Methodological Challenges in Studying Clinical Communication in Cancer Care*

This chapter focuses on four major methodological issues in studying communication in cancer settings: measurement of patient-centered communication, mediators between communication and health outcomes, moderators of the link between communication and health outcomes, and study design.

5.1 Measurement of Patient-Centered Communication

Psychometrically sound (reliable and valid) measures of communication behaviors are essential for conducting communication research in clinical settings.[1] *Reliability* refers to the extent to which a measure yields the same number or score each time it is administered. Thus, all other things being equal, the measure should reflect true change in the attribute being measured and not an intrinsic flaw of the measurement itself. Reliability is a necessary but not sufficient condition for validity of a particular measurement. *Validity* is the extent to which an instrument measures what it was intended to measure. In order to evaluate and support the construct validity of communication measures, the specific purpose of each measure and hypothesized associations between it and other constructs need to be specified. Also, because some overarching models of communication, such as the "patient-centered" model, are multifaceted constructs, each measure generally will assess some aspects better than others.

Communication can be measured with use of a variety of methods, including patient report, clinician report, peer assessment, observational measures (direct observation, video or audio recording), medical records, diaries, and unannounced standardized patients (SPs; actors who portray patient roles consistently and reliably and present covertly in clinical practices with clinicians' prior consent). Each method has different strengths and weaknesses and can yield different results. For example, observational measures often do not correlate strongly with patient perceptions of the same encounter as reported in surveys.[2] However, Tisnado et al.[3] found generally good agreement between medical record and patient survey data measures of process of care in a study of 1,270 patients with diabetes, ischemic heart disease, asthma or chronic obstructive pulmonary disease, or low back pain. Concordance was best for areas in which there was little ambiguity, such as medication use, and worst in situations requiring interpretation and judgment, such as having received "counseling." Similarly, in a study of 500 adults presenting with a physical symptom, there was good agreement between clini-

cian and patient reports of whether a prescription was given, a test was ordered, and a referral was made, with kappa values ranging from 0.83 to 0.91.[4] However, there was poor agreement about whether the clinician communicated a diagnosis and prognosis; clinicians reported communicating this information in 93% and 78% of visits, respectively, compared with patient reports of receiving this information in 63% and 43% of visits. Such studies do little, however, to elucidate the reasons for the discrepancies. It may have been that physician use of jargon or patient cognitive impairment interfered with mutual understanding of the information exchanged. Or, patients may have understood but then forgotten. Also, interpretation of some elements of communication may be broad, leading to discrepant reporting on the same events. For example, clinicians and patients often disagree on whether "counseling" occurred during a particular encounter, or whether "information about prognosis" was provided.

The most commonly used methods in communication studies to date have been qualitative data from interviews and focus groups and both qualitative and quantitative data from direct observation of clinical encounters and from patient surveys. Focus groups and interviews are useful for eliciting perceptions and gaining insight into possible reasons for behavior.[5] These techniques help ensure that what is important to patients and their families is captured. Often,

the techniques become the basis for the development of quantitative instruments or are used to deepen the researcher's understanding of statistical findings.

Observational approaches have the advantage of providing a direct view of a sample of behavior. However, they can require direct observation and audio recording, which some clinicians find intrusive. Also, clinicians who are not confident about their communication skills may be less likely to participate, thus perhaps limiting the degree of observed variability in clinicians' communication behavior. Although direct observation studies capture the immediate experience of the visit, most cannot account for conversations in prior visits, nonverbal communication, and the overall experience of receiving care. For that reason, some studies in which visits are recorded on either audio or video also involve debriefing of clinicians or patients after the visit to clarify the reasons for their own actions and their perspectives on the other's communication behaviors.[6] Some coding systems have third-party coders listen to or view audio or video recordings and then place the clinician's and patient's verbal and nonverbal behavior into certain categories (e.g., providing information, expressing empathy). However, these coding systems are complex and fail to capture the salience of the acts from the participants' perspectives. Coders require substantial training and experience. Few such systems are based on a particular theory of

communication or patient-centered care. Comparing findings derived from different coding systems can be difficult. There are at least two reports of poor correlation among instruments that claim to measure the same communication construct of the same data set (e.g., patient-centered communication, shared decision-making).[7,8] Observed clinical encounters also can be analyzed qualitatively by applying text-based analytic methods to the actual encounter or field notes generated by the observer. These methods encourage new themes and observations to emerge from analysis of the data.

