The Impact of Clinical

Using Guidelines to Inform Medical Policy

One of the benefits of evidence-based clinical guidelines is that they help define medically necessary services. Ineffective therapies are not included, and therapies that are still under investigation are identified as such. Defining medically necessary services helps health plans create medical policies that are defensible and acceptable to the medical community.

The Premera experience with the growth factors filgrastim (Neupogen®) and sargramostim (Leukine®) illustrates how medical policies can be directed by guidelines, then refined by measuring compliance. When our disease managers interacted with patients, it quickly became obvious that providers, even those on the advisory panel, were not adhering to the agreed-upon, evidence-based guidelines for using colony-stimulating factors. These drugs were being used prophylactically in the adjuvant setting without first attempting the dose delays or reductions called for in the guidelines. Certain practitioners were using colony-stimulating factors even in the presence of febrile neutropenia, when the guidelines called for antibiotic use only except in special circumstances.

Once the problem was identified, it was presented to the advisory panel. Discussion revealed that current medical evidence defined adjuvant therapy as curative, and physicians were uncomfortable delaying or reducing chemotherapy doses in the adjuvant setting. On the other hand, physicians agreed that medical evidence did not support changing the guidelines to include the use of colony-stimulating factors in the presence of febrile neutropenia. The guidelines and medical policies were updated to reflect these changes, which are now consistent with both regional and national medical guidelines and policies.

Using clinical guidelines, which are the basis for the practice of evidence-based medicine, presents a number of challenges for cancer care clinicians. First, clinical evidence does not exist or is controversial for many aspects of cancer care, especially in metastatic disease. Second, the quick pace of research and the continuous release of new drugs mean that guidelines must constantly be revised to maintain credibility in the medical community. Third, dying patients who want to continue treatment beyond a reasonable expectation of response may not be influenced by evidence that this course of action will not bring them the desired results. They will ignore the guidelines and insist that their physician ignore them as well. Finally, if each biologically distinct cancer requires a separate guideline with different plans for each stage of the disease, massive and complex documents will be created. Using these documents will be especially burdensome for community cancer programs, which treat a vast number of distinct malignancies.

Although following clinical guidelines does not result in consistently positive patient outcomes, clinical guidelines do help create a consistently high quality of care based on evidence, not anecdote. Clinical guidelines can also help health plans determine which treatment regimens are effective and should be supported with dwindling health care dollars, and which ones identify unproven, disproven, or highly experimental therapies.

Developing an Oncology Disease Management Program

Premera Blue Cross (PBC) in Seattle, Wash., in collaboration with CTCA Care Management Services/CorSolutions Medical, (CTCA/CS, Buffalo Grove, Ill.), designed and built a successful oncology disease management program using clinical guidelines. The program has been operational since September 1998 and now covers 100,000 people in western Washington state, with plans to expand coverage to the entire state and to Alaska within the next year.

The following goals were essential to the success and acceptance of the program:

- Improving the quality and consistency of cancer care
- Improving the patient experience with cancer treatment

ILLUSTRATION BY NEIL BRENNAN

Guidelines on Oncology Care

Premera Blue Cross builds an oncology disease management program that supports the early and consistent adaptation of clinical best practices. *by Judith K. Sanoshy, R.N., OCN®, and Peter A. West, M.D., M.P.H.*

- Involving the local oncology community in the design of the program
- Ensuring adequate health care resources by directing health care dollars towards effective practices and away from ineffective treatments through the use of guidelines.

Prior to the program, an analysis was conducted of paid claims data from the previous three years. Although claims-based analyses have their pitfalls, the results clearly suggested that physicians did not always use nationally accepted best practices and there were significant differences in practice treatment patterns within the region.

Guideline Development

Developing a successful clinical guidelines program has three essential steps. First, engage leading local oncologists to develop the clinical guidelines and oversee the program. Second, establish a comprehensive program to both support patients and encourage providers to adhere to the guidelines. Third, monitor and report quality-of-care outcomes, patient and physician satisfaction, and physician guideline compliance.

