

The Patterns of Care Study: A Model for Clinical Quality Assessment

Jean B. Owen, Ph.D.*
Gerald E. Hanks, M.D.†

For 20 years the Patterns of Care Study in Radiation Oncology (PCS) has sought to improve the quality and accessibility of radiation therapy in the United States. The background and approach of the study have been described in previous publications by Simon Kramer, the first Principal Investigator; David Herring, the first statistician; and Gerald Hanks, the current Principal Investigator (Hanks and Kramer, 1983; Kramer, 1977; Kramer, Hanks, and Diamond, 1988; Kramer and Herring, 1976). The rationale of the PCS stemmed from observations that differences exist across types of practice, differences can be documented, and differences can affect patient outcome. The study has examined the care received by patients in all types of radiation therapy facilities throughout the United States and has identified patterns of differences in attributes of the care patients receive.

The work of Donabedian (1966, 1980, 1982, 1985) was a major source of the framework for the PCS. The PCS has assessed the structure, process, and outcome of medical care, as well as the interrelationships among structure, process, and outcome. Structure includes the material, equipment, and personnel used to provide care. Process refers to the actions the provider takes to evaluate and treat the patient. Outcome is the result for the patient in terms of changes in health status. The relationships among structure, process, and outcome have also been investigated to identify critical variables.

The PCS has developed guidelines for the workup and treatment of many types of cancer and has developed techniques to measure not only compliance with the guidelines but also the outcome for patients.

Methods—The PCS Model

The PCS approaches the assessment of medical care through a series of steps:

1. Definition and justification of the problem to be studied
2. Structure—definition and facilities survey
3. Process—consensus panel and process survey
4. Outcome—definition and outcome survey
5. *Interrelationships among structure, process, and outcome*

Definition and justification of the problem to be studied

The first step is definition and justification of the problem. The PCS has developed guidelines for patients treated with radiation therapy for cancer in many disease sites. The criteria for selection of a disease site by the PCS are:

- The cancer involves a large number of patients
- Radiation therapy plays a major role in treatment
- Scientific questions about workup or treatment exist, which a PCS might help answer

The number of patients treated by radiation therapy is substantial. In 1989, the estimated number of new cancer cases, excluding carcinoma in situ and nonmelanoma skin cancer, was 1,010,000 in the United States and Puerto Rico (*Cancer Facts and Figures—1989*), and radiation oncologists treated 492,120 new patients (Owen, Coia, and Hanks, 1992). Of all cancer patients, 48 percent are treated with radiation therapy. Thus, a study of patterns of care in radiation oncology can affect a large number of patients and a large amount of money spent on their care.

The initial step for each study is the definition of the guidelines to be developed and tested and the type of surveys to be conducted. For example, a study might develop guidelines for workup and treatment of cancer of the breast and then design and conduct a series of surveys to measure actual workup, treatment, and outcome for the population of patients in the United States.

*From the American College of Radiology, Philadelphia, PA.

†From the Fox Chase Cancer Center, Philadelphia, PA.

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Abbreviation: PCS = Patterns of Care Study in Radiation Oncology.

Structure

Definition. Structure encompasses the settings in which medical care takes place and the resources available to provide care. The structure of the practice of radiation oncology includes the number and characteristics of the equipment and personnel in all facilities doing megavoltage radiation therapy. The PCS defines and measures structure on the assumption that good structure is necessary for the delivery of good medical care and is likely to be associated with good outcome.

Facilities survey. The PCS conducts facilities surveys to measure the structure of the specialty. The methods have been described in detail (Diamond, Hanks, and Kramer, 1988; Kramer, Hanks, Herring et al., 1982; Owen, Coia, and Hanks, 1992). The PCS defines the unit of observation as the facility—each separate physical location in which megavoltage radiation therapy is delivered. The PCS maintains a mailing list of all radiation oncology facilities in the country and updates the list before each survey with information from American College of Radiology sources and from the radiation control officers in each State. The facilities survey uses a self-administered questionnaire, which is mailed to the head of each radiation oncology facility. The short survey questionnaire asks for information on validity, treatment machines, personnel, number of new patients, and types of procedures. The returned forms are reviewed and data are entered into a data base and verified. Multiple mailings and followup phone calls lead to responses from virtually all facilities.

