

REFERENCES

Oncology Nursing

Coordinated standards for nursing practice accepted by the oncology nursing professional and implemented in places of health care delivery is congruent with:

- A. Nursing Practice Standards developed by the American Nurses Association.
- B. Outcome Standards for Cancer Nursing Practice developed by Oncology Nursing Society and American Nurses Association.
- C. Outcome Standards for Cancer Nursing Education developed by Oncology Nursing Society.
- D. Outcome Standards for Public Education and Patient Education developed by Oncology Nursing Society.

In preparing these standards, the ACCC endorses the efforts of the Oncology Nursing Society. It is recommended that the standards and guidelines published by the ONS be considered when devising a plan for standard compliance. Standards and guidelines include:

- A. Outcome Standards for Cancer Nursing Practice.
- B. Outcome Standards for Cancer Patient Education.
- C. Guidelines for Nursing Care for Individuals and Families Living with Cancer.
- D. Cancer Chemotherapy Guidelines and Recommendations for Nursing Education and Practice.

Pharmacy Services

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STRIVING FOR EXCELLENCE: EVALUATING QUALITY OF CARE IN ONCOLOGY

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Is it possible to evaluate and compare institutions on the basis of differences in the quality of their oncology care? Recent attempts to do this kind of evaluation with cardiac care have drawn considerable criticism from a variety of quarters.¹ Yet, in oncology, there is a long history of evaluating the efficacy of treatments using explicit outcome standards such as length of survival and disease free interval. Unlike many

medical specialties, oncology is built from a base of research protocols with specific comparative measures. In addition, programs such as the American College of Surgeons' Patterns of Care Evaluations (PCEs), the community oncology programs of the National Cancer Institute, and studies of the patterns of care, have laid the groundwork for evaluations of quality. Our future efforts in evaluating quality, however, will need to surmount major methodologic and political problems. In this review article, we assess the obstacles and the opportunities facing organizations that wish to evaluate the quality of cancer care.

The First Problem: Whose Definition(s) of Quality Will Prevail?

Increasing pressure to establish standards of quality has accompanied the new Federal and business initiatives to lower costs.² Unfortunately, the interpretation of "quality" varies with the motivation of the interpreter. To the Federal government, quality, for the moment, seems to be defined by efficient utilization of services and cost containment. To the Joint Commission on Accreditation of Hospitals, quality was assured by adherence to their structurally-oriented standards, which encompass requirements

for management, medical staff organization and function, hospital services, and physical plant design and function.³ The American College of Surgeons (ACoS) also maintains a concept of quality, which, as demonstrated in its criteria for approval of hospital cancer programs, is based on the organizational structure of the program.⁴ The JCAH now plans to focus on outcomes of care, as does the Health Care Financing Administration (HCFA).

Definitions of quality also reflect attempts by investigators to find a concrete, tangible means of identifying and measuring quality. In some studies, quality is defined to mean a reduction in mortality or complication rates; in others, it is the performance of a minimum number of accepted procedures for a given diagnosis. Rutstein and co-workers propose the use of sentinel health events; unnecessary disease and disability, and unnecessary deaths, as definitions as well as measures of outcome.⁵ The measures for quality, in these instances, actually become the definition of quality.

Amidst this range of proposed definitions and criteria for "quality health care," no single definition, criteria, or methodology for the determination of quality has emerged as a standard.⁶ Few investigations of the overall quality of American health care have been conducted,

and none have put forth a standard set of definitions that have been acceptable to a diverse audience.⁷

The Evaluation Conundrum

While no methodology can compensate for obscure objectives or intangible criteria, there are a number of other formidable issues that plague researchers.

Over the past decade a number of evaluators have developed ways of looking at all of the components of care.^{8 9 10 11} Influenced primarily by Donabedian, other researchers and health care program evaluators have utilized strategies parallel to his evaluation model, incorporating aspects of his three major approaches to evaluation: "structure," "process," and "outcome." In his description, Donabedian defines structure as the resources used and environment provided in the delivery of care; process as the activities that constitute care, such as the actions of the health care professionals; and outcomes as the consequences or end results of the care provided.¹²

The quandary of defining quality also complicates the measurement and evaluation of quality care. Structure and process approaches alone (with their emphasis on resource capabilities and efficiency) may fail to detect unfavorable patient outcomes, and as some evaluators have argued, measures of capability and efficiency are not reliable determinants of outcomes of care.¹³ Even outcomes (and proxy measures such as complication or mortality rates) are open to questions of reliability and validity.