High-quality national guidelines for the treatment of cancer already exist. The National Comprehensive Cancer Network, an organization of 18 National Cancer Institute-designated cancer centers, has developed guidelines for more than 98 percent of all types of cancer. The guidelines are written by physician committees drawn from the leading academic and research institutions in the country and are detailed and complete. They are based on the best available medical evidence, or committee consensus when the evidence is controversial or absent, and are reviewed and revised continuously.

Instead of imposing national guidelines on our physicians, the Premera program chose to develop regional guidelines. A physician advisory panel was chosen to represent 1) community and academic practices, 2) urban, suburban, and rural settings, and 3) the disciplines of medical, surgical, and radiation oncology. Panel physicians had to be willing to participate in the guidelines process, representatives of high-volume practices, and respected within the oncology community. The advisory panel physicians share the guidelines with their partners and referral sources and are the principal way the guidelines are communicated to the general oncology community.

The panel's primary goal was to use consensus to craft guidelines that reflected regional practice patterns and were based on medical evidence. The selected physicians agreed that regional guidelines should be less directive than national guidelines and should also be simple to follow—a living document regularly revisited. Multiple options are included in each guideline so treatment can be tailored to physician and patient preferences.

Although the health plan hosts the advisory panel meetings, it has no control over the decisions of the panel's physicians. To be credible, the guidelines must be based on the best available medical evidence, regardless of economic or coverage issues. When the panel identified guideline choices not normally covered by the health plan, PBC agreed to consider all guideline-based requests on a case-by-case basis. CorSolutions' oncology staff monitors new research and drugs and evaluates changes in the national guidelines, calling the panel together as often as required to keep the guidelines current.

The advisory panel also annually identifies clinical outcomes that either demonstrate that quality of care is being maintained or provide data to help physicians make decisions when gaps exist in the medical evidence. A benefit of monitoring clinical outcomes is that clinical practices can be changed during treatment to ensure patients receive the best care possible.

Program Design and Development

The second step involved building a disease management program that supported the patient, the provider, and the clinical guidelines. Goals included improving the patient experience through support and education; helping providers utilize the guidelines; helping providers access services such as home health, durable medical equipment and supplies (DME) and hospice; and monitoring program operations and outcomes.

Communication is an essential element of the program, both external (to patients, providers, and the community) and internal (to health plan staff). The panel-approved guidelines were sent to all primary care practitioners and oncology specialists within the Premera network.

Figure 1. Breast Cancer—Use of Adjuvant Therapy

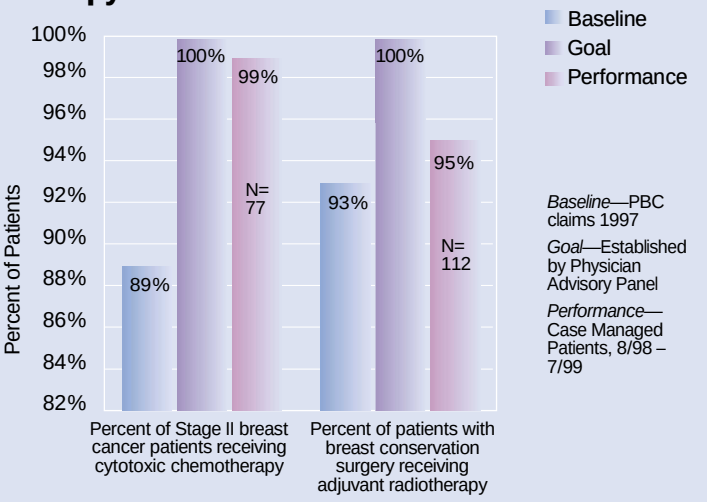
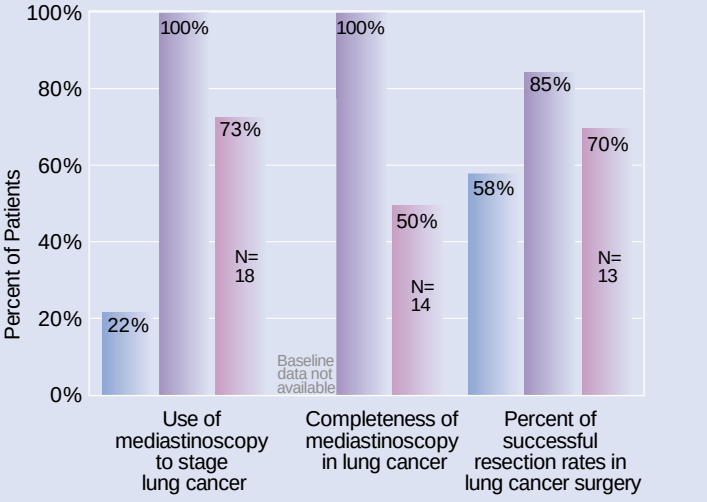