The survey provides a current census of radiation oncology resources, including personnel and machines, for the entire population of facilities in the United States. Analysis of the data has shown the trends in the resources available, such as the increase in freestanding facilities, the decline in part-time radiation oncologists, and the shift in treatment machines from cobalt machines to linear accelerators. In addition, the survey provides data on the population of eligible facilities from which a stratified random sample is drawn for PCS process and outcome surveys.

Process

Consensus panel. After defining the general problem, the PCS forms a panel of experts to define the problem in detail, review the literature, develop the guidelines, and plan a survey to test the guidelines. The sponsoring organization must be able to gain broad support among the providers involved and must represent the full range of accepted schools of treatment. The panel includes physicians and physicists, as appropriate for the particu-

lar disease. The physicians represent various strata of practice, such as academic treatment centers and private practice, and different medical specialties, such as radiation oncology and medical oncology. All are experts in treating patients with the disease under study. The panels develop criteria for the quality assessment process (Hanks and Kramer, 1984).

Before the first meeting of the panel, the investigators review the literature pertinent to the problem and circulate the information to panel members.

At the first meeting of the panel the agenda includes:

- Definition of the problem—review and refinement
- Development of the working draft of the decision tree
- Development of the working draft of the recommended treatment systems
- Preliminary plans for a survey of compliance with guidelines

The panel discusses and refines the problem. The panel might limit the eligible patient population for the particular type of cancer to patients treated with curative intent, patients with the more frequently encountered cell types, or patients without distant metastases. The time period for the consensus is set, usually the current year or another recent year.

The PCS uses a decision tree as a framework to depict the division of patients into treatment groups. The decision tree presents the series of decisions that should be made with each patient to determine optimal treatment. The decision points include determination of eligibility for the study and classification of the extent and type of the disease. Details of workup may include diagnostic procedures necessary to classify patients into treatment groups. The panel reviews the patient characteristics crucial in determining treatment for the disease under study. Patients with similar values of these characteristics are candidates for similar treatment in type and intensity. The panel uses the decision tree to organize the discussion of the steps needed to classify patients into appropriate treatment groups.

The panel seeks a consensus on the acceptable treatment systems appropriate for each of the patient groups identified in the decision tree. The panel discusses and seeks a consensus on the recommended treatments. Details of the consensus may include modality, type of equipment, dose ranges, treatment areas, and adjuvant therapy.

The panel reaches a consensus by systematic discussion of the problem, going through the decision tree and treatment systems point by point. Evidence considered at each point includes results of previous PCSs, results from

the literature, information from ongoing clinical trials or other research in progress, and clinical experience. The panel chair tries to achieve consensus among all members of the panel. Any disagreements are discussed by the panel, which seeks resolution by discussing the point in question, reviewing the evidence, and considering compromise.

The decision tree and treatment systems are the schematic depiction of the guidelines for workup and treatment of the patients under study. The panel chair writes a document describing and justifying the guidelines, explaining any limitations, and documenting the sources for the consensus. This consensus statement is circulated for comment to all panel members, revised to incorporate comments, and circulated again.

The panel holds a second meeting to review the consensus statement, discuss any remaining areas of disagreement, and complete plans for the survey of compliance with the consensus guidelines. The consensus statements are completed and published. A number of examples are available (Brickner, 1990-1991; Coia and Wizenberg, 1990-1991; Fowble, 1990-1991; Hanks, 1990-1991; Hoppe, 1990-1991).

Process survey. After the guidelines are developed and documented, the panel designs the survey to test compliance with the guidelines. The survey questionnaire is based on the elements of workup and treatment that the panel found to be critical in its consensus guidelines. Included are questions on eligibility, diagnostic procedures to determine patient stage or treatment category, type of treatment, and treatment details.

The PCS process surveys are retrospective studies of patients treated in a recent year, for which the guidelines are designed to be appropriate. The sample design, developed by Joseph Sedransk, produces estimates of population means and totals for the process questions, which represent the national averages for all patients treated in the country (Malec and Sedransk, 1985; Sedransk and Sedransk, 1979). The sample design uses stratified, two-stage cluster sampling with simple random sampling at each stage for each stratum.

The first stage is the selection of facilities from all facilities in the United States. The PCS has information on the population of all facilities doing megavoltage radiation therapy from the facilities survey, described in the "Structure" section. The facilities are stratified into groups expected to be homogeneous, using such variables as resident training status, type of equipment, facility size, or hospital ties. The need to provide data for comparisons among strata of interest determines sample size per stratum. A random sample of facilities

from each stratum is selected and invited to participate. The head of the department of each selected facility receives an invitation to participate in the survey, and most agree.

