EVALUATING QUALITY OF CARE: ACCC'S CLINICAL INDICATOR PROJECT

Part III: Validating Indicators - How Do We Know That A Clinical Indicator Is Meaningful?

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After the ACCC Core Committee has selected a data item as a possible clinical indicator, there are a series of steps necessary to validate the utility of the item. We want to know if the item is collectible, how frequently the item is recorded in the patient's chart, whether it is time consuming to collect the information, and whether it is truly useful as a measure of the quality of care. In order to find the answers to these questions, ACCC and ELM Services' research staff have developed a multi-step methodology for validating clinical indicators.

At its initial sessions, the Core Committee reviewed information that is currently collected by ELM's CHOP-DS system. Many of the site-specific clinical variables on this system were originally selected as possible measures of quality by oncologists from 14 National Cancer Institute-funded Community Hospital Oncology Program (CHOP) contractors. These items were later refined through the input of more than 100 cancer committees participating in the data system.

Thus, a large number of potential indicators were selected through an iterative process over the past five years, and reflect the impressions of a large number of cancer specialists about items of importance in the clinical decision-making process.

From the outset, the research team thought it would be important to both narrow and expand the data set. We hoped to narrow the data set to only those items that the Core Committee designated as currently meeting our criteria, and we hoped to include additional items or qualifiers that might provide a better picture of the quality of cancer care delivered. The Core Committee deliberations that Dr. Fleming describes in this article accomplished both of these ends. Subsequent to the Core Committee's January 1988 meeting, additional comments were solicited from each committee member and an initial data set was assembled for further evaluation.

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Using the CHOP-DS National Data Base, the next stage of evaluation will check on data items that have been collected and recorded for several years. There are several things that we hope to ascertain from a review of the existing items and the data base. First, are institutions consistently able to collect a given data item, or does the record show a high percentage of "unknowns?" If a high percentage of "unknowns" appears for a given item, is this caused by a lack of access to the information or some other data collection problem? For instance, is the problem of unknowns related to where a particular procedure is done or whether or not it appears on the patient's chart?

During the study of the CHOP programs several years ago, we noticed a statistically significant decline in the use of estrogen receptors for breast cancer patients in one city. Was this a data entry mistake or were patients receiving a lower quality of care? Investigation showed that it was neither. In the earlier years of the study, patients had been worked up in the hospital with all of the laboratory tests being done in-house. By the end of the study, a number of tests were being conducted on an outpatient basis with independent laboratories involved. These results were not always as readily accessible as earlier tests when all of the information could be found in patient charts.

This problem of data collection will continue to confound clinical indicator research as shifts in reimbursement alter the locations of diagnostic work-ups and the patterns of inpatient and outpatient care.

Those data items that have not been previously collected are subjected to a different kind of process. More than 90 institutions have agreed to review new indicators and to comment on their availability in the medical record, the ease of data collection, and each indicator's importance to quality patient care.

In some cases, individual institutions are being asked to collect or record new data items and to provide us with detailed information on the time and effort required to retrieve each particular item. If the data item is not available in the patient chart, do the data collectors have to have the information routed from another source? Is the data readily available or difficult to retrieve? And, in an attempt to evaluate the importance of each data item in relation to the expense of collection, participating hospitals will provide information on the cost of retrieving each data item.

After we have determined which items are collectible, we want to know whether or not the data item is meaningful from a research perspective. In specific, we want to know if a given indicator has sufficient variation to

