether in fee for service or managed care, could have profound impact on the current practice of oncology, as listed in Table 2.

Table 2: Impact of cost cutting on oncology decisions (modified from Miles<sup>9</sup> and Smith<sup>7</sup>, 1997)

Impact	Comment
<i>Potentially good</i>	
1. Care may improve if standardized with clinical practice guidelines, education of patients and providers, and monitoring.	No data yet, but reason to expect improvement based on other types of chronic care.
2. Reimbursement for some "overvalued" services, such as the technical aspects of radiotherapy administration or profit margin on chemotherapy will go down.	Good. Lower reimbursement is a social good.
3. Less costly but less reimbursable palliative care, e.g. hypofractionated radiotherapy, may increase.	Good.
4. Hospice care and other types of "undervalued" care will increase with more emphasis on education about end of life care.	Good.
5. Organizations may rationalize types of treatments based on efficacy.	Good. It is probably more "ethical" for a group of people to make decisions about limits of care than the individual physician.
6. Patients will have less access to low-yield treatments, e.g. high dose chemotherapy for chemotherapy-insensitive metastatic breast cancer.	It may be easier to say "no" with institutional support and legal protection.
<i>Potentially Harmful</i>	
1. Patients could be forced into hospice care without access to palliative chemotherapy.	Unsubstantiated but likely.
2. Patients may not be offered all the options for care, e.g. marginally more effective or less toxic but more expensive drugs like mitoxantrone for breast cancer (less alopecia and mucositis compared to adriamycin, but 2-5 times more expensive).	Unclear, except that patient autonomy will be lessened.
3. Patients may not be given treatments judged by their medical care organization to be of little benefit, e.g. chemotherapy which extends life by 4 weeks.	One health care system has decided not to cover an expensive palliative chemotherapy for pancreas cancer, gemcytabine, due to its high cost (about \$1,000/week) and low efficacy (improved survival from 4 to 5 months, but no long term benefit.) (Personal communication, G. Katterhagen, June 1998)
4. Palliative care may suffer at the expense of curative or adjuvant chemotherapy, and vice versa.	This may happen if oncology budgets are capped; experience from other countries suggests that palliative care with less chemotherapy is usually maintained.
5. Fewer home care and hospice services are likely to be available, regardless of type of management.	Highly likely, in the current trend to cost savings.
6. Terminally ill patients may be undervalued.	
7. Institutions, groups, or managed care plans have conflicts of interest without the same loyalty to individual patients as practitioners.	On the other hand, the individual practitioner may make inappropriate judgements about either rationing (or the converse) at the bedside without considering the implications. <sup>10;11</sup>

One approach to quality of care improvement and cost control has been clinical practice guidelines. Clinical practice guidelines are defined as “systemically developed statements to assist both practitioner and patient decisions about appropriate health care for specific clinical circumstances.”<sup>12</sup>

*What has been the impact of practice guidelines on medical care?*

The data from other medical disciplines are favorable, with some evidence for improved care and better outcomes.<sup>13-16</sup> In the most rigorous review, explicit guidelines improved the process of care in 55 of 59 published evaluations, and in 9 of 11 that assessed outcomes.<sup>14</sup> There may be publication bias against negative reports, or reluctance to report failed attempts to improve practice, so enthusiasm for any single report should be tempered with the skepticism accorded a high response rate in a phase II chemotherapy trial. However, the weight of the “Phase II” evidence is in favor of the standardized guideline process, and there are a number of randomized “Phase III” non-randomized trials showing efficacy.<sup>14</sup>

However, the influence of guidelines has not been stringently evaluated in cancer treatment. The purpose of this section is to review the current data on creation, dissemination, evaluation, and practical use of clinical practice guidelines and clinical pathways in oncology. This report has four sections: 1) The Background on Guidelines. 2) Review of published data, with concentration on articles that included evaluation programs. 3) Interviews with leaders in the field. And 4) Recommendations.

## **Section 1: The Background on Guidelines**

*Our perspective as clinicians and health service researchers*

There are many valid perspectives from which to view the discussion on quality of care. These might include, but are not be limited to, those of patients, families, health care providers, the community, the health care organization, the health care system, the insurer, one group of insured patients such as those in Medicaid, and society as a whole.

In this report, we have taken the perspective of the clinician or health care provider interested in health service research, since that is what we know. When possible, we have tried to point out the biases inherent in this approach.

*The ethics of guidelines*

A full discussion of the ethics of these issues is beyond the scope of this paper, but the issues important to the practice of cancer medicine.<sup>17</sup> Practice guidelines are not inherently unethical. They do include non-medical values such as cost control, utilization review, oversight, decreasing liability risk, etc. which presents some opportunity for misuse.<sup>17</sup> Allowing care that is acceptable but could be improved can also pose ethical issues often not addressed. Probably the most

important and simple tests is the morning paper test: “How would it look on the front page of the morning paper?”<sup>18</sup> All the interventions discussed herein meet that simple criterion. It is important to remember that there is no one right perspective, and often each health care provider will wear different hats during the lifecycle of care.<sup>19</sup>

*The legal aspects of guidelines*

This subject has been the topic of numerous reviews. Although a full review of this issue is beyond the scope of this report, Miller notes “good medicine makes good law.”<sup>20</sup> In brief, guidelines may define a standard of care. If the professional follows that standard, he or she “...has little to worry about with regard to malpractice liability.” If he or she deviates from the guideline, the malpractice standard will continue to be the ordinary practice of oncologists.

*A practical model to evaluate the likelihood of guideline success*

Grimshaw and Russell report a plan to improve effectiveness of clinical practice guidelines by Development, Dissemination, and Implementation strategy. The guidelines with highest likelihood of success include those with internal development, specific educational intervention, and a patient specific reminder at the time of consultation. They suggest that national external, published-only, general reminder programs will have low probability of success, and review the evidence that guidelines by themselves do not change process or outcomes substantially. We have modified their original framework to include Accountability. Within the text, we will try to analyze each program based on this model.

Table 3: A framework for analysis of clinical practice guideline success (modified from Grimshaw and Russell<sup>14</sup>)

Likelihood of success	Development	Dissemination	Implementation	Accountability
High	Internal	Specific educational intervention	Patient specific reminder at time of encounter	Practice monitored, feedback given
Above Average	Intermediate	Continuing Education	Patient specific feedback	Practice monitored
Below Average	External. local	Mailing targeted groups	General Feedback	None
Low	National/external	Publication in journal	General feedback	None

*What guidelines are available, and who is making them?*

There are two general types of guidelines: path, or algorithm, guidelines which may be, used to describe the current standard of care; and boundary guidelines, used to define the appropriate use of a new (and generally expensive) technology.<sup>21;22</sup>

There are multiple groups making oncology clinical practice guidelines, and at least 40 making medical care guidelines. The major ones are the National Comprehensive Cancer Network

*Clinical Practice Guidelines*

(NCCN), and American Society of Clinical Oncology (ASCO). Representative samples are listed in Table 4. The AHCPR is developing a free website with listings of all available guidelines, but no information is available yet on scope of participation. Many other hospitals and health care systems have developed their own guidelines; for instance, Medical College of Virginia Hospitals has guidelines in place for febrile neutropenia, use of anti-emetics, use of single daily dose antibiotics for infection, etc. but they are not commercially available.

Table 4: Guidelines available in the literature

Group	Guidelines	Comment
National Comprehensive Cancer Network (NCCN)	Path or algorithm guidelines for all common cancers.	Evidence-based, with consensus; when no consensus possible, options listed  Intended for mandatory use for all participating cancer centers. No set date for implementation. No set benchmarks for care. Adopted in the community for use outside of NCCN cancer centers.
American Society of Clinical Oncology	Boundary guidelines for new technologies. Hematopoietic growth factors Outcomes important enough to justify treatment Anti-emetics Surveillance of breast and colorectal cancer patients	No data yet on compliance or outcomes. Evidence based with consensus demanded before approval.  Adopted by the community but no data available on compliance or outcomes.
Society for Surgical Oncology	Path or algorithm guidelines for specific diseases: Management of non small cell lung cancer Metastatic prostate cancer Path guidelines for management of common surgical problems <sup>23-31</sup>	Likely that all future guidelines will be boundary guidelines for new technologies, with overlap of ASCO and NCCN methods and topics.  Consensus panels
American Urology Association	Path guidelines for common urology problems Localized prostate cancer	Consensus based on evidence.
University of California Cancer Care Consortium (UC and PONA, Inc.)	Path guidelines for most solid tumors	PONA did systematic reviews, reviewed with UC faculty for consensus.
Guidelines not available (proprietary)		

Kaiser Permanente Salicknet, Inc. Value Health Science, Inc. Multiple others	Path guidelines for management of common oncology problems	Consensus based on evidence. Not available outside the corporation. Kaiser plans to have a full complement of guidelines within 2 years (personal communication, Allen Brecht.)
--	---	--

*What is the quality of published guidelines?*

It is difficult to make any generalizations about the quality of guidelines because there are so few competing guidelines, and so little evaluation. In general, the published guidelines have met some of the published Institute of Medicine standards for creation and publication.<sup>12</sup>

Table 5: Institute of Medicine Desirable Attributes of Clinical Practice Guidelines<sup>12</sup>

<b>Attribute</b>	<b>Description</b>
Validity	Lead to health and cost outcomes projected for them
Reliability	Given the same evidence and methods, another set of experts would produce essentially the same statement
Applicability	Explicitly state the population to which they apply
Flexibility	Identify specific exemptions
Clarity	Unambiguous language and precise definition of terms
Multi-disciplinary Input	Participation by representatives of key affected groups
Scheduled Review whether revisions are warranted	When they should be reviewed
Documentation	All procedures, participant, assumptions, analytic methods must be documented and described.

Both the ASCO and the NCCN guidelines meet the standard criteria of the Institute of Medicine for validity, reliability, etc. However, even within these broad categories there can be discrepancy since the process of creation has not been disclosed. For example, the guidelines for follow up of breast cancer patients<sup>32</sup> were changed by the ASCO Board to be consistent with board policy, when the data conflicted with board policy. There has been one well done randomized clinical trial that showed general practice doctors who followed breast cancer patients had the same patient outcomes as specialist surgeons.<sup>33</sup> The original guideline that stated a primary care physician could follow patients was changed to reflect the ASCO policy that all cancer patients have the right to see a cancer specialist at all times. Without documentation of the internal history of the guideline, it is not possible to show adherence to the data, versus consensus or policy. Regardless, the published guidelines appear to be “state of the art” guidelines and are similar for content when they overlap.

There have been few comparisons of alternative guidelines except 1) one for follow up care of colorectal cancer patients, 2) one of breast cancer, and 3) one of non-small cell lung cancer. There were significant disparities between the guidelines suggested by NCCN, the National Surgical Adjuvant Breast and Bowel Program (NSABP) suggestions for patients on clinical trials,<sup>34</sup> and guidelines that could be made from the evidence of the just-published largest randomized clinical trial.<sup>35</sup> As noted in Table 4, the clinical trial evidence that annual colonoscopy, annual chest radiograph, and regular CAT scans did not improve survival could lead to marked decrease in resources spent on follow up of colorectal cancer patients with little if any clinical harm. (It is important to note that this is not clinical nihilism, but rather directed surveillance care to ensure that what is proven helpful gets done.) The new evidence will provide an opportunity to assess the rate of change of guidelines, and see if and when new material is adapted.