In the final analysis, most evaluators recognize the power of Donabedian's model and the deficiencies of reviewing data from only one approach. For example, if a group of cancer patients live longer than another group of patients, what made the difference? Was it the oncologists? Were they well trained? Did they have the better equipment? These questions elicit information about Donabedian's measures of "structure."

Perhaps the oncologists in this institution used a new form of therapy, did better work-ups, or secured more appropriate consults. Maybe it was the nursing care. All of these activities are measures of "process." Or, perhaps the

only measures available are length of survival or disease free interval, clearly "outcome" measures.

One can quickly see the problems of using just one or the other or even a combination of two of these evaluation approaches. Good training doesn't guarantee good outcomes. Outcomes alone, on the other hand, do not tell you whether it was the physicians, the protocols, the treatment after discharge, or just random luck. In fact, none of the factors above even takes into account patient variables, like age, sex, race, severity, performance status, stage of disease, and so on.

Structural evaluations, such as a typical JCAH hospital accreditation review, are labor intensive, subject to wide variations over time (for example, three weeks prior, during, and two weeks after a JCAH inspection), and are incredibly costly. Essentially, they give you a very expensive snapshot. Process evaluation requires ongoing data collection and involves ongoing monitoring (although this is something we have learned to do with utilization review) and significant evaluation resources to analyze the data. Outcome evaluations have their own set of problems, which we will review in depth below. Gathering data on all of these parameters is a costly proposition. Thus, the pressure is to simplify, find good proxies that are not too subjective, too costly, or too ridiculous.

Identifying the Evaluators

Despite the absence of a standard definition of quality, regardless of the high costs involved, ignoring the methodologic quagmires, the compulsion to measure quality continues. The Federal government wants it. Payers demand it. Patients want to read about it. Ad agencies want to tout it. Accreditors, evaluators, and utilization review experts all want to measure it...one way or another. And everyone wants to influence it...presumably for the better.

Using standards (structural evaluation), the JCAH, the ACoS, state and local licensing authorities, even Medicare, all use periodic review and site visits for evaluation. Classically, JCAH and ACoS have asked the institution to monitor its own quality by performing studies.

Now, JCAH is considering outcome evaluations as well.

HCFA, PROs (Peer Review Organizations), and even the National Institutes of Health (NIH) are involved in process evaluation, albeit from different perspectives. HCFA and PROs want to review for medically unnecessary procedures, to minimize utilization of services, and increase cost containment. NIH, through a series of consensus conferences, wants to establish standards of practice, or process criteria. Thus, NIH tells you what is good science and good patient care, while HCFA and the PROs tell you for what they will and will not pay.

While less frequently utilized, there is a growing arsenal of methodologic weapons available for use in the quality of care evaluation wars. The NIH consensus panels, for example, use a variety of group process techniques to isolate and identify the "key decision points" that should occur during the process of patient assessment and treatment. These "key decision points" can then be organized to form a "decision tree," which becomes the basis for a standard of care.¹⁴

Diagnosis-related groups (DRGs) also have been used as a focal point for the development of patterns and standards of care. In one study, patterns were derived from diagnosis and treatment practices for subsets of homogeneous diagnoses within a DRG, and then were used as guidelines to account for utilization of patient resources as well as to suggest standards of care.¹⁵

The JCAH is exploring the use of the "tracer" method, developed by the Institute of Medicine. The method identifies discrete health problems for which criteria for treatment are then defined and used as a conceptual framework for the evaluation of interactions between providers, patients, and the environment. A particularly appealing feature of the tracer method is that it tracks problems through the health care system, and thus has the potential to measure both the process and outcome of care.¹⁶

Another similar concept, explored by HCFA in collaboration with Blue Cross of Pennsylvania, was the development of Patient Management Categories (PMCs), a computerized patient classification system. Produced by physicians from 50 disease-specific panels,¹⁷ the PMCs were

then used to construct patient management pathways, physician-specified clinical management strategies. The PMCs incorporated severity of illness determinations, and a set of relative cost weights (one for each PMC) were also derived.

Patterns and Standards of Practice in Oncology

Patterns of care and process evaluations serve as proxies for outcomes in much the same way that following a protocol leads to desired result. Assuming that you follow the protocol (more or less) and that the patient meets the eligibility standards of the protocol (more or less), then one can assume that patient outcomes will be similar.