Standardized patients (SPs) have been used to capture clinician behavior in response to nearly identical stimuli. Using SPs can overcome some difficulties in using real patients to study clinicians' communication behavior:

- Clinicians' patients differ in case mix and patient demographics, thus making comparisons among clinicians difficult.

- Real patients and clinicians tend to self-select and accommodate to each others' behaviors over time.

- The condition in question may occur with low frequency, requiring multiple observations in order to find relevant ones for the purpose of the study.

SPs often carry hidden audio recorders, which allows for subsequent qualitative and quantitative analysis of the interaction. This

approach has documented noteworthy differences in utilization of health services, clinician prescribing, history taking, and communication with patients.[9-16] Standardized patients also can report on their own subjective experience by completing some of the same surveys as do patients. Because they learn some principles of communication and present the identical role to multiple clinicians, SPs become "connoisseurs of care."[17] Compared with real patients, SPs tend to rate clinicians more harshly, thus avoiding very high mean scores characteristic of patient ratings (ceiling effects); and rate individual clinicians with higher reliability.[17,18] In addition, there are larger standard deviations in the scores given by SPs compared with those given by real patients, thus discriminating among clinicians to a greater degree. However, there are some limitations of SP-based methods: training and deploying SPs can be expensive, SP visits by nature are first visits to the clinician,[19] some physical signs cannot be accurately portrayed, and SPs normally cannot undergo invasive procedures that might occur in real clinical settings.

Patient surveys allow the patient to reflect on the effectiveness of communication and the nature of the patient-clinician relationship. There are numerous scales that claim to measure different aspects of clinician communication. Although patients may be considered the ultimate arbiters of patient-centered communication by clinicians, their survey responses are limited by recall and reporting bias. Many measures demonstrate ceiling effects and small standard deviations. Also, patients' responses to survey items appear to reflect global impressions of the clinician and do not discriminate among different aspects of communication; thus measurements of different constructs (e.g., trust, explanations, listening, autonomy support, clinician knowledge of the patient) share a substantial amount of common variance.[20,21]

Ecological momentary assessment is a method of collecting data as quickly as possible after events take place to minimize problems with recall.[22,23] Using pen and paper, the Internet, or handheld devices, a patient can record answers to survey items or narrative impressions. Different studies have used scheduled entries, entries triggered by specific events (such as a medical visit), or randomly prompted entries. Advances in information technology have increased the potential use of other sources of data for diaries, such as entries into shared medical records, e-mail text, and mobile telephone communications. Much more needs to be learned about the unique value of each source of data, however.

Although family members are present in a large percentage of visits,[24-26] their input is often not recorded or analyzed using observation methods, and the ways in which they affect and are affected by the patient's illness often are studied only in the context of caregiving at home and burnout. In reality, however, cancer care is most often a web of communications: among family members, among various clinicians, and between the patient/family network and the network of clinicians and clinical teams caring for the patient. However, limited attention has been directed at the assessment of communication among patients, family members, and the health care delivery team. When family members are present during one or more clinical encounters, their input contributes to the evolution of the conversation. Studies of family involvement in care often extend beyond the patient's death. For example, family members tended to perceive that their loved one had a "good death" if they also reported that the health care team listened and were effective in explaining the decedent's condition.[27] Similarly, the input of multiple clinicians should be accounted for in some way. In reality, while dyadic communication may occur during individual encounters, normally the patterns of communication over time are much more complex and include the patient, multiple family members (some of whom may also be patients), and a variety of clinicians of different professional training and specialization. Research methods and design should account for the network of relationships of varying intensity between multiple members of the family and the many clinicians comprising the health care team.