The second stage of the sample design selects patients from the facilities in the survey. The chief of the department receives a listing of the eligibility criteria for the survey and is asked to provide a list of identification numbers for patients meeting the eligibility criteria. The PCS process surveys conducted in the past have surveyed between 5 and 10 patients for a disease site from each institution. If the number of eligible cases is below the desired number, all cases are surveyed; otherwise, from the list of eligible patients the PCS selects a random sample of cases. The PCS process surveys have collected data for three to five disease sites in each survey.

The tradeoffs in designing the process survey revolve around the number of facilities, the number of disease sites, and the number of cases per disease site at each facility. The number of cases per disease site was set in the range of 5 to 10, based on the finding that variation has consistently been higher between facilities than within facilities, which implies that national averages do not require large numbers of cases from each facility.

The PCS process survey collects data by reviewing patient charts and abstracting the data for the survey questionnaires, which were derived from the consensus guidelines. A survey team, consisting of a data manager, a radiation oncologist, and a radiological physicist, visits the facility, reviews the patient charts, and abstracts data. The information provides details of workup and treatment for each patient. All patients are restaged from the information in the chart to ensure consistent staging definitions. The physicist surveyor recalculates doses to critical points. The PCS questionnaires and survey procedures ensure that the cases from many institutions have common staging and common dose calculations at consistently defined critical points.

Data are entered into the data base and verified before analysis. The data are analyzed using programs weighted in accordance with the sample design of the sampling statistician, Joseph Sedransk. The results of the process survey analysis, thus, reflect the national averages. The PCS has reported the results of process surveys for a number of disease sites (Coia, Hanks, Martz et al., 1988; MacLean, Davis, Herring et al., 1981; Newall, Cooper, Powers et al., 1979; Solin, Fowble, Martz et al., 1991).

Outcome

Definition. Because the PCS has studied patients with cancer in various disease sites, the outcomes of interest have reflected the potentially fatal consequences of the disease. Most PCS studies have examined patients treated with curative intent. Death from the disease is a possible outcome for all patients, but cure is also possible. The outcomes in the PCSs have been survival, recurrence, and complications. Details relating to these outcomes are collected. For survival, data include date of death or date last known alive and cause of death. For recurrence, data include any recurrence, the date of recurrence, and the site of recurrence. For complications, data include any complication, date of occurrence, severity, site of occurrence, and type of complication.

Outcome survey. The PCS has collected data on outcome for the same patients included in process surveys for a number of studies. The methods of data collection have varied with different surveys. One type of outcome survey involved a second site visit by a survey team to each facility several years after the process survey to conduct chart reviews and collect data on outcome. In a second type of survey, a survey team conducted one site visit to review charts and collect data on both process and outcome at the same time. A third type of survey used self-administered questionnaires mailed from headquarters to each facility to collect information on outcome.

Each method of data collection has advantages and disadvantages. A site visit by a survey team reviewing charts can provide more detailed information and more consistent data than a survey with a self-administered, mailed questionnaire. Surveys with site visits, however, are more expensive than mail surveys. The option of collecting both process and outcome data in one site visit is appealing, but only early outcome data can be collected this way. For a disease with an expected median survival of 5 years or more and rapidly changing consensus guidelines, collecting process and outcome data in one on-site survey means either the process data are old when collected or the outcome data cover too short a time to provide desired survival, recurrence, and late effects data. Various combinations of data collection methods can be used to provide followup over time.

Analysis of outcome data includes actuarial analysis of survival, recurrence, and complications with tables and graphs displaying the results. These surveys have provided data on outcomes for many disease sites treated by radiation therapy. The data are unusual in that they provide outcome information for patients treated outside

a clinical trial setting and in multiple institutions. The PCS has published many reports on the results of outcome surveys (Coia, Won, Lanciano et al., 1990; Hanks, 1991; Hanks, Diamond, Krall et al., 1987; Hanks, Herring, and Kramer, 1981 and 1983; Hanks, Kinzie, Herring et al., 1982; Hanks, Kramer, Diamond et al., 1982; Hanks, Kramer, Kinzie et al., 1983; Kramer, 1981; Kramer, Hanks, and MacLean, 1983; Leibel, Hanks, and Kramer, 1984; Lustig, MacLean, Hanks et al., 1984; Wallner, Hanks, Kramer et al., 1986).