Figure 2. Lung Cancer—Use and Effectiveness of Mediastinoscopy and Resections



Source: Premera Blue Cross

CorSolutions' staff visited high-volume medical and radiation oncologists and surgeons to discuss the program and guidelines. CorSolutions arranged in-service meetings to discuss the guidelines with providers that did not receive personal visits. A general mailing was sent to program-eligible patients.

CorSolutions' oncology disease managers combine clinical oncology knowledge and case management experience to support the guidelines during their interactions with physicians and patients. The CorSolutions oncology disease manager becomes the patient and provider's key contact at the health plan—providing education, care facilitation, and claims resolution assistance. When patients enroll in PBC's cancer program, the oncology disease managers contact the patients' providers to ensure that they are familiar with the guidelines followed by the program.

CorSolutions employs skilled oncology nurses to compare the provider's treatment plan to the guidelines. These nurses determine when off-guideline care is driven by a patient's condition and is, therefore, not a true variance. Guideline variances that are not quality-of-care issues are noted but not pursued. For example, baseline bone scans are not indicated in Stage I patients without symptoms or an elevated alkaline phosphatase, yet the physician is not questioned if the examination is done. If the variance appears to be a quality-of-care issue, as in the case of a breast cancer patient who has a partial mastectomy but is not offered radiation therapy, the nurse contacts the provider to discuss the situation. Physician-driven variances are referred to the director of PBC's oncology program, who discusses them with the physician in question. If the variance is patient-driven, the matter is referred to the oncology disease manager who:

- verbally explores the patient's options and allows the patient to ventilate
- educates the patient, through discussion and written materials, on the risks and benefits of refusing recommended treatment
- supports the patient's *informed* decision.

The oncology disease manager provides written and verbal patient education, monitors the adverse effects of both therapy and disease, authorizes hospital and home health services and equipment, explains the benefits and limitations of treatment plans, and assists with claims payment issues. Following treatment, the oncology disease manager provides the patient with information regarding lifestyle changes and survivor issues and sends patients reminder cards for follow-up appointments and diagnostic testing.

Assessing Program Results

The PBC program is assessed on clinical, financial, and satisfaction measures. The clinical measures include physician adherence to the guidelines proposed by the physician advisory panel.

Eighteen months after the guidelines were first introduced, an adherence report based on medical record and claims-based reviews was discussed with the advisory panel and then disseminated to all the medical oncologists included in the review. Oncologists received unblinded results on their practice's adherence to 11 separate indicators, and blinded results on how well the other surveyed practices complied. The findings showed a 73 percent overall adherence to the guidelines. Solo/community practitioners followed the guidelines most closely, while institutional physicians followed them least closely. As might be expected, undertreatment was rarely a problem

The View From Inside

Frank M. Senecal, M.D., is one of the 15 physicians in the Puget Sound area of Washington state who developed Premera's clinical guidelines for oncology. A current member of Premera's medical oncology guidelines advisory committee, Senecal notes that the guidelines are very useful, but even he does not refer to them on a daily basis.