Table 6: Comparison of follow-up plans for colorectal cancer patients (adapted from Smith and Bear<sup>34</sup>)

Test	Evidence based, based on the randomized clinical trial standard group <sup>35</sup>	National Comprehensive Cancer Network <sup>36</sup>	NSABP* C-06 Follow up Regimen
History and Exam	Every 3 months x 2y Every 6 months x 3y	Every 3 months x 2y Every 6 months x 3y	Every 6 months x 5y then yearly
Fecal occult Blood	Every 3 months x 2y Every 6 months x 3y	Every 3 months x 2y Every 6 months x 3y	Every 6 months x 5y then yearly
CBC	Every 3 months x 2y	Every 3 months x 2y	Every 6 months x 5y
LFT	Every 6 months x 3y	then every 6 months x 3y	
CEA	Every 3 months	If elevated at diagnosis then every 6 months x 2y, every 12 months x 5y	Every 6 months x 5y
Colonoscopy	Every 5 years	Repeat at 1 year, then every 3 years	Barium enema and/or endoscopic exam at 12 months post-therapy, then at least every 3 years
CXR	As indicated	Every 12 months x 5 years	12 months x 5y
CAT abdomen	As indicated	Every 6 months x 4y then every 12 months x 3y	as indicated

\*NSABP = National Surgical Adjuvant Breast and Bowel Project.

Edge<sup>37</sup> compared the breast cancer guidelines of the Ontario Cancer Treatment Practice Guidelines initiative, Revlon/UCLA, Association of Community Cancer Centers, Surgical Society of Oncologists, and NCCN breast guidelines<sup>38:39</sup>. Others exist, as well<sup>40</sup> No formal evaluation of standard characteristics was done. He notes that axillary node dissection is required by all but that practice in the community is changing due to new studies showing extremely low risk in some patients and the use of the sentinel node technique. He notes a study of NCCN guidelines at his own institution, Roswell Park Cancer Institute, showing fair compliance but with variations that met acceptable standards of care.<sup>37</sup>

In the only other published comparison of guidelines, both the ASCO<sup>41</sup> and Ontario Evidence-Based Medicine Guideline<sup>42</sup> for management of non-small cell lung cancer agree that chemotherapy for metastatic lung cancer is indicated to improve survival.<sup>43</sup>

*Guidelines, evidence, and differing philosophies*

One of the conundrums of guideline preparation can be simply stated:

- If there is good scientific evidence for a procedure, then practice should be uniform and no guideline is needed. However,
- ...where practice is least uniform, and a guideline is most needed to standardize practice for good outcomes, the evidence on which to base a guideline is most likely to be lacking.

Cook and colleagues<sup>44</sup> show that systematic reviews of the evidence can assist in the process of guideline creation and implementation in several ways: 1. To provide the basis for the guideline. 2. Point out areas of needed research. And 3. Educate practitioners and help keep them up to date with the literature. They point out that if the data to make a guideline is inconclusive, then the guideline should be targeted for early assessment to make certain that outcomes due to it are acceptable. After the systematic review, however there will be differences of opinion on what to do with the evidence.

There will be lack of uniformity for some parts of guidelines based on the following, for which there is no “right” answer. Such plurality in medical thinking is both a strength and weakness of United States medicine. Any guidelines for cancer must directly address each of the issues listed below.

- *The process of development will be different*, from strictly evidence based to consensus.
- *The management of consensus (or lack thereof) will vary*, with some groups demanding only one option, others allowing more.
- *The interpretation of data may be different based on available resources*. Those centers with high dose chemotherapy facilities will be more likely to adapt their guidelines to include high dose chemotherapy.
- *The interpretation of the data based on “effect size” and acceptance of statistical probability will be different*. Some patients and practitioners will think a 6-month improvement in disease free survival with a p value of 0.07 (for high dose chemotherapy in lymphoma) is sufficient evidence of clinical benefit; others will not.
- *The interpretation of preliminary evidence will vary from practitioner to practitioner*. A phase II trial of high dose chemotherapy in women with > 10 positive lymph nodes that

### *Clinical Practice Guidelines*

shows 72% disease free survival at 6 years, compared to contemporary controls with worse results, will be accepted as standard treatment at some centers. Others centers will point out the bias in selection and treatment, and wait for the randomized clinical trials to be completed before adopting a more aggressive treatment. Either approach can be justified according to rules evidence in place.

- *The interpretation of what to do until evidence is available will vary from practitioner to practitioner.* For example, there are no randomized clinical trials of best supportive care vs. second line chemotherapy of non-small cell lung cancer. There are limited phase II data from single institutions. The ASCO guidelines noted that no benefit could be proven in either survival or quality of life, so no recommendation could be made for or against second line chemotherapy.<sup>41</sup> In a survey of practices for dying patients, however, over 50% of ASCO members would give second line chemotherapy to a 43 year old woman with progressive non-small cell lung cancer, nearly 20% would give third line chemotherapy, and a substantial number would give fourth line chemotherapy. (Personal communication, Ezekiel Emmanuel, 1998)

### *Barriers to physician compliance*

Katterhagen outlined the obstacles to overcome in his attempts to implement guidelines in the California health care system: 1. “A lack of market awareness and need to decrease costs and produce superior outcomes...” 2. “Anger over declining autonomy and power”. And 3. “Falling incomes”. He noted that physicians, like other people, “... basically respond to three forces: financial reward, a desire for a good reputation, and peer pressure.” He also advocates that 10% of the time be spent on guideline development and 90% on implementation, and that 80% of the efforts on change be directed on the 20% of medical staff members who are the opinion leaders.<sup>45</sup>

Grilli and Lomas and colleagues attempted to define the characteristics of guidelines and practitioners that led to compliance and improved care. They showed that change in practice was most significant when the guideline was based on solid data, had discrete and concrete steps for change, and did not require knowledge or skills outside of the practitioner’s current realm.<sup>46</sup> This evaluation was done only for guidelines with voluntary implementation and no discrete accountability, so the study may not be applicable to health care systems that incorporate accountability and specific education. (It is also not heartening for those attempting to impart new and must-be-learned knowledge to old practitioners.)

### *Using guidelines to monitor practice*

The guideline is intended to influence practice; in order to assess the impact, the guideline must be converted into an evaluation tool. This process has been well described in AHCPR literature<sup>47;48</sup> but the design of a guideline explicitly for this process is often overlooked. For instance, each guideline should have readily discernible benchmarks, or targets for good practice.<sup>49</sup> but most do not.

*The audience for guidelines and their evaluations*

The audience for the guidelines will determine the guideline content and scope, as well. Informal discussions about the ASCO guidelines often centered on “If we do not make them, someone else will” as much as a commitment to improved care. If guidelines are made to illustrate compliance with regulations, they are less likely to take on the most controversial issues. If they are made to illustrate high quality as a marketing tool, then they will be made to achieve achievable targets. For example, the rate of breast conserving surgery nationwide is about 25%. A reasonable target would be 60%<sup>50</sup>. If the current standard in your organization is 50%, audit would show that you have twice the national average rate. Getting practitioners to change the remaining 10% would require careful goal setting, auditing, and feedback. It might not be worth the trouble if the goal is to reach a good rather than maximize quality of care.

## **Section 2: Review of Published Data**

### **Literature review**

#### *Methods*

Medline was searched from 1966 to the present with the terms clinical practice guidelines, clinical pathways, care maps, outcomes management, and oncology. A directed search of primary papers was undertaken.

There have been a small number of major modern day attempts to improve cancer care using clinical practice guidelines. A full listing is available in Appendix I. Only studies that included an evaluation component are included here with no other exclusions. Of these, only a few could be considered as unqualified successes, but all give useful information about the process of improving care. We have included both European and American studies here, as the methods are similar even if the medical reimbursement methods differ somewhat.

#### ***U.S. Experience***

U.S., 1987: The Community Hospital Oncology Program (CHOP)

Ford and colleagues concluded that the attempts of the Community Hospital Oncology Program (CHOP) to improve or standardize cancer care in U.S. hospitals had “no evidence of diffusion of guideline principles to the majority of practicing physicians.”<sup>51</sup> While the study is old, the methods are still in common use and shed light on current results.

The authors anchor the project in the demonstration of marked practice variations during the 1970s, with concerted attempts to improve and standardize care by Professional Standards Review

Organizations and the audit technique. The CHOP program was funded in 1981 for 18 months of planning to include 23 programs. In summary, the health care professionals who saw the most cancer patients in each community developed “site-specific patient management guidelines for staging, medical management, nursing, and rehabilitation.” From 1982 to 1984, 17 CHOP programs were funded for implementation.

Data were abstracted retrospectively from newly diagnosed breast (n=1,922), rectal (n=592), and small cell lung (n=388) cancer patients at the 17 CHOPs. The study was performed in 1985-6 after the full implementation of the CHOP. The “gold standard” was that all breast and lung cancer patients would have clinical staging before definitive therapy, and all but lymph node negative breast cancer patients have a radiation therapy consultation. For the presence or absence of ANY breast cancer clinical staging noted in the chart, the range was 3% to 90%, and only 33% of all charts had clinical stage noted before definitive therapy. For women with positive lymph nodes, 73% had a medical oncology consultation. For rectal cancer patients, only 27% had a radiation therapy consultation, considered the standard of care. For small cell lung cancer patients, 67% had clinical staging, but only 50% had a radiation therapy consultation, which had also been defined as standard.

Table 7: Conformance to accepted standards of care

Cancer	Standard(%)	Conformance (%)
<i>Breast</i>		
Clinical staging	100	33
Medical oncology consultation if node positive	100	73
Radiation oncology consultation	100	27
<i>Rectal</i>		
Staging	100	67
Radiation therapy consultation	100	27
<i>Small cell lung cancer</i>		
Radiation oncology consultation	100	50

Some of the most important variance was associated with physician characteristics, not patient or disease characteristics. Those who were principal investigators or on the Executive Committee conformed slightly better, but there was no evidence of diffusion (Table 8). Younger physicians tended to give “more” therapy. Physicians with more and better cancer training tended to perform better when measured against the accepted guidelines.

Table 8: Adherence to guidelines by physician characteristics

Element	Compliance with guidelines (%)			
	PI/Exec committee	Participation Guideline committee	Other MD	
Breast cancer staging	49.5	28.5	31.9	P<.001
Breast cancer Med onc consultation if node +	73.4	76.0	71.0	NS

*Clinical Practice Guidelines*

Small cell lung clinical staging	80.4	59.5	60.2	P<0.2
Small cell lung radiation oncology consultation	50.0	50.0	51.0	NS
	Years in practice			
	0-9	10-19	20-29	
Breast cancer staging	50.3	38.0	31.3	P<0.001
Breast cancer Med onc consultation if node +	91.5	73.3	72.9	P<.01
Rectal cancer radiation consultation	37.5	31.5	24.8	P<.01
Small cell lung clinical staging	60.8	66.4	60.0	NS
Small cell lung radiation oncology consultation	45.4	50.0	50.7	NS

PI=principle investigator; Exec comm=executive committee

The authors conclude that there was no demonstrable impact of the guideline management program, and that the data fail to support that participation in the development process enhances adoption (and thus diffusion of state of the art cancer management.) It is also important to note that the study was only of the process of medical care, and data on actual patient outcomes is unknown.

Some CHOPs developed more intense programs to encourage compliance that included tumor boards, educational efforts, peer pressure, and administrative action. The CHOPs that were able to ensure staging did so only by requiring completion of forms before submission of specimens to pathology, or loss of privileges if forms were not completed. As the authors note, these measures were successful but did not even require guidelines. The authors conclude that for clinical practice guidelines, "...leadership and organizational commitment appear to be the necessary ingredients."