The Patterns of Care Study, initiated in 1973 by the American College of Radiology, included structure, process and outcome criteria in its evaluation, and surveyed more than 300 radiotherapy facilities. Process assessment was accomplished with "decision trees" which represented the consensus of a large number of radiotherapists on "key decisions" in the evaluation and management of ten particular types of cancer.¹⁹ The assessments were performed by a site visit team doing chart reviews. Patient outcome information was obtained through the use of survey questionnaires, which requested follow-up information such as tumor control, survival, and complications of treatment. The key decision method of assessment seemed to appropriately reflect the "common logic" of radiotherapeutic practice.²⁰ Vaughn used this same "patterns of care" model to analyze multidisciplinary cancer patient management for four disease sites and found it useful for the evaluation of other cancer treatment modalities.²¹

Miransky et al, using retrospective data, investigated the relationship between hospital size and selected treatment-related issues in the management of primary breast cancer at fourteen community hospitals with current or previous affiliations with Memorial Sloan-Kettering Cancer Center's Cancer Control Network.²² In a prior study, Kerner and associates also conducted an audit, through the Memorial Sloan-Kettering Cancer Control Network, to compare the

differences in diagnosis and treatment of primary colorectal cancer patients in ten community hospitals and at Memorial Sloan-Kettering.²³ The multi-institutional audit was designed in a collaborative effort, using a series of developmental meetings, and included criteria for morphologic descriptions and staging characteristics. While community hospitals were found to have a higher percentage of missing information, the audit served as an effective evaluation tool.

Two other programs were initiated by NCI to facilitate the transfer of new cancer information to community physicians; the Community Oncology Program (COP) in 1975, and the Community Hospital Oncology Program (CHOP) in 1980.²⁴

Several major studies of the impact of CHOPs in the community were conducted; one by a collaborative group of CHOP grantees, the other by the National Cancer Institute. The methodology of evaluation was similar in both cases. It targeted the process of care, with information on the use of guidelines or other key decision points gathered through tumor registrars at the individual hospitals. One evaluation looked at changes in use of the diagnostic tests pre- and post-implementation of CHOPs in participating institutions, and in other institutions not involved in the development of patient management guidelines.²⁵ Others evaluated patterns of patient management and multidisciplinary consultation, and utilization of patient management guidelines.^{26 27}

There are several points to be made about these cancer evaluations. First, there was little difficulty in arriving at measurable variables for several major cancer sites. Researchers found that a wide range of diagnostic, consultative, and treatment variables could be identified and collected. While some variables had a large number of "unknowns," and many of the variables were so mundane that little, if any, variation was noted, evaluators were able to identify some critical variables that could discriminate between adequate and inadequate processes of care, which were collectible and available for analysis.

Second, there is an existing resource at many hospitals that can facilitate patterns of care research, the tumor registry. In fact, oncology, unlike other medical specialties, can readily provide information

on both process and outcome variables, since these are exactly the kinds of data that registries have been designed to collect. Moreover, registrars already have a series of standardized coding conventions developed by the American College of Surgeons and the National Cancer Institute's Surveillance, Epidemiology and End Results (SEER) program. This makes data collection easy and lowers costs substantially, since the major component of cost (personnel) may already be on the hospital payroll. Tumor registries also have a high capture rate for information on outcomes. The College of Surgeons insists that at least 90% of tumor registry cases have complete follow-up and survival information.

Thus, they have the right personnel in place, standardized coding, and access to process and outcome information. All of the COP and CHOP evaluations previously cited leaned heavily on the tumor registries to gather their information.

Third, all of these evaluators preferred to look at the outcomes of care, but in some cases found the evaluation period to be too short, or retrospective data to be too out-of-date to be useful in measuring current treatment.

Methodologic Obstacles to the Evaluation of Quality

HCFA and JCAH both wish to use outcome evaluation to determine quality of care. This "bottom line" approach makes sense to the payers of care, requires less data collection and monitoring, and gives institutions direct incentives to improve inadequate care since the results are bound to be published in the local newspaper. Yet this approach has some serious pitfalls, which need to be addressed if the evaluation process is to work.

The use of outcome criteria alone raises a special series of methodological problems, specifically: variations in individual and regional medical practices; differences in size and composition of patient populations (including severity of illness factors); problems with the "unit of analysis"; changing patterns of care and survival information; problems in the assignment of responsibility for outcomes; and, changing patterns of data availability on the chart.