FIGURE 1

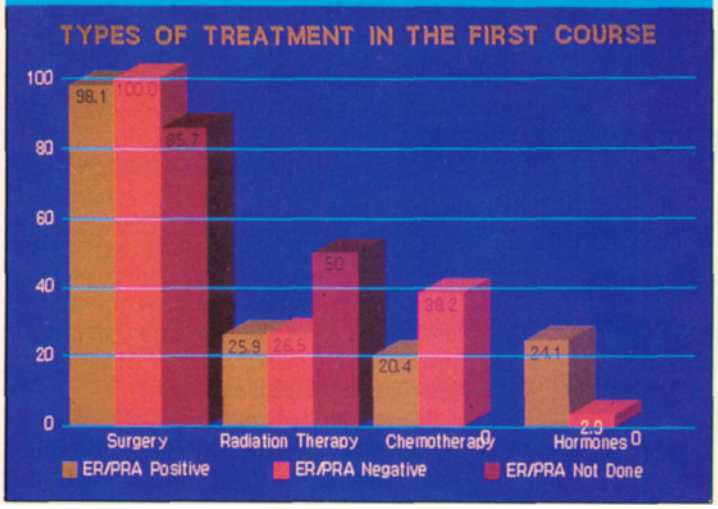


FIGURE 2

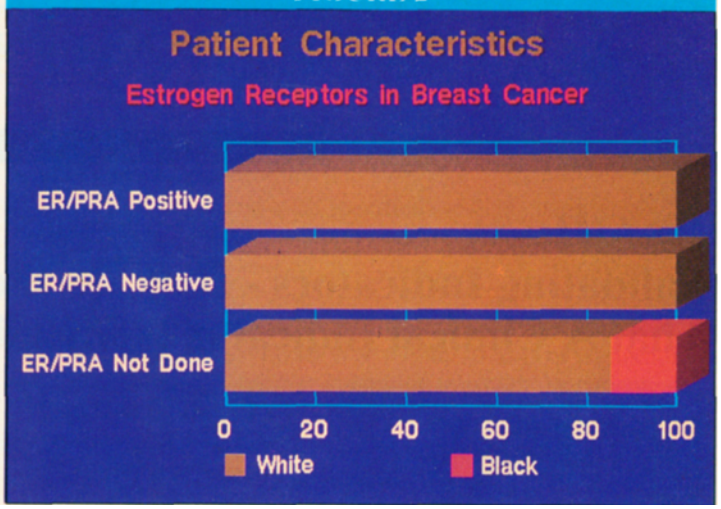
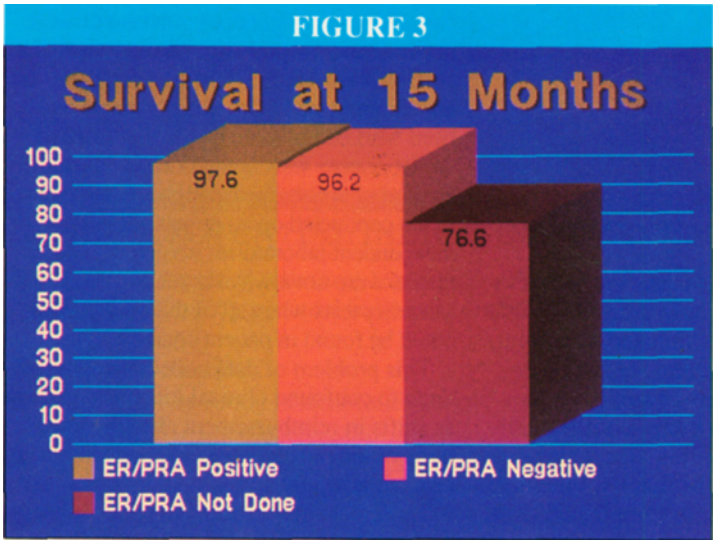


FIGURE 3



discriminate between the quality of care delivered at various institutions. If, for example, estrogen receptor (ER) testing is done on every patient at every institution, there is no reason to select it as an indicator of quality, even if it is a clinically meaningful test. If, however, there are apparent variations in the use of estrogen receptors by hospitals, and if these variations reflect differences in the process of care and outcomes, then ER testing might be a good candidate as a clinical indicator.

To demonstrate the kinds of studies that should be done on each clinical indicator, ELM research staff analyzed information on ER use at five hospitals from the National Data Base to see how its use correlates with treatment, patient demographics and outcomes. Of course, the actual validation process will be run against the entire National Data Base—a five hospital sample is far too small for the validation process.

Figure 1 illustrates differences in the treatment of patients that were ER and PR (progesterone receptor) positive, ER and PR negative, and where ERs and PRs were not done. Those cases that were recorded as "unknown" were dropped from this preliminary study. In this analysis, we found variations in the treatments that were provided to cancer patients that were positive and those that were negative. For example, chemotherapy was given to almost twice as many ER/PR negative patients than positive patients in this sample, and far fewer ER/PR negative patients received hormone therapy. Of course, the next logical analytic step is to categorize these patients by stage of disease and by age.

Figure 2 illustrates the next step in the validation process: determining patient characteristics that are different. In this small sample, we found that those patients without an ER/PR test recorded tended to be black. One might ask if these patients were referred from another facility with incomplete records, or if the lack of reimbursement for such testing played a role.

Figure 3 illustrates another key step in the validation process: relating a given clinical indicator to outcomes. As we noted in a previous article[1], the Joint Commission has indicated that outcome analysis is a key component of its initiative. Yet, with chronic diseases such as cancer, outcomes of care are not always apparent until well after discharge. Thus, process of care variables serve as a surrogate for outcomes. To ensure that a given indicator is valuable as a surrogate, the Core Committee will draw upon published studies and the National Data Base. In Figure 3, we see differences in survival at 15 months for breast cancer patients that did not have ER/PR tests completed. This suggests that the indicator may have an impact on patient management decisions, or that the initial study has not stratified the sample correctly. With a larger data base, we will be doing more refined patient characteristic studies to ensure that, indeed, differences in indicator use correlate with outcomes.

All three of these examples were done with patients as the unit of analysis. The next stage of analysis will be done with hospitals as the unit of analysis. In our earlier studies of hospital variations in cancer patient management[2], we found that differences that were apparent at the patient level were not of sufficient variance at the hospital level for us to attribute the difference to the hospital cancer program or the NCI-funded CHOP initiative.

Thus, through a lengthy series of steps, we will research each of the proposed indicators and provide the Core Committee with feedback on each of the selected indicators. Once a set of clinical indicators has been finalized and adopted by the Joint Commission's Task Force, we plan to monitor each indicator over time to determine whether or not it remains valid.

The Joint Commission's initiative to develop clinical indicators remains a unique and difficult task. Shifts in quality, reimbursement, patterns of care, and regional variations will all impact the analysis. However, the importance of developing comparisons and "flags" that can be raised by comparative data analysis is a concept that we in the oncology community have long utilized. Throughout this next year, we will see if a total quality evaluation of cancer programs can actually be accomplished and provide us with useful, actionable information. ■

[1] Mortenson L., Kerner J., and Novak, C. Striving For Excellence: Evaluating Quality of Care in Oncology. *The Journal of Cancer Program Management*, 1987. Vol.2, 1:21-28.

[2] Mortenson L., and others. Changes in the Patterns of Patient Work-Up in Community Hospital Oncology Programs and in Comparison Hospitals. *Advances In Cancer Control: Health Care Financing and Research*. Alan R. Liss Inc., 1986, 105-115.