On the CPG Success chart, this intervention would be predicted to have a low chance of success; even if the guideline is developed locally, if there is no plan for implementation and no accountability the guideline will not change practice.<sup>45</sup>

Likelihood of success	Development	Dissemination	Implementation	Accountability
High	Internal	Specific educational intervention	Patient specific reminder at time of encounter	Practice monitored, feedback given
Above Average	Intermediate	Continuing Education	Patient specific feedback	Practice monitored
Below Average	External. local	Mailing targeted groups	General Feedback	None
Low	National/external	Publication in journal	General feedback	None

U.S.1995: Outcomes management for gynecologic oncology

Morris and colleagues at M. D. Anderson<sup>49</sup> established practice guidelines and collaborative care paths in 1994 for total abdominal hysterectomy with oophorectomy and staging biopsies; tumor reduction surgery; radical hysterectomy with node dissection; and vulvar resection with groin dissection. The program was started by a group of four gynecologic oncologists and one nurse practitioner, with a strong administrative mandate to control costs and maximize patient outcomes. The draft care paths were circulated to all involved groups for comment. Accountability was maximized by documentation for each care path, including standard forms, standard data collection sets, patient education forms, etc.

The results from the first 30 patients who underwent surgery following the path were compared to 29 patients matched for age, indications for surgery, stage, and attending surgeon. These patients were chosen from the time when the care paths were being discussed, to see if there was a “Hawthorne Effect” of better behavior while under observation. Another control group of 73 patients was chosen from the time before the care paths were being discussed. All groups were comparable, and differences among the groups could not account for the findings. Results are shown in Table 9.

Table 9: Results of the care path implementation

Outcome of interest	Prepath N=73	Planning N=29	Path N=30	P
Costs				
Total	8435	9046	6794	<.002
Medications	1042	1203	675	<.001
Laboratory tests	375	1203	96	<.001
Room	4080	3515	2885	<.001
Supplies	1182	1310	1099	NS
Procedures	584	806	655	NS
Pathology	627	689	643	NS
Professional fees			Unchanged	
Length of stay (days)	7	5	4	<.001
Complication rates			Unchanged	
Patient satisfaction			High	

Morris and colleagues concluded that the implementation of the care path, and being held accountable to results from it, significantly improved outcomes, decreased length of stay, decreased costs, and kept patient satisfaction high. They made could not identify any adverse outcomes, even as they further reduced length of stay to 3 days. The authors made some very specific points based on their experience but not otherwise verified: 1. Care paths must be physician driven to work. The team approach is essential. 2. The paths must define desired outcomes, e.g. discharge when pain is controlled, not on day 4. There must be ongoing assessment of meeting the desired outcome. And 3.Care paths should be defined using formal methods, based

on evidence and consensus. This study is immediately applicable to most surgical cancer admissions in the United States.

In summary, the likelihood of success of this program was high, and it appears to have improved the process, outcomes, and cost of surgical care.

Likelihood of success	Development	Dissemination	Implementation	Accountability
High	Internal	Specific educational intervention	Patient specific reminder at time of encounter	Practice monitored, feedback given
Above Average	Intermediate	Continuing Education	Patient specific feedback	Practice monitored
Below Average	External. local	Mailing targeted groups	General Feedback	None
Low	National/external	Publication in journal	General feedback	None

U.S., 1994: Management of prostatectomy

Radical prostatectomy is the most common urologic cancer operation. After implementation of a clinical pathway<sup>52</sup> LOS decreased from 5 to 3.6 days, and costs decreased from \$7916 to \$6934 (-12%). The team concluded that standardized preop and postop management led to significant cost savings. The hospital LOS each year had already decreased from 7, 6.1, 5, to 3.6 days so trend was evident even before the guideline. After CP Implementation, formal quality of life scores were high, as was patient satisfaction, but there was no data before the CP.<sup>53</sup> Of note, the decreased LOS did not lower patient satisfaction. (Or, alternatively, the instrument is not sensitive, or the differences were missed.) Further improvements can be made, based on data from Edmonton, Alberta where transurethral resection of the prostate (TURP) patients were compared in a home vs. hospital stay study. Readmission to hospital, reuse of health care services, complications, satisfaction, etc. were all the same. Based on the success of the pilot program, this early discharge program was implemented community wide.<sup>54</sup>

U.S., 1997: Model comprehensive practice

One cancer group redesigned their care model to include medical, radiation, surgical and all other services in one system.<sup>55</sup> Clinical pathways and treatment protocols were made for all common illness. In three years, the practice increased from 16 to 24 physicians, the number of offices increased from 12 to 17, and physician compensation went up 20%. The cost of service was reported to be reduced by 50%, mostly by reduced hospitalization. Patient encounters were doubled, and clinical research referrals up 300%. According to the authors, this model has preserved autonomy, decreased variance, and facilitated clinical research. However, this is the equivalent of an abstract of a promising phase II trial, with little actual data presented and needs to be confirmed.

U.S., 1996: Endoscopic sinus surgery

A clinical practice guideline for endoscopic sinus surgery was developed by consensus at an academic medical center practice<sup>56</sup>. The 41 patients on the CPG were compared to a random sample of 50 patients off it, with the same doctors doing the surgery. There was no evidence of selection bias. There were no differences in most surgical variables. However, CPG patients had fewer unplanned admissions, lower costs and charges. Costs decreased for all, whether the patient was on the CPG or not, suggesting some diffusion or similar trends in each group. Acceptable short term health outcomes at lower costs are the advantage of the CPG.

U.S., 1995-96: Management of high dose chemotherapy

All 94 Scripps clinic patients undergoing high dose chemotherapy with stem cell transplantation (HDC) were allocated to full outpatient, short stay, or full inpatient HDC based on their preference and the availability of a care taker. All were treated on set programs with standardization. There was no difference in short term outcomes such as short term survival or toxic deaths. The average LOS of patient was reduced from 17.3 to 8.2 to 2.7 days. Mean cost decreased from \$39,700 to \$36,200 to \$29,400 (p<0.029). The authors conclude that for patients with a caretaker, this standardized outpatient approach maintains outcomes, and reduces cost.<sup>57</sup>

U.S.1994-present: The American Society of Clinical Oncology

The ASCO clinical practice guidelines program began in 1993 under the chairmanship of Dr. Rodger Winn from M.D. Anderson Cancer Center, the national director of the Community Clinical Oncology Program (CCOP). In a survey of ASCO members, guidelines for cancer treatment had been highly ranked among priorities. The current guidelines program is summarized in Table 10.

Table 10: Status of ASCO Guidelines

Year started	Guideline	Status
1993	Hematopoietic growth factors	Published, 1994
1994	Tumor markers	Published, 1996
1995	Breast cancer follow up	Published, 1997
1995	Colorectal cancer Follow up	Submitted
1995	NSCLC, IIIB/IV	Published, 1997
1996	Prostate cancer, advanced	Pending
1996	Anti-emetics	Submitted for approval
1996	In fusal FU, ADR	Cancelled due to perceived lack of data
1996	Biphosphonates	In development
1996	Chemoprotectants	In development

The ASCO guidelines on hematopoietic growth factors are the only ones that have been subjected to analysis of use and impact. Before the publication of the guidelines, the majority of projected uses fit the ASCO guidelines. However, there were significant variances from evidence-based use. For example, there was no evidence to support use in febrile neutropenia, febrile neutropenia, dose intensification outside a clinical trial, and in acute leukemia. In 1994, the survey showed that a significant number of practitioners were using the CSFs these ways. Of note, the use

of CSFs was strongly related to type of practice, with Health Maintenance Organization and academic physicians using less CSFs and more often choosing a strategy of dose reduction.<sup>58</sup>

Evaluation of the guideline offered opportunity to assess change in use patterns. A survey done by marketing firm Goldman Sachs<sup>59</sup> a few months after the publication of the ASCO guidelines showed that half of respondents expected to increase their use of CSFs, with a small decline in expected increase reflecting saturation of the market. About 20% of respondents had experienced an impact of the ASCO guidelines. 9% had reduced usage for treatment of neutropenia; 7% indicated that guidelines led to more restrictive reimbursement; 6% had increased use for secondary prophylaxis. More non-hospital based physicians changed their patterns of use based on ASCO guidelines than hospital based physicians, 24% vs. 14%.

The actual impact of the ASCO guidelines has been hard to prove. We performed surveys in 1997 after the membership had been exposed to the 1994 guideline and 1996 update, both published in the *Journal of Clinical Oncology*. The data can be interpreted in two ways: either showing substantial improvement from before the guideline<sup>60</sup>, or, continued overuse never supported by the evidence. (Bennett, Smith, Weeks, et al, in preparation.) There was less overuse of CSFs in one scenario, treatment of febrile neutropenia, with use dropping from 39% to 29% ( $p < 0.05$ .) However, the evidence-based use should be near 0%. Treatment of febrile neutropenia with a right lower lobe pneumonia diminished slightly from 54% to 46% ( $p < 0.05$ ). Again, the evidence-based use should be near 0%. Significant routine overuse of CSFs persisted in primary prophylaxis, 6 to 39% depending on scenario; the use should be near 0%, as there is no evidence to support efficacy. Significant overuse (up to 30% of respondents stating they "always, usually, or sometimes" use CSF) as treatment for afebrile neutropenia persisted despite published evidence of no benefit<sup>61</sup> as well as the ASCO guideline. Physician characteristics were again likely to predict use: those in academic medical centers or HMOs were still more likely to use dose-reduction strategies and less likely to use CSFs than physicians in private practice.

In the 1997 survey, we also asked about use of CSFs for acute leukemia, a new indication since the 1994 guidelines.<sup>62:63</sup> Physicians were ambivalent in their use of CSFs for acute leukemia patients, as is appropriate from the available data showing no harm but no major disease benefit. (The largest trial published in December 1997 showed a five day reduction in hospital stay, but there has been no consistent effect on mortality; Heil, Blood, 1997) Physician or practice characteristics were strongly correlated with propensity to use growth factors: those in fee for service or those who were hematologists or hematologists/oncologists were more likely to use CSFs. The majority of physicians use CSFs in ways proven to be effective: 79% of respondents would start CSF after chemotherapy or when bone marrow aplasia was documented, both proven strategies. However, 21% would start CSF after the patient became neutropenic or neutropenic and febrile, both unproven strategies almost certain not to work as successfully.