Future research on communication in cancer settings must be designed

to evaluate the relative utility of combinations of different data collection methods and sources of information. The best method of gauging communication may depend on a variety of factors, such as which communication function (e.g., fostering healing relationships, exchanging information) is assessed, and what is the most appropriate source of information for a particular aspect of care. A combination of data from multiple sources is needed to portray communication accurately between providers and patients. Studies involving both qualitative and quantitative analytic methods often yield more insight than studies involving either method alone.

5.2 Mediators between Communication and Health Outcomes

Communication sometimes affects health outcomes directly, but more often these effects are mediated through intermediate or proximal outcomes. Pathways between these proximal and intermediate outcomes of communication and subsequent health outcomes are poorly understood. For example, a patient with prostate cancer may decide to stop hormone therapy after completing radiation therapy if he thinks that his continued need to urinate at night means the treatment is ineffective (an illness representation[28,29]). Nonadherence in this case is due to communication problems: the patient made a false assumption about the treatment and did not ask the clinician for clarification. Meanwhile, the clini-

cian did not elicit the patient's understanding of the illness and its treatment and therefore was unable to correct the misconception. Some links between communication and health outcomes may be immediate whereas others are delayed. For example, communication interventions that improve adherence to chemotherapy for breast cancer will increase symptoms and decrease quality of life initially[30] but increase the duration of survival.

Potentially important mediators between communication and health outcomes were described in Chapter 3 and include improvements in patient knowledge, emotional self-management, patient empowerment, therapeutic alliance, quality of medical decisions, access to care, and social support. Mediation can occur through more than one pathway. For example, a study may involve a comparison of two potential pathways explaining the effects of communication on health outcomes: patient acceptance of treatment and patient self-efficacy. Alternatively, the association between communication and health may be mediated by reaching a high-quality decision (i.e., clinically sound and consistent with patient values), which, in turn, may be mediated by better clinician understanding of the patient's disease experience or better patient knowledge about the disease and treatment options.

One or more mediation hypotheses can be tested using a stepwise process (Figure 5.1). The example illustrated in Figure 5.1 is a study

of a patient activation intervention in which patients are coached to be more participatory in clinical settings, by asking questions and participating to a greater degree in decisions, for example. The figure suggests that an association between patient activation and pain may be mediated by patient adherence to treatment.[31] If this were true, visits characterized by good communication would result in improved pain relief only when the patient took medications as prescribed, and no such effect would be noted if the patient did not adhere to treatment. In order to assess mediation, a series of bivariate models can be estimated to see whether patient activation is associated with pain (Model 1, solid line) and adherence (Model 2, dashed line) and whether adherence is associated with pain (Model 3, dotted line). A multivariate model (Model 4) that uses both adherence and patient activation to predict pain should show that the direct effect of patient activation on pain is smaller than it was in Model 1.

In addition to the stepwise process, structural equation modeling can be used to evaluate mediators directly. Structural equation modeling permits the simultaneous assessment of multiple dependent variables and both direct and indirect effects of one variable on another. Each variable can be treated as both an independent variable and a dependent variable. This approach allows the estimation of latent variables rather than only measured variables and