"They're guidelines, not mandates," Senecal said. "I use them, but I don't consult them. Nevertheless, they've proven to be very valuable, both to the insurance company and to those of us who get to revise them every six months or so."

Senecal believes Premera really listens to the doctors. "They want patients to receive the best treatment possible and want to be flexible, not heavy-handed."

It's flexibility that makes the program work, Senecal said. "When physicians treat a patient outside the guidelines, it doesn't mean they've ignored the guidelines. It means that their patients are in unique situations. Having to review exceptions to the rule gives the insurer a chance to look at clinical predicaments that would have been missed under normal circumstances."

Keeping the guidelines current also gives the physicians on Premera's advisory committee a highly valued opportunity to discuss current research and clinical findings with their colleagues. "Those of us who developed the guidelines got a lot out of reviewing the literature, and we get as much or more out of our revision meetings," said Senecal.

"After ASCO and the San Antonio Breast Conference, there's enough new information to warrant guideline revisions. When we meet to do the revisions, we discuss current clinical research and the evolving issues in the field to which we want to be sensitive.

"A lot is going on in the fields of breast and lung cancer right now, both in screening and treatment. They are both moving targets, so a forum to review new findings in these fields as soon as they come out is really valuable. A lot of preparation is required to make sure that the medical literature we review is relevant, but in spite of the extra work I find the meetings invigorating and useful."

Senecal said that an example of how the guidelines have affected clinical practice in his area is the use of bone scans and CT scans for staging early breast cancer. Both the tests were considered standard practice, but when the advisory committee found a wealth of medical literature saying they were useless and expensive in early-stage disease, the guidelines were changed. The result was an immediate drop in the number of scans that physicians ordered.

Strode Weaver, F.A.C.H.E., M.B.A., M.S.H.A., administrative director of the Swedish Cancer Institute in Seattle, Wash., also thought that Premera's flexibility and responsiveness were the keys to the program's success.

"When we first saw the guidelines, our initial reaction was one of concern," Weaver said. "For example, Premera wanted its nurses to call our patients directly to get feedback on treatment. We thought that would simply confuse the patients, who wouldn't know why the company was calling and probably wouldn't have the answers the company needed. We met with Premera at our office and recommended that Premera call us for clinical information, but suggested that having their nurses call patients to find out how they were doing and offer them the company's extensive list of available local support services might do some good. Premera adopted our ideas, and now it's a workable situation for everyone. We're a big practice. Maybe we have more clout than smaller groups, but it's crucial for providers to become involved. If the insurer asks you to serve on a committee and you don't do it, you lose a big chance for input."

Weaver believes that Premera's response to the growth factor debate (see box on page 20) facilitated acceptance of the program in general. "When Premera modified their guidelines to reflect actual practice in our community, they earned a lot of respect. By being flexible in one area, the whole program gained credibility," he said. "I believe that their willingness to be responsive when the rules didn't work made people think that the rest of their rules were probably pretty reasonable."

—Astara March, ACCC associate editor

and diagnostic work-up and follow-up tests continued to be overused in spite of evidence-based standards.

Measuring adherence serves several purposes. Physicians are reminded that the guidelines exist and are being monitored. Practices that are in agreement with medical evidence are listed, as well as those that are not, and physicians can compare their practices with those of others in the region. Guideline recommendations that are consistently ignored by providers are reviewed by the advisory panel to determine if the guidelines need to be changed or if physicians could use additional evidence to support the recommendations.

