Research, intervention, and evaluation of programs to reduce behavioral risks for incident cancers, promote early detection, alleviate pain and dysfunction, and improve the quality of life of patients with cancer typically address these issues from the perspective of individual patients. This reflects the disciplinary bases of psychosocial oncology research (predominately the clinical, patient-oriented focus of medicine and psychology) and their research methods. While providing valuable insights into the course of disease and the impact of coping strategies, this approach does not place the findings in a broader context. The extent to which these experiences can be generalized cannot be determined.

A complementary approach to assessing the variables we aggregate under the headings “life-style factors” and “health promotion” is the epidemiologic method. As the basic framework of public health, insights gathered from epidemiologic investigations on these issues offer avenues for addressing factors of interest in behavioral and psychosocial research.

Under the rubric of life-style factors and health promotion we include the following: (1) those factors that reflect societal position, including social class/socioeconomic status and occupation; (2) behavioral risk factors associated with elevated rates of cancer, principally smoking (and smoking cessation), alcohol consumption, diet, and exposure to sunlight; (3) screening behaviors, factors associated with adherence to early detection of premalignant disease; and (4) psychosocial factors, including personality, coping, social support, and related issues. Several recent reviews (1, 2) have addressed many of the issues in considering life-style factors in relation to cancer initiation and promotion.

**THE EPIDEMIOLOGIC PERSPECTIVE**

Epidemiology is principally concerned with describing the distribution of diseases within defined populations and assessing the determinants of disease (etiology) (3, 4).
Kleinbaum et al. (5) added two additional aims: to predict future cases and the health of the population and to control disease by prevention, eradication, prolongation of life, and improving the quality of patients' lives. An understanding of the natural history of disease and how psychosocial factors affect it suggests points for intervention to influence its course.

Fletcher et al. (6) contrasted epidemiology from clinical approaches along the following domains: (1) epidemiology locates its observations within specific groups (representativeness), (2) including all members, whether or not they have come to the attention of the medical care system; and (3) data are analyzed on an aggregate level using (4) somewhat crude categories of disease by clinical standards. Epidemiology is somewhat more interested in determining (5) how often and in what circumstances an event occurs, rather than exactly how it occurs and (6) analyzing data based on populations to determine the relative increases or chances that exposures lead to disease. Clearly, this approach differs dramatically from individually based perspectives. Table 1 outlines a comparison of clinical and epidemiologic approaches to addressing psychosocial and behavioral factors in cancer research. It serves as a heuristic for defining key epidemiologic parameters differentiating these perspectives.

The unifying framework of the epidemiologic approach is the host-agent-environment paradigm initially developed to explicate infectious disease cycles (7). Three influences must simultaneously be addressed to determine the likelihood of disease: (1) the susceptibility of the host (an individual, a subgroup, or the entire population); (2) the agent, or that which is directly implicated as the source of the problem; and (3) the environment, which includes all other aspects of the situation, and must be viewed as dynamic in nature. The clinical perspective is focused on decision-making oriented toward disease mechanisms of the basic sciences to alter the course of disease. These paradigm differences lead to separate pathways to conceptualization and intervention.

An example demonstrates these sources of influence and differences in the public health approach to intervention from the clinical approach. In viewing the influence of cigarette smoking on lung cancer, it is clear that although we have not yet uncovered the etiologic, mechanistic level, the epidemiologic evidence is clear. Rather than a simple cause-effect relationship, environmental factors must also be addressed, including other exposures that might elevate the risks for lung cancer (e.g., the synergistic relationship between cigarette smoking and asbestos exposure on lung cancer

### TABLE 1. Comparison of Clinical and Epidemiologic Approaches to the Investigation of Life-style Behaviors in Cancer Research