Regional Variations

Significant variations in both individual practice preferences and regional characteristics of practice have been widely reported in the literature. Individual styles of practice have shown greatest variation in areas where accepted standards for practice are ambiguous or unsubstantiated, or where outmoded practices are in use.²⁸ Physician uncertainty regarding outcomes of procedures or practices has been suggested as the primary explanation for these practice variations.²⁹ Researchers suggest that a reduction in reported variations in outcomes may only be accomplished when conclusive studies are conducted to resolve questions regarding appropriateness and effectiveness of procedures and treatments.³⁰

Regional variations in practice are best explained by the tendency of physicians to adopt similar strategies for managing problems in their communities, essentially "following the pack" and establishing norms of practice.³¹ As a result, a standard of care that is suitable for one region may be too narrow to explain differences in practice in another region. Further research into the links between medical practices and outcomes in areas of uncertainty or ambiguity will be needed before appropriate standards can be devised. Certainly this will be an issue in some sites of cancer care.

Patient Differences

If you are attempting to evaluate survival of cancer patients across multiple institutions, there are some obvious complications. Adjustments will be necessary to account for differences in case mix, which, in turn will affect outcomes. A 100-bed community hospital and a 700-bed university hospital do not see the same types of cancer patients or the same types of cancers. Since survival is affected by age, sex, race, site, stage, and severity of illness, evaluators will have to adjust samples to compensate for these variables. Cancer is multiple diseases with different outcomes at different stages, so sample sizes of similar cases at smaller institutions are likely to be so small that considerable random variation

in patient outcomes can be anticipated. Certainly it will be difficult to evaluate the relationship between management and outcomes in an institution that sees a single leukemia patient each year compared with an institution with an active leukemia service. Thus, it is possible that we may have to confine the evaluation of oncology programs to the more common sites. And, we may have to define outcomes differently. It could be, for example, that the most important "decision points" for a smaller hospital will be in the proper work-up of the patient, and the most important outcome, rather than survival, will be appropriate referral for treatment.

Severity of illness is a relatively new area of concern. In a recent article, Dr. Susan Horn pointed out the substantial variation in severity of illness of cancer patients at different types of institutions.³² Several systems of severity rating are trying to address some of the pitfalls of quality evaluation. Knaus and associates developed the APACHE index to measure levels of severity among acutely ill hospitalized patients as a means of estimating pretreatment risk of death and ensuring comparability of patient groups in studies of acute illness.^{33 34} Knaus and others also reported the use of a revised index, APACHE II, to reduce variation in patient factors so as to examine more precisely the influence of structure and process variables on outcomes of care.³⁵ Gonella and co-workers described the "staging" method of measuring disease severity, adapted from concepts in clinical medicine, especially oncology, that diseases have discrete, clinically definable stages of progression.³⁶

Brewster and colleagues have developed the Medical Illness Severity Grouping System (MEDISGRPS), a chart-based review system that classifies levels of severity, but in addition, measures changes in severity during inpatient hospitalization and monitors results of care provided as well as resources consumed.³⁷ Other investigators have proposed the use of the Adverse Patient Occurrences Inventory, a measure of the relative occurrence of adverse patient events as an alternative to severity indices.³⁸

Clearly a number of researchers are tackling the severity problem. The

challenge to evaluators will be the selection of an appropriate system of severity rating that will be usable across multiple institutions and multiple disease sites, and that will not be too expensive to implement. HCFA, for one, is unlikely to encourage severity rating with any national reimbursement schemes, since the policy of the current administration is to plunge onward toward capitation.

Unit of Analysis: Patients, Doctors, Hospitals, or the Health Care System?

Now we get to one of the more complex methodologic problems, selecting the unit of analysis. In other words, what are we measuring...patients, physicians, hospitals, or health care systems? Several investigators have reported that unit of analysis errors occur most frequently in studies of interventions of providers of care, and are due to the inappropriate use of patient-level observations to draw conclusions about providers.³⁹ For example, Kerner and Mortenson, in their studies of differences in the CHOP and non-CHOP hospitals, analyzed differences between patient groups and also between hospitals.⁴⁰

Obviously focusing on patients as the "unit of analysis" provided larger sample sizes capable of detecting smaller significant differences. When the same analyses were done utilizing the hospital as the unit of analysis many of the significant differences disappeared. When differences in patient populations among the hospitals are added to the picture, interpretation problems are more complex.

Survival Data and Outcomes

Does survival information adequately reflect the institution's current delivery of cancer care? Most likely, the answer is no. One problem is that many of the high incidence sites, with large samples of patients that could be compared at the same stage, also have relatively long survival periods. While this is not true for non-small cell and small cell lung cancer, a large portion of breast cancer, prostate cancer, and colon cancer survivals will be

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five or more years out. This means that the very sites one may want to study are going to take a long time to evaluate if you depend only upon survival information. At the point where you have adequate samples and adequate survival information, the treatments used may no longer be contemporary.