For example, clinical outcomes in breast cancer that were monitored include the use of radiation following partial mastectomy, the incidence of lymphedema, and the administration of cytotoxic chemotherapy in women with stage II cancer regardless of menopausal status. Lung cancer outcomes measured the quality of staging mediastinoscopy prior to surgery and the appropriate selection of candidates for curative surgery. Results after 18 months are illustrated in Figures 1 and 2.

The report noted an increase in the use of hospice services for terminal breast and lung cancer patients from a baseline of 15 percent (determined by medical record review) to 58 percent of patients who died while in disease management services. The average stay in a hospice was 24.4 days per patient.

Patients are regularly surveyed on their satisfaction with the program. The tool used measures which services are most important to the patient, the quality and usefulness of the written educational materials, and the relationship between the disease manager and the patient. The

A Look at Other Programs

Oncology Issues looked for similar insurer-formulated clinical guidelines for oncology in New York, Pennsylvania, North Carolina, Florida, Texas, Ohio, Illinois, Michigan, Oregon, California, Arizona, and their surrounding regions, but the insurance companies and physicians we contacted said that none existed. There was, however, great interest in the subject.

The principal oncology guideline organization is the National Comprehensive Cancer Network (NCCN). The NCCN's guidelines are based on evidence from multicenter clinical trials and have been recommended to practitioners and cancer care facilities by the National Cancer Institute (NCI). These are no more than recommendations, however. While facilities might be asked if they follow NCCN standards, their positive reply is considered sufficient, and a "no" is not penalized. There are no compliance requirements, and no one checks to see if an institution is as good as its word.

Richard B. Reiling, M.D., a standards compliance surveyor for the Commission on Cancer of the American College of Surgeons (ACoS), said that the large institutions he visits integrate parts of national guidelines into their private hospital "care paths," but most small cancer centers do not. Instead, they concentrate on creating standards of care that suit their region and their affiliated physicians. The ACoS requires that hospitals have clinical guidelines in place for accreditation, but these guidelines do not need to conform to any nationally established program.

Some insurance plans are hiring disease management companies to provide oncology services for their members and most of these companies formulate their own standards of care. PacifiCare Health Systems, Inc., for example, recently hired Quality Oncology (a subsidiary of LifeMetrix, Inc., based in Sunrise, Fla.) to run its oncology programs in southern California and according to its chair and CEO Edmund Bujalski, Quality Oncology has more than 200 site-specific oncology guidelines already in place.

In an interview with *Oncology Issues*, Bujalski said the guidelines were put together four or five years ago by Quality Oncology's founding physicians, in consultation with physicians at the University of Florida and the University of Miami. An internal guidelines review committee meets monthly to review the latest literature. If the committee finds evidence that a guideline should be changed, it makes a recommendation to the Clinical Advisory Board (CAB), which is composed of representatives from M.D. Anderson, Johns Hopkins, the Mayo Clinic, the University of Maryland, and other institutions. The CAB members review the recommendation, and if they approve it, the new guideline immediately becomes part of the company's web-based system. Quality Oncology physicians can type a disease, site, and stage into their computers and receive a clinical guideline back immediately. Patients can visit the company's web site (*www.cancerpage.com*), which is recommended by both the NCI and the FDA and was named one of the "Best of the Web" by *Forbes* magazine. Clinical trials are also covered. Physicians who want to use a treatment not included in the guidelines are allowed to do so if they can back up their changes with scientific evidence.

Trial and error have proven the need for rigorous, research-based evidence to stand behind any group's recommendations. Doctors are insisting on frequent guideline revisions and case-by-case examinations of special circumstances as well. Bujalski said that Quality Oncology's guidelines are very similar to the NCCN's, which he thought made sense since, "at the end of the day, we are all basing our standards on the same literature and research."

—Astara March, ACCC associate editor

results of the patient satisfaction survey showed overwhelming member satisfaction with the new program, and even surpassed the goal set by program staff. Ninety-nine percent of case managed members who returned the survey expressed belief that the case management program was helpful.