<table>
<thead>
<tr>
<th>Issue</th>
<th>Clinical Approach</th>
<th>Epidemiologic Approach</th>
</tr>
</thead>
<tbody>
<tr>
<td>Purpose</td>
<td>Determine occurrence in individual patients</td>
<td>Determined relative frequency in population</td>
</tr>
<tr>
<td>Focus</td>
<td>Biologic, personal traits</td>
<td>Interaction of host, agent, and environment</td>
</tr>
<tr>
<td>Source of subjects</td>
<td>Patient series (referrals, admissions)</td>
<td>Patients, community, or population survey</td>
</tr>
<tr>
<td>Designs</td>
<td>Experimental, quasi-experimental</td>
<td>Observational, analytic</td>
</tr>
<tr>
<td>Treatment of time</td>
<td>Change, survival</td>
<td>Retrospective and prospective, survival</td>
</tr>
<tr>
<td>Statistical methods</td>
<td>Comparison of groups (means, ANOVA) or to published norms</td>
<td>Analysis of risk, assessment of dose-response effects</td>
</tr>
<tr>
<td>Reliability</td>
<td>Test-retest, internal consistency</td>
<td>Internal consistency, record verification, information bias</td>
</tr>
<tr>
<td>Validity</td>
<td>Criteria (physiologic and/or &quot;expert&quot;)</td>
<td>Selection bias, confounding</td>
</tr>
<tr>
<td>Generalizability</td>
<td>Prognosis, recovery, personality</td>
<td>To population from which derived</td>
</tr>
<tr>
<td>Inferences</td>
<td>Individual behavior change, group norms</td>
<td>Relative risk, etiology, social context</td>
</tr>
<tr>
<td>Prevention focus</td>
<td></td>
<td>Community and cultural change, public policy</td>
</tr>
</tbody>
</table>
incidence). Other workplace exposures might prove equally important in either initiating or promoting the carcinogenic process. The clinical approach would also include a similar line of questioning, although the aim would be to determine the biologic significance for the patient in question. For example, in approaching a smoking history, equivalent information would be assessed, although the use of these data would differ. For the epidemiologist, the rate of smoking in the subpopulation from which the case resides would be of paramount interest, as well as the comparison of this rate to a larger defined population and its rates of lung cancer occurrence. Furthermore, the fact that smoking is more common among blacks and persons of lower socioeconomic status would be analyzed to determine if excess deaths were associated with these factors, simultaneously being aware that access to medical care, preventive intervention services, and counseling strategies are less available to high-risk subgroups. Prevention strategies would go beyond advising smoking cessation and include policy level strategies to decrease smoking by advocating tax code changes and reducing availability of tobacco products for particularly vulnerable populations.

**SOURCES OF SUBJECTS**

The source of subjects demonstrates a major difference in the two methods. Traditionally, clinical (and psychologic) research has relied upon patients presenting for treatment at a given facility. If there are no barriers to health care utilization and if the factor under consideration is independent of care seeking, patient series are an acceptable method of subject accrual. Much of the psychologic and behavioral literature on life-style risk factors and cancer utilizes just such samples. If, however, there are selection criteria operable that differentially triage patients to treatment on the basis of other characteristics associated with the factor under investigation, then bias emerges as an important consideration. Selection bias is the amount to which we overestimate or underestimate the effect (risk) resulting from how subjects are selected for the study. The principal sources of selection bias are the following: (1) comparison groups, common to almost all research designs, (2) sampling frame, (3) incomplete follow-up and nonresponse, and (4) selective survival (8). Of particular concern is the reliance upon hospital-based comparison groups (referred to as Berksonian bias (9)).