Interrelationships among structure, process, and outcome

The PCS conducts outcome surveys, not only to report outcome information, but also to examine the interrelationships among process survey criteria and subsequent outcome. The PCS is based on the assumption that good processes of care are important in providing the patient with the best chance of surviving cancer. This assumption can be confirmed if relationships can be shown between good processes of care and improved outcome. The sample design of the PCS allows an assessment of patient characteristics, treatment parameters, and the relationship between process measures and outcome measures. The PCS has made many reports of these relationships (Coia and Hanks, 1988; Hanks, Krall, Martz et al., 1988; Hanks, Leibel, Krall et al., 1985; Hanks, Leibel, and Kramer, 1983; Hanks, Martz, and Diamond, 1988; Hanks, Martz, Krall et al., 1989; Kinzie, Hanks, MacLean et al., 1983; Lanciano, Martz, Coia et al., 1991; Lanciano, Martz, Montana et al., 1992; Lanciano, Won, Coia et al., 1991; Lanciano, Won, and Hanks, 1992; Lustig, Krall, Curran et al., 1991; Marcial, Marcial, Krall et al., 1991; Montana, Martz, and Hanks, 1991). In many instances these reports have provided unique insights because the data reflect the diversity of treatments actually delivered in the United States, including patterns of treatment not possible in a clinical trial setting.

Since the PCS can also identify the type of facilities in which patients are treated, it can examine correlations between structure and process variables (Hanks, Edland, and Diamond, 1989) and between structure and outcome variables (Diamond, Steinfeld, and Hanks, 1991; Hanks, Diamond, and Kramer, 1985). Such analyses have shown that better equipment and better techniques can be associated with better outcome.

Application—Management of Cancer-Related Pain

The PCS model can be applied to many clinical research problems. This section will describe its application to the management of cancer-related pain, one of the panel topics currently under way in the Office of the Forum for Quality and Effectiveness in Health Care.

The PCS would approach this problem through the series of steps described in the "Methods" section:

1. Definition and justification of the problem to be studied
2. Structure—definition and facilities survey
3. Process—consensus panel and process survey
4. Outcome—definition and outcome survey
5. Interrelationships among structure, process, and outcome

Definition and justification of the problem to be studied

Cancer patients undergoing treatment can be divided into two broad groups: those treated with the intent of curing the disease and those treated with the intent of relieving symptoms. For patients in the latter group, treated with palliative intent, pain relief is often the primary purpose of the treatment. One form of treatment frequently used to relieve cancer-related pain is radiation therapy. Although the PCS model could be applied to developing guidelines for all modalities used to manage cancer-related pain, we will limit this description of the application problem to the following:

Developing guidelines for the management of cancer-related pain in all patients treated in the United States with radiation therapy for whom pain relief is the primary objective of treatment.

At each step in the PCS model, corresponding steps could be followed for other modalities used to treat cancer-related pain.

Of the 48 percent of all cancer patients in the United States treated with radiation therapy, the 1990 facilities survey shows that approximately 50 percent are treated with palliative intent. About 250,000 cancer patients in the United States are treated by radiation therapy with palliative intent. A PCS conducted in 1985 found that 73 percent of a stratified national sample of patients treated with palliative intent were treated with the primary stated purpose of pain relief (Coia, Hanks, Martz et al., 1988). Thus, guidelines developed for this set of patients would affect a large number of patients.

Structure—Definition and facilities survey

To obtain the basic information on the structure of practice and the population information on all facilities necessary for the sampling design of a process and outcome survey, the PCS would conduct a facilities survey as described in the "Methods" section.

Process

Consensus panel. After defining the problem—developing guidelines for the management of cancer-related pain using radiation therapy—the sponsoring organization would form a panel to refine the definition of the problem, develop the guidelines, and plan a survey to test the guidelines. The panel would consist of radiation oncologists and other medical specialists with experience in treating patients for pain relief, including representatives of different strata of practice, such as academic treatment centers and private practice. The panel would also include other health professionals, such as radiological physicists. The panel could include consumer representatives.

Before the panel's first meeting a review of the literature pertinent to the problem would be conducted by the principal investigator, other investigators, and the staff. The information would be circulated to panel members. At the first meeting the panel would review and refine the definition of the problem, develop the working draft of the decision tree and the recommended treatment systems, and make preliminary plans for a survey of process and outcome for these patients.

In refining the definition of the problem, the panel would consider such questions as:

- Will patients from all treatment sites be included?
- Will patients with all primary cancers be included?
- Will patients with first, second, and subsequent recurrences all be included?
- Will patients with any extent of disease be included?