The physician satisfaction evaluation investigates a number of issues. For example, physicians are asked whether they agree with the guidelines, if they find them easy to use, and if they share them with their patients. (Physicians who respond that they are not familiar with the guidelines are sent a copy.) Physicians are also polled about which patient and provider services they find most helpful. A narrative section allows physicians to express comments and concerns. The office and facility section assesses whether the amount of interaction and requests from the oncology disease managers are acceptable to the physician's office staff, and whether the services delivered by the oncology disease managers are helpful.

As shown in Figure 3, although the number of returned surveys is small, 61 percent of physicians familiar with the guidelines expressed satisfaction with them. More than 90 percent of provider staff agree that the guidelines are helpful to patients.

Financial results were assessed 18 months after the start of the program (Figure 4). This allowed for 12 months of claims paid data with a five-month run-out. Actual charges in the performance year were compared to actual costs in the baseline year prior to program implementation. Adjustments were made for nationwide changes in clinical practice, changes in reimbursement levels, and increased drug costs. Savings in the program-eligible population were 10.7 percent. An identical analysis done on a control population with the same demographics, geographical locations, and provider networks returned an increase in costs of approximately 5 percent, so the gross overall program savings were considered to be more than 15 percent in the first year of operation. Preliminary results from the second program year demonstrate even greater financial savings during the second year.

Guidelines: A Collaborative Effort

Using clinical guidelines in the health plan setting facilitates collaboration between providers and the health plan managers, encourages best practices across the health care region, and directs dialogue between oncology disease managers and patients regarding evidence-supported care. Within the health plan, guidelines help develop the medical policies that drive payment decisions. Ultimately, clinical guidelines promote discussions between providers and patients, thereby decreasing unintended variations in care and improving care quality and efficiency. All three factors reduce overall health care cost.

Guidelines should be developed in collaboration with regional medical practitioners. For the guidelines to be accepted by the medical community they must reflect evidence-based decision making divorced from considerations of insurance coverage and cost. Guidelines must also be reviewed and revised continuously to incorporate new medical discoveries and products. Finally, guideline compliance must be measured and reported back to the physician community. If there are compliance problems, they should be discussed and modified without compromising the highest quality of care.

The Premera Oncology Disease Management Program is an effort to support the early and consistent adaptation of clinical best practices. The program continues to consistently demonstrate that using clinical guidelines increases patient satisfaction, improves the quality of care, and ultimately promotes cost savings.