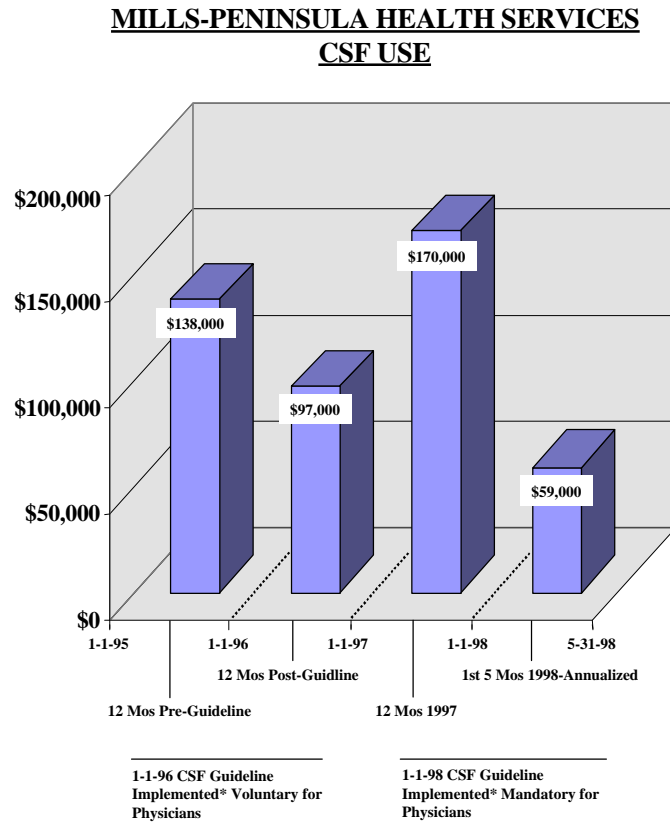
It is important to note that none of the ASCO evaluations have involved actual chart audits. Until these difficult and expensive studies are done, one cannot show that CSF use in survey actually parallels CSF use in practice. One must not underestimate the difficulty in performing community-based surveys. The large practices with the high volume and good databases that would

support such an audit of actual use are those where practitioners, by report, were least likely to use CSFs. It is also important to note that patient outcomes are not likely to be harmed either way with CSF use, since evidence of marked patient benefit for routine oncology care is still not evident.<sup>64;65</sup>

There is anecdotal evidence that the ASCO guidelines can be used to reduce inappropriate used CSF's, if accountability is made a prominent component. Dr. Gale Katterhagen described markedly disparate uses of growth factor among oncologists in Northern California when he merged a number of practices. Some oncologists used them routinely after standard chemotherapy as primary and secondary prophylaxis, and for treatment of afebrile and febrile neutropenia, while others used them rarely if at all. He instituted a common review mechanism: there would be no restrictions of the use of CSFs, but the prescribing oncologist must first call his office and describe under which ASCO guideline the use was warranted. According to Dr. Katterhagen, use of CSFs declined immediately -- except for those uses that clearly fit the ASCO guidelines, as shown below. Again, accountability and mandatory review of the guidelines were key to changing prescribing behavior. (personal communication, Dr. Gale Katterhagen, June 1998) This approach of increased scrutiny for high-ticket items, and behavior by physicians (when they have capital at risk) similar to managed care organizations, has been well described.<sup>55</sup> Figure 1 shows the dramatic decline in CSF use in one hospital system after implementation of a patient specific reminder and accountability.

**Figure 1: Change in CSF Use**

There are several lessons to be learned from the ASCO experience with growth factor guidelines. First, high visibility of the guidelines alone does not ensure change in knowledge or



**\*Pre-Authorization of Medical Director for Cancer Program necessary before drug is released from Pharmacy**

behavior. Second, the guidelines must be presented to a membership ready and willing to change. There are no disincentives to giving CSFs at present, and no reason to change for most practitioners. The CSFs rarely do harm, and can be a significant source of income to the practice. Thirdly, the dissemination of guidelines without accountability is unlikely to lead to significant change in practice. Fourth, a minimal amount of accountability and mandatory review can almost certainly improve physician prescribing practices without special incentive systems.

The likelihood of success of the ASCO CSF guidelines would be predicted to be low, as demonstrated. However, the process can be made to succeed with minor changes (printed in *italics*,

below) and by adding a high level of patient-specific implementation and accountability. (“Call the doctor’s office before each use.”)

Likelihood of success	Development	Dissemination	Implementation	Accountability
High	Internal	<i>Specific educational intervention</i>	<i>Patient specific reminder at time of encounter</i>	<i>Practice monitored, feedback given</i>
Above Average	Intermediate	Continuing Education	Patient specific feedback	Practice monitored
Below Average	External. local	Mailing targeted groups	General Feedback	None
Low	National/external	Publication in journal	General feedback	None

U. S., 1994 Lung, breast, and colorectal cancer management

Patton and Katterhagen<sup>66</sup> described a successful program to standardize care for cancer patients in Northern California, partly in response to managed care influences. They formulated critical pathways using a set method, reproduced here for illustration.(Table 11)

Table 11: Steps in the process of pathway design and implementation

Step	
1.	Representative charts of patients with the study condition are audited.
2.	Working group reviews representative charts of patients with the study condition. Key physician serves as facilitator.
3.	Chart reviews, current practice science, and financial data are shared with the group.
4.	Disparities between current practice and science/system efficiencies are illuminated.
5.	Linkage of historical practices and outcomes made to current clinical and financial outcomes.
6.	Consensus of medical staff and hospital staff for the critical pathway and target outcomes is written.
7.	Education of hospital and medical staff first, then implementation.

The authors used a “pre/post” method of comparing patients on the guideline to those in the year before. Results are shown in Table 12. The exact contribution of their critical pathways to the change in outcomes cannot be assessed, as there is no control group (a similar health system immune to the same cost pressures) possible in Northern California.

Table 12: Comparison of patient on and off pathways

Pathway	Pre	Post
Pathway 82: Respiratory Cancer		
LOS	5.9 days	4.5 days
Costs	\$6200	\$5700
Pathway 75: major chest procedure (n=95)		
LOS	11 days	5 days

Costs	\$20,000	\$10,000
Pathway 148: bowel surgery		
LOS	12 days	6 days
Costs	\$18,000	\$8,000

All figures estimated from Patton and Katterhagen.<sup>66</sup>

The authors noted a number of standardized patient procedures that were perceived to be better medical and nursing care, including the following: 1) mandatory pre-op teaching for respiratory care and bowel cleansing. 2. Use of patient controlled analgesia with morphine rather than “prn” meperidine or morphine (with a drop in post op confusion from 11% to 2%). And 3) discharges distributed throughout the week rather than concentrated on the pre-weekend.

The authors note that success of their system depends on understanding the process of medical care and the power of group process to change practice once consensus is reached. Their methods are notable for involvement of the whole practice group, practice based on evidence, practice based on outcomes, and accountability.

The likelihood of their program to succeed is high, as shown by the results.

Likelihood of success	Development	Dissemination	Implementation	Accountability
High	Internal	Specific educational intervention	Patient specific reminder at time of encounter	Practice monitored, feedback given
Above Average	Intermediate	Continuing Education	Patient specific feedback	Practice monitored
Below Average	External. local	Mailing targeted groups	General Feedback	None
Low	National/external	Publication in journal	General feedback	None

U.S., 1996: Cancer pain relief in Utah

A number of studies have documented inadequate pain relief among cancer patients<sup>67-70</sup> and the terminally ill.<sup>71</sup> Similar studies have found under use of radiation as palliative care in Sweden.<sup>72</sup> The Agency for Health Care Policy and Research (AHCPR) established a Clinical Practice Guideline for Management of Cancer Pain in 1994. Baseline data collected on 10 patients at 7 acute care hospitals in Utah showed low compliance with the guidelines. Follow up data in 1996 showed improved compliance with six “core” guidelines, and data was reported on seven audited components.<sup>73</sup>

Table 13. Compliance with core guidelines (10 patients at each of 7 hospitals, n=70)

Guideline	Pre	Post	P value
1. Opioids prescribed	99	100	1.00
2. Initial pain assessment			
Rating scale used	64	79	.090

3. Ongoing pain assessment			
Pain rating scale repeated at regular intervals	27	74	<.001
Efficacy reported	83	97	.011
4. analgesic use			
Pain medicines on regular schedule	70	91	.003
5. bowel treatment plan			
Laxatives ordered	66	69	.857
6. education of family/patient			
Education about cancer pain	6	34	<.001
Written education	16	26	.238
7. patient satisfaction evaluated (not actual patient satisfaction)			
	24	97	<.001

There are not enough data to tell if the program is successful or not. Note that pain scores, as the most important outcome, were not measured. Note also the high baseline use of opioids. Based on the need for better pain management, the program has been initiated statewide but no results are available.

#### U.S., 1996: The American Urologic Association Early Prostate Cancer Guideline

In December 1995 the AUA recommended, based on the evidence, that surgery, radiation, or surveillance be offered as treatment options for patients with localized prostate cancer. The guideline was highly publicized in the literature, at scientific meetings, and in the prostate cancer patient community.

After the guidelines were released, 1000 men were surveyed from the CHAMPUS database; 500 who underwent radical prostatectomy before the guideline, and 500 6 months after the guideline. 674 patients responded. The average number of treatments offered before the guideline was 1.98, rising to 2.30 after ( $p=0.003$ ). The total number of specialists consulted before and after the guidelines was 1.35 and 1.47 ( $p=0.03$ ). 30% of the patients reported receiving a copy of the patient guide to treatment for localized prostate cancer.<sup>74</sup>

The authors conclude that the purpose of the guidelines was served: more patients had the opportunity to make informed choices. The full manuscript is under review. (Personal communication, Col. I. Thompson.)

These guidelines would be expected to have a good probability of implementation based on the specific educational intervention, and the mailing of the guidelines to each practitioner. In addition, the required change in practice is minimal and fits with societal changes in prostate cancer treatment. Their actual success, if confirmed, is encouraging; alternative explanations for success could include the intense media exposure and growing consumer movement in the prostate cancer community.

Likelihood of success	Development	Dissemination	Implementation	Accountability
-----------------------	-------------	---------------	----------------	----------------

*Clinical Practice Guidelines*

High	Internal	Specific educational intervention	Patient specific reminder at time of encounter	Practice monitored, feedback given
Above Average	Intermediate	Continuing Education	Patient specific feedback	Practice monitored
Below Average	External. Local	Mailing targeted groups	General Feedback	None
Low	National/external	Publication in journal	General feedback	None

***Relevant Experience in the World***

Canada, 1991: Compliance with clinical practice guidelines for axillary node negative breast cancer patients

The British Columbia Cancer Agency (BCCA) has attempted to improve cancer care with guidelines since the 1970's. <sup>75</sup>These guidelines were formulated based on the evidence but not made after a formal explicit review process; in essence, they were consensus guidelines of best practice. (personal communication, George Browman, MD, 1998) In 1991 there were two BCCA 2 centers, where all provincial radiation oncology was done and all 16 radiation oncologists worked. 18 of 28 medical oncologists worked there, as well, with 10 community clinical oncologists. Surgery was provided in hospitals throughout the province. The BCCA audited the charts of 2,317 breast cancer cases; in 1991; of these, 939 were node negative and eligible for this retrospective study; 661 were referred to BCCA.

The processes of care were relatively uniform. For those with indications for treatment, compliance was 95%, 77% and 68% for the radiation, chemotherapy, and tamoxifen arms. No subjects got radiation without a radiation oncology consult, or chemotherapy without a medical oncology consult. Referral to and indications for adjuvant radiation were high, 95.4% for adjuvant treatment after breast conservation. Only 7 subjects received radiation without a demonstrable indication. Chemotherapy compliance was also high, 95.9%. Of 83 women with an indication for chemo, 64 received it (77.1%). All who saw a medical oncologist received chemotherapy if it was indicated. 19 did not receive indicated chemotherapy, 13 did not see medical oncologists and 6 saw the community medical oncologists. Referral and hence treatment were far more likely for patients < 50 years. Compliance for tamoxifen when indicated (including use when indicated and non-use when non-indicated) was 89.2%, but only 67.8% for those with indication to use it actually received it.