Figure 5.1 One or more mediation hypotheses can be tested using a stepwise process. The question being tested here is Does greater adherence to medication mediate the effect of a patient activation intervention on lower levels of pain? In order to assess mediation, a series of bivariate models can be estimated to see whether patient activation is associated with pain (Model 1) and adherence (Model 2) and whether adherence is associated with pain (Model 3). A multivariate model (Model 4) that uses both adherence and patient activation to predict pain should show that the direct effect of patient activation on pain is smaller than it was in Model 1.
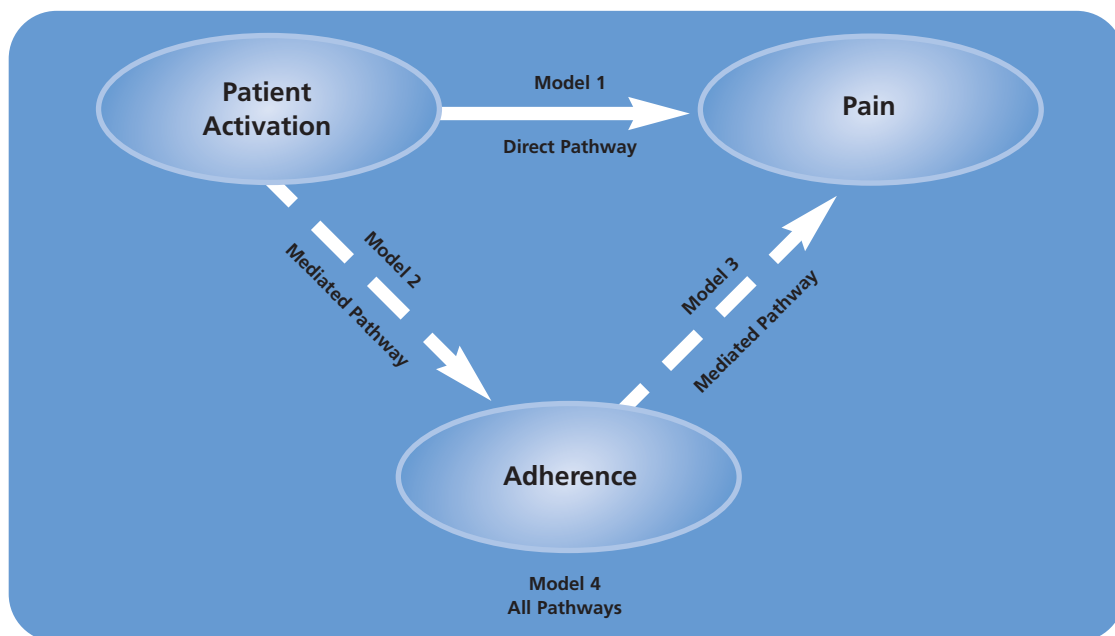
thereby accounts for random error. For example, structural equation modeling was used to provide support for a conceptual model of health-related quality of life developed by Wilson and Cleary.[32] Used with analysis of data on patients after myocardial infarction structural equation modeling demonstrated that the severity of cardiac disease influenced health-related quality of life through two pathways. The first, a direct pathway, was not mediated, whereas the second, an indirect pathway, was mediated by the presence of patient-reported symptoms.[33]

Communication functions also can serve as mediators of health outcomes. A recent study of 272 health plans showed that the percentage of clinical care delivered by staff and group model systems (rather than independent practice association and network models) was significantly related to higher rates of immunization and of screening for cervical and breast cancer, heart disease, and diabetes. However, the type of health care system was not related to patient reports and ratings of care.[34] Thus, although communication may have contributed to better preventive care through other pathways, com-

munication (measured from the patient's perspective) did not explain the relationship between the type of system and preventive care. These findings suggest further research is needed to find changes in health care systems that may be able to enhance the provision of patient-centered communication. These changes may include receiving care at a comprehensive cancer care center, having a health care team to facilitate access to information, and having a "medical home" where the patient could do one-stop shopping for coordination of care.

5.3 Moderators of the Link between Communication and Health Outcomes

Possible moderators of the relationships between communication and outcomes were discussed in Chapter 3 (and listed in Table 3.4). Moderators are variables that qualify associations of independent variables with a dependent variable. A moderator is identified when there is a significant interaction between two independent variables in a regression model. For example, the use of health care navigators to help patients receive adequate follow-up after abnormal findings on cancer screening tests may improve health outcomes for poor patients but not for wealthy patients. Similarly, interventions to improve patient participation in clinical care may have different effects depending on the patient's level of education. Education would be a moderator of the relationship between patient participation in the consultation and subsequent satisfaction with care if patient participation had a positive effect on satisfaction for those with at least a high school degree, and patient participation had a non-significant effect for those without a high school degree.