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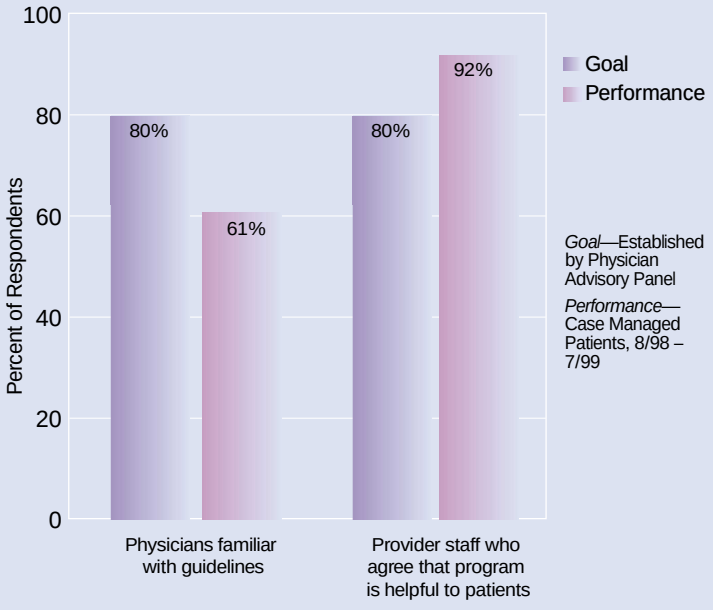
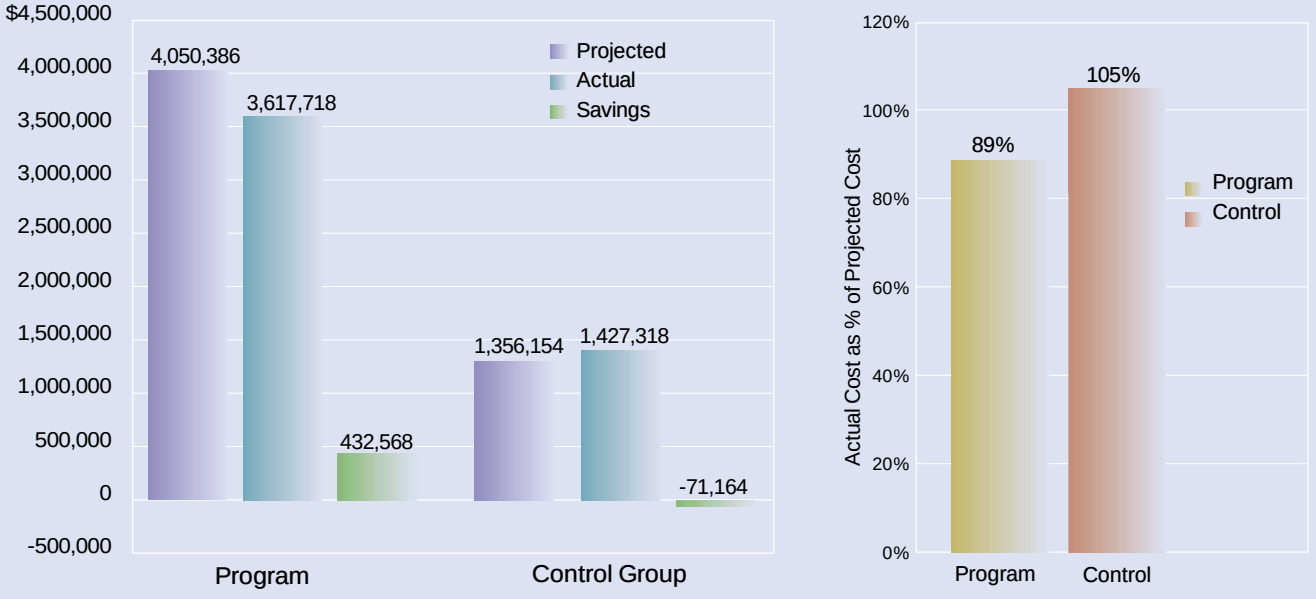
Figure 3. Provider Satisfaction



77 surveys sent—30% returned

Source: Premera Blue Cross

Figure 4. First-Year Program Evaluation: Medical Costs



Program = Insured PPO population covered by pilot program (225 active patients)
Control group = Self-funded PPO group's enrollees King, Pierce, Snohomish counties (97 active Patients)
Same time periods used and data adjustments made for Program and control groups

Source: Premera Blue Cross

Clinical Guidelines on the Internet

National Comprehensive Cancer Network

(*http://www.nccn.org*) offers *Practice Guidelines in Oncology for Health Professionals*, and a separate version for consumers called *NCCN/ACS Treatment Guidelines for Patients*. To access the guidelines online, site users must first order the CD version via mail, then type in a special CD code number on the Internet site.

Cancer and Treatment-Related Anemia Practice Guidelines were developed to assist clinicians in making decisions about when and how to treat cancer and therapy-related anemia.

The NCCN and the American Cancer Society (ACS) have also released a complimentary patient information resource. *The NCCN/ACS Cancer-Related Fatigue Treatment Guidelines for Patients* help patients discuss fatigue issues with their physicians. They also address treatment options for other causes of cancer-related fatigue, including pain, emotional distress, sleep problems, and decreased thyroid function.