Assigning Responsibility for Care (Who is Responsible?)

Data from tumor registry studies indicates that cancer patients are seen, on average, at 1.5 institutions. Since a growing proportion of cancer patient care is outpatient, with a considerable amount being done in physician offices, in ambulatory chemotherapy settings, and at free-standing cancer centers a large portion of the patient's care is totally out of the control of the hospital. If one evaluates length of survival as an outcome, then how does one assess the role that each component of care plays in the overall outcome?

Should the hospitals that first treat cancer patients bear the primary responsibility for the health outcomes of these patients? If so, it seems likely that hospitals will decide to increase their control over physicians who deliver care in the community to maximize positive outcomes of care. How will the impact of patient compliance on outcomes of care be assessed in this situation? And, who will be responsible for the collection and management of post-hospitalization data?

Collection of Patient Data

Collectibility of data items will pose innumerable problems. Investigators cite lack of documentation and missing information as a major impediment to chart reviews and retrieval of critical data items.^{41 42 43 44} In an extensive review of the CHOP program, insufficient documentation in the medical record and changes in availability of information as procedures and treatments moved out of the hospital setting into the community, were two of the primary causes of data collection problems.⁴⁵

Issues of responsibility in the collection of data will also need to be re-

solved, and procedures implemented to insure accurate retrieval of data. Collectibility of data, therefore, will need to be carefully controlled and monitored, and the burden of data management placed on hospitals and other providers weighed against the value of the desired items.

What Needs to be Done?

Our review indicates that quality of care evaluations can be done on cancer programs. A number of successful evaluations have been done. It does indicate, however, evaluations based on outcomes alone, such as survival and disease free interval, may be difficult to carry out if this is the only evaluation methodology utilized.

There are several approaches we would advocate. First, a combination of all three of Donabedian's methodologies seems most appropriate. While it may be possible to look at length of survival for a number of cancer sites, process of care variables, like protocols, can serve as proxies for quality outcomes. Process of care evaluations can also analyze a larger sample of patients for such things as work-ups or consultations that are less likely to be stage-specific, and thus do not have the restricted sample sizes of survival analyses. Recently, the American Medical Association published a report from the Council on Medical Service that also supports the use of all three types of evaluation, particularly in an approach that would verify relationships between structure and process, and outcomes.⁴⁶

Second, although JCAH does not currently accredit cancer program resources with standards (structural criteria), it may be necessary to blend in standards like those under development by the Association of Community Cancer Centers (ACCC), for cancer care. It seems likely that with a combination approach, some methodological problems could be circumvented.

Third, the cancer community already has a great deal of prior experience with developing and evaluating process of care variables. While the findings of these prior studies is somewhat limited by the time that has elapsed since their completion, the oncology community should be able to readily understand the strategy and the validity of any proposed process of

care variables. Indeed, data from clinical trials, from COP, CHOP, and CCOP programs should be useful in evaluating the potential accuracy of patterns of care guidelines.

Fourth, the cancer community already has developed mechanisms for the retrieval of information on quality of care and survival that have proven to be reliable and relatively standard in their collection and reporting of information. These cancer data systems or tumor registries can play a major role in the hospital's collection of data for JCAH kinds of program evaluations.

Fifth, there should be consideration of other standards for cancer care besides length of survival and disease free interval. As we noted above, it may be that one of the standards for some hospitals may be proper work-up and referral to appropriate treatment. Another might be development of other standards such as completion of a treatment plan. Special attention must be given to the multiple modalities involved when the cancer patient is first evaluated. It seems likely that limited outcome standards for surgical procedures may be easier to develop than standards for medical oncology but may be no more indicative of ultimate patient survival. Medical oncology and in some cases, radiation therapy, are more divorced from the hospital and may be more difficult to account.

Further research on many aspects of quality is still sorely needed. Studies examining the relationship between structure and process, and outcomes of care would help clarify the critical items needed for reliable assessments. Additional documentation of variations in medical practice would assist in the development of reasonable, representative standards of practice. The identification and validation of criteria for measuring outcomes of care will facilitate the design and implementation of valid evaluations of quality care.

Ultimately, structural standards, similar to those under development by the ACCC; process standards, such as the CHOP prototypes; and outcome measures, tempered with strategies to manage the methodological problems that lead to interpretation difficulties discussed above, will be the most comprehensive

approach to the accurate appraisal of quality cancer care.

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