The impact of the guidelines appears to be impressive, but there may be other explanations for the good care. There was an influential multi-disciplinary clinic in 1991 at BCCA that had some impact on practice patterns as well as the structure of the guidelines. The care in British Columbia has tended to be centralized, with much emphasis on the expert opinions of the BCCA leaders. (personal communication, George Browman MD, July 2, 1998)

*Clinical Practice Guidelines*

This study represents the only guideline that may be associated with improved survival. Olivotto and colleagues showed that the improvements in disease free (DFS) and overall survival (OS) noted during the time period of guideline implementation were similar to those seen in clinical trials.<sup>76</sup> For patients < 50, DFS increased from 65 to 76%; OS from 65 to 75%. For women 50-89, DFS at 7 years increased from 63 to 70%, and OS 54 to 58%. (p all =/< 0.05.) The timing correlated with implementation of guidelines in BCCA and province, but causality can not be demonstrated. For instance, the influence of strong expert opinion in the centralized cancer treatment system, education interventions and conferences about the evidence rather than the guidelines, or increased accountability and pressure to conform could all be partly responsible. In addition, one cannot tell if patients of cancer center and community oncology patients had the same survival.

In summary, BCCA showed that compliance with breast cancer guidelines was high overall, but could be improved. There were more variations from the guidelines among patients of the community oncologists, and those who did not get referred to the other specialist from the surgeon. The guidelines would be predicted to have a good chance of success, and did.

Likelihood of success	Development	Dissemination	Implementation	Accountability
High	Internal	Specific educational intervention	Patient specific reminder at time of encounter	Practice monitored, feedback given
Above Average	Intermediate	Continuing Education	Patient specific feedback	Practice monitored (unclear from report)
Below Average	External. Local	Mailing targeted groups	General Feedback	None
Low	National/external	Publication in journal	General feedback	None

Ontario, 1995: Experience with paclitaxel for metastatic breast cancer. Changing practice with accountability.

Levine et al describe the experience with paclitaxel, wherein practitioners had to evaluate cancer response to get a reimbursement for the drug; 412 of 418 forms were completed and , most patient received the specified dose.<sup>77</sup>There was only a 17% response rate. This report shows that form completion and compliance with guidelines can be improved by a patient specific reminder at the time of the encounter, accountability, and reimbursement; an alternative explanation is that those who bother to treat with new drugs can fill out forms.

Likelihood of success	Development	Dissemination	Implementation	Accountability
High	Internal	Specific educational intervention	Patient specific reminder at time of encounter	Practice monitored, feedback given
Above Average	Intermediate	Continuing Education	Patient specific feedback	Practice monitored

Below Average	External. Local	Mailing targeted groups	General Feedback	None
Low	National/external	Publication in journal	General feedback	None

Italy, 1987: The Italian National Research Council Evaluation

Grilli and colleagues<sup>78</sup> evaluated a program similar to the “CHOP” one begun in Italy after repeated demonstrations of a gap “...between best care and that which is actually delivered in the community”. The National Research Council began an educational strategy of disease-oriented task forces and written guidelines targeted to cancer doctors in about 1977. An evaluation of the system was performed in 1987 to assess the care given to breast, colorectal, and ovarian cancer patients; these sites were chosen as they most commonly received care at general hospitals. Guideline booklets (a total of 18,500 with updates) were made available to practitioners at scientific meetings, mailed to hospitals and sometimes practitioners. Acceptance was voluntary, and there was no feedback on performance or accountability.

The evaluation was designed to answer three questions: 1) Did the guidelines reach doctors? 2) Did the guidelines influence opinions? And 3) did doctors comply with the guidelines? Surveys were done at 45 hospitals; 770 physicians (44%) filed valid answers. Responders were slightly more likely to be younger, more likely to be women, and medical oncologists and radiotherapists rather than surgeons or other. For the audit, 742 breast, 641 colorectal and 100 ovarian cancer patient records were reviewed. A “gold standard” was made of 36 of the 53 most important and agreed-upon recommendations clearly and unarguably reported in the text of the guidelines.

Diffusion and acceptance of the survey guidelines was unsatisfactory. Only 60% (breast), 47% (colon) and 44% (ovarian) of the doctors knew of the guidelines. Non-participants in the survey showed even less awareness: 45%, 26%, and 10% respectively.

Acceptance of the guidelines, as measured by agreement with the expert panel choice, was satisfactory only for the breast cancer guidelines. For example, 93% of the respondents agreed with segmental mastectomy and adjuvant chemotherapy for a pre-menopausal woman. However, only 65% of doctors agreed with segmental mastectomy for a postmenopausal woman, and only 70% for tamoxifen adjuvant therapy. There was less agreement on colorectal cancer, with agreement only 71% that left hemicolectomy was best for a sigmoid colon cancer, and 58% agreement for no adjuvant treatment for resected colon cancer. (This 1987 study was before the evidence of efficacy for adjuvant treatment was known.) There was slightly better agreement on treatment of ovarian cancer, with 79% agreeing that a second look procedure was indicated to evaluate complete clinical response, and 60% agreeing that adjuvant therapy was not indicated in early ovarian cancer.

Physician practice volumes and personal characteristics were significantly associated with choices of treatment. High volume doctors more often favored breast conserving surgery and active adjuvant treatment. Appropriate surgery for patients with a sigmoid colon cancer and a watch/no adjuvant therapy for patients with resected colon cancer. There were similar findings for recommendations for watch/no adjuvant therapy in stage I ovarian cancer, and chemotherapy for

advanced disease. (All  $p < 0.01$  or  $0.05$ .) Physicians aware of the guidelines made better therapy choices, even when adjusted for volume and other confounding variables. They more often chose breast conservation in an older patient, adjuvant therapy for a pre-menopausal patient and adjuvant hormone therapy for a postmenopausal patient. (All odds ratios with 95% confidence intervals  $> 1.0$ .) Doctors who were aware of the guidelines also preferred more appropriate surgery for colon cancer patients but there was no difference in recommendations about adjuvant therapy. Doctors who were aware of the guidelines more often preferred second look surgery for ovarian cancer, and appropriate use of adjuvant chemotherapy and/or radiation therapy.

Compliance with the guideline recommendations, as shown by actual chart audit, was highly variable and showed some "...important failures in some critical aspects of patient care." Full results for the most significant and most likely to influence patient care criteria are reproduced in Table 14. For breast cancer, only 37% had full staging, and only 61% had a bilateral mammogram at the time of surgery. After segmental mastectomy, 35% did not receive adjuvant radiation, and 48% did not have adjuvant chemotherapy started within 4 weeks of surgery.

For colon cancer, CEA and liver echography were performed in only 40% of patients, 52% did not have documented clear resection borders, and 34% did not have a documented abdominal search for metastases. Radiation was used in only 11% of rectal cancers. Choices for adjuvant treatment were more appropriate.

For ovarian cancer, compliance with the guidelines was poor overall.

Table 14: Compliance with national guidelines as measured by chart audit, 1987

Recommendation	Compliance
<i>Breast cancer</i>	Gold standard of 100% (%)
Bilateral mammography	61
Clinical stage	37
Pathological stage	60
Evaluation of axillary lymph nodes	89
Avoidance of radical mastectomy if T < 2.0 cm	84
Radiotherapy after quadrantectomy	65
Adjuvant chemo started < 4 weeks	52
Polychemotherapy if < 50, + lymph nodes	71
Chemotherapy delivered at full dosage	86
 <i>Colon cancer</i>	
CEA levels and liver ultrasound	40
TNM staging	78
Search for intraabdominal metastasis	67
Information on resection borders	48
Evaluation of regional lymph nodes	66
Miles resection in lower rectal cancer	68
Radiotherapy in rectal and rectosigmoid cancer	11
No adjuvant chemotherapy in colon cancer	79
If chemo, 5-FU containing regimen	90

<i>Ovarian cancer</i>	
Full information on tumor grading	30
Staging including abdominal echography	75
Histologic type according to standard classifications	89
Chest x ray	97
Evaluation of residual tumor	45
Disease stage according to standard classification	85
Alkylating agent as part of chemotherapy for early disease	18
Cisplatin containing regimens for advanced disease	34
Monitoring of toxicity while on chemotherapy	91
Monitoring of nephrotoxicity while on chemotherapy	84

The authors note that results were “disappointing” and that efforts to improve cancer care with a “guidelines diffusion” approach appear to have had a negligible effect on cancer treatment.

- The major indication of failure was that diffusion of the guidelines was very limited. The majority of physicians were marginally aware, if at all, of their existence; those who were aware had better patterns of care, but might simply have been more aware of the scientific evidence.
- The physicians who had highest volume had more appropriate care, but that cannot be attributed to the guidelines. The low rate of compliance cannot be attributed to any other explanation such as limitations of data or sample size. The guideline development and diffusion method of changing practice did not work, in Italy. The authors note that for practice to change, the scientifically sound message must get to the right professional audience who must be willing and able to act on it.

In summary, the likelihood of success of this program was expected to be low, and was.

Likelihood of success	Development	Dissemination	Implementation	Accountability
High	Internal	Specific educational intervention	Patient specific reminder at time of encounter	Practice monitored, feedback given
Above Average	Intermediate	Continuing Education	Patient specific feedback	Practice monitored
Below Average	External. local	Mailing targeted groups	General Feedback	None
Low	National/external	Publication in journal	General feedback	None

France, 1995: Improving Care with Breast and Colon Cancer Guidelines in a French Cancer Center

Clinical Practice Guidelines is a regional quality assurance project started by the comprehensive cancer center in Lyon, Centre Leon Berard.<sup>79</sup> The center has 235 beds, 80 oncologists, and treats 3000 new cases each year. The goals were to assist oncologists in their decision making, reduce variation, optimize health benefit, ensure rational chemotherapy

prescription within the center, and provide local leadership. A task force of medical, radiation, and surgical oncologists developed the guidelines in 1993 based on evidence with consensus, then the guidelines were reviewed by all practitioners. The guidelines were disseminated in 1994 and are available in paper, computer disk, and online at the center. Practitioners did not receive feedback but were aware of the ongoing audit and accountability.

A “before/after” study was done using 1993 and 1995 as comparison years. 100 randomly selected breast cancer patients, about 80 (77 pre and 81 post) colon cancer patients were studied, enough to detect a 25% difference in compliance rate. The initial treatment sequence was audited and compared to the guidelines. The main outcome was the number of medical decisions that conformed to the guidelines. The secondary outcome was the number of medical decisions judged to be based on either the guidelines or published evidence (determined beforehand.)

The observed compliance rate in 1995 was significantly better than in 1993. In 1993, only 42% of initial treatments conformed to the clinical practice guidelines or were based on scientific evidence, compared to 68% in 1995. Specific results for compliance with guidelines are given in Table 15.

Table 15. Compliance rates of medical decisions with guidelines

Type of procedure	Compliance with CPGs (%)		
	1993	1995	P value
<i>Breast cancer</i>			
Initial evaluation	75	86	.09
Surgery	96	92	.26
Chemotherapy	71	85	.01
Radiotherapy	72	93	<.001
Hormonal therapy	83	94	.01
Follow up	31	80	<.001
Overall treatment sequence	19	54	<.001
<i>Colon cancer</i>			
Initial evaluation	100	100	
Surgery	100	99	.56
Chemotherapy	56	78	.02
Follow up	62	54	.69
Overall treatment sequence	50	70	.009

Overall, there was a striking increase in the number of decisions compliant with the guideline or based on scientific evidence, from 19% to 54%,  $p < .001$ . There were breast cancer medical decisions judged not to be based on evidence. These included over frequent measurement of serum tumor markers CEA and CA 15-3 which declined from 21 in 1993 to 7 in 1995, use of bone scans for asymptomatic patients; lack of adjuvant radiation, lack of hormonal therapy for estrogen receptor positive patients; lack of axillary dissection, and radical mastectomy for small intraductal carcinoma.