In research on physiological mechanisms, factors (such as blood pressure) can often be clearly classified as mediators, moderators, or outcomes. In behavioral research, however, the situation is more complex.[35] Patient trust in the physician, for example, can be considered a mediator, moderator, or outcome, depending on the situation. If trust mediates the relationship between information sharing and subsequent agreement to participate in psychotherapy for depression, patients presented with information about depression will choose to undergo psychotherapy only if their level of trust is sufficient. In other circumstances, trust in the physician may be a moderator; trust would moderate the relationship between recommending treatment and actually taking it, if, for example, patients with high levels of trust are more likely than patients with lower levels of trust to take medication as prescribed. Trust is also an intermediate outcome if it is on a pathway linking communication with a health outcome such as lower levels of anxiety. Decisions about whether a particular variable is a mediator or moderator may be based on theoretical reasons, such as testing a model predicting either the mediating or moderating effects of trust, or on empirical evidence, such as trying to uncover reasons why a hypothesized communication-outcome relationship did or did not occur.

5.4 Study Design

Most research on communication in cancer settings is cross sectional, primarily because such studies are less expensive and easier to do than longitudinal studies. In contrast, longitudinal studies provide a stronger basis for demonstrating the development of patient-centered behaviors over time and for drawing causal inferences between communication processes and health outcomes.

By virtue of their rigorous experimental design, randomized clinical trials provide a strong basis for causal inference about the effects of communication function on outcomes. Variables other than the randomized factor(s) that can affect the outcome are controlled by the random assignment of patients to conditions. But randomized controlled trials of communication interventions are challenging because of the complexity of interventions that involve patients, clinicians, and health care systems. In some situations, clinical trials can be impractical, impossible for ethical reasons, or prohibitively expensive. Most randomized clinical trials represent a distortion of clinical practice in a number of ways. They can give a false impression of the effect of treatment at a population level. Also, care provided in the context of a randomized trial is more consistent and more closely monitored than care in the community. In addition, participants who have characteristics that might complicate the interpretation of intervention effects (e.g., other comorbid illnesses commonly associated with the index condition) are excluded. As a result, the participants in clinical trials differ substantially from patients who do not participate.[36] Hence, randomized clinical trials can only suggest what is possible (i.e., efficacy) rather than what actually will happen when an intervention is implemented beyond the confines of the trial. The findings might not generalize to care once it is implemented in other less controlled settings.

Nonrandomized study designs are used when randomized clinical trials are not possible or feasible. The intention of effectiveness research is to document variations in the real world, including factors that are not under the investigator's control (e.g., delays in care, inability to afford a medication), in order to provide a basis for plausible inferences about underlying mechanisms. Because of the weaker study design, making sense of associations is more difficult in nonrandomized studies.

Case-mix adjustment can help by statistically equating naturally occurring groups on variables such as age, education, and indicators of health (e.g., comorbidity) that are measured at baseline. But case mix cannot account for some factors, such as unmeasured burden of illness; in effect, the observed differences are the result of an unknown combination of disease state, treatment effect, and patient and clinician behavior. These factors make inferences about the effects of an intervention difficult. For example, in the Medical Outcomes Study, detection of depression was not significantly related to mental health outcomes. This nonsignificant result was due in part to the fact that sicker patients tended to receive more intensive care, which, in turn, increased recognition and treatment of other conditions such as depression. Because the Medical Outcomes Study measures of sickness failed to fully capture this factor,[37] standard analyses showed no effect. Standard analyses also can show a paradoxical

relationship in which more intensive and higher quality care appears to be associated with worse outcomes.[38] Sophisticated analytic methods such as instrumental variable models may help account for unmeasured burden of illness.[39]

Multicomponent interventions are likely to be more successful than testing of individual elements ("molar" approach). Although each individual element may have a small effect, interventions that focus on synergistic approaches at multiple levels of the health care system (patients, clinicians, care managers, system design) may have a cumulatively larger effect. For a variety of reasons, studies of interventions targeted to more than just the patient or the clinician are rare, as are interventions that include family members and multiple clinicians. Because patients with cancer meet with multiple health professionals, studies of patients' experiences over time require designs of clinicians nested within patients; most prior studies have designs in which patients are nested within clinicians. Also, the unit of analysis for system interventions generally should be the health care system.