**STUDY DESIGN**

Design differences also are apparent in the comparison of the clinical and the epidemiologic/public health approach. Clinically based investigations typically use experimental protocols or quasi-experimental designs. Although control groups are commonly used, their source and generalizability are often open to question. More commonly, patients are randomized to various treatments, and group means are then compared over time. With respect to life-style behavior modification, individualized approaches are compared (e.g., individual counseling versus group counseling versus physician advice) and relative quit rates monitored over time. Similar interventions are seen for other factors, such as dietary modifications, controlling alcohol use, and promoting aerobic exercise. Public health approaches tend to focus more on altering the community and cultural context within which the individual lives (10). To address these issues, data are collected using strategies that provide information that can be transcribed into comparisons of rates among those with and without specific risk factors (and combinations thereof). Typically, when the disease is rare, case-control epidemiologic studies are utilized (11), in which retrospective recall of exposures to risks is ascertained for defined cases and selected controls (e.g., cases with invasive cervical cancer matched with a random sample of women from the same area who are of the same age and race (12)). Cohort studies
prospectively observe a population enrolled at baseline to determine directly the risks associated with incident disease. The latter design avoids many of the biases associated with case-control studies, but the time and expense required must be considered (13). Clinical trials (both nonrandom and randomized) can be viewed as subsets of cohort studies, allowing a more informed assessment of association and cause.

TREATMENT OF TIME

Clinical approaches to the analysis of time are predominately focused on assessing change in physiologic functioning as well as patient illness status; recall of history or events is also manifest. Issues of survival are essential in clinical research. Epidemiologic approaches to the subject of time take similar perspectives, although the research designs treat time somewhat differently. Retrospective recall of exposures in cases and controls is commonly assessed, whether in the case-control design or in prospective cohorts, to elucidate risk. Survivorship, whether based on proportional hazards models or simpler life table enumeration, is a common way of treating time.

STATISTICAL METHODS

The analytic methods selected for making comparisons directly follow the design and purpose of the investigation. Clinical reports frequently compare groups (treated versus not treated; smokers versus nonsmokers) and report on differences in mean values or compare the results of a patient series to published normative data. Epidemiology has its own set of statistics (odds ratio, relative risk, attributable risk) that have been developed to assess different types of risk assessments; in addition, the concern with dose-response relationships also calls for alternative forms of determining differences in groups (hence the variety of chi-square methods). In particular, there is a heavy reliance in epidemiology for using multivariate statistical analysis, often logistic regression methods, reflecting the underlying multifactorial framework. In clinical studies the use of ANOVA and similar techniques predominates, reflecting small sample sizes but the general approach as well.

RELIABILITY

Test-retest methods of assessing reliability (or precision) predominate in clinical frameworks, although there is concern with measures of internal consistency for multi-item scales. Epidemiology relies more heavily upon record verification for the detection of information bias, distortion in the estimation of impact (or risk) due to measurement error, or subject misclassification (5). This emerges from faulty measurement of the exposure condition (poorly worded questionnaire, interview procedure, or indicator) or the disease condition (any inaccurate diagnostic procedure).

VALIDITY

Assessments of validity are most commonly appeals to criteria in clinical research. Either consensus (or prevailing wisdom) exists on cutting points for the determination of important treatment decisions or critical values are accepted. For example, investigations of psychologic functioning might be verified by a psychiatrist's rating or by exceeding standard values. In epidemiologic research two issues are of greatest relevance: ruling out selection bias and confounding. Kleinbaum et al. (8) demonstrated how selection factors can be corrected or avoided, principally through design considerations or through analysis. In either case a determination can be made when selection bias exists and its impact on both the magnitude and direction of the bias. Confounding results can be achieved by a risk factor being
affected by other extraneous (and perhaps causally linked) factors. In general, comparisons of crude versus adjusted effects are made to determine if distortions are present.

**GENERALIZABILITY**

The extent to which one may generalize from clinical investigations is dependent upon the factor being addressed. Certainly, if measures of interest are independent of patient selection factors, there are no limits to generalizability. However, if the investigation includes factors that might be affected by patient characteristics also associated with their referral status (e.g., patients treated at a comprehensive cancer center), then inferences must be closely held. One of the features of the epidemiologic investigation is that one may generalize directly to the population from which cases and controls, or the prevalent cohort, are drawn.