*Clinical Practice Guidelines*

For colorectal cancer overall, the compliance for the whole treatment sequence increased from 50% to 70%,  $p=.009$ . In 1993 71% of the decisions were compliant or judged in accordance with the scientific evidence, with an increase to 81%, not statistically significant. The compliance rates did not change except for administration of adjuvant chemotherapy.

The success of the guidelines program in improving quality was attributed in part to the development process used. The guidelines were developed with local participation, and did not threaten either livelihood or autonomy. The guidelines were made widely available to the 80 physicians at medical meetings, and specific reminders were mailed to each physician. Finally, the guidelines were readily available throughout the center. Of note, no specific penalty or reward system except peer pressure was used.

France, 1996: Improving Care with Guidelines in a French Regional Cancer Program

This process was reported at the 1998 American Society of Clinical Oncology meeting to improve compliance rates in a French Cancer Network.<sup>80</sup> The Centre Leon Bernard and 28 hospitals established a regional cancer network. The guidelines were reviewed by all the practicing physicians, then used in a continuing education program of 12 meetings and specific reminders mailed to all physicians in 1995. The compliance rate for breast cancer improved from 12% in 1994 to 37% in 1996; for colon cancer, from 14% to 45% (all  $p<.001$ ). The range of improvements was similar to those reported in the original study, with improvements in diagnosis, surgery, chemotherapy, and radiation. (data not shown) Again, these modest changes in practice were accomplished without formal penalty or reward other than education, awareness, and peer pressure.

In summary, the likelihood of success of the program was high, and it appears to have made major improvement in the process of care.

Likelihood of success	Development	Dissemination	Implementation	Accountability
High	Internal	Specific educational intervention	Patient specific reminder at time of encounter	Practice monitored, feedback given
Above Average	Intermediate	Continuing Education	Patient specific feedback	Practice monitored
Below Average	External. local	Mailing targeted groups	General Feedback	None
Low	National/external	Publication in journal	General feedback	None

Problems anticipated in U.S. medicine: *Evidence Based Medicine meets Demand Based Medicine*

We would anticipate at least two major problems with the use of clinical practice guidelines in the U.S.: 1) the use of guidelines where patient demand for therapy may be high; and 2) ethical conflict among provider and patient.

There have been no major guideline attempts beyond care that is primarily driven by the health care professional, especially the primary treatment sequence that is surgical. However, the range of oncology decisions for a typical solid tumor patient encompasses much more, including at least the following:

- primary treatment
- diagnosis of recurrence/surveillance (especially with serum tumor markers that predict recurrence sooner but so far have not led to any demonstrable improvement in disease or patient outcomes except earlier knowledge of recurrence)
- second line treatment
- third line treatment
- a choice between hospice care and continuing treatment, etc. We have outlined the spectrum of decisions against where clinical practice guidelines have been proven useful in Table 16. Many of these procedures or treatments are in high demand from patients; examples might include antibody treatment for refractory metastatic breast cancer, with a response rate of about 15%, average duration of response about 3 months, and a cost of >\$1,000 per week. Another example might be treatment of unresectable pancreas cancer with gemcitabine, with an improved survival from 4 months to 5 months, at a cost of >\$1,000 per week (which one managed care organization has chosen not to cover.) There have been a substantial number of court decisions allowing patients access to high dose chemotherapy for metastatic refractory breast cancer, in the absence of definitive clinical trial evidence that proves benefit.

How Americans will react to limits on such treatment is unknown, and the ethics of limiting treatment are likely to be highly debated.<sup>81</sup> It is clear that patients will choose treatments that their health care professionals would not, and are willing to sacrifice toxicity for small chances of response and improved short term survival.<sup>82-84</sup> We and others have argued that health care professionals have an ethical obligation to discuss the options with patients, even if they may not be available within the current limits of the health care system.<sup>85</sup> Others have argued that clinical practice guidelines<sup>86</sup> and advanced directives<sup>87:88</sup> should not be used to ration care for specific patients at the bedside or for specific groups such as the elderly. There may well be clinical practice guidelines that deny treatment that might give small benefits important to patients (such as gemcytabine for pancreas cancer), but judged not to be important enough to justify treatment by providers; how such guidelines will fare in the current legal and political climate is unknown.

Table 16: Spectrum of clinical decisions and where clinical practice guidelines have been proven useful

Choices facing the patient And Health care professional	Spectrum of treatment decisions					
	Primary Treatment	Surveillance	First recurrence	Second recurrence	Third recurrence	Fourth recurrence
	Surgery	Who follows, specialist or generalist	ChemoRx	ChemoRx	ChemoRx	ChemoRx

*Clinical Practice Guidelines*

	Adjuvant treatment	Exam frequency	Hospice	Hospice	Hospice	Hospice
	Adjuvant radiation	Blood and other tests that improve disease outcomes	Clinical trial	Clinical trial	Clinical trial	Clinical trial
		Blood and other tests that do not improve disease outcomes	Phase I	Phase I	Phase I	Phase I
Areas of Proven Clinical Practice Guidelines	Yes (breast, colon, lung, prostate, gynecologic)	No	No	No	No	No

## **Summary**

There have a modest number of successful clinical practice guideline/critical pathway efforts in the United States, Canada, and France. Improvements have been demonstrated in compliance to evidence-based guidelines or evidence-based medicine, and in short term length of stay, complication rates, and financial outcomes. There has been one example of documented improvement in disease-free survival and overall survival of breast cancer patients, but causality from the guidelines cannot be inferred. The published data suggests that patient complications can be reduced with standardized care, and that satisfaction can be maintained.

The components of successful clinical practice guideline program can be summarized; the necessity of each component cannot be determined from the data.

- **Development:** the guideline is based on evidence, and formulated by key physicians in the group.
- **Dissemination:** all affected physicians and health care professionals are given the guideline to review, and are expected to critique.
- **Implementation:** successful guidelines have given direct feedback on performance to physicians, or general feedback on system performance
- **Accountability:** all physicians must be accountable for meeting certain standards. This accountability can be simple peer-pressure to conform to evidence based medicine, and does not require financial reward or penalty. There must be some willingness to change, based on perceived opportunity or real threat.

Conversely, those programs that have not succeeded have relied on voluntary change in practice behavior, or have had no accountability. Simply making information available at meetings, mailings, or publication has not lead to significant or timely change in prescribing patterns or practice changes. Alternately, compliance with established guidelines such as clinical staging can be accomplished by administrative directive, such as threat of loss of privileges or deselection, without the guideline process.

**Section III: Interviews with leaders in the field**

Methods

Structured interviews were conducted with opinion leaders known to Drs. Smith and Hillner (from national conferences and work groups) to answer the following questions:

1. What are the characteristics of a good clinical practice guidelines program? Development, Implementation, Tracking, Incentive programs, Potential for Harm and Good; Other
2. Do you use good clinical practice guidelines in your own practice? If so, what and why? Are they helpful? If not, why?
3. What should we tell the IOM about good clinical practice guidelines in oncology? Can we define a process of development and use of good clinical practice guidelines in oncology that IOM can recommend?

These questions were posed to the following group:

1. Rodger Winn, M.D., M. D. Anderson Cancer Center, Houston Texas. The original chair of the ASCO health service research program, charged with making the ASCO clinical practice guidelines, and now in charge of guidelines for the National Cancer Center Network (NCCN).
2. Charles Bennett, M.D., Ph.D. Northwestern Medical Center, Chicago, Illinois; health service research specialist who has led the ASCO efforts to evaluate its guidelines program.
3. Mark R. Somerfield, Ph.D. Director of Health Service Research, American Society of Clinical Oncology, Alexandria VA.
4. Albert Brady, M.D., Mercy Health System, Michigan. Former head of a Community Clinical Oncology Program, he is now a leader in the development of model cancer programs.

The characteristics of good guidelines were summarized by these authorities as follows in Table 17. Full comments and text of the interview are listed in Appendix x.

Table 17. Interview summary for clinical practice guidelines

Topic	Comments
Characteristics of good guidelines	
Development	Standard IOM model works well, but must be local development and “buy-in”.
Implementation	Need education program, then local opinion leaders, and positive reinforcement. Must be commitment to change.
Tracking	Need full information system to track guidelines, variance, so that use of guidelines can be measured. Accountability is key.
Incentives	Educational preferred; peer pressure felt to be more effective in changing practice than any other measure.

Potential for harm and good	Major opportunities for improved care. Some chance of harm for patients with unusual situations., or if the guideline is applied to the wrong clinical scenario.
Does your practice use guidelines?	No center, at present, has fully implemented clinical practice guidelines.  All sites have imminent plans to use the National Cancer Center Network (NCCN) guidelines; 2 sites were involved in their design. These are widely available at present but there is no accountability.  All sites have plans to make physicians accountable within the next year or two. One center will roll out the guidelines as a voluntary measure.
What to tell the IOM?	Unless there is accountability, the guidelines will not work. This accountability can take the form of peer pressure, financial incentives, or administrative sanction.  Path guidelines provide useable map for most clinical situations, and offer the best chance to standardize and improve cancer care. They must be tied to adequate information systems.  “Boundary guidelines” for new technology may be useful but have not been formally evaluated.

---

This group of experts confirmed the findings from the literature review. All are convinced that clinical care processes and outcomes and financial outcomes can be substantially improved. All except Dr. Somerfield have substantial clinical experience and are considered users of guidelines as well as developers. One has been a two-time cancer survivor.

Their key concern was accountability. Unless there is accountability for improving care, there will be no improvement. A corollary is that the health care system must have an information system that can give practitioners useful feedback. As seen in the M. D. Anderson and Northern California<sup>66</sup> study, such feedback can be given based on sample chart audit, and does not require new or expensive tools. Other management teams have proposed similar tools and methods.<sup>89</sup>

This group of experts was not convinced that the method of developing guidelines was crucial, as long as the guidelines were based on scientific evidence and had consensus.

This group thought accountability and willingness to change were more important than local development or review of the guidelines.

Interestingly, there was consensus of the experts on the best model for changing physician behavior – peer pressure. Rather than develop incentive or penalty systems, their organizations are using group process to standardize care. How that will work with more reticent physicians is unknown since all these experts work at organizations committed to excellence and where the climate has embraced management by outcomes.

#### **IV: Recommendations**

Clinical practice guidelines have improved disease management process and outcomes in other medical fields, and there is evidence that they may improve care in cancer treatment. Improvements in process, complications, short term outcomes, and cost have been demonstrated so far. Patient satisfaction appears to be maintained.

A specific process can be recommended for clinical practice guidelines based on experience. Development of the guidelines should include all local users, with opportunity to provide critique. Dissemination of the guidelines should be done with specific mailing and educational conferences, not by publication in a journal alone. Implementation of the guidelines should be done with patient specific reminders, i.e. the guideline must be readily available for reference, and the doctor “prompted” to use it. Accountability for process and outcomes is a key component of guideline success, probably the most important. Such accountability can take the form of peer pressure to financial incentives, to administrative mandate.

The use of guidelines in private fee for service practice (vs. health maintenance or academic settings) and with practitioners or health care systems without an explicit goal of improvement has not been studied. The use of guidelines to limit care that may be judged to be of benefit by the patient but not by the guideline developer has not been studied.

Recommendations can include the following:

- Endorsement of the guideline process, as long as accountability for good process and outcome is part of the process.
- The specific process of guideline development, including rules of evidence, methods of achieving consensus, and alternative treatments not covered by the guideline, must be visible.
- Guidelines made for situations with the least data, e.g. second line chemotherapy for non small cell lung cancer, should be the ones subjected to the most intense early evaluation.
- Encouragement of model programs in fee for service practice, non-integrated health care delivery systems, and programs that are likely to have the worst performance.