The panel might decide to limit the guidelines for workup and treatment to those patients receiving palliative irradiation for pain at a treatment site of bone. It might decide to include patients with single or multiple metastases, any recurrence, and any primary site. The panel would then discuss the problems of identifying groups of patients whose similar characteristics make them candidates for the same type and intensity of treatment. The decision tree would be developed to depict the series of decisions that should be made with each patient to determine optimal treatment. Unlike most previous PCS decision trees developed for cancers

treated with curative intent, the decision points of the decision tree for treatment of cancer-related pain would not focus on staging. The decision points would include questions on:

- Eligibility
- Symptoms and indications
- Results of alternative forms of treatment
- Whether metastasis is solitary or multiple
- Whether metastases are recurrent
- Whether intent of treatment is pain relief only, or includes other intents as well

After the panel achieved consensus on the key decision points that would alter the recommended treatment for patients, the members would develop the alternative acceptable treatment systems appropriate for the patient groups identified in the decision tree. The panel chair would write a document describing the consensus and justifying the decision tree and treatment systems. The document would note questions requiring more data for consensus. The consensus panel would also develop a plan for a survey of the process and outcome of patients who met the eligibility criteria.

Process survey. The panel would make plans for the process survey to determine how eligible patients are actually treated throughout the United States. The process survey is conducted for patients in three to five disease sites at the same time. The stratification system would be designed with the objectives of all disease sites considered. Since all types of radiation oncology facilities treat patients for cancer-related pain, the full range of practice would be represented. A stratified random sample of facilities would be selected and asked to submit lists of eligible patients. A random sample of patients would be selected from the lists submitted.

The survey questionnaire would include questions on eligibility, workup, and treatment that derive from the panel's consensus criteria as expressed in the decision tree, treatment systems, and consensus statement.

The survey team—usually a data manager, radiation oncologist, and physicist—would travel to each facility, review charts of selected patients, and abstract information. The data would be entered, verified, and analyzed. The questions for analysis would include:

- What processes of care are given to the patients?
- Does compliance with the guideline vary by strata?
- Does compliance with the guideline vary by patient characteristics?

- Does compliance with the guideline vary by disease characteristics?

Outcome

Definition. For a PCS of management of cancer-related pain, the outcome measures would focus on pain relief. The best measures of outcome would be quality of life measures on pain relief that could be obtained from chart review. Survival and complications data would be secondary outcome measures. The major goals of the outcome survey would be to identify variations in outcome and to examine their relationships to process variations.

Outcome survey. The time period of the survey could be a recent year and plans could be made for further followup, or, alternatively, the time period could be a previous year so that complete followup could be obtained at the time of the initial survey. The survey team would collect outcome data on-site at the same time on the same patient charts as the process survey. Additional followup by mail might be obtained, depending on the time periods of the survey. The data would be entered, verified, and analyzed to establish the variations in outcome by strata, patient characteristics, or disease characteristics.

Interrelationships among structure, process, and outcome

The PCS would analyze the data on the structure, process, and outcome of patients treated for management of cancer-related pain and examine interrelationships of the three sets of elements. Questions for analysis would include:

- Do patients whose treatment conforms to the guidelines have better outcome?
- Do some types of facilities conform to the guidelines more consistently than others?
- Do patients treated in some strata of facilities have better outcomes than others?

Conclusion

The PCS model provides an integrated method not only for developing a guideline, but also for designing and conducting surveys to assess all components necessary for quality care. The PCS model uses the available results from other studies, such as randomized controlled trials, to develop the guideline. The PCS surveys provide methods for collection of data to help answer the entire range of questions identified in the development of the guideline. Examples of situations in which the PCS

methods are particularly useful include (1) providing evidence in diagnosis and assessment where few randomized controlled trials are likely to be available and (2) providing evidence for all of the population, not just the subgroups for which results of other studies are available.

The PCS has a 20-year history of defining quality assessment problems, conducting surveys, and analyzing the data in radiation oncology. It has established a profile of the structure of practice, reported trends in the structure over time, established consensus guidelines for management of patients in many disease sites, conducted process surveys to test compliance with the guidelines, collected outcome data on patients in process surveys, and reported results of analysis of the data. The PCS model could be applied to a wide range of problems in treatment and management of disease. Among the requirements is the ability to define clearly the patient and provider populations and to achieve cooperation of the provider groups involved.

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