The guidelines are part of a series to help patients and their families make more informed treatment decisions. Available in both English and Spanish, the series covers other supportive care topics, such as nausea and vomiting and cancer pain, and provides information on cancer of the prostate, breast, colon and rectum, and lung.

Both publications are available online at *www.nccn.org* or by sending a letter to NCCN, 50 Huntingdon Pike, Suite 200, Rockledge, PA 10946, or faxing a letter of request to 215-728-3877. They may also be ordered by calling NCCN (1-888-909-NCCN) or ACS (1-800-ACS-2345).

National Guideline Clearinghouse

(*http://www.guideline.gov*)
The NGC is a public resource for evidence-based clinical practice guidelines. The NGC is sponsored by the Agency for Healthcare Research and Quality (AHRQ) in partnership with the American Medical Association and the American Association of Health Plans. As a centralized source for almost all medical guidelines, this clearinghouse is a valuable resource for physicians. Each guideline is presented in various levels of detail, and physicians can compare key attributes of similar guidelines side-by-side.

AHRQ Evidence Reports/Technology Assessments (*http://www.guideline.gov/STATIC/resources.epc.asp?view=resources.epc*) provide users with links to summaries and full-text reports for evidence reports and technology assessments produced through the 12 evidence-based practice centers established by the AHRQ. These clinical evidence reports and technology assessments cover issues common, expensive, and/or significant for the Medicare and Medicaid populations.

NGC's Guideline Index (*http://www.guideline.gov/STATIC/whatsnew.guidel.asp?view=whatsnew.guidel*) is a complete list of guideline summaries available through NGC's web site. The listing is organized alphabetically by organization name, then disease/condition and treatment/intervention. The NGC Web site is updated weekly.

Other Resources

Many associations, medical societies, and organizations offer medical guidelines on the Internet, usually limited to a single medical specialty or area of clinical practice. Here are a few web sites that might be of interest to the cancer care community:

American College of Radiology
(*http://www.acr.org/departments/stand_accred/standards/dl_list.html*)
Each standard in this ACR listing has been developed through an expert review and consensus process. The ACR standards define principles of practice that should produce high-quality radiological care.

Cancer Care Ontario Practice Guidelines Initiative (CCOPGI)
(*http://www.ccopebc.ca/*)
This is a CCOPGI inventory of international cancer clinical guidelines—categorized according to the method used to generate the recommendations. The extent to which each guideline was generated using an evidence-based process is indicated with a categorization scheme developed by the CCOPGI. This list will be updated over time.

eRisk Working Group for Healthcare
(*http://www.medem.com/corporate/corporate_erisk.cfm*)
Log onto this web site for guidelines for physician/patient interaction and communication via the Internet. These guidelines were developed in collaboration with more than a dozen U.S. medical societies and 30 malpractice carriers that represent more than 70 percent of the nation's insured physicians. The guidelines include a series of documents addressing potential online liability issues and offering guidance for patient/physician communication on the Internet.

Institute for Clinical Systems Improvement
(*http://www.icsi.org/index.htm*)
The Institute for Clinical Systems Improvement (ICSI) is a collaboration of health care organizations dedicated to championing health care quality and to helping its members accelerate the implementation of best clinical practices for their patients. The ICSI program offers prevention and treatment guidelines that have been reviewed by ICSI member medical groups and are re-evaluated periodically. The ICSI also develops technology assessment reports for providers who want to learn about new and emerging medical technology and how they can apply these technologies to care.

Usability Analysis of Guideline Encoding and Application in Clinical Practice
(*http://www.glif.org/workshop/position_stmt/vpatel3_0101.pdf*)
An InterMed guideline workshop position paper by Vimla Patel, Ph.D., D.Sc., and colleagues outlines the analytical steps needed to define how computerized clinical guidelines can be employed effectively in clinical practice. InterMed is a joint project of researchers at Harvard and Columbia Universities and the ACP-ASIM.