**Appendix I: Clinical Practice guidelines Interviews with Experts in the Field**

20-Jun-98

T. Smith  
MD  
Interview

**Characteristics of good guidelines**

Interview	Date	Development	Implementation	Tracking	Incentives	Potential for harm and good	Other	Do you use clinical practice guidelines in your own practice	What to tell IOM
Winn, Rodger	4-Jun	Standard IOM model. Must be some way to allow consensus for areas of contention; there will always be some. Emphasis on evidence based consensus.	Need an education program, local tie in with opinion leaders, eventually some authority to change practice. Developing these strategies.	Need full information system to track the processes of care given, and the outcomes at least by center, for comparability. Individual may not have enough cases for comparison. Must be able to show compliance, variance.	Educational. Peer pressure; group consensus. Changing the culture can be difficult.	Good: increased standardization, best care models. Harm: lack of flexibility possible.	None.	Yes. NCCN and local practice.	Boundary guidelines useful for new technologies. Algorithms very important to regular practice.
Bennett, Charles	10-Jun	Local development is key. Local resources dictate what is available, useable. Must be evidence based, multi-disciplinary. Accessible. Friendly to users. Not cumbersome. Must be concrete. Best if algorithm.	Cedars - Sinai model including evaluation. On/off per month. Software accessible. No big thick binders. Positive, not punitive, for providers. Rolled out over time, e.g. 6-12 months. Revise based on feedback.	Track at both physician/provider and organizational level. May be hard with cross over of personnel, change of physicians, housestaff. Easiest in mutually exclusive doctor systems.. Actions must be ascribe able. Pre and post testing. Feedback must be useable. Time series. Focus groups; leader effort; collegial; written and oral feedback may be useful.	No demerits. Identify outliers, used educational feedback. No financial disincentives to re-training; e.g. if urologist had too high mortality, could go back and retrain with no loss of income/prestige. CME credits essential.	Better care if good guideline and good care given. May increase clinical trials. Standardized outcomes and guidelines may standardize practice. Continuous updating of new regimens. Potential for harm small but present if care denied.	None.	No. Voluntarily mandated in NCCN. Will phase them in at VAMC, non-mandatory. Will be mandatory at Northwestern for NCCN, but timetable under discussion.	Only part of the answer to improved care. Not a miracle cure. Money must be spent on information systems, changing the culture. Forces: 1. Strategic focus that this is important. 2. Cultural focus that this is the way that we practice medicine. 3. Technical focus of useable guidelines. 4. Structural focus to make sure the guidelines can be implemented.

*Clinical Practice Guidelines*

Sommerfield, Mark	Standard IOM approach: interdisciplinary, timely completion and implementation, room for flexibility.	Buy-in necessary. Use approach of sending to all doctors first; can be cumbersome but useful to generate educational need and familiarity. Enforcement is institution specific. Trouble shoot adoption first rather than anticipate trouble.	Evaluation included. Consumer satisfaction. Knowledge of/use of/change in practice attributable to guideline can all be measured.	Buying-in may be more important. More likely to be accepted than if just thrust upon the practitioner.	If mandated, harm for individual patient. Flexibility could take a back seat to needs of practice, economics. There is a time burden to call, check on guideline.	think constructively about evidence based medicine. It can be a big wake up call to realize that what the practitioner is doing is very different from prior experience. Calls attention to practice variation, need for guidance and/or guidelines.	Evidence in France: if commitment, if accountability, then the guidelines work to increase evidence based medical care. This is the age of accountability. Important to recognize the broad cultural context of medicine, not just the technical prescribing aspect	
Brady, Albert	3-Jun Standard IOM model.	Significant commitment to clinical trials. Weekly group meetings, and group treatment planning. Peer pressure relied on to reign in outliers. Group mission to standardize care. Mandate participation in new medical group where this is standard.	Electronic medical record tracks deviations, outliers.	1. Peer pressure. 2. Total of 30% set aside of salary. 10-12% salary withhold, for discretionary rewards (decreased LOS, better patient satisfaction, and meeting threshold for clinical trial enrollment.)	Good: increased clinical trials, standardized care, making financial incentive for better care. Harm: reverse of above.	None.	No, not using at present. Posed to bring on full set consolidating all the practices into one. Using NCCN for start.	Must move in this direction, and must study as we go. Example: in Dallas, 7 doctors in 2 practices had 14 ways of giving adjuvant breast cancer treatment when only 2 Or 3 at most were needed. Inevitably led to dosing errors, non-standard outcomes. For anal cancer patients, 17 different regimens of chemotherapy. Has designed accountability based on peer pressure, groups process model; and incentives.

**References:**

1. Lord, J. and Littlejohns, P. Evaluating healthcare policies: the case of clinical audit. *BMJ* 315, 688-671. 1997.
2. Poloniecki, J. Half of all doctors are below average. *BMJ* 316, 1734-1736. 1998.
3. Brook, R. H. Managed Care Is Not the Problem, Quality Is. *JAMA* 278(19), 1612-1614. 1997.
4. Pear, R. Greenspan, Issuing Warning, Urges Changes in Medicare. *New York Times* . 1998. New York.
5. Brown ML: The national economic burden of cancer. *JNCI* 1990;82:1811-1814.
6. Rundle, R. L. Salick Pioneers Selling Cancer Care to HMOs. *The Wall Street Journal* Monday, August 12, B1-B2. 1996.
7. Smith, T. J. End of Life Care: Preserving Quality and Quantity of Life in Managed Care. *ASCO Educ Book* 33rd Annual Meeting, 303-307. 1997.
8. The Boston Consulting Group: *The Promise of Disease Management*, Boston, The Boston Consulting Group, Inc.; 1995:
9. Miles SH, Weber EP, Koepp R: End-of-life treatment in managed care. The potential and the peril. *West J Med* 1995;163:302-305.
10. Sulmasy DP: Physicians, cost control, and ethics. *Ann Intern Med* 1992;116:920-926.
11. Bochner F, Martin ED, Burgess ND, Somogyi AA, Misan GM: How can hospitals ration drugs? Drug rationing in a teaching hospital: a method to assign priorities. Drug Committee of the Royal Adelaide Hospital. *BMJ* 1994;308:901-905.
12. Field MJ, Lohr KN: *Clinical Practice Guidelines*, Washington, D.C., Institute of Medicine, National Academy Press; 1990:
13. Grol, R. Beliefs and evidence in changing clinical practice. *BMJ* 315, 418-421. 1997.
14. Grimshaw, J. M. and Russell, T. I. Effect of clinical guidelines on medical practice. *Lancet* 342, 1317-1322. 1993.
15. Hayward, R. S. and Laupacis, A. Initiating, conducting and maintaining guidelines development programs. *Can Med Assoc J* 148, 507-512. 1993.
16. Wolf, S. H. Practice guidelines: A new reality in medicine, III: Impact of patient care. *Arch Intern Med* 153, 2646-2655. 1993.
17. Berger, J. T. and Rosner, F. The Ethics of Practice Guidelines. *Arch Intern Med* 156, 2051-2056. 1996.
18. Smith TJ, Bodurtha JN: Ethical considerations in oncology: balancing the interests of patients, oncologists, and society. *J Clin Oncol* 1995;13:2464-2470.
19. Smith TJ: Which hat do I wear? *JAMA* 1993;270:1657-1659.

20. Miller, F. H. The Legal Ramifications of the NCCN Practice Guidelines. *Oncology Hunting* 10(11 Supplement), 35-39. 1996.
21. Winn RJ, Smith TJ: The American Society of Clinical Oncology Guidelines Program. *Pharm Pract Manage Qrtly* 1996;16:31-38.
22. Winn, R. J. The Role of Oncology Clinical Practice Guidelines in the Managed Care Era. *Oncology* 9(11 Supplement), 177-183. 1995.
23. Figlin, R. A., Gilden, R., and Taylor, C. Methodology of the Practice Guidelines. *The Cancer Journal* 2(3A Supplement), S4-S6. 1996.
24. Love, S., Parker, B., Ames, M., Taylor, C., Gilden, R., and Figlin, R. A. Practice Guidelines for Breast Cancer. *The Cancer Journal* 2(3A Supplement), S7-S21. 1996.
25. Venook, A., Goodnight, J., Kumar, S., Taylor, C., Gilden, R., and Figlin, R. A. Practice Guidelines for Colorectal Cancer. *The Cancer Journal* 2(3A Supplement), S23-S36. 1996.
26. Goodnight, J., Venook, A., Ames, M., Taylor, C., Gilden, R., and Figlin, R. A. Practice Guidelines for Esophageal Cancer. *The Cancer Journal* 2(3A Supplement), S37-S43. 1996.
27. Venook, A., Goodnight, J., Smith, N. G., Taylor, C., Gilden, R., and Figlin, R. A. Practice Guidelines for Gastric Cancer. *The Cancer Journal* 2(3A Supplement), S45-S52. 1996.
28. Goodnight, J., Venook, A., Fringer, J., Taylor, C., Gilden, R., and Figlin, I. Practice Guidelines for Pancreatic Cancer. *The Cancer Journal* 2(3A), S53-S60. 1996.
29. Camerson, R., Fringer, J., Taylor, C., Gilden, R., and Figlin, R. A. Practice Guidelines for Non-Small Cell Lung Cancer. *The Cancer Journal* 2(3A), S61-S68. 1996.
30. Camerson, R., Smith, N. G., Taylor, C., Gilden, R., and Figlin, R. A. Practice Guidelines for Small Cell Lung Cancer. *The Cancer Journal* 2(3A Supplement), S69-S75. 1996.
31. Ahlering, T., Parker, R., Kumar, S., Taylor, C., Gilden, R., and Figlin, R. A. Practice Guidelines for Prostate Cancer. *The Cancer Journal* 2(3A Supplement), S77-S86. 1996.
32. Recommended Breast Cancer Surveillance Guidelines. *J Clin Oncol* 15(5), 2149-2156. 1997.
33. Grunfeld E, Mant D, Yudkin P, et al: Routine follow up of breast cancer in primary care: randomised trial. *BMJ* 1996;313:665-669.
34. Smith, T. J. and Bear, H. D. Standard follow-up of colorectal cancer patients: finally, we can make practice guidelines based on evidence. *Gastroenterology* 114(1), 211-213. 1998.
35. Schoemaker, D., Toouli, J., Black, R., and Giles, L. Yearly Colonoscopy, CT Liver and Ches X-Ray Do Not Influence 5 year survival of Colorectal Cancer Patients. *Gastroenterology* 114(1), 7-14. 1998.
36. Engstrom, P. F. NCCN Colorectal Cancer Practice Guidelines. *Oncology* 10(11), 140-175. 1997.
37. Edge, S. B. Breast Cancer Practice Guidelines: Evaluation and Quality Improvement. *Oncology Hunting* 11(11A), 151-154. 1997.