5.5 Conclusion

For designing studies in cancer communication research, much can be learned from innovative approaches to measurement, conceptual models, and study design in other areas of research. The role of mediating and moderating vari-

ables has not been explored fully. Longitudinal designs and novel methods of data collection have been used in only a few studies. Sophisticated analytic methods, including multilevel modeling, structural equations, and instrumental variable models may help sort out the complex network of factors that influences the relationship of communication behavior to subsequent health outcomes.

References

(1)   Epstein RM, Franks P, Fiscella K, et al. Measuring patient-centered communication in patient-physician consultations: theoretical and practical issues. *Soc Sci Med.* 2005;61:1516-1528.

(2)   Street RL Jr. Analyzing communication in medical consultations. Do behavioral measures correspond to patients' perceptions? *Med Care.* 1992;30:976-988.

(3)   Tisnado DM, Adams JL, Liu H, et al. What is the concordance between the medical record and patient self-report as data sources for ambulatory care? *Med Care.* 2006;44:132-140.

(4)   Jackson JL. Communication about symptoms in primary care: impact on patient outcomes. *J Altern Complement Med.* 2005;11 Suppl 1:S51-S56.

(5)   Crabtree BF, Miller WL. *Doing Qualitative Research*. Newbury Park, CA: Sage Publications; 1992.

(6)   Epstein RM, Morse DS, Frankel RM, et al. Awkward moments in patient-physician communication about HIV risk. *Ann Intern Med.* 1998;128:435-442.

(7)   Mead N, Bower P. Measuring patient-centredness: a comparison of three observation-based instruments. *Patient Educ Couns.* 2000;39:71-80.

(8)   Rimal RN. Analyzing the physician-patient interaction: an overview of six methods and future research directions. *Health Communication.* 2001;13:89-99.

(9)   Carney PA, Eliassen MS, Wolford GL, et al. How physician communication influences recognition of depression in primary care. *J Fam Pract.* 1999;48:958-964.

(10)   Epstein RM, Franks P, Shields CG, et al. Patient-centered communication and diagnostic testing. *Ann Fam Med.* 2005;3:415-421.

(11)   Franz CE, Epstein R, Miller KN, et al. Caught in the act? Prevalence, predictors, and consequences of physician detection of unannounced standardized patients. *Health Serv Res.* 2006;41:2290-2302.

(12)   Kravitz RL, Franks P, Feldman M, et al. What drives referral from primary care physicians to mental health specialists? A randomized trial using actors portraying depressive symptoms. *J Gen Intern Med.* 2006;21:584-589.

(13)   Kravitz RL, Epstein RM, Feldman MD, et al. Influence of patients' requests for direct-to-consumer advertised antidepressants: a randomized controlled trial. *JAMA.* 2005;293:1995-2002.

(14)   McLeod PJ, Tamblyn RM, Gayton D, et al. Use of standardized patients to assess between-physician variations in resource utilization. *JAMA.* 1997;278:1164-1168.

(15)   Tamblyn R, Berkson L, Dauphinee WD, et al. Unnecessary prescribing of NSAIDs and the management of NSAID-related gastropathy in medical practice. *Ann Intern Med.* 1997;127:429-438.

(16)   Tamblyn RM. Use of standardized patients in the assessment of medical practice. *CMAJ.* 1998;158:205-207.

(17)   Srinivasan M, Franks P, Meredith LS, et al. Connoisseurs of care? Unannounced standardized patients' ratings of physicians. *Med Care.* 2006;44:1092-1098.

(18)   Fiscella K, Franks P, Scrinivasan M, Kravitz RL, Epstein R. How do real and standardized patient ratings of physician communication compare? *Ann Fam Med.* (in press)

(19)   Tamblyn RM, Abrahamowicz M, Berkson L, et al. First-visit bias in the measurement of clinical competence with standardized patients. *Acad Med.* 1992;67:S22-S24.

(20)   Franks P, Jerant AF, Fiscella K, et al. Studying physician effects on patient outcomes: physician interactional style and performance on quality of care indicators. *Soc Sci Med.* 2006;62:422-432.