**INFECTION**

The principal aim of the clinical approach is to predict patient prognosis and to determine factors that may impede optimal functioning or recovery. The focus is on the individual patient or the treatment. The epidemiologic aim is to ferret out presumed risk factors impinging upon the population at large and to compare these risks within the dynamic of the environment. In some respect the community focus of epidemiology is sometimes forgotten but underlies the generic approach.

**PREVENTION FOCUS**

Altering individual behavior to reduce risk or to improve outcome is the ultimate goal of both the clinician and the public health practitioner. The route by which each reaches this goal differs, however. Individual behavior change is generally the strategy employed clinically. Physicians provide advice (smoking cessation, alcohol consumption reduction, weight and cholesterol control, increased exercise) or make referrals to formal programs (e.g., SmokeEnders, AA, Weight-Watchers), which also have the individual as the focal point. Family members or peers may be involved (e.g., in cardiac rehabilitation exercise programs) but primarily as a source of support to maintain adherence to the recommendation. The public health approach seeks to alter individual behavior through interventions focused upon the community at large. Whether via public policy (banning of smoking in public areas, on airplanes, or in offices) or through mass media and other community-based approaches, the intent is to alter community norms. Environmental alteration (eliminating or reducing risk or exposure) is the preferable route to promote behavior change, thereby removing decision-making or the need for behavior change by individuals.

**SUMMARY**

This discussion is limited in the depth of the comparisons being drawn. In some respects we have used a heuristic to demonstrate the utility of epidemiologic methods to understand life-style behavior factors in cancer research, such as tobacco use and alcohol consumption, and issues such as personality and coping style. An appreciation of the epidemiologic method and the public health paradigm demonstrates the remarkable difference in approach from the traditional clinical approach. Both approaches are essential to understand the dynamics of patient behavior and risks for cancer. In addition, these perspectives must be simultaneously integrated with psychosocial (stress) paradigms in which personal and social resources are considered.

It is clear that a great deal has been written concerning life-style risk factors and their im-
pact on cancer risks. If we review the evidence outlined by Doll and Peto (14), the majority of risks for cancer deaths are self-imposed, principally reflecting tobacco use and dietary factors. Other factors, such as alcohol use, sexual behavior, and occupational exposures, surely should not be ignored, but they contribute little in comparison to smoking and dietary fat (although they have unique and important public health relevance for other problems). In reviewing the evidence for smoking and dietary interventions, it is clear that we have been relatively unsuccessful to date in modifying cancer risk behaviors. Whether this reflects inappropriate paradigms, naive views of the intervention process, or a lack of awareness of the behaviors themselves must be addressed (15).

Social epidemiology, the study of the psychosocial determinants of physical health status, recognizes that social and cultural factors are important in the etiology of chronic disease (16–18). Kasl (19) suggested that the contribution of this approach lies in the level of aggregation and abstraction of psychosocial/behavioral factors compared with biologic factors. For example, associating trace elements or specific dietary constituents with a specific physiologic response may be demonstrated but would certainly remain masked were we to reduce our focus to “dietary intake.” Many of our measures of behavioral risk factors [How many cigarettes do you smoke per day? How often do you exercise? What did you eat for the last 24 hours?] are at this aggregated level. The new measurement methods developed in the Stanford Five-Cities Project for exercise may serve as a model for the developmental activities required for other behaviors (20).

Clearly, we face a challenge in devising reliable, valid, and simple measures of human behavior that lead to risks for cancer. Only through links with medicine can we develop such measures and approaches, but it will also require education on the part of the social sciences. Furthermore, a challenge confronting the field of psychosocial cancer research is the integration of a variety of research traditions and paradigms, including basic medical sciences, health psychology, medical sociology, anthropology, and epidemiology. This integration stretches our contemporary knowledge and requires new thinking and perspectives on how people confront and cope with cancer.

REFERENCES