*Clinical Practice Guidelines*

38. Morrow, M., Bland, K. I., and Foster, R. Breast Cancer Surgical Practice Guidelines: Scope and Format of Guidelines. *Oncology Hunting* 11(6), 877-886. 1997.
39. Carlson, R. W., Goldstein, L. J., Gradishar, W. J., Lichter, A. S., McCormick, B., Moe, R. E., and Theriault, R. L. NCCN Breast Cancer Practice Guidelines. *Oncology Hunting* 10(11 (Supplement)), 47-75. 1996.
40. Hamel, M. B., Phillips, R. S., Davis, B. R., Desbiens, N., Connors, A. F., Jr., Teno, J. M., Wenger, N., Lynn, J., Wu, A. W., Fulkerson, W., and Tsevat, J. Outcomes and Cost-Effectiveness of Initiating Dialysis and Continuing Aggressive Care in Seriously Ill Hospitalized Adults. *Ann Intern Med* 127(3), 195-202. 1997.
41. American Society of Clinical Oncology. Clinical Practice Guidelines for the Treatment of Unresectable Non-Small-Cell Lung Cancer. *Journal of Clinical Oncology* 15(8), 2996-3018. 1997.
42. Evans, W. K., Newman, T., Graham, I., Rusthoven, J. J., Logan, D., Shepard, F. A., and Chamberlain, D. Lung Cancer Practice Guidelines: Lessons Learned and Issues Addressed by the Ontario Lung Cancer Disease Site Group. *Journal of Clinical Oncology* 15(9), 3049-3059. 1997.
43. Smith, T. J., Hillner, B. E., and Mitchell, R. B. Decision Analysis in Non-Small-Cell Lung Cancer: Not Back to the Drawing Modeling Board, Back to the Bedside. *Journal of Clinical Oncology* 15(3), 870-872. 1997.
44. Cook, D. J., Greengold, N. L., Ellrodt, A. G., and Weingarten, S. R. The Relation between Systematic Reviews and Practice Guidelines. *Ann Intern Med* 127(3), 210-216. 1997.
45. Katterhagen, G. Physician Compliance With Outcome-Based Guidelines and Clinical Pathways in Oncology. *Oncology Hunting* 10(11 Supplement), 113-121. 1996.
46. Grilli, R. and Lomas, J. Evaluating the Message: The Relationship Between Compliance Rate and the Subject of a Practice Guideline. *Med Care* 32, 202-213. 1994.
47. Schoenbaum SC, Sundwall DN, Bergman D, et al: *Using Clinical Practice Guidelines To Evaluate Quality of Care: Issues*, Rockvill, MD, U.S. Department of Health and Human Services; 1995:
48. Schoenbaum SC, Sundwall DN, Bergman D, et al: *Using Clinical Practice Guidelines To Evaluate Quality of Care: Methods*, Rockvill, MD, U.S. Department of Health and Human Services; 1995:
49. Morris, M., Levenback, C., Burke, T. W., Dejesus, Y., Lucas, K. R., and Gershenson, D. M. An Outcomes Management Program in Gynecologic Oncology. *Obstet Gynecol* 89(4), 485-492. 1997.
50. West, J. G., Sutherland, M. L., Link, J. S., and Margileth, D. A. A Breast Cancer Care Report Card: An Assessment of Performance and a Pursuit of Value. *West J. Med* 166(4), 248-252. 1997.
51. Ford, L. G., Hunter, C. P., Diehr, P., Frelick, R. W., and Yates, J. Effects of Patients Management Guidelines on Physician Practice Patterns: The Community Hospital Oncology Program Experience. *J Clin Oncol* 5(3), 504-511. 1987.
52. Litwin, M. S., Smith, R. B., Thind, A., Reccius, N., Blanco-Yarosh, M., and deKernion, J. B. Cost-Efficient Radical Prostatectomy with a Clinical Care Path. *J Urology* 155, 989-993. 1996.
53. Litwin, M. S., Shpall, A. I., and Dorey, F. Patient Satisfaction with Short Stays for Radical Prostatectomy. *Urology* 49(6), 898-906. 1997.

*Clinical Practice Guidelines*

54. Wilson, D. E., Jirsch, D. W., Mador, D. R., Halliwell, G. E., Raiwet, C. J., Grace, M. P., Predy, G. N., and Redfern, L. E. Caremap management for postoperative prostatectomy care at home: a comparative study. *Can J Surg* 40(1), 39-43. 1997.
55. Feinberg, B. and Feinberg, I. Overall survival of the medical oncologist: a new outcome measurement in cancer medicine. *Cancer* 82(10 Supplement), 2047-2056. 1998.
56. Stewart, M. G., Hillman, E. J., Donovan, D. T., and Tanli, S. H. The effects of a practice guideline on endoscopic sinus surgery at an academic center. *Am J Rhinol* 11(2), 161-165. 1997.
57. Meisenberg, B. R., Ferran, K., Hollenbach, K., Brehm, T., Jollon, J., and Piro, L. D. Reduced charges and costs associated with outpatient autologous stem cell transplantation. *Bone Marrow Transplant* 21, 927-932. 1998.
58. American Society of Clinical Oncology. 1997 update of recommendations for the use of hematopoietic colony-stimulating factors: evidence-based, clinical practice guidelines. *J Clin Oncol* 15(10), 3288. 1997.
59. Ho, M. 1995 Survey Results on Colony Stimulating Factors. 1995. New York.
60. Somerfield MR, Feinglass J, Smith TJ: Decrease in Misuse/Overuse of Hematopoietic Colony Stimulating Factors (CSF's) for Solid Tumors and Lymphomas: Resulting from ASCO Surveys Related to the 1994 and 1996 ASCO CSF Guidelines. *Proc Am Soc Clin Oncol* 1998;17:421a(Abstract)
61. Hartmann, L. C., Tschetter, L. K., Habermann, T. M., Ebbert, L. P., Johnson, P. S., Mailliard, J. A., Levitt, R., Suman, V. J., Witzig, T. E., Wieand, H. S., Miller, L. L., and Moertel, C. G. Granulocyte colony-stimulating factor in severe chemotherapy-induced afebrile neutropenia. *N Engl J Med* 336(25), 1776-1780. 1997.
62. American Society of Clinical Oncology. Recommendations for the use of hematopoietic colony-stimulating factors: evidence based, clinical practice guidelines. *J Clin Oncol* 1994;12:2471-2508.
63. American Society of Clinical Oncology. Outcomes of Cancer Treatment for Technology Assessment and Cancer Treatment Guidelines. *Journal of Clinical Oncology* 14(2), 671-679. 1996.
64. Ozer, H. American Society of Clinical Oncology guidelines for the clinical use of hematopoietic colony-stimulating factors. *Curr Opin Hematol* 3(1), 3-10. 1996.
65. Smith TJ: Economic analysis of the clinical uses of the colony-stimulating factors. *Current Opinion in Hematology* 1996;3:175-179.
66. Patton MD, Katterhagen JG: Critical pathways in oncology: aligning resource expenditures with clinical outcomes. *J Oncol Manage* 1994;July/August:16-21.
67. Von Roenn JH, Cleeland CS, Gonin R, Hatfield AK, Pandya KJ: Physician attitudes and practice in cancer pain management. A survey from the Eastern Cooperative Oncology Group. *Ann Intern Med* 1993;119:121-126.
68. Cleeland CS, Gonin R, Hatfield AK, et al: Pain and its treatment in outpatients with metastatic cancer. *N Engl J Med* 1994;330:592-596.
69. Cleeland, C. S., Gonin, R., Baez, L., Loehrer, P., and Pandya, K. J. Pain and Treatment of Pain in Minority Patients with Cancer. *Ann Intern Med* 127(9), 813-816. 1997.
70. Zenz, M., Zenz, T., Tryba, M., and Strumpf, M. Severe Undertreatment of Cancer Pain: A 3-Year Survey of the German Situation. *J Pain Symptom Manage* 10(3), 187-191. 1995.

*Clinical Practice Guidelines*

71. A controlled trial to improve care for seriously ill hospitalized patients. The study to understand prognoses and preferences for outcomes and risks of treatments (SUPPORT). The SUPPORT Principal Investigators. *JAMA* 1995;274:1591-1598.
72. Skolnick, A. A. New Study Suggests Radiation Often Underused for Palliation. *JAMA* 279(5), 343-344. 1998.
73. Rischer, J. B. and Childress, S. B. Cancer Pain Management: Pilot Implementation of the AHCPR Guideline in Utah. *Journal of Quality Improvement* 22(10), 683-700. 1996.
74. Thompson I, Optenberg S, Segura J, Pope B: AUA Prostate Cancer Clinical Guidelines Have a Significant Impact Upon Patient Care in a National Study Population. *J Urology* 1995;59:257(Abstract)
75. Olivotto, I. A., Coldman, A. J., Hislop, T. G., Trevisan, C. H., Kula, J., Goel, V., and Sawka, C. Compliance With Practice Guidelines for Node-Negative Breast Cancer. *J Clin Oncol* 15(1), 216-222. 1997.
76. Olivotto IA, Bajdik CD, Plenderleith IH, et al: Adjuvant systemic therapy and survival after breast cancer. *N Engl J Med* 1994;330:805-810.
77. Levine, M., Browman, G., Newman, T., and Cowan, D. H. The Ontario Cancer Treatment Practice Guidelines Initiative. *Oncology Nursing* 10(11 Supplement), 19-22. 1996.
78. Grilli, R., Apolone, G., Marsoni, S., Nicolucci, A., Zola, P., and Liberati, A. The Impact of Patient Management Guidelines on the Care of Breast, Colorectal, and Ovarian Cancer Patients in Italy. *Medical Care* 29(1), 50-63. 1991.
79. Ray-Coquard, I., Philip, T., Lehmann, M., Fervers, B., Farsi, F., and Chauvin, F. Impact of a Clinical Guidelines Program for Breast and Colon Cancer in a French Cancer Center. *JAMA* 278(19), 1591-1595. 1997.
80. Ray-Coquard I, Philip T, De Laroche G, et al: Impact of a Clinical Guidelines Program on Medical Practice in a French Cancer Network. *Proc Am Soc Clin Oncol* 1998;17:421a(Abstract)
81. Daniels N: Why saying no to patients in the United States is so hard. Cost containment, justice, and provider autonomy. *N Engl J Med* 1986;314:1380-1383.
82. Slevin ML, Stubbs L, Plant HJ, et al: Attitudes to chemotherapy: comparing views of patients with cancer with those of doctors, nurses, and general public. *BMJ* 1990;300:1458-1460.
83. Davies E, Clarke C, Hopkins A: Malignant cerebral glioma - I: Survival, disability, and morbidity after radiotherapy. *BMJ* 1996;313:1507-1512.
84. Davies E, Clarke C, Hopkins A: Malignant cerebral glioma - II: Perspectives of patients and relatives on the value of radiotherapy. *BMJ* 1996;313:1512-1516.
85. Smith, T. J. and Bodurtha, J. N. Ethical Considerations in Oncology: Balancing the Interests of Patients, Oncologists, and Society. *Journal of Clinical Oncology* 13(9), 2464-2470. 1995.
86. Orentlicher, D. Practice Guidelines: A Limited Role in Resolving Rationing Decisions. *J Am Geriatr Soc* 46(3), 369-372. 1998.

*Clinical Practice Guidelines*

87. Levinsky NG: The purpose of advance medical planning - autonomy for patients or limitation of care? *N Engl J Med* 1996;335:741-743.
88. Ozer H, Miller LL, Schiffer CA, Winn RJ, Smith TJ: American Society of Clinical Oncology. Update of recommendations for the use of hematopoietic colony-stimulating factors: evidence-based, clinical practice guidelines. *J Clin Oncol* 1996;14:1957-1960.
89. Clemmer, T. P., Spuhler, V. J., Berwick, D. M., and Nolan, T. W. Cooperation: The Foundation of Improvement. *Ann Intern Med* 128(12), 1004-1009. 1998.