(21)   Franks P, Fiscella K, Shields CG, et al. Are patients' ratings of their physicians related to health outcomes? *Ann Fam Med.* 2005;3:229-234.

(22)   Patrick K, Intille SS, Zabinski MF. An ecological framework for cancer communication: implications for research. *J Med Internet Res.* 2005;7:e23.

(23)   Bolger N, Davis A, Rafaeli E. Diary methods: capturing life as it is lived. *Annu Rev Psychol.* 2003;54:579-616.

(24)   Shields CG, Epstein RM, Fiscella K, et al. Influence of accompanied encounters on patient-centeredness with older patients. *J Am Board Fam Pract.* 2005;18: 344-354.

(25)   Flocke SA, Goodwin MA, Stange KC. The effect of a secondary patient on the family practice visit. *J Fam Pract.* 1998;46:429-434.

(26)   Ballard-Reisch DS, Letner JA. Centering families in cancer communication research: acknowledging the impact of support, culture and process on client/ provider communication in cancer management. *Patient Educ Couns.* 2003; 50:61-66.

(27)   Curtis JR, Patrick DL, Engelberg RA, et al. A measure of the quality of dying and death. Initial validation using after-death interviews with family mem-

bers. *J Pain Symptom Manage.* 2002;24:17-31.

(28)   Leventhal H, Carr S. Speculations on the relationship of behavioral theory to psychosocial research on cancer. In: Baum A, Andersen BL, eds. *Psychosocial Interventions for Cancer*. Washington, DC: American Psychological Association; 2001:375-400.

(29)   Leventhal H, Diefenbach M, Leventhal EA. Illness cognition: Using common sense to understand treatment adherence and affect cognition interactions. *Cogn Ther Res.* 1992;16:143-163.

(30)   Martin M, Lluch A, Segui MA, et al. Toxicity and health-related quality of life in breast cancer patients receiving adjuvant docetaxel, doxorubicin, cyclophosphamide (TAC) or 5-fluorouracil, doxorubicin and cyclophosphamide (FAC): impact of adding primary prophylactic granulocyte-colony stimulating factor to the TAC regimen. *Ann Oncol.* 2006;17:1205-1212.

(31)   Oliver JW, Kravitz RL, Kaplan SH, Meyers FJ. Individualized patient education and coaching to improve pain control among cancer outpatients. *J Clin Oncol.* 2001;19:2206-2212.

(32)   Wilson IB, Cleary PD. Linking clinical variables with health-related quality of life. A conceptual model of patient outcomes. *JAMA.* 1995;273:59-65.

(33)   Hays RD, Revicki D, Coyne KS. Application of structural equation modeling to health outcomes research. *Eval Health Prof.* 2005;28:295-309.

(34)   Gillies RR, Chenok KE, Shortell SM, Pawlson G, Wimbush JJ. The impact of health plan delivery system organization on clinical quality and patient satisfaction. *Health Serv Res.* 2006;41:1181-1199.

(35)   Bauman AE, Sallis JF, Dzewaltowski DA, Owen N. Toward a better understanding of the influences on physical activity: the role of determinants, correlates, causal variables, mediators, moderators, and confounders. *Am J Prev Med.* 2002;23:5-14.

(36)   Cunningham WE, Bozzette SA, Hays RD, Kanouse DE, Shapiro MF. Comparison of health-related quality of life in clinical trial and nonclinical trial human immunodeficiency virus-infected cohorts. *Med Care.* 1995;33:AS15-AS25.

(37)   Wells KB, Katon W, Rogers B, Camp P. Use of minor tranquilizers and antidepressant medications by depressed outpatients: results from the medical outcomes study. *Am J Psychiatry.* 1994;151: 694-700.

(38)   Kahn K, Tisnado D, Adams J, et al. Does ambulatory process of care predict health-related quality of life outcomes? *Health Serv Res.* (in press)

(39)   McClellan M, McNeil BJ, Newhouse JP. Does more intensive treatment of acute myocardial infarction in the elderly reduce mortality? Analysis using instrumental variables. *JAMA.* 1994;